STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABALOPARATIDE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of postmenopausal osteoporosis and meet **ONE** of the following criteria?
   - The patient has a high risk for fractures defined as ONE of the following:
     - History of osteoporotic (i.e., fragility, low trauma) fracture(s)
     - 2 or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, BMD T-score less than or equal to -2.5, corticosteroid use, or use of GnRH analogs such as Synarel [nafarelin])
     - No prior treatment for osteoporosis AND FRAX score ≥ 20% for any major fracture OR ≥ 3% for hip fracture
   - The patient is unable to use oral therapy (i.e., upper gastrointestinal [GI] problems - unable to tolerate oral medication, lower GI problems - unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine)
   - The patient had a trial of, intolerance to, or a contraindication to a bisphosphonate (e.g., Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate])

   If yes, continue to #3.
   If no, continue to #2.

2. Is the request to increase bone density in a male patient with osteoporosis who meets **ONE** of the following criteria?
   - The patient is at high risk for fracture defined as ONE of the following:
     - History of osteoporotic fracture (e.g., fragility, low trauma)
     - Multiple risk factors for fracture (e.g., history of multiple recent low trauma fractures, BMD T-score less than or equal to -2.5, corticosteroid use, use of GnRH analogs such as Synarel [nafarelin])
   - The patient has failed or is intolerant to other available osteoporosis therapy (e.g., Forteo [teriparatide], Prolia [denosumab], Fosamax [alendronate], Actonel [risedronate])

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ABALOPARATIDE

GUIDELINES FOR USE (CONTINUED)

3. Has the patient received a total of 24 months cumulative treatment with any parathyroid hormone therapy (e.g., Tymlos [abaloparatide], Forteo [teriparatide])?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, **approve up to 24 months cumulative lifetime treatment duration by HICL or GPI-10 with a quantity limit of #1.56mL per 30 days.**

DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **ABALOPARATIDE (Tymlos)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Postmenopausal osteoporosis (a type of bone condition)
   2. Increase bone density in a male patient with osteoporosis (a type of bone condition)

B. **If the request is for postmenopausal osteoporosis, approval also requires:**
   1. You have NOT received a total of 24 months or more of treatment with any parathyroid hormone therapy (such as Tymlos [abaloparatide], Forteo [teriparatide])
   2. You meet ONE of the following (a, b, or c):
      a. You have high risk for fractures defined as ONE of the following:
         i. History of osteoporotic fracture(s) (broken bones) due to trauma (injury) or fragility (weakness)
         ii. Two or more risk factors for fracture such as history of multiple recent low trauma fractures, bone mineral density T-score (a type of lab test) less than or equal to -2.5, corticosteroid use, or use of GnRH (gonadotropin-releasing hormone) analogs such as Synarel (nafarelin)
         iii. No prior treatment for osteoporosis AND FRAX (Fracture Risk Assessment Tool) score greater than or equal to 20 percent for any major fracture OR greater than or equal to 3 percent for hip fracture
      b. You are unable to use oral therapy due to upper gastrointestinal (stomach and intestine) problems, you cannot tolerate oral medication, you have lower gastrointestinal problems (unable to absorb oral medications), you have trouble remembering to take oral medications or cannot plan to use an oral bisphosphonate (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate]) with other oral medications in your daily routine
      c. You had a trial of, intolerance (side effect) to, or a contraindication (harmful for) to a bisphosphonate (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate])

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ABALOPARATIDE

GUIDELINES FOR USE (CONTINUED)

C. **If the request is to increase bone density in a male patient with osteoporosis, approval also requires:**
   1. You have NOT received a total of 24 months or more of treatment with any parathyroid hormone therapy (such as Tymlos [abaloparatide], Forteo [teriparatide])
   2. You meet ONE of the following (a or b):
      a. You have high risk for fractures defined as ONE of the following:
         i. History of osteoporotic fracture (such as fragility [weakness] fracture, low trauma [injury] fracture)
         ii. Multiple risk factors for fracture (such as history of multiple recent low trauma fractures, bone mineral density T-score (a type of lab test) less than or equal to -2.5, corticosteroid use, use of GnRH [gonadotropin-releasing hormone] analogs such as Synarel [nafarelin])
      b. You have failed or are intolerant (side effect) to other available osteoporosis therapy (such as Forteo [teriparatide], Prolia [denosumab], Fosamax [alendronate], Actonel [risedronate])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tymlos.

REFERENCES

- Tymlos [Prescribing Information]. Boston, MA: Radius Health, Inc.; December 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/17/23
Created: 04/17
Client Approval: 03/23
P&T Approval: 01/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABATACEPT - SQ

NOTE: For requests for the IV dosage form of Orencia, please see the ABATACEPT - IV PA guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
   - The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14 as follows:**
   - **125mg/mL: #4mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Xeljanz (tofacitinib IR), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 6 months by GPID or GPI-14 for all of the following:**
     - **50mg/0.4mL: #1.6mL per 28 days.**
     - **87.5mg/0.7mL: #2.8mL per 28 days.**
     - **125mg/mL: #4mL per 28 days.**

     If no, continue to #4.

4. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

     If yes, continue to #5.
     If no, do not approve.
     DENIAL TEXT: See the initial denial text at the end of the guideline.

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ABATACEPT - SQ

INITIAL CRITERIA (CONTINUED)

5. Does the patient meet **ONE** of the following criteria?
   - The patient is 2 to 5 years of age AND had a trial of or contraindication to the preferred agent: Enbrel (etanercept)
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to BOTH of the preferred agents: Enbrel (etanercept), Stelara (ustekinumab)
   - The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Stelara (ustekinumab), Taltz (ixekizumab), Humira (adalimumab), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 6 months by GPID or GPI-14 for all of the following:**
     - **50mg/0.4mL: #1.6mL per 28 days.**
     - **87.5mg/0.7mL: #2.8mL per 28 days.**
     - **125mg/mL: #4mL per 28 days.**

     If no, do not approve.

     INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

     Our guideline named **ABATACEPT - SQ (Orencia subcutaneous)** requires the following rule(s) be met for approval:

     A. You have ONE of the following:
        1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
        2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
        3. Psoriatic arthritis (PsA: a type of skin and joint condition)

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INITIAL CRITERIA (CONTINUED)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You meet ONE of the following:
      a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
      b. You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Xeljanz IR (tofacitinib immediate-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

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ABATACEPT – SQ

INITIAL CRITERIA (CONTINUED)

D. **If you have psoriatic arthritis, approval also requires:**
   1. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   2. You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   3. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You meet ONE of the following:
      a. You are 2 to 5 years of age AND have tried or have a contraindication to (harmful for you to use) the preferred agent: Enbrel (etanercept)
      b. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) BOTH of the preferred agents: Enbrel (etanercept), Stelara (ustekinumab)
      c. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Stelara (ustekinumab), Taltz (ixekizumab), Humira (adalimumab), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ABATACEPT - SQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
   - The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14 as follows:**
   - **125mg/mL: #4mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Xeljanz (tofacitinib IR), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
     - **50mg/0.4mL: #1.6mL per 28 days.**
     - **87.5mg/0.7mL: #2.8mL per 28 days.**
     - **125mg/mL: #4mL per 28 days.**

     If no, continue to #4.

4. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication

     If yes, continue to #5.
     If no, do not approve.
     DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ABATACEPT - SQ

RENEWAL CRITERIA (CONTINUED)

5. Does the patient meet **ONE** of the following criteria?
   - The patient is 2 to 5 years of age AND had a trial of or contraindication to the preferred agent: Enbrel (etanercept)
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to BOTH of the preferred agents: Enbrel (etanercept), Stelara (ustekinumab)
   - The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Stelara (ustekinumab), Taltz (ixekizumab), Humira (adalimumab), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [**NOTE**: Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
     - **50mg/0.4mL: #1.6mL per 28 days.**
     - **87.5mg/0.7mL: #2.8mL per 28 days.**
     - **125mg/mL: #4mL per 28 days.**

     If no, do not approve.

     RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

     Our guideline named **ABATACEPT - SQ (Orencia subcutaneous)** requires the following rule(s) be met for renewal:

     A. You have ONE of the following:
        1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
        2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
        3. Psoriatic arthritis (PsA: a type of skin and joint condition)

     (Renewal denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You meet ONE of the following:
      a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
      b. You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Xeljanz IR (tofacitinib immediate-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

(Renewal denial text continued on next page)

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ABATACEPT - SQ

RENEWAL CRITERIA (CONTINUED)

D. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   3. You meet ONE of the following:
      a. You are 2 to 5 years of age AND had a trial of or contraindication to (harmful for you to use) the preferred agent: Enbrel (etanercept)
      b. You are 6 to 17 years of age AND had a trial of or contraindication to (harmful for you to use) BOTH of the preferred agents: Enbrel (etanercept), Stelara (ustekinumab)
      c. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Stelara (ustekinumab), Taltz (ixekizumab), Humira (adalimumab), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orencia SQ.

REFERENCES

- Orencia [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; October 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/01/24
Created: 11/11
Client Approval: 04/24
P&T Approval: 04/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABEMACICLIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of early breast cancer and meet **ALL** of the following criteria?
   - The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive
   - Verzenio will be used in combination with endocrine therapy (tamoxifen or an aromatase inhibitor such as anastrozole, letrozole, exemestane) for adjuvant treatment
   - The patient is at high risk of recurrence

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #2.

2. Does the patient have advanced or metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Will Verzenio be used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) **AND** the patient meets the following criterion?
   - Verzenio will be used as initial endocrine-based therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #4.

4. Will Verzenio be used in combination with fulvestrant **AND** the patient meets the following criterion?
   - The patient has experienced disease progression following endocrine therapy (e.g., anastrozole, letrozole, tamoxifen)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #5.

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ABEMACICLIB

GUIDELINES FOR USE (CONTINUED)

5. Will Verzenio be used as monotherapy **AND** the patient meets the following criterion?
   - The patient has experienced disease progression following endocrine therapy (e.g., anastrozole, letrozole, tamoxifen) and prior chemotherapy in the metastatic setting

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ABEMACICLIB (Verzenio)** requires the following rules be met for approval:
   A. You have ONE of the following diagnoses:
      1. Early breast cancer (initial stage of breast cancer)
      2. Advanced or metastatic breast cancer (cancer that has progressed or has spread to other parts of the body)
   B. **If you have early breast cancer, approval also requires:**
      1. Your cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive (a type of protein)
      2. Verzenio will be used in combination with endocrine therapy (tamoxifen or an aromatase inhibitor such as letrozole, anastrozole, exemestane) for adjuvant (add-on) treatment
      3. You are at high risk of recurrence (disease returning)
   C. **If you have advanced or metastatic breast cancer, approval also requires:**
      1. Your cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (a type of protein)
      2. You meet ONE of the following:
         a. Verzenio will be used in combination with an aromatase inhibitor (such as letrozole, anastrozole, exemestane) as initial endocrine-based therapy
         b. Verzenio will be used in combination with fulvestrant, and you have had disease progression following endocrine therapy (such as letrozole, anastrozole, tamoxifen)
         c. Verzenio will be used as monotherapy (one drug), and you have had disease progression following endocrine therapy (such as letrozole, anastrozole, tamoxifen) and prior chemotherapy (drugs used to treat cancer) in the metastatic setting (cancer that has spread to other parts of the body)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABEMACICLIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Verzenio.

REFERENCES

- Verzenio [Prescribing Information]. Indianapolis, IN. Eli Lilly and Company; March 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 10/17
Client Approval: 05/23
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABIRATERONE

GUIDELINES FOR USE

1. Does the patient have **ONE** of the following diagnoses?
   - Metastatic castration-resistant prostate cancer (mCRPC)
   - Metastatic high-risk castration-sensitive prostate cancer (mCSPC)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Will the requested medication be used in combination with an oral corticosteroid (e.g., prednisone, prednisolone, methylprednisolone)?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient had a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., less than 50 ng/dL)
   - The requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the patient concomitantly using a strong CYP3A4 inducer (e.g., phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital)?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **250mg: #8 per day.**
   - **500mg: #4 per day.**

   If no, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **250mg: #4 per day.**
   - **500mg: #2 per day.**

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ABIRATERONE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ABIRATERONE (Zytiga)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)
   2. Metastatic high-risk castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread to other parts of the body and may respond to testosterone lowering treatment)

B. The requested medication will be used in combination with an oral corticosteroid (such as prednisone, prednisolone, methylprednisolone)

C. You meet ONE of the following:
   1. You had a bilateral orchiectomy (both testicles have been surgically removed)
   2. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
   3. The requested medication will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zytiga.

REFERENCES

- Zytiga [Prescribing Information]. Horsham, PA: Janssen Biotech; August 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/22/24
Created: 06/11
Client Approval: 01/24
P&T Approval: 07/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABIRATERONE SUBMICRONIZED

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) and meet **ALL** of the following criteria?
   - The requested medication will be used in combination with an oral corticosteroid (e.g., prednisone, prednisolone, methylprednisolone)
   - The patient had a trial of or contraindication to Zytiga (abiraterone acetate)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., < 50 ng/dL)
   - The requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the patient concomitantly using a strong CYP3A4 inducer (e.g., phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**

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ABIRATERONE SUBMICRONIZED

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ABIRATERONE SUBMICRONIZED (Yonsa)** requires the following rule(s) be met for approval:

A. You have metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)
B. The requested medication will be used in combination with an oral corticosteroid (such as prednisone, prednisolone, methylprednisolone)
C. You have tried or have a contraindication to (harmful for) Zytiga (abiraterone acetate)
D. You meet ONE of the following:
   1. You had a bilateral orchiectomy (both testicles have been surgically removed)
   2. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
   3. The requested medication will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Yonsa.

REFERENCES

- Yonsa [Prescribing Information]. Cranbury, NJ: Sun Pharmaceuticals Industries, Inc.; March 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/23
Created: 03/23
Client Approval: 06/23
P&T Approval: 07/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABROCITINIB

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of refractory, moderate to severe atopic dermatitis and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist, allergist, or immunologist
   - The patient has atopic dermatitis involving at least 10% of body surface area (BSA) OR atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas
   - The patient has TWO of the following: intractable pruritus, cracking and oozing/bleeding of affected skin, impaired activities of daily living
   - The patient had a trial of or contraindication to ONE preferred agent: Dupixent (dupilumab), Rinvoq (upadacitinib)
   - Cibinqo will NOT be used concurrently with other systemic biologics (e.g., Adbry [tralokinumab-ldrm], Dupixent [dupilumab]) for atopic dermatitis or other JAK inhibitors (e.g., Xeljanz [tofacitinib], topical Opzelura [ruxolitinib]) for any indication

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have a trial of or contraindication to **TWO** of the following?
   - High or super-high potency topical corticosteroid (e.g., triamcinolone acetonide, fluocinonide, clobetasol propionate)
   - Topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus)
   - Topical PDE-4 inhibitor (e.g., crisaborole)
   - Topical JAK inhibitor (e.g., ruxolitinib)
   - Phototherapy

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ABROCITINIB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ABROCITINIB (Cibinqo)** requires the following rule(s) be met for approval:

A. You have refractory, moderate to severe atopic dermatitis (a type of skin condition)
B. You are 12 years of age or older
C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
D. You have atopic dermatitis involving at least 10% of body surface area (BSA) OR atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas (between skin folds, the hands, feet, etc.)
E. You have TWO of the following: intractable pruritus (severe itching), cracking and oozing/bleeding of affected skin, impaired activities of daily living
F. You had a trial of or contraindication (harmful for) to TWO of the following:
    1. High or super-high potency topical corticosteroid (such as triamcinolone acetonide, fluocinonide, clobetasol propionate)
    2. Topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus)
    3. Topical PDE-4 inhibitor (Phosphodiesterase-4 Inhibitors such as crisaborole)
    4. Topical Janus kinase (JAK) inhibitor (Janus kinase inhibitor such as ruxolitinib)
    5. Phototherapy (light therapy)
G. You had a trial of or contraindication (harmful for) to ONE preferred medication: Dupixent (dupilumab), Rinvoq (upadacitinib)
H. You will NOT use Cibinqo concurrently (at the same time) with other systemic biologics (such as Adbry [tralokinumab-ldrm], Dupixent [dupilumab]) for atopic dermatitis or other Janus kinase (JAK) inhibitors (such as Xeljanz [tofacitinib], topical Opzelura [ruxolitinib]) for any indication

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABROCITINIB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of refractory, moderate to severe atopic dermatitis and meet **ALL** of the following criteria?
   - The patient has shown improvement while on therapy
   - The patient had a trial of or contraindication to ONE preferred agent: Dupixent (dupilumab), Rinvoq (upadacitinib)
   - Cibinqo will NOT be used concurrently with other systemic biologics (e.g., Adbry [tralokinumab-ldrm], Dupixent [dupilumab]) for atopic dermatitis or other JAK inhibitors (e.g., Xeljanz [tofacitinib], topical Opzelura [ruxolitinib]) for any indication

   If yes, **approve for 12 months by HICL with a quantity limit of #1 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ABROCITINIB (Cibinqo)** requires the following rule(s) be met for renewal:
   A. You have refractory, moderate to severe atopic dermatitis (a type of skin condition)
   B. You have shown improvement while on therapy
   C. You had a trial of or contraindication (harmful for) to ONE preferred medication: Dupixent (dupilumab), Rinvoq (upadacitinib)
   D. You will NOT use Cibinqo concurrently (at the same time) with other systemic biologics (such as Adbry [tralokinumab-ldrm], Dupixent [dupilumab]) for atopic dermatitis or other Janus kinase (JAK) inhibitors (such as Xeljanz [tofacitinib], topical Opzelura [ruxolitinib]) for any indication

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cibinqo.

REFERENCES

- Cibinqo [Prescribing Information]. New York, NY: Pfizer Labs; February 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/23
Created: 02/22
Client Approval: 08/23
P&T Approval: 07/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ACALABRUTINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of mantle cell lymphoma (MCL) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least one prior therapy for mantle cell lymphoma (e.g., rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone [R-CHOP])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ACALABRUTINIB (Calquence)** requires the following rules be met for approval:
   A. You have ONE of the following:
      1. Mantle cell lymphoma (MCL: a type of blood cancer)
      2. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
      3. Small lymphocytic lymphoma (SLL: a type of blood cancer)
   B. **If you have mantle cell lymphoma, approval also requires:**
      1. You are 18 years of age or older
      2. You have received at least one prior therapy for mantle cell lymphoma (such as R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone])
   C. **If you have chronic lymphocytic leukemia or small lymphocytic lymphoma, approval also requires:**
      1. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ACALABRUTINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Calquence.

REFERENCES

- Calquence [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals; August 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 02/18
Client Approval: 11/23
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ADAGRASIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a KRAS G12C mutation as determined by an FDA-approved test
   - The patient has received at least one prior systemic therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ADAGRASIB (Krazati)** requires the following rule(s) be met for approval:
   A. You have locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
   B. You are 18 years of age or older
   C. Your cancer has a KRAS G12C mutation (a type of abnormal gene) as determined by a Food and Drug Administration (FDA)-approved test
   D. You have received at least one prior systemic therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Krazati.

REFERENCES

- Krazati [Prescribing Information]. San Diego, CA: Mirati Therapeutics, Inc.; December 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/23
Created: 01/23
Client Approval: 02/23
P&T Approval: 01/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ADALIMUMAB

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by GPID or GPI-14 for Humira 40mg/0.4mL OR 40mg/0.8mL with a quantity limit of #2 per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #2 per 28 days for all of the following:**
   - **10mg/0.2mL**
   - **10mg/0.1mL**
   - **20mg/0.4mL**
   - **20mg/0.2mL**
   - **40mg/0.8mL**
   - **40mg/0.4mL**

   If no, continue to #3.

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by GPID or GPI-14 for 40mg/0.8mL OR 40mg/0.4mL with a quantity limit of #2 per 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)

   If yes, **approve for 6 months by GPID or GPI-14 for 40mg/0.8mL OR 40mg/0.4mL with a quantity limit of #2 per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient had a trial of or contraindication to ONE or more forms of conventional therapies, (e.g., PUVA [psoralen and ultraviolet light A], UVB [ultraviolet light B], topical corticosteroids [e.g., betamethasone dipropionate, clobetasol propionate], calcipotriene, acitretin, methotrexate, or cyclosporine)

   If yes, continue to #6.
   If no, continue to #7.

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INITIAL CRITERIA (CONTINUED)

6. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic and is switching to Humira
   - The patient has psoriasis covering 3 percent or more of body surface area (BSA)
   - The patient has psoriatic lesions affecting the hands, feet, genital area, or face

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve the requested strength for 1 month as follows:**
     - **40mg/0.8mL PSOR-UVEITS-ADOL HS Starter Package #4 pens.**
     - **80mg-40mg PSOR-UV-ADOL HS Starter Package: #3 pens.**
   - **SECOND APPROVAL: Approve the requested strength for 5 months as follows:**
     - **40mg/0.8mL: #2 per 28 days.**
     - **40mg/0.4mL: #2 per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to ONE conventional agent, such as corticosteroids (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve the requested strength for 1 month as follows:**
     - **40mg/0.8mL CROHN'S-UC-HS Starter Package: #6 pens.**
     - **80mg/0.8mL CROHN'S-UC-HS Starter Package: #3 pens.**
     - **40mg/0.8mL Pediatric Crohn's Starter Package: #3 syringes or #6 syringes.**
     - **80mg/0.8mL Pediatric Crohn's Starter Package: #3 syringes.**
     - **80mg-40mg Pediatric Crohn's Starter Package: #2 syringes.**
   - **SECOND APPROVAL: Approve the requested strength for 5 months as follows (enter a start date of 3 days before the end date of the first approval):**
     - **20mg/0.4mL: #2 per 28 days.**
     - **20mg/0.2mL: #2 per 28 days.**
     - **40mg/0.8mL: #2 per 28 days.**
     - **40mg/0.4mL: #2 per 28 days.**

   If no, continue to #8.

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

8. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?
   - The patient is 5 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to ONE conventional agent, such as corticosteroids (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve the requested strength for 1 month as follows:**
     - **40mg/0.8mL CROHN'S-UC-HS Starter Package: #6 pens.**
     - **80mg/0.8mL CROHN'S-UC-HS Starter Package: #3 pens.**
     - **80mg/0.8mL Pediatric UC Starter Package: #4 pens.**
     - **40mg/0.8mL OR 40mg/0.4mL: #4 pens/syringes.**
   - **SECOND APPROVAL: Approve the requested strength for 5 months as follows (enter a start date of 3 days before the end date of the first approval):**
     - **20mg/0.4mL: #4 per 28 days.**
     - **20mg/0.2mL: #4 per 28 days.**
     - **40mg/0.8mL: #4 per 28 days.**
     - **40mg/0.4mL: #4 per 28 days.**
     - **80mg/0.8mL: #2 per 28 days.**

   If no, continue to #9.

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

9. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - Humira will NOT be used together with other systemic biologics (e.g., Cosentyx [secukinumab]) for the treatment of HS or other TNF inhibitors (e.g., Enbrel [etanercept], Cimzia [certolizumab pegol]) for any indication

   If yes, **approve for a total of 3 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve the requested strength for 1 month as follows:**
     - **40mg/0.8mL CROHN'S-UC-HS Starter Package: #6 pens.**
     - **80mg/0.8mL CROHN'S-UC-HS Starter Package: #3 pens.**
     - **80mg-40mg PSOR-UV-ADOL HS Starter Package: #3 pens.**
     - **40mg/0.8mL PSOR-UVEITS-ADOL HS Starter Package: #4 pens.**
   - **SECOND APPROVAL: Approve the requested strength for 2 months as follows (enter a start date of 3 days before the end date of the first approval):**
     - **40mg/0.8mL: #4 per 28 days.**
     - **40mg/0.4mL: #4 per 28 days.**
     - **80mg/0.8mL: #2 per 28 days.**

   If no, continue to #10.

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

10. Does the patient have a diagnosis of non-infectious intermediate, posterior and panuveitis and meet **ALL** of the following criteria?
    - The patient is 2 years of age or older
    - Therapy is prescribed by or in consultation with an ophthalmologist
    - The patient does NOT have isolated anterior uveitis

    If yes, **approve for a total of 6 months by GPID or GPI-14 as follows:**
    - **For age 2 to 17 years, approve for all of the following with a quantity limit of #2 per 28 days:**
      - **10mg/0.2mL**
      - **10mg/0.1mL**
      - **20mg/0.4mL**
      - **20mg/0.2mL**
      - **40mg/0.8mL**
      - **40mg/0.4mL**
    - **For age 18 years and above, please enter two authorizations as follows:**
      - **FIRST APPROVAL: Approve the requested strength for 1 month as follows:**
        - **40mg/0.8mL PSOR-UVEITS-ADOL HS Starter Package: #4 pens.**
        - **80mg-40mg PSOR-UV-ADOL HS Starter Package: #3 pens.**
      - **SECOND APPROVAL: Approve the requested strength for 5 months as follows:**
        - **40mg/0.8mL: #2 per 28 days.**
        - **40mg/0.4mL: #2 per 28 days.**

    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADALIMUMAB (Humira)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   4. Ankylosing spondylitis (AS: a type of joint condition)
   5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   6. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   8. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
   9. Non-infectious intermediate posterior and panuveitis (a type of eye condition)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

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INITIAL CRITERIA (CONTINUED)

E. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

F. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You have tried or have a contraindication to (harmful for you to use) ONE or more forms of standard therapies, such as PUVA (psoralen and ultraviolet light A: a type of light therapy), UVB (ultraviolet light B: a type of light therapy), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), calcipotriene, acitretin, methotrexate, or cyclosporine
   4. You meet ONE of the following:
      a. You were previously stable on another biologic and are switching to Humira
      b. You have psoriasis covering 3 percent or more of body surface area (BSA)
      c. You have psoriatic lesions (rashes) affecting the face, hands, feet, or genital area

G. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
   3. You have tried or have a contraindication to (harmful for you to use) ONE standard therapy, such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

H. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 5 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
   3. You have tried or have a contraindication to (harmful for you to use) ONE standard therapy, such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

I. **If you have moderate to severe hidradenitis suppurativa, approval also requires:**
   1. You are 12 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You will NOT use Humira together with other systemic biologics (such as Cosentyx [secukinumab]) for the treatment of hidradenitis suppurativa or other tumor necrosis factor (TNF) inhibitors (such as Enbrel [etanercept], Cimzia [certolizumab pegol]) for any indication

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

J. **If you have non-infectious intermediate, posterior and panuveitis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor)
   3. You do not have isolated anterior uveitis (a different type of eye inflammation)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ADALIMUMAB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA)?

   If yes, continue to #2.
   If no, continue to #4.

2. Is the request for **Humira 40mg dosed every other week AND** the patient meets the following criterion?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for 40mg/0.8mL OR 40mg/0.4mL with a quantity limit of #2 per 28 days.**

   If no, continue to #3.

3. Is the request for **Humira 40mg dosed every week OR Humira 80mg dosed every other week** and the patient meets **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient had a trial of at least a 3-month regimen of Humira 40mg dosed every other week

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **40mg/0.8mL: #4 per 28 days.**
   - **40mg/0.4mL: #4 per 28 days.**
   - **80mg/0.8mL: #2 per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   PAC NOTE: Please enter a proactive prior authorization for 12 months by GPID or GPI-14 for Humira 40mg/0.8mL syringe/pen OR 40mg/0.4mL syringe/pen with a quantity limit of #2 syringes/pens per month.

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ADALIMUMAB

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2 per 28 days for ONE of the following as requested:**
   - **10mg/0.2mL**
   - **10mg/0.1mL**
   - **20mg/0.4mL**
   - **20mg/0.2mL**
   - **40mg/0.8mL**
   - **40mg/0.4mL**

   If no, continue to #5.

5. Does the patient have a diagnosis of psoriatic arthritis (PsA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for Humira 40mg/0.8mL OR 40mg/0.4mL with a quantity limit of #2 per 28 days.**

   If no, continue to #6.

6. Does the patient have a diagnosis of ankylosing spondylitis (AS) **AND** meet the following criterion?
   - The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for Humira 40mg/0.8mL OR 40mg/0.4mL with a quantity limit of #2 per 28 days.**

   If no, continue to #7.

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ADALIMUMAB

RENEWAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?
   - The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for Humira 40mg/0.8mL OR 40mg/0.4mL with a quantity limit of #2 per 28 days.**

   If no, continue to #8.

8. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD)?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2 per 28 days for ONE of the following as requested:**
   - **20mg/0.4mL**
   - **20mg/0.2mL**
   - **40mg/0.8mL**
   - **40mg/0.4mL**

   If no, continue to #9.

9. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC)?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **20mg/0.4mL: #4 per 28 days.**
   - **20mg/0.2mL: #4 per 28 days.**
   - **40mg/0.8mL: #4 per 28 days.**
   - **40mg/0.4mL: #4 per 28 days.**
   - **80mg/0.8mL: #2 per 28 days.**

   If no, continue to #10.

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ADALIMUMAB

RENEWAL CRITERIA (CONTINUED)

10. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) and meet **ALL** of the following criteria?
    - The patient has experienced improvement on therapy
    - Humira will NOT be used together with other systemic biologics (e.g., Cosentyx [secukinumab]) for the treatment of HS or other TNF inhibitors (e.g., Enbrel [etanercept], Cimzia [certolizumab pegol]) for any indication

    If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
    - **40mg/0.8mL: #4 per 28 days.**
    - **40mg/0.4mL: #4 per 28 days.**
    - **80mg/0.8mL: #2 per 28 days.**

    If no, continue to #11.

11. Does the patient have a diagnosis of non-infectious intermediate, posterior and panuveitis **AND** meet the following criterion?
    - The patient has not experienced treatment failure, defined as ONE of the following criteria:
      - Development of new inflammatory chorioretinal or retinal vascular lesions
      - A 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade
      - A worsening of best-corrected visual acuity (BCVA) by at least 15 letters relative to best state achieved

    If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2 per 28 days for ONE of the following as requested:**
    - **10mg/0.2mL**
    - **10mg/0.1mL**
    - **20mg/0.4mL**
    - **20mg/0.2mL**
    - **40mg/0.8mL**
    - **40mg/0.4mL**

    If no, do not approve.
    DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ADALIMUMAB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADALIMUMAB (Humira)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   4. Ankylosing spondylitis (AS: a type of joint condition)
   5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   6. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   8. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
   9. Non-infectious intermediate posterior and panuveitis (a type of eye condition)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. If you are requesting Humira 40mg weekly dosing OR Humira 80mg every other week dosing, at least a 3-month trial of Humira 40mg every other week dosing is required

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

D. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

E. **If you have ankylosing spondylitis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

F. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy

(Renewal denial text continued on next page)

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ADALIMUMAB

RENEWAL CRITERIA (CONTINUED)

G. **If you have moderate to severe hidradenitis suppurativa, renewal also requires:**
   1. You have experienced improvement on therapy
   2. You will NOT use Humira together with other systemic biologics (such as Cosentyx [secukinumab]) for the treatment of hidradenitis suppurativa or other tumor necrosis factor (TNF) inhibitors (such as Enbrel [etanercept], Cimzia [certolizumab pegol]) for any indication

H. **If you have non-infectious intermediate, posterior and panuveitis, renewal also requires:**
   1. You have not experienced treatment failure, defined as ONE of the following:
      a. You have developed new inflammatory chorioretinal or retinal vascular lesions (types of eye tumors)
      b. You have a 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade (types of classifications on how bad eye inflammation is)
      c. You have a worsening of best-corrected visual acuity (BCVA) by at least 15 letters relative to best visual acuity achieved

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Humira.

REFERENCES

- Humira [Prescribing Information]. North Chicago, IL: AbbVie Inc.; November 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 05/03
Client Approval: 03/24
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ADALIMUMAB-ADAZ

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by GPID or GPI-14 for the requested agent with a quantity limit as follows:**
   - **40mg/0.4mL: #0.8mL per 28 days.**
   - **40mg/0.8mL: #1.6mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by GPID or GPI-14 for all of the following:**
   - **10mg/0.1mL: #0.2mL per 28 days.**
   - **20mg/0.2mL: #0.4mL per 28 days.**
   - **40mg/0.4mL: #0.8mL per 28 days.**
   - **40mg/0.8mL: #1.6mL per 28 days.**

   If no, continue to #3.

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ADALIMUMAB-ADAZ

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by GPID or GPI-14 for the requested agent with a quantity limit as follows:**
   - **40mg/0.4mL: #0.8mL per 28 days.**
   - **40mg/0.8mL: #1.6mL per 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)

   If yes, **approve for 6 months by GPID or GPI-14 for the requested agent with a quantity limit as follows:**
   - **40mg/0.4mL: #0.8mL per 28 days.**
   - **40mg/0.8mL: #1.6mL per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient had a trial of or contraindication to ONE or more forms of conventional therapies (e.g., PUVA [psoralen and ultraviolet light A], UVB [ultraviolet light B], topical corticosteroids [e.g., betamethasone dipropionate, clobetasol propionate], calcipotriene, acitretin, methotrexate, or cyclosporine)

   If yes, continue to #6.
   If no, continue to #7.

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ADALIMUMAB-ADAZ

INITIAL CRITERIA (CONTINUED)

6. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic and is switching to Hyrimoz
   - The patient has psoriasis covering 3 percent or more of body surface area (BSA)
   - The patient has psoriatic lesions affecting the hands, feet, genital area, or face

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve Hyrimoz 80-40mg Psoriasis Starter Package for 1 month with a quantity limit of #1.6mL.**
   - **SECOND APPROVAL: Approve for the requested strength for 5 months as follows:**
     - **40mg/0.4 mL: #0.8mL per 28 days.**
     - **40mg/0.8 mL: #1.6mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to ONE conventional agent, such as corticosteroids (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve the requested strength for 1 month as follows:**
     - **80mg/0.8mL Crohn-UC Starter Package: #2.4 mL.**
     - **80-40mg Pediatric Crohn's Starter Package: #1.2mL.**
     - **80mg/0.8mL Pediatric Crohn's Starter Package: #2.4mL.**
   - **SECOND APPROVAL: Approve the requested strength for 5 months as follows (enter a start date of 3 DAYS before the end date of the first approval):**
     - **20mg/0.2mL: #0.4mL per 28 days.**
     - **40mg/0.4mL: #0.8mL per 28 days.**
     - **40mg/0.8mL: #1.6mL per 28 days.**

   If no, continue to #8.

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ADALIMUMAB-ADAZ

INITIAL CRITERIA (CONTINUED)

8. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?
   - The patient is 5 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to ONE conventional agent, such as corticosteroids (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve the requested strength for 1 month as follows:**
     - **80mg/0.8mL Crohn-UC Starter Package: #2.4 mL.**
     - **40mg/0.4mL: #1.6mL.**
     - **40mg/0.8mL: #3.2mL.**
     - **80mg/0.8mL: #3.2mL.**
   - **SECOND APPROVAL: Approve the requested strength for 5 months as follows (enter a start date of 3 DAYS before the end date of the first approval):**
     - **20mg/0.2mL: #0.8mL per 28 days.**
     - **40mg/0.4mL: #1.6mL per 28 days.**
     - **40mg/0.8mL: #3.2mL per 28 days.**
     - **80mg/0.8mL: #1.6mL per 28 days.**

   If no, continue to #9.

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ADALIMUMAB-ADAZ

INITIAL CRITERIA (CONTINUED)

9. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - Hyrimoz will NOT be used together with other systemic biologics (e.g., Cosentyx [secukinumab]) for the treatment of HS or other TNF inhibitors (e.g., Enbrel [etanercept], Cimzia [certolizumab pegol]) for any indication

   If yes, **approve for a total of 3 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **Approve the requested strength for 1 month as follows:**
     - **40mg/0.4mL: #1.6mL.**
     - **80mg/0.8mL: #2.4mL.**
     - **40mg/0.8mL: #3.2mL.**
   - **Approve the requested strength for 2 months as follows (enter a start date of 3 DAYS before the end date of the first approval):**
     - **40mg/0.4mL: #1.6mL per 28 days.**
     - **80mg/0.8mL: #1.6mL per 28 days.**
     - **40mg/0.8mL: #3.2mL per 28 days.**

   If no, continue to #10.

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ADALIMUMAB-ADAZ

INITIAL CRITERIA (CONTINUED)

10. Does the patient have a diagnosis of non-infectious intermediate, posterior and panuveitis and meet **ALL** of the following criteria?
    - The patient is 2 years of age or older
    - Therapy is prescribed by or in consultation with an ophthalmologist
    - The patient does NOT have isolated anterior uveitis

    If yes, **approve for a total of 6 months by GPID or GPI-14 as follows:**
    - **For age 2 to 17 years, approve all of the following:**
      - **10mg/0.1mL: #0.2mL per 28 days.**
      - **20mg/0.2mL: #0.4mL per 28 days.**
      - **40mg/0.4mL: #0.8mL per 28 days.**
      - **40mg/0.8mL: #1.6mL per 28 days.**
    - **For age 18 years and above, please enter two authorizations as follows:**
      - **Approve for 1 month for ONE of the following as requested:**
        - **40mg/0.4mL: #1.6mL.**
        - **40mg/0.8mL: #3.2mL.**
      - **Approve for 5 months for ONE of the following as requested (enter a start date of 1 WEEK after the end date of the first approval):**
        - **40mg/0.4 mL: #0.8mL per 28 days.**
        - **40mg/0.8 mL: #1.6mL per 28 days.**

    If no, do not approve.

    INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **ADALIMUMAB-ADAZ (Hyrimoz)** requires the following rule(s) be met for approval:

    A. You have ONE of the following:
       1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
       2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
       3. Psoriatic arthritis (PsA: a type of skin and joint condition)
       4. Ankylosing spondylitis (AS: a type of joint condition)
       5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
       6. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
       7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
       8. Moderate to severe hidradenitis suppurativa (a type of skin condition)
       9. Non-infectious intermediate posterior and panuveitis (a type of eye condition)

    (Initial denial text continued on next page)

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ADALIMUMAB-ADAZ

INITIAL CRITERIA (CONTINUED)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

E. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

F. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You have tried or have a contraindication (harmful for) to ONE or more forms of standard therapies, such as PUVA (psoralen and ultraviolet light A: a type of light therapy), UVB (ultraviolet light B: a type of light therapy), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), calcipotriene, acitretin, methotrexate, or cyclosporine
   4. You meet ONE of the following:
      a. You were previously stable on another biologic and are switching to Hyrimoz
      b. You have psoriasis covering 3 percent or more of body surface area (BSA)
      c. You have psoriatic lesions (rashes) affecting the face, hands, feet, or genital area

(Initial denial text continued on next page)

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ADALIMUMAB-ADAZ

INITIAL CRITERIA (CONTINUED)

G. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
   3. You have tried or have a contraindication to (harmful for you to use) ONE standard therapy, such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

H. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 5 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
   3. You have tried or have a contraindication to (harmful for you to use) ONE standard therapy, such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

I. **If you have moderate to severe hidradenitis suppurativa, approval also requires:**
   1. You are 12 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You will NOT use Hyrimoz together with other systemic biologics (such as Cosentyx (secukinumab) for the treatment of hidradenitis suppurativa or other tumor necrosis factor (TNF) inhibitors (such as Enbrel [etanercept], Cimzia [certolizumab pegol]) for any indication

J. **If you have non-infectious intermediate, posterior and panuveitis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor)
   3. You do not have isolated anterior uveitis (a different type of eye inflammation)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ADALIMUMAB-ADAZ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA)?

   If yes, continue to #2.
   If no, continue to #4.

2. Is the request for Hyrimoz 40 mg dosed **every other week AND** the patient meets the following criterion?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent with a quantity limit as follows:**
   - **40mg/0.4mL: #0.8mL per 28 days.**
   - **40mg/0.8mL: #1.6mL per 28 days.**

   If no, continue to #3.

3. Is the request for Hyrimoz 40 mg dosed **every week OR 80 mg dosed every other week** and the patient meets **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient had a trial of at least a 3-month regimen of Hyrimoz 40 mg dosed every other week

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent with a quantity limit as follows:**
   - **40mg/0.4mL: #1.6mL per 28 days.**
   - **80mg/0.8mL: #1.6mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   PAC NOTE: Please enter a proactive prior authorization for 12 months by GPID for 40mg/0.4mL with a quantity limit of #0.8 mL per 28 days OR 40mg/0.8mL with a quantity limit of #1.6 mL per 28 days.

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ADALIMUMAB-ADAZ

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **10mg/0.1mL: #0.2mL per 28 days.**
   - **20mg/0.2mL: # 0.4mL per 28 days.**
   - **40mg/0.4mL: #0.8mL per 28 days.**
   - **40mg/0.8mL: #1.6mL per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of psoriatic arthritis (PsA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent with a quantity limit as follows:**
   - **40mg/0.4mL: #0.8mL per 28 days.**
   - **40mg/0.8mL: #1.6mL per 28 days.**

   If no, continue to #6.

6. Does the patient have a diagnosis of ankylosing spondylitis (AS) **AND** meet the following criterion?
   - The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent with a quantity limit as follows:**
   - **40mg/0.4mL: #0.8mL per 28 days.**
   - **40mg/0.8mL: #1.6mL per 28 days.**

   If no, continue to #7.

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ADALIMUMAB-ADAZ

RENEWAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?
   - The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent with a quantity limit as follows:**
   - **40mg/0.4mL: #0.8mL per 28 days.**
   - **40mg/0.8mL: #1.6mL per 28 days.**

   If no, continue to #8.

8. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD)?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent with a quantity limit as follows:**
   - **20mg/0.2mL: #0.4mL per 28 days.**
   - **40mg/0.4mL: #0.8mL per 28 days.**
   - **40mg/0.8mL: #1.6mL per 28 days.**

   If no, continue to #9.

9. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC)?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent with a quantity limit as follows:**
   - **20mg/0.2mL: #0.8mL per 28 days.**
   - **40mg/0.4mL: #1.6mL per 28 days.**
   - **80mg/0.8mL: #1.6mL per 28 days.**

   If no, continue to #10.

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RENEWAL CRITERIA (CONTINUED)

10. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) and meet **ALL** of the following criteria?
    - The patient has shown improvement while on therapy
    - Hyrimoz will NOT be used together with other systemic biologics (e.g., Cosentyx [secukinumab]) for the treatment of HS or other TNF inhibitors (e.g., Enbrel [etanercept], Cimzia [certolizumab pegol]) for any indication

    If yes, **approve for 12 months by GPID or GPI-14 for the requested agent with a quantity limit as follows:**
    - **40mg/0.4mL: #1.6mL per 28 days.**
    - **40mg/0.8mL: #3.2mL per 28 days.**
    - **80mg/0.8mL: #1.6mL per 28 days.**

    If no, continue to #11.

11. Does the patient have a diagnosis of non-infectious intermediate, posterior and panuveitis **AND** meet the following criterion?
    - The patient has not experienced treatment failure, defined as ONE of the following:
      - Development of new inflammatory chorioretinal or retinal vascular lesions
      - A 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade
      - A worsening of best-corrected visual acuity (BCVA) by at least 15 letters relative to best state achieved

    If yes, **approve for 12 months by GPID or GPI-14 for the requested agent with a quantity limit as follows:**
    - **10mg/0.1mL: #0.2mL per 28 days.**
    - **20mg/0.2mL: #0.4mL per 28 days.**
    - **40mg/0.4mL: #0.8mL per 28 days.**
    - **40mg/0.8mL: #1.6mL per 28 days.**

    If no, do not approve.
    DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ADALIMUMAB-ADAZ

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADALIMUMAB-ADAZ (Hyrimoz)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   3. Psoriatic arthritis (PsA: a type of skin and joint condition)
   4. Ankylosing spondylitis (AS: a type of joint condition)
   5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   6. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   8. Moderate to severe hidradenitis suppurativa (a type of skin condition)
   9. Non-infectious intermediate posterior and panuveitis (a type of eye condition)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. If you are requesting Hyrimoz 40 mg weekly dosing OR Hyrimoz 80 mg every other week dosing, at least a 3-month trial of Hyrimoz 40 mg every other week dosing is required

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

D. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

E. **If you have ankylosing spondylitis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy

F. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy

(Renewal denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

G. **If you have moderate to severe hidradenitis suppurativa, renewal also requires:**
   1. You have shown improvement while on therapy
   2. You will NOT use Hyrimoz (adalimumab-adaz) with other systemic biologics (such as Cosentyx (secukinumab) for the treatment of hidradenitis suppurativa or other tumor necrosis factor (TNF) inhibitors (such as Enbrel [etanercept], Cimzia [certolizumab pegol]) for any indication

H. **If you have non-infectious intermediate, posterior and panuveitis, renewal also requires:**
   1. You have not experienced treatment failure, defined as ONE of the following:
      a. You have development of new inflammatory chorioretinal or retinal vascular lesions (eye tumors)
      b. You have a 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade (types of classifications on how bad eye inflammation is)
      c. you have a worsening of best-corrected visual acuity (BCVA) by at least 15 letters relative to best visual acuity achieved

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Hyrimoz and Humira.

REFERENCES

- Hyrimoz [Prescribing Information]. Princeton, NJ: Sandoz Inc.; September 2023.
- Humira [Prescribing Information]. North Chicago, IL: AbbVie Inc.; February 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 11/23
Client Approval: 03/24
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ADALIMUMAB-ADBM

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by GPID or GPI-14 for Cyltezo 40mg/0.8mL pens and syringes with a quantity limit of #2 per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #2 per 28 days for all of the following:**
   - **10mg/0.2mL.**
   - **20mg/0.4mL.**
   - **40mg/0.8mL pens and syringes.**

   If no, continue to #3.

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INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by GPID or GPI-14 for Cyltezo 40mg/0.8mL pens and syringes with a quantity limit of #2 per 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)

   If yes, **approve for 6 months by GPID or GPI-14 for Cyltezo 40mg/0.8mL pens and syringes with a quantity limit of #2 per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient had a trial of or contraindication to ONE or more forms of conventional therapies, (e.g., PUVA [psoralen and ultraviolet light A], UVB [ultraviolet light B], topical corticosteroids [e.g., betamethasone dipropionate, clobetasol propionate], calcipotriene, acitretin, methotrexate, or cyclosporine)

   If yes, continue to #6.
   If no, continue to #7.

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INITIAL CRITERIA (CONTINUED)

6. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic and is switching to Cyltezo
   - The patient has psoriasis covering 3 percent or more of body surface area (BSA)
   - The patient has psoriatic lesions affecting the hands, feet, genital area, or face

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve the requested strength for 1 month as follows:**
     - **40mg/0.8mL PSORIASIS-UV Starter Package: #4 pens.**
   - **SECOND APPROVAL: Approve Cyltezo 40mg/0.8mL pens and syringes for 5 months with a quantity limit of #2 per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to ONE conventional agent, such as corticosteroids (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve the requested strength for 1 month as follows:**
     - **40mg/0.8mL CROHN'S-UC-HS Starter Package: #6 pens.**
     - **40mg/0.8mL: #3 pens/syringes.**
   - **SECOND APPROVAL: Approve the requested strength for 5 months as follows (enter a start date of 3 days before the end date of the first approval):**
     - **20mg/0.4mL: #2 per 28 days.**
     - **40mg/0.8mL: #2 pens and syringes per 28 days.**

   If no, continue to #8.

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INITIAL CRITERIA (CONTINUED)

8. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?
   - The patient is 5 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to ONE conventional agent, such as corticosteroids (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve the requested strength for 1 month as follows:**
     - **40mg/0.8mL CROHN'S-UC-HS Starter Package: #6 pens.**
     - **40mg/0.8mL: #8 pens/syringes.**
   - **SECOND APPROVAL: Approve the requested strength for 5 months as follows (enter a start date of 3 days before the end date of the first approval):**
     - **20mg/0.4mL: #4 per 28 days.**
     - **40mg/0.8mL: #4 pens and syringes per 28 days.**

   If no, continue to #9.

9. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - Cyltezo will NOT be used together with other systemic biologics (e.g., Cosentyx [secukinumab]) for the treatment of HS or other TNF inhibitors (e.g., Enbrel [etanercept], Cimzia [certolizumab pegol]) for any indication

   If yes, **approve for a total of 3 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve the requested strength for 1 month as follows:**
     - **40mg/0.8mL CROHN'S-UC-HS Starter Package: #6 pens.**
     - **40mg/0.8mL: #8 pens/syringes.**
   - **SECOND APPROVAL: Approve the requested strength for 5 months as follows (enter a start date of 3 days before the end date of the first approval):**
     - **20mg/0.4mL: #4 per 28 days.**
     - **40mg/0.8mL: #4 pens and syringes per 28 days.**

   If no, continue to #10.

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INITIAL CRITERIA (CONTINUED)

10. Does the patient have a diagnosis of non-infectious intermediate, posterior and panuveitis and meet **ALL** of the following criteria?
    - The patient is 2 years of age or older
    - Therapy is prescribed by or in consultation with an ophthalmologist
    - The patient does NOT have isolated anterior uveitis

    If yes, **approve for a total of 6 months by GPID or GPI-14 as follows:**
    - **For age 2 to 17 years, approve all of the following with a quantity limit of #2 per 28 days:**
      - **10mg/0.2mL.**
      - **20mg/0.4mL.**
      - **40mg/0.8mL pens and syringes.**
    - **For age 18 years and above, please enter two authorizations as follows:**
      - **FIRST APPROVAL: Approve the requested strength for 1 month as follows:**
        - **40mg/0.8mL PSORIASIS-UV Starter Package: #4 pens.**
      - **SECOND APPROVAL: Approve Cyltezo 40mg/0.8mL pens and syringes for 5 months with a quantity limit of #2 per 28 days.**

    If no, do not approve.

    INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **ADALIMUMAB-ADBM (Cyltezo)** requires the following rule(s) be met for approval:

    A. You have ONE of the following:
       1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
       2. Psoriatic arthritis (PsA: a type of skin and joint condition)
       3. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
       4. Ankylosing spondylitis (AS: a type of joint condition)
       5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
       6. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
       7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
       8. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
       9. Non-infectious intermediate posterior and panuveitis (a type of eye condition)

    (Initial denial text continued on next page)

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INITIAL CRITERIA (CONTINUED)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

E. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

F. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You have tried or have a contraindication to (harmful for you to use) ONE or more forms of standard therapies, such as PUVA (psoralen and ultraviolet light A: a type of light therapy), UVB (ultraviolet light B: a type of light therapy), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), calcipotriene, acitretin, methotrexate, or cyclosporine

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INITIAL CRITERIA (CONTINUED)

4. You meet ONE of the following:
   a. You were previously stable on another biologic and are switching to Cyltezo
   b. You have psoriasis covering 3 percent or more of body surface area (BSA)
   c. You have psoriatic lesions (rashes) affecting the hands, feet, genital area, or face

G. **If you have moderate to severe Crohn's disease, approval also requires:**
1. You are 6 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
3. You have tried or have a contraindication to (harmful for you to use) ONE standard therapy, such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

H. **If you have moderate to severe ulcerative colitis, approval also requires:**
1. You are 5 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
3. You have tried or have a contraindication to (harmful for you to use) ONE standard therapy, such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

I. **If you have moderate to severe hidradenitis suppurativa, approval also requires:**
1. You are 12 years of age or older
2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
3. You will NOT use Cyltezo together with other systemic biologics (such as Cosentyx [secukinumab]) for the treatment of hidradenitis suppurativa or other tumor necrosis factor (TNF) inhibitors (such as Enbrel [etanercept], Cimzia [certolizumab pegol]) for any indication

J. **If you have non-infectious intermediate, posterior and panuveitis, approval also requires:**
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor)
3. You do NOT have isolated anterior uveitis (a different type of eye inflammation)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ADALIMUMAB-ADBM

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA)?

   If yes, continue to #2.
   If no, continue to #4.

2. Is the request for **Cyltezo 40mg dosed every other week AND** the patient meets the following criterion?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for Cyltezo 40mg/0.8mL pens and syringes with a quantity limit of #2 per 28 days.**

   If no, continue to #3.

3. Is the request for **Cyltezo 40mg dosed every week OR 80mg dosed every other week** and the patient meets **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient had a trial of at least a 3-month regimen of Cyltezo 40mg dosed every other week

   If yes, **approve for 12 months by GPID or GPI-14 for Cyltezo 40mg/0.8mL pens and syringes with a quantity limit of #4 per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   PAC NOTE: Please enter a proactive prior authorization for 12 months by GPID or GPI-14 for Cyltezo 40mg/0.8mL with a quantity limit of #2 per 28 days.

4. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2 per 28 days for ONE of the following as requested:**
   - **10mg/0.2mL.**
   - **20mg/0.4mL.**
   - **40mg/0.8mL pens and syringes.**

   If no, continue to #5.

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ADALIMUMAB-ADBM

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of psoriatic arthritis (PsA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for Cyltezo 40mg/0.8mL pens and syringes with a quantity limit of #2 per 28 days.**

   If no, continue to #6.

6. Does the patient have a diagnosis of ankylosing spondylitis (AS) **AND** meet the following criterion?
   - The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for Cyltezo 40mg/0.8mL pens and syringes with a quantity limit of #2 per 28 days.**

   If no, continue to #7.

7. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?
   - The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for Cyltezo 40mg/0.8mL pens and syringes with a quantity limit of #2 per 28 days.**

   If no, continue to #8.

8. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD)?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2 per 28 days for ONE of the following as requested:**
   - **20mg/0.4mL.**
   - **40mg/0.8mL pens and syringes.**

   If no, continue to #9.

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RENEWAL CRITERIA (CONTINUED)

9. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC)?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #4 per 28 days for ONE of the following as requested:**
   - **20mg/0.4mL.**
   - **40mg/0.8mL pens and syringes.**

   If no, continue to #10.

10. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) and meet **ALL** of the following criteria?
    - The patient has experienced improvement on therapy
    - Cyltezo will NOT be used together with other systemic biologics (e.g., Cosentyx [secukinumab]) for the treatment of HS or other TNF inhibitors (e.g., Enbrel [etanercept], Cimzia [certolizumab pegol]) for any indication

    If yes, **approve for 12 months by GPID or GPI-14 for Cyltezo 40mg/0.8mL pens and syringes with a quantity limit of #4 per 28 days.**

    If no, continue to #11.

11. Does the patient have a diagnosis of non-infectious intermediate, posterior and panuveitis **AND** meet the following criterion?
    - The patient has NOT experienced treatment failure, defined as ONE of the following:
      - Development of new inflammatory chorioretinal or retinal vascular lesions
      - A 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade
      - A worsening of best-corrected visual acuity (BCVA) by at least 15 letters relative to best state achieved

    If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2 per 28 days for ONE of the following as requested:**
    - **10mg/0.2mL.**
    - **20mg/0.4mL.**
    - **40mg/0.8mL pens and syringes.**

    If no, do not approve.
    DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ADALIMUMAB-ADBM

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADALIMUMAB-ADBM (Cyltezo)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   4. Ankylosing spondylitis (AS: a type of joint condition)
   5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   6. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   8. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
   9. Non-infectious intermediate posterior and panuveitis (a type of eye condition)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. If you are requesting Cyltezo 40mg weekly dosing OR Cyltezo 80mg every other week dosing, you have tried at least 3 months of Cyltezo 40mg every other week dosing

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

D. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

   If you have ankylosing spondylitis, renewal also requires:
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: a type of disease evaluation tool) while on therapy

E. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy

(Renewal denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

F. **If you have moderate to severe hidradenitis suppurativa, renewal also requires:**
   1. You have experienced improvement on therapy
   2. You will NOT use Cyltezo together with other systemic biologics (such as Cosentyx [secukinumab]) for the treatment of hidradenitis suppurativa or other tumor necrosis factor (TNF) inhibitors (such as Enbrel [etanercept], Cimzia [certolizumab pegol]) for any indication

G. **If you have non-infectious intermediate, posterior and panuveitis, renewal also requires:**
   1. You have NOT experienced treatment failure, defined as ONE of the following:
      a. You have developed new inflammatory chorioretinal or retinal vascular lesions (eye tumors)
      b. You have a 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade (types of classifications on severity of eye inflammation)
      c. Your best-corrected visual acuity (BCVA) has worsened by at least 15 letters relative to your best visual acuity achieved

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cyltezo and Humira.

REFERENCES

- Cyltezo [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; June 2023.
- Humira [Prescribing Information]. North Chicago, IL: AbbVie Inc.; February 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 07/03
Client Approval: 03/24
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ADALIMUMAB-ATTO

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
   - **40mg/0.4mL: #0.8mL per 28 days.**
   - **40mg/0.8mL: #1.6mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths as follows:**
   - **10mg/0.2mL: #0.4mL per 28 days.**
   - **20mg/0.2mL: #0.4mL per 28 days.**
   - **20mg/0.4mL: #0.8mL per 28 days.**
   - **40mg/0.4mL: #0.8mL per 28 days.**
   - **40mg/0.8mL: #1.6mL per 28 days.**

   If no, continue to #3.

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ADALIMUMAB-ATTO

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
   - **40mg/0.4mL: #0.8mL per 28 days.**
   - **40mg/0.8mL: #1.6mL per 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
   - **40mg/0.4mL: #0.8mL per 28 days.**
   - **40mg/0.8mL: #1.6mL per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient had a trial of or contraindication to ONE or more forms of conventional therapies, (e.g., PUVA [psoralen and ultraviolet light A], UVB [ultraviolet light B], topical corticosteroids [e.g., betamethasone dipropionate, clobetasol propionate], calcipotriene, acitretin, methotrexate, or cyclosporine)

   If yes, continue to #6.
   If no, continue to #7.

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INITIAL CRITERIA (CONTINUED)

6. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another and is switching to Amjevita
   - The patient has psoriasis covering 3 percent or more of body surface area (BSA)
   - The patient has psoriatic lesions affecting the hands, feet, genital area, or face

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve for the requested strength for 1 month as follows:**
     - **40mg/0.4mL: #1.6mL.**
     - **40mg/0.8mL: #3.2mL.**
   - **SECOND APPROVAL: Approve for the requested strength for 5 months as follows:**
     - **40mg/0.4mL: #0.8mL per 28 days.**
     - **40mg/0.8mL: #1.6mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to ONE conventional agent, such as corticosteroids (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve for the requested strength for 1 month as follows:**
     - **80mg/0.8mL: #2.4mL.**
     - **40mg/0.4mL: #2.4mL.**
     - **40mg/0.8mL: #4.8mL.**
   - **SECOND APPROVAL: Approve for the requested strength for 5 months as follows (enter a start date of 3 days before the end date of the first approval):**
     - **20mg/0.2mL: #0.4mL per 28 days.**
     - **20mg/0.4mL: #0.8mL per 28 days.**
     - **40mg/0.4mL: #0.8mL per 28 days.**
     - **40mg/0.8mL: #1.6mL per 28 days.**

   If no, continue to #8.

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ADALIMUMAB-ATTO

INITIAL CRITERIA (CONTINUED)

8. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?
   - The patient is 5 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to ONE conventional agent, such as corticosteroids (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve for the requested strength for 1 month as follows:**
     - **80mg/0.8mL: #3.2mL.**
     - **40mg/0.4mL: #3.2mL.**
     - **40mg/0.8mL: #6.4mL.**
   - **SECOND APPROVAL: Approve for the requested strength for 5 months as follows (enter a start date of 3 days before the end date of the first approval):**
     - **20mg/0.2mL: #0.8mL per 28 days.**
     - **20mg/0.4mL: #1.6mL per 28 days.**
     - **40mg/0.4mL: #1.6mL per 28 days.**
     - **40mg/0.8mL: #3.2mL per 28 days.**
     - **80mg/0.8mL: #1.6mL per 28 days.**

   If no, continue to #9.

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ADALIMUMAB-ATTO

INITIAL CRITERIA (CONTINUED)

9. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - Amjevita will NOT be used together with other systemic biologics (e.g., Cosentyx [secukinumab]) for the treatment of HS or other TNF inhibitors (e.g., Enbrel [etanercept], Cimzia [certolizumab pegol]) for any indication

   If yes, **approve for a total of 3 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve for the requested strength for 1 month as follows:**
     - **80mg/0.8mL: #2.4mL.**
     - **40mg/0.4mL: #2.4mL.**
     - **40mg/0.8mL: #4.8mL.**
   - **SECOND APPROVAL: Approve for the requested strength for 2 months as follows (enter a start date of 3 days before the end date of the first approval):**
     - **80mg/0.8mL: #1.6mL per 28 days.**
     - **40mg/0.4mL: #1.6mL per 28 days.**
     - **40mg/0.8mL: #3.2mL per 28 days.**

   If no, continue to #10.

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ADALIMUMAB-ATTO

INITIAL CRITERIA (CONTINUED)

10. Does the patient have a diagnosis of non-infectious intermediate, posterior and panuveitis and meet **ALL** of the following criteria?
    - The patient is 2 years of age or older
    - Therapy is prescribed by or in consultation with an ophthalmologist
    - The patient does NOT have isolated anterior uveitis

    If yes, **approve for a total of 6 months by GPID or GPI-14 as follows:**
    - **For age 2 to 17 years, approve for all strengths as follows:**
      - **10mg/0.2mL: #0.4mL per 28 days.**
      - **20mg/0.2mL: #0.4mL per 28 days.**
      - **20mg/0.4mL: #0.8mL per 28 days.**
      - **40mg/0.4mL: #0.8mL per 28 days.**
      - **40mg/0.8mL: #1.6mL per 28 days.**
    - **For age 18 years and above, please enter two authorizations as follows:**
      - **FIRST APPROVAL: Approve the requested strength for 1 month as follows:**
        - **40mg/0.4mL: #1.6mL.**
        - **40mg/0.8mL: #3.2mL.**
      - **SECOND APPROVAL: Approve the requested strength for 5 months as follows:**
        - **40mg/0.4mL: #0.8mL per 28 days.**
        - **40mg/0.8mL: #1.6mL per 28 days.**

    If no, do not approve.

    INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **ADALIMUMAB-ATTO (Amjevita)** requires the following rule(s) be met for approval:

    A. You have ONE of the following:
       1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
       2. Psoriatic arthritis (PsA: a type of skin and joint condition)
       3. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
       4. Ankylosing spondylitis (AS: a type of joint condition)
       5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
       6. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
       7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
       8. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
       9. Non-infectious intermediate posterior and panuveitis (a type of eye condition)

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ADALIMUMAB-ATTO

INITIAL CRITERIA (CONTINUED)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

E. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

F. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You have tried or have a contraindication to (harmful for you to use) ONE or more forms of standard therapies, such as PUVA (psoralen and ultraviolet light A: a type of light therapy), UVB (ultraviolet light B: a type of light therapy), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), calcipotriene, acitretin, methotrexate, or cyclosporine
   4. You meet ONE of the following:
      a. You were previously stable on another biologic and are switching to Amjevita
      b. You have psoriasis covering 3 percent or more of body surface area (BSA)
      c. You have psoriatic lesions (rashes) affecting the hands, feet, genital area, or face

(Initial denial text continued on next page)

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ADALIMUMAB-ATTO

INITIAL CRITERIA (CONTINUED)

G. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
   3. You have tried or have a contraindication to (harmful for you to use) ONE standard therapy, such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

H. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 5 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
   3. You have tried or have a contraindication to (harmful for you to use) ONE standard therapy, such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

I. **If you have moderate to severe hidradenitis suppurativa, approval also requires:**
   1. You are 12 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You will NOT use Amjevita together with other systemic biologics (such as Cosentyx [secukinumab]) for the treatment of hidradenitis suppurativa or other tumor necrosis factor (TNF) inhibitors (such as Enbrel [etanercept], Cimzia [certolizumab pegol]) for any indication

J. **If you have non-infectious intermediate, posterior and panuveitis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor)
   3. You do not have isolated anterior uveitis (a different type of eye inflammation)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ADALIMUMAB-ATTO

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA)?

   If yes, continue to #2.
   If no, continue to #4.

2. Is the request for **Amjevita 40mg dosed every other week AND** the patient meets the following criterion?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **40mg/0.4mL: #0.8mL per 28 days.**
   - **40mg/0.8mL: #1.6mL per 28 days.**

   If no, continue to #3.

3. Is the request for **Amjevita 40mg dosed every week OR 80mg dosed every other week** and the patient meets **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient had a trial of at least a 3-month regimen of Amjevita 40mg dosed every other week

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **80mg/0.8mL: #1.6mL per 28 days.**
   - **40mg/0.4mL: #1.6mL per 28 days.**
   - **40mg/0.8mL: #3.2mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   PAC NOTE: Please enter a proactive prior authorization for 12 months by GPID for 40mg/0.8mL with a quantity limit of #1.6mL per 28 days.

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ADALIMUMAB-ATTO

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **10mg/0.2mL: #0.4mL per 28 days.**
   - **20mg/0.2mL: #0.4mL per 28 days.**
   - **20mg/0.4mL: #0.8mL per 28 days.**
   - **40mg/0.4mL: #0.8mL per 28 days.**
   - **40mg/0.8mL: #1.6mL per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of psoriatic arthritis (PsA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **40mg/0.4mL: #0.8mL per 28 days.**
   - **40mg/0.8mL: #1.6mL per 28 days.**

   If no, continue to #6.

6. Does the patient have a diagnosis of ankylosing spondylitis (AS) **AND** meet the following criterion?
   - The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **40mg/0.4mL: #0.8mL per 28 days.**
   - **40mg/0.8mL: #1.6mL per 28 days.**

   If no, continue to #7.

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ADALIMUMAB-ATTO

RENEWAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?
   - The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **40mg/0.4mL: #0.8mL per 28 days.**
   - **40mg/0.8mL: #1.6mL per 28 days.**

   If no, continue to #8.

8. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD)?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **20mg/0.2mL: #0.4mL per 28 days.**
   - **20mg/0.4mL: #0.8mL per 28 days.**
   - **40mg/0.4mL: #0.8mL per 28 days.**
   - **40mg/0.8mL: #1.6mL per 28 days.**

   If no, continue to #9.

9. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC)?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **20mg/0.2mL: #0.8mL per 28 days.**
   - **20mg/0.4mL: #1.6mL per 28 days.**
   - **40mg/0.4mL: #1.6mL per 28 days.**
   - **40mg/0.8mL: #3.2mL per 28 days.**
   - **80mg/0.8mL: #1.6mL per 28 days.**

   If no, continue to #10.

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RENEWAL CRITERIA (CONTINUED)

10. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) and meet **ALL** of the following criteria?
    - The patient has experienced improvement on therapy
    - Amjevita will NOT be used together with other systemic biologics (e.g., Cosentyx [secukinumab]) for the treatment of HS or other TNF inhibitors (e.g., Enbrel [etanercept], Cimzia [certolizumab pegol]) for any indication

    If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
    - **40mg/0.4mL: #1.6mL per 28 days.**
    - **40mg/0.8mL: #3.2mL per 28 days.**
    - **80mg/0.8mL: #1.6mL per 28 days.**

    If no, continue to #11.

11. Does the patient have a diagnosis of non-infectious intermediate, posterior and panuveitis **AND** meet the following criterion?
    - The patient has not experienced treatment failure, defined as ONE of the following criteria:
      - Development of new inflammatory chorioretinal or retinal vascular lesions
      - A 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade
      - A worsening of best-corrected visual acuity (BCVA) by at least 15 letters relative to best state achieved

    If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
    - **10mg/0.2mL: #0.4mL per 28 days.**
    - **20mg/0.2mL: #0.4mL per 28 days.**
    - **20mg/0.4mL: #0.8mL per 28 days.**
    - **40mg/0.4mL: #0.8mL per 28 days.**
    - **40mg/0.8mL: #1.6mL per 28 days.**

    If no, do not approve.
    DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ADALIMUMAB-ATTO

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADALIMUMAB-ATTO (Amjevita)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   4. Ankylosing spondylitis (AS: a type of joint condition)
   5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   6. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   8. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
   9. Non-infectious intermediate posterior and panuveitis (a type of eye condition)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. If you are requesting Amjevita 40mg weekly dosing OR Amjevita 80mg every other week dosing, we require you have tried at least a 3-month trial of Amjevita 40mg every other week

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

D. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

E. **If you have ankylosing spondylitis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

F. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy

(Renewal denial text continued on next page)

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ADALIMUMAB-ATTO

RENEWAL CRITERIA (CONTINUED)

G. **If you have moderate to severe hidradenitis suppurativa, renewal also requires:**
   1. You have experienced improvement on therapy
   2. You will NOT use Amjevita together with other systemic biologics (such as Cosentyx [secukinumab]) for the treatment of hidradenitis suppurativa or other tumor necrosis factor (TNF) inhibitors (such as Enbrel [etanercept], Cimzia [certolizumab pegol]) for any indication

H. **If you have non-infectious intermediate, posterior and panuveitis, renewal also requires:**
   1. You have not experienced treatment failure, defined as ONE of the following:
      a. You have development of new inflammatory chorioretinal or retinal vascular lesions (eye tumors)
      b. A 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade (types of classifications on how bad eye inflammation is)
      c. A worsening of best-corrected visual acuity (BCVA) by at least 15 letters relative to best visual acuity achieved

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Amjevita or Humira.

REFERENCES

- Amjevita [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; August 2023.
- Humira [Prescribing Information]. North Chicago, IL: AbbVie Inc.; February 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 07/23
Client Approval: 03/24
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AFATINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic squamous non-small cell lung cancer (NSCLC) **AND** meet the following criterion?
   - The patient has disease progression after platinum-based chemotherapy (i.e., cisplatin, carboplatin, oxaliplatin)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient's tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test
   - Gilotrif will NOT be used concurrently with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (e.g., Tarceva [erlotinib], Tagrisso [Osimertinib], Iressa [gefitinib])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AFATINIB (Gilotrif)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Metastatic squamous non-small cell lung cancer (type of lung cancer that has spread to other parts of the body)
      2. Metastatic non-small cell lung cancer (a different type of lung cancer that has spread to other parts of the body)
   B. **If you have metastatic squamous non-small cell lung cancer, approval also requires:**
      1. Your disease has worsened after using platinum-based chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
   C. **If you have metastatic non-small cell lung cancer, approval also requires:**
      1. Your tumors have non-resistant epidermal growth factor receptor (EGFR: type of protein) mutations as shown by an FDA (Food and Drug Administration)-approved test
      2. You will NOT be using Gilotrif concurrently (at the same time) with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (such as Tarceva [erlotinib], Tagrisso [Osimertinib], Iressa [gefitinib])

   (Denial text continued on next page)

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AFATINIB

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gilotrif.

REFERENCES

- Gilotrif (afatinib) [prescribing information]. Boehringer Ingelheim Pharmaceuticals, Inc.; Ridgefield, CT. April 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 10/13
Client Approval: 05/22
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALECTINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) **AND** meet the following criterion?
   - Patient is positive for anaplastic lymphoma kinase (ALK) fusion oncogene as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #240 per 30 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ALECTINIB (Alecensa)** requires the following rules be met for approval:
   1. You have a diagnosis of metastatic non-small cell lung cancer (NSCLC; type of cancer that has spread)
   2. You are positive for anaplastic lymphoma kinase (ALK; gene mutation) fusion oncogene as detected by an FDA (Food and Drug Administration) -approved test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Alcensa.

REFERENCES

- Alecensa [Prescribing Information]. South San Francisco, CA: Genentech, Inc. May 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21

Created: 12/15
Client Approval: 03/21

P&T Approval: 01/18

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALLERGEN EXTRACT-HOUSE DUST MITE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of house dust mite (HDM)-induced allergic rhinitis with or without conjunctivitis and meet **ALL** of the following criteria?
   - The patient is 12 to 65 years of age
   - The patient's diagnosis is confirmed by in vitro testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, or skin testing to licensed house dust mite allergen extracts
   - Therapy is prescribed by or in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases
   - The patient has persistent symptoms of allergic rhinitis (defined as symptoms presenting at least 4 days a week or for at least 4 weeks)
   - The patient has moderate to severe symptoms of allergic rhinitis (including one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, impairment of school or work)
   - The patient has a current claim or prescription for auto-injectable epinephrine within the past 365 days

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ALLERGEN EXTRACT-HOUSE DUST MITE (Odactra)** requires the following rule(s) be met for approval:
   A. You have allergic rhinitis (itchy, watery eyes, sneezing) caused by house dust mites, with or without conjunctivitis (type of inflammation of eye and eyelid)
   B. You are 12 to 65 years of age
   C. Therapy is prescribed by or in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
   D. Your diagnosis is confirmed by in vitro testing (testing outside of your body in a tube) for IgE (Immunoglobulin E) antibodies *to Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, or skin testing to licensed house dust mite allergen extracts

   (Initial denial text continued on next page)

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ALLERGEN EXTRACT-HOUSE DUST MITE

INITIAL CRITERIA (CONTINUED)

E. You have persistent symptoms of allergic rhinitis (defined as symptoms presenting for at least 4 days a week or for at least 4 weeks)
F. You have moderate to severe symptoms of allergic rhinitis (including one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, impairment of school or work)
G. You have a current claim or prescription for auto-injectable epinephrine within the past 365 days

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Has the patient experienced an improvement in signs and symptoms of allergic rhinitis from baseline?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ALLERGEN EXTRACT-HOUSE DUST MITE (Odactra)** requires the following rule is met for renewal:
   A. You have experienced an improvement in signs and symptoms of allergic rhinitis (itchy, watery eyes, sneezing) from baseline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ALLERGEN EXTRACT-HOUSE DUST MITE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Odactra.

REFERENCES

- Odactra [Prescribing Information]. Merck, Sharp & Dohme Corp. Whitehouse Station, NJ. January 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/01/23
Created: 02/18
Client Approval: 05/23
P&T Approval: 07/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALLERGEN EXTRACT-MIXED GRASS POLLEN

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of grass pollen-induced allergic rhinitis that is confirmed by a positive skin prick test and/or a positive titer to specific IgE antibodies for any of the five grass (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens) species included in Oralair?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Was Oralair prescribed by or given in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have persistent and moderate-to-severe symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include of one or more of the following items: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does patient have a current claim or prescription for auto-injectable epinephrine?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ALLERGEN EXTRACT-MIXED GRASS POLLEN

INITIAL CRITERIA (CONTINUED)

5. Is the patient between the ages of 5 and 17 years of age?

   If yes, **approve for 12 months by GPID or GPI-14 for a quantity limit of #3 tablets of 100 IR for the first 2 days of therapy initiation and #1 tablet of 300 IR per day thereafter.**
   APPROVAL TEXT: Renewal requires that the patient has experienced an improvement in signs and symptoms of allergic rhinitis from baseline.

   If no, continue to #6.

6. Is the patient between 18 and 65 years of age?

   If yes, **approve for 12 months by GPID or GPI-10 for a quantity limit of #1 tablet (300 IR) per day.**
   APPROVAL TEXT: Renewal requires that the patient has experienced an improvement in signs and symptoms of allergic rhinitis from baseline.

   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **ALLERGEN EXTRACT-MIXED GRASS POLLEN (Oralair)** requires the following rule(s) be met for approval:
   A. You have a diagnosis of allergic rhinitis (itchy, watery eyes, sneezing) caused by grass pollen
   B. Your diagnosis is confirmed by a positive skin prick test and/or a positive titer (the amount of antibodies in the blood) to specific IgE (Immunoglobulin E) antibodies for any of the five grass types included in Oralair (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens)
   C. Therapy is prescribed by or given in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
   D. You have persistent and moderate-to-severe symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
   E. You have a current claim or prescription for auto-injectable epinephrine
   F. You are between 5 and 65 years of age
   (Initial denial text continued on next page)

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ALLERGEN EXTRACT-MIXED GRASS POLLEN

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Has the patient experienced an improvement in signs and symptoms of allergic rhinitis from baseline?

   If yes, **approve for 12 months by HICL or GPI-14 for a quantity limit of #1 tablet per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ALLERGEN EXTRACT-MIXED GRASS POLLEN (Oralair)** requires the following rules be met for renewal:
   A. You have experienced an improvement in signs and symptoms of allergic rhinitis (itchy, watery eyes, sneezing) from baseline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Oralair.

REFERENCES

- Oralair [Prescribing Information]. Lenoir, NC: GREER Laboratories, Inc., December 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/01/20
Created: 05/14
Client Approval: 04/20
P&T Approval: 01/19

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALLERGEN EXTRACT-SHORT RAGWEED POLLEN

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of short ragweed pollen-induced allergic rhinitis and meet **ALL** of the following criteria?
   - The patient is between 5 and 65 years of age
   - Diagnosis is confirmed by a positive skin test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen
   - Therapy was prescribed by or given in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases
   - The patient has persistent and moderate-to-severe symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include one or more of the following items: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
   - The patient has a current claim or prescription for auto-injectable epinephrine

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ALLERGEN EXTRACT-SHORT RAGWEED POLLEN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALLERGEN EXTRACT-SHORT RAGWEED POLLEN (Ragwitek)** requires the following rule(s) be met for approval:

A. You have allergic rhinitis (itchy, watery eyes, sneezing) caused by short ragweed pollen
B. You are between 5 and 65 years of age
C. Your diagnosis is confirmed by a positive skin test or in vitro testing (testing outside of your body in a tube) for pollen-specific IgE (Immunoglobulin E) antibodies for short ragweed pollen
D. Therapy is prescribed by or given in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
E. You have persistent and moderate-to-severe symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
F. You have a current claim or prescription for auto-injectable epinephrine

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Has the patient experienced an improvement in signs and symptoms of allergic rhinitis from baseline?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ALLERGEN EXTRACT-SHORT RAGWEED POLLEN

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALLERGEN EXTRACT-SHORT RAGWEED POLLEN (Ragwitek)** requires the following rule(s) be met for renewal:
A. You have experienced an improvement in signs and symptoms of allergic rhinitis from baseline

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ragwitek.

REFERENCES

- Ragwitek [Prescribing Information]. Swindon, UK: Catalent Pharma Solutions Limited; April 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/01/21
Created: 05/14
Client Approval: 05/21
P&T Approval: 07/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of grass pollen-induced allergic rhinitis and meet **ALL** of the following criteria?
   - The patient is between 5 and 65 years of age
   - Diagnosis is confirmed by a positive skin prick test and/or a positive titre to specific IgE antibodies for Timothy grass or cross-reactive grass pollens
   - Therapy is prescribed by or in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases
   - The patient has persistent and moderate-to-severe symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
   - The patient has a current claim or prescription for auto-injectable epinephrine

   If yes, **approve for 12 months by GPID or GPI-14 for a quantity limit of #1 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN (Grastek)** requires the following rule(s) be met for approval:
   A. You have allergic rhinitis (itchy, watery eyes, sneezing) caused by grass pollen
   B. You are between 5 and 65 years of age
   C. Your diagnosis is confirmed a positive skin prick test and/or a positive titre (the amount of antibodies in the blood) to specific IgE (Immunoglobulin E) antibodies for Timothy grass or cross-reactive grass pollens
   D. Therapy is prescribed by or in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
   (Initial denial text continued on next page)

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ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN

INITIAL CRITERIA (CONTINUED)

E. You have persistent and moderate-to-severe symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
F. You have a current claim or prescription for auto-injectable epinephrine

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Has the patient experienced an improvement in signs and symptoms of allergic rhinitis from baseline?

   If yes, **approve for 12 months by GPID or GPI-14 for a quantity limit of #1 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN (Grastek)** requires the following rule be met for renewal:
   A. You have experienced an improvement in signs and symptoms of allergic rhinitis (itchy, watery eyes, sneezing) from baseline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Grastek.

REFERENCES

- Grastek [Prescribing Information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; August 2020.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 05/14
Client Approval: 12/21
P&T Approval: 01/18

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALPELISIB-PIQRAY

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced or metastatic breast cancer and meet **ALL** of the following criteria?
   - Piqray will be used in combination with Faslodex (fulvestrant)
   - The patient's breast cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative
   - The patient's tumor is PIK3CA-mutated as detected by an FDA-approved test
   - The patient has disease progression on or after an endocrine-based regimen (e.g., letrozole, anastrozole, tamoxifen)

   If yes, **approve for 12 months by GPID or GPI -14 for all strengths as follows:**
   - **300mg daily dose: #56 per 28 days.**
   - **250mg daily dose: #56 per 28 days.**
   - **200mg daily dose: #28 per 28 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ALPELISIB-PIQRAY** requires the following rule(s) be met for approval:
   A. You have advanced or metastatic breast cancer (breast cancer that has spread to other parts of the body)
   B. Piqray will be used in combination with Faslodex (fulvestrant)
   C. Your breast cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
   D. Your tumor has a PIK3CA mutation (abnormal change in a type of gene) as detected by a Food and Drug Administration (FDA)-approved test
   E. You have disease progression (condition has worsened) on or after an endocrine (hormone)-based regimen (such as letrozole, anastrozole, tamoxifen)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALPELISIB-PIQRAY

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Piqray.

REFERENCES

- Piqray [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/12/24
Created: 08/19
Client Approval: 01/24
P&T Approval: 04/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALPELISIB - VIJOICE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of PIK3CA-related overgrowth spectrum (PROS) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient has severe manifestations of PROS that require systemic therapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **50 mg daily dose: #28 per 28 days.**
   - **125 mg daily dose: #28 per 28 days.**
   - **250 mg daily dose: #56 per 28 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ALPELISIB - VIJOICE** requires the following rule(s) be met for approval:
   A. You have PIK3CA-related overgrowth spectrum (PROS: group of disorders that cause overgrowth of parts of the body due to mutations in a type of gene)
   B. You are 2 years of age or older
   C. You have severe manifestations of PROS that require systemic therapy (treatment that targets the entire body)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vijoice.

REFERENCES

- Vijoice [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals, Corp.; April 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/22
Created: 08/22
Client Approval: 09/22
P&T Approval: 07/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMANTADINE EXTENDED RELEASE

**** Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE

GOCOVRI

1. Does the patient have a diagnosis of Parkinson's disease and meet **ALL** of the following criteria?
   - The patient has dyskinesia
   - The patient is receiving levodopa-based therapy
   - The patient had a trial of generic amantadine capsules, tablets, or solution

   If yes, **approve for 12 months by GPID or GPI-14 for all the following strengths with the following quantity limits:**
   - **Gocovri 68.5mg: #1 per day.**
   - **Gocovri 137mg: #2 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of Parkinson's disease and meet **ALL** of the following criteria?
   - The patient is experiencing 'off' episodes
   - Therapy is given as an adjunctive treatment to levodopa/carbidopa therapy
   - The patient had a trial of generic amantadine capsules, tablets, or solution

   If yes, **approve for 12 months by GPID or GPI-14 for all the following strengths with the following quantity limits:**
   - **Gocovri 68.5mg: #1 per day.**
   - **Gocovri 137mg: #2 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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AMANTADINE EXTENDED RELEASE

GUIDELINES FOR USE - GOCOVRI (CONTINUED)

GOCOVRI DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMANTADINE EXTENDED RELEASE (Gocovri)** requires the following rule(s) be met for approval:

A. You have Parkinson's disease (nervous system disorder that affects movement)
   B. **If you have dyskinesia (abnormal involuntary movements), approval also requires:**
   1. You are receiving levodopa-based therapy
   2. You have previously tried generic amantadine capsules, tablets, or solution

C. **If you are experiencing 'off' episodes (when the medication stops working), approval also requires:**
   1. You are also receiving levodopa-carbidopa therapy
   2. You have previously tried generic amantadine capsules, tablets, or solution

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

OSMOLEX ER

1. Does the patient have a diagnosis of Parkinson's disease?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the request for the treatment of drug-induced extrapyramidal symptoms (EPS) **AND** the patient meets the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE - OSMOLEX ER (CONTINUED)

3. Does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or given in consultation with a psychiatrist, neurologist, or geriatrician
   - The patient has had a trial of generic amantadine IR capsules, tablets, or solution

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with a quantity limit of #1 per day.**
   If no, do not approve.

   OSMOLEX ER DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AMANTADINE EXTENDED RELEASE (Osmolex ER)** requires the following rule(s) be met for approval:
   A. You have Parkinson's disease (nervous system disorder that affects movement) OR you are being treated for drug-induced extrapyramidal symptoms (group of movement disorders)
   B. Therapy is prescribed by or given in consultation with a psychiatrist (mental disorder doctor), neurologist (nerve doctor), or geriatrician (doctor who treats elderly people)
   C. You have previously tried generic amantadine immediate-release capsules, tablets or solution
   D. **If you are being treated for drug-induced extrapyramidal symptoms, approval also requires:**
      1. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gocovri and Osmolex ER.

REFERENCES

- Gocovri [Prescribing Information]. Emeryville, CA: Adamas Pharma, LLC.; January 2021.
- Osmolex ER [Prescribing Information]. Bridgewater, NJ: Vertical Pharmaceuticals, LLC. October 2019.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMANTADINE EXTENDED RELEASE

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/21
Created: 09/17
Client Approval: 05/21
P&T Approval: 04/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMBRISENTAN

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The patient does NOT have idiopathic pulmonary fibrosis (IPF)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have documentation (e.g., chart note, lab result, diagnostic test result, etc.) confirming a PAH diagnosis based on right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **AMBRISENTAN (Letairis)** requires the following rule(s) be met for approval:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   C. You do NOT have idiopathic pulmonary fibrosis (scarring of the lungs due to an unknown cause)
   (Initial denial text continued on next page)

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AMBRISENTAN

INITIAL CRITERIA (CONTINUED)

D. There is documentation (such as, chart note, lab result, diagnostic test result) showing you have pulmonary arterial hypertension based on ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
   1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
   3. Pulmonary vascular resistance (PVR) greater than 2 Wood units

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AMBRISENTAN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AMBRISENTAN (Letairis)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Letairis.

REFERENCES

- Letairis [Prescribing Information]. Foster City, CA: Gilead Sciences, Inc.; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 10/22
Client Approval: 02/24
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMIFAMPRIDINE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a neurologist or hematologist-oncologist
   - Diagnosis is confirmed by ALL of the following:
     - Electrodiagnostic studies (e.g., reduced compound muscle action potential (CMAP)) and/or voltage-gated calcium channel (VGCC) antibody testing
     - Clinical triad of muscle weakness, autonomic dysfunction, and decreased tendon reflexes

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the request for **Firdapse** and the patient meets the following criterion?
   - The patient is 6 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, continue to #3.

3. Is the request for **Ruzurgi**?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #10 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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AMIFAMPRIDINE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMIFAMPRIDINE (Firdapse, Ruzurgi)** requires the following rule(s) be met for approval:

A. You have Lambert-Eaton myasthenic syndrome (a type of muscle disorder)
B. Therapy is prescribed by or in consultation with a neurologist (type of brain doctor) or hematologist-oncologist (a type of blood-cancer doctor)
C. Diagnosis is confirmed by ALL of the following:
    1. Electrodiagnostic studies and/or voltage-gated calcium channel (types of lab tests) antibody testing
    2. Three clinical symptoms of muscle weakness, autonomic dysfunction (nerve dysfunction), and decreased tendon reflexes
D. **If you are requesting Firdapse, approval also requires:**
    1. You are 6 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) **AND** meet the following criterion?
    - The patient has experienced improvement or stabilization in muscle weakness compared to baseline

    If yes, **approve for 12 months for the requested drug as follows:**
    - **Firdapse: Approve by HICL or GPI-10 with a quantity limit of #8 per day.**
    - **Ruzurgi: Approve by HICL or GPI-10 with a quantity limit of #10 per day.**

    If no, do not approve.
    DENIAL TEXT: See the renewal denial text at the end of the guideline.

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AMIFAMPRIDINE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMIFAMPRIDINE (Firdapse, Ruzurgi)** requires the following rule(s) be met for renewal:

A. You have Lambert-Eaton myasthenic syndrome (a type of muscle disorder)
B. You have experienced improvement or stabilization in muscle weakness compared to baseline

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Firdapse and Ruzurgi.

REFERENCES

- Firdapse [Prescribing Information]. Coral Gables, FL: Catalyst Pharmaceuticals, Inc; September 2022.
- Ruzurgi [Prescribing Information]. Princeton, NJ: Jacobus Pharmaceutical Company, Inc., May 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/01/22
Created: 02/19
Client Approval: 10/22
P&T Approval: 10/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMIKACIN LIPOSOMAL INHALATION

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

1. Does the patient have a diagnosis of *Mycobacterium avium complex* (MAC) lung disease with limited or no alternative treatment options and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has **NOT** achieved negative sputum cultures after a minimum of 6 consecutive months of multidrug background regimen therapy
   - Arikayce will be used as part of a combination antibacterial drug regimen
   - Arikayce is being prescribed by or given in consultation with a pulmonologist or infectious disease specialist physician

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #8.4mL (1 vial) per day.**
   APPROVAL TEXT: Renewal requires that the patient has not had a positive MAC sputum culture after consecutive negative cultures and also has had improvement in symptoms. Additionally, for first renewal requests, approval requires documentation of at least one negative sputum culture for MAC by six months of Arikayce treatment. For second and subsequent renewal requests, approval requires documentation of at least three negative sputum cultures for MAC by 12 months of Arikayce treatment.

   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **AMIKACIN LIPOSOMAL INHALATION (Arikayce)** requires the following rule(s) be met for approval:
   A. You have *Mycobacterium avium complex* (MAC – group of bacteria that cause serious infections) lung disease with limited or no alternative treatment options
   B. You are 18 years of age or older
   C. You have NOT achieved negative sputum cultures (mucus tests) after using multidrug background regimen therapy for at least 6 months in a row
   D. Arikayce will be used as part of a combination antibacterial drug regimen
   E. Arikayce is being prescribed by or given in consultation with a pulmonologist (lung doctor) or infectious disease specialist physician
   (Initial denial text continued on next page)

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AMIKACIN LIPOSOMAL INHALATION

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Is the request for the first renewal of Arikayce for the treatment of patients with a diagnosis of *Mycobacterium avium complex* (MAC) lung disease and the patient meets **ALL** of the following criteria?
   - There is documentation of at least **ONE** negative sputum culture for MAC by 6 months of Arikayce treatment
   - The patient has **NOT** had a positive MAC sputum culture after consecutive negative cultures
   - The patient has had an improvement in symptoms

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #8.4mL (1 vial) per day.**
   If no, continue to #2.

2. Is the request for the second or subsequent renewal of Arikayce for treatment of patients with a diagnosis of *Mycobacterium avium complex* (MAC) lung disease and the patient meets **ALL** of the following criteria?
   - There is documentation of at least **THREE** negative sputum cultures for MAC by 12 months of Arikayce treatment
   - The patient has **NOT** had a positive MAC sputum culture after consecutive negative cultures
   - The patient has had an improvement in symptoms

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #8.4mL (1 vial) per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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AMIKACIN LIPOSOMAL INHALATION

INITIAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMIKACIN LIPOSOMAL INHALATION (Arikayce)** requires the following rule(s) be met for renewal:

A. You have *Mycobacterium avium complex* (MAC- group of bacteria that cause serious infections) lung disease
B. You have not had a positive *Mycobacterium avium complex* sputum culture (mucus test) after repeated negative cultures
C. You have experienced an improvement in symptoms
D. You meet ONE of the following:
    1. For first renewal requests, approval also requires documentation of at least ONE negative sputum culture (mucus test) for *Mycobacterium avium complex* by 6 months of Arikayce treatment
    2. For second or later renewal requests, approval also requires documentation of at least THREE negative sputum cultures (mucus test) for *Mycobacterium avium complex* by 12 months of Arikayce treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Arikayce.

REFERENCES

- Arikayce [Prescribing information]. Bridgewater, NJ: Insmed Incorporated; September 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/01/20
Created: 11/18
Client Approval: 04/20
P&T Approval: 10/18

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMLODIPINE SUSPENSION

GUIDELINES FOR USE

1. Is the patient unable to swallow oral amlodipine tablets at prescribed dose?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of 10mL per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AMLODIPINE SUSPENSION (Katerzia)** requires the following rule(s) be met for approval:
   A. You are unable to swallow oral amlodipine tablets at prescribed dose

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Katerzia.

REFERENCES

- Katerzia [Prescribing Information]. Greenwood Village, CO: Silvergate Pharmaceuticals, Inc., July 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20
Created: 02/20
Client Approval: 02/20
P&T Approval: 01/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMLODIPINE/CELECOXIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of both hypertension and osteoarthritis and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of amlodipine AND celecoxib
   - The patient has an adherence or other challenge which requires the use of the combination product over separate agents
   - Consensi will NOT be used together with any other calcium channel blocker agents (e.g. diltiazem, felodipine, verapamil)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AMLODIPINE/CELECOXIB (Consensi)** requires the following rule(s) be met for approval:
   A. You have both hypertension (abnormal high blood pressure) and osteoarthritis (a type of arthritis that occurs when tissue at the ends of your bones wears down)
   B. You are 18 years of age or older
   C. You have previously tried amlodipine AND celecoxib
   D. You have an adherence or other challenge requiring the use of the combination product over separate agents
   E. You will NOT use Consensi together with any other calcium channel blocker agents (such as diltiazem, felodipine, verapamil)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AMLODIPINE/CELECOXIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Consensi.

REFERENCES

- Consensi [Prescribing Information]. Hot Springs, AR: Burke Therapeutics, LLC; February 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20
Created: 02/20
Client Approval: 02/20
P&T Approval: 01/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMPHETAMINE SULFATE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of narcolepsy **AND** meet the following criterion?
   - The patient is 6 years of age or older

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with a quantity limit of #6 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of attention deficit disorder with hyperactivity and meet **ALL** of the following criteria?
   - The patient is 3 years of age or older
   - The patient had a previous trial of at least **ONE** of the following stimulant medications: mixed amphetamine salts (Adderall IR), methylphenidate (Ritalin IR), or dextroamphetamine (Dexedrine)

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with a quantity limit of #4 per day.**
   If no, continue to #3.

3. Is the requested medication being used for weight loss or exogenous obesity?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Are weight loss products (anti-obesity medications) a covered benefit?

   If yes, continue to #5.
   If no, guideline does not apply for plans that exclude treatment of obesity.

5. Is this an initial request (per MRF and claims history)?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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AMPHETAMINE SULFATE

GUIDELINES FOR USE (CONTINUED)

6. Does the patient meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient had a previous trial of other weight loss medications (e.g., Contrave, Belviq, Qsymia, Xenical, phentermine, phendimetrazine, benzphetamine, diethylpropion)

   If yes, **approve the requested strength for 12 weeks by GPID or GPI-14 with a quantity limit of #3 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it

   Our guideline named **AMPHETAMINE SULFATE (Evekeo)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Narcolepsy (condition where you suddenly fall asleep)
      2. Attention deficit disorder with hyperactivity (difficulty paying attention)
      3. Use for weight loss or exogenous obesity (overweight due to overeating)
   B. **If you have narcolepsy, approval also requires:**
      1. You are 6 years of age or older
   C. **If you have attention deficit disorder with hyperactivity, approval also requires:**
      1. You are 3 years of age or older
      2. You had a previous trial of at least ONE of the following stimulant medications: mixed amphetamine salts (Adderall immediate release), methylphenidate (Ritalin immediate release), dextroamphetamine (Dexedrine)
   D. **If the request is for weight loss or exogenous obesity, approval also requires:**
      1. You are 12 years of age or older
      2. You had a previous trial of other weight loss medications such as Contrave, Belviq, Qsymia, Xenical, phentermine, phendimetrazine, benzphetamine, diethylpropion

      Note: The approval of Evekeo for use as a short-term adjunct (add-on) in a regimen of weight reduction is for a maximum duration of 12 weeks

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AMPHETAMINE SULFATE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Evekeo.

REFERENCES

- Evekeo [Prescribing Information]. Atlanta, GA: Arbor Pharmaceuticals LLC; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/01/20
Created: 05/15
Client Approval: 04/20
P&T Approval: 07/19

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMPHETAMINE SULFATE ODT

GUIDELINES FOR USE

1. Does the patient have a diagnosis of attention deficit disorder with hyperactivity (ADHD) and meet **ALL** of the following criteria?
   - The patient is 6 to 17 years of age
   - The patient is unable to swallow amphetamine sulfate tablets
   - The patient had a trial of **TWO** of the following immediate-release stimulant medications: methylphenidate, dexmethylphenidate, amphetamine, dextroamphetamine, dextroamphetamine-amphetamine

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **5 mg: #8 per day.**
   - **10 mg: #4 per day.**
   - **15 mg and 20 mg: #2 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AMPHETAMINE SULFATE ODT (Evekeo ODT)** requires the following rule(s) be met for approval:
   A. You have attention deficit disorder with hyperactivity (ADHD: difficulty paying attention)
   B. You are 6 to 17 years of age
   C. You are unable to swallow amphetamine sulfate tablets
   D. You had a trial of TWO of the following immediate-release stimulant medications: methylphenidate, dexmethylphenidate, amphetamine, dextroamphetamine, dextroamphetamine-amphetamine

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AMPHETAMINE SULFATE ODT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Evekeo ODT.

REFERENCES

- Evekeo ODT [Prescribing Information]. Atlanta, GA: Arbor Pharmaceuticals LLC; September 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/23
Created: 11/22
Client Approval: 02/23
P&T Approval: 10/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ANABOLIC STEROIDS

****Please use the criteria for the specific drug requested****

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

ANADROL-50

1. Does the patient have a diagnosis of anemia and meet **ALL** of the following criteria?
   - The anemia is caused by one of the following conditions: acquired aplastic anemia, congenital aplastic anemia, myelofibrosis and the hypoplastic anemias, or Fanconi's anemia
   - The patient does **not** have any of the following contraindications to anabolic steroid therapy:
     - Known or suspected carcinoma of the prostate or breast in male patients
     - Known or suspected carcinoma of the breast in females with hypercalcemia
     - Known or suspected nephrosis (the nephrotic phase of nephritis)
     - Known or suspected hypercalcemia
     - Severe hepatic dysfunction
   - The patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #2.

CONTINUED ON NEXT PAGE

ANABOLIC STEROIDS

INITIAL CRITERIA - ANADROL-50 (CONTINUED)

2. Does the patient have a diagnosis of cachexia associated with AIDS and meet the following criteria?
   - The patient is on anti-retroviral therapy
   - The patient has a documented viral load (with date) of less than 200 copies per mL within the past 3 months
   - Therapy is prescribed by or given in consultation with a gastroenterologist, nutritional Support Specialist (SBS) or Infectious Disease specialist
   - The patient meets **ONE** of the following criteria:
     - The patient has 10% unintentional weight loss over 12 months
     - The patient has 7.5% unintentional weight loss over 6 months
     - The patient has 5% body cell mass (BCM) loss within 6 months
     - The patient has a body cell mass (BCM) of less than 35% (men) and a body mass index (BMI) of less than 27 kg per meter squared
     - The patient has a body cell mass (BCM) of less than 23% (women) of total body weight and a body mass index (BMI) of less than 27 kg per meter squared
     - The patient has a BMI of less than 18.5 kg per meter squared
   - The patient does **not** have any of the following contraindications to anabolic steroid therapy:
     - Known or suspected carcinoma of the prostate or breast in male patients
     - Known or suspected carcinoma of the breast in females with hypercalcemia
     - Known or suspected nephrosis (the nephrotic phase of nephritis)
     - Known or suspected hypercalcemia
     - Severe hepatic dysfunction
   - The patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

   If yes, **approve for 12 weeks by HICL or GPI-10.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ANABOLIC STEROIDS (Anadrol-50)** requires the following rule(s) be met for approval:

   A. You have anemia (lack of healthy red blood cells) or cachexia (condition with extreme weight loss and muscle loss) associated with AIDS (acquired immune deficiency syndrome)
   B. You will be monitored for peliosis hepatis (blood-filled spaces in the liver), liver cell tumors and blood lipid (fats) changes

   (Initial denial text continued on next page)

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ANABOLIC STEROIDS

INITIAL CRITERIA - ANADROL-50 (CONTINUED)

C. You do not have ANY of the following reasons why you cannot use anabolic steroid therapy:
   1. Known or suspected prostate or breast cancer in male patients
   2. Known or suspected breast cancer in females with hypercalcemia (high calcium levels)
   3. Known or suspected nephrosis (the nephrotic phase of nephritis-kidney inflammation)
   4. Known or suspected hypercalcemia (high calcium levels)
   5. Severe hepatic (liver) dysfunction

D. **If you have anemia, approval also requires:**
   1. The anemia is caused by one of the following conditions: acquired aplastic anemia, congenital aplastic anemia, myelofibrosis and the hypoplastic anemias, or Fanconi's

E. **If you have cachexia associated with AIDS, approval also requires:**
   1. You are on anti-retroviral therapy (therapy that treats a type of immune system virus)
   2. You have a documented viral load (amount of virus in your blood) of less than 200 copies per mL dated within the past 3 months
   3. Therapy is prescribed by or given in recommendation with a gastroenterologist (doctor of the stomach, intestine and related organs), nutritional support specialist (SBS), or infectious disease specialist
   4. You meet ONE of the following:
      a. You have 10% unintentional weight loss over 12 months
      b. You have 7.5% unintentional weight loss over 6 months
      c. You have 5% body cell mass (BCM) loss within 6 months
      d. You have a BCM of less than 35% (men) and a body mass index (BMI) of less than 27 kg per meter squared
      e. You have a BCM of less than 23% (women) of total body weight and a body mass index (BMI) of less than 27 kg per meter squared
      f. You have a BMI of less than 18.5 kg per meter squared

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ANABOLIC STEROIDS

INITIAL CRITERIA (CONTINUED)

OXANDRIN

1. Is the request for adjunctive therapy to promote weight gain and the patient meet **ALL** of the following criteria?
   - The patient's weight loss is due to one of the following conditions: extensive surgery, chronic infections, or severe trauma
   - The patient does not have any of the following contraindications to anabolic steroid therapy:
     - Known or suspected carcinoma of the prostate or breast in male patients
     - Known or suspected carcinoma of the breast in females with hypercalcemia
     - Known or suspected nephrosis (the nephrotic phase of nephritis)
     - Known or suspected hypercalcemia
     - Severe hepatic dysfunction
   - The patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

   If yes, **approve for 12 weeks by HICL or GPI-10.**
   If no, continue to #2.

2. Is the request for adjunctive therapy to offset the protein catabolism associated with prolonged administration of corticosteroids and the patient meet **ALL** of the following criteria?
   - The patient does not have any of the following contraindications to anabolic steroid therapy:
     - Known or suspected carcinoma of the prostate or breast in male patients
     - Known or suspected carcinoma of the breast in females with hypercalcemia
     - Known or suspected nephrosis (the nephrotic phase of nephritis)
     - Known or suspected hypercalcemia
     - Severe hepatic dysfunction
   - The patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #3.

3. Is the request for the relief of the bone pain accompanying osteoporosis and the patient meet **ALL** of the following criteria?
   - The patient does not have any of the following contraindications to anabolic steroid therapy:
     - Known or suspected carcinoma of the prostate or breast in male patients
     - Known or suspected carcinoma of the breast in females with hypercalcemia
     - Known or suspected nephrosis (the nephrotic phase of nephritis)
     - Known or suspected hypercalcemia
     - Severe hepatic dysfunction
   - The patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #4.

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ANABOLIC STEROIDS

INITIAL CRITERIA - OXANDRIN (CONTINUED)

4. Does the patient have a diagnosis of cachexia associated with AIDS and meet **ALL** of the following criteria?
   - The patient is on anti-retroviral therapy
   - The patient has a documented viral load (with date) of less than 200 copies per mL within the past 3 months
   - Therapy is prescribed by or given in consultation with a gastroenterologist, nutritional support specialist (SBS) or Infectious disease specialist
   - The patient meets ONE of the following criteria:
     - The patient has 10% unintentional weight loss over 12 months,
     - The patient has 7.5% unintentional weight loss over 6 months
     - The patient has 5% body cell mass (BCM) loss within 6 months
     - The patient has a body cell mass (BCM) of less than 35% (men) and a body mass index (BMI) less than 27 kg per meter squared
     - The patient has a body cell mass (BCM) of less than 23% (women) of total body weight and a body mass index (BMI) less than 27 kg per meter squared
     - The patient has a BMI of less than 18.5 kg per meter squared
   - The patient does not have any of the following contraindications to anabolic steroid therapy:
     - Known or suspected carcinoma of the prostate or breast in male patients
     - Known or suspected carcinoma of the breast in females with hypercalcemia
     - Known or suspected nephrosis (the nephrotic phase of nephritis)
     - Known or suspected hypercalcemia
     - Severe hepatic dysfunction
   - The patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

   If yes, **approve for 12 weeks by HICL or GPI-10.**
   If no, continue to #5.

5. Does the patient have a diagnosis of Turner's Syndrome and meet **ALL** of the following criteria?
   - The patient does not have any of the following contraindications to anabolic steroid therapy:
     - Known or suspected carcinoma of the prostate or breast in male patients
     - Known or suspected carcinoma of the breast in females with hypercalcemia
     - Known or suspected nephrosis (the nephrotic phase of nephritis)
     - Known or suspected hypercalcemia
     - Severe hepatic dysfunction
   - The patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: ***See Oxandrin initial denial text on the next page.***

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ANABOLIC STEROIDS

INITIAL CRITERIA - OXANDRIN (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ANABOLIC STEROIDS (Oxandrin)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Weight loss
   2. Protein catabolism (breakdown) caused by long-term use of corticosteroids
   3. Bone pain accompanying osteoporosis (weak and brittle bones)
   4. Cachexia (condition with extreme weight loss and muscle loss) associated with AIDS (acquired immune deficiency syndrome)
   5. Turner's Syndrome (disorder where female has one X chromosome

B. You will be monitored for peliosis hepatis (blood-filled spaces in the liver), liver cell tumors and blood lipid (fats) changes

C. You do not have ANY of the following reasons why you cannot use anabolic steroid therapy:
   1. Known or suspected prostate or breast cancer in male patients
   2. Known or suspected breast cancer in females with hypercalcemia (high calcium levels)
   3. Known or suspected nephrosis (the nephrotic phase of nephritis-kidney inflammation)
   4. Known or suspected hypercalcemia (high calcium levels)
   5. Severe hepatic (liver) dysfunction

D. **If you have weight loss, approval also requires:**
   1. Your weight loss is caused by extensive surgery, chronic infections, or severe trauma
   2. Medication is being used as add-on therapy to help weight gain

E. **If you have cachexia associated with AIDS, approval also requires:**
   1. You are on anti-retroviral therapy (therapy that treats a type of immune system virus)
   2. You have a documented viral load (amount of virus in your blood) of less than 200 copies per mL dated within the past 3 months
   3. Therapy is prescribed by or given in consultation with a gastroenterologist (doctor of the stomach, intestine and related organs), nutritional support specialist (SBS) or infectious disease specialist
   4. You meet ONE of the following:
      a. You have 10% unintentional weight loss over 12 months
      b. You have 7.5% unintentional weight loss over 6 months
      c. You have 5% body cell mass (BCM) loss within 6 months
      d. You have a BCM of less than 35% (men) and a body mass index (BMI) of less than 27 kg per meter squared
      e. You have a BCM of less than 23% (women) of total body weight and a body mass index (BMI) of less than 27 kg per meter squared
      f. You have a BMI of less than 18.5 kg per meter squared

(Initial denial text continued on next page)

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ANABOLIC STEROIDS

INITIAL CRITERIA - OXANDRIN (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

(**NOTE:** For the diagnosis of anemia, weight loss, protein catabolism associated with prolonged administration of corticosteroids, bone pain accompanying osteoporosis, or Turner's Syndrome, please refer to the Initial Criteria section)

OXANDRIN and ANADROL-50

1. Is the request for cachexia associated with AIDS and the patient meet **ALL** of the following criteria?
   - The patient is on anti-retroviral therapy
   - The patient's viral load is less than 200 copies per mL within the past 3 months
   - The patient has responded to therapy as measured by at least a 10% increase in weight from baseline (current weight must have been measured within the last 4 weeks, document date of measurement)
   - The patient has not received more than 24 weeks of therapy in a calendar year

   If yes, **approve for 12 weeks by HICL or GPI-10.** (**Note**: therapy is limited to 24 weeks per calendar year.)
   If no, do not approve.
   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **ANABOLIC STEROIDS (Oxandrin and Anadrol-50)** requires the following rule(s) be met for renewal:
   A. You have cachexia (condition with extreme weight loss and muscle loss) associated with AIDS (acquired immune deficiency syndrome)
   B. You are on anti-retroviral therapy (therapy that treats a type of immune system virus)
   C. Your viral load (amount of virus in your blood) is less than 200 copies per mL within the past 3 months
   D. You have a 10% increase in weight from baseline (current weight must have been measured within the last 4 weeks, document date of measurement)
   E. You have not received more than 24 weeks of therapy in a calendar year
   (Renewal denial text continued on next page)

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ANABOLIC STEROIDS

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Anadrol-50 and Oxandrin.

REFERENCES

- Anadrol-50 [Prescribing Information]. Marietta, GA: Alaven Pharmaceutical LLC; October 2012
- Oxandrin [Prescribing Information]. East Brunswick, NJ: Savient Pharmaceuticals; April 2007.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 05/15
Client Approval: 04/20
P&T Approval: 05/15

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ANAKINRA

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the treatment of coronavirus disease 2019 (COVID-19) in a hospitalized adult?

   If yes, **do not approve**. [NOTE: This indication is for hospital use only.]
   DENIAL TEXT: See initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
   - The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #0.67 mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of cryopyrin-associated periodic syndromes (CAPS) including neonatal-onset multisystem inflammatory disease (NOMID) and meet **ALL** of the following criteria?
   - The patient has genetic testing for gain-of-function mutations in the *NLRP3* gene OR has inflammatory markers (i.e., elevated CRP, ESR, serum amyloid A protein (SAA) or S100 proteins)
   - The patient has TWO of the following: urticarial-like rash (neutrophilic dermatitis), cold-triggered episodes, sensorineural hearing loss, musculoskeletal symptoms, chronic aseptic meningitis, skeletal abnormalities
   - Kineret will NOT be used concurrently with other IL-1 inhibitors (e.g., Arcalyst [rilonacept], Ilaris [canakinumab])

   If yes, **approve for lifetime by HICL or GPI-10.**
   If no, continue to #5.

5. Does the patient have a diagnosis of deficiency of interleukin-1 receptor antagonist (DIRA) and meet **ALL** of the following criteria?
   - The patient has genetic testing for gain-of-function mutations in the *IL1RN* gene OR has inflammatory markers (i.e., elevated CRP, ESR)
   - The patient has ONE of the following: pustular psoriasis-like rashes, osteomyelitis, absence of bacterial osteomyelitis, nail changes (i.e., onychomadesis)
   - Kineret will NOT be used concurrently with other IL-1 inhibitors (e.g., Arcalyst [rilonacept], Ilaris [canakinumab])

   If yes, **approve for lifetime by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ANAKINRA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ANAKINRA (Kineret)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Cryopyrin-associated periodic syndromes (CAPS) including neonatal-onset multisystem inflammatory disease (NOMID) (types of immune system disorders)
   3. Deficiency of interleukin-1 receptor antagonist (DIRA: a type of immune system disorder)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You meet ONE of the following:
      a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
      b. You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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ANAKINRA

INITIAL CRITERIA (CONTINUED)

C. **If you have cryopyrin-associated periodic syndromes including neonatal-onset multisystem inflammatory disease, approval also requires:**
   1. You had genetic testing for gain-of-function mutations (abnormal change in gene) in the *NLRP3* gene (a type of gene) OR you have inflammatory markers (elevated C-reactive protein [CRP: sign of inflammation], erythrocyte sedimentation rate [ESR: a type of blood test], serum amyloid A protein [SAA: a type of protein] or S100 proteins [a type of protein])
   2. You have TWO of the following: urticarial-like rash (neutrophilic dermatitis: a type of skin condition), cold-triggered episodes, sensorineural hearing loss (SNHL: a type of hearing loss), musculoskeletal symptoms (symptoms related to the skin and bones), chronic aseptic meningitis (inflammation of the brain and spinal cord), and skeletal (bone) abnormalities
   3. Kineret will NOT be used concurrently (at the same time) with other IL-1 inhibitors (such as Arcalyst [rilonacept], Ilaris [canakinumab])

D. **If you have deficiency of interleukin-1 receptor antagonist, approval also requires:**
   1. You had genetic testing for gain-of-function mutations (abnormal change in gene) in the *IL1RN gene* (a type of gene) OR you have inflammatory markers (elevated C-reactive protein [CRP: sign of inflammation], erythrocyte sedimentation rate [ESR: a type of blood test])
   2. You have ONE of the following: pustular psoriasis-like rashes (a type of skin condition), osteomyelitis (bone infection), absence of bacterial osteomyelitis, nail changes (onychomadesis: nail shedding)
   3. Kineret will NOT be used concurrently (at the same time) with other IL-1 inhibitors (such as Arcalyst [rilonacept], Ilaris [canakinumab])

E. NOTE: Kineret will not be approved for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ANAKINRA

RENEWAL CRITERIA

NOTE: For the diagnoses of cryopyrin-associated periodic syndromes including neonatal-onset multisystem inflammatory disease and deficiency of interleukin-1 receptor antagonist, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
   - The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.67 mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ANAKINRA

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ANAKINRA (Kineret)** requires the following rule(s) be met for renewal:

A. You have moderate to severe rheumatoid arthritis (RA: a type of joint condition)
B. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
C. You meet ONE of the following:
    1. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
    2. You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib immediate-release or extended-release]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kineret.

REFERENCES

- Kineret [Prescribing Information]. Stockholm, Sweden: Swedish Orphan Biovitrum; December 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/01/24
Created: 02/03
Client Approval: 04/24
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

APALUTAMIDE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of metastatic castration-sensitive prostate cancer (mCSPC)?

   If yes, continue to #3.
   If no, continue to #2.

2. Does the patient have a diagnosis of non-metastatic castration-resistant prostate cancer (nmCRPC) **AND** meet the following criterion?
   - The patient has high risk prostate cancer (i.e., rapidly increasing prostate specific antigen [PSA] levels)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient previously received a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., < 50 ng/dL)
   - The requested medication will be used concurrently with a gonadotropin releasing hormone GnRH) analog (e.g., leuprolide, goserelin, histrelin, degarelix)

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **60mg: #3 per day.**
   - **240mg: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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APALUTAMIDE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **APALUTAMIDE (Erleada)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Non-metastatic castration-resistant prostate cancer (nmCRPC: prostate cancer that does not respond to hormone reduction therapy and has not spread to other parts of the body)
   2. Metastatic castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread to other parts of the body and responds to hormone therapy)

B. You meet ONE of the following:
   1. You previously received a bilateral orchiectomy (both testicles have been surgically removed)
   2. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
   3. The requested medication will be used together with a gonadotropin releasing hormone analog (such as leuprolide, goserelin, histrelin, degarelix)

C. **If you have a non-metastatic castration-resistant prostate cancer, approval also requires:**
   1. You have high risk prostate cancer (rapidly increasing prostate specific antigen [PSA] levels)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
   - Metastatic castration-sensitive prostate cancer (mCSPC)
   - Non-metastatic castration-resistant prostate cancer (nmCRPC)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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APALUTAMIDE

RENEWAL CRITERIA (CONTINUED)

2. Does the patient meet **ONE** of the following criteria?
   - The patient previously received a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., < 50 ng/dL)
   - The requested medication will be used concurrently with a gonadotropin releasing hormone (GnRH) analog (e.g., leuprolide, goserelin, histrelin, degarelix)

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **60mg: #3 per day.**
   - **240mg: #1 per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **APALUTAMIDE (Erleada)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Non-metastatic castration-resistant prostate cancer (nmCRPC: prostate cancer that does not respond to hormone reduction therapy but has not spread)
      2. Metastatic castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread and responds to hormone therapy)

   B. You meet ONE of the following:
      1. You previously received a bilateral orchiectomy (both testicles have been surgically removed)
      2. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
      3. The requested medication will be used together with a gonadotropin releasing hormone analog (such as leuprolide, goserelin, histrelin, degarelix)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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APALUTAMIDE

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Erleada.

REFERENCES

- Erleada [Prescribing Information]. Horsham, PA: Janssen; February 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 05/18
Client Approval: 05/23
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

APOMORPHINE - SL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Parkinson's disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a neurologist
   - The physician has optimized drug therapy as evidenced by **BOTH** of the following:
     - Change in levodopa/carbidopa dosing strategy or formulation
     - Trial of or contraindication to at least **TWO** Parkinson's agents from two different classes: dopamine agonist (i.e., ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitor (MAO-I) (i.e., selegiline, rasagiline), or catechol-O-methyl transferase (COMT) inhibitors (i.e., entacapone, tolcapone)
   - Kynmobi is being used for the acute, intermittent treatment of 'OFF' episodes

   If yes, **approve for 6 months for all strengths by GPID or GPI-14 as follows:**
   - **Kynmobi Titration Kit: no quantity limit.**
   - **Kynmobi 10mg, 15mg, 20mg, 25mg and 30mg: #5 per day.**

   APPROVAL TEXT: Renewal requires the patient had improvement with motor fluctuations during OFF episodes with the use of Kynmobi (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair).

   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **APOMORPHINE (Kynmobi)** requires the following rule(s) be met for approval:
   A. You have Parkinson's disease (central nervous system disorder that affects movement, often including tremors)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or given in consultation with a neurologist
   (Initial denial text continued on next page)

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APOMORPHINE - SL

INITIAL CRITERIA (CONTINUED)

D. The physician has optimized drug therapy as evidenced by **BOTH** of the following:
   1. Change in levodopa/carbidopa dosing strategy or formulation
   2. Trial of or contraindication to at least two Parkinson's agents from two different classes: dopamine agonist (i.e., ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitor (MAO-I) (i.e., selegiline, rasagiline), or catechol-o-methyl transferase (COMT) inhibitors (i.e., entacapone, tolcapone)

E. The requested medication is being used for acute, intermittent treatment (sudden and periodic treatment) of 'OFF' episodes (when symptoms return due to your medication for Parkinson's disease wearing off)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Parkinson's disease **AND** meet the following criterion?
   - The patient had improvement with motor fluctuations during 'OFF' episodes with the use of Kynmobi (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **Kynmobi 10mg, 15mg, 20mg, 25mg and 30mg: #5 per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **APOMORPHINE (Kynmobi)** requires the following rule(s) be met for renewal:
   A. You have Parkinson's disease (central nervous system disorder that affects movement, often including tremors)
   B. You had improvement with motor fluctuations during 'OFF' episodes (when symptoms return due to your medications for Parkinson's disease wearing off) with the use of Kynmobi (such as improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

   (Renewal denial text continued on next page)

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APOMORPHINE - SL

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kynmobi.

REFERENCES

- Kynmobi [Prescribing Information]. Marlborough, MA: Sunovion Pharmaceuticals Inc., May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/20
Created: 08/20
Client Approval: 08/20
P&T Approval: 07/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

APOMORPHINE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of advanced Parkinson's disease and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a neurologist
   - Apokyn will be used for the acute, intermittent treatment of hypomobility, OFF episodes associated with advanced Parkinson's disease
   - The physician has optimized drug therapy as evidenced by BOTH of the following:
     - Change in levodopa/carbidopa dosing strategy or formulation
     - Trial of or contraindication to TWO Parkinson disease agents from two different classes: dopamine agonist (i.e., ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (i.e., selegiline, rasagiline), catechol-O-methyl transferase (COMT) inhibitors (i.e., entacapone, tolcapone)

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #60mL per month.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **APOMORPHINE (Apokyn)** requires the following rule(s) be met for approval:
   A. You have a diagnosis of advanced Parkinson's disease (a type of movement disorder)
   B. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
   C. The requested medication will be used for acute, intermittent treatment of hypomobility (short and sudden episodes where you have decreased ability to move), OFF episodes associated with advanced Parkinson's disease
   D. Your doctor has optimized your drug therapy as evidenced by BOTH of the following:
      1. Change in levodopa/carbidopa dosing strategy or formulation
      2. You have had a trial of or contraindication (harmful for) to TWO Parkinson disease agents from two different classes: dopamine agonist (ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (selegiline, rasagiline), catechol-O-methyl transferase (COMT) inhibitors (entacapone, tolcapone)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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APOMORPHINE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of advanced Parkinson's disease **AND** meet the following criterion?
   - Patient has experienced improvement with motor fluctuations during OFF episodes with the use of Apokyn (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

     If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #60mL per month.** If no, do not approve.
     RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

     Our guideline named **APOMORPHINE (Apokyn)** requires the following rule(s) be met for renewal:
     A. You have a diagnosis of advanced Parkinson's disease (a type of movement disorder)
     B. You have had improvement with motor fluctuations during OFF episodes with the use of Apokyn (such as improvement in speech, facial expression, tremor [shaking] at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

     Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Apokyn.

REFERENCES

- Apokyn [Prescribing Information]. Louisville, KY: US WorldMeds, LLC, April 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 11/04
Client Approval: 03/22
P&T Approval: 04/19

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

APREMILAST

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **enter approval(s) by GPID or GPI-14 as follows:**
   - **If the starter pack is requested for dosage titration, approve for 1 fill for either #1 Otezla Two Week Starter Pack (#27 tablets) OR for #1 Otezla 28-day Starter Pack (#55 tablets) AND**
   - **Approve for 6 months for #2 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of mild plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient had a trial of or contraindication to one conventional systemic agent (e.g., methotrexate, acitretin, cyclosporine) OR one conventional topical agent (e.g., topical corticosteroids [e.g., betamethasone dipropionate, clobetasol propionate])

   If yes, continue to #3.
   If no, continue to #4.

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APREMILAST

INITIAL CRITERIA (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic and is switching to Otezla
   - The patient has a static Physician Global Assessment (sPGA) score of 2
   - The patient has a Psoriasis Area and Severity Index (PASI) score of 2 to 9

   If yes, **enter approval(s) by GPID or GPI-14 as follows:**
   - **If the starter pack is requested for dosage titration, approve for 1 fill for either #1 Otezla Two Week Starter Pack (#27 tablets) OR for #1 Otezla 28-day Starter Pack (#55 tablets) AND**
   - **Approve for 6 months for #2 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient had a trial of or contraindication to ONE or more forms of conventional therapies, (e.g., PUVA [psoralen and ultraviolet light A], UVB [ultraviolet light B], topical corticosteroids [e.g., betamethasone dipropionate, clobetasol propionate], calcipotriene, acitretin, methotrexate, or cyclosporine)

   If yes, continue to #5.
   If no, continue to #6.

5. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic and is switching to Otezla
   - The patient has psoriasis covering 3 percent or more of body surface area (BSA)
   - The patient has psoriatic lesions affecting the hands, feet, face, or genital area

   If yes, **enter approval(s) by GPID or GPI-14 as follows:**
   - **If the starter pack is requested for dosage titration, approve for 1 fill for either #1 Otezla Two Week Starter Pack (#27 tablets) OR for #1 Otezla 28-day Starter Pack (#55 tablets) AND**
   - **Approve for 6 months for #2 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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APREMILAST

INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of Behcet's disease with oral ulcers or history of recurrent oral ulcers based on clinical symptoms and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to ONE or more conservative treatments (e.g., colchicine, topical corticosteroid [e.g., triamcinolone], oral corticosteroid [e.g., prednisolone])

   If yes, **enter approval(s) by GPID or GPI-14 as follows:**
   - **If the starter pack is requested for dosage titration, approve for 1 fill for either #1 Otezla Two Week Starter Pack (#27 tablets) OR for #1 Otezla 28-day Starter Pack (#55 tablets) AND**
   - **Approve for 6 months for #2 per day.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **APREMILAST (Otezla)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Psoriatic arthritis (a type of skin and joint condition)
      2. Plaque psoriasis (a type of skin condition)
      3. Behcet's disease (a type of inflammation disorder) with oral ulcers or history of recurrent oral ulcers based on clinical symptoms

   B. **If you have psoriatic arthritis, approval also requires:**
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
      3. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   C. **If you have mild plaque psoriasis, approval also requires:**
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
      3. You have tried or have a contraindication to (harmful for you to use) one conventional (standard) systemic (treatment that targets the entire body) agent (such as methotrexate, acitretin, cyclosporine) OR one conventional topical agent (such as topical corticosteroids [such as betamethasone dipropionate, clobetasol propionate])

   (Initial denial text continued on next page)

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APREMILAST

INITIAL CRITERIA (CONTINUED)

4. You meet ONE of the following:
   a. You were previously stable on another biologic and are switching to Otezla
   b. You have a static Physician Global Assessment (sPGA: a measure used to evaluate severity of the disease) score of 2
   c. You have a Psoriasis Area and Severity Index (PASI: a measure used to evaluate severity of the disease) score of 2 to 9

D. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You have tried or have a contraindication to (harmful for you to use) ONE or more forms of standard therapies, such as PUVA (psoralen and ultraviolet light A: a type of light therapy), UVB (ultraviolet light B: a type of light therapy), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), calcipotriene, acitretin, methotrexate, or cyclosporine
   4. You meet ONE of the following:
      a. You were previously stable on another biologic and are switching to Otezla
      b. You have psoriasis covering 3 percent or more of body surface area (BSA)
      c. You have psoriatic lesions (rashes) affecting your hands, feet, face, or genital area

E. **If you have Behcet's disease with oral ulcers or history of recurrent oral ulcers based on clinical symptoms, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) ONE or more conservative treatments (such as colchicine, topical corticosteroid [such as triamcinolone], oral corticosteroid [such as prednisolone])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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APREMILAST

RENEWAL CRITERIA

1. Does the patient have psoriatic arthritis (PsA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender or swollen joint count while on therapy

   If yes, **approve for 12 months by HICL or GPI-10 for #2 per day.**
   If no, continue to #2.

2. Does the patient have mild plaque psoriasis (PsO) **AND** meet the following criterion?
   - The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more OR a decrease in sPGA (static Physician Global Assessment) by at least a 2-point reduction from baseline

   If yes, **approve for 12 months by HICL or GPI-10 for #2 per day.**
   If no, continue to #3.

3. Does the patient have moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?
   - The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more

   If yes, **approve for 12 months by HICL or GPI-10 for #2 per day.**
   If no, continue to #4.

4. Does the patient have Behcet's disease with oral ulcers or history of recurrent oral ulcers based on clinical symptoms **AND** meet the following criterion?
   - The patient has achieved or maintained clinical benefit compared to baseline (e.g., pain scores, number of ulcers)

   If yes, **approve for 12 months by HICL or GPI-10 for #2 per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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APREMILAST

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **APREMILAST (Otezla)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Psoriatic arthritis (a type of skin and joint condition)
   2. Plaque psoriasis (a type of skin condition)
   3. Behcet's disease (a type of inflammation disorder) with oral ulcers or history of recurrent oral ulcers based on clinical symptoms

B. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

C. **If you have mild plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease OR a decrease in Psoriasis Area and Severity Index (PASI: a measure used to evaluate severity of the disease) of at least 50 percent or more OR a decrease in static Physician Global Assessment (sPGA: a measure used to evaluate severity of the disease) by at least a 2-point reduction from baseline

D. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You achieved or maintained clear or minimal disease OR a decrease in Psoriasis Area and Severity Index (PASI: a measure used to evaluate severity of the disease) of at least 50 percent or more

E. **If you have Behcet's disease with oral ulcers or history of recurrent oral ulcers based on clinical symptoms, renewal also requires:**
   1. You have achieved or maintained clinical benefit compared to baseline (such as an improvement in pain scores, number of ulcers)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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APREMILAST

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Otezla.

REFERENCES

- Otezla [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; July 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 04/14
Client Approval: 03/24
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

APROCITENTAN

GUIDELINES FOR USE

INITIAL CRITERA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hypertension (ICD-10 I10) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a cardiologist, nephrologist, or endocrinologist
   - The patient's blood pressure is not controlled on at least three anti-hypertensive agents of different pharmacologic classes (e.g., an angiotensin receptor blocker [e.g., valsartan], a calcium channel blocker [e.g., amlodipine], a diuretic [e.g., hydrochlorothiazide]) at a maximally tolerated dose for at least 4 weeks
   - The patient does not have resistant hypertension due to white coat effect, medical inertia, poor therapeutic adherence, or secondary causes of hypertension (except sleep apnea)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient is on concurrent treatment with at least three other anti-hypertensive agents (e.g., valsartan, amlodipine, hydrochlorothiazide) at maximally tolerated doses
   - The patient had a trial of or contraindication to a potent diuretic (i.e., chlorthalidone or indapamide) AND a mineralocorticoid receptor antagonist (i.e., spironolactone or eplerenone)

   If yes, **approve for 2 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **APROCITENTAN (Tryvio)** requires the following rule(s) be met for approval:
   A. You have hypertension (high blood pressure)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor), nephrologist (a type of kidney doctor), or endocrinologist (a type of hormone doctor)

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APROCITENTAN

INITIAL CRITERIA (CONTINUED)

D. Your blood pressure is not controlled on at least three anti-hypertensive medications (drugs used to treat high blood pressure) with different mechanisms of action (such as an angiotensin receptor blocker [such as valsartan], a calcium channel blocker [such as amlodipine], a diuretic [such as hydrochlorothiazide]) at maximally tolerated dose for at least 4 weeks
E. You do not have resistant hypertension (a type of high blood pressure) due to white coat effect (a condition where blood pressure is higher in a medical setting), medical inertia (when healthcare providers do not make changes to treatment even if the medical condition is poorly controlled), poor therapeutic adherence (not keeping up with therapy), or secondary causes of hypertension (high blood pressure that is caused by another medical condition) (except sleep apnea [a type of sleep condition with difficulty breathing])
F. You are being treated at the same time with at least three other anti-hypertensive medications (drugs used to treat high blood pressure such as valsartan, amlodipine, hydrochlorothiazide) at maximally tolerated doses
G. You have tried or have a contraindication to (harmful for you to use) a potent diuretic (chlorthalidone or indapamide) AND a mineralocorticoid receptor antagonist (spironolactone or eplerenone)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

APROCITENTAN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hypertension (ICD-10 I10) and meet **ALL** of the following criteria?
   - The patient continues to benefit from the medication
   - The patient is on concurrent treatment with at least three other anti-hypertensive agents (e.g., valsartan, amlodipine, hydrochlorothiazide) at maximally tolerated doses

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **APROCITENTAN (Tryvio)** requires the following rule(s) be met for renewal:
   A. You have hypertension (high blood pressure)
   B. You continue to benefit from the medication
   C. You are being treated at the same time with at least three other anti-hypertensive medications (drugs used to treat high blood pressure such as valsartan, amlodipine, hydrochlorothiazide) at maximally tolerated doses

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tryvio.

REFERENCES

- Tryvio [Prescribing Information]. Radnor, PA: Idorsia Pharmaceuticals US Inc.; March 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/13/24
Created: 05/24
Client Approval: 05/24
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ARIPIPRAZOLE SENSOR TABS

GUIDELINES FOR USE

1. Does the patient have a diagnosis of schizophrenia and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a psychiatrist
   - The patient has a medical necessity for tracking medication ingestion

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with a quantity limit of #1 kit per 30 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of major depressive disorder and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a psychiatrist
   - Abilify MyCite will be used as an adjunctive treatment
   - The patient has a medical necessity for tracking medication ingestion

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with a quantity limit of #1 kit per 30 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of bipolar I disorder and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a psychiatrist
   - The patient has a medical necessity for tracking medication ingestion

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   - The request is for acute treatment of manic and mixed episodes as monotherapy, OR as an adjunct to lithium or valproate
   - The request is for maintenance treatment as monotherapy, OR as an adjunct to lithium or valproate

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with a quantity limit of #1 kit per 30 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ARIPIPRAZOLE SENSOR TABS (Abilify MyCite)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Schizophrenia (a type of mental health disorder)
      2. Bipolar I disorder (a type of mood disorder)
      3. Major depressive disorder (MDD: a type of mental health disorder)
   B. **If you have schizophrenia, approval also requires:**
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with a psychiatrist (a type of mental health doctor)
      3. You have a medical necessity for medication ingestion tracking
   C. **If you have major depressive disorder, approval also requires:**
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with a psychiatrist (a type of mental health doctor)
      3. Abilify MyCite will be used as an adjunctive (add-on) treatment
      4. You have a medical necessity for medication ingestion tracking
   D. **If you have bipolar I disorder, approval also requires:**
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with a psychiatrist (a type of mental health doctor)
      3. You have a medical necessity for medication ingestion tracking
      4. You meet ONE of the following:
         i. The request is for acute (short-term) treatment of manic and mixed episodes as monotherapy (used alone), OR as an adjunct (add-on) to lithium or valproate
         ii. The request is for maintenance treatment as monotherapy, OR as an adjunct to lithium or valproate

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ARIPIPRAZOLE SENSOR TABS

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Abilify MyCite.

REFERENCES

- Abilify MyCite [Prescribing Information]. Redwood City, CA: Proteus Digital Health, Inc.: February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/24/22
Created: 02/19
Client Approval: 10/22
P&T Approval: 01/19

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ASCIMINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a mutational analysis prior to initiation AND Scemblix is appropriate per the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile *(Please see header CML-5 of the current NCCN guidelines)*

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient's cancer positive for the T315I mutation?

   If yes, **approve Scemblix 40mg for 12 months by GPID or GPI-14 with a quantity limit of #10 per day.**
   If no, continue to #3.

3. Has the patient been previously treated with at least TWO tyrosine kinase inhibitors (TKIs) (e.g., bosutinib, dasatinib, imatinib, nilotinib)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **ASCIMINIB (Scemblix)** requires the following rule(s) be met for approval:
   A. You have Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML: type of blood cancer) in chronic phase (CP)
   B. You are 18 years of age or older
   C. You had a mutational analysis prior to initiation of therapy AND Scemblix is appropriate per the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1; a type of abnormal gene) profile
   D. You meet ONE of the following:
      1. Your cancer has the T315I mutation (a type of abnormal gene)
      2. You have been previously treated with at least TWO tyrosine kinase inhibitors (TKIs), such as bosutinib, dasatinib, imatinib, nilotinib

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ASCIMINIB

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Scemblix.

REFERENCES

- Scemblix [Prescribing Information]. East Hanover, New Jersey: Novartis Pharmaceuticals Co.; October 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective:04/01/22
Created: 02/22
Client Approval: 02/22
P&T Approval: 01/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ASFOTASE ALFA

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is this a request for treatment of perinatal/infantile-onset hypophosphatasia (HPP)?

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient have a documented diagnosis of perinatal/infantile-onset hypophosphatasia (HPP) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient was 6 months of age or younger at hypophosphatasia (HPP) onset
   - The patient is NOT currently receiving treatment with a bisphosphonate [e.g., Boniva (ibandronate), Fosamax (alendronate), Actonel (risedronate)].
   - The patient is positive for a tissue non-specific alkaline phosphatase (TNSALP) (ALPL) gene mutation as confirmed by genetic testing OR meets at least TWO of the following criteria:
     - Serum alkaline phosphatase (ALP) level below that of normal range for patient age
     - Serum pyridoxal-5'-phosphate (PLP) levels elevated AND patient has not received vitamin B_6 supplementation in the previous week
     - Urine phosphoethanolamine (PEA) level above that of normal range for patient age
     - Radiographic evidence of hypophosphatasia (HPP) (e.g., flared and frayed metaphyses, osteopenia, widened growth plates, areas of radiolucency or sclerosis)
     - Presence of two or more of the following:
       - Rachitic chest deformity
       - Craniosynostosis (premature closure of skull bones)
       - Delay in skeletal growth resulting in delay of motor development
       - History of vitamin B_6 dependent seizures
       - Nephrocalcinosis or history of elevated serum calcium
       - History or presence of non-traumatic postnatal fracture and delayed fracture healing

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is this a request for treatment of juvenile-onset hypophosphatasia (HPP)?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ASFOTASE ALFA

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a documented diagnosis of juvenile-onset hypophosphatasia (HPP) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient was 18 years of age or younger at hypophosphatasia (HPP) onset
   - The patient is NOT currently receiving treatment with a bisphosphonate [e.g., Boniva (ibandronate), Fosamax (alendronate), Actonel (risedronate)].
   - The patient is positive for a tissue non-specific alkaline phosphatase (TNSALP) (ALPL) gene mutation as confirmed by genetic testing OR meets at least TWO of the following criteria:
     - Serum alkaline phosphatase (ALP) level below that of normal range for patient age
     - Serum pyridoxal-5'-phosphate (PLP) levels elevated AND patient has not received vitamin B_6 supplementation in the previous week
     - Urine phosphoethanolamine (PEA) level above that of normal range for patient age
     - Radiographic evidence of hypophosphatasia (HPP) (e.g., flared and frayed metaphyses, osteopenia, osteomalacia, widened growth plates, areas of radiolucency or sclerosis)
     - Presence of two or more of the following:
       - Rachitic deformities (rachitic chest, bowed legs, knock-knees)
       - Premature loss of primary teeth prior to 5 years of age
       - Delay in skeletal growth resulting in delay of motor development
       - History or presence of non-traumatic fractures or delayed fracture healing

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Does the patient meet **ANY** of the following criteria?
   - The patient's serum calcium or phosphate level is below the normal range
   - The patient has a treatable form of rickets

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline

   If no, **approve for 6 months by HICL or GPI-10.**

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ASFOTASE ALFA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ASFOTASE ALFA (Strensiq)** requires the following rules be met for approval:

A. You have a documented diagnosis of perinatal/infantile-onset hypophosphatasia (HPP: a type of genetic condition) or juvenile-onset hypophosphatasia (HPP).
B. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
C. You are NOT currently receiving treatment with a bisphosphonate [such as Boniva (ibandronate), Fosamax (alendronate), Actonel (risedronate)]
D. **If you have perinatal/infantile-onset hypophosphatasia, approval also requires:**
    1. You were 6 months of age or younger at hypophosphatasia onset
    2. You are positive for a tissue non-specific alkaline phosphatase (a type of enzyme) (ALPL) gene mutation as confirmed by genetic testing OR you meet at least TWO of the following criteria:
        a. Serum alkaline phosphatase (type of enzyme) level below that of normal range for your age
        b. Serum pyridoxal-5'-phosphate (PLP) levels elevated AND you have not received vitamin B6 supplementation in the previous week
        c. Urine phosphoethanolamine (PEA) level above that of normal range for your age
        d. Radiographic evidence of hypophosphatasia [such as flared and frayed metaphyses (narrow part of long bone), osteopenia (bone loss), widened growth plates, areas of radiolucency (ability to see through with x-rays/ radiation) or sclerosis (hardening of an area)]
        e. Presence of two or more of the following:
            i. Rachitic chest deformity (chest bones are not normal)
            ii. Craniosynostosis (premature closure of skull bones)
            iii. Delay in skeletal growth resulting in delay of motor development
            iv. History of vitamin B6 dependent seizures
            v. Nephrocalcinosis (high calcium levels in kidney) or history of elevated serum calcium
            vi. History or presence of fracture after birth not due to injury or delayed fracture healing

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ASFOTASE ALFA

INITIAL CRITERIA (CONTINUED)

E. **If you have juvenile-onset hypophosphatasia, approval also requires:**
   1. You were 18 years of age or younger at hypophosphatasia onset
   2. You are positive for a tissue non-specific alkaline phosphatase (TNSALP) (ALPL) gene mutation as confirmed by genetic testing OR meet at least TWO of the following criteria:
      a. Serum alkaline phosphatase (type of enzyme) level below that of normal range for your age
      b. Serum pyridoxal-5'-phosphate (PLP) levels elevated AND you have not received vitamin B6 supplementation in the previous week
      c. Urine phosphoethanolamine (PEA) level above that of normal range for your age
      d. Radiographic evidence of hypophosphatasia [such as flared and frayed metaphyses (narrow part of long bone), osteopenia (bone loss), osteomalacia (bone softening), widened growth plates, areas of radiolucency or sclerosis (hardening of an area)]
      e. Presence of two or more of the following:
         i. Rachitic deformities (rachitic chest, bowed legs, knock-knees)
         ii. Premature loss of primary teeth prior to 5 years of age
         iii. Delay in skeletal growth leading to motor development delay
         iv. History or presence of fracture after birth not due to injury or delayed fracture healing

Strensiq will not be approved if you meet any of the following:

A. Your serum calcium or phosphate level is below the normal range
B. You have a treatable form of rickets (softening and weakening of bones in children, usually due to low vitamin D)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ASFOTASE ALFA

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. During the last 6 months of treatment, has the patient experienced improvement in the skeletal characteristics of hypophosphatasia (HPP) (e.g., improvement of the irregularity of the provisional zone of calcification, physeal widening, metaphyseal flaring, radiolucencies, patchy osteosclerosis, ratio of mid-diaphyseal cortex to bone thickness, gracile bones, bone formation and fractures)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient currently receiving treatment with a bisphosphonate [e.g., Boniva (ibandronate), Fosamax (alendronate), Actonel (risedronate)]?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, **approve for 12 months by HICL or by GPI-10.**

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ASFOTASE ALFA (Strensiq)** requires that the following rule(s) be met for renewal:
   A. You have experienced improvement in the skeletal characteristics of hypophosphatasia (HPP: genetic disorder causing abnormal development of bones and teeth). Characteristics may include irregularity of the provisional zone of calcification (area on long bone for calcium build-up), physeal widening (area of bone that helps length growth), metaphyseal flaring (a narrow part of long bone grows), radiolucencies (ability to see with x-rays/ radiation), patchy osteosclerosis (parts of abnormal hardening of bone), ratio of mid-diaphyseal cortex to bone thickness, gracile (slender) bones, bone formation and fractures.
   B. You are NOT currently receiving treatment with a bisphosphonate [such as Boniva (ibandronate), Fosamax (alendronate), Actonel (risedronate)].

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ASFOTASE ALFA

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Strensiq.

REFERENCES

- Strensiq [Prescribing Information]. Cheshire, CT: Alexion Pharmaceuticals, Inc.; June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 11/15
Client Approval: 05/22
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ASPARAGINASE ERWINIA-RYWN

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute lymphoblastic leukemia (ALL) or lymphoblastic lymphoma (LBL) and meet **ALL** of the following criteria?
   - The patient is 1 month of age or older
   - The patient has developed hypersensitivity to E. coli-derived asparaginase
   - Rylaze will be used as a component of a multi-agent chemotherapeutic regimen

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ASPARAGINASE ERWINIA-RYWN (Rylaze)** requires the following rule(s) be met for approval:
   A. You have acute lymphoblastic leukemia (ALL: type of blood cancer) or lymphoblastic lymphoma (LBL: type of cancer affecting the immune system)
   B. You are 1 month of age or older
   C. You have developed hypersensitivity to E.coli-derived asparaginase (you are allergic to an enzyme/protein that is from a type of bacteria)
   D. Rylaze will be used as a component of a multi-agent chemotherapeutic regimen

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rylaze.

REFERENCES

- Rylaze [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; June 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 10/21
Client Approval: 11/21
P&T Approval: 10/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ATOGEPANT

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of episodic migraines and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Qulipta is prescribed for the preventive treatment of migraines
   - Qulipta will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet]) for migraine prevention
   - The patient had a trial of or contraindication to ONE of the following preventive migraine treatments: divalproex sodium/sodium valproate, topiramate, propranolol, timolol, metoprolol, atenolol, nadolol, amitriptyline, venlafaxine

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of chronic migraines and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Qulipta is prescribed for the preventive treatment of migraines
   - Qulipta will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet]) for migraine prevention
   - The patient had a trial of or contraindication to ONE of the following preventive migraine treatments: divalproex sodium/sodium valproate, topiramate, propranolol, timolol, metoprolol, atenolol, nadolol, amitriptyline, venlafaxine, Botox [Note: For Botox, previous trial of only NDCs # 00023-1145-01 or 00023-3921-02 are allowable]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ATOGEPANT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ATOGEPANT (Qulipta)** requires the following rule(s) be met for approval:

A. You have migraines
B. **If you have episodic migraines (0-14 headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Qulipta is prescribed for the preventive treatment of migraines
   3. You will NOT use Qulipta concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet]) for migraine prevention
   4. You have tried or have a contraindication (harmful for) to ONE of the following preventive migraine treatments: divalproex sodium/sodium valproate, topiramate, propranolol, timolol, metoprolol, atenolol, nadolol, amitriptyline, venlafaxine
C. **If you have chronic migraines (15 or more headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Qulipta is prescribed for the preventive treatment of migraines
   3. You will NOT use Qulipta concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet]) for migraine prevention
   4. You have tried or have a contraindication (harmful for) to ONE of the following preventive migraine treatments: divalproex sodium/sodium valproate, topiramate, propranolol, timolol, metoprolol, atenolol, nadolol, amitriptyline, venlafaxine, Botox [Note: For Botox, previous trial of only National Drug Code (NDC) 00023-1145-01 or NDC 00023-3921-02 are allowable]

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ATOGEPANT

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Is the request for the preventive treatment of migraines **AND** does the patient meet the following criterion?
   - Qulipta will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet]) for migraine prevention

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month with Qulipta therapy
   - The patient has experienced a reduction in migraine severity with Qulipta therapy
   - The patient has experienced a reduction in migraine duration with Qulipta therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ATOGEPANT (Qulipta)** requires the following rule(s) be met for renewal:
   A. Qulipta is prescribed for the preventive treatment of migraines
   B. You will NOT use Qulipta concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet]) for migraine prevention
   C. You meet ONE of the following:
      1. You have experienced a reduction in migraine or headache frequency of at least 2 days per month with Qulipta therapy
      2. You have experienced a reduction in migraine severity with Qulipta therapy
      3. You have experienced a reduction in migraine duration with Qulipta therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ATOGEPANT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Qulipta.

REFERENCES

- Qulipta [Prescribing Information]. Dublin, Ireland: AbbVie, Inc.; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/22/23

Created: 10/21
Client Approval: 05/23

P&T Approval: 01/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ATORVASTATIN

GUIDELINES FOR USE

1. Is the patient 18 years of age or older and the request is to reduce the risk of **ONE** of the following?
   - Myocardial infarction (MI), stroke, revascularization procedures, or angina and the patient has multiple risk factors for coronary heart disease (CHD) but without clinically evident CHD
   - MI or stroke and the patient has type 2 diabetes mellitus and multiple risk factors for CHD but without clinically evident CHD
   - Non-fatal MI, fatal or non-fatal stroke, revascularization procedures, hospitalization for congestive heart failure, or angina and the patient has clinically evident CHD

   If yes, continue to #6.
   If no, continue to #2.

2. Does the patient have a diagnosis of primary hyperlipidemia and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Atorvaliq will be used in addition to diet

   If yes, continue to #6.
   If no, continue to #3.

3. Does the patient have a diagnosis of heterozygous familial hypercholesterolemia (HeFH) and meet **ALL** of the following criteria?
   - The patient is 10 years of age or older
   - Atorvaliq will be used in addition to diet

   If yes, continue to #6.
   If no, continue to #4.

4. Does the patient have a diagnosis of homozygous familial hypercholesterolemia (HoFH) and meet ALL of the following criteria?
   - The patient is 10 years of age or older
   - Atorvaliq will be used in addition to other LDL-C lowering therapies (e.g., ezetimibe, fenofibrate) OR will be used alone if other LDL-C lowering therapies are unavailable

   If yes, continue to #6.
   If no, continue to #5.

CONTINUED ON NEXT PAGE

ATORVASTATIN

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of primary dysbetalipoproteinemia or hypertriglyceridemia and meet **ALL** of the following?
   - The patient is 18 years of age or older
   - Atorvaliq will be used in addition to diet

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient meet **ALL** of the following criteria?
   - The patient had a trial of or contraindication to generic atorvastatin tablets
   - The patient cannot swallow atorvastatin tablets AND had a trial of rosuvastatin (Ezallor) sprinkle capsule

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Is the patient also requesting a zero-dollar cost share exception (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

   If yes, continue to #8.
   If no, **approve for 12 months by GPID or GPI-14 with a quantity limit of #20 mL per day.**

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ATORVASTATIN

GUIDELINES FOR USE (CONTINUED)

8. Is the patient between 40-75 years of age without a history of cardiovascular disease and has NOT used any of the following secondary prevention medications for cardiovascular disease within the past 120 days based on the patient's prescription claims profile or medical records?
   - Aspirin/dipyridamole (Aggrenox)
   - Clopidogrel (Plavix)
   - Dipyridamole
   - Nitroglycerin (i.e., oral, sublingual, transdermal patch or ointment, translingual dosage forms)
   - Prasugrel (Effient)
   - Praluent Pen
   - Repatha
   - Ticagrelor (Brilinta)
   - Ticlopidine
   - Vorapaxar sulfate (Zontivity)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #5 mL per day at zero copay.**

   If no, **approve for 12 months by GPID or GPI-14 with a quantity limit of #20 mL per day.**

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ATORVASTATIN (Atorvaliq)** requires the following rule(s) be met for approval:

   A. The request is for ONE of the following:
      1. To reduce the risk of one of the following and you are 18 years of age or older:
         i. Myocardial infarction (MI: heart attack), stroke, revascularization procedures (restoring blood flow to heart and other areas), or angina (chest pain) and you have multiple risk factors for coronary heart disease (CHD: heart arteries get blocked with fats and plaques) but without clinically evident CHD
         ii. MI or stroke and you have type 2 diabetes mellitus (a disorder with high blood sugar) and multiple risk factors for CHD but without clinically evident CHD
         iii. Non-fatal (not deadly) MI, fatal (deadly) or non-fatal stroke, revascularization procedures, hospitalization for congestive heart failure (a type of heart failure), or angina and you have clinically evident CHD
      2. Primary hyperlipidemia (high level of fat in the blood due to genetic causes)
      3. Heterozygous familial hypercholesterolemia (HeFH: a type of inherited high cholesterol)
      4. Homozygous familial hypercholesterolemia (HoFH: a type of inherited high cholesterol)
      5. Primary dysbetalipoproteinemia (a condition leading to increased total cholesterol and triglyceride levels in the blood)
      6. Hypertriglyceridemia (high level of fat in the blood)

(Denial text continued on next page)

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ATORVASTATIN

GUIDELINES FOR USE (CONTINUED)

B. You had a trial of or contraindication (harmful for) to generic atorvastatin tablets
C. You cannot swallow atorvastatin tablets AND had a trial of rosuvastatin (Ezallor) sprinkle capsule
D. **If you have primary hyperlipidemia, approval also requires:**
   1. You are 18 years of age or older
   2. Atorvaliq will be used in addition to diet
E. **If you have heterozygous familial hypercholesterolemia, approval also requires:**
   1. You are 10 years of age or older
   2. Atorvaliq will be used in addition to diet
F. **If you have homozygous familial hypercholesterolemia, approval also requires:**
   1. You are 10 years of age or older
   2. Atorvaliq will be used in addition to other LDL-C lowering therapies (such as ezetimibe, fenofibrate) OR will be used alone if other LDL-C lowering therapies are unavailable
G. **If you have dysbetalipoproteinemia or hypertriglyceridemia, approval also requires:**
   1. You are 18 years of age or older
   2. Atorvaliq will be used in addition to diet
H. Requests for zero dollar cost share also requires that you are between 40-75 years of age without a history of cardiovascular disease (relating to heart and blood vessels) and you have not used any of the following secondary prevention medications for cardiovascular disease within the past 120 days based on your prescription claims profile or medical records:
   1. Aspirin/dipyridamole (Aggrenox)
   2. Clopidogrel (Plavix)
   3. Dipyridamole
   4. Nitroglycerin (i.e., oral, sublingual, transdermal patch or ointment, translingual dosage forms)
   5. Prasugrel (Effient)
   6. Praluent Pen
   7. Repatha
   8. Ticagrelor (Brilinta)
   9. Ticlopidine
   10. Vorapaxar sulfate (Zontivity)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ATORVASTATIN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Atorvaliq.

REFERENCES

- Atorvaliq [Prescribing Information]. Farmville, NC: CMP Pharma, Inc.; February 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 12/01/23
Created: 05/23
Client Approval: 11/23
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AVACOPAN

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] or microscopic polyangiitis [MPA]) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or nephrologist
   - The patient is ANCA seropositive (anti-PR3 or anti-MPO)
   - Tavneos will be used as adjunctive therapy in combination with standard therapy including glucocorticoids (e.g., methylprednisolone, prednisone)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AVACOPAN (Tavneos)** requires the following rule(s) be met for approval:
   A. You have severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (inflammation of blood vessels) (granulomatosis with polyangiitis [GPA: condition that affects the blood vessels] or microscopic polyangiitis [MPA: condition that affects the blood vessels])
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or nephrologist (a type of kidney doctor)
   D. You are ANCA seropositive for anti-PR3 or anti-MPO (a type of lab test)
   E. Tavneos will be used as adjunctive (add-on) therapy in combination with standard therapy including glucocorticoids (such as methylprednisolone, prednisone)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AVACOPAN

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] or microscopic polyangiitis [MPA]) AND meet the following criterion?
   - The patient continues to benefit from therapy (e.g., improvement of clinical manifestations, if renal vasculitis - improvement in eGFR and proteinuria values, reduction of corticosteroid dose without disease flares)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AVACOPAN (Tavneos)** requires the following rule(s) be met for renewal:
   A. You have severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (inflammation of blood vessels) (granulomatosis with polyangiitis [GPA: condition that affects the blood vessels] or microscopic polyangiitis [MPA: condition that affects the blood vessels])
   B. You continue to benefit from the medication

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tavneos.

REFERENCES

- Tavneos [Prescribing Information]. Cincinnati, OH: ChemoCentryx Inc.; October 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/24/22
Created: 02/22
Client Approval: 10/22
P&T Approval: 01/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AVAPRITINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic gastrointestinal stromal tumor (GIST) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of advanced systemic mastocytosis (AdvSM), including aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL), **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of indolent systemic mastocytosis (ISM) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day**.
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AVAPRITINIB (Ayvakit)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Unresectable or metastatic gastrointestinal stromal tumor (GIST: a type of digestive tumor that cannot be removed through surgery or has spread to other parts of the body)
      2. Advanced systemic mastocytosis (AdvSM: a type of blood disorder), including aggressive systemic mastocytosis (ASM: a type of blood disorder), systemic mastocytosis with an associated hematological neoplasm (SM-AHN: a type of blood disorder), or mast cell leukemia (MCL: a type of blood cancer)
      3. Indolent systemic mastocytosis (ISM: a type of blood disorder)

   (Denial text continued on next page)

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AVAPRITINIB

GUIDELINES FOR USE (CONTINUED)

B. **If you have unresectable or metastatic gastrointestinal stromal tumor, approval also requires:**
   1. You are 18 years of age or older
   2. You have a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations (a type of gene mutation)

C. **If you have advanced systemic mastocytosis, approval also requires:**
   1. You are 18 years of age or older

D. **If you have indolent systemic mastocytosis, approval also requires:**
   1. You are 18 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ayvakit.

REFERENCES

- Ayvakit [Prescribing Information]. Cambridge, MA: Blueprint Medicines Corporation, May 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/23

Created: 05/20
Client Approval: 06/23

P&T Approval: 07/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AVATROMBOPAG

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of thrombocytopenia and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist, gastroenterologist, hepatologist, immunologist, surgeon, or endocrinologist
   - The patient has chronic liver disease
   - The patient is scheduled to undergo a procedure 10 to 13 days following the initiation of Doptelet therapy
   - The patient has a platelet count of $<50 \times 10^9$/L measured within the last 30 days
   - The patient is NOT receiving other thrombopoietin receptor agonist therapy (e.g., Promacta)

   If yes, **approve by HICL or GPI-10 for 1 fill with a quantity limit of #15.**
   If no, continue to #2.

2. Does the patient have a diagnosis of chronic immune thrombocytopenia (cITP) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist or immunologist
   - The patient had a trial of or contraindication to corticosteroids or immunoglobulins OR had an insufficient response to splenectomy

   If yes, **approve for 2 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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AVATROMBOPAG

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it

Our guideline named **AVATROMBOPAG (Doptelet)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   a. Thrombocytopenia (a type of blood disorder)
   b. Chronic immune thrombocytopenia (immune system attacks your blood platelets)

B. **If you have thrombocytopenia, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor), gastroenterologist (doctor who treats digestive conditions), hepatologist (a type of liver doctor), immunologist (a type of immune system doctor), surgeon, or endocrinologist (a type of hormone doctor)
   3. You have chronic (long-term) liver disease
   4. You are scheduled to undergo a procedure 10 to 13 days after starting Doptelet therapy
   5. You have a platelet (type of blood cell that prevents bleeding) count of less than 50 x 10(9)/L measured within the last 30 days
   6. You are NOT receiving other thrombopoietin receptor agonist therapy such as Promacta

C. **If you have chronic immune thrombocytopenia (cITP), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or immunologist (a type of immune system doctor)
   3. You had a trial of or contraindication (harmful for) to corticosteroids or immunoglobulins OR you had an insufficient response to splenectomy (surgical removal of spleen did not work)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AVATROMBOPAG

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

NOTE: For the diagnosis of thrombocytopenia in chronic liver disease, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of chronic immune thrombocytopenia (cITP) **AND** meet the following criterion?
   - Patient had a clinical response to therapy as defined by an increase in platelet count to at least 50 x 10^9/L (at least 50,000 per microliter), compared to baseline.

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AVATROMBOPAG (Doptelet)** requires the following rule(s) be met for renewal:
   A. You have a diagnosis of chronic immune thrombocytopenia (immune system attacks your blood platelets)
   B. You had a clinical response to therapy as defined by an increase in platelet count to at least 50 x 10(9)/L (at least 50,000 per microliter), compared to baseline.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Doptelet.

REFERENCES

- Doptelet [prescribing information]. Durham, NC. Dova Pharmaceuticals, Inc. July 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 08/18
Client Approval: 02/22
P&T Approval: 01/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AXITINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) and meet **ONE** of the following criteria?
   - The patient has tried at least **ONE** systemic therapy for the treatment of RCC [e.g., Nexavar (sorafenib), Torisel (temsirolimus), Sutent (sunitinib), Votrient (pazopanib), or Avastin (bevacizumab) in combination with interferon]
   - Inlyta will be used in combination with avelumab (Bavencio) as a first-line treatment
   - Inlyta will be used in combination with pembrolizumab (Keytruda) as a first-line treatment

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Inlyta 1mg: #6 per day.**
   - **Inlyta 5mg: #4 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AXITINIB (Inlyta)** requires the following rule(s) be met for approval:
   A. You have advanced renal cell carcinoma (RCC; type of kidney cancer)
   B. You also meet ONE of the following:
      1. You have tried at least ONE systemic therapy (treatment that spreads throughout the body) for the treatment of renal cell carcinoma such as Nexavar (sorafenib), Torisel (temsirolimus), Sutent (sunitinib), Votrient (pazopanib), or Avastin (bevacizumab) in combination with interferon
      2. Inlyta will be used in combination with avelumab (Bavencio) as a first-line treatment
      3. Inlyta will be used in combination with pembrolizumab (Keytruda) as a first-line treatment

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AXITINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Inlyta.

REFERENCES

- Inlyta [Prescribing Information]. New York, NY: Pfizer; June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 02/12
Client Approval: 03/21
P&T Approval: 07/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AZACITIDINE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute myeloid leukemia and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy
   - The patient is not able to complete intensive curative therapy

   If yes, **approve for 12 months for all strengths by GPID or GPI-14 with a quantity limit of #14 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AZACITIDINE (Onureg)** requires the following rule(s) be met for approval:
   A. You have acute myeloid leukemia (AML: type of blood and bone marrow cancer with too many white blood cells)
   B. You are 18 years of age or older
   C. You have achieved first complete remission (CR: signs or symptoms of cancer have disappeared) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy (medications for cancer)
   D. You are not able to complete intensive curative therapy (treatment to cure the disease)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Onureg.

REFERENCES

- Onureg [Prescribing Information]. Summit, NJ: Celgene Corporation; September 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21
Created: 10/20
Client Approval: 11/20
P&T Approval: 10/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AZTREONAM INHALED

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cystic fibrosis and meet **ALL** of the following criteria?
   - The patient is 7 years of age or older
   - The patient has a lung infection with a Gram negative species (such as *Pseudomonas aeruginosa*; not *Staphylococcus aureus* because it is not a Gram negative species)

   If yes, **approve for 12 months by GPI-10 for 6 fills of #84 vials per 56 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AZTREONAM INHALED** requires the following rule(s) be met for approval:
   A. You have a diagnosis of cystic fibrosis (inherited life-threatening disorder that damages the lungs and digestive system)
   B. You are 7 years of age or older
   C. You have a lung infection with a Gram negative species such as *Pseudomonas aeruginosa*

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cayston.

REFERENCES

- Cayston [Prescribing Information]. Foster City, CA. Gilead Sciences, Inc.; November 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 05/12
Client Approval: 04/20
P&T Approval: 05/12

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BACLOFEN

GUIDELINES FOR USE

1. Is the request for Ozobax (baclofen) or Ozobax DS (baclofen) and the patient meets **ALL** of the following criteria?
   - The patient had a trial of or contraindication to generic baclofen tablets
   - The patient is unable to swallow generic baclofen tablets

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **5mg/5mL: #80mL per day.**
   - **10mg/5mL: #40mL per day.**

   If no, continue to #2.

2. Is the request for Fleqsuvy (baclofen) and the patient meets **ALL** of the following criteria?
   - The patient had a trial of or contraindication to generic baclofen tablets
   - The patient is unable to swallow generic baclofen tablets

   If yes**, approve for 12 months by GPID or GPI-14 with a quantity limit of #16mL per day.**
   If no, continue to #3.

3. Is the request for Lyvispah and the patient meets **ALL** of the following criteria?
   - The patient had a trial of or contraindication to generic baclofen tablets
   - The patient is unable to swallow generic baclofen tablets

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **5mg: #9 per day.**
   - **10mg: #3 per day.**
   - **20mg: #4 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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BACLOFEN

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BACLOFEN (Ozobax, Ozobax DS, Fleqsuvy, Lyvispah)** requires the following rule(s) be met for approval:
A. You have tried or have a contraindication (harmful for you to use) to generic baclofen tablets
B. You are unable to swallow generic baclofen tablets

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ozobax, Ozobax DS, Fleqsuvy, and Lyvispah.

REFERENCES

- Ozobax [Prescribing Information]. Athens, GA: Metacel Pharmaceuticals, LLC; May 2020.
- Ozobax DS [Prescribing Information]. Athens, GA: Metacel Pharmaceuticals, LLC; October 2023.
- Fleqsuvy [Prescribing Information]. Woburn, MA: Azurity Pharmaceuticals, Inc.; February 2023.
- Lyvispah [Prescribing Information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/13/23
Created: 11/19
Client Approval: 11/23
P&T Approval: 07/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BARICITINIB

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz) [**Note:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Is the request for the treatment of coronavirus disease 2019 (COVID-19) in a hospitalized adult?

   If yes, **do not approve**. [**NOTE:** This indication is for hospital use only.]
   DENIAL TEXT: See initial denial text at the end of the guideline.

   If no, continue to #3.

3. Does the patient have a diagnosis of severe alopecia areata and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has had at least 50 percent scalp hair loss as measured by the Severity of Alopecia Tool (SALT) for more than 6 months
   - Olumiant will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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BARICITINIB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BARICITINIB (Olumiant)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Severe alopecia areata (a type of hair loss)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

C. **If you have severe alopecia areata, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You have had at least 50 percent scalp hair loss as measured by the Severity of Alopecia Tool (SALT: a type of disease evaluation tool) for more than 6 months
   4. You will NOT use Olumiant concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

D. NOTE: Olumiant will NOT be approved for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults.

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BARICITINIB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz) [**Note:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of severe alopecia areata and meet **ALL** of the following criteria?
   - The patient has had improvement while on therapy (e.g., scalp hair coverage)
   - Olumiant will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BARICITINIB (Olumiant)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Severe alopecia areata (a type of hair loss)
   B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
      1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
      2. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

   (Renewal denial text continued on next page)

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BARICITINIB

RENEWAL CRITERIA (CONTINUED)

C. **If you have severe alopecia areata, renewal also requires:**
   1. You have experienced improvement while on therapy (such as scalp hair coverage)
   2. You will NOT use Olumiant concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Olumiant.

REFERENCES

- Olumiant [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; June 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/01/24
Created: 06/18
Client Approval: 04/24
P&T Approval: 04/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEDAQUILINE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of pulmonary multi-drug resistant tuberculosis (MDR-TB) (i.e., an isolate of M. tuberculosis that is resistant to at least isoniazid and rifampin) and meet **ALL** of the following criteria?
   - The patient meets ONE of the following:
     - The patient is 5 to less than 18 years of age **AND** weighs at least 15kg
     - The patient is 18 years of age or older
   - Sirturo will be used in combination with at least 3 other antibiotics

   If yes, **approve for a total of 24 weeks by GPID or GPI-14 as follows:**
   - **FIRST APPROVAL: Approve for 4 weeks for the requested strength as follows:**
     - **Sirturo 20mg: #340 per 28 days.**
     - **Sirturo 100mg: #68 per 28 days.**
   - **SECOND APPROVAL: Approve for 20 weeks (total fill count 5) for the requested strength as follows:**
     - **Sirturo 20mg: #120 per 28 days.**
     - **Sirturo 100mg: #24 per 28 days.**

     Please enter a start date of 3 WEEKS AFTER the START date of the first approval.

   If no, continue to #2.

2. Does the patient have a diagnosis of pulmonary multi-drug resistant tuberculosis (MDR-TB) (i.e., an isolate of M. tuberculosis that is resistant to at least isoniazid and rifampin) **OR** pulmonary extensively drug resistant tuberculosis (XDR-TB) (i.e., an isolate of M. tuberculosis that is resistant to at least isoniazid, rifampin, a fluoroquinolone, and an aminoglycoside) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Sirturo will be used in combination with pretomanid and linezolid

   If yes, **approve for a total of 26 weeks for Sirturo 100mg by GPID or GPI-14 as follows:**
   - **FIRST APPROVAL: Approve for 4 weeks with a quantity limit of #68 per 28 days.**
   - **SECOND APPROVAL: Approve for 22 weeks (total fill count 6) with a quantity limit of #24 per 28 days. Please enter a start date of 3 WEEKS AFTER the START date of the first approval.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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BEDAQUILINE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEDAQUILINE (Sirturo)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Pulmonary multi-drug resistant tuberculosis (MDR-TB: tuberculosis bacteria in lungs does not respond to multiple drugs, including at least isoniazid and rifampin)
   2. Pulmonary extensively drug resistant tuberculosis (XDR-TB: tuberculosis bacteria is resistant to at least isoniazid, rifampin, a fluoroquinolone [type of antibiotic], and an aminoglycoside [a type of antibiotic])

B. **If you have pulmonary multi-drug resistant tuberculosis, approval also requires ONE of the following:**
   1. You are 5 years to less than 18 years of age AND weigh at least 15 kg (33 lbs), AND will be using Sirturo in combination with at least 3 other antibiotics
   2. You are 18 years of age, AND will be using Sirturo in combination with at least 3 other antibiotics
   3. You are 18 years of age, AND will be using Sirturo in combination with pretomanid and linezolid

C. **If you have pulmonary extensively drug resistant tuberculosis, approval also requires:**
   1. You are 18 years of age or older
   2. You will be using Sirturo in combination with pretomanid and linezolid

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sirturo.

REFERENCES

- Sirturo [Prescribing Information]. Titusville, NJ: Janssen Therapeutics; May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 12/01/21
Created: 05/13
Client Approval: 11/21
P&T Approval: 07/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BELIMUMAB - SQ

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of systemic lupus erythematosus (SLE) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient is currently using corticosteroids, antimalarials, NSAIDs, or immunosuppressives

   If yes, **approve for 6 months by GPID or GPI-14 for the requested product with a quantity limit of #4mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of lupus nephritis and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or nephrologist
   - The patient is receiving standard therapy (e.g., steroids, antimalarials, NSAIDs, immunosuppressives)

   If yes, **approve for a total of 6 months by GPID or GPI-14 for the requested product as follows:**
   FIRST APPROVAL:
   - **200mg/mL: Approve for 1 month with a quantity limit of #8mL per 28 days.**

   SECOND APPROVAL:
   - **200mg/mL: Approve for 5 months with a quantity limit of #4mL per 28 days (Please enter a start date 3 weeks after the start date of the first approval).**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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BELIMUMAB - SQ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BELIMUMAB - SQ (Benlysta)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Systemic lupus erythematosus (SLE: a type of immune condition)
   2. Lupus nephritis (LN: A type of immune condition that affects the kidneys)

B. **If you have systemic lupus erythematosus, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You are currently using corticosteroids, antimalarials (drugs that treat parasites), non-steroidal anti-inflammatory drugs (NSAIDS), or immunosuppressives (drugs that weaken your immune system)

C. **If you have lupus nephritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or nephrologist (a type of kidney doctor)
   3. You are receiving standard treatment (such as steroids, antimalarials, nonsteroidal anti-inflammatory drugs (NSAIDs), or immunosuppressives (drugs that weaken your immune system)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of systemic lupus erythematosus (SLE) **AND** meet the following criterion?
   - The patient has had clinical improvement while on Benlysta

   If yes, **approve for 12 months by GPID or GPI-14 for the requested product with a quantity limit of #4mL per 28 days.**

   If no, continue to #2.

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BELIMUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of lupus nephritis **AND** meet the following criterion?
   - The patient has had clinical improvement in renal response as compared to baseline laboratory values (i.e., eGFR or proteinuria) and/or clinical parameters (e.g., fluid retention, use of rescue drugs, glucocorticoid dose)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested product with a quantity limit of #4mL per 28 days.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BELIMUMAB - SQ (Benlysta)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Systemic lupus erythematosus (SLE: a type of immune condition)
      2. Lupus nephritis (LN: a type of immune condition that affects the kidneys)
   B. **If you have systemic lupus erythematosus, renewal also requires:**
      1. You have had clinical improvement while on Benlysta
   C. **If you have lupus nephritis, renewal also requires:**
      1. You have had clinical improvement in renal (kidney) response as compared to baseline laboratory values (eGFR [measurement of kidney function] or proteinuria [level of protein in urine]), and/or clinical parameters (such as fluid retention, use of rescue drugs, glucocorticoid dose)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Benlysta.

REFERENCES

- Benlysta [Prescribing Information]. Philadelphia, PA: GlaxoSmithKline LLC; February 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/01/23
Created: 08/17
Client Approval: 04/23
P&T Approval: 01/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BELUMOSUDIL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic graft-versus-host-disease (cGVHD) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has failed at least TWO prior lines of systemic therapy (e.g., prednisone, Imbruvica [ibrutinib], Jakafi [ruxolitinib])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BELUMOSUDIL (Rezurock)** requires the following rule(s) be met for approval:
   A. You have chronic graft-versus-host-disease (cGVHD: a long-term type of immune disorder)
   B. You are 12 years of age or older
   C. You have failed at least TWO prior lines of systemic therapy (treatment that spreads throughout the body such as prednisone, Imbruvica [ibrutinib], Jakafi [ruxolitinib])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rezurock.

REFERENCES

- Rezurock [Prescribing Information]. Bridgewater, NJ: Kadmon Pharmaceuticals, LLC; November 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/15/24
Created: 08/21
Client Approval: 03/24
P&T Approval: 07/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BELZUTIFAN

GUIDELINES FOR USE

1. Does the patient have a diagnosis of von Hippel-Lindau (VHL) disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient requires therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET)
   - The patient does NOT require immediate surgery

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, continue to #2.

2. Does the patient have advanced renal cell carcinoma (RCC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient was previously treated with a programmed death receptor-1 (PD-1) inhibitor (e.g., Keytruda [pembrolizumab]) OR a programmed death-ligand 1 (PD-L1) inhibitor (e.g., Bavencio [avelumab])
   - The patient was previously treated with a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI; e.g., Nexavar [sorafenib])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BELZUTIFAN (Welireg)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Von Hippel-Lindau (VHL) disease (genetic disorder that causes tumors to grow in the body)
      2. Advanced renal cell carcinoma (RCC: a type of kidney cancer)
   B. **If you have von Hippel-Lindau disease, approval also requires:**
      1. You are 18 years of age or older
      2. You require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas (tumor in the brain or spinal cord), or pancreatic neuroendocrine tumors (pNET: tumor in the pancreas)
      3. You do NOT require immediate surgery

   (Denial text continued on next page)

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BELZUTIFAN

GUIDELINES FOR USE (CONTINUED)

C. **If you have advanced renal cell carcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. You were previously treated with a programmed death receptor-1 (PD-1) inhibitor (such as Keytruda [pembrolizumab]) OR a programmed death-ligand 1 (PD-L1) inhibitor (such as Bavencio [avelumab])
   3. You were previously treated with a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI: a type of treatment such as Nexavar [sorafenib])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Welireg.

REFERENCES

- Welireg [Prescribing Information]. Rahway, NJ: Merck Sharp & Dohme LLC; December 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/15/24
Created: 10/21
Client Approval: 12/23
P&T Approval: 01/24

STANDARD COMMERCIAL AND NSA DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BENRALIZUMAB

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with a physician specializing in pulmonary medicine or allergy medicine
   - The patient has a documented (e.g., chart notes, lab results, diagnostic test results, etc.) blood eosinophil level of at least 150 cells/mcL within the past 12 months
   - The patient is concurrently treated with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline, or an oral corticosteroid [e.g., prednisone])
   - Fasenra will NOT be used concurrently with Xolair (omalizumab), Dupixent (dupilumab), Tezspire (tezepelumab-ekko), or another anti-IL-5 biologic (e.g., Nucala [mepolizumab], Cinqair [reslizumab]) when these are used for the treatment of asthma

     If yes, continue to #2.
     If no, do not approve.
     DENIAL TEXT: See the initial denial text at the end of the guideline.

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BENRALIZUMAB

INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced at least ONE asthma exacerbation requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months
   - The patient has experienced at least ONE serious asthma exacerbation requiring hospitalization or an emergency room visit within the past 12 months

   If yes, **approve for a total of 4 months by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: approve for 2 months with a quantity limit of #1mL per 28 days.**
   - **SECOND APPROVAL: approve for 2 months with a quantity limit of #1mL per 56 days. (Please enter a start date of 1 week before the end date of the first approval).**

   If no, continue to #3.

3. Does the patient have poor symptom control despite current therapy as evidenced by at least **THREE** of the following within the past 4 weeks?
   - Daytime asthma symptoms more than twice per week
   - Any night waking due to asthma
   - Use of a short-acting inhaled beta2-agonist (SABA) reliever (e.g., albuterol) for symptoms more than twice per week
   - Any activity limitation due to asthma

   If yes, **approve for a total of 4 months by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: approve for 2 months with a quantity limit of #1mL per 28 days.**
   - **SECOND APPROVAL: approve for 2 months with a quantity limit of #1mL per 56 days. (Please enter a start date of 1 week before the end date of the first approval).**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BENRALIZUMAB (Fasenra)** requires the following rule(s) be met for approval:
   A. You have severe asthma with an eosinophilic phenotype (a type of lung condition with inflammation)
   B. You are 12 years of age or older
   C. Therapy is prescribed by or in consultation with a physician specializing in pulmonary (relating to lungs/breathing) medicine or allergy medicine
   (Initial denial text continued on next page)

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BENRALIZUMAB

INITIAL CRITERIA (CONTINUED)

D. You have a documented (such as chart notes, lab results, diagnostic test results) blood eosinophil (a type of white blood cell) level of at least 150 cells/mcL within the past 12 months
E. You are being treated at the same time with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)
F. You meet ONE of the following:
    1. You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months, OR at least ONE serious asthma exacerbation requiring a hospitalization or an emergency room visit within the past 12 months
    2. You have poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks:
        a. Daytime asthma symptoms more than twice per week
        b. Any night waking due to asthma
        c. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
        d. Any activity limitation due to asthma
G. You will NOT use Fasenra concurrently (at the same time) with Xolair (omalizumab), Dupixent (dupilumab), Tezspire (tezepelumab-ekko), or another anti-IL-5 (interleukin-5) biologic (such as Nucala [mepolizumab], Cinqair [reslizumab]) when these are used for the treatment of asthma

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BENRALIZUMAB

RENEWAL CRITERIA

1. Does the patient meet **ALL** of the following criteria?
   - The patient will continue to use an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline, or an oral corticosteroid [e.g., prednisone])
   - Fasenra will NOT be used concurrently with Xolair (omalizumab), Dupixent (dupilumab), Tezspire (tezepelumab-ekko), or another anti-IL-5 biologic (e.g., Nucala [mepolizumab], Cinqair [reslizumab]) when these are used for the treatment of asthma

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient shown a clinical response as evidenced by **ONE** of the following?
   - Reduction in asthma exacerbation from baseline
   - Decreased utilization of rescue medications (e.g., albuterol)
   - Increase in percent predicted FEV1 from pretreatment baseline
   - Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 56 days.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **BENRALIZUMAB (Fasenra)** requires the following rule(s) be met for renewal:
   A. You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)
   (Renewal denial text continued on next page)

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BENRALIZUMAB

RENEWAL CRITERIA (CONTINUED)

B. You will NOT use Fasenra concurrently (at the same time) with Xolair (omalizumab), Dupixent (dupilumab), Tezspire (tezepelumab-ekko), or another anti-IL-5 (interleukin-5) biologic (such as Nucala [mepolizumab], Cinqair [reslizumab]) when these are used for the treatment of asthma
C. You have shown a clinical response as evidenced by ONE of the following:
   1. Reduction in asthma exacerbation (worsening of symptoms) from baseline
   2. Decreased use of rescue medications (such as albuterol)
   3. Increase in percent predicted FEV1 (type of lung test) from pre-treatment baseline
   4. Reduction in the severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fasenra.

REFERENCES

- Fasenra [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceutical LP.; February 2021.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 02/18
Client Approval: 03/24
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEROTRALSTAT

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The diagnosis of HAE is confirmed via documentation of complement testing
   - Orladeyo is being used for prophylaxis against HAE attacks
   - Therapy is prescribed by or in consultation with an allergist, immunologist or hematologist
   - The patient is NOT on concurrent treatment with an alternative prophylactic agent for HAE (e.g., Takhzyro, Haegarda, Cinryze, danazol)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BEROTRALSTAT (Orladeyo)** requires the following rule(s) be met for approval:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. Your diagnosis is confirmed by documented complement testing (a type of blood test)
   C. You are 12 years of age or older
   D. Orladeyo is being used for prevention of hereditary angioedema attacks
   E. Therapy is prescribed by or in consultation with an allergist, immunologist (allergy or immune system doctor) or hematologist (blood doctor)
   F. You will NOT use Orladeyo concurrently (at the same time) with an alternative preventive agent for HAE (such as Takhzyro, Haegarda, Cinryze, danazol)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BEROTRALSTAT

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet **ALL** of the following criteria?
   - The patient has experienced improvement (i.e., reductions in attack frequency or attack severity) compared to baseline in HAE attacks
   - The patient is NOT on concurrent treatment with an alternative prophylactic agent for HAE (e.g., Takhzyro, Haegarda, Cinryze, danazol)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BEROTRALSTAT (Orladeyo)** requires the following rule(s) be met for renewal:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. You have experienced improvement (reductions in attack frequency or attack severity) compared to baseline in HAE attacks
   C. You will NOT use Orladeyo concurrently (at the same time) with an alternative preventive agent for HAE (such as Takhzyro, Haegarda, Cinryze, danazol)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orladeyo.

REFERENCES

- Orladeyo [Prescribing Information]. Durham, NC: BioCryst Pharmaceuticals, Inc.; December 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 12/20
Client Approval: 05/22
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BETAINE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of homocystinuria (including cystathionine beta-synthase (CBS) deficiency, 5,10-methylenetetrahydrofolate reductase (MTHFR) deficiency, and cobalamin cofactor metabolism (cbl) defect)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #20 grams per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BETAINE (Cystadane)** requires the following rule(s) be met for approval:
   A. You have homocystinuria (a type of genetic metabolic disorder), including cystathionine beta-synthase (CBS: a type of enzyme) deficiency, 5,10-methylenetetrahydrofolate reductase (MTHFR: a type of enzyme) deficiency, and cobalamin cofactor metabolism (cbl: vitamin B12 that is required for enzyme activity) defect

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cystadane.

REFERENCES

- Cystadane [Prescribing Information]. Lebanon, NJ: Recordati Rare Diseases, Inc.; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/23
Created: 05/22
Client Approval: 02/23
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEXAROTENE

GUIDELINES FOR USE

TARGRETIN (BEXAROTENE) CAPSULE

1. Does the patient have a diagnosis of cutaneous T-cell lymphoma (CTCL) **AND** meet the following criterion?
   The patient is refractory to at least one prior systemic therapy (e.g., gemcitabine, methotrexate, liposomal doxorubicin, bortezomib)

   If yes, **approve for 12 months by GPID or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **BEXAROTENE (Targretin capsule)** requires the following rule(s) be met for approval:
   A. You have cutaneous T-cell lymphoma (CTCL: a type of blood cancer)
   B. You are refractory (resistant) to at least one prior systemic therapy (therapy that spreads through the blood) such as gemcitabine, methotrexate, liposomal doxorubicin, or bortezomib

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

TARGRETIN (BEXAROTENE) GEL

1. Does the patient have a diagnosis of cutaneous T-cell lymphoma (CTCL) (stage IA or IB) and meet **ONE** of the following criteria?
   - The patient has refractory or persistent disease after other therapies
   - The patient has not tolerated other therapies

   If yes, **approve for 12 months by GPID or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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BEXAROTENE

GUIDELINES FOR USE - TARGRETIN (BEXAROTENE) GEL (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEXAROTENE (Targretin gel)** requires the following rule(s) to be met for approval:

A. You have cutaneous T-cell lymphoma (CTCL: a type of blood cancer) (stage IA or IB)
B. You meet ONE of the following:
    1. You have refractory (resistant) or persistent disease after other therapies
    2. You have not tolerated other therapies

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Targretin.

REFERENCES

- Targretin Capsule [Prescribing Information]. Bridgewater, NJ: Bausch Health US, LLC; April 2020.
- Targretin Gel [Prescribing Information]. Bridgewater, NJ: Bausch Health US, LLC; February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/15/22
Created: 05/12
Client Approval: 05/22
P&T Approval: 04/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BIMEKIZUMAB-BKZX

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient is a candidate for systemic therapy or phototherapy
   - The patient has psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, genital area, or face
   - Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, continue to #2.
     If no, do not approve.
     DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of plaque psoriasis
   - The patient has a contraindication or intolerance to both immunosuppressant AND PUVA (phototherapy) for the treatment of plaque psoriasis
   - The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

     If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.**
     If no, do not approve.
     DENIAL TEXT: See the initial denial text at the end of the guideline.

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BIMEKIZUMAB-BKZX

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BIMEKIZUMAB-BKZX (Bimzelx)** requires the following rule(s) be met for approval:

A. You have moderate to severe plaque psoriasis (PsO: a type of skin condition)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
D. You are a candidate for systemic therapy (treatment that targets the entire body) or phototherapy (light therapy)
E. You have psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
F. You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
G. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
H. You meet ONE of the following:
    1. You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
    2. You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) AND PUVA (phototherapy) for the treatment of plaque psoriasis
    3. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BIMEKIZUMAB-BKZX

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy
   - Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.** If no, do not approve.

     RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

     Our guideline named **BIMEKIZUMAB-BKZX (Bimzelx)** requires the following rule(s) be met for renewal:
     A. You have moderate to severe plaque psoriasis (PsO: a type of skin condition)
     B. You have achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index: a tool for evaluating the severity of psoriasis) of at least 50 percent or more while on therapy
     C. You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
     D. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

     (Renewal denial text continued on next page)

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BIMEKIZUMAB-BKZX

RENEWAL CRITERIA (CONTINUED)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Bimzelx.

REFERENCES

- Bimzelx [Prescribing Information]. Smyrna, GA: UCB, Inc.; October 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/01/24
Created: 10/23
Client Approval: 04/24
P&T Approval: 04/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BINIMETINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E or V600K mutation, as detected by an FDA-approved test
   - Mektovi will be used in combination with Braftovi (encorafenib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a BRAF V600E mutation, as detected by an FDA-approved test
   - Mektovi will be used in combination with Braftovi (encorafenib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BINIMETINIB (Mektovi)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Unresectable or metastatic melanoma (a type of skin cancer that cannot be removed by surgery or has spread to other parts of the body)
      2. Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)

   B. **If you have unresectable or metastatic melanoma, approval also requires:**
      1. You have a BRAF V600E or V600K mutation (types of gene mutations), as detected by a Food and Drug Administration (FDA)-approved test
      2. Mektovi will be used in combination with Braftovi (encorafenib)

   C. **If you have metastatic non-small cell lung cancer, approval also requires**:
      1. You are 18 years of age or older
      2. You have a BRAF V600E mutation (a type of gene mutation), as detected by a Food and Drug Administration (FDA)-approved test
      3. Mektovi will be used in combination with Braftovi (encorafenib)

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BINIMETINIB

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mektovi.

REFERENCES

- Mektovi [Prescribing Information]. Boulder, CO: Array BioPharma Inc.; October 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/13/23

Created: 08/18
Client Approval: 10/23

P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BOSENTAN

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
   - The patient is 3 years of age or older
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The patient does NOT have idiopathic pulmonary fibrosis (IPF)
   - Tracleer will NOT be used concurrently with cyclosporine A or glyburide

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have documentation (e.g., chart note, lab result, diagnostic test result, etc.) confirming a PAH diagnosis based on right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **62.5mg tablet: #2 per day.**
   - **125mg tablet: #2 per day.**
   - **32mg tablet for suspension: #4 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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BOSENTAN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BOSENTAN (Tracleer)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. You are 3 years of age and older
C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
D. You do NOT have idiopathic pulmonary fibrosis (scarring of the lungs due to an unknown cause)
E. You will NOT use Tracleer concurrently (at the same time) with cyclosporine A or glyburide
F. There is documentation (such as chart note, lab result, diagnostic test result) showing you have pulmonary arterial hypertension based on ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 2 Wood units

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BOSENTAN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) **AND** meet the following criterion?
   - Tracleer will NOT be used concurrently with cyclosporine A or glyburide

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **62.5mg tablet: #2 per day.**
   - **125mg tablet: #2 per day.**
   - **32mg tablet for suspension: #4 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BOSENTAN (Tracleer)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   B. You will NOT use Tracleer concurrently (at the same time) with cyclosporine A or glyburide

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tracleer.

REFERENCES

- Tracleer [Prescribing Information]. South San Francisco, CA: Actelion Pharmaceuticals US, Inc.; June 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 10/22
Client Approval: 02/24
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BOSUTINIB

GUIDELINES FOR USE

1. Does the patient have chronic phase (CP) Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) **AND** meet the following criterion?
   - The patient is 1 year of age or older

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient newly diagnosed?

   If yes, **approve for 12 months by GPID or GPI-14, for the requested strength, with the following quantity limits:**
   - **500mg: #1 per day.**
   - **400mg: #1 per day.**
   - **100mg: #6 per day.**
   - **50mg: #1 per day.**

   If no, continue to #3.

3. Does the patient have resistance or intolerance to prior therapy [e.g., Gleevec (imatinib), Sprycel (dasatinib), Tasigna (nilotinib)] and meet **ALL** of the following criteria?
   - The patient had a mutational analysis prior to initiation
   - Bosulif is appropriate per the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile
     (Please see header CML-5 of the current NCCN guidelines)

   If yes, **approve for 12 months by GPID or GPI-14, for the requested strength, with the following quantity limits:**
   - **500mg: #1 per day.**
   - **400mg: #1 per day.**
   - **100mg: #6 per day.**
   - **50mg: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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BOSUTINIB

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of accelerated phase (AP) or blast phase (BP) Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had resistance or intolerance to prior therapy [e.g., Gleevec (imatinib), Sprycel (dasatinib), Tasigna (nilotinib)]
   - The patient had a mutational analysis prior to initiation
   - Bosulif is appropriate per the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile
     (Please see header CML-5 of the current NCCN guidelines)

   If yes, **approve for 12 months by GPID or GPI-14, for the requested strength, with the following quantity limits:**
   - **500mg: #1 per day.**
   - **400mg: #1 per day.**
   - **100mg: #6 per day.**
   - **50mg: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BOSUTINIB (Bosulif)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Chronic phase (CP) Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML; a type of blood cancer)
      2. Accelerated phase (AP) or blast phase (BP) Philadelphia chromosome-positive chronic myelogenous leukemia

   B. **If you have chronic phase Philadelphia chromosome-positive chronic myeloid leukemia, approval also requires:**
      1. You are 1 year of age or older
      2. You meet ONE of the following:
         a. You are newly diagnosed
         b. You had resistance or intolerance to prior therapy [such as Gleevec (imatinib), Sprycel (dasatinib), Tasigna (nilotinib)] AND you had a mutational analysis prior to initiation of therapy AND Bosulif is appropriate per the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1: a type of abnormal gene) profile

   (Denial text continued on next page)

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BOSUTINIB

GUIDELINES FOR USE (CONTINUED)

C. If you have accelerated or blast phase Philadelphia chromosome-positive chronic myeloid leukemia, approval also requires:
   1. You are 18 years of age or older
   2. You had resistance or intolerance to prior therapy [such as Gleevec (imatinib), Sprycel (dasatinib), Tasigna (nilotinib)]
   3. You had a mutational analysis prior to initiation of therapy
   4. Bosulif is appropriate per the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1: a type of abnormal gene) profile

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Bosulif.

REFERENCES

- Bosulif [Prescribing Information]. New York, NY: Pfizer Inc.; September 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/22/24
Created: 09/12
Client Approval: 01/24
P&T Approval: 04/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BREMELANOTIDE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is Vyleesi (bremelanotide) a covered benefit?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) (also referred to as female sexual interest/arousal disorder [FSIAD] per DSM-5), as defined by **ALL** of the following criteria?
   - Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
   - HSDD is **NOT** a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
   - HSDD symptom causes marked distress or interpersonal difficulty

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ALL** of the following criteria?
   - The patient is a premenopausal female
   - The patient is 18 years of age or older
   - The patient had a previous trial of or contraindication to bupropion
   - The patient is **NOT** currently using Addyi (flibanserin)

   If yes, **approve for 8 weeks by HICL or GPI-10 with a quantity limit of #2.4mL per month.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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BREMELANOTIDE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BREMELANOTIDE (Vyleesi)** requires the following rule(s) be met for approval:

A. You have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD; also referred to as female sexual interest/arousal disorder where you do not desire sexual activity), as defined by **ALL** of the following:
   1. Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
   2. HSDD is **NOT** a result of a co-existing medical or psychiatric (mental) condition, a problem within the relationship or the effects of a medication or drug substance
   3. HSDD symptom causes marked distress or interpersonal difficulty
B. You are a premenopausal female
C. You are 18 years of age or older
D. You had a previous trial of bupropion, unless there is a medical reason why you cannot (contraindication)
E. You are **NOT** currently using Addyi (flibanserin)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) (also referred to as female sexual interest/arousal disorder [FSIAD] per DSM-5), as defined by **ALL** of the following criteria?
   - Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
   - HSDD is **NOT** a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
   - HSDD symptom causes marked distress or interpersonal difficulty

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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BREMELANOTIDE

RENEWAL CRITERIA (CONTINUED)

2. Does the patient meet **ALL** of the following criteria?
   - The patient is a premenopausal female
   - The patient is **NOT** currently using Addyi (flibanserin)
   - The patient has demonstrated continued improvement in symptoms of HSDD/FSIAD (e.g., increased sexual desire, lessened distress)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2.4mL per month.** If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BREMELANOTIDE (Vyleesi)** requires the following rule(s) be met for approval:
   A. You have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD; also referred to as female sexual interest/arousal disorder [FSIAD] where you do not desire sexual activity), as defined by **ALL** of the following:
      1. Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
      2. HSDD is **NOT** a result of a co-existing medical or psychiatric (mental) condition, a problem within the relationship or the effects of a medication or drug substance
      3. HSDD symptom causes marked distress or interpersonal difficulty
   B. You are a premenopausal female
   C. You are **NOT** currently using Addyi (flibanserin)
   D. You have experienced continued improvement in symptoms of HSDD/FSIAD such as increased sexual desire, lessened distress)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BREMELANOTIDE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vyleesi.

REFERENCES

- Vyleesi [Prescribing Information]. Waltham, MA: AMAG Pharmaceuticals, Inc.; June 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 08/19
Client Approval: 04/20
P&T Approval: 07/19

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BRIGATINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet ALL of the following criteria?
   - The patient is 18 years of age or older
   - The patient is positive for anaplastic lymphoma kinase (ALK) fusion oncogene as detected by an FDA-approved test

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Alunbrig 30mg: #120 per 30 days.**
   - **Alunbrig 90mg: #30 per 30 days.**
   - **Alunbrig 180mg: #30 per 30 days.**
   - **Alunbrig 90mg-180mg initiation pack: #30 per 30 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BRIGATINIB (Alunbrig)** requires the following rule(s) be met for approval:
   A. You have metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
   B. You are 18 years of age or older
   C. You are positive for anaplastic lymphoma kinase (ALK) fusion oncogene (a type of gene mutation that causes a change in your DNA) as detected by a Food and Drug Administration (FDA)-approved test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Alunbrig.

REFERENCES

- Alunbrig [Prescribing Information]. Cambridge, MA: Ariad Pharmaceuticals; May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 07/17
Client Approval: 03/21
P&T Approval: 07/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BRODALUMAB

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, genital area, or face
   - The patient has been counseled on and expresses understanding of the risk of suicidal ideation and behavior
   - Siliq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [NOTE: Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify.]

     If yes, continue to #2.
     If no, do not approve.
     DENIAL TEXT: See the initial denial text at the end of the guideline.

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BRODALUMAB

INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ONE** of the following criteria?
   - The patient has had at least a 3-months trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of plaque psoriasis
   - The patient has a contraindication or intolerance to both immunosuppressant and PUVA (phototherapy) for the treatment of plaque psoriasis
   - The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, **approve for 6 months by entering TWO approvals by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: approve for 1 month with a quantity limit of #6mL.**
   - **SECOND APPROVAL: approve for 5 months with a quantity limit of #3mL per 28 days (Enter a start date that is 5 weeks AFTER the START date of the first approval).**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BRODALUMAB (Siliq)** requires the following rule(s) be met for approval:
   A. You have moderate to severe plaque psoriasis (PsO: a type of skin condition)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   D. You have psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   E. You have been counseled on and express an understanding of the risk of suicidal thoughts and behavior
   F. You will NOT use Siliq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   G. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

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BRODALUMAB

INITIAL CRITERIA (CONTINUED)

H. You meet ONE of the following:
   1. You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
   2. You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) AND PUVA (phototherapy) for the treatment of plaque psoriasis
   3. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BRODALUMAB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more
   - The patient has NOT developed or reported worsening depressive symptoms or suicidal ideation and behaviors
   - Siliq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [NOTE: Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify.]

     If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3mL per 28 days.** If no, do not approve.

     RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

     Our guideline named **BRODALUMAB (Siliq)** requires the following rule(s) be met for renewal:
     A. You have moderate to severe plaque psoriasis (PsO: a type of skin condition)
     B. You have achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more
     C. You have NOT developed or reported worsening depressive symptoms or suicidal thoughts and behaviors while on treatment with Siliq
     D. You will NOT use Siliq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

     (Renewal denial text continued on next page)

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BRODALUMAB

RENEWAL CRITERIA (CONTINUED)

E. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Siliq.

REFERENCES

- Siliq [Prescribing Information]. Bridgewater, NJ: Bausch Health US, LLC; April 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/01/24

Created: 01/17
Client Approval: 04/24

P&T Approval: 04/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BUDESONIDE - EOHILIA

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of eosinophilic esophagitis (EoE) and meet **ALL** of the following criteria?
   - The patient is 11 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist or allergist
   - The patient has evidence of at least 15 eosinophils/hpf in the esophagus as confirmed by a biopsy
   - The patient had a trial of or contraindication to one inhaled corticosteroid (e.g., Flovent [fluticasone], Pulmicort [budesonide]) OR one generic proton pump inhibitor (e.g., omeprazole, lansoprazole, pantoprazole)

   If yes, **approve for 3 months by GPID or GPI-14 with a quantity limit of #20mL per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BUDESONIDE - EOHILIA** requires the following rule(s) be met for approval:
   A. You have eosinophilic esophagitis (a type of immune system disorder)
   B. You are 11 years of age or older
   C. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions) or allergist (a type of allergy doctor)
   D. You have at least 15 eosinophils/high powered field (a type of lab test) in the esophagus as confirmed by a biopsy (removal of cells or tissue from the body for examination)
   E. You have tried or have a contraindication to (harmful for you to use) one inhaled corticosteroid (such as Flovent [fluticasone], Pulmicort [budesonide]) OR one proton pump inhibitor (such as omeprazole, lansoprazole, pantoprazole)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BUDESONIDE - EOHILIA

RENEWAL CRITERIA

1. Does the patient have a diagnosis of eosinophilic esophagitis (EoE) and meet **ONE** of the following criteria?
   - There is documentation (e.g., chart notes, lab results, diagnostic test results, etc.) of evidence of less than 15 eosinophils/hpf in the esophagus after treatment with Eohilia
   - The patient has experienced improvement in dysphagia compared to baseline

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #20mL per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BUDESONIDE - EOHILIA** requires the following rule(s) be met for renewal:
   A. You have eosinophilic esophagitis (a type of immune system disorder)
   B. You meet ONE of the following:
      1. There is documentation (such as chart notes, lab results, diagnostic test results, etc.) confirming that you have less than 15 eosinophils/high powered field (eos/hpf: a type of lab test) after treatment with Eohilia
      2. You have experienced improvement in dysphagia (difficulty swallowing) compared to baseline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Eohilia.

REFERENCES

- Eohilia [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; February 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 03/04/24
Created: 02/24
Client Approval: 02/24
P&T Approval: 07/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BUDESONIDE - ORTIKOS

GUIDELINES FOR USE

1. Does the patient have a diagnosis of mild to moderate active Crohn's Disease and meet **ALL** of the following criteria?
   - The patient is 8 years of age or older
   - The patient had a trial of generic budesonide 3mg capsules **OR** the patient cannot tolerate the pill burden associated with the generic product

   If yes, **approve for 6 months for all strengths by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of mild to moderate Crohn's Disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication is being used for the maintenance of clinical remission
   - The patient had a trial of generic budesonide 3mg capsules **OR** the patient cannot tolerate the pill burden associated with the generic product

   If yes, **approve for 6 months for all strengths by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BUDESONIDE - ORTIKOS** requires the following rule(s) be met for approval:
   A. You have mild to moderate Crohn's Disease (a type of bowel disorder)
   B. **If you have mild to moderate active Crohn's Disease, approval also requires:**
      1. You are 8 years of age or older
      2. You have tried generic budesonide 3mg capsules OR you cannot tolerate the pill burden associated with the generic product

   (Denial text continued on the next page)

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BUDESONIDE - ORTIKOS

GUIDELINES FOR USE (CONTINUED)

C. **If you have mild to moderate Crohn's Disease, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication is being used for the maintenance of clinical remission (signs and symptoms of disease have either improved or disappeared)
   3. You have tried generic budesonide 3mg capsules OR you cannot tolerate the pill burden associated with the generic product

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ortikos.

REFERENCES

- Ortikos [Prescribing Information]. Cranbury, NJ: Sun Pharmaceuticals Industries, Inc. June 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/17/22
Created: 11/20
Client Approval: 01/22
P&T Approval: 10/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BUDESONIDE - TARPEYO

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a nephrologist
   - The patient's diagnosis is confirmed by a renal biopsy
   - The patient is currently on an ACE inhibitor (e.g., benazepril, lisinopril) or an ARB (e.g., losartan, valsartan) at maximum tolerated dose for at least three months OR has a contraindication to both
   - The patient has a progressively declining glomerular filtration rate (GFR) and/or worsening proteinuria (e.g., >1 gram protein/24-hour urine collection or UPCR [urine protein to creatinine ratio] ≥1 g/g)
   - The patient had a trial of or contraindication to one generic systemic corticosteroid therapy (e.g., oral prednisone, oral prednisolone)

   If yes, **approve for 9 months by GPID or GPI-14 with a quantity limit of #4 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **BUDESONIDE - TARPEYO** requires the following rule(s) be met for approval:
   A. You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
   D. Your diagnosis is confirmed by a renal biopsy (removal of cells or tissue from the kidney for examination)
   E. You are currently on an angiotensin converting enzyme inhibitor (ACE-I: a type of drug used to protect kidneys such as benazepril, lisinopril, etc.) or an angiotensin receptor blocker (ARB: a type of drug used to protect kidneys such as losartan, valsartan, etc.) at maximum tolerated dose for at least three months OR have a contraindication (harmful for) to both

   (Initial denial text continued on the next page)

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BUDESONIDE - TARPEYO

INITIAL CRITERIA (CONTINUED)

F. You have a progressively declining glomerular filtration rate (GFR: a tool for evaluating kidney function) and/or worsening proteinuria (such as greater than 1 gram protein in a 24-hour urine collection or greater than or equal to 1g/g urine protein to creatinine ratio [UPCR: test that measures the amount of protein in urine])
G. You had a trial of or contraindication to one generic systemic corticosteroid therapy (such as oral prednisone, oral prednisolone)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) and meet **ONE** of the following criteria?
   - The patient has improved, or stable kidney function compared to baseline
   - The patient has had a reduction in proteinuria

   If yes, **approve for 9 months by GPID or GPI-14 with a quantity limit of #4 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BUDESONIDE - TARPEYO** requires the following rule(s) be met for renewal:
   A. You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
   B. You have improved, or stable kidney function compared to baseline OR a reduction in proteinuria

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BUDESONIDE - TARPEYO

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tarpeyo.

REFERENCES

- Tarpeyo [Prescribing Information]. Stockholm, Sweden: Calliditas Therapeutics, Inc.; December 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/17/22
Created: 01/22
Client Approval: 01/22
P&T Approval: 07/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

C1 ESTERASE INHIBITOR - BERINERT

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an allergist, immunologist or hematologist
   - The patient's diagnosis of HAE is confirmed via complement testing
   - Berinert is being used for acute attacks of hereditary angioedema
   - Berinert will NOT be used concurrently with alternative acute treatment for HAE attacks (e.g., Ruconest, Firazyr, Kalbitor)

   If yes, **approve for 12 months by NDC.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **C1 ESTERASE INHIBITOR - BERINERT** requires the following rule(s) be met for approval:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor) or hematologist (a type of blood doctor)
   C. Your diagnosis is confirmed by complement testing (a type of lab test)
   D. Berinert is being used for acute (short term) attacks of hereditary angioedema
   E. You will NOT be using Berinert concurrently (at the same time) with alternative acute treatment for HAE attacks (such as Ruconest, Firazyr, Kalbitor)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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C1 ESTERASE INHIBITOR - BERINERT

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) **AND** meet the following criterion?
   - Berinert will NOT be used concurrently with alternative acute treatment for HAE attacks (e.g., Ruconest, Firazyr, Kalbitor)

   If yes, **approve for 12 months by NDC.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **C1 ESTERASE INHIBITOR - BERINERT** requires the following rule(s) be met for renewal:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. You will NOT be using Berinert concurrently (at the same time) with alternative acute treatment for HAE attacks (such as Ruconest, Firazyr, Kalbitor)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Berinert.

REFERENCES

- Berinert [Prescribing Information]. Kankakee, IL: CSL Behring LLC. May 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/01/22
Created: 04/09
Client Approval: 10/22
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

C1 ESTERASE INHIBITOR - CINRYZE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with an allergist, immunologist or hematologist
   - The patient's diagnosis of HAE is confirmed via documentation of complement testing
   - Cinryze is being used for prophylaxis against HAE attacks
   - Cinryze is NOT being used concurrently with alternative prophylactic agent for HAE (e.g., Takhzyro, Haegarda, danazol)

   If yes, **approve for 12 months for all NDCs with a quantity limit of #40 vials per 28 days.** If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **C1 ESTERASE INHIBITOR - CINRYZE** requires the following rule(s) be met for approval:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. You are 6 years of age or older
   C. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor) or hematologist (a type of blood doctor)
   D. Your diagnosis is confirmed by documented complement testing (a type of lab test)
   E. Cinryze is being used for prevention of hereditary angioedema attacks
   F. You will not be using Cinryze concurrently (at the same time) with an alternative preventive agent for HAE (such as Takhzyro, Haegarda, danazol)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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C1 ESTERASE INHIBITOR - CINRYZE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet **ALL** of the following criteria?
   - The patient has experienced improvement (i.e., reductions in attack frequency or attack severity) compared to baseline in HAE attacks
   - Cinryze will NOT be used concurrently with alternative prophylactic agent for HAE (e.g., Takhzyro, Haegarda, danazol)

   If yes, **approve for 12 months by NDC with a quantity limit of #40 vials per 28 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **C1 ESTERASE INHIBITOR - CINRYZE** requires the following rule(s) be met for renewal:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. You have experienced improvement (reductions in attack frequency or attack severity) compared to baseline in HAE attacks
   C. You will NOT be using Cinryze concurrently (at the same time) with alternative prophylactic (preventive) agent for HAE (such as Takhzyro, Haegarda, danazol)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cinryze.

REFERENCES

- Cinryze [Prescribing Information]. Lexington, MA: Shire Viropharma Inc. December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/01/22
Created: 10/22
Client Approval: 10/22
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

C1 ESTERASE INHIBITOR - HAEGARDA

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with an allergist, immunologist or hematologist
   - The patient's diagnosis of HAE is confirmed via documentation of complement testing
   - Haegarda is being used for prophylaxis against HAE attacks
   - Haegarda will NOT be used concurrently with alternative prophylactic agent for HAE (e.g., Takhzyro, Cinryze, danazol)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **C1 ESTERASE INHIBITOR - HAEGARDA** requires the following rule(s) be met for approval:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. You are 6 years of age or older
   C. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor) or hematologist (a type of blood doctor)
   D. Your diagnosis of HAE is confirmed by documented complement testing (a type of lab test)
   E. Haegarda is being used for prevention of hereditary angioedema attacks
   F. You will not be using Haegarda concurrently (at the same time) with an alternative preventive agent for HAE (such as Takhzyro, Cinryze, danazol)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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C1 ESTERASE INHIBITOR - HAEGARDA

GUIDELINES FOR USE (CONTINUD)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet **ALL** of the following criteria?
   - The patient has experienced improvement (i.e., reductions in attack frequency or attack severity) compared to baseline in HAE attacks
   - Haegarda will NOT be used concurrently with alternative prophylactic agent for HAE (e.g., Takhzyro, Cinryze, danazol)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **C1 ESTERASE INHIBITOR - HAEGARDA** requires the following rule(s) be met for renewal:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. You have experienced improvement (reductions in attack frequency or attack severity) compared to baseline in HAE attacks
   C. You will NOT be using Haegarda concurrently (at the same time) with alternative prophylactic (preventive) agent for HAE (such as Takhzyro, Cinryze, danazol)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Haegarda.

REFERENCES

- Haegarda [Prescribing Information]. Marburg, German: CSL Behring LLC. September 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/01/22
Created: 10/22
Client Approval: 10/22
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

C1 ESTERASE INHIBITOR - RUCONEST

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an allergist, immunologist or hematologist
   - The patient's diagnosis of HAE is confirmed via complement testing
   - Ruconest is being used for acute attacks of hereditary angioedema
   - Ruconest will NOT be used concurrently with alternative acute treatment for HAE attacks (e.g., Berinert, Firazyr, Kalbitor)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 vials per fill.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **C1 ESTERASE INHIBITOR - RUCONEST** requires the following rule(s) be met for approval:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor) or hematologist (a type of blood doctor)
   C. Your diagnosis is confirmed by complement testing (a type of lab test)
   D. Ruconest is being used for acute (short term) attacks of hereditary angioedema
   E. You will NOT be using Ruconest concurrently (at the same time) with alternative acute treatment for HAE attacks (such as Berinert, Firazyr, Kalbitor)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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C1 ESTERASE INHIBITOR - RUCONEST

GUIDELINES FOR USE (CONTINED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) **AND** meet the following criterion?
   - Ruconest will NOT be used concurrently with alternative acute treatment for HAE attacks (e.g., Berinert, Firazyr, Kalbitor)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #8 vials per fill.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **C1 ESTERASE INHIBITOR - RUCONEST** requires the following rule(s) be met for renewal:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. You will NOT be using Ruconest concurrently (at the same time) with alternative acute treatment for HAE attacks (such as Berinert, Firazyr, Kalbitor)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ruconest.

REFERENCES

- Ruconest [Prescribing Information]. Raleigh, NC: Salix Pharmaceuticals; December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/01/22
Created: 10/22
Client Approval: 10/22
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CABOZANTINIB S-MALATE

**** Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE

COMETRIQ

1. Does the patient have a diagnosis of progressive, metastatic medullary thyroid cancer (MTC)?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #112 per 28 days for the requested daily dose pack. (NOTE: Cometriq is available in three dosage packs each containing 7 days supply)**
   - **Cometriq 140mg daily dose pack.**
   - **Cometriq 100mg daily dose pack.**
   - **Cometriq 60mg daily dose pack.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CABOZANTINIB S-MALATE (Cometriq)** requires the following rule be met for approval:
   A. You have progressive, metastatic medullary thyroid cancer (type of thyroid cancer that has spread)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CABOZANTINIB S-MALATE

GUIDELINES FOR USE (CONTINUED)

CABOMETYX

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) and meet **ONE** of the following criteria?
   - Cabometyx will be used as a single agent
   - Cabometyx will be used in combination with Opdivo (nivolumab) as first-line treatment (no prior treatment for advanced RCC)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **Cabometyx 60mg: #1 per day.**
   - **Cabometyx 40mg: #2 per day.**
   - **Cabometyx 20mg: #1 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of hepatocellular carcinoma (HCC) **AND** meet the following criterion?
   - The patient has previously been treated with Nexavar (sorafenib)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **Cabometyx 60mg: #1 per day.**
   - **Cabometyx 40mg: #2 per day.**
   - **Cabometyx 20mg: #1 per day.**

   If no, continue to #3.

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CABOZANTINIB S-MALATE

GUIDELINES FOR USE - CABOMETYX (CONTINUED)

3. Does the patient have a diagnosis of locally advanced or metastatic differentiated thyroid cancer (DTC) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has disease progression following prior vascular endothelial growth factor receptor (VEGFR)-targeted therapy
   - The patient is radioactive iodine-refractory or ineligible

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **Cabometyx 60mg: #1 per day.**
   - **Cabometyx 40mg: #2 per day.**
   - **Cabometyx 20mg: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CABOZANTINIB S-MALATE (Cabometyx)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Advanced renal cell carcinoma (RCC: type of kidney cancer)
      2. Hepatocellular carcinoma (HCC: type of liver cancer)
      3. Locally advanced or metastatic differentiated thyroid cancer (DTC: type of thyroid cancer)
   B. **If you have advanced renal cell carcinoma, approval also requires ONE of the following:**
      1. Cabometyx will be used as a single agent (used alone)
      2. Cabometyx will be used in combination with Opdivo (nivolumab) as first-line treatment (You have not received prior treatment for advanced renal cell carcinoma)
   C. **If you have hepatocellular carcinoma, approval also requires:**
      1. You have previously been treated with Nexavar (sorafenib)
   D. **If you have locally advanced or metastatic differentiated thyroid cancer, approval also requires:**
      1. You are 12 years of age or older
      2. You have disease progression (disease has gotten worse) following prior vascular endothelial growth factor receptor (VEGFR)-targeted therapy (a type of cancer therapy)
      3. You are radioactive iodine-refractory (resistant to) or ineligible

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CABOZANTINIB S-MALATE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cometriq or Cabometyx.

REFERENCES

- Cometriq [Prescribing Information]. South San Francisco, CA: Exelixis, Inc.; February 2020.
- Cabometyx [Prescribing Information]. South San Francisco, CA: Exelixis, Inc.; September 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/04/21
Created: 01/13
Client Approval: 09/21
P&T Approval: 10/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CANTHARIDIN

GUIDELINES FOR USE

1. Does the plan benefit include non-self-administered (NSA) medications?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient have a diagnosis of molluscum contagiosum **AND** meet the following criterion?
   - The patient is 2 years of age or older

   If yes, **approve for 12 months by HICL with a quantity limit of #2 per 21 days.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CANTHARIDIN (Ycanth)** requires the following rule(s) be met for approval:
   A. You have molluscum contagiosum (a viral skin infection)
   B. You are 2 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ycanth.

REFERENCES

- Ycanth [Prescribing Information]. West Chester, PA: Verrica Pharmaceuticals Inc.; July 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 12/01/23
Created: 10/23
Client Approval: 11/23
P&T Approval:10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CAPECITABINE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Stage III colon cancer **AND** meet the following criterion?
   - The requested medication will be used as adjuvant treatment

   If yes, **approve for 12 months by HICL or GPI-10 for 8 fills.**
   If no, continue to #2.

2. Does the patient have a diagnosis of locally advanced rectal cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used as perioperative treatment
   - The requested medication will be used as part of chemoradiotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have a diagnosis of unresectable or metastatic colorectal cancer?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

4. Does the patient have a diagnosis of advanced or metastatic breast cancer and meet **ONE** of the following criteria?
   - The requested medication will be used as a single agent, if an anthracycline- or taxane-containing chemotherapy is not indicated
   - The requested medication will be used in combination with docetaxel after disease progression on prior anthracycline-containing chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

5. Does the patient have a diagnosis of unresectable or metastatic gastric, esophageal, or gastroesophageal junction cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used as part of a combination chemotherapy regimen

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #6.

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CAPECITABINE

GUIDELINES FOR USE (CONTINUED)

6. Does the patient have a diagnosis of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has not received prior treatment for metastatic disease
   - The requested medication will be used as part of a combination regimen

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #7.

7. Does the patient have a diagnosis of pancreatic adenocarcinoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used as adjuvant treatment
   - The requested medication will be used as part of a combination chemotherapy regimen

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CAPECITABINE (Xeloda)** requires the following rule(s) to be met for approval:
   A. You have ONE of the following diagnoses:
      1. Stage III colon cancer (colon cancer that has spread to lymph nodes)
      2. Locally advanced rectal cancer (cancer that has spread from where it started to nearby tissue or lymph nodes)
      3. Unresectable (unable to remove by surgery) or metastatic colorectal cancer (a type of digestive cancer that has spread to other parts of the body)
      4. Metastatic breast cancer (breast cancer that has spread to other parts of the body)
      5. Unresectable or metastatic gastric, esophageal, or gastroesophageal junction cancer (a type of digestive system cancer that has spread to other parts of the body)
      6. HER2 (a type of protein)-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma (a type of digestive system cancer that has spread to other parts of the body)
      7. Pancreatic adenocarcinoma (a type of cancer of the pancreas)
   B. **If you have Stage III colon cancer, approval also requires:**
      1. The requested medication will be used as adjuvant (add-on) treatment

   (Denial text continued on next page)

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CAPECITABINE

GUIDELINES FOR USE (CONTINUED)

C. **If you have locally advanced rectal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used as perioperative (the time period before and after surgery) treatment
   3. The requested medication will be used as part of chemoradiotherapy (a type of cancer treatment)

D. **If you have advanced or metastatic breast cancer, approval also requires ONE of the following:**
   1. The requested medication will be used as a single agent (used alone), if an anthracycline (such as doxorubicin, daunorubicin)- or taxane (such as paclitaxel, docetaxel)-containing chemotherapy is not indicated
   2. The requested medication will be used in combination with docetaxel after disease progression (worsens) on prior anthracycline (such as doxorubicin, daunorubicin)-containing chemotherapy

E. **If you have unresectable or metastatic gastric, esophageal, or gastroesophageal junction cancer, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used as part of a combination chemotherapy (drugs used to treat cancer) regimen

F. **If you have HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have not received prior treatment for metastatic disease
   3. The requested medication will be used as part of a combination regimen (such as with cisplatin, trastuzumab)

G. **If you have pancreatic adenocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used as adjuvant (add-on) treatment
   3. The requested medication will be used as part of a combination chemotherapy regimen (such as with gemcitabine)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CAPECITABINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xeloda.

REFERENCES

- Xeloda [Prescribing Information]. South San Francisco, CA: Genentech Inc., December 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/23/23
Created: 02/13
Client Approval: 01/23
P&T Approval: 01/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CAPIVASERTIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic breast cancer and meet **ALL** of the following criteria?
   - Truqap will be used in combination with Faslodex (fulvestrant)
   - The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, with one or more PIK3CA/AKT1/PTEN-alterations as detected by an FDA-approved test
   - The patient has disease progression on an endocrine-based regimen (e.g., letrozole, anastrozole, tamoxifen)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #64 per 28 days.** If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CAPIVASERTIB (Truqap)** requires the following rule(s) be met for approval:
   A. You have locally advanced or metastatic breast cancer (breast cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
   B. Truqap will be used together with Faslodex (fulvestrant)
   C. Your breast cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative, with one or more PIK3CA/AKT1/PTEN-mutations (abnormal changes in a type of gene) as detected by a Food and Drug Administration (FDA)-approved test
   D. You have experienced disease progression (your condition has worsened) on an endocrine (hormone)-based regimen (such as letrozole, anastrozole, tamoxifen)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CAPIVASERTIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Truqap.

REFERENCES

- Truqap [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 11/23
Client Approval: 11/23
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CAPLACIZUMAB-YHDP

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acquired thrombotic thrombocytopenia purpura (aTTP) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient experienced more than two recurrences of aTTP, while on Cablivi therapy (i.e., new drop in platelet count requiring repeat plasma exchange during 30 days post-plasma exchange therapy [PEX] and up to 28 days of extended therapy)?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #3.

3. Is the request for continuation of Cablivi therapy from inpatient (hospital) setting **AND** the patient meets the following criterion?
   - Cablivi was previously initiated as part of the FDA approved treatment regimen in combination with plasma exchange and immunosuppressive therapy within the inpatient setting

   If yes, **approve for 1 month by HICL or GPI-10 for a maximum quantity of #30 vials.**
   If no, continue to #4.

4. Is the request for continuation of Cablivi therapy from the initial 30 days treatment course (e.g., no break in therapy) and the patient meets **ALL** of the following criteria?
   - The patient is receiving immunosuppressive therapy
   - The patient is experiencing signs of persistent underlying disease (e.g., suppressed ADAMTS13 [a disintegrin and metalloproteinase with thrombospondin type 1 motif, member 13] activity level remain present)

   If yes, **approve for 1 month by HICL or GPI-10 for a maximum quantity of #28 vials.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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CAPLACIZUMAB-YHDP

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it

Our guideline named **CAPLACIZUMAB-YHDP (Cablivi**) requires the following rule(s) be met for approval:

A. You have a diagnosis of acquired thrombotic thrombocytopenia purpura (aTTP- a type of blood disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a hematologist (blood specialist)
D. You have NOT experienced more than two recurrences of acquired thrombotic thrombocytopenia purpura, while on Cablivi therapy. For example there's a new drop in platelet count requiring repeat plasma exchange during 30 days post-plasma exchange therapy (process of replacing a liquid part of the blood) and up to 28 days of extended therapy
E. You also meet ONE of the following:
    1. Your request is for continuation of Cablivi therapy from inpatient (hospital) setting and you previously received plasma exchange and immunosuppressive therapy (treatment that weakens your immune system) within the inpatient setting
    2. Your request is for continuation of Cablivi therapy from the initial 30 days treatment course (no break in therapy) AND:
        a. You are receiving immunosuppressive therapy, and
        b. You are experiencing signs of persistent underlying disease (such as suppressed ADAMTS13 [a disintegrin and metalloproteinase with thrombospondin type 1 motif, member 13: type of blood clot disorder] activity level remain present)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cablivi.

REFERENCES

- Cablivi [Prescribing Information]. Cambridge, MA: Genzyme Corporation; February 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/21/22
Created: 05/19
Client Approval: 11/22
P&T Approval: 04/19

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CAPMATINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CAPMATINIB (Tabrecta)** requires the following rule(s) be met for approval:
   A. You have metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
   B. You are 18 years of age or older
   C. Your tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping (an abnormal change in a gene that makes MET protein) as detected by an FDA-approved test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tabrecta.

REFERENCES

- Tabrecta [Prescribing Information]. East Hanover, NJ: Novartis; May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 08/20
Client Approval: 03/21
P&T Approval: 07/20

LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

CAPSAICIN

GUIDELINES FOR USE

1. Does the patient have neuropathic pain associated with **ONE** of the following conditions?
   - Postherpetic neuralgia (PHN)
   - Diabetic peripheral neuropathy (DPN) of the feet

   If yes, **approve for 12 months by HICL or GPI-10 for 4 fills with a quantity limit of up to #4 patches per fill (maximum dose is 4 patches every 3 months).**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CAPSAICIN (Qutenza)** requires the following rule be met for approval:
   A. You have a diagnosis of neuropathic pain associated with ONE of the following conditions:
      - Postherpetic neuralgia (PHN) (painful condition that affects the nerve fibers and skin after having shingles)
      - Diabetic peripheral neuropathy (DPN) of the feet (numbness of the feet that is caused by diabetes)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Qutenza.

REFERENCES

- Qutenza [Prescribing Information]. Ardsley, NY. Acorda Therapeutics, Inc. July 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/24/20
Created: 05/10
Client Approval: 07/20
P&T Approval: 10/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CARBIDOPA-LEVODOPA

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced Parkinson's disease?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #100mL per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CARBIDOPA-LEVODOPA (Duopa)** requires the following rule be met for approval:
   A. You have a diagnosis of advanced Parkinson's disease (nerve system disorder that affects movement)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Duopa.

REFERENCES

- Duopa [Prescribing Information]. North Chicago, IL: Abbvie, Inc. Februrary 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 05/15
Client Approval: 04/20
P&T Approval: 05/15

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CARGLUMIC ACID

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acute or chronic hyperammonemia (HA) due to N-acetylglutamate synthase (NAGS) deficiency **AND** meet the following criterion?
   - NAGS gene mutation is confirmed by biochemical or genetic testing

   If yes, continue to #2**.**
   If no, continue to #4.

2. Is the request for generic carglumic acid?

   If yes, **approve carglumic acid (generic only) by HICL or GPI-10 as follows:**
   - **Acute HA due to NAGS deficiency: approve for 7 days.**
   - **Chronic HA due to NAGS deficiency: approve for 6 months.**

   If no, continue to #3.

3. Is the request for brand Carbaglu **AND** the patient meets the following criterion?
   - The patient had a trial of generic carglumic acid

   If yes, **approve by HICL or GPI-10 as follows:**
   - **Acute HA due to NAGS deficiency: approve for 7 days.**
   - **Chronic HA due to NAGS deficiency: approve for 6 months.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of acute hyperammonemia (HA) due to propionic acidemia (PA) **AND** meet following criterion?
   - The diagnosis is confirmed by the presence of elevated methylcitric acid and normal methylmalonic acid OR genetic testing confirming mutation in the PCCA or PCCB gene

   If yes, **approve for 7 days by HICL or GPI-10.**
   If no, continue to #5.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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CARGLUMIC ACID

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of acute hyperammonemia (HA) due to methylmalonic acidemia (MMA) **AND** meet following criterion?
   - The diagnosis is confirmed by the presence of elevated methylmalonic acid, methylcitric acid OR genetic testing confirming mutation in the MMUT, MMA, MMAB or MMADHC genes

   If yes, **approve for 7 days by HICL or GPI-10.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CARGLUMIC ACID (Carbaglu)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Acute or chronic hyperammonemia (HA) due to N-acetylglutamate synthase (NAGS) deficiency (short-term or long-term high ammonia blood levels due to a genetic disorder)
      2. Acute hyperammonemia (HA) due to propionic acidemia (PA) or methylmalonic acidemia (MMA) (short-term high ammonia blood levels due to a genetic disorder)
   B. **If you have acute or chronic hyperammonemia due to N-acetylglutamate synthase deficiency, approval also requires**:
      1. Your N-acetylglutamate synthase gene mutation is confirmed by biochemical or genetic testing (types of lab test)
      2. Requests for brand Carbaglu requires a trial of generic carglumic acid
   C. **If you have acute hyperammonemia due to propionic acidemia, approval also requires**:
      1. Your diagnosis is confirmed by the presence of elevated methylcitric acid and normal methylmalonic acid (substances that indicate presence of a disease) OR genetic testing confirming mutation in the PCCA or PCCB gene (types of abnormal genes)
   D. **If you have acute hyperammonemia due to methylmalonic acidemia, approval also requires**:
      1. Your diagnosis is confirmed by the presence of elevated methylmalonic acid, methylcitric acid OR genetic testing confirming mutation in the MMUT, MMA, MMAB or MMADHC genes (types of abnormal genes)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CARGLUMIC ACID

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

NOTE: For the diagnoses of acute hyperammonemia (HA) due to N-acetylglutamate synthase (NAGS) deficiency or acute hyperammonemia (HA) due to propionic acidemia (PA) or methylmalonic acidemia (MMA), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of chronic hyperammonemia (HA) due to N- acetylglutamate synthase (NAGS) deficiency **AND** meet the following criterion?
   - The patient has clinical improvement or improved plasma (blood) ammonia levels

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CARGLUMIC ACID (Carbaglu)** requires the following rule(s) be met for renewal:
   A. You have chronic hyperammonemia (HA) due to N-acetylglutamate synthase (NAGS) (long-term high ammonia blood levels due to a genetic disorder)
   B. You have clinical improvement or improved plasma (blood) ammonia levels

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Carbaglu.

REFERENCES

- Carbaglu [Prescribing Information]. Lebanon, NJ: Recordati Rare Diseases, Inc.; August 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 05/22
Client Approval: 05/22
P&T Approval: 01/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CELECOXIB

GUIDELINES FOR USE

1. Is the request for the acute treatment of migraine and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of generic celecoxib AND OTC or generic aspirin, diclofenac, ibuprofen, or naproxen
   - The patient is unable to swallow pills (e.g., tablets or capsules)

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #38.4 mL per 30 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CELECOXIB (Elyxyb)** requires the following rule(s) be met for approval:
   A. The request is for the acute (quick onset) treatment of migraines
   B. You are 18 years of age or older
   C. You had a trial of generic celecoxib AND over-the-counter (OTC) or generic aspirin, diclofenac, ibuprofen, or naproxen
   D. You are unable to swallow pills (such as tablets or capsules)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Elyxyb.

REFERENCES

- Elyxyb [Prescribing Information]. Raleigh, NC: BioDelivery Sciences International, Inc.; September 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 02/22
Client Approval: 02/22
P&T Approval: 01/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CENEGERMIN-BKBJ

GUIDELINES FOR USE

1. Does the patient have a diagnosis of neurotrophic keratitis (NK) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or given in consultation with an ophthalmologist
   - The patient has a medical history supportive of causative etiology for trigeminal nerve damage (e.g., herpes zoster infection, multiple sclerosis, diabetes, ocular surgical damage)
   - The patient has loss of corneal sensitivity, corneal epithelium changes, and/or loss of tear production
   - The patient is refractory to conservative management (i.e., artificial tears, ocular lubricants, topical antibiotics, therapeutic contact lenses)

   If yes, **approve for 8 weeks per lifetime by HICL or GPI-10 as follows:**
   - **If treatment is for 1 eye: #28 vials per 28 days for 2 fills.**
   - **If treatment is for 2 eyes: #56 vials per 28 days for 2 fills.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CENEGERMIN-BKBJ (Oxervate)** requires the following rule(s) be met for approval:
   A. You have a diagnosis of neurotrophic keratitis (an eye disease due to a damaged eye nerve)
   B. Therapy is prescribed by or given in consultation with an ophthalmologist (eye doctor)
   C. You have a medical history that supports a cause for trigeminal nerve damage (damage to a nerve in the head) such as herpes zoster infection (shingles virus), multiple sclerosis (disorder where immune system attacks nerves), diabetes, ocular surgical (eye surgery) damage
   D. You have loss of corneal sensitivity, corneal epithelium changes, and/or loss of tear production
   E. You are refractory (not fully responsive) to conservative management that includes artificial tears, ocular lubricants, topical antibiotics, therapeutic contact lenses

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CENEGERMIN-BKBJ

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Oxervate.

REFERENCES

- Oxervate [Prescribing Information]. Boston, MA: Dompe U.S., Inc., December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/04/20
Created: 02/19
Client Approval: 09/20
P&T Approval: 01/19

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CERITINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumors are anaplastic lymphoma kinase (ALK)-positive, as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CERITINIB (Zykadia)** requires the following rule(s) be met for approval:
   A. You have metastatic non-small cell lung cancer (type of lung cancer that has spread)
   B. You are 18 years of age or older
   C. Your tumors are anaplastic lymphoma kinase (ALK: a type of enzyme) positive as confirmed by a Food and Drug Administration-approved test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zykadia.

REFERENCE

- Zykadia [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/25/21
Created: 05/14
Client Approval: 10/21
P&T Approval: 10/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CERTOLIZUMAB PEGOL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
   - The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**Note:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for a total of 6 months. Please enter two authorizations by HICL or GPI-10 as follows:**
   - **<u>FIRST APPROVAL:</u> Approve for 1 month with a quantity limit of #3 kits.**
   - **<u>SECOND APPROVAL:</u> Approve for 5 months with a quantity limit of #1 kit per 28 days (Enter a start date that is 1 week AFTER the END date of the first approval).**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Taltz (ixekizumab), Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
   - [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for a total of 6 months. Please enter two authorizations by HICL or GPI-10 as follows:**
   - **<u>FIRST APPROVAL:</u> Approve for 1 month with a quantity limit of #3 kits.**
   - **<u>SECOND APPROVAL:</u> Approve for 5 months with a quantity limit of #1 kit per 28 days (Enter a start date that is 1 week AFTER the END date of the first approval).**

   If no, continue to #4.

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for a total of 6 months. Please enter two authorizations by HICL or GPI-10 as follows:**
   - **<u>FIRST APPROVAL:</u> Approve for 1 month with a quantity limit of #3 kits.**
   - **<u>SECOND APPROVAL:</u> Approve for 5 months with a quantity limit of #1 kit per 28 days (Enter a start date that is 1 week AFTER the END date of the first approval).**

   If no, continue to #5.

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INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to ONE conventional therapy (e.g., corticosteroids [e.g., budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Humira (adalimumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for a total of 6 months. Please enter two authorizations by HICL or GPI-10 as follows:**
     - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #3 kits.**
     - **SECOND APPROVAL: Approve for 5 months with a quantity limit of #1 kit per 28 days (Enter a start date that is 3 weeks AFTER the END date of the first approval).**

     If no, continue to #6.

6. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, genital area, or face
   - The patient had a trial of or contraindication to ONE or more forms of conventional therapies, (e.g., PUVA [psoralen and ultraviolet light A], UVB [ultraviolet light B], topical corticosteroids [e.g., betamethasone dipropionate, clobetasol propionate], calcipotriene, acitretin, methotrexate, cyclosporine)
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 kits per 28 days.**
     If no, continue to #7.

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

8. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic and is switching to Cimzia
   - The patient has C-reactive protein (CRP) levels above the upper limit of normal
   - The patient has sacroiliitis on magnetic resonance imaging (MRI)

   If yes, **approve for a total of 6 months. Please enter two authorizations by HICL or GPI-10 as follows:**
   - **<u>FIRST APPROVAL:</u> Approve for 1 month with a quantity limit of #3 kits.**
   - **<u>SECOND APPROVAL:</u> Approve for 5 months with a quantity limit of #1 kit per 28 days (Enter a start date that is 1 week AFTER the END date of the first approval).**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CERTOLIZUMAB PEGOL (Cimzia)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Ankylosing spondylitis (AS: a type of joint condition)
      4. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
      5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
      6. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)

   (Initial denial text continued on next page)

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INITIAL CRITERIA (CONTINUED)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) to at least 3 months of ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You meet ONE of the following:
      a. You have tried or have a contraindication (harmful for) to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
      b. You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have tried or have a contraindication to (harmful for you to use) to TWO of the following preferred medications: Taltz (ixekizumab), Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

D. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam)
   4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

E. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
   3. You have tried or have a contraindication to (harmful for you to use) ONE standard therapy, such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. You have tried or have a contraindication to (harmful for you to use) to ONE of the following preferred agents: Humira (adalimumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

F. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You have psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You have tried or have a contraindication to (harmful for you to use) ONE or more forms of standard therapies, such as PUVA (psoralen and ultraviolet light A: a type of light therapy), UVB (ultraviolet light B: a type of light therapy), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), calcipotriene, acitretin, methotrexate, or cyclosporine
   5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred agents: Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

G. **If you have non-radiographic axial spondyloarthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam)
   4. You meet ONE of the following criteria:
      a. You were previously stable on another biologic and you are switching to Cimzia
      b. You have C-reactive protein (CRP: a measure of how much inflammation is in the body) levels above the upper limit of normal
      c. You have sacroiliitis (type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet the following criterion?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
   - The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Taltz (ixekizumab), Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit per 28 days.**
   If no, continue to #4.

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RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit per 28 days.**
     If no, continue to #5.

5. Does the patient have non-radiographic axial spondyloarthritis (nr-axSpA) **AND** meet the following criterion?
   - The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

     If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit per 28 days.**
     If no, continue to #6.

6. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) **AND** meet the following criterion?
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Humira (adalimumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit per 28 days.**
     If no, continue to #7.

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 kits per 28 days.**

     If no, do not approve.

     RENEWAL DENIAL TEXT: Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

     Our guideline named **CERTOLIZUMAB PEGOL (Cimzia)** requires the following rule(s) be met for renewal:
     A. You have ONE of the following:
        1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
        2. Psoriatic arthritis (PsA: a type of skin and joint condition)
        3. Ankylosing spondylitis (AS: a type of joint condition)
        4. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
        5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
        6. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)

     (Renewal denial text continued on next page)

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You meet ONE of the following:
      a. You have tried or have a contraindication (harmful for) to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
      b. You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You have tried or have a contraindication to (harmful for you to use) to TWO of the following preferred medications: Taltz (ixekizumab), Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

D. **If you have ankylosing spondylitis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
   2. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

(Renewal denial text continued on next page)

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

E. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
   2. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

F. **If you have moderate to severe Crohn's disease, renewal also requires ONE of the following:**
   1. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Humira (adalimumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

G. **If you have non-radiographic axial spondyloarthritis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cimzia.

REFERENCES

- Cimzia [Prescribing Information]. Smyrna, GA: UCB, Inc.; December 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 05/08
Client Approval: 03/24
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CHENODIOL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being prescribed for the treatment of cerebrotendinous xanthomatosis (CTX)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 daily.**
   If no, continue to #2.

2. Is the requested medication being prescribed for the treatment of radiolucent gallstones?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Has the patient received previous chenodiol therapy with a total duration exceeding 24 months?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #4.

4. Has the patient had a previous trial of or contraindication to ursodiol?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #7 daily.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CHENODIOL (Chenodal)** requires the following rule(s) be met for approval:
   A. You have radiolucent gallstones (hard deposits in your gall bladder that can barely be seen with x-rays) OR cerebrotendinous xanthomatosis (condition of missing an enzyme that changes cholesterol into a bile acid)
   B. **If you have radiolucent gallstones, approval also requires:**
      1. You have tried ursodiol, unless there is a medical reason why you cannot (contraindication)
      2. You have not received previous chenodiol therapy for more than a total of 24 months

   (Initial denial text continued on next page)

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CHENODIOL

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Is the requested medication being used for radiolucent gallstones?

   If yes, continue to #2.
   If no, continue to #5.

2. Has the patient previously received a total duration of chenodiol therapy exceeding 24 months?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #3.

3. Does the patient have complete or no gallstone dissolution seen on imaging after 12 months of therapy?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #4.

4. Does the patient have partial gallstone dissolution seen on imaging after 12 months of therapy?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #7 daily.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

5. Does the patient have a diagnosis of cerebrotendinous xanthomatosis (CTX) **AND** meet the following criterion?
   - The patient has experienced improvement in **ONE** of the following:
     - Normalization of elevated serum or urine bile alcohols
     - Normalization of elevated serum cholestanol levels
     - Improvement in neurologic and psychiatric symptoms (dementia, pyramidal tract and cerebellar signs)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 daily.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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CHENODIOL

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CHENODIOL (Chenodal)** requires the following rule(s) be met for renewal:

A. You have radiolucent gallstones (hard deposits in your gall bladder that can barely be seen with x-rays) OR cerebrotendinous xanthomatosis (condition of missing an enzyme that changes cholesterol into a bile acid)
B. **If you have radiolucent gallstones, renewal also requires:**
   1. You have **NOT** had chenodiol therapy for more than a total of 24 months
   2. You do **NOT** have complete or no gallstone dissolution (disappearance) seen on imaging (such as oral cholecystograms or ultrasonograms) after 12 months of therapy
   3. You have partial gallstone dissolution seen on imaging (such as oral cholecystograms or ultrasonograms) after 12 months of therapy
C. **If you have cerebrotendinous xanthomatosis, renewal also requires you have experienced an improvement** in **ONE** of the following:
   1. Normalization of elevated serum or urine bile alcohols
   2. Normalization of elevated serum cholestanol levels
   3. Improvement in neurologic and psychiatric symptoms (dementia, pyramidal tract and cerebellar signs)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Chenodal.

REFERENCES

- Chenodal [Prescribing Information]. Manchester Pharmaceuticals, Inc. Fort Collins, CO. July 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 11/09
Client Approval: 04/20
P&T Approval: 07/18

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CHOLIC ACID

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption secondary to **ONE** of the following conditions?
   - Bile acid synthesis disorders
   - Peroxisomal disorders (i.e., Zellweger spectrum disorders)

   If yes, **approve for 3 months by HICL or GPI-10.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CHOLIC ACID (Cholbam)** requires the following rule(s) be met for approval:
   A. You show signs of liver disease, steatorrhea (excess fat in feces), or complications from your body not being able to absorb fat-soluble vitamins that occur from ONE of the following conditions:
      1. Bile acid synthesis disorders (your body has a problem making bile acid)
      2. Peroxisomal disorders (Zellweger spectrum disorders) (problems with a part of a cell that contains enzymes)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Did the patient experience improvement in liver function (as defined by at least **ONE** of the following criteria)?
   - ALT or AST values reduced to less than 50 U/L or baseline levels reduced by 80%
   - Total bilirubin values reduced to less than 1 mg/dL
   - No evidence of cholestasis on liver biopsy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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CHOLIC ACID

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CHOLIC ACID (Cholbam)** requires the following rule(s) be met for renewal:

A. You have experienced an improvement in your liver function as defined by at least ONE of the following criteria:

1. ALT (alanine aminotransferase) or AST (aspartate transaminase) (types of liver enzymes) values have been lowered to less than 50 U/L or baseline levels reduced by 80%
2. Total bilirubin values reduced to less than 1 mg/dL
3. No evidence of cholestasis (condition where bile cannot flow from liver) on liver biopsy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cholbam.

REFERENCES

- Cholbam [Prescribing Information]. Baltimore, MD: Asklepion Pharmaceuticals, LLC; March 2015.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 04/15
Client Approval: 04/20
P&T Approval: 05/15

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CLADRIBINE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., relapsing-remitting MS [RRMS], active secondary progressive MS [SPMS], etc.) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 48 weeks by GPID or GPI-10.**
   APPROVAL TEXT: Renewal requires 1) physician attestation that the patient has demonstrated a clinical benefit compared to pre-treatment baseline, 2) the patient does not have lymphopenia, and 3) the patient has not received a total of two years of Mavenclad treatment (i.e., two treatment cycles divided into 2 yearly treatment courses).

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.
   Our guideline named **CLADRIBINE (Mavenclad)** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: disease where body attacks its own nerves and returns after having no symptoms). This includes relapsing- remitting MS [RRMS], active secondary progressive MS [SPMS], etc.
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (e.g. relapsing-remitting MS [RRMS], active secondary progressive MS [SPMS], etc.)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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CLADRIBINE

RENEWAL CRITERIA (CONTINUED)

2. Has the patient received a total of two years of Mavenclad treatment (i.e., two treatment cycles divided into 2 yearly treatment courses)?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #3.

3. Does the patient meet **ALL** of the following criteria?
   - The patient has demonstrated a clinical benefit compared to pre-treatment baseline
   - The patient does not have lymphopenia

   If yes, **approve for 48 weeks by GPID or GPI-10.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.***
   Our guideline named **CLADRIBINE (Mavenclad)** requires the following rule(s) be met for renewal:
   A. You have a relapsing form of multiple sclerosis (MS: disease where body attacks its own nerves and returns after having no symptoms). This includes relapsing- remitting MS [RRMS], active secondary progressive MS [SPMS], etc.
   B. You have demonstrated a clinical benefit compared to pre-treatment baseline (before you started therapy)
   C. You do not have lymphopenia (low amount of a type of white blood cell called lymphocyte)
   D. You have not received a total of two years of treatment with Mavenclad

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mavenclad.

REFERENCES

- Mavenclad [Prescribing Information]. Rockland, MA: EMD Serono, Inc., March 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 04/19
Client Approval: 04/20
P&T Approval: 10/19

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CLASCOTERONE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acne vulgaris and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or given in consultation with a dermatologist
   - The patient had a trial of or contraindication to **BOTH** of the following:
     - ONE oral acne agent (e.g. oral antibiotics or oral isotretinoin)
     - TWO topical acne agents (e.g. topical retinoids, topical antibiotics, benzoyl peroxide)

   If yes, **approve for 3 months by HICL or GPI-10 with a quantity limit of #60 grams (1 tube) per 30 days.**
   APPROVAL TEXT: Renewal requires the patient had improvement of acne lesions.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CLASCOTERONE (Winlevi)** requires the following rule(s) be met for approval:
   A. You have acne vulgaris (skin condition in which hair follicles become plugged with oil and dead skin cells)
   B. You are 12 years of age or older
   C. Therapy is prescribed by or given in consultation with a dermatologist (skin doctor)
   D. You have previously tried BOTH of the following unless there is a medical reason why you cannot (contraindication):
      1. ONE oral acne agent (such as oral antibiotics or oral isotretinoin)
      2. TWO topical acne agents (such as topical retinoids, topical antibiotics, benzoyl peroxide)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CLASCOTERONE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acne vulgaris **AND** meet the following criterion?
   - The patient had improvement of acne lesions

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #60 grams (1 tube) per 30 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CLASCOTERONE (Winlevi)** requires the following rule(s) be met for approval:
   A. You have acne vulgaris (skin condition in which hair follicles become plugged with oil and dead skin cells)
   B. You had improvement of acne lesions

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Winlevi.

REFERENCES

- Winlevi [Prescribing Information]. Milan, Italy: Cosmo S.p.A.; August 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21
Created: 12/20
Client Approval: 12/20
P&T Approval: 10/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CLOBAZAM-SYMPAZAN

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Lennox-Gastaut syndrome and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - Sympazan will be used for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome
   - The patient is unable to take tablets or suspension
   - The patient had a trial of or contraindication to generic/branded clobazam products (Onfi)

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths with a quantity limit of #2 per day:**
   - **5mg film**
   - **10mg film**
   - **20mg film**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CLOBAZAM-SYMPAZAN** requires the following rule(s) be met for approval:
   A. You have Lennox-Gastaut Syndrome (a type of seizure disorder in young children)
   B. You are 2 years of age or older
   C. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
   D. Sympazan will be used for adjunctive (add-on) treatment of seizures associated with Lennox-Gastaut syndrome
   E. You are unable to take tablets or suspension
   F. You had a trial of or contraindication (harmful for) to generic/branded clobazam products (Onfi)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CLOBAZAM-SYMPAZAN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sympazan.

REFERENCES

- Sympazan [Prescribing Information]. Warren, NJ. Aquestive Therapeutics; March 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 02/19
Client Approval: 05/22
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

COBIMETINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumor has a BRAF V600E OR V600K mutation
   - Cobimetinib will be used in combination with vemurafenib (Zelboraf)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #63 per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of histiocytic neoplasms and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Cobimetinib will be used as a single agent

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #63 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **COBIMETINIB (Cotellic)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Unresectable or metastatic melanoma (skin cancer that has spread or cannot be completely removed with surgery)
      2. Hystiocytic neoplasms (a type of white blood cell disorder)
   B. **If you have unresectable or metastatic melanoma, approval also requires:**
      1. You are 18 years of age or older
      2. Your tumor has a BRAF V600E OR V600K mutation (a type of gene mutation)
      3. Cobimetinib will be used in combination with vemurafenib (Zelboraf)
   C. **If you have histiocytic neoplasms, approval also requires:**
      1. You are 18 years of age or older
      2. Cobimetinib will be used as a single agent

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

COBIMETINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cotellic.

REFERENCES

- Cotellic [Prescribing Information]; San Francisco, CA: Genentech USA, Inc.; October 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/21/22
Created: 11/15
Client Approval: 11/22
P&T Approval: 01/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

COLLAGENASE TOPICAL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic dermal ulcer(s) or severe burn(s) that require(s) debridement?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the requested quantity for one tube (30 grams) or less?

   If yes, **approve by GPID or GPI-14 for one fill with a quantity limit of #30 grams.**
   If no, continue to #3.

3. Are **BOTH** of the following provided?
   - The patient's wound size (width/length)
   - The anticipated duration of therapy

   If yes, **approve by GPID or GPI-14 for one fill with a quantity limit based on the Santyl dosing calculator (https://santyl.com/hcp/dosing).**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **COLLAGENASE TOPICAL (Santyl)** requires the following rule(s) be met for approval:
   A. You have chronic dermal (skin) ulcer(s) or severe burn(s) that require(s) debridement (removal of damaged tissue from a wound)
   B. **If the requested quantity is more than one tube (30 grams), approval also requires:**
      1. The higher quantity is based on the size of your wound (width/length) and the anticipated duration of therapy, using the Santyl dosing calculator (https://santyl.com/hcp/dosing)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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COLLAGENASE TOPICAL

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Santyl.

REFERENCES

- Santyl [Prescribing Information]. Fort Worth, TX: Smith & Nephew, Inc., May 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 11/21
Client Approval: 02/22
P&T Approval: 10/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CORTICOTROPIN

GUIDELINES FOR USE

1. Does the patient have a diagnosis of infantile spasms and meet the following criterion?
   - The patient is less than 2 years of age

   If yes, **approve for 28 days by HICL or GPI-10 with a maximum of #8 vials (each 5mL vial contains 400 units).**

   If no, continue to #2.

2. Is the request for any other indications other than infantile spasms?

   If yes, do not approve. See note and use denial text below.
   Note: Off-label guideline should not be used for Acthar because it hasn't demonstrated proven benefits in the other indications and has no proven advantage over synthetic steroids. Therefore, there isn't a pathway to approval for any other listed indications.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CORTICOTROPIN (Acthar, Cortrophin)** requires the following rule(s) be met for approval:
   A. You have infantile spasms (type of seizure disorder in young children)
   B. You are less than 2 years of age

   Acthar will not be approved for any other indications other than infantile spasms. Acthar has not demonstrated proven benefits or advantage over synthetic steroids in the treatment of other indications.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CORTICOTROPIN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Acthar.

REFERENCES

- Acthar Gel [Prescribing Information]. Bedminster, NJ: Mallinckrodt ARD LLC; April 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/23
Created: 11/07
Client Approval: 11/22
P&T Approval: 04/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CRIZOTINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   - The patient's tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test
   - The patient's tumors are ROS1-positive as detected by an FDA-approved test

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the patient unable to swallow capsules?

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **50mg pellet: #4 per day.**
   - **150mg pellet: #2 per day.**

   If no, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **200mg capsule: #2 per day.**
   - **250mg capsule: #2 per day.**

4. Does the patient have a diagnosis of relapsed or refractory systemic anaplastic large cell lymphoma (ALCL) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient's tumors are anaplastic lymphoma kinase (ALK)-positive

   If yes, continue to #6.
   If no, continue to #5.

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CRIZOTINIB

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of unresectable, recurrent, or refractory inflammatory myofibroblastic tumor (IMT) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient's tumors are anaplastic lymphoma kinase (ALK)-positive

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Is the patient unable to swallow capsules?

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **20mg pellet: #8 per day.**
   - **50mg pellet: #4 per day.**
   - **150mg pellet: #6 per day.**

   If no, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **200mg capsule: #4 per day.**
   - **250mg capsule: #4 per day.**

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CRIZOTINIB (Xalkori)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
      2. Relapsed (disease that has returned) or refractory (disease does not respond to treatment), systemic anaplastic large cell lymphoma (ALCL: a type of blood cell cancer)
      3. Unresectable (unable to remove by surgery), recurrent, or refractory (disease does not respond to treatment) inflammatory myofibroblastic tumor (IMT: a rare type of tumor)
   B. **If you have metastatic non-small cell lung cancer, approval also requires:**
      1. You are 18 years of age or older
      2. Your tumors are anaplastic lymphoma kinase (ALK: a type of enzyme)-positive or ROS1 (a type of gene)-positive as detected by a Food and Drug Administration (FDA)-approved test
   C. **If you have relapsed or refractory systemic anaplastic large cell lymphoma, approval also requires:**
      1. You are 1 year of age or older
      2. Your tumors are anaplastic lymphoma kinase (ALK: a type of enzyme)-positive

   (Denial text continued on next page)

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CRIZOTINIB

GUIDELINES FOR USE (CONTINUED)

D. **If you have unresectable, recurrent, or refractory inflammatory myofibroblastic tumor, approval also requires:**
   1. You are 1 year of age or older
   2. Your tumors are anaplastic lymphoma kinase (ALK: a type of enzyme)-positive

E. **If the request is for Xalkori oral pellets, approval also requires:**
   1. You are unable to swallow capsules

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xalkori.

REFERENCE

- Xalkori [Prescribing Information]. New York, New York: Pfizer Inc.; September 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 09/11
Client Approval: 11/23
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CYCLOSPORINE - VERKAZIA

GUIDELINES FOR USE

1. Does the patient have a diagnosis of vernal keratoconjunctivitis **AND** meet the following criterion?
   - The patient had a trial of or contraindication to TWO ophthalmic dual-acting mast cell stabilizer/antihistamines (e.g., ketotifen) or mast cell stabilizers (e.g., cromolyn)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #4 vials per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CYCLOSPORINE - VERKAZIA** requires the following rule(s) be met for approval:
   A. You have vernal keratoconjunctivitis (allergic eye disease)
   B. You have tried or have a contraindication to (harmful for you to use) TWO ophthalmic dual-acting mast cell stabilizer/antihistamines (such as ketotifen) or mast cell stabilizers (such as cromolyn)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Verkazia.

REFERENCES

- Verkazia [Prescribing Information]. Emeryville, CA: Santen Inc.; June 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 08/22
Client Approval: 12/23
P&T Approval: 07/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CYCLOSPORINE - VEVYE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of dry eye disease (DED) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an ophthalmologist or optometrist
   - The patient has ONE positive diagnostic test (e.g., tear breakup time, tear film osmolarity, ocular surface staining, Schirmer test)
   - The patient had a trial of or contraindication to ONE ocular lubricant (e.g., carboxymethylcellulose [Refresh, Celluvisc, TheraTears], polyvinyl alcohol [LiquiTears, Refresh Classic], or wetting agent [Systane, Lacri-Lube])
   - The patient had a trial of or contraindication to BOTH of the following preferred agents: Restasis (cyclosporine) and Xiidra (lifitegrast)

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #2mL per 50 days.** If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CYCLOSPORINE - VEVYE** requires the following rule(s) be met for approval:
   A. You have dry eye disease (DED: a type of eye condition)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with an ophthalmologist or optometrist (types of eye doctors)
   D. You have ONE positive diagnostic test (such as tear breakup time, tear film osmolarity, ocular surface staining, Schirmer test)
   E. You have tried or have a contraindication to (harmful for you to use) ONE ocular lubricant (such as carboxymethylcellulose [such as Refresh, Celluvisc, TheraTears], polyvinyl alcohol [such as LiquiTears, Refresh Classic], or a wetting agent [such as Systane, Lacri-Lube])
   F. You have tried or have a contraindication to BOTH of the following preferred medications: Restasis (cyclosporine) and Xiidra (lifitegrast)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CYCLOSPORINE – VEVYE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of dry eye disease (DED) **AND** meet the following criterion?
   - The patient has demonstrated improvement of dry eye disease

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2mL per 50 days.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CYCLOSPORINE - VEVYE** requires the following rule(s) be met for renewal:
   A. You have dry eye disease (DED: a type of eye condition)
   B. You have demonstrated improvement of your dry eye disease (the treatment is working)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vevye.

REFERENCES

- Vevye [Prescribing Information]. Nashville, TN: Harrow Eye, LLC.; November 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 12/23
Client Approval: 12/23
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CYCLOSPORINE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of vernal keratoconjunctivitis **AND** meet the following criterion?
   - The patient had a trial of or contraindication to TWO ophthalmic dual-acting mast cell stabilizer/antihistamines (e.g., ketotifen) or mast cell stabilizers (e.g., cromolyn)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #4 vials per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CYCLOSPORINE (Verkazia)** requires the following rule(s) be met for approval:
   A. You have vernal keratoconjunctivitis (allergic eye disease)
   B. You had a trial of or contraindication (harmful for) to TWO ophthalmic dual-acting mast cell stabilizer/antihistamines (such as ketotifen) or mast cell stabilizers (such as cromolyn)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Verkazia.

REFERENCES

- Verkazia [Prescribing Information]. Emeryville, CA: Santen Inc.; June 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/22
Created: 08/22
Client Approval: 09/22
P&T Approval: 07/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CYSTEAMINE BITARTRATE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of nephropathic cystinosis and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient has previously tried an immediate-release formulation of cysteamine bitartrate such as Cystagon

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CYSTEAMINE BITARTRATE (Procysbi)** requires the following rule(s) be met for approval:
   A. You have nephropathic cystinosis (rare genetic, metabolic disease which results in an abnormal accumulation of a protein known as cysteine)
   B. You are 1 year of age or older
   C. You have previously tried an immediate-release formulation of cysteamine bitartrate such as Cystagon

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Procysbi.

REFERENCES

- Procysbi [Prescribing Information]. Novato, CA: Raptor Pharmaceuticals Inc.; February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 08/13
Client Approval: 04/20
P&T Approval: 11/15

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CYSTEAMINE HYDROCHLORIDE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cystinosis?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient require treatment for corneal cystine crystal accumulation or deposits?

   If yes, **approve the requested drug for 12 months by GPID or GPI-14 with a quantity limit as follows:**
   - **Cystaran: #60mL (4 bottles) per 28 days.**
   - **Cystadrops: #20mL (4 bottles) per 28 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CYSTEAMINE HYDROCHLORIDE (Cystaran/Cystadrops)** requires the following rule(s) be met for approval:
   A. You have cystinosis (a type of genetic disorder where a substance called cysteine builds up in body organs)
   B. You require treatment for corneal cystine crystal accumulation or deposits (buildup of cysteine in the eye)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CYSTEAMINE HYDROCHLORIDE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cystaran/Cystadrops.

REFERENCES

- Cystaran [Prescribing Information]. Gaithersburg, MD: Leadiant Biosciences, Inc.; May 2018.
- Cystadrops [Prescribing Information]. Lebanon, NJ: Recordati Rare Diseases Inc.; August 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/20
Created: 05/13
Client Approval: 09/20
P&T Approval: 05/13

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DABIGATRAN

GUIDELINES FOR USE

1. Is the request for the treatment of a venous thromboembolic event (VTE) **AND** the patient meets the following criterion?
   - The patient has been treated with a parenteral anticoagulation agent for at least 5 days

   If yes, continue to #3.
   If no, continue to #2.

2. Is the request to reduce the risk of venous thromboembolic event (VTE) recurrence **AND** the patient meets the following criterion?
   - The patient has been previously treated

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient is 3 months to 7 years of age
   - The patient is 8 to 11 years of age AND unable to swallow dabigatran (Pradaxa) capsule

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of guideline.

4. Has the patient had a trial of or contraindication to rivaroxaban (Xarelto) suspension?

   If yes, **approve for 12 months for all strengths by GPID or GPI-14 with a quantity limit of #4 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of guideline.

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DABIGATRAN

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DABIGATRAN (Pradaxa)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Treatment of a venous thromboembolic event (VTE: a type of blood clot disease in your veins)
   2. Reduce the risk of venous thromboembolic event recurrence (happening again)

B. You meet ONE of the following:
   1. You are 3 months to 7 years of age
   2. You are 8 to 11 years of age AND are unable to swallow dabigatran (Pradaxa) capsules

C. You have tried or have a contraindication (harmful for) to rivaroxaban (Xarelto) suspension

D. **If the request is for the treatment of a venous thromboembolic event, approval also requires:**
   1. You have been treated with parenteral anticoagulation agent (type of medication) for at least 5 days

E. **If the request is to reduce the risk of venous thromboembolic event recurrence, approval also requires:**
   1. You have been previously treated

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pradaxa.

REFERENCES

- Pradaxa [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; June 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 10/10
Client Approval: 05/23
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DABRAFENIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma and meet **ONE** of the following criteria?
   - The patient has a BRAF V600E mutation as detected by an FDA-approved test AND the requested medication will be used as a single agent
   - The patient has a BRAF V600E or V600K mutation as detected by an FDA-approved test AND the requested medication will be used in combination with Mekinist (trametinib)

   If yes, continue to #7.
   If no, continue to #2.

2. Does the patient have a diagnosis of melanoma and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E or V600K mutation as detected by an FDA-approved test
   - The requested medication has not previously been used for more than one year
   - The requested medication will be used in combination with Mekinist (trametinib) for adjuvant treatment
   - There is involvement of lymph node(s) following complete resection

   If yes, continue to #7.
   If no, continue to #3.

3. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E mutation as detected by an FDA-approved test
   - The requested medication will be used in combination with Mekinist (trametinib)

   If yes, continue to #7.
   If no, continue to #4.

4. Does the patient have a diagnosis of locally advanced or metastatic anaplastic thyroid cancer (ATC) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E mutation
   - The requested medication will be used in combination with Mekinist (trametinib)
   - The patient has no satisfactory locoregional treatment options available

   If yes, continue to #7.
   If no, continue to #5.

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DABRAFENIB

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of unresectable or metastatic solid tumor and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient has a BRAF V600E mutation
   - The requested medication will be used in combination with Mekinist (trametinib)
   - The patient's disease has progressed following prior treatment and have no satisfactory alternative treatment options

   If yes, continue to #7.
   If no, continue to #6.

6. Does the patient have a diagnosis of low-grade glioma (LGG) and meet **ALL** of the following criteria?
   - The patient is 1 to 17 years of age
   - The patient has a BRAF V600E mutation
   - The requested medication will be used in combination with Mekinist (trametinib)
   - The patient requires systemic therapy

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Is the request for the capsule formulation?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #4 per day.**
   If no, continue to #8.

8. Is the request for the tablet for oral suspension **AND** the patient meets the following criterion?
   - The patient cannot swallow Tafinlar (dabrafenib) capsules

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #30 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DABRAFENIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DABRAFENIB (Tafinlar)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Unresectable or metastatic melanoma (skin cancer that cannot be completely removed by surgery or has spread to other parts of the body)
   2. Melanoma (a type of skin cancer)
   3. Metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
   4. Locally advanced or metastatic anaplastic thyroid cancer (ATC: a type of thyroid cancer that has spread from where it started to nearby tissue or lymph nodes, or it has spread to other parts of the body)
   5. Unresectable or metastatic solid tumor (tumor that cannot be completely removed by surgery or has spread to other parts of the body)
   6. Low-grade glioma (LGG: a type of brain cancer)

B. **If you have unresectable or metastatic melanoma, approval also requires ONE of the following:**
   1. You have a BRAF V600E mutation (type of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test AND the requested medication will be used as a single agent (by itself)
   2. You have a BRAF V600E or V600K mutation (types of gene mutations) as detected by an FDA (Food and Drug Administration)-approved test AND the requested medication will be used in combination with Mekinist (trametinib)

C. **If you have melanoma, approval also requires:**
   1. You have a BRAF V600E or V600K mutation (types of gene mutations) as detected by an FDA (Food and Drug Administration)-approved test
   2. The requested medication has not previously been used for more than one year
   3. The requested medication will be used in combination with Mekinist (trametinib) for adjuvant (additional) treatment
   4. There is involvement of lymph node(s) following complete resection (removal by surgery)

D. **If you have metastatic non-small cell lung cancer, approval also requires:**
   1. You have a BRAF V600E mutation (type of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test
   2. The requested medication will be used in combination with Mekinist (trametinib)

(Denial text continued on next page)

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DABRAFENIB

GUIDELINES FOR USE (CONTINUED)

E. **If you have locally advanced or metastatic anaplastic thyroid cancer, approval also requires:**
   1. You have a BRAF V600E mutation (type of gene mutation)
   2. The requested medication will be used in combination with Mekinist (trametinib)
   3. You have no satisfactory locoregional (restricted to a localized region of the body) treatment options available

F. **If you have an unresectable or metastatic solid tumor, approval also requires:**
   1. You are 1 year of age or older
   2. You have a BRAF V600E mutation (type of gene mutation)
   3. The requested medication will be used in combination with Mekinist (trametinib)
   4. Your disease has progressed following prior treatment and have no satisfactory alternative treatment options

G. **If you have low-grade glioma, approval also requires:**
   1. You are 1 to 17 years of age
   2. You have a BRAF V600E mutation (type of gene mutation)
   3. The requested medication will be used in combination with Mekinist (trametinib)
   4. You require systemic therapy (treatment that targets the entire body)

H. **If the request is for the tablet for oral suspension, approval also requires:**
   1. You cannot swallow Tafinlar (dabrafenib) capsules

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tafinlar.

REFERENCES

- Tafinlar [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/23
Created: 06/13
Client Approval: 09/23
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DACLATASVIR

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hepatitis C, genotype 1 or genotype 3 infection and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - There is evidence of current HCV infection and chronic HCV infection documented by at least ONE detectable HCV RNA level within the past 6 months
   - The patient is 1) without cirrhosis or 2) has decompensated cirrhosis or 3) post-liver transplant patient (with or without cirrhosis)
   - The request is for Daklinza in combination with Sovaldi

   CLINICAL PHARMACIST: Patient must also meet all criteria in Sovaldi guideline to be approvable for both agents. Review hepatitis C MRF and Sovaldi request to ensure patient meets criteria for both agents.

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (e.g., physician attestation)
   - The patient is concurrently taking the following medications:
     - For Daklinza: amiodarone, carbamazepine, phenytoin, or rifampin **OR**
     - For Sovaldi: phenobarbital, oxcarbazepine, rifabutin, rifapentine, or tipranavir/ritonavir

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #3.

3. Does the patient meet **ONE** of the following?
   - The patient is decompensated cirrhosis (moderate or severe hepatitis impairment (Child-Pugh B or C))
   - The patient is post-liver transplant (with or without cirrhosis)

   If yes, continue to #4.
   If no, continue to #6.

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DACLATASVIR

GUIDELINES FOR USE (CONTINUED)

4. Is the request for triple therapy using Daklinza/Sovaldi **WITH** ribavirin?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Does the patient meet **ONE** of the following criteria for the patient type? [**NOTE:** An individual who has completed a full course of therapy with Mavyret, Harvoni or Epclusa that did not achieve SVR will not be approved]
   - Genotype 1, decompensated cirrhosis: short trial of Harvoni or Epclusa OR contraindication to Harvoni and Epclusa
   - Genotype 1, post-liver transplant: short trial of Harvoni or Mavyret OR contraindication to Harvoni and Mavyret
   - Genotype 3, decompensated cirrhosis short trial of or contraindication to Epclusa
   - Genotype 3, post-liver transplant WITHOUT cirrhosis: short trial of or contraindication to Mavyret
   - Genotype 3, post-liver transplant with compensated cirrhosis: short trial of Epclusa or Mavyret OR contraindication to Epclusa and Mavyret

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient meet **ONE** of the following criteria? [**NOTE:** An individual who has completed a full course of therapy with Mavyret, Harvoni or Epclusa that did not achieve SVR will not be approved]
   - Genotype 1, without cirrhosis: treatment naïve or treatment experienced with a peginterferon and ribavirin regimen AND a short trial of Epclusa, Harvoni or Mavyret OR a contraindication Epclusa, Harvoni and Mavyret
   - Genotype 3, without cirrhosis: treatment naïve or treatment experienced with a peginterferon and ribavirin regimen AND a short trial of Epclusa or Mavyret OR a contraindication to Epclusa and Mavyret

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DACLATASVIR

GUIDELINES FOR USE (CONTINUED)

7. Is the patient using any of the following moderate CYP3A inducers while taking Daklinza in combination with Sovaldi: rifapentine, bosentan, dexamethasone, efavirenz, etravirine, modafinil, nafcillin, or nevirapine?
   CLINICAL PHARMACIST: Patient is on combination therapy with Sovaldi; please also review Sovaldi prior authorization guideline, member history, and hepatitis C MRF, if available to ensure appropriate length of approval and that the patient also meets approval for Sovaldi.

   If yes, **approve Daklinza 90mg strength for 12 weeks by GPID or GPI-14 with a quantity limit of #1 tablet per day. (NOTE: 90mg tablet used for drug interactions listed above)**

   If no, continue to #8.

8. Is the patient concurrently using any of the following with Daklinza?
   - HIV protease inhibitors (atazanavir with ritonavir, indinavir, nelfinavir, saquinavir)
   - A cobicistat-containing regimen (exception: darunavir/cobicistat does not require Daklinza 30mg dose), such as atazanavir/cobicistat, elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate, or other cobicistat-containing regimen
   - Strong CYP3A inhibitors, such as clarithromycin, itraconazole, ketoconazole, nefazodone, posaconazole, telithromycin, or voriconazole

   If yes, **approve Daklinza 30mg strength for 12 weeks by GPID or GPI-14 with a quantity limit of #1 tablet per day. (NOTE: 30mg tablet used for drug interactions listed above)**

   If no, **approve Daklinza 60mg strength for 12 weeks by GPID or GPI-14 with a quantity limit of #1 tablet per day.**

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DACLATASVIR (Daklinza)** requires the following rule(s) be met for approval:
   A. You have hepatitis C, with genotype 1 or genotype 3 infection
   B. You are 18 years of age or older
   C. You have documentation showing at least ONE detectable HCV (hepatitis C virus) RNA level (amount of virus in your blood) within the past 6 months as evidence of a current and chronic HCV infection.
   D. You must be taking Daklinza in combination with Sovaldi, and must meet all required criteria for Sovaldi
   (Denial text continued on next page)

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DACLATASVIR

GUIDELINES FOR USE (CONTINUED)

E. **For Genotype 1 infection approval also requires:**
   1. *Patients without cirrhosis (liver scarring):*
      a. You are treatment naïve (never previously treated) or treatment experienced with a peginterferon and ribavirin regimen
      b. You have previously tried Epclusa, Harvoni or Mavyret required and you had adverse effects, intolerance early in therapy or contraindication to (medical reason why you cannot use) Epclusa, Harvoni and Mavyret; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virological response) will not be approved]
   2. *Patients with decompensated cirrhosis (you have symptoms related to liver scarring):*
      a. You have previously tried Epclusa or Harvoni and you had adverse effects, intolerance early in therapy, or contraindication to (medical reason why you cannot use) Epclusa and Harvoni; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virological response) will not be approved]
      b. Concurrent (used at the same time with) ribavirin use required
   3. *Patients status post liver transplant:*
      a. You have previously tried Harvoni or Mavyret and you had adverse effects, intolerance early in therapy, or contraindication to (medical reason why you cannot use) Harvoni and Mavyret; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virological response) will not be approved]
      b. Concurrent (used at the same time with) ribavirin use required

F. **For Genotype 3 infection approval also requires:**
   1. *Patients without cirrhosis:*
      a. You are treatment naïve (never previously treated) or treatment experienced with a peginterferon and ribavirin regimen
      b. You have previously tried Epclusa or Mavyret and you had adverse effect, intolerance early in therapy, or contraindication to (medical reason why you cannot use) Epclusa and Mavyret; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virological response) will not be approved]
   2. *Patients with decompensated cirrhosis (Child-Pugh B or C; you have symptoms related to liver scarring):*
      a. You have previously tried Epclusa and you had adverse effect, intolerance early in therapy, or contraindication to (medical reason why you cannot use) therapy; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virologic response) will not be approved]
      b. Concurrent (used at the same time with) ribavirin use required

(Denial text continued on next page)

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DACLATASVIR

GUIDELINES FOR USE (CONTINUED)

3. *Post-liver transplant, without cirrhosis:*
   a. Previous trial of Mavyret required and you had adverse effects, intolerance early in therapy, or contraindication to (medical reason why you cannot use) therapy; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virologic response) will not be approved]
   b. Concurrent (used at the same time with) ribavirin use required
4. *Post-liver transplant, with compensated cirrhosis*
   a. Previous trial of Epclusa or Mavyret required and you had adverse effects, intolerance early in therapy or contraindication to (medical reason why you cannot use) Epclusa and Mavyret; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virologic response) will not be approved]
   b. Concurrent (used at the same time with) ribavirin use required

Daklinza will not be approved if you meet ANY of the following:

A. You are using any of the following medications at the same time while on Daklinza: amiodarone, carbamazepine, phenytoin, or rifampin
B. You are using any of the following medications at the same time while on Sovaldi: phenobarbital, oxcarbazepine, rifabutin, rifapentine, or tipranavir/ritonavir
C. You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)
D. You have compensated cirrhosis (Child-Pugh A; you have no symptoms related to liver damage) and are not status post liver transplant (you have not had a liver transplant)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Daklinza.

REFERENCES

- Daklinza [Prescribing Information]. Princeton, NJ: Bristol Myers Squibb; February 2017.
- Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed July 26, 2016.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/23
Created: 08/15
Client Approval: 11/22
P&T Approval: 10/17

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DACOMITINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient has epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test
   - Vizimpro will be used as first-line treatment
   - Vizimpro will NOT be used concurrently with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (e.g., Tarceva [erlotinib], Tagrisso [osimertinib], Iressa [gefitinib])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DACOMITINIB (Vizimpro)** requires the following rule(s) be met for approval:
   A. You have metastatic non-small cell lung cancer (type of cancer that has spread) to other parts of the body)
   B. You have epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations (types of gene mutations) as detected by an FDA (Food and Drug Administration)-approved test
   C. Vizimpro will be used as first-line treatment
   D. You will NOT be using Vizimpro concurrently (at the same time) with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (such as Tarceva [erlotinib], Tagrisso [osimertinib], Iressa [gefitinib])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DACOMITINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vizimpro.

REFERENCES

- Vizimpro [Prescribing Information]. New York, NY: Pfizer Labs; December 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 11/18
Client Approval: 05/22
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DALFAMPRIDINE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of multiple sclerosis (MS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient has symptoms of a walking disability such as mild to moderate bilateral lower extremity weakness or unilateral weakness plus lower extremity or truncal ataxia

   If yes, **approve for 3 months by HICL or GPI-10 for #2 tablets per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DALFAMPRIDINE (Ampyra)** requires the following rule(s) be met for approval:
   A. You have multiple sclerosis (MS: a type of nerve disorder)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
   D. You have symptoms of a walking disability such as mild to moderate bilateral (both sides) lower extremity weakness or unilateral (one side) weakness plus lower extremity or truncal ataxia (impaired balance or coordination)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DALFAMPRIDINE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of multiple sclerosis (MS) **AND** meet the following criterion?
   - The patient has experienced or maintained at least a 15% improvement in walking ability

   If yes, **approve for 12 months by HICL or GPI-10 for #2 tablets per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DALFAMPRIDINE (Ampyra)** requires the following rule(s) be met for renewal:
   A. You have multiple sclerosis (MS: a type of nerve disorder)
   B. You have experienced or maintained at least a 15% improvement in walking ability

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ampyra.

REFERENCES

- Ampyra [Prescribing Information]. Ardsley, NY: Acorda Therapeutics; November 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/29/22
Created: 02/10
Client Approval: 07/22
P&T Approval: 07/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DANICOPAN

GUIDELINES FOR USE

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Voydeya will be used for the treatment of extravascular hemolysis (EVH)
   - Voydeya will be used as add-on therapy to Ultomiris (ravulizumab-cwvz) or Soliris (eculizumab)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DANICOPAN (Voydeya)** requires the following rule(s) be met for approval:
   A. You have paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder).
   B. You are 18 years of age or older.
   C. You will use Voydeya for the treatment of extravascular hemolysis (EVH: break down of blood cells outside of your blood stream).
   D. You will use Voydeya as add-on therapy with Ultomiris (ravulizumab-cwvz) or Soliris (eculizumab).

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Voydeya.

REFERENCES

Voydeya [Prescribing Information]. Boston, MA: Alexion Pharmaceuticals, Inc.; March 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/22/24
Created: 04/24
Client Approval: 04/24
P&T Approval: 07/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DAPRODUSTAT

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a nephrologist
   - The patient has been receiving dialysis for at least 4 months
   - The patient has an eGFR of less than 60 mL/min/1.73m(2) corresponding to stage 3, 4, or 5 chronic kidney disease (CKD)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient currently being treated with an erythropoiesis-stimulating agent (ESA) (e.g., Epogen, Procrit)?

   If yes, continue to #4.
   If no, continue to #3.

3. Does the patient have a hemoglobin level of less than 11 g/dL?

   If yes, **approve for 24 weeks by GPID or GPI-14 for all strengths as follows:**
   - **1mg: #1 per day.**
   - **2mg: #1 per day.**
   - **4mg: #1 per day.**
   - **6mg: #2 per day.**
   - **8mg: #3 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DAPRODUSTAT

INITIAL CRITERIA (CONTINUED)

4. Does the patient meet **ALL** of the following criteria?
   - The patient has a hemoglobin level of less than 12 g/dL
   - The patient will discontinue the erythropoiesis-stimulating agent (ESA) (e.g., Epogen, Procrit) prior to starting Jesduvroq

   If yes, **approve for 24 weeks by GPID or GPI-14 for all strengths as follows:**
   - **1mg: #1 per day.**
   - **2mg: #1 per day.**
   - **4mg: #1 per day.**
   - **6mg: #2 per day.**
   - **8mg: #3 per day.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DAPRODUSTAT (Jesduvroq)** requires the following rule(s) be met for approval:

   A. You have a diagnosis of anemia (low amount of healthy red blood cells) due to chronic kidney disease (CKD: long-term kidney disease)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
   D. You have been receiving dialysis (process of removing excess water, toxins from the blood) for at least 4 months
   E. You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) less than 60 mL/min/1.73m(2), confirming stage 3, 4, or 5 chronic kidney disease (CKD)
   F. **If you are NOT currently being treated with an erythropoiesis-stimulating agent (ESA: drugs used to treat anemia such as Epogen or Procrit), approval also requires:**
      1. You have a hemoglobin level (a type of blood test) of less than 11 g/dL
   G. **If you are currently being treated with an erythropoiesis-stimulating agent (ESA: drugs used to treat anemia such as Epogen or Procrit), approval also requires:**
      1. You have a hemoglobin level (a type of blood test) of less than 12 g/dL
      2. You will discontinue ESA therapy before starting Jesduvroq

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DAPRODUSTAT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD) and meet **ONE** of the following criteria?
   - The patient has a hemoglobin level of greater than or equal to 10 g/dL
   - The patient's hemoglobin level has increased by at least 2 g/dL from their baseline level

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **1mg: #1 per day.**
   - **2mg: #1 per day.**
   - **4mg: #1 per day.**
   - **6mg: #2 per day.**
   - **8mg: #3 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DAPRODUSTAT (Jesduvroq)** requires the following rule(s) be met for approval:
   A. You have a diagnosis of anemia (low amount of healthy red blood cells) due to chronic kidney disease (CKD: long-term kidney disease)
   B. You meet ONE of the following:
      1. You have a hemoglobin level (a type of blood test) of greater than or equal to 10 g/dL
      2. Your hemoglobin level has increased by at least 2 g/dL from your baseline level

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Jesduvroq.

REFERENCES

- Jesduvroq [Prescribing Information]. Durham, NC: GlaxoSmithKline; February 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/09/23
Created: 09/23
Client Approval: 09/23
P&T Approval: 01/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DARBEPOETIN ALFA

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD) and meet **ALL** of the following criteria?
   - The patient had a trial of the preferred agent: Retacrit (epoetin alfa-epbx)
   - The patient's hemoglobin level is less than 10g/dL

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mcg/mL vial: #4mL per 28 days.**
   - **40mcg/mL vial: #4mL per 28 days.**
   - **60mcg/mL vial: #4mL per 28 days.**
   - **100mcg/mL vial: #4mL per 28 days.**
   - **200mcg/mL vial: #4mL per 28 days.**
   - **300mcg/mL vial: #4mL per 28 days.**
   - **10mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **25mcg/0.42mL syringe: #1.68mL per 28 days.**
   - **40mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **60mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **100mcg/0.5mL syringe: #2mL per 28 days.**
   - **150mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **200mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **300mcg/0.6mL syringe: #2.4mL per 28 days.**
   - **500mcg/mL syringe: #4mL per 28 days.**

   If no, continue to #2.

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DARBEPOETIN ALFA

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy and meet **ALL** of the following criteria?
   - The patient had a trial of the preferred agent: Retacrit (epoetin alfa-epbx)
   - The patient has a hemoglobin level of less than 11g/dL OR the patient's hemoglobin level has decreased at least 2g/dL below baseline level

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mcg/mL vial: #4mL per 28 days.**
   - **40mcg/mL vial: #4mL per 28 days.**
   - **60mcg/mL vial: #4mL per 28 days.**
   - **100mcg/mL vial: #4mL per 28 days.**
   - **200mcg/mL vial: #4mL per 28 days.**
   - **300mcg/mL vial: #4mL per 28 days.**
   - **10mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **25mcg/0.42mL syringe: #1.68mL per 28 days.**
   - **40mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **60mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **100mcg/0.5mL syringe: #2mL per 28 days.**
   - **150mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **200mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **300mcg/0.6mL syringe: #2.4mL per 28 days.**
   - **500mcg/mL syringe: #4mL per 28 days.**

   If no, continue to #3.

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DARBEPOETIN ALFA

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet **ALL** of the following criteria?
   - The patient had a trial of the preferred agent: Retacrit (epoetin alfa-epbx)
   - The patient's hemoglobin level is less than 10g/dL
   - The patient had a trial of or contraindication to ribavirin dose reduction

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mcg/mL vial: #4mL per 28 days.**
   - **40mcg/mL vial: #4mL per 28 days.**
   - **60mcg/mL vial: #4mL per 28 days.**
   - **100mcg/mL vial: #4mL per 28 days.**
   - **200mcg/mL vial: #4mL per 28 days.**
   - **300mcg/mL vial: #4mL per 28 days.**
   - **10mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **25mcg/0.42mL syringe: #1.68mL per 28 days.**
   - **40mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **60mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **100mcg/0.5mL syringe: #2mL per 28 days.**
   - **150mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **200mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **300mcg/0.6mL syringe: #2.4mL per 28 days.**
   - **500mcg/mL syringe: #4mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DARBEPOETIN ALFA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DARBEPOETIN ALFA (Aranesp)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease
   2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

B. **If you have anemia due to chronic kidney disease, approval also requires:**
   1. You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
   2. Your hemoglobin level (a type of blood test) is less than 10g/dL

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires:**
   1. You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
   2. You have a hemoglobin level of less than 11g/dL OR your hemoglobin level has decreased at least 2g/dL below your baseline level

D. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:**
   1. You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
   2. You have tried or have a contraindication (harmful for) to a lower ribavirin dose
   3. Your hemoglobin level is less than 10g/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DARBEPOETIN ALFA

RENEWAL CRITERIA

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD)?

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient an adult (18 years of age or older) and meets **ONE** of the following criteria?
   - The patient's hemoglobin level is less than 10g/dL if not on dialysis
   - The patient's hemoglobin level is less than 11g/dL if on dialysis
   - The patient's hemoglobin level has reached 10g/dL (if not on dialysis) and the dose is being reduced/interrupted to decrease the need for blood transfusions
   - The patient's hemoglobin level has reached 11g/dL (if on dialysis) and the dose is being reduced/interrupted to decrease the need for blood transfusions

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mcg/mL vial: #4mL per 28 days.**
   - **40mcg/mL vial: #4mL per 28 days.**
   - **60mcg/mL vial: #4mL per 28 days.**
   - **100mcg/mL vial: #4mL per 28 days.**
   - **200mcg/mL vial: #4mL per 28 days.**
   - **300mcg/mL vial: #4mL per 28 days.**
   - **10mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **25mcg/0.42mL syringe: #1.68mL per 28 days.**
   - **40mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **60mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **100mcg/0.5mL syringe: #2mL per 28 days.**
   - **150mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **200mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **300mcg/0.6mL syringe: #2.4mL per 28 days.**
   - **500mcg/mL syringe: #4mL per 28 days.**

   If no, continue to #3.

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DARBEPOETIN ALFA

RENEWAL CRITERIA (CONTINUED)

3. Is the request for a pediatric patient (less than 18 years of age) and meets **ONE** of the following criteria?
   - The patient's hemoglobin level is less than 10g/dL
   - The patient's hemoglobin level has approached or exceeds 12g/dL and the dose is being reduced/interrupted to decrease the need for blood transfusions

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mcg/mL vial: #4mL per 28 days.**
   - **40mcg/mL vial: #4mL per 28 days.**
   - **60mcg/mL vial: #4mL per 28 days.**
   - **100mcg/mL vial: #4mL per 28 days.**
   - **200mcg/mL vial: #4mL per 28 days.**
   - **300mcg/mL vial: #4mL per 28 days.**
   - **10mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **25mcg/0.42mL syringe: #1.68mL per 28 days.**
   - **40mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **60mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **100mcg/0.5mL syringe: #2mL per 28 days.**
   - **150mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **200mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **300mcg/0.6mL syringe: #2.4mL per 28 days.**
   - **500mcg/mL syringe: #4mL per 28 days.**

   If no, continue to #4.

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DARBEPOETIN ALFA

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy **AND** meet the following criterion?
   - The patient's a hemoglobin level is between 10g/dL and 12g/dL

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mcg/mL vial: #4mL per 28 days.**
   - **40mcg/mL vial: #4mL per 28 days.**
   - **60mcg/mL vial: #4mL per 28 days.**
   - **100mcg/mL vial: #4mL per 28 days.**
   - **200mcg/mL vial: #4mL per 28 days.**
   - **300mcg/mL vial: #4mL per 28 days.**
   - **10mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **25mcg/0.42mL syringe: #1.68mL per 28 days.**
   - **40mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **60mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **100mcg/0.5mL syringe: #2mL per 28 days.**
   - **150mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **200mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **300mcg/0.6mL syringe: #2.4mL per 28 days.**
   - **500mcg/mL syringe: #4mL per 28 days.**

   If no, continue to #5.

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DARBEPOETIN ALFA

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa **AND** meet the following criterion?
   - The patient's hemoglobin level is between 10g/dL and 12g/dL

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mcg/mL vial: #4mL per 28 days.**
   - **40mcg/mL vial: #4mL per 28 days.**
   - **60mcg/mL vial: #4mL per 28 days.**
   - **100mcg/mL vial: #4mL per 28 days.**
   - **200mcg/mL vial: #4mL per 28 days.**
   - **300mcg/mL vial: #4mL per 28 days.**
   - **10mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **25mcg/0.42mL syringe: #1.68mL per 28 days.**
   - **40mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **60mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **100mcg/0.5mL syringe: #2mL per 28 days.**
   - **150mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **200mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **300mcg/0.6mL syringe: #2.4mL per 28 days.**
   - **500mcg/mL syringe: #4mL per 28 days.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DARBEPOETIN ALFA (Aranesp)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease
      2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
      3. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

   (Renewal denial text continued on next page)

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DARBEPOETIN ALFA

RENEWAL CRITERIA (CONTINUED)

B. **If you are an adult (you are 18 years of age or older) with anemia due to chronic kidney disease, renewal also requires ONE of the following:**
   1. Your hemoglobin level (a type of blood test) is less than 10g/dL if you are not on dialysis (process of removing excess water, toxins from the blood)
   2. Your hemoglobin level is less than 11g/dL if you are on dialysis
   3. Your hemoglobin has reached 10g/dL (if you are not on dialysis) and your dose is being reduced or interrupted to decrease the need for blood transfusions
   4. Your hemoglobin has reached 11g/dL (if you are on dialysis) and your dose is being reduced or interrupted to decrease the need for blood transfusions

C. **If you are a pediatric patient (you are less than 18 years of age) with anemia due to chronic kidney disease, renewal also requires ONE of the following:**
   1. Your hemoglobin level is less than 10g/dL
   2. Your hemoglobin level has approached or exceeds 12g/dL and your dose is being reduced or interrupted to decrease the need for blood transfusions

D. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:**
   1. Your hemoglobin level is between 10g/dL and 12g/dL

E. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:**
   1. Your hemoglobin level is between 10g/dL and 12g/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Aranesp.

REFERENCES

- Aranesp [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; January 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 02/11
Client Approval: 11/23
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DARIDOREXANT

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of insomnia and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has premature awakening and/or abnormal sleep onset delay lasting 30 minutes or longer, occurring 3 or more times weekly for the last month for acute insomnia or for at least 3 months for chronic insomnia
   - The patient has daytime impairment despite adequate time attempting to sleep and treatment of any treatable causes
   - The patient is NOT concurrently using Z hypnotics (e.g., eszopiclone, zaleplon, zolpidem) or benzodiazepines (e.g., estazolam, temazepam, triazolam) for sleep
   - The patient does NOT have narcolepsy
   - The patient had a trial of or contraindication to TWO generic insomnia medications (e.g., eszopiclone, zaleplon, zolpidem) AND Belsomra

   If yes, **approve for 3 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DARIDOREXANT (Quviviq)** requires the following rule(s) be met for approval:
   A. You have insomnia (a type of sleep condition)
   B. You are 18 years of age or older
   C. You have premature awakening (waking up too early) and/or abnormal sleep onset delay (cannot fall asleep) lasting 30 minutes or longer, occurring 3 or more times weekly for the last month for acute (short-term) insomnia or for at least 3 months for chronic (long-term) insomnia
   D. You have daytime impairment despite adequate time attempting to sleep and treatment of any treatable causes
   E. You are NOT using Quviviq at the same time with Z hypnotics (such as eszopiclone, zaleplon, zolpidem) or benzodiazepines (such as estazolam, temazepam, triazolam) for sleep
   F. You do NOT have narcolepsy (a type of sleep condition)
   G. You had a trial of or contraindication (harmful for) to TWO generic insomnia medications (such as eszopiclone, zaleplon, zolpidem) AND Belsomra
   (Initial denial text continued on next page)

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DARIDOREXANT

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of insomnia and meet **ALL** of the following criteria?
   - The patient has demonstrated improvement of insomnia symptoms but is not currently a candidate for discontinuation
   - The patient is NOT concurrently using Z hypnotics (e.g., eszopiclone, zaleplon, zolpidem) or benzodiazepines (e.g., estazolam, temazepam, triazolam) for sleep

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DARIDOREXANT (Quviviq)** requires the following rule(s) be met for renewal:
   A. You have insomnia (a type of sleep condition)
   B. You have demonstrated improvement of insomnia symptoms but are not currently a candidate for discontinuation
   C. You are NOT using Quviviq at the same time with Z hypnotics (such as eszopiclone, zaleplon, zolpidem) or benzodiazepines (such as estazolam, temazepam, triazolam) for sleep

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DARIDOREXANT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Quviviq.

REFERENCES

- Quviviq [Prescribing Information]. Radnor, PA: Idorsia Pharmaceuticals US, Inc.; January 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/09/22
Created: 04/22
Client Approval: 04/22
P&T Approval: 10/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DAROLUTAMIDE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of non-metastatic castration resistant prostate cancer (nmCRPC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has high risk prostate cancer (i.e., rapidly increasing prostate specific antigen [PSA] levels)

   If yes, continue to #3.
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic hormone-sensitive prostate cancer (mHSPC) **AND** meet the following criterion?
   - The requested medication will be used in combination with docetaxel

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient previously received a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., < 50 ng/dL)
   - The requested medication will be used concurrently with a gonadotropin releasing hormone (GnRH) analog (e.g., leuprolide, goserelin, histrelin, degarelix)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DAROLUTAMIDE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DAROLUTAMIDE (Nubeqa)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Non-metastatic castration resistant prostate cancer (nmCRPC: prostate cancer that has not spread to other parts of the body and does not respond to hormone therapy)
   2. Metastatic hormone-sensitive prostate cancer (mHSPC: prostate cancer that has spread to other parts of the body and responds to hormone therapy)

B. You meet ONE of the following:
   1. You previously received a bilateral orchiectomy (both testicles have been surgically removed)
   2. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
   3. The requested medication will be used together with a gonadotropin releasing hormone analog (such as leuprolide, goserelin, histrelin, degarelix)

C. **If you have non-metastatic castration resistant prostate cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have high risk prostate cancer (rapidly increasing prostate specific antigen [PSA: lab result that may indicate prostate cancer] levels)

D. **If you have metastatic hormone-sensitive prostate cancer, approval also requires:**
   1. The requested medication will be used in combination with docetaxel

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of non-metastatic castration resistant prostate cancer (nmCRPC)?

   If yes, continue to #3.
   If no, continue to #2.

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DAROLUTAMIDE

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of metastatic hormone-sensitive prostate cancer (mHSPC) **AND** meet the following criterion?
   - The requested medication will be used in combination with docetaxel

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient previously received a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., < 50 ng/dL)
   - The requested medication will be used concurrently with a gonadotropin releasing hormone (GnRH) analog (e.g., leuprolide, goserelin, histrelin, degarelix)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DAROLUTAMIDE (Nubeqa)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Non-metastatic castration resistant prostate cancer (nmCRPC: prostate cancer that has not spread to other parts of the body and does not respond to hormone therapy)
      2. Metastatic hormone-sensitive prostate cancer (mHSPC: prostate cancer that has spread to other parts of the body and responds to hormone therapy)

   B. You meet ONE of the following:
      1. You previously received a bilateral orchiectomy (both testicles have been surgically removed)
      2. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
      3. The requested medication will be used together with a gonadotropin releasing hormone analog (such as leuprolide, goserelin, histrelin, degarelix)

   C. **If you have metastatic hormone-sensitive prostate cancer, approval also requires:**
      1. The requested medication will be used in combination with docetaxel

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DAROLUTAMIDE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nubeqa.

REFERENCES

- Nubeqa [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; August 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/23
Created: 11/19
Client Approval: 11/22
P&T Approval: 10/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DASATINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase and meet **ONE** of the following criteria?
   - The patient is 18 years of age or older **AND** is newly diagnosed
   - The patient is between 1 and 17 years of age

   If yes, **approve for all strengths for 12 months by GPID or GPI-14 as follows:**
   - **SPRYCEL 20MG with a quantity limit of #3 per day.**
   - **SPRYCEL 50MG with a quantity limit of #1 per day.**
   - **SPRYCEL 70MG with a quantity limit of #1 per day.**
   - **SPRYCEL 80MG with a quantity limit of #1 per day.**
   - **SPRYCEL 100MG with a quantity limit of #1 per day.**
   - **SPRYCEL 140MG with a quantity limit #1 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is in chronic, accelerated, or myeloid or lymphoid blast phase
   - The patient has a resistance or intolerance to prior therapy including imatinib (Gleevec)
   - The patient had a mutational analysis prior to initiation AND Sprycel is appropriate per the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile *(Please see header CML-5 of the current NCCN guidelines)*

   If yes, **approve for all strengths for 12 months by GPID or GPI-14 as follows:**
   - **SPRYCEL 20MG with a quantity limit of #3 per day.**
   - **SPRYCEL 50MG with a quantity limit of #1 per day.**
   - **SPRYCEL 70MG with a quantity limit of #1 per day.**
   - **SPRYCEL 80MG with a quantity limit of #1 per day.**
   - **SPRYCEL 100MG with a quantity limit of #1 per day.**
   - **SPRYCEL 140MG with a quantity limit #1 per day.**

   If no, continue to #3.

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DASATINIB

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a resistance or intolerance to prior therapy (e.g., imatinib (Gleevec), or nilotinib (Tasigna))

   If yes, **approve for all strengths for 12 months by GPID or GPI-14 as follows:**
   - **SPRYCEL 20MG with a quantity limit of #3 per day.**
   - **SPRYCEL 50MG with a quantity limit of #1 per day.**
   - **SPRYCEL 70MG with a quantity limit of #1 per day.**
   - **SPRYCEL 80MG with a quantity limit of #1 per day.**
   - **SPRYCEL 100MG with a quantity limit of #1 per day.**
   - **SPRYCEL 140MG with a quantity limit #1 per day.**

   If no, continue to #4.

4. Does the patient have a diagnosis of Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL) and meet **ALL** of the following criteria?
   - The patient is between 1 and 17 years of age
   - The patient is newly diagnosed
   - The patient is using Sprycel in combination with chemotherapy

   If yes, **approve for all strengths for 12 months by GPID or GPI-14 as follows:**
   - **SPRYCEL 20MG with a quantity limit of #3 per day.**
   - **SPRYCEL 50MG with a quantity limit of #1 per day.**
   - **SPRYCEL 70MG with a quantity limit of #1 per day.**
   - **SPRYCEL 80MG with a quantity limit of #1 per day.**
   - **SPRYCEL 100MG with a quantity limit of #1 per day.**
   - **SPRYCEL 140MG with a quantity limit #1 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DASATINIB (Sprycel)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML: a type of blood cancer) in chronic, accelerated, or myeloid or lymphoid blast phase
      2. Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL: a type of blood cancer)

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DASATINIB

GUIDELINES FOR USE (CONTINUED)

B. **If you have Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, approval also requires ONE of the following:**
   1. You are 18 years of age or older AND are newly diagnosed
   2. You are between 1 and 17 years of age

C. **If you have Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, accelerated phase, or myeloid or lymphoid blast phase, approval also requires:**
   1. You are 18 years of age or older
   2. You have resistance or intolerance (side effect) to prior therapy including imatinib (Gleevec)
   3. You had a mutational analysis prior to initiation of therapy AND Sprycel is appropriate per the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1; a type of abnormal gene) profile

D. **If you have Philadelphia chromosome-positive acute lymphoblastic leukemia, approval also requires ONE of the following:**
   1. You are 18 years of age or older AND you have a resistance or intolerance (side effect) to prior therapy such as imatinib (Gleevec) or nilotinib (Tasigna)
   2. You are newly diagnosed, between 1 and 17 years of age, AND using Sprycel in combination with chemotherapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sprycel.

REFERENCES

- Sprycel [Prescribing information]. Princeton, NJ: Bristol-Myers Squibb; December 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 05/12
Client Approval: 02/22
P&T Approval: 01/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DECITABINE/CEDAZURIDINE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of myelodysplastic syndromes (MDS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has **ONE** of the following International Prognostic Scoring System groups: intermediate-1, intermediate-2, or high-risk

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #5 per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of chronic myelomonocytic leukemia (CMML) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #5 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DECITABINE/CEDAZURIDINE (Inqovi)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Myelodysplastic syndromes (MDS: type of blood cancer)
      2. Chronic myelomonocytic leukemia (CMML: rare form of blood cancer)
   B. You are 18 years of age or older
   C. **If you have myelodysplastic syndromes (MDS), approval also requires:**
      1. You meet ONE of the following International Prognostic Scoring System groups (scoring system used to predict the course of a patient's disease):
         a. Intermediate-1
         b. Intermediate-2
         c. High-risk

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DECITABINE/CEDAZURIDINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Inqovi.

REFERENCES

- Inqovi [Prescribing Information]. Pleasanton, CA: Astex Pharmaceuticals, Inc.; July 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21

Created: 10/20
Client Approval: 11/20

P&T Approval: 10/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEFERASIROX

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request prescribed by or given in consultation with a hematologist or hematologist-oncologist?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have a diagnosis of chronic iron overload due to blood transfusions?

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient's serum ferritin levels are consistently greater than 1000mcg/L (at least 2 lab values in the previous 3 months)

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of chronic iron overload resulting from non-transfusion dependent thalassemia (NTDT)?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DEFERASIROX

INITIAL CRITERIA (CONTINUED)

5. Does the patient meet **ALL** of the following criteria?
   - The patient is 10 years of age or older
   - The patient's serum ferritin levels are consistently greater than 300mcg/L (at least 2 lab values in the previous 3 months)
   - The patient's liver iron concentration (LIC) is at least 5mg Fe/g dry weight

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Is the request for Exjade or Jadenu tablets?

   If yes, **approve Exjade or Jadenu tablets for all strengths of the requested drug for 6 months by GPID or GPI-14.**
   If no, continue to #7.

7. Is the request for Jadenu sprinkle packets **AND** the patient has tried a generic equivalent of Exjade or Jadenu tablets?

   If yes, **approve Jadenu Sprinkle for all strengths for 6 months by GPID or GPI-14.**
   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **DEFERASIROX (EXJADE, JADENU, JADENU SPRINKLE, DEFERASIROX)** requires the following rule(s) be met for approval:
   A. You have chronic iron overload due to blood transfusions (you have too much iron from blood transfers) or non-transfusion dependent thalassemia (a blood disorder involving less than normal amounts of an oxygen-carrying protein)
   B. The medication is prescribed by or given in consultation with a hematologist (blood specialty doctor) or hematologist/oncologist (tumor/cancer doctor)
   C. **If you have chronic iron overload due to blood transfusions, approval also requires:**
      1. You are 2 years of age or older
      2. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 1000mcg/L (we need at least 2 lab values taken within the previous 3 months)

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DEFERASIROX

INITIAL CRITERIA (CONTINUED)

D. **If you have chronic iron overload resulting from non-transfusion dependent thalassemia (NTDT), approval also requires:**
   1. You are 10 years of age or older
   2. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 300mcg/L (we need at least 2 lab values taken within the previous 3 months)
   3. Your liver iron concentration (LIC) is at least 5mg Fe/g dry weight or greater

E. Requests for Jadenu sprinkle packets require a trial of equivalent generic Exjade or Jadenu tablets

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic iron overload due to blood transfusions **AND** meet the following criterion?
   - The patient's serum ferritin levels are consistently greater than 500mcg/L (at least 2 lab values in the previous 3 months)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of chronic iron overload resulting from non-transfusion dependent thalassemia (NTDT) and meet **ONE** of the following criteria?
   - The patient's serum ferritin levels are consistently greater than 300mcg/L (at least 2 lab values in the previous 3 months)
   - The patient's liver iron concentration (LIC) is at least 3mg Fe/g dry weight (*Liver iron concentration supersedes serum ferritin level when both measurements are available*)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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DEFERASIROX

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DEFERASIROX (EXJADE, JADENU, JADENU SPRINKLE, DEFERASIROX)** requires the following rule(s) be met for renewal:

A. You have chronic iron overload due to blood transfusions (you have too much iron from blood transfers) or non-transfusion dependent thalassemia (a blood disorder involving less than normal amounts of an oxygen-carrying protein)
B. **If you have chronic Iron overload due to blood transfusions, renewal also requires:**
   1. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 500 mcg/L (we need at least 2 lab values taken within the previous 3 months)
C. **If you have chronic iron overload resulting from non-transfusion dependent thalassemia (NTDT), renewal also requires ONE of the following:**
   1. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 300mcg/L (we need at least 2 lab values taken within the previous 3 months)
   2. Your liver iron concentration (LIC) is at least 3mg Fe/g dry weight or greater

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Exjade and Jadenu.

REFERENCES

- Jadenu [Package Insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2017.
- Exjade [Package Insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2016.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/07/20
Created: 08/17
Client Approval: 08/20
P&T Approval: 01/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEFERIPRONE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have **ONE** of the following diagnoses?
   - Transfusional iron overload due to thalassemia syndrome
   - Transfusional iron overload due to sickle cell disease or other anemias

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or given in consultation with a hematologist or hematologist/oncologist
   - The patient had a trial of or contraindication to at least ONE of the following: Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the patient experiencing intolerable toxicities, clinically significant adverse effects, has a contraindication to current chelators: Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine), **OR** current chelation therapy is inadequate?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient meet **ONE** of the following criteria?
   - The request is for Ferriprox (deferiprone) tablets **AND** the patient is 8 years of age or older
   - The request is for Ferriprox oral solution **AND** the patient is 3 years of age or older

   If yes, **approve for 6 months for all strengths of the requested formulation by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DEFERIPRONE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DEFERIPRONE (Ferriprox)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Transfusional iron overload due to a thalassemia syndrome (you have too much iron in your body due to a type of blood disorder)
   2. Transfusional iron overload due to a sickle cell disease or other anemias (you have too much iron in your body due to a type of blood disorder)

B. Therapy is prescribed by or given in consultation with a hematologist (a type of blood doctor) or hematologist/oncologist (a type of cancer doctor)

C. You have tried or have a contraindication (harmful for) to at least ONE of the following: Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine)

D. You meet ONE of the following:
   1. You are experiencing intolerable toxicities or clinically significant adverse effects or have a contraindication (harmful for) to current chelators (drugs that bind to iron): Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine)
   2. Current chelation therapy (therapy that lowers iron levels) with Exjade [deferasirox], Jadenu [deferasirox], or Desferal [deferoxamine]) is not working well enough

E. **If the request is for Ferriprox (deferiprone) tablets, approval also requires:**
   1. You are 8 years of age or older

F. **If the request is for Ferriprox oral solution, approval also requires:**
   1. You are 3 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
   - Transfusional iron overload due to thalassemia syndrome
   - Transfusional iron overload due to a sickle cell disease or other anemias

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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DEFERIPRONE

RENEWAL CRITERIA (CONTINUED)

2. Does the patient meet the following criterion?
   - The patient has serum ferritin levels consistently greater than 500mcg/L (at least 2 lab values in the previous 3 months)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The request is for Ferriprox (deferiprone) tablets **AND** the patient is 8 years of age or older
   - The request is for Ferriprox oral solution **AND** the patient is 3 years of age or older

   If yes, **approve for 12 months for all strengths of the requested formulation by GPID or GPI-14.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **DEFERIPRONE (Ferriprox)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Transfusional iron overload due to thalassemia syndrome (you have too much iron in your body due to a type of blood disorder)
      2. Transfusional iron overload due to a sickle cell disease or other anemias (you have too much iron in your body due to a type of blood disorder)
   B. Your serum ferritin levels (amount of iron-containing blood cell proteins) stay above 500mcg/L (at least 2 lab values in the previous 3 months)
   C. **If the request is for Ferriprox (deferiprone) tablets, approval also requires:**
      1. You are 8 years of age or older
   D. **If the request is for Ferriprox oral solution, approval also requires:**
      1. You are 3 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DEFERIPRONE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ferriprox.

REFERENCES

- Ferriprox [Prescribing Information]. Weston, FL: ApoPharma USA, Inc.; April 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 08/17
Client Approval: 02/22
P&T Approval: 01/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEFEROXAMINE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic iron overload due to transfusion-dependent anemias and meet **ALL** of the following criteria?
   - The medication is prescribed by or given in consultation with a hematologist or hematologist-oncologist
   - The patient is 3 years of age or older
   - The patient has a serum ferritin levels that are consistently greater than 1000mcg/L (at least 2 lab values in the previous 3 months)

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DEFEROXAMINE (Desferal)** requires the following rule(s) be met for approval:
   A. You have chronic iron overload due to transfusion-dependent anemias (blood doesn't have enough healthy red blood cells)
   B. Therapy is prescribed by or given in consultation with a hematologist (blood specialty doctor) or hematologist-oncologist (tumor/cancer doctor)
   C. You are 3 years of age or older
   D. Your serum ferritin levels (amount of iron-containing blood cell proteins) stay greater than 1000mcg/L (shown by at least 2 lab values in the previous 3 months)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DEFEROXAMINE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic iron overload due to transfusion-dependent anemias and meet the following criterion?
   - The patient has a serum ferritin levels that are consistently greater than 500mcg/L (at least 2 lab values in the previous 3 months)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DEFEROXAMINE (Desferal)** requires the following rules be met for renewal:
   A. You have chronic iron overload due to transfusion-dependent anemias (blood doesn't have enough healthy red blood cells)
   B. Your serum ferritin levels (amount of iron-containing blood cell proteins) stay greater than 500mcg/L (at least 2 lab values in the previous 3 months)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Desferal.

REFERENCES

- Desferal [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/17/23
Created: 08/17
Client Approval: 03/23
P&T Approval: 07/17

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEFLAZACORT

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist specializing in the treatment of Duchenne muscular dystrophy (DMD) at a DMD treatment center
   - The patient's diagnosis of DMD is confirmed by genetic testing

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the patient tried prednisone or prednisolone for at least 6 months?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DEFLAZACORT

INITIAL CRITERIA (CONTINUED)

3. Did the patient experience a lack of efficacy with prednisone or prednisolone and meets **ALL** of the following criteria?
   - The patient is not in Stage 1 of the disease (the pre-symptomatic phase)
   - Steroid myopathy has been ruled out
   - The patient has experienced deterioration in ambulation, functional status, or pulmonary function while on prednisone or prednisolone that is consistent with advancing disease (stage 2 or higher) and assessed using standard measures over time (e.g., 6-minute walking distance [6MWD], time to ascend/descend 4 stairs, rise from floor time [Gower's maneuver], 10-meter run/walk time, North Star Ambulatory Assessment [NSAA], Physician Global Assessments [PGA], pulmonary function tests [FVC, PFTs], upper limb strength [propelling a wheelchair 30 feet])

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **6mg tablet: #2 per day.**
   - **18mg tablet: #1 per day.**
   - **30mg tablet: #2 per day.**
   - **36mg tablet: #2 per day.**
   - **22.75mg/mL oral suspension: #1.3mL per day.**

   If no, continue to #4.

4. Did the patient experience a significant adverse effect (e.g., weight gain) on prednisone or prednisolone that is negatively impacting a comorbid condition (e.g., diabetes)?

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **6mg tablet: #2 per day.**
   - **18mg tablet: #1 per day.**
   - **30mg tablet: #2 per day.**
   - **36mg tablet: #2 per day.**
   - **22.75mg/mL oral suspension: #1.3mL per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DEFLAZACORT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DEFLAZACORT (Emflaza)** requires the following rules be met for approval:

A. You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
B. You are 2 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (nerve system doctor) specializing in the treatment of Duchenne muscular dystrophy (DMD) at a DMD treatment center
D. Your diagnosis of DMD is confirmed by genetic testing
E. You have tried prednisone or prednisolone for at least 6 months
F. You meet ONE of the following:
    1. Prednisone or prednisolone did not work for you, and you meet **ALL** of the following:
        a. You are not in Stage 1 of the disease (the pre-symptomatic phase)
        b. There is no steroid myopathy (muscle disease due to steroid use)
        c. You have experienced a decrease in ambulation (walking), functional status, or pulmonary (lung) function, while treated with prednisone or prednisolone, that is consistent with advancing disease (stage 2 or higher) and that is assessed by standard measures over time (such as the 6-minute walking distance [6MWD], time to go up or down 4 stairs, time to rise from the floor [Gower's maneuver], 10-meter run/walk time, North Star Ambulatory Assessment [NSAA: a tool for evaluating Duchenne muscular dystrophy], Physician Global Assessment [PGA: an evaluation by a physician], pulmonary function [forced vital capacity, lung function tests], upper limb strength [moving a wheelchair 30 feet])
    2. You have experienced a significant adverse effect (such as weight gain) on prednisone or prednisolone that is negatively impacting a co-existing comorbid condition (such as diabetes [a disorder with high blood sugar])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DEFLAZACORT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient currently ambulatory **AND** meets the following criterion?
   - The patient has shown function or improvement since being on Emflaza, as assessed by a standard set of ambulatory or functional status measures (e.g., 6-minute walking distance [6MWD], time to ascend/descend 4 stairs, rise from floor time [Gower's maneuver], 10-meter run/walk time, North Star Ambulatory Assessment [NSAA], Physician Global Assessment [PGA])

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **6mg tablet: #2 per day.**
   - **18mg tablet: #1 per day.**
   - **30mg tablet: #2 per day.**
   - **36mg tablet: #2 per day.**
   - **22.75mg/mL oral suspension: #1.3mL per day.**

   If no, continue to #3.

3. Is the patient currently non-ambulatory **AND** meets the following criterion?
   - The patient has maintained or demonstrated a less than expected decline in pulmonary function or upper limb strength since being on Emflaza, as assessed by standard measures (e.g., pulmonary function [FVC, PFTs], upper limb strength measures [propelling a wheelchair 30 feet], Physician Global Assessment [PGA])

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **6mg tablet: #2 per day.**
   - **18mg tablet: #1 per day.**
   - **30mg tablet: #2 per day.**
   - **36mg tablet: #2 per day.**
   - **22.75mg/mL oral suspension: #1.3mL per day.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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DEFLAZACORT

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DEFLAZACORT (Emflaza)** requires the following rules be met for renewal:

A. You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
B. **If you are currently ambulatory (can walk), approval also requires:**
   1. You have shown function or improvement since being on Emflaza as measured by a standard set of ambulatory or functional status measures (such as the 6-minute walking distance [6MWD], time to go up or down 4 stairs, time to rise from the floor [Gower's maneuver], 10-meter run/walk time, North Star Ambulatory Assessment [NSAA: a tool for evaluating Duchenne muscular dystrophy], Physician Global Assessment [PGA: an evaluation by a physician])
C. **If you are currently non-ambulatory (cannot walk), approval also requires:**
   1. You have maintained or had a less than expected decrease in pulmonary (lung) function or upper limb strength since being on Emflaza as assessed by standard measures (such as pulmonary function [forced vital capacity, pulmonary function tests], upper limb strength measures [moving in a wheelchair 30 feet], Physician Global Assessment [PGA: an evaluation by a physician])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Emflaza.

REFERENCES

- Emflaza [Prescribing Information]. South Plainfield, NJ: PTC Therapeutics, Inc.; June 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 03/04/24
Created: 02/17
Client Approval: 02/24
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DELAFLOXACIN

GUIDELINES FOR USE

1. Is therapy prescribed by or in consultation with an Infectious Disease (ID) specialist?

   If yes, **approve as follows:**
   - **Acute bacterial skin or skin structure infection (ABSSSI): approve 450mg tablets for one fill by GPID or GPI-14 with a quantity limit of #28 tablets per 14 days.**
   - **Community-acquired bacterial pneumonia (CABP): approve 450mg tablets for one fill by GPID or GPI-14 with a quantity limit of #20 tablets per 10 days.**
   - **Other indications: approve 450mg tablets for one fill by GPID or GPI-14 with a quantity limit of #28 tablets per 14 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of acute bacterial skin or skin structure infection (ABSSSI) and meet **ALL** of the following?
   - The patient is 18 years of age or older
   - The infection is caused by **ONE** of the following susceptible organisms: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin susceptible [MSSA] isolates)*, Staphylococcus haemolyticus*, *Staphylococcus lugdunensis, Streptococcus agalactiae*, *Streptococcus anginosus Group* (including *Streptococcus anginosus, Streptococcus intermedius,* and *Streptococcus constellatus), Streptococcus pyogenes, Enterococcus faecalis, Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae,* or *Pseudomonas aeruginosa*

   If yes, continue to #3.
   If no, continue to #6.

3. Is the requested medication being used for an animal or human bite, necrotizing fasciitis, diabetic foot infection, decubitis ulcer formation, myonecrosis or ecthyma gangrenosum?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #4.

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DELAFLOXACIN

GUIDELINES FOR USE (CONTINUED)

4. Has antimicrobial susceptibility testing been performed that meets **ALL** of the following criteria?
   - The results from the infection site culture indicate pathogenic organism(s) with resistance to ONE standard of care agent for acute bacterial skin or skin structure infection (ABSSSI) (e.g., sulfamethoxazole/trimethoprim, levofloxacin, clindamycin, cephalexin, or vancomycin)
   - The results from the infection site culture indicate pathogenic organism(s) that are susceptible to delafloxacin

   If yes, **approve 450mg tablets for one fill by GPID or GPI-14 with a quantity limit of #28 tablets per 14 days.**
   If no, continue to #5.

5. Does the patient meet **ALL** of the following criteria?
   - Antimicrobial susceptibility results are unavailable
   - The patient has had a trial of or contraindication to ONE of the following agents:
     - Gram positive targeting antibiotic (e.g., linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin)
     - Penicillin antibiotic (e.g., amoxicillin)
     - Fluoroquinolone antibiotic (e.g., levofloxacin, ciprofloxacin, moxifloxacin)
     - Cephalosporin antibiotic (e.g., ceftriaxone, cephalexin, cefazolin)

   If yes, **approve 450mg tablets for one fill by GPID or GPI-14 with a quantity limit of #28 tablets per 14 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient have a diagnosis of community-acquired bacterial pneumonia (CABP) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The infection is caused by any of the following susceptible microorganisms: *Streptococcus pneumonia, Staphylococcus aureus (methicillin-susceptible [MSSA] isolates only), Klebsiella pneumoniae, Escherichia coli, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae, Chlamydia pneumoniae, Legionella pneumophila* or *Mycoplasma pneumoniae*

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DELAFLOXACIN

GUIDELINES FOR USE (CONTINUED)

7. Has antimicrobial susceptibility testing been performed that meets **ALL** of the following criteria?
   - The results from the infection site culture indicate pathogenic organism(s) with resistance to at least TWO standard of care agents for community-acquired bacterial pneumonia (CABP) (e.g., macrolide, doxycycline, alternative fluoroquinolone, beta-lactam, linezolid)
   - The results from the infection site culture indicate pathogenic organism(s) that are susceptible to delafloxacin

   If yes, **approve 450mg tablets for one fill by GPID or GPI-14 with a quantity limit of #20 tablets per 10 days.**
   If no, continue to #8.

8. Does the patient meet **ALL** of the following criteria?
   - Antimicrobial susceptibility results are unavailable
   - The patient had a trial of or contraindication to TWO standard of care agents for community-acquired bacterial pneumonia (CABP) (e.g., macrolide, doxycycline, alternative fluoroquinolone, beta-lactam, linezolid)

   If yes, **approve 450mg tablets for one fill by GPID or GPI-14 with a quantity limit of #20 tablets per 10 days.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DELAFLOXACIN (Baxdela)** requires the following rule(s) be met for approval:
   A. You meet ONE of the following:
      1. The requested medication is prescribed by or in consultation with an infectious disease (ID) specialist
      2. You have an acute (serious and short-term) bacterial skin or skin structure infection (ABSSSI)
      3. You have community-acquired bacterial pneumonia (CABP: type of lung infection)
   B. **If you have an acute bacterial skin or skin structure infection, approval also requires:**
      1. You are 18 years of age or older
      2. The infection is caused by any of the following bacteria: *Staphylococcus aureus* (including methicillin-resistant [MRSA] *and methicillin susceptible [MSSA] isolates), Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae, Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), Streptococcus pyogenes, and Enterococcus faecalis, Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae, and Pseudomonas aeruginosa*

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DELAFLOXACIN

GUIDELINES FOR USE (CONTINUED)

3. You are not using the requested medication for an animal or human bite, necrotizing fasciitis (flesh eating disease), diabetic foot infection, decubitis ulcer formation (pressure/bed ulcer), myonecrosis (dead muscle tissue) or ecthyma gangrenosum
4. You meet ONE of the following criteria:
    1. If antimicrobial susceptibility test is available (you have a test showing what drugs work on which bacteria of the infection site), we require the results of the test from the infection site show the bacteria is both a) resistant to ONE standard of care agent for acute bacterial skin or skin structure infection (such as sulfamethoxazole/trimethoprim, levofloxacin, clindamycin, cephalexin, or vancomycin), AND b) delafloxacin will work against the bacteria
    2. If antimicrobial susceptibility test is not available (you do not have a test showing what drugs work on which bacteria of the infection site), we require you had a trial of or contraindication to (harmful for) ONE of the following agents: a penicillin (such as amoxicillin), a fluoroquinolone (such as levofloxacin, ciprofloxacin, moxifloxacin), a cephalosporin (such as ceftriaxone, cephalexin, cefazolin), or a gram positive targeting antibiotic (such as linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin)

C. **If you have community-acquired bacterial pneumonia (CABP: type of lung infection), approval also requires:**
1. You are 18 years of age or older
2. The infection is caused by any of the following bacteria: Streptococcus pneumonia, Staphylococcus aureus (methicillin-susceptible [MSSA] isolates only), Klebsiella pneumoniae, Escherichia coli, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae, Chlamydia pneumoniae, Legionella pneumophila or Mycoplasma pneumoniae
3. You meet ONE of the following criteria:
    1. If antimicrobial susceptibility test is available (you have a test showing what drugs work on which bacteria of the infection site), we require the results of the test from the infection site show the bacteria is both a) resistant to TWO standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid) AND b) delafloxacin will work against the bacteria
    2. If antimicrobial susceptibility test is not available (you do not have a test showing what drugs work on which bacteria of the infection site), we require you had a trial or contraindication to (harmful for) TWO standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DELAFLOXACIN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Baxdela.

REFERENCES

- Baxdela [Prescribing Information]. Lincolnshire, Illinois USA: Melinta Therapeutics, Inc.; June 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/28/23

Created: 10/17
Client Approval: 07/23

P&T Approval: 01/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DESIRUDIN

GUIDELINES FOR USE

1. Is the request for Iprivask for the prevention (prophylaxis) of deep vein thrombosis (DVT) for a patient undergoing elective hip replacement surgery?

   If yes, **approve for a total of 35 days of treatment. Enter two authorizations as follows:**
   - **Approve for 12 days by HICL or GPI-10 for #24 vials.**
   - **Also enter one fill for 23 days by HICL or GPI-10 for #46 vials with a start date of 7 days following the initial approval.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DESIRUDIN (Iprivask)** requires that you are receiving Iprivask for the prevention of deep vein thrombosis (DVT; blood clot in a deep vein, usually in the legs) and you are undergoing elective hip replacement surgery.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Iprivask.

REFERENCES

- Iprivask [Prescribing Information]. Northbrook, IL: Marathon Pharmaceuticals; November 2014.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20

Created: 08/10
Client Approval: 04/20

P&T Approval: 11/13

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEUCRAVACITINIB

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, face, or genital area
   - The patient had a trial of or contraindication to ONE conventional therapy (e.g., PUVA [phototherapy ultraviolet light A], UVB [ultraviolet light B], topical corticosteroids (e.g., betamethasone dipropionate, clobetasol propionate), calcipotriene, acitretin, methotrexate, cyclosporine)
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **DEUCRAVACITINIB (Sotyktu)** requires the following rule(s) be met for approval:
   A. You have moderate to severe plaque psoriasis (a type of skin condition)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   D. You have psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, face, or genital area
   E. You have tried or have a contraindication to (harmful for you to use) ONE standard therapy (such as PUVA [phototherapy ultraviolet light A: a type of light therapy], UVB [ultraviolet light B: a type of light therapy], topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), calcipotriene, acitretin, methotrexate, cyclosporine)

   (Initial denial continued on next page)

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DEUCRAVACITINIB

INITIAL CRITERIA (CONTINUED)

F. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DEUCRAVACITINIB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
     If no, do not approve.

     RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

     Our guideline named **DEUCRAVACITINIB (Sotyktu)** requires the following rule(s) be met for renewal:
     A. You have moderate to severe plaque psoriasis (a type of skin condition)
     B. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: a tool for evaluating severity of psoriasis) of at least 50 percent or more while on therapy
     C. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

     NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

     Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DEUCRAVACITINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sotyktu.

REFERENCES

- Sotyktu [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company, September 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 09/22
Client Approval: 03/24
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEUTETRABENAZINE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chorea (involuntary movements) associated with Huntington's disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist or movement disorder specialist

   If yes, **approve for 12 months by GPID or GPI-14 for ALL of the following:**
   - **6-12-24mg XR titration kit: #42 per 28 days for 1 fill.**
   - **6mg: #2 per day.**
   - **9mg: #4 per day.**
   - **12mg: #4 per day.**
   - **6mg XR: #7 per day.**
   - **12mg XR: #3 per day.**
   - **24mg XR: #2 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe tardive dyskinesia (TD) and meet ALL of the following criteria?
   - The patient is 18 years of age or older
   - The patient's TD has been present for at least 3 months
   - Therapy is prescribed by or in consultation with a neurologist, movement disorder specialist, or psychiatrist
   - The patient has a prior history of using antipsychotic medications (e.g., aripiprazole, haloperidol, ziprasidone) or metoclopramide for at least 3 months (or at least 1 month if patient is 60 years of age or older) as documented in the prescription claims history

   If yes, **approve for 12 months by GPID or GPI-14 for ALL of the following:**
   - **6-12-24mg XR titration kit: #42 per 28 days for 1 fill.**
   - **6mg: #2 per day.**
   - **9mg: #4 per day.**
   - **12mg: #4 per day.**
   - **6mg XR: #7 per day.**
   - **12mg XR: #3 per day.**
   - **24mg XR: #2 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DEUTETRABENAZINE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DEUTETRABENAZINE (Austedo)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Chorea (involuntary muscle movements) associated with Huntington's disease
   2. Moderate to severe tardive dyskinesia (uncontrolled body movements)

B. You are 18 years of age or older

C. **If you have chorea associated with Huntington's disease, approval also requires:**
   1. Therapy is prescribed by or in consultation with a neurologist (type of brain doctor) or movement disorder specialist

D. **If you have moderate to severe tardive dyskinesia, approval also requires:**
   1. Moderate to severe tardive dyskinesia (uncontrolled body movements) has been present for at least 3 months
   2. Therapy is prescribed by or in consultation with a neurologist (type of brain doctor), movement disorder specialist, or psychiatrist (type of mental health doctor)
   3. You have a prior history of using antipsychotic medications (such as aripiprazole, haloperidol, ziprasidone) or metoclopramide for at least 3 months (or at least 1 month if you are 60 years of age or older) as documented in your prescription claims history

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Austedo, Austedo XR.

REFERENCES

- Austedo, Austedo XR [Prescribing Information]. Parsippany, NJ: Teva Neuroscience, Inc.; February 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/21/23

Created: 04/17
Client Approval: 07/23

P&T Approval: 01/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEXMEDETOMIDINE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for treatment of acute agitation associated with schizophrenia or bipolar I or II disorder and does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a psychiatrist
   - The patient had a trial and failure of or contraindication to THREE antipsychotics (e.g., olanzapine, ziprasidone, haloperidol)

   If yes, **approve for 1 month by GPID or GPI-14 for the requested strength with a quantity limit of #3 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DEXMEDETOMIDINE (Igalmi)** requires the following rule(s) be met for approval:
   A. You have acute (short-term) agitation associated with schizophrenia (a type of mental health disorder) or bipolar I or II disorder (a type of mood disorder)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a psychiatrist (a type of mental health doctor)
   D. You had a trial and failure of or contraindication (harmful for) to THREE antipsychotics (such as olanzapine, ziprasidone, haloperidol)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DEXMEDETOMIDINE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Is the request for treatment of acute agitation associated with schizophrenia or bipolar I or II disorder?

   If yes, continue to #2.
   If no, do no approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient's maintenance therapy for the underlying psychiatric disorder currently being adjusted/optimized to reduce or eliminate the need for continued PRN medications for acute agitation?

   If yes, **approve for 3 months by GPID or GPI-14 for the requested strength with a quantity limit of #3 per day.**
   If no, continue to #3.

3. Have attempts to adjust medications been exhausted **AND** the physician has determined that chronic PRN medications are required for the continued safety of the patient or caregivers?

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength with a quantity limit of #3 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **DEXMEDETOMIDINE (Igalmi)** requires the following rule(s) be met for renewal:
   A. You have acute (short-term) agitation associated with schizophrenia (a type of mental health disorder) or bipolar I or II disorder (a type of mood disorder)
   B. You meet ONE of the following:
      1. Your maintenance therapy for the underlying psychiatric (mental) disorder is currently being adjusted/optimized to reduce or eliminate the need for continued PRN medications (as needed drugs) for acute agitation
      2. Attempts to adjust medications have been exhausted AND your physician (doctor) has determined that chronic PRN medications (long-term as needed drugs) are required for the continued safety of you or your caregivers

   (Renewal denial text continued on next page)

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DEXMEDETOMIDINE

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Igalmi.

REFERENCES

- Igalmi [Prescribing Information]. New Haven, CT: BioXcel Therapeutics, Inc.; April 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/01/22
Created: 05/22
Client Approval: 05/22
P&T Approval: 10/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEXTROMETHORPHAN with QUINIDINE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of pseudobulbar affect (PBA)?

   If yes, **approve for 12 months by HICL or GPI-10 for #2 per day per month.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DEXTROMETHORPHAN with QUINIDINE (Nuedexta)** requires you have a pseudobulbar affect (sudden, uncontrollable laughter) for approval.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nuedexta.

REFERENCES

- Nuedexta [Prescribing Information]. Aliso Viejo, CA: Avanir Pharmaceuticals, Inc.; June 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 02/11
Client Approval: 04/20
P&T Approval: 01/15

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEXTROMETHORPHAN-BUPROPION

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of major depressive disorder (MDD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to Trintellix
   - The patient had a trial of or contraindication to any generic antidepressant indicated for the treatment of MDD (e.g., sertraline, duloxetine)

   If yes, **approve for 2 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DEXTROMETHORPHAN-BUPROPION (Auvelity)** requires the following rule(s) be met for approval:
   A. You have major depressive disorder (MDD: a type of mental illness)
   B. You are 18 years of age or older
   C. You had a trial of or contraindication (harmful for) to Trintellix
   D. You had a trial of or contraindication (harmful for) to any generic antidepressant indicated for the treatment of major depressive disorder (such as sertraline, duloxetine)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DEXTROMETHORPHAN-BUPROPION

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of major depressive disorder (MDD) **AND** meet the following criterion?
   - The patient has responded to therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DEXTROMETHORPHAN-BUPROPION (Auvelity)** requires the following rule(s) be met for renewal:
   A. You have major depressive disorder (MDD: a type of mental illness)
   B. You have responded to therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Auvelity.

REFERENCES

- Auvelity [Prescribing Information]. New York, NY: Axsome Therapeutics, Inc., August 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective:10/17/22
Created: 10/22
Client Approval: 10/22
P&T Approval:07/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DICHLORPHENAMIDE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary hyperkalemic periodic paralysis or related variants, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient has tried acetazolamide AND a thiazide diuretic (i.e., hydrochlorothiazide)
   - The patient does NOT have hepatic insufficiency, pulmonary obstruction, or a health condition that warrants concurrent use with high-dose aspirin

   If yes, **approve for 2 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of primary hypokalemic periodic paralysis or related variants, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient has tried acetazolamide AND a potassium-sparing diuretic (i.e., spironolactone, triamterene)
   - The patient does NOT have hepatic insufficiency, pulmonary obstruction, or a health condition that warrants concurrent use with high-dose aspirin

   If yes, **approve for 2 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DICHLORPHENAMIDE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DICHLORPHENAMIDE (Keveyis, Ormalvi)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Primary hyperkalemic periodic paralysis (extreme muscle weakness with high potassium levels in your blood) or related variants
   2. Primary hypokalemic periodic paralysis (extreme muscle weakness with low potassium levels in your blood) or related variants

B. **If you have primary hyperkalemic periodic paralysis or related variants**, **approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
   3. You have tried acetazolamide AND a thiazide diuretic (hydrochlorothiazide)
   4. You do NOT have hepatic insufficiency (liver failure), pulmonary obstruction (difficulty breathing due to blockage of airflow), or a health condition that requires you to use high-dose aspirin at the same time

C. **If you have primary hypokalemic periodic paralysis or related variants, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
   3. You have tried acetazolamide AND a potassium-sparing diuretic (spironolactone, triamterene)
   4. You do NOT have hepatic insufficiency (liver failure), pulmonary obstruction (difficulty breathing due to blockage of airflow), or a health condition that requires you to use high-dose aspirin at the same time

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DICHLORPHENAMIDE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, or related variants, **AND** meet the following criterion?
   - The patient has experienced at least TWO fewer attacks per week from baseline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DICHLORPHENAMIDE (Keveyis, Ormalvi)** requires the following rule(s) be met for renewal:
   A. You have primary hyperkalemic periodic paralysis (extreme muscle weakness with high potassium levels in your blood), primary hypokalemic periodic paralysis (extreme muscle weakness with low potassium levels in your blood), or related variants
   B. You have experienced at least TWO fewer attacks per week from baseline (before you started treatment)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Keveyis or Ormalvi.

REFERENCES

- Keveyis [Prescribing Information]. Chicago, IL: Xeris Pharmaceuticals, Inc.; January 2024.
- Ormalvi [Prescribing Information]. Cambridge, UK: Cycle Pharmaceuticals Ltd.; February 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/06/24
Created: 09/15
Client Approval: 04/24
P&T Approval: 11/15

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DICLOFENAC TOPICAL GEL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of actinic keratosis and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a dermatologist or oncologist
   - The patient had a trial of or contraindication to topical fluorouracil (e.g., Efudex, Fluoroplex, Carac)

   If yes, **approve for 3 months by GPID or GPI-10 with a quantity limit of #100 grams per 30 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DICLOFENAC TOPICAL GEL (Solaraze)** requires the following rule(s) be met for approval:
   A. You have actinic keratosis (a type of skin condition)
   B. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor) or oncologist (a type of cancer doctor)
   C. You had a trial of or contraindication (harmful for) to topical fluorouracil (such as Efudex, Fluoroplex, Carac)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Solaraze.

REFERENCES

- Solaraze [Prescribing Information]. PharmaDerm: Melville, NY; May 2016.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/01/22
Created: 10/22
Client Approval: 10/22
P&T Approval: 01/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DICLOFENAC TOPICAL SOLUTION

GUIDELINES FOR USE

1. Does the patient have a diagnosis of osteoarthritis of the knee(s) **AND** meet the following criterion?
   - The patient had a trial of diclofenac 1% gel AND diclofenac 1.5% drops

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #224 grams per 28 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DICLOFENAC TOPICAL SOLUTION (Pennsaid)** requires the following rule(s) be met for approval:
   A. You have osteoarthritis (a type of joint condition) of the knee(s)
   B. You had a trial of diclofenac 1% gel AND diclofenac 1.5% drops

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pennsaid.

REFERENCES

- Pennsaid [Prescribing Information]. Lake Forest, IL: Horizon Pharma USA Inc.; January 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/01/22
Created: 10/22
Client Approval: 10/22
P&T Approval: 01/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DIGOXIN

GUIDELINES FOR USE

1. Does the patient have a diagnosis of heart failure?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of chronic atrial fibrillation **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DIGOXIN** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Heart failure (a type of heart condition)
      2. Chronic atrial fibrillation (a type of heart condition)
   B. **If you have chronic atrial fibrillation, approval also requires:**
      1. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lanoxin.

REFERENCES

- Lanoxin [Prescribing Information]. 17 Northwood House, Dublin 9, Ireland: Concordia Pharmaceuticals, Inc.; February 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 05/22
Client Approval: 05/22
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DIMETHYL FUMARATE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the request for generic dimethyl fumarate?

   If yes, **approve generic dimethyl fumarate for 12 months by HICL or GPI-10 with a quantity limit of #2 per day and override 'Generic Only' field.**
   If no, continue to #3.

3. Is the request for brand Tecfidera **AND** the patient meets the following criterion?
   - The patient had a previous trial of generic dimethyl fumarate

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: ****Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **DIMETHYL FUMARATE (Tecfidera)** requires the following rules be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older
   C. If you are requesting brand Tecfidera, you must have previously tried generic dimethyl fumarate

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DIMETHYL FUMARATE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Tecfidera.

REFERENCES

- Tecfidera [Prescribing Information]. Cambridge, MA: Biogen Inc.; February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/19/20
Created: 05/13
Client Approval: 10/20
P&T Approval: 01/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DIROXIMEL FUMARATE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 capsules per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DIROXIMEL FUMARATE (Vumerity)** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (immune system eats away at protective covering of nerves and you have new or increasing symptoms), to include clinically isolated syndrome, relapsing-remitting disease (symptoms return and go away) and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vumerity.

REFERENCES

- Vumerity [Prescribing Information]. Waltham, MA: Alkermes, Inc.; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20
Created: 11/19
Client Approval: 02/20
P&T Approval: 01/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DONEPEZIL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of dementia associated with Alzheimer's disease and meet **ALL** of the following criteria?
   - The patient had a trial of or contraindication to TWO generic oral acetylcholinesterase inhibitors (e.g., donepezil, galantamine)
   - The patient had a trial of or contraindication to one generic acetylcholinesterase inhibitor patch (e.g., rivastigmine)

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with a quantity limit of #4 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DONEPEZIL (Adlarity)** requires the following rule(s) be met for approval:
   A. You have dementia (a type of memory disorder) associated with Alzheimer's disease (a progressive brain disorder that slowly destroys memory and thinking skills)
   B. You had a trial of or contraindication (harmful for) to TWO generic oral acetylcholinesterase inhibitors (such as donepezil, galantamine)
   C. You had a trial of or contraindication (harmful for) to one generic acetylcholine inhibitor patch (such as rivastigmine)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Adlarity.

REFERENCES

- Adlarity [Prescribing Information]. Grand Rapids, MI: Astellas Corium, Inc.; March 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/18/22
Created: 06/22
Client Approval: 06/22
P&T Approval: 01/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DORNASE ALFA

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cystic fibrosis?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the request for once daily dosing (30 ampules per month)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #30 ampules per month.**
   If no, continue to #3.

3. Has the patient tried once daily dosing (30 ampules per month per MRF or claims history)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #60 ampules per month.**
   If no, do not approve. **Enter a proactive authorization for 12 months by HICL or GPI-10 with a quantity limit of #30 ampules per month.**
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **DORNASE ALFA (Pulmozyme)** requires the following rule(s) be met for approval:
   A. You have cystic fibrosis (CF: an inherited disorder that damages lung and digestive system with fluid build up)
   B. If you are requesting twice daily dosing, we require that you have tried and failed once daily dosing

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DORNASE ALFA

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pulmozyme.

REFERENCE

- Pulmozyme [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; December 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 05/12
Client Approval: 04/20
P&T Approval: 05/12

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DROXIDOPA

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a documented diagnosis of neurogenic orthostatic hypotension (NOH) caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy and meets **ALL** of the following criteria?
   - Patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a neurologist or cardiologist
   - The patient had a previously had a trial of or contraindication to midodrine **OR** fludrocortisone

   If yes, continue to #2.
   If no, do not approve
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the prescriber performed baseline blood pressure readings while the patient is sitting and also within minutes of standing from a supine (lying face up) position?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a documented decrease of at least 20mmHg in systolic blood pressure or 10mmHg diastolic blood pressure within 3 minutes after standing from a sitting position?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DROXIDOPA

INITIAL CRITERIA (CONTINUED)

4. Does the patient have persistent symptoms of neurogenic orthostatic hypotension, which include dizziness, lightheadedness, and the feeling of 'blacking out'?

   If yes, **approve for 1 month by HICL or GPI-10 for #180 per 30 days.**
   APPROVAL TEXT: Renewal requires a diagnosis of Neurogenic Orthostatic Hypotension (NOH) and that the patient meets **ALL** of the following criteria while on therapy with Northera:
   - Patient has demonstrated improvement in severity from baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like the patient may black out
   - Patient had an increase in systolic blood pressure from baseline of at least 10mmHg upon standing from a supine (laying face up) position

   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.***

   Our guideline named **DROXIDOPA (Northera)** requires the following rules be met for approval:
   A. You have neurogenic orthostatic hypotension (a type of low blood pressure)
   B. You are 18 years of age or older
   C. You have a documented diagnosis of neurogenic orthostatic hypotension caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency (you are missing a type of enzyme), or non-diabetic autonomic neuropathy (nerve pain/damage)
   D. You have previously tried midodrine OR fludrocortisone, unless there is a medical reason why you cannot (contraindication)
   E. Theray is prescribed or given in consultation with a neurologist (nerve doctor) or cardiologist (heart doctor)
   F. Your doctor performed baseline blood pressure readings while you are sitting and also within 3 minutes of standing from a supine (lying face up) position
   G. You have a documented decrease of at least 20 mmHg in systolic blood pressure or 10 mmHg diastolic blood pressure within 3 minutes after standing from a sitting position
   H. You have persistent symptoms of neurogenic orthostatic hypotension which includes dizziness, lightheadedness, and the feeling of 'blacking out'

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DROXIDOPA

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of neurogenic orthostatic hypotension (NOH) and meets **ALL** of the following criteria?
   - The patient has demonstrated improvement in severity from baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like the patient may black out
   - The patient had an increase in systolic blood pressure from baseline of at least 10mmHg upon standing from a supine (lying face up) position

   If yes, **approve for 3 months by HICL or GPI-10 for #180 per 30 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DROXIDOPA (Northera)** requires the following rule(s) be met for renewal:
   A. You have neurogenic orthostatic hypotension (NOH)
   B. You have demonstrated improvement in severity from baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like you may black out
   C. You had an increase in systolic blood pressure from baseline of at least 10mmHg upon standing from a supine (lying face up) position

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Northera.

REFERENCES

- Northera [Prescribing Information]. Deerfield, IL: Lundbeck Pharmaceuticals LLC; July 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 03/15/21
Created: 9/14
Client Approval: 03/21
P&T Approval: 11/14

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DULOXETINE

GUIDELINES FOR USE

1. Does the patient have **ONE** of the following diagnoses?
   - Major depressive disorder
   - Diabetic peripheral neuropathy
   - Fibromyalgia
   - Chronic musculoskeletal pain

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of generic duloxetine
   - The patient cannot swallow duloxetine capsules

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **20 mg, 30 mg, 40 mg: #1 per day.**
   - **60 mg: #2 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of generalized anxiety disorder and meet **ALL** of the following criteria?
   - The patient is 7 years of age or older
   - The patient had a trial of generic duloxetine
   - The patient cannot swallow duloxetine capsules

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **20 mg, 30 mg, 40 mg: #1 per day.**
   - **60 mg: #2 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DULOXETINE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DULOXETINE (Drizalma Sprinkle)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Major depressive disorder (a type of mental illness)
   2. Generalized anxiety disorder (a type of mental illness)
   3. Diabetic peripheral neuropathy (a type of nerve damage caused by high blood sugar)
   4. Fibromyalgia (a type of pain disorder)
   5. Chronic musculoskeletal pain (severe pain relating to muscles and bones)

B. **If you have major depressive disorder, diabetic peripheral neuropathy, fibromyalgia, or chronic musculoskeletal pain, approval also requires:**
   1. You are 18 years of age or older
   2. You had a trial of generic duloxetine
   3. You cannot swallow duloxetine capsules

C. **If you have generalized anxiety disorder, approval also requires:**
   1. You are 7 years of age or older
   2. You had a trial of generic duloxetine
   3. You cannot swallow duloxetine capsules

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Drizalma Sprinkle.

REFERENCES

- Drizalma Sprinkle [Prescribing Information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; July 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/23
Created:11/22
Client Approval: 02/23
P&T Approval: 10/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DUPILUMAB

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) and meet **ALL** of the following criteria?
   - The patient is 6 months of age or older
   - Therapy is prescribed by or in consultation with a dermatologist, allergist, or immunologist
   - Dupixent will NOT be used concurrently with other systemic biologics (e.g., Adbry [tralokinumab-ldrm]) or any JAK inhibitors (e.g., Rinvoq [upadacitinib], topical Opzelura [ruxolitinib], Cibinqo [abrocitinib]) for the treatment of atopic dermatitis

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic (e.g., Rinvoq [upadacitinib]) and is switching to the requested drug
   - The patient has atopic dermatitis involving at least 10 percent of body surface area (BSA)
   - The patient has atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a trial of or contraindication to **ONE** of the following?
   - Topical corticosteroid (e.g., hydrocortisone, clobetasol propionate, halobetasol propionate)
   - Topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]
   - Topical PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]
   - Topical JAK inhibitor [e.g., Opzelura (ruxolitinib)]
   - Phototherapy

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve the requested strength for 1 month as follows:**
     - **200mg/1.14mL: #4.56mL.**
     - **300mg/2mL: #8mL.**
   - **SECOND APPROVAL: Approve the requested strength for 5 months as follows (enter a start date of 1 week after the end date of the first approval):**
     - **200mg/1.14mL: #2.28mL per 28 days.**
     - **300mg/2mL: #4mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of moderate to severe asthma with an eosinophilic phenotype **AND** meet the following criterion?
   - The patient has a pre-treatment blood eosinophil level of 150 to 1500 cells/mcL

   If yes, continue to #6.
   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe oral corticosteroid-dependent asthma?

   If yes, continue to #6.
   If no, continue to #10.

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

6. Does the patient meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a physician specializing in pulmonary or allergy medicine
   - The patient is on concurrent treatment with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., salmeterol, formoterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline)
   - Dupixent will NOT be used concurrently with Xolair (omalizumab), Tezspire (tezepelumab-ekko), or an anti-IL-5 biologic (e.g., Nucala [mepolizumab], Cinqair [reslizumab], Fasenra [benralizumab]) when these are used for the treatment of asthma

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced at least ONE asthma exacerbation requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months
   - The patient has experienced at least ONE serious asthma exacerbation requiring hospitalization or an emergency room visit within the past 12 months

   If yes, continue to #9.
   If no, continue to #8.

8. Does the patient have poor symptom control despite current therapy as evidenced by at least **THREE** of the following within the past 4 weeks?
   - Daytime asthma symptoms more than twice per week
   - Any night waking due to asthma
   - Use of a short-acting inhaled beta2-agonist (SABA) reliever (e.g., albuterol) for symptoms more than twice per week
   - Any activity limitation due to asthma

   If yes, continue to #9.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

9. Is the request for the 100mg/0.67mL strength?

   If yes**, approve 100mg/0.67mL by GPID or GPI-14 for 4 months with a quantity limit of #1.34mL per 28 days.**

   If no, **approve for a total of 4 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve the requested strength for 1 month as follows:**
     - **200mg/1.14mL: #4.56mL.**
     - **300mg/2mL: #8mL.**
   - **SECOND APPROVAL: Approve the requested strength for 3 months as follows (enter a start date of 1 week after the end date of the first approval):**
     - **200mg/1.14mL: #2.28mL per 28 days.**
     - **300mg/2mL: #4mL per 28 days.**

10. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Therapy is prescribed by or in consultation with an otolaryngologist, allergist, or immunologist
    - There is evidence of nasal polyps by direct examination, endoscopy, or sinus CT scan
    - Dupixent will be used as add-on maintenance treatment (i.e., in conjunction with maintenance intranasal steroids)
    - The patient had a previous 56-day trial of ONE intranasal corticosteroid (e.g., mometasone nasal spray)

    If yes, continue to #11.
    If no, continue to #12.

11. Does the patient have inadequately controlled disease as determined by **ONE** of the following criteria?
    - Use of systemic steroids (e.g., prednisone) in the past 2 years
    - Endoscopic sinus surgery

    If yes, **approve 300mg/2mL for 6 months by GPID or GPI-14 with a quantity limit of #4mL per 28 days.**

    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

12. Does the patient have a diagnosis of eosinophilic esophagitis (EoE) and meet **ALL** of the following criteria?
    - The patient is 1 year of age or older
    - The patient weighs at least 15 kg (33 lbs)
    - Therapy is prescribed by or in consultation with a gastroenterologist, allergist, or immunologist
    - The patient had a trial of or contraindication to dietary therapy
    - The patient had a trial of or contraindication to a proton pump inhibitor (e.g., omeprazole, lansoprazole, pantoprazole)

    If yes, **approve for 6 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
    - **200mg/1.14mL: #2.28mL per 28 days.**
    - **300mg/2mL: #8mL per 28 days.**

    If no, continue to #13.

13. Does the patient have a diagnosis of prurigo nodularis (PN) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Therapy is prescribed by or in consultation with a dermatologist, immunologist or allergist
    - The patient has the presence of multiple pruriginous lesions (localized or general)
    - The patient had a trial of or contraindication to ONE of the following: topical capsaicin, topical ketamine/amitriptyline/lidocaine, gabapentinoids (e.g., gabapentin, pregabalin), antidepressants (SNRI, SSRI, TCA), k-/mu-opioid receptor antagonists (e.g., naltrexone, butorphanol), thalidomide, topical corticosteroids, topical calcineurin inhibitors, topical calcipotriol, intralesional corticosteroids, phototherapy, methotrexate, cyclosporine, azathioprine

    If yes, **approve 300mg/2mL for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
    - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #8mL.**
    - **SECOND APPROVAL: Approve for 5 months with a quantity limit of #4mL per 28 days (enter a start date of 1 week after the end date of the first approval).**

    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DUPILUMAB (Dupixent)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe atopic dermatitis (AD: a type of skin condition)
   2. Moderate to severe asthma (a type of lung condition)
   3. Chronic rhinosinusitis with nasal polyposis (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)
   4. Eosinophilic esophagitis (EoE: a type of immune system disorder)
   5. Prurigo nodularis (PN: a type of skin condition)

B. **If you have moderate to severe atopic dermatitis, approval also requires:**
   1. You are 6 months of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) ONE of the following: topical corticosteroid (such as hydrocortisone, clobetasol propionate, halobetasol propionate), topical calcineurin inhibitor [Elidel (pimecrolimus), Protopic (tacrolimus)], topical PDE-4 inhibitor [Eucrisa (crisaborole)], topical JAK inhibitor [Opzelura (ruxolitinib)], phototherapy (light therapy)
   4. You will NOT use Dupixent concurrently (at the same time) with other systemic biologics (such as Adbry [tralokinumab-ldrm]) or any JAK inhibitors (such as Rinvoq [upadacitinib], topical Opzelura [ruxolitinib], Cibinqo [abrocitinib]) for the treatment of atopic dermatitis
   5. You meet ONE of the following:
      a. You were previously stable on another biologic (such as Rinvoq [upadacitinib]) and are switching to the requested drug
      b. You have atopic dermatitis involving at least 10 percent of body surface area (BSA)
      c. Your atopic dermatitis affects the face, head, neck, hands, feet, groin, or intertriginous areas (between skin folds)

(Initial denial text continued on next page)

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

C. **If you have moderate to severe asthma, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a physician specializing in pulmonary (relating to lungs/breathing) or allergy medicine
   3. You have an eosinophilic phenotype asthma (a type of inflammatory asthma) with a pre-treatment blood eosinophil level (a type of lab test) of 150 to 1500 cells/mcL, OR you have oral corticosteroid-dependent asthma
   4. You are being treated at the same time with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as salmeterol, formoterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), or theophylline
   5. You will NOT use Dupixent concurrently (at the same time) with Xolair (omalizumab), Tezspire (tezepelumab-ekko), or an anti-IL-5 (interleukin-5) biologic (such as Nucala [mepolizumab], Cinqair [reslizumab], Fasenra [benralizumab]) when these are used for the treatment of asthma
   6. You meet ONE of the following:
      a. You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
      b. You have experienced at least ONE serious asthma exacerbation requiring a hospitalization or an emergency room visit within the past 12 months
      c. You have poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks:
         i. Daytime asthma symptoms more than twice per week
         ii. Any night waking due to asthma
         iii. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
         iv. Any activity limitation due to asthma

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

D. **If you have chronic rhinosinusitis with nasal polyposis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an otolaryngologist (ear, nose, and throat doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
   3. There is evidence of nasal polyps (non-cancerous growths) by direct examination, endoscopy (using a small camera) or sinus CT scan (a type of imaging test)
   4. You have inadequately controlled disease as determined by ONE of the following:
      a. Use of systemic steroids (such as prednisone) in the past 2 years
      b. Endoscopic sinus surgery (a type of surgery that uses a small camera)
   5. Dupixent will be used as add-on maintenance treatment (in conjunction [together] with maintenance intranasal steroids)
   6. You had a previous 56-day trial of ONE intranasal corticosteroid (such as mometasone nasal spray)

E. **If you have eosinophilic esophagitis, approval also requires:**
   1. You are 1 year of age or older
   2. You weigh at least 15 kilograms (33 pounds)
   3. Therapy is prescribed by or in consultation with a gastroenterologist (a type of doctor who treats digestive conditions), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
   4. You have tried or have a contraindication to (harmful for you to use) dietary therapy
   5. You have tried or have a contraindication to (harmful for you to use) a proton pump inhibitor (such as omeprazole, lansoprazole, pantoprazole)

F. **If you have prurigo nodularis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), immunologist (a type of immune system doctor), or allergist (a type of allergy doctor)
   3. You have multiple pruriginous lesions (wounds)
   4. You have tried or have a contraindication to (harmful for you to use) ONE of the following: topical capsaicin, topical ketamine/amitriptyline/lidocaine, gabapentinoids (such as gabapentin, pregabalin), antidepressants (serotonin-norepinephrine reuptake inhibitor [SNRI], selective serotonin reuptake inhibitor [SSRI], tricyclic antidepressant [TCA]), k-/mu-opioid receptor antagonists (such as naltrexone, butorphanol), thalidomide, topical corticosteroids (such as hydrocortisone), topical calcineurin inhibitors (such as Elidel [pimecrolimus]), topical calcipotriol, intralesional corticosteroids, phototherapy (light therapy), methotrexate, cyclosporine, azathioprine

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DUPILUMAB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) and meet **ALL** of the following criteria?
   - The patient has shown improvement while on Dupixent
   - Dupixent will NOT be used concurrently with other systemic biologics (e.g., Adbry [tralokinumab-ldrm]) or any JAK inhibitors (e.g., Rinvoq [upadacitinib], topical Opzelura [ruxolitinib], Cibinqo [abrocitinib]) for the treatment of atopic dermatitis

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **200mg/1.14mL: #2.28mL per 28 days.**
   - **300mg/2mL: #4mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe asthma and meet **ALL** of the following criteria?
   - The patient will continue to use an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., salmeterol, formoterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline)
   - Dupixent will NOT be used concurrently with Xolair (omalizumab), Tezspire (tezepelumab-ekko), or an anti-IL-5 biologic (e.g., Nucala [mepolizumab], Cinqair [reslizumab], Fasenra [benralizumab]) when these are used for the treatment of asthma

   If yes, continue to #3.
   If no, continue to #4.

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RENEWAL CRITERIA (CONTINUED)

3. Has the patient shown a clinical response as evidenced by **ONE** of the following criteria?
   - Reduction in asthma exacerbations from baseline
   - Decreased utilization of rescue medications (e.g., albuterol)
   - Increase in percent predicted FEV1 from pretreatment baseline
   - Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **100mg/0.67mL: #1.34mL per 28 days.**
   - **200mg/1.14mL: #2.28mL per 28 days.**
   - **300mg/2mL: #4mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) **AND** meet the following criterion?
   - The patient has shown clinical benefit compared to baseline (e.g., improvements in nasal congestion, sense of smell or size of polyps)

   If yes, **approve 300mg/2mL for 12 months by GPID or GPI-14 with a quantity limit of #4mL per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of eosinophilic esophagitis (EoE) **AND** meet the following criterion?
   - The patient has shown improvement while on Dupixent (e.g., symptom improvement or achieving histological remission defined as peak esophageal intraepithelial eosinophil count of 6 eos/hpf or less)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **200mg/1.14mL: #2.28mL per 28 days.**
   - **300mg/2mL: #8mL per 28 days.**

   If no, continue to #6.

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DUPILUMAB

RENEWAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of prurigo nodularis (PN) **AND** meet the following criterion?
   - The patient has had prurigo nodularis improvement (reduction) of pruritis or pruriginous lesions

   If yes, **approve 300mg/2mL for 12 months by GPID or GPI-14 with a quantity limit of #4mL per 28 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DUPILUMAB (Dupixent)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Moderate to severe atopic dermatitis (AD: a type of skin condition)
      2. Moderate to severe asthma (a type of lung condition)
      3. Chronic rhinosinusitis with nasal polyposis (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)
      4. Eosinophilic esophagitis (EoE: a type of immune system disorder)
      5. Prurigo nodularis (PN: a type of skin condition)
   B. **If you have moderate to severe atopic dermatitis, renewal also requires:**
      1. You have shown improvement while on Dupixent
      2. You will NOT use Dupixent concurrently (at the same time) with other systemic biologics (such as Adbry [tralokinumab-ldrm]) or any JAK inhibitors (such as Rinvoq [upadacitinib], topical Opzelura [ruxolitinib], Cibinqo [abrocitinib]) for the treatment of atopic dermatitis

   (Renewal denial text continued on next page)

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DUPILUMAB

RENEWAL CRITERIA (CONTINUED)

C. **If you have moderate to severe asthma, renewal also requires:**
   1. You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as salmeterol, formoterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), or theophylline)
   2. You will NOT use Dupixent concurrently (at the same time) with Xolair (omalizumab), Tezspire (tezepelumab-ekko), or an anti-IL-5 (interleukin-5) biologic (such as Nucala [mepolizumab], Cinqair [reslizumab], Fasenra [benralizumab]) when these are used for the treatment of asthma
   3. You have shown a clinical response as evidenced by ONE of the following:
      a. You have experienced a decrease in asthma exacerbations (worsening of symptoms) from baseline
      b. You have decreased your use of rescue medications (such as albuterol)
      c. You have an increase in the percent predicted FEV1 (a type of lung test) from pre-treatment baseline (before starting Dupixent)
      d. You have a decrease in severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

D. **If you have chronic rhinosinusitis with nasal polyposis, renewal also requires:**
   1. You have shown a clinical benefit compared to baseline (such as improvements in nasal congestion, sense of smell, size of polyps)

E. **If you have eosinophilic esophagitis, renewal also requires**:
   1. You have shown improvement while on Dupixent (such as symptom improvement or achieving histological remission defined as peak esophageal intraepithelial eosinophil count of 6 eos/hpf or less [a type of test that evaluates disease status])

F. **If you have prurigo nodularis, renewal also requires:**
   1. You have had prurigo nodularis improvement or reduction of pruritis (itching) or pruriginous lesions (wounds)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DUPILUMAB

RATIONALE

For further information, refer to the Prescribing Information and/or Drug Monograph for Dupixent.

REFERENCES

- Dupixent [Prescribing Information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; January 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 01/17
Client Approval: 03/24
P&T Approval: 04/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DUVELISIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least two prior therapies for CLL or SLL

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DUVELISIB (Copiktra)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Relapsed or refractory chronic lymphocytic leukemia (CLL: a type of blood cancer that has returned after treatment or does not fully respond to treatment)
      2. Small lymphocytic lymphoma (SLL: a type of blood cancer)
   B. You are 18 years of age or older
   C. You have received at least two prior therapies for chronic lymphocytic leukemia or small lymphocytic lymphoma

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Copiktra.

REFERENCES

- Copiktra [Prescribing Information]. Needham, MA: Verastem, Inc.; December 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 11/18
Client Approval: 03/22
P&T Approval: 10/18

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EDARAVONE ORAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) and meet **ALL** the following?
   - Therapy is prescribed by or in consultation with a neurologist or ALS specialist at an ALS Specialty Center or Care Clinic
   - The duration of patient's disease (from onset of symptoms) is 3 years or less
   - The patient has a forced vital capacity (FVC) greater than 70%
   - The patient has mild to moderate ALS with a score of 2 or higher in all of the following 12 items of the Amyotrophic Lateral Sclerosis Functional Rating Scale Revised (ALSFRS-R): speech, salivation, swallowing, handwriting, cutting food, dressing and hygiene, turning in bed, walking, climbing stairs, dyspnea, orthopnea, respiratory insufficiency
   - The patient has tried riluzole OR is currently taking riluzole

   If yes, **enter two approvals by GPID or GPI-14 for a total of 6 months as follows:**
   - **FIRST APPROVAL: Approve for 30 days with a quantity limit of #70mL per 28 days.**
   - **SECOND APPROVAL: Approve for 5 months with a quantity limit of #50mL per 28 days (Enter a start date of 2 days before the end of the first approval).**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EDARAVONE ORAL (Radicava ORS)** requires the following rule(s) be met for approval:
   A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
   B. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor) or ALS specialist at an ALS Specialty Center or Care Clinic
   C. You have had ALS (from onset of symptoms) for 3 years or less
   D. You have a forced vital capacity (FVC: amount of air exhaled from lungs) of greater than 70 percent
   E. You have tried riluzole OR are currently taking riluzole
   (Initial denial text continued on next page)

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EDARAVONE ORAL

INITIAL CRITERIA (CONTINUED)

F. You have mild to moderate ALS with a score of 2 or higher in all of the following 12 items of the Amyotrophic Lateral Sclerosis Functional Rating Scale Revised (ALSFRS-R: a tool for evaluating functional status): speech, salivation, swallowing, handwriting, cutting food, dressing and hygiene, turning in bed, walking, climbing stairs, dyspnea (difficulty breathing), orthopnea (shortness of breath while lying down), respiratory insufficiency (a type of breathing condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) and meet **ALL** of the following criteria?
   - The patient does not require invasive ventilation
   - The patient has improved baseline functional ability OR the patient has maintained a score of 2 or greater in all 12 items of the ALSFRS-R

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #50mL per 28 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EDARAVONE ORAL (Radicava ORS)** requires the following rule(s) be met for renewal:
   A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
   B. You do not require invasive ventilation (inserting a breathing tube into your throat)
   C. You have improved baseline functional ability OR you have maintained a score of 2 or greater in all 12 items of the Amyotrophic Lateral Sclerosis Functional Rating Scale Revised (ALSFRS-R)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EDARAVONE ORAL

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Radicava ORS.

REFERENCES

- Radicava ORS [Prescribing Information].]. Jersey City, NJ: Mitsubishi Tanabe Pharma America, Inc.; May 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/15/22
Created: 05/22
Client Approval: 05/22
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EFINACONAZOLE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of onychomycosis (fungal infection) of the toenail(s) and meets the following criteria?
   - The patient previously tried or has a contraindication to oral terbinafine **OR** oral itraconazole **AND** ciclopirox topical solution
   - The patient has at least **ONE** of the following conditions:
     - The patient has diabetes, peripheral vascular disease (PVD), or immunosuppression
     - The patient has pain surrounding the nail or soft tissue involvement

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Are five or less toenails affected?

   If yes, **approve for 48 weeks by HICL or GPI-10 with a quantity limit of #4mL (1 bottle) per 30 days.**
   If no, **approve for 48 weeks by HICL or GPI-10 with a quantity limit of #8mL (2 bottles) per 30 days.**

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EFINACONAZOLE (Jublia)** requires the following rule(s) be met for approval:
   A. You have onychomycosis of the toenail(s) (toenail fungus)
   B. You have previously tried the following unless contraindicated (a medical reason why you cannot use): ciclopirox topical solution AND either oral terbinafine OR oral itraconazole
   C. You have at least ONE of the following conditions:
      1. Diabetes, peripheral vascular disease (narrowed blood vessels reduce blood flow to the limbs), or immunosuppression (weakened immune system)
      2. Pain surrounding the nail or soft tissue involvement

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EFINACONAZOLE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Jublia.

REFERENCES

- Jublia [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals; September 2016.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 06/14
Client Approval: 04/20
P&T Approval: 01/17

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EFLAPEGRASTIM-XNST

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a non-myeloid malignancy and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient is receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of neutropenia with fever
   - The patient had a trial of or contraindication to the preferred agent: Nyvepria (pegfilgrastim-apgf)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EFLAPEGRASTIM-XNST (Rolvedon)** requires the following rule(s) be met for approval:
   A. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   D. You are receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of neutropenia (a type of blood condition) with fever
   E. You had a trial of or contraindication (harmful for) to the preferred medication: Nyvepria (pegfilgrastim-apgf)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EFLAPEGRASTIM-XNST

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rolvedon.

REFERENCES

- Rolvedon [Prescribing Information]. Irvine, CA: Spectrum Pharmaceuticals, Inc.; June 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/23
Created: 10/22
Client Approval: 06/23
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EFLORNITHINE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of high-risk neuroblastoma (HRNB) **AND** meet the following criterion?
   - The patient has demonstrated a partial response to prior therapy, including anti-GD2 immunotherapy (e.g., Unituxin [dinutuximab])

   If yes, **approve for 24 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EFLORNITHINE (Iwilfin)** requires the following rule(s) be met for approval:
   A. You have high-risk neuroblastoma (HRNB: a type of rare cancer)
   B. You have shown a partial response (the cancer partly responded to treatment, but still did not go away) to prior therapy, including anti-GD2 immunotherapy (such as Unituxin [dinutuximab])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Iwilfin.

REFERENCES

- Iwilfin [Prescribing Information]. Louisville, KY: US WorldMeds, LLC.; December 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/15/24
Created: 12/23
Client Approval: 12/23
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELACESTRANT

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced or metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient's breast cancer is estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative with estrogen receptor 1 gene (ESR1) mutation(s)
   - The patient has disease progression following endocrine therapy

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths, with the following quantity limits:**
   - **345 mg: #1 per day.**
   - **86 mg: #3 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELACESTRANT (Orserdu)** requires the following rule(s) be met for approval:
   A. You have advanced or metastatic breast cancer (breast cancer that has spread to other parts of the body)
   B. Your breast cancer is estrogen receptor (ER: type of protein)-positive, human epidermal growth factor receptor 2 (HER2: type of protein)-negative with estrogen receptor 1 (ESR1: a gene) mutation(s)
   C. You have disease progression following endocrine therapy (disease has worsened after using a type of hormone therapy)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELACESTRANT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orserdu.

REFERENCES

- Orserdu [Prescribing Information]. New York, NY: Stemline Therapeutics, Inc.; January 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 05/23
Client Approval: 05/23
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELAGOLIX

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Has the patient previously received **ONE** of the following regimens?
   - A 6-month course of Orilissa 200mg twice daily
   - A 6-month course of Orilissa 150mg once daily and the patient has moderate hepatic impairment (Child-Pugh Class B)
   - A 24-month course of Orilissa 150mg once daily and the patient has normal liver function or mild hepatic impairment (Child-Pugh Class A)

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe pain associated with endometriosis and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an obstetrician/gynecologist
   - The diagnosis is confirmed via surgical or direct visualization (e.g., pelvic ultrasound) or histopathological confirmation (e.g., laparoscopy or laparotomy) in the last 10 years
   - Orilissa will NOT be used concurrently with another GnRH-modulating agent (e.g., Lupron Depot [leuprolide], Synarel [nafarelin], Zoladex [goserelin])

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have moderate hepatic impairment (Child-Pugh Class B)?

   If yes, **approve 150 mg for 6 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, continue to #4.

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ELAGOLIX

INITIAL CRITERIA (CONTINUED)

4. Does the patient meet ONE of the following?
   - The patient has normal liver function
   - The patient has mild hepatic impairment (Child-Pugh Class A)

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **150mg: #1 per day.**
   - **200mg: #2 per day.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELAGOLIX (Orilissa)** requires the following rule(s) be met for approval:
   A. You have moderate to severe pain associated with endometriosis (condition affecting the uterus)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with an obstetrician/gynecologist (a type of women's health doctor)
   D. Your diagnosis of endometriosis is confirmed by surgical or direct visualization (such as pelvic ultrasound [type of imaging]) or histopathological (tissue) confirmation (such as laparoscopy [type of surgery] or laparotomy [type of surgery]) in the last 10 years
   E. Orilissa will NOT be used at the same time with another GnRH-modulating agent (such as Lupron Depot [leuprolide], Synarel [nafarelin], Zoladex [goserelin])
   F. Requests for Orilissa 200mg twice daily will only be approved if you have normal liver function or mild hepatic (liver) impairment (Child-Pugh Class A)
   G. Requests will not be approved if you previously received ONE of the following:
      1. A 6-month course of Orilissa 200mg twice daily
      2. A 6-month course of Orilissa 150mg once daily and you have moderate hepatic (liver) impairment (Child-Pugh Class B)
      3. A 24-month course of Orilissa 150mg once daily and you have normal liver function or mild (liver) hepatic impairment (Child-Pugh Class A)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELAGOLIX

RENEWAL CRITERIA

1. Has the patient previously received **ONE** of the following regimens?
   - A 6-month course of Orilissa 200mg twice daily
   - A 6-month course of Orilissa 150mg once daily and the patient has moderate hepatic impairment (Child-Pugh Class B)
   - A 24-month course of Orilissa 150mg once daily and the patient has normal liver function or mild hepatic impairment (Child-Pugh Class A)

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe pain associated with endometriosis and meet **ALL** of the following criteria?
   - The patient has had improvement of pain related to endometriosis while on therapy
   - The patient has normal liver function OR mild hepatic impairment (Child-Pugh Class A)
   - Orilissa will NOT be used concurrently with another GnRH-modulating agent (e.g., Lupron Depot [leuprolide], Synarel [nafarelin], Zoladex [goserelin])

   If yes, **approve 150mg for 18 months by GPID or GPI-14 with a quantity limit of #1 per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **ELAGOLIX (Orilissa)** requires the following rule(s) be met for renewal:
   A. You have moderate to severe pain associated with endometriosis (condition affecting the uterus)
   B. You have improvement of pain related to endometriosis while on therapy
   C. You have normal liver function or mild hepatic (liver) impairment (Child-Pugh Class A)
   D. Orilissa will NOT be used at the same time with another GnRH-modulating agent (such as Lupron Depot [leuprolide], Synarel [nafarelin], Zoladex [goserelin])
   E. Requests will not be approved if you previously received ONE of the following:
      1. A 6-month course of Orilissa 200mg twice daily
      2. A 6-month course of Orilissa 150mg once daily and you have moderate hepatic (liver) impairment (Child-Pugh Class B)
      3. A 24-month course of Orilissa 150mg once daily and you have normal liver function or mild (liver) hepatic impairment (Child-Pugh Class A)

   (Renewal denial text continued on next page)

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ELAGOLIX

RENEWAL CRITERIA

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orilissa.

REFERENCES

- Orilissa [Prescribing Information]. North Chicago, IL: AbbVie Inc.; June 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/09/23
Created: 08/18
Client Approval: 09/23
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELAGOLIX/ESTRADIOL/NORETHINDRONE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Has the patient received a total of 24 months cumulative treatment with Oriahnn?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #2.

2. Is the request for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) and the patient meets **ALL** of following criteria?
   - The patient is 18 years of age or older
   - The patient is a premenopausal woman
   - Therapy is prescribed by or given in consultation with an OB/GYN

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   APPROVAL TEXT: Renewal for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) requires the patient had improvement of heavy menstrual bleeding.

   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **ELAGOLIX/ESTRADIOL/NORETHINDRONE (Oriahnn)** requires the following rule(s) be met for approval:
   A. The request is for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
   B. You are 18 years of age or older
   C. You are a premenopausal woman
   D. Therapy is prescribed by or given in consultation with an obstetrician or gynecologist (OB/GYN: doctor who specializes in women's reproductive system)
   E. You have not received a total of 24 months cumulative treatment with Oriahnn
   (Initial denial text continued on next page)

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ELAGOLIX/ESTRADIOL/NORETHINDRONE

INTIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Has the patient received a total of 24 months cumulative treatment with Oriahnn?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #2.

2. Is the request for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) **AND** the patient meets the following criterion?
   - The patient has had improvement of heavy menstrual bleeding

   If yes, **approve for 18 months (or up to 24 months cumulative lifetime treatment duration) by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELAGOLIX/ESTRADIOL/NORETHISTERONE (Oriahnn)** requires the following rule(s) be met for renewal:
   A. The request is for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
   B. You had improvement of heavy menstrual bleeding on therapy
   C. You have not received a total of 24 months cumulative treatment with Oriahnn

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELAGOLIX/ESTRADIOL/NORETHINDRONE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Oriahnn.

REFERENCES

- Oriahnn [Prescribing Information]. North Chicago, IL: AbbVie Inc., May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21
Created: 08/20
Client Approval: 11/20
P&T Approval: 07/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELAPEGADEMASE-LVLR

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID) as manifested by **ONE** of the following?
   - Confirmatory genetic test
   - Suggestive laboratory findings (e.g. elevated deoxyadenosine nucleotide [dAXP] levels, lymphopenia) **AND** hallmark signs/symptoms (e.g. recurrent infections, failure to thrive, persistent diarrhea)

   If yes, continue to #2.
   If no, do not approve
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is therapy prescribed by or given in consultation with an immunologist, hematologist/oncologist, or physician specializing in inherited metabolic disorders?

   If yes, continue to #3.
   If no, do not approve
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient has failed or is not a candidate for hematopoietic cell transplantation (HCT)
   - The requested medication will be used as a bridging therapy prior to planned hematopoietic cell transplant or gene therapy

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT: Renewal requires 1) documentation of trough plasma ADA activity greater than or equal to 30 mmol/hr/L and trough dAXP levels less than 0.02 mmol/L, **AND** 2) improvement in/maintenance of immune function from baseline, and patient has not received successful hematopoietic cell transplant (HCT) or gene therapy.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ELAPEGADEMASE-LVLR

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ELAPEGADEMASE-LVLR (Revcovi)** requires the following rule(s) be met for approval:

A. You have adenosine deaminase severe combined immune deficiency (type of inherited disorder that damages immune system) as shown by ONE of the following:
   1. Confirmatory generic test
   2. Suggestive laboratory findings such as elevated deoxyadenosine nucleotide levels or lymphopenia (not enough of a type of white blood cell) AND you have hallmark signs/symptoms such as recurrent infections, failure to thrive, persistent diarrhea

B. The requested medication is prescribed by or given in consultation with an immunologist (immune system doctor), hematologist/oncologist (blood/cancer doctor), or physician specializing in inherited metabolic disorders

C. You have failed or are not a candidate for hematopoietic cell transplant (blood cell transplant from bone marrow), OR the requested medication will be used as a bridging therapy prior to planned hematopoietic cell transplant or gene therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID) and meet **ALL** of the following criteria?
   - Documentation of trough plasma ADA activity ≥30 mmol/hr/L **AND** trough dAXP levels <0.02 mmol/L
   - The patient has improvement in/maintenance of immune function from baseline (e.g. decrease in number and severity of infections), **AND** has not received successful hematopoietic cell transplant (HCT) or gene therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ELAPEGADEMASE-LVLR

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ELAPEGADEMASE-LVLR (Revcovi)** requires the following rule(s) be met for renewal:

A. You have adenosine deaminase severe combined immune deficiency (type of inherited disorder that damages immune system)
B. You have documentation of trough plasma adenosine deaminase activity greater than or equal to 30 mmol/hr/L AND trough deoxyadenosine nucleotide levels less than 0.02 mmol/L
C. You have improvement in/maintenance of immune function from baseline (such as decrease in number and severity of infections), AND you have not received successful hematopoietic cell transplantation (HCT) or gene therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Revcovi.

REFERENCES

- Revcovi [Prescribing Information]. Gaithersburg, MD: Leadiant Biosciences Inc., October 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 02/19
Client Approval: 04/20
P&T Approval: 01/19

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELBASVIR/GRAZOPREVIR

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C, with genotype 1 or genotype 4 **AND** meet the following criterion?
   - The patient is 12 years of age or older OR weighs at least 30kg

   If yes, continue to #2.
   If no, continue to #7.

2. Does the patient have an HCV RNA level within the past 6 months?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ANY** of the following criteria?
   - The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
   - The patient has moderate or severe hepatitis impairment (decompensated cirrhosis; Child-Pugh B or C)
   - Zepatier will be used concurrently with any of the following medications: phenytoin, carbamazepine, rifampin, efavirenz (e.g., Atripla, Sustiva), atazanavir (e.g., Evotaz, Reyataz), darunavir (e.g., Prezcobix, Prezista), lopinavir, saquinavir, Aptivus (tipranavir), cyclosporine, nafcillin, ketoconazole, modafinil, bosentan, etravirine, elvitegravir/cobicistat/emtricitabine/tenofovir (e.g., Stribild, Genvoya), atorvastatin at doses higher than 20mg daily, rosuvastatin at doses greater than 10mg daily, Sovaldi (sofosbuvir; as a single agent), Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Mavyret (glecaprevir/pibrentasvir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #4.

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ELBASVIR/GRAZOPREVIR

GUIDELINES FOR USE (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   - The patient has a contraindication to Epclusa (velpatasvir/sofosbuvir) AND Harvoni (ledipasvir/sofosbuvir)
   - The patient has failed a short trial of Epclusa (velpatasvir/sofosbuvir) or Harvoni (ledipasvir/sofosbuvir) (e.g., inability to tolerate, adverse effect during therapy)

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the patient treatment naive and meets **ONE** of the following criteria?
   - The patient has genotype 1 or 4
   - The patient is post-kidney transplant AND does not have baseline NS5A RAS polymorphism

   If yes, **approve for 12 weeks by HICL or GPI-10 for #1 per day.**
   If no, continue to #6.

6. Is the patient treatment experienced and meets **ALL** of the following criteria?
   - The patient is post-kidney transplant
   - The patient is treatment experienced with a non-DAA (e.g., interferon)
   - The patient does not have baseline NS5A RAS polymorphism

   If yes, **approve for 12 weeks by HICL or GPI-10 for #1 per day.**
   If no, continue to #7.

7. Is the requested regimen recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment?

   If yes, **approve as indicated per guidance in AASLD/IDSA.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ELBASVIR/GRAZOPREVIR

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline for **ELBASVIR/GRAZOPREVIR (Zepatier)** requires the following rule(s) be met for approval:

A. The requested regimen is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment
B. You have chronic hepatitis C, genotype 1 or genotype 4 (liver inflammation caused by a type of virus)
C. You are 12 years of age or older OR weigh at least 30kg (66 pounds)
D. You have an HCV RNA level (amount of hepatitis C virus in your blood) within the past 6 months
E. You will NOT use Zepatier concurrently (at the same time) with any of the following medications: phenytoin, carbamazepine, rifampin, efavirenz (such as Atripla, Sustiva), atazanavir (such as Evotaz, Reyataz), darunavir (such as Prezcobix, Prezista), lopinavir, saquinavir, Aptivus (tipranavir), cyclosporine, nafcillin, ketoconazole, modafinil, bosentan, etravirine, elvitegravir/cobicistat/emtricitabine/tenofovir (such as Stribild, Genvoya), atorvastatin at doses higher than 20mg daily, rosuvastatin at doses greater than 10mg daily, Sovaldi (sofosbuvir), Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Mavyret (glecaprevir/pibrentasvir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)
F. You do NOT have moderate or severe liver impairment (decompensated cirrhosis; Child-Pugh B or C: symptoms related to liver damage)
G. You do NOT have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)
H. You had a short trial of (you stopped due to reasons such as inability [not able] to tolerate or adverse effects [side effects] during therapy) Epclusa or Harvoni, OR you have a contraindication to (harmful for you to use) both Epclusa and Harvoni
I. **If you are treatment naive (never previously treated), approval also requires ONE of the following:**
    1. You have genotype 1 or 4
    2. You received a kidney transplant (replaced your kidney) AND you do not have baseline
J. **If you are treatment experienced (failed prior treatment), approval also requires ALL of the following:**
    1. You received a kidney transplant (replaced your kidney)
    2. You received prior treatment with a non-direct acting antiviral (such as interferon)
    3. You do not have baseline NS5A RAS polymorphism (a type of HCV [hepatitis C virus] strain)
    4. NS5A RAS polymorphism (a type of HCV [hepatitis C virus] strain)

(Denial text continued on next page)

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ELBASVIR/GRAZOPREVIR

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zepatier.

REFERENCES

- Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed November 29, 2023.
- Zepatier [Prescribing Information]. Rahway, NJ: Merck; May 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/15/24
Created: 02/16
Client Approval: 12/23
P&T Approval: 07/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELEXACAFTOR/TEZACAFTOR/IVACAFTOR

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cystic fibrosis (CF) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist or cystic fibrosis expert

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - There is documentation (e.g., chart note, lab result, diagnostic test result, etc.) that the patient has at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene
   - There is documentation (e.g., chart note, lab result, diagnostic test result, etc.) that the patient has at least one of the following mutations in the CFTR gene:

3141del9	*E822K*	*G1069R*	*L967S*	*R117L*	*S912L*
546insCTA	*F191V*	*G1244E*	*L997F*	*R117P*	*S945L*
A46D	*F311del*	*G1249R*	*L1077P*	*R170H*	*S977F*
A120T	*F311L*	*G1349D*	*L1324P*	*R258G*	*S1159F*
A234D	*F508C*	*H139R*	*L1335P*	*R334L*	*S1159P*
A349V	*F508C; S1251N*	*H199Y*	*L1480P*	*R334Q*	*S1251N*
A455E	*F508del*	*H939R*	*M152V*	*R347H*	*S1255P*
A554E	*F575Y*	*H1054D*	*M265R*	*R347L*	*T338I*
A1006E	*F1016S*	*H1085P*	*M952I*	*R347P*	*T1036N*
A1067T	*F1052V*	*H1085R*	*M952T*	*R352Q*	*T1053I*
D110E	*F1074L*	*H1375P*	*M1101K*	*R352W*	*V201M*
D110H	*F1099L*	*I148T*	*P5L*	*R553Q*	*V232D*
D192G	*G27R*	*I175V*	*P67L*	*R668C*	*V456A*
D443Y	*G85E*	*I336K*	*P205S*	*R751L*	*V456F*
D443Y; G576A; R668C	*G126D*	*I502T*	*P574H*	*R792G*	*V562I*
D579G	*G178E*	*I601F*	*Q98R*	*R933G*	*V754M*
D614G	*G178R*	*I618T*	*Q237E*	*R1066H*	*V1153E*
D836Y	*G194R*	*I807M*	*Q237H*	*R1070Q*	*V1240G*
D924N	*G194V*	*I980K*	*Q359R*	*R1070W*	*V1293G*
D979V	*G314E*	*I1027T*	*Q1291R*	*R1162L*	*W361R*
D1152H	*G463V*	*I1139V*	*R31L*	*R1283M*	*W1098C*
D1270N	*G480C*	*I1269N*	*R74Q*	*R1283S*	*W1282R*
E56K	*G551D*	*I1366N*	*R74W*	*S13F*	*Y109N*

E60K	*G551S*	*K1060T*	*R74W; D1270N*	*S341P*	*Y161D*
E92K	*G576A*	*L15P*	*R74W; V201M*	*S364P*	*Y161S*
E116K	*G576A; R668C*	*L165S*	*R74W; V201M; D1270N*	*S492F*	*Y563N*
E193K	*G622D*	*L206W*	*R75Q*	*S549N*	*Y1014C*
E403D	*G628R*	*L320V*	*R117C*	*S549R*	*Y1032C*
E474K	*G970D*	*L346P*	*R117G*	*S589N*	
E588V	*G1061R*	*L453S*	*R117H*	*S737F*	

If yes, **approve for 24 weeks by GPID or GPI-14 for all of the formulations and strengths with the following quantity limits:**

- **80-40-60mg granule packets: #2 per day.**
- **100-50-75mg granule packets: #2 per day.**
- **50-25-37.5mg tablets: #3 per day.**
- **100-50-75mg tablets: #3 per day.**

If no, do not approve.

INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **ELEXACAFTOR/TEZACAFTOR/IVACAFTOR (Trikafta)** requires the following rule(s) be met for approval:

A. You have cystic fibrosis (a type of lung disorder)
B. You are 2 years of age or older
C. Therapy is prescribed by or in consultation with a pulmonologist (doctor who specializes in lungs) or cystic fibrosis expert
D. You meet ONE of the following:
   1. There is documentation (such as chart notes, lab result, diagnostic test result) that you have at least one *F508del* mutation (an abnormal change in your gene) in the cystic fibrosis transmembrane conductance regulator (CFTR) gene
   2. There is documentation (such as chart notes, lab result, diagnostic test result) that you have at least one of the following mutations in the CFTR gene:

3141del9	*E822K*	*G1069R*	*L967S*	*R117L*	*S912L*
546insCTA	*F191V*	*G1244E*	*L997F*	*R117P*	*S945L*
A46D	*F311del*	*G1249R*	*L1077P*	*R170H*	*S977F*
A120T	*F311L*	*G1349D*	*L1324P*	*R258G*	*S1159F*
A234D	*F508C*	*H139R*	*L1335P*	*R334L*	*S1159P*
A349V	*F508C; S1251N*	*H199Y*	*L1480P*	*R334Q*	*S1251N*
A455E	*F508del*	*H939R*	*M152V*	*R347H*	*S1255P*
A554E	*F575Y*	*H1054D*	*M265R*	*R347L*	*T338I*
A1006E	*F1016S*	*H1085P*	*M952I*	*R347P*	*T1036N*
A1067T	*F1052V*	*H1085R*	*M952T*	*R352Q*	*T1053I*

D110E	*F1074L*	*H1375P*	*M1101K*	*R352W*	*V201M*
D110H	*F1099L*	*I148T*	*P5L*	*R553Q*	*V232D*
D192G	*G27R*	*I175V*	*P67L*	*R668C*	*V456A*
D443Y	*G85E*	*I336K*	*P205S*	*R751L*	*V456F*
D443Y; G576A; R668C	*G126D*	*I502T*	*P574H*	*R792G*	*V562I*
D579G	*G178E*	*I601F*	*Q98R*	*R933G*	*V754M*
D614G	*G178R*	*I618T*	*Q237E*	*R1066H*	*V1153E*
D836Y	*G194R*	*I807M*	*Q237H*	*R1070Q*	*V1240G*
D924N	*G194V*	*I980K*	*Q359R*	*R1070W*	*V1293G*
D979V	*G314E*	*I1027T*	*Q1291R*	*R1162L*	*W361R*
D1152H	*G463V*	*I1139V*	*R31L*	*R1283M*	*W1098C*
D1270N	*G480C*	*I1269N*	*R74Q*	*R1283S*	*W1282R*
E56K	*G551D*	*I1366N*	*R74W*	*S13F*	*Y109N*
E60K	*G551S*	*K1060T*	*R74W; D1270N*	*S341P*	*Y161D*
E92K	*G576A*	*L15P*	*R74W; V201M*	*S364P*	*Y161S*
E116K	*G576A; R668C*	*L165S*	*R74W; V201M; D1270N*	*S492F*	*Y563N*
E193K	*G622D*	*L206W*	*R75Q*	*S549N*	*Y1014C*
E403D	*G628R*	*L320V*	*R117C*	*S549R*	*Y1032C*
E474K	*G970D*	*L346P*	*R117G*	*S589N*	
E588V	*G1061R*	*L453S*	*R117H*	*S737F*	

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELEXACAFTOR/TEZACAFTOR/IVACAFTOR

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cystic fibrosis (CF) and improvement in clinical status compared to baseline as shown by **ONE** of the following?
   - The patient has improved, maintained, or demonstrated less than expected decline in FEV1
   - The patient has improved, maintained, or demonstrated less than expected decline in BMI
   - The patient has experienced a reduction in rate of pulmonary exacerbations

   If yes, **approve for lifetime by GPID or GPI-14 for all of the formulations and strengths with the following quantity limits:**
   - **80-40-60mg granule packets: #2 per day.**
   - **100-50-75mg granule packets: #2 per day.**
   - **50-25-37.5mg tablets: #3 per day.**
   - **100-50-75mg tablets: #3 per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELEXACAFTOR/TEZACAFTOR/IVACAFTOR (Trikafta)** requires the following rule(s) be met for renewal:
   A. You have cystic fibrosis (a type of lung disorder)
   B. You have shown improvement in clinical (medical) status compared to baseline as shown by ONE of the following:
      1. You have improved, maintained, or demonstrated less than expected decline in forced expiratory volume (FEV1: amount of air you can exhale in 1 second)
      2. You have improved, maintained, or demonstrated less than expected decline in body mass index (BMI: a tool for evaluating body fat)
      3. You have experienced a reduction in rate of pulmonary exacerbations (you have less attacks of breathing problems)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELEXACAFTOR/TEZACAFTOR/IVACAFTOR

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Trikafta.

REFERENCES

- Trikafta [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Inc.; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/15/23

Created: 02/20
Client Approval: 05/23

P&T Approval: 07/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELTROMBOPAG - ALVAIZ

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of persistent or chronic immune (idiopathic) thrombocytopenia (ITP) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist or immunologist
   - The patient had a trial of or contraindication to corticosteroids or immunoglobulins, or had an insufficient response to a splenectomy

   If yes, **approve for 2 months by HICL with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of thrombocytopenia due to chronic hepatitis C and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths:**
   - **9 mg tablet: #1 per day.**
   - **18 mg tablet: #1 per day.**
   - **36 mg tablet: #2 per day.**
   - **54 mg tablet: #1 per day.**

   If no, continue to #3.

3. Does the patient have a diagnosis of severe aplastic anemia and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had an insufficient response to immunosuppressive therapy

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths:**
   - **18 mg tablet: #1 per day.**
   - **36 mg tablet: #2 per day.**
   - **54 mg tablet: #2 per day.**

   If no, do not approve.
   DENIAL TEXT: See initial denial text at the end of the guideline.

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ELTROMBOPAG - ALVAIZ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ELTROMBOPAG - ALVAIZ** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Persistent or chronic immune (idiopathic) thrombocytopenia (a type of blood disorder)
   2. Thrombocytopenia (a type of blood disorder) due to chronic hepatitis C
   3. Severe aplastic anemia (a type of blood disorder)

B. **If you have persistent or chronic immune (idiopathic) thrombocytopenia, approval also requires:**
   1. You are 6 years of age and older
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or immunologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) corticosteroids or immunoglobulins, or you did not have a good enough response to a splenectomy (spleen removal)

C. **If you have thrombocytopenia due to chronic hepatitis C, approval also requires:**
   1. You are 18 years of age or older
   2. Your thrombocytopenia does not allow you to start interferon-based therapy (a type of drug for hepatitis) or limits your ability to maintain interferon-based therapy

D. **If you have severe aplastic anemia, approval also requires:**
   1. You are 18 years of age or older
   2. You did not have a good enough response to immunosuppressive therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELTROMBOPAG - ALVAIZ

RENEWAL CRITERIA

NOTE: For the diagnoses of thrombocytopenia due to chronic hepatitis C or severe aplastic anemia, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of persistent or chronic immune (idiopathic) thrombocytopenia (ITP) **AND** meet the following criterion?
   - The patient has had a clinical response, as defined by an increase in platelet count to at least $50X10^9$/L (at least 50,000 per microliter)

   If yes, **approve for 12 months by HICL with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELTROMBOPAG - ALVAIZ** requires the following rules be met for renewal:
   A. You have persistent or chronic immune (idiopathic) thrombocytopenia (a type of blood disorder)
   B. You have had a clinical response, as defined by an increase in platelet (a type of blood cell) count to at least 50X10(9)/L (at least 50,000 per microliter)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Alvaiz.

REFERENCES

- Alvaiz [Prescribing Information]. East Parsippany, NJ: Teva Pharmaceuticals; November 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 03/04/24
Created: 02/24
Client Approval: 02/24
P&T Approval: 07/19

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELTROMBOPAG - PROMACTA

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic immune (idiopathic) thrombocytopenia (cITP) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - Therapy is prescribed by or in consultation with a hematologist or immunologist
   - The patient had a trial of or contraindication to corticosteroids or immunoglobulins, or had an insufficient response to a splenectomy

   If yes, continue to #2.
   If no, continue to #5.

2. Is the request for Promacta tablets?

   If yes, **approve for 2 months by GPID or GPI-14 for all of the following strengths:**
   - **12.5mg tablet: #1 per day.**
   - **25mg tablet: #1 per day.**
   - **50mg tablet: #1 per day.**
   - **75mg tablet: #1 per day.**

   If no, continue to #3.

3. Is the request for Promacta packets **AND** the patient is 12 years of age or less?

   If yes, **approve for 2 months by GPID or GPI-14 for all of the following strengths:**
   - **12.5mg packets: #1 per day.**
   - **25mg packets: #3 per day.**

   If no, continue to #4.

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INITIAL CRITERIA (CONTINUED)

4. Is the request for Promacta packets and the patient meets **ALL** of the following criteria?
   - The patient is greater than 12 years of age
   - The patient had a trial of Promacta tablets
   - The patient has a medical need for powder packets

   If yes, **approve for 2 months by GPID or GPI-14 for all of the following strengths:**
   - **12.5mg packets: #1 per day.**
   - **25mg packets: #3 per day.**

   If no, do not approve for Promacta packets.
   Please enter proactive approvals for all of the following strengths of Promacta tablets for 2 months by GPID or GPI-14:
   - **12.5mg tablet: #1 per day.**
   - **25mg tablet: #1 per day.**
   - **50mg tablet: #1 per day.**
   - **75mg tablet: #1 per day.**

   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Does the patient have a diagnosis of thrombocytopenia due to chronic hepatitis C **AND** meet the following criterion?
   - The patient's thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy

   If yes, continue to #6.
   If no, continue to #9.

6. Is the request for Promacta tablets?

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths:**
   - **12.5mg tablet: #1 per day.**
   - **25mg tablet: #1 per day.**
   - **50mg tablet: #2 per day.**
   - **75mg tablet: #1 per day.**

   If no, continue to #7.

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INITIAL CRITERIA (CONTINUED)

7. Is the request for Promacta packets **AND** the patient is 12 years of age or less?

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths:**
   - **12.5mg packets: #1 per day.**
   - **25mg packets: #4 per day.**

   If no, continue to #8.

8. Is the request for Promacta packets and the patient meets **ALL** of the following criteria?
   - The patient is greater than 12 years of age
   - The patient had a trial of Promacta tablets
   - The patient has a medical need for powder packets

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths:**
   - **12.5mg packets: #1 per day.**
   - **25mg packets: #4 per day.**

   If no, do not approve for Promacta packets.
   Please enter proactive approvals for all of the following strengths of Promacta tablets for 12 months by GPID or GPI-14:
   - **12.5mg tablet: #1 per day.**
   - **25mg tablet: #1 per day.**
   - **50mg tablet: #2 per day.**
   - **75mg tablet: #1 per day.**

   DENIAL TEXT: See the initial denial text at the end of the guideline.

9. Does the patient have a diagnosis of severe aplastic anemia and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Promacta will be used in combination with standard immunosuppressive therapy as first-line treatment

   If yes, continue to #10.
   If no, continue to #13.

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ELTROMBOPAG - PROMACTA

INITIAL CRITERIA (CONTINUED)

10. Is the request for Promacta tablets?

    If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths:**
    - **12.5mg tablet: #3 per day.**
    - **25mg tablet: #1 per day.**
    - **50mg tablet: #2 per day.**
    - **75mg tablet: #2 per day.**

    If no, continue to #11.

11. Is the request for Promacta packets **AND** the patient is 12 years of age or less?

    If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths:**
    - **12.5mg packets: #3 per day.**
    - **25mg packets: #6 per day.**

    If no, continue to #12.

12. Is the request for Promacta packets and the patient meets **ALL** of the following criteria?
    - The patient is greater than 12 years of age
    - The patient had a trial of Promacta tablets
    - The patient has a medical need for powder packets

    If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths:**
    - **12.5mg packets: #3 per day.**
    - **25mg packets: #6 per day.**

    If no, do not approve for Promacta packets.
    Please enter proactive approvals for all of the following strengths of Promacta tablets for 12 months by GPID or GPI-14:
    - **12.5mg tablet: #3 per day.**
    - **25mg tablet: #1 per day.**
    - **50mg tablet: #2 per day.**
    - **75mg tablet: #2 per day.**

    DENIAL TEXT: See the initial denial text at the end of the guideline.

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ELTROMBOPAG - PROMACTA

INITIAL CRITERIA (CONTINUED)

13. Does the patient have a diagnosis of severe aplastic anemia **AND** meet the following criterion?
    - The patient had an insufficient response to immunosuppressive therapy

    If yes, continue to #14.
    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

14. Is the request for Promacta tablets?
    If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths:**
    - **12.5mg tablet: #1 per day.**
    - **25mg tablet: #1 per day.**
    - **50mg tablet: #2 per day.**
    - **75mg tablet: #2 per day.**

    If no, continue to #15.

15. Is the request for Promacta packets **AND** the patient is 12 years of age or less?

    If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths:**
    - **12.5mg packets: #1 per day.**
    - **25mg packets: #6 per day.**

    If no, continue to #16.

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ELTROMBOPAG - PROMACTA

INITIAL CRITERIA (CONTINUED)

16. Is the request for Promacta packets and the patient meets **ALL** of the following criteria?
    - The patient is greater than 12 years of age
    - The patient had a trial of Promacta tablets
    - The patient has a medical need for powder packets

    If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths:**
    - **12.5mg packets: #1 per day.**
    - **25mg packets: #6 per day.**

    If no, do not approve for Promacta packets.
    Please enter proactive approvals for all of the following strengths of Promacta tablets for 12 months by GPID or GPI-14:
    - **12.5mg tablet: #1 per day.**
    - **25mg tablet: #1 per day.**
    - **50mg tablet: #2 per day.**
    - **75mg tablet: #2 per day.**

    DENIAL TEXT: See the initial denial text at the end of the guideline.

    INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

    Our guideline named **ELTROMBOPAG - PROMACTA** requires the following rule(s) be met for approval:

    A. You have ONE of the following:
        1. Chronic immune (idiopathic) thrombocytopenia (a type of blood disorder)
        2. Thrombocytopenia (a type of blood disorder) due to chronic hepatitis C
        3. Severe aplastic anemia (a type of blood disorder)

    B. **If you have chronic immune (idiopathic) thrombocytopenia, approval also requires:**
        1. You are 1 year of age or older
        2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or immunologist (a type of immune system doctor)
        3. You have tried or have a contraindication to (harmful for you to use) corticosteroids or immunoglobulins, or you did not have a good enough response to a splenectomy (spleen removal)
        4. If you are older than 12 years of age and the request is for Promacta packets, approval also requires you meet ALL of the following:
            a. You have tried Promacta tablets
            b. You have a medical need for powder packets

    (Initial denial text continued on next page)

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INITIAL CRITERIA (CONTINUED)

C. **If you have thrombocytopenia due to chronic hepatitis C, approval also requires:**
   1. Your thrombocytopenia does not allow you to start interferon-based therapy (a type of drug for hepatitis) or limits your ability to maintain interferon-based therapy
   2. If you are older than 12 years of age and the request is for Promacta packets, approval also requires you meet ALL of the following:
      a. You have tried Promacta tablets
      b. You have a medical need for powder packets

D. **If you have severe aplastic anemia, approval also requires:**
   1. You meet ONE of the following:
      a. You are 2 years of age or older and Promacta will be used in combination with standard immunosuppressive therapy (treatment that prevents activity from your immune system) as first-line treatment
      b. You did not have a good enough response to immunosuppressive therapy
   2. If you are older than 12 years of age and the request is for Promacta packets, approval also requires you meet ALL of the following:
      a. You have tried Promacta tablets
      b. You have a medical need for powder packets

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELTROMBOPAG - PROMACTA

RENEWAL CRITERIA

NOTE: For the diagnoses of thrombocytopenia due to chronic hepatitis C or severe aplastic anemia, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of chronic immune (idiopathic) thrombocytopenia (cITP) **AND** meet the following criterion?
   - The patient has had a clinical response, as defined by an increase in platelet count to at least $50X10^9$/L (at least 50,000 per microliter)

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths and formulations:**
   - **12.5mg tablet: #1 per day.**
   - **25mg tablet: #1 per day.**
   - **50mg tablet: #1 per day.**
   - **75mg tablet: #1 per day.**
   - **12.5mg packets: #1 per day.**
   - **25mg packets: #3 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELTROMBOPAG - PROMACTA** requires the following rules be met for renewal:
   A. You have chronic immune (idiopathic) thrombocytopenia (a type of blood disorder)
   B. You have had a clinical response, as defined by an increase in platelet (a type of blood cell) count to at least 50X10(9)/L (at least 50,000 per microliter)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELTROMBOPAG - PROMACTA

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Promacta.

REFERENCES

- Promacta [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 03/04/24
Created: 01/09
Client Approval: 02/24
P&T Approval: 07/19

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELUXADOLINE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of irritable bowel syndrome with diarrhea (IBS-D) and meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to Xifaxan (rifaximin) **AND** either tricyclic anti-depressants (e.g., amitriptyline, desipramine) **OR** dicyclomine

   If yes, continue to #2.
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELUXADOLINE (Viberzi)** requires the following rule(s) be met for approval:
   A. You have irritable bowel syndrome with diarrhea (an intestinal problem causing pain in the belly, gas, diarrhea, and constipation)
   B. You are 18 years of age or older
   C. The medication is prescribed by or given in consultation with a gastroenterologist (a doctor who specializes in conditions of the stomach, intestine and related organs)
   D. You had a trial of Xifaxan (rifaximin) AND either tricyclic anti-depressants (such as amitriptyline, desipramine) OR dicyclomine, unless there is a medical reason why you cannot (contraindication)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELUXADOLINE

INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ANY** of the following criteria?
   - Patient does not have a gallbladder
   - Patient is receiving concomitant OATP1B1 inhibitors (e.g., atazanavir, cyclosporine, eltrombopag, gemfibrozil, lopinavir, rifampin, ritonavir, saquinavir, tipranavir)
   - Patient has mild or moderate hepatic impairment
   - Patient is intolerant to Viberzi 100mg

   If yes, **approve ELUXADOLINE 75MG for 12 weeks by GPID or GPI-14 with a quantity limit of #2 per day.**
   APPROVAL TEXT: Renewal requires that the patient has experienced at least 30% decrease in abdominal pain (on a 0-10 point pain scale) and the patient has experienced at least 50% reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7).

   If no, **approve ELUXADOLINE 100MG for 12 weeks by GPID or GPI-14 with a quantity limit of #2 per day.**
   APPROVAL TEXT: Renewal requires that the patient has experienced at least 30% decrease in abdominal pain (on a 0-10 point pain scale) and the patient has experienced at least 50% reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7).

RENEWAL CRITERIA

1. Is the patient being treated for irritable bowel syndrome with diarrhea (IBS-D) and meets **ALL** of the following criteria?
   - Patient has experienced at least 30% decrease in abdominal pain (on a 0-10 point pain scale)
   - Patient has experienced at least 50% reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text on the next page.

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ELUXADOLINE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ELUXADOLINE (Viberzi)** requires the following rule(s) be met for renewal:

1. You have irritable bowel syndrome with diarrhea (an intestinal problem causing pain in the belly, gas, diarrhea, and constipation)
2. You had at least 30% decrease in abdominal pain (stomach pain) on a 0-10 point pain scale
3. You had at least 50% reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7).

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Viberzi.

REFERENCES

- Viberzi [Prescribing Information]. Madison, NJ: Allergan USA, Inc; June 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20

Created: 02/16
Client Approval: 04/20

P&T Approval: 02/16

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EMICIZUMAB-KXWH

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hemophilia A (congenital factor VIII deficiency) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist
   - The requested medication will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the request for a patient **WITH** factor VIII inhibitors **AND** the patient meets the following criterion?
   - The patient has a history of a high titer of factor VIII inhibitor defined as at least 5 or more Bethesda units per milliliter

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Is the request for a patient **WITHOUT** factor VIII inhibitors?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have moderate to severe hemophilia A, defined as less than 5% factor VIII activity compared to normal?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

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EMICIZUMAB-KXWH

INITIAL CRITERIA (CONTINUED)

5. Does the patient have mild hemophilia A, defined as 5%-40% factor VIII activity compared to normal, and meet **ONE** of the following criteria?
   - The patient has experienced severe, traumatic, or spontaneous bleeding episode(s) (may occur in joint or muscle)
   - The patient has experienced a life-threatening bleed (e.g., intracranial hemorrhage [ICH])
   - The patient has venous access difficulties impeding regular clotting factor infusions

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EMICIZUMAB-KXWH (Hemlibra)** requires the following rule(s) be met for approval:
   A. You have hemophilia A (congenital factor VIII deficiency: a type of bleeding disorder)
   B. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
   C. The requested medication will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
   D. **If you have hemophilia A with factor VIII inhibitors (a type of protein), approval also requires:**
      1. You have a history of a high titer (concentration) of factor VIII inhibitor defined as at least 5 or more Bethesda units per milliliter
   E. **If you have hemophilia A without factor VIII inhibitors (a type of protein), approval also requires ONE of the following criteria:**
      1. You have moderate to severe hemophilia A, defined as less than 5% factor VIII activity compared to normal
      2. You have mild hemophilia A, defined as 5%-40% factor VIII activity compared to normal, and meet ONE of the following:
         a. You have experienced severe, traumatic, or spontaneous (sudden) bleeding episode(s) (may occur in joint or muscle)
         b. You have experienced a life-threatening bleed (for example intracranial hemorrhage [ICH: a type of bleeding in your head])
         c. It is difficult to access your veins which prevents or delays you in receiving regular clotting factor infusions

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EMICIZUMAB-KXWH

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hemophilia A (congenital factor VIII deficiency) **AND** meet the following criterion?
   - The patient has had clinical benefit compared to baseline

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EMICIZUMAB-KXWH (Hemlibra)** requires the following rule(s) be met for renewal:
   A. You have hemophilia A (congenital factor VIII deficiency: a type of bleeding disorder)
   B. You had a clinical benefit after using the medication compared to baseline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Hemlibra.

REFERENCES

- Hemlibra [Prescribing Information]. Genentech, Inc.: South San Francisco, CA; June 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/23
Created: 02/18
Client Approval: 02/23
P&T Approval: 01/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ENASIDENIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory acute myeloid leukemia (AML) **AND** meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is isocitrate dehydrogenase-2 (IDH2) mutation positive as detected by an FDA-approved diagnostic test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ENASIDENIB (Idhifa)** requires the following rule(s) be met for approval:

   A. You have relapsed or refractory acute myeloid leukemia (a type of blood and bone marrow cancer that has returned after or is resistant to treatment)
   B. You are 18 years of age or older
   C. You are isocitrate dehydrogenase-2 (a type of enzyme) mutation positive as detected by an FDA (Food and Drug Administration)-approved diagnostic test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Idhifa.

REFERENCES

- Idhifa [Prescribing Information]. Summit, NJ: Celgene Corporation; September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 08/17
Client Approval: 04/20
P&T Approval: 10/17

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ENCORAFENIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E or V600K mutation, as detected by an FDA-approved test
   - Braftovi will be used in combination with Mektovi (binimetinib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a BRAF V600E mutation, as detected by an FDA-approved test
   - Braftovi will be used in combination with Erbitux (cetuximab)
   - The patient has previously received prior therapy (e.g., irinotecan)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a BRAF V600E mutation, as detected by an FDA-approved test
   - Braftovi will be used in combination with Mektovi (binimetinib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ENCORAFENIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ENCORAFENIB (Braftovi)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Unresectable or metastatic melanoma (a type of skin cancer that cannot be completely removed with surgery or has spread to other parts of the body)
   2. Metastatic colorectal cancer (a type of digestive cancer that has spread to other parts of the body)
   3. Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)

B. **If you have unresectable or metastatic melanoma, approval also requires:**
   1. You have a BRAF V600E or V600K mutation (types of gene mutations), as detected by a Food and Drug Administration (FDA)-approved test
   2. Braftovi will be used in combination with Mektovi (binimetinib)

C. **If you have metastatic colorectal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have a BRAF V600E mutation (a type of gene mutation), as detected by a Food and Drug Administration (FDA)-approved test
   3. Braftovi will be used in combination with Erbitux (cetuximab)
   4. You have previously received treatment (such as irinotecan)

D. **If you have metastatic non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have a BRAF V600E mutation (a type of gene mutation), as detected by a Food and Drug Administration (FDA)-approved test
   3. Braftovi will be used in combination with Mektovi (binimetinib)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ENCORAFENIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Braftovi.

REFERENCES

- Braftovi [Prescribing Information]. Boulder, CO: Array BioPharma Inc.; October 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/13/23

Created: 08/18
Client Approval: 10/23

P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ENTRECTINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has *ROS1*-positive tumors, as detected by an FDA-approved test

   If yes, continue to #3.
   If no, continue to #2.

2. Does the patient have a diagnosis of solid tumors and meet **ALL** of the following criteria?
   - The patient is 1 month of age or older
   - The tumor has a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, as detected by an FDA-approved test
   - The tumor is metastatic or surgical resection is likely to result in severe morbidity
   - The patient has progressed following treatment or there are no satisfactory alternative treatments

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the request for Rozlytrek (100mg or 200mg) capsules?

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **100mg: #5 per day.**
   - **200mg: #3 per day.**

   If no, continue to #4.

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ENTRECTINIB

GUIDELINES FOR USE (CONTINUED)

4. Is the request for Rozlytrek 50mg pellets and the patient meets **ALL** of the following criteria?
   - The patient had a trial of or contraindication to Rozlytrek capsules made into an oral suspension
   - The patient has difficulty or is unable to swallow capsules

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **50mg: #12 per day.**
   - **100mg: #5 per day.**
   - **200mg: #3 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ENTRECTINIB (Rozlytrek)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
      2. Solid tumors (an abnormal mass)
   B. **If you have metastatic non-small cell lung cancer, approval also requires:**
      1. You are 18 years of age or older
      2. You have ROS1-positive (abnormal change in a type of gene) tumors, as detected by a Food and Drug Administration (FDA)-approved test
   C. **If you have solid tumors, approval also requires:**
      1. You are 1 month of age or older
      2. The tumor has a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation (you have an abnormal change in a type of gene that does not have any known resistance), as detected by a Food and Drug Administration (FDA)-approved test
      3. Your tumor is metastatic (has spread to other parts of the body) or surgical resection (removal) is likely to result in severe morbidity (disease)
      4. You have progressed (gotten worse) after treatment or there are no satisfactory alternative treatments
   D. **If the request is for Rozlytrek 50mg pellets, approval also requires:**
      1. You have tried or have a contraindication to (harmful for you to use) Rozlytrek capsules that are used to make an oral suspension
      2. You have difficulty or are not able to swallow capsules

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ENTRECTINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rozlytrek.

REFERENCES

- Rozlytrek [Prescribing Information]. South San Francisco, CA: Genentech USA, Inc.; October 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 12/01/23
Created: 11/19
Client Approval: 11/23
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ENZALUTAMIDE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have **ONE** of the following diagnoses?
   - Metastatic castration-resistant prostate cancer (mCRPC)
   - Metastatic castration-sensitive prostate cancer (mCSPC)

   If yes, continue to #4.
   If no, continue to #2.

2. Does the patient have a diagnosis of non-metastatic castration-resistant prostate cancer (nmCRPC) **AND** meet the following criterion?
   - The patient has high risk prostate cancer (i.e., rapidly increasing prostate specific antigen [PSA] levels)

   If yes, continue to #4.
   If no, continue to #3.

3. Does the patient have a diagnosis of non-metastatic castration-sensitive prostate cancer (nmCSPC) **AND** meet the following criterion?
   - The patient is at high risk for metastasis (i.e., prostate specific antigen [PSA] doubling time over 9 months or less)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ENZALUTAMIDE

INITIAL CRITERIA (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   - The patient has received a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., less than 50 ng/dL)
   - Xtandi will be used concurrently with a gonadotropin releasing hormone (GnRH) analog (e.g., Lupron Depot [leuprolide], Zoladex [goserelin], Supprelin LA [histrelin], Firmagon [degarelix])

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **40 mg: #4 per day.**
   - **80 mg: #2 per day.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ENZALUTAMIDE (Xtandi)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and does not respond to hormone therapy)
      2. Metastatic castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread to other parts of the body and responds to hormone therapy)
      3. Non-metastatic castration-resistant prostate cancer (nmCRPC: prostate cancer that has not spread to other parts of the body and does not respond to hormone therapy)
      4. Non-metastatic castration-sensitive prostate cancer (nmCSPC: prostate cancer that has not spread to other parts of the body and responds to hormone therapy)

   B. **If you have metastatic castration-resistant prostate cancer or metastatic castration-sensitive prostate cancer, approval also requires that you meet ONE of the following:**
      1. You have received a bilateral orchiectomy (surgical removal of both testicles)
      2. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
      3. Xtandi will be used concurrently (at the same time) with a gonadotropin releasing hormone analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Supprelin LA [histrelin], Firmagon [degarelix])

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ENZALUTAMIDE

INITIAL CRITERIA (CONTINUED)

C. **If you have non-metastatic castration-resistant prostate cancer, approval also requires:**
   1. You have high-risk prostate cancer (rapidly increasing prostate specific antigen levels)
   2. You meet ONE of the following:
      a. You have received a bilateral orchiectomy (surgical removal of both testicles)
      b. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
      c. Xtandi will be used concurrently (at the same time) with a gonadotropin releasing hormone analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Supprelin LA [histrelin], Firmagon [degarelix])

D. **If you have non-metastatic castration-sensitive prostate cancer, approval also requires:**
   1. You are at high risk for metastasis (your prostate specific antigen level has doubled over 9 months or less)
   2. You meet ONE of the following:
      a. You have received a bilateral orchiectomy (surgical removal of both testicles)
      b. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
      c. Xtandi will be used concurrently (at the same time) with a gonadotropin releasing hormone analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Supprelin LA [histrelin], Firmagon [degarelix])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ENZALUTAMIDE

RENEWAL CRITERIA

NOTE: For the diagnosis of non-metastatic castration-sensitive prostate cancer (nmCSPC), please refer to the Initial Criteria section.

1. Does the patient have **ONE** of the following diagnoses?
   - Metastatic castration-resistant prostate cancer (mCRPC)
   - Metastatic castration-sensitive prostate cancer (mCSPC)
   - Non-metastatic castration-resistant prostate cancer (nmCRPC)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has received a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., less than 50 ng/dL)
   - Xtandi will be used concurrently with a gonadotropin releasing hormone (GnRH) analog (e.g., Lupron Depot [leuprolide], Zoladex [goserelin], Supprelin LA [histrelin], Firmagon [degarelix])

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   40 mg: #4 per day.
   80 mg: #2 per day.

   If no, do not approve.

   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **ENZALUTAMIDE (Xtandi)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and does not respond to hormone therapy)
      2. Metastatic castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread to other parts of the body and responds to hormone therapy)
      3. Non-metastatic castration-resistant prostate cancer (nmCRPC: prostate cancer that has not spread to other parts of the body and does not respond to hormone therapy)

   (Renewal denial text continued on next page)

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ENZALUTAMIDE

RENEWAL CRITERIA (CONTINUED)

B. You meet ONE of the following:
   1. You have received a bilateral orchiectomy (surgical removal of both testicles)
   2. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
   3. Xtandi will be used concurrently (at the same time) with a gonadotropin releasing hormone analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Supprelin LA [histrelin], Firmagon [degarelix])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Xtandi.

REFERENCES

- Xtandi [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc.; November 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 09/12
Client Approval: 02/24
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EPLONTERSEN

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.8mL per 30 days.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EPLONTERSEN (Wainua)** requires the following rule(s) be met for approval:
   A. You have hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN: a rare genetic disorder with widespread nerve damage/pain)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Wainua.

REFERENCES

- Wainua [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/15/24
Created: 01/24
Client Approval: 01/24
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EPOETIN ALFA

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD) and meet **ALL** of the following criteria?
   - The patient had a trial of the preferred agent: Retacrit (epoetin alfa-epbx)
   - The patient's hemoglobin level is less than 10g/dL

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent as follows:**
   - **Procrit 2,000U/mL: #12mL per 28 days.**
   - **Procrit 3,000U/mL: #12mL per 28 days.**
   - **Procrit 4,000U/mL: #12mL per 28 days.**
   - **Procrit 10,000U/mL: #12mL per 28 days.**
   - **Procrit 20,000U/mL: #12mL per 28 days.**
   - **Procrit 40,000U/mL: #4mL per 28 days.**
   - **Procrit 20,000U/2mL: #12mL per 28 days.**
   - **Epogen 2,000U/mL: #12mL per 28 days.**
   - **Epogen 3,000U/mL: #12mL per 28 days.**
   - **Epogen 4,000U/mL: #12mL per 28 days.**
   - **Epogen 10,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/2mL: #12mL per 28 days.**

   If no, continue to #2.

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EPOETIN ALFA

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy and meet **ALL** of the following criteria?
   - The patient had a trial of the preferred agent: Retacrit (epoetin alfa-epbx)
   - The patient has a hemoglobin level of less than 11g/dL OR the patient's hemoglobin level has decreased at least 2g/dL below baseline level

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent as follows:**
   - **Procrit 2,000U/mL: #12mL per 28 days.**
   - **Procrit 3,000U/mL: #12mL per 28 days.**
   - **Procrit 4,000U/mL: #12mL per 28 days.**
   - **Procrit 10,000U/mL: #12mL per 28 days.**
   - **Procrit 20,000U/mL: #12mL per 28 days.**
   - **Procrit 40,000U/mL: #4mL per 28 days.**
   - **Procrit 20,000U/2mL: #12mL per 28 days.**
   - **Epogen 2,000U/mL: #12mL per 28 days.**
   - **Epogen 3,000U/mL: #12mL per 28 days.**
   - **Epogen 4,000U/mL: #12mL per 28 days.**
   - **Epogen 10,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/2mL: #12mL per 28 days.**

   If no, continue to #3.

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EPOETIN ALFA

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of anemia related to zidovudine (Retrovir) therapy and meet **ALL** of the following criteria?
   - The patient had a trial of the preferred agent: Retacrit (epoetin alfa-epbx)
   - The patient's hemoglobin level is less than 10g/dL

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent as follows:**
   - **Procrit 2,000U/mL: #12mL per 28 days.**
   - **Procrit 3,000U/mL: #12mL per 28 days.**
   - **Procrit 4,000U/mL: #12mL per 28 days.**
   - **Procrit 10,000U/mL: #12mL per 28 days.**
   - **Procrit 20,000U/mL: #12mL per 28 days.**
   - **Procrit 40,000U/mL: #4mL per 28 days.**
   - **Procrit 20,000U/2mL: #12mL per 28 days.**
   - **Epogen 2,000U/mL: #12mL per 28 days.**
   - **Epogen 3,000U/mL: #12mL per 28 days.**
   - **Epogen 4,000U/mL: #12mL per 28 days.**
   - **Epogen 10,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/2mL: #12mL per 28 days.**

   If no, continue to #4.

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EPOETIN ALFA

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet **ALL** of the following criteria?
   - The patient had a trial of the preferred agent: Retacrit (epoetin alfa-epbx)
   - The patient's hemoglobin level is less than 10g/dL
   - The patient had a trial of or contraindication to ribavirin dose reduction

   If yes, **approve for 6 months by GPID or GPI-14 for the requested agent as follows:**
   - **Procrit 2,000U/mL: #12mL per 28 days.**
   - **Procrit 3,000U/mL: #12mL per 28 days.**
   - **Procrit 4,000U/mL: #12mL per 28 days.**
   - **Procrit 10,000U/mL: #12mL per 28 days.**
   - **Procrit 20,000U/mL: #12mL per 28 days.**
   - **Procrit 40,000U/mL: #4mL per 28 days.**
   - **Procrit 20,000U/2mL: #12mL per 28 days.**
   - **Epogen 2,000U/mL: #12mL per 28 days.**
   - **Epogen 3,000U/mL: #12mL per 28 days.**
   - **Epogen 4,000U/mL: #12mL per 28 days.**
   - **Epogen 10,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/2mL: #12mL per 28 days.**

   If no, continue to #5.

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EPOETIN ALFA

INITIAL CRITERIA (CONTINUED)

5. Is the patient undergoing elective, noncardiac, nonvascular surgery and meet **ALL** of the following criteria?
   - The patient had a trial of the preferred agent: Retacrit (epoetin alfa-epbx)
   - The patient's hemoglobin level is less than 13g/dL

   If yes, **approve for 1 month by GPID or GPI-14 for the requested agent as follows:**
   - **Procrit 2,000U/mL: #12mL per 28 days.**
   - **Procrit 3,000U/mL: #12mL per 28 days.**
   - **Procrit 4,000U/mL: #12mL per 28 days.**
   - **Procrit 10,000U/mL: #12mL per 28 days.**
   - **Procrit 20,000U/mL: #12mL per 28 days.**
   - **Procrit 40,000U/mL: #4mL per 28 days.**
   - **Procrit 20,000U/2mL: #12mL per 28 days.**
   - **Epogen 2,000U/mL: #12mL per 28 days.**
   - **Epogen 3,000U/mL: #12mL per 28 days.**
   - **Epogen 4,000U/mL: #12mL per 28 days.**
   - **Epogen 10,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/2mL: #12mL per 28 days.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EPOETIN ALFA (Procrit, Epogen)** requires the following rules be met for approval:

   A. You have ONE of the following:
      1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease (CKD)
      2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
      3. Anemia related to zidovudine (Retrovir) therapy (a type of drug to treat human immunodeficiency virus)
      4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
      5. You are undergoing elective, noncardiac, nonvascular surgery (surgery not relating to the heart or blood vessels)

   (Initial denial text continued on next page)

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EPOETIN ALFA

INITIAL CRITERIA (CONTINUED)

B. **If you have anemia due to chronic kidney disease, approval also requires:**
   1. You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
   2. Your hemoglobin level (a type of blood test) is less than 10g/dL
C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires:**
   1. You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
   2. You have a hemoglobin level of less than 11g/dL OR your hemoglobin level has decreased at least 2g/dL below your baseline level
D. **If you have anemia related to zidovudine (Retrovir) therapy, approval also requires:**
   1. You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
   2. Your hemoglobin level is less than 10g/dL
E. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:**
   1. You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
   2. You have tried or have a contraindication (harmful for) to a lower ribavirin dose
   3. Your hemoglobin level is less than 10g/dL
F. **If you are undergoing elective, noncardiac, nonvascular surgery, approval also requires:**
   1. You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
   2. Your hemoglobin level is less than 13g/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EPOETIN ALFA

RENEWAL CRITERIA

NOTE: Requests for patients undergoing elective, noncardiac, nonvascular surgery, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD)?

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient an adult (18 years of age or older) and meet **ONE** of the following criteria?
   - The patient's hemoglobin level is less than 10g/dL if not on dialysis
   - The patient's hemoglobin level is less than 11g/dL if on dialysis
   - The patient's hemoglobin level has reached 10g/dL (if not on dialysis) and the dose is being reduced/interrupted to decrease the need for blood transfusions
   - The patient's hemoglobin level has reached 11g/dL (if on dialysis) and the dose is being reduced/interrupted to decrease the need for blood transfusions

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent as follows:**
   - **Procrit 2,000U/mL: #12mL per 28 days.**
   - **Procrit 3,000U/mL: #12mL per 28 days.**
   - **Procrit 4,000U/mL: #12mL per 28 days.**
   - **Procrit 10,000U/mL: #12mL per 28 days.**
   - **Procrit 20,000U/mL: #12mL per 28 days.**
   - **Procrit 40,000U/mL: #4mL per 28 days.**
   - **Procrit 20,000U/2mL: #12mL per 28 days.**
   - **Epogen 2,000U/mL: #12mL per 28 days.**
   - **Epogen 3,000U/mL: #12mL per 28 days.**
   - **Epogen 4,000U/mL: #12mL per 28 days.**
   - **Epogen 10,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/2mL: #12mL per 28 days.**

   If no, continue to #3.

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EPOETIN ALFA

RENEWAL CRITERIA (CONTINUED)

3. Is the request for a pediatric patient (less than 18 years of age) and meets **ONE** of the following criteria?
   - The patient's hemoglobin level is less than 10g/dL
   - The patient's hemoglobin level has reached or exceeds 12g/dL and the dose is being reduced/interrupted to decrease the need for blood transfusions

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent as follows:**
   - **Procrit 2,000U/mL: #12mL per 28 days.**
   - **Procrit 3,000U/mL: #12mL per 28 days.**
   - **Procrit 4,000U/mL: #12mL per 28 days.**
   - **Procrit 10,000U/mL: #12mL per 28 days.**
   - **Procrit 20,000U/mL: #12mL per 28 days.**
   - **Procrit 40,000U/mL: #4mL per 28 days.**
   - **Procrit 20,000U/2mL: #12mL per 28 days.**
   - **Epogen 2,000U/mL: #12mL per 28 days.**
   - **Epogen 3,000U/mL: #12mL per 28 days.**
   - **Epogen 4,000U/mL: #12mL per 28 days.**
   - **Epogen 10,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/2mL: #12mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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EPOETIN ALFA

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy **AND** meet the following criterion?
   - The patient's hemoglobin level is between 10g/dL and 12g/dL

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent as follows:**
   - **Procrit 2,000U/mL: #12mL per 28 days.**
   - **Procrit 3,000U/mL: #12mL per 28 days.**
   - **Procrit 4,000U/mL: #12mL per 28 days.**
   - **Procrit 10,000U/mL: #12mL per 28 days.**
   - **Procrit 20,000U/mL: #12mL per 28 days.**
   - **Procrit 40,000U/mL: #4mL per 28 days.**
   - **Procrit 20,000U/2mL: #12mL per 28 days.**
   - **Epogen 2,000U/mL: #12mL per 28 days.**
   - **Epogen 3,000U/mL: #12mL per 28 days.**
   - **Epogen 4,000U/mL: #12mL per 28 days.**
   - **Epogen 10,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/2mL: #12mL per 28 days.**

   If no, continue to #5.

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EPOETIN ALFA

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of anemia related to zidovudine (Retrovir) therapy **AND** meet the following criterion?
   - The patient's hemoglobin level is between 10g/dL and 12g/dL

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent as follows:**
   - **Procrit 2,000U/mL: #12mL per 28 days.**
   - **Procrit 3,000U/mL: #12mL per 28 days.**
   - **Procrit 4,000U/mL: #12mL per 28 days.**
   - **Procrit 10,000U/mL: #12mL per 28 days.**
   - **Procrit 20,000U/mL: #12mL per 28 days.**
   - **Procrit 40,000U/mL: #4mL per 28 days.**
   - **Procrit 20,000U/2mL: #12mL per 28 days.**
   - **Epogen 2,000U/mL: #12mL per 28 days.**
   - **Epogen 3,000U/mL: #12mL per 28 days.**
   - **Epogen 4,000U/mL: #12mL per 28 days.**
   - **Epogen 10,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/2mL: #12mL per 28 days.**

   If no, continue to #6.

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EPOETIN ALFA

RENEWAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa **AND** meet the following criterion?
   - The patient's hemoglobin level is between 10g/dL and 12g/dL

   If yes, **approve for 6 months by GPID or GPI-14 for the requested agent as follows**:
   - **Procrit 2,000U/mL: #12mL per 28 days.**
   - **Procrit 3,000U/mL: #12mL per 28 days.**
   - **Procrit 4,000U/mL: #12mL per 28 days.**
   - **Procrit 10,000U/mL: #12mL per 28 days.**
   - **Procrit 20,000U/mL: #12mL per 28 days.**
   - **Procrit 40,000U/mL: #4mL per 28 days.**
   - **Procrit 20,000U/2mL: #12mL per 28 days.**
   - **Epogen 2,000U/mL: #12mL per 28 days.**
   - **Epogen 3,000U/mL: #12mL per 28 days.**
   - **Epogen 4,000U/mL: #12mL per 28 days.**
   - **Epogen 10,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/2mL: #12mL per 28 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EPOETIN ALFA (Procrit, Epogen)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease (CKD)
      2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
      3. Anemia related to zidovudine (Retrovir) therapy (a type of drug to treat human immunodeficiency virus)
      4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

   (Renewal denial text continued on next page)

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EPOETIN ALFA

RENEWAL CRITERIA (CONTINUED)

B. **If you are an adult (you are 18 years of age or older) with anemia due to chronic kidney disease, renewal also requires ONE of the following:**
   1. Your hemoglobin level (a type of blood test) is less than 10g/dL if you are not on dialysis (process of removing excess water, toxins from the blood)
   2. Your hemoglobin level is less than 11g/dL if you are on dialysis
   3. Your hemoglobin level has reached 10g/dL (if you are not on dialysis) and your dose is being reduced/interrupted to decrease the need for blood transfusions
   4. Your hemoglobin level has reached 11g/dL (if you are on dialysis) and your dose is being reduced or interrupted to decrease the need for blood transfusions

C. **If you are a pediatric patient (you are less than 18 years of age) with anemia due to chronic kidney disease, renewal also requires ONE of the following:**
   1. Your hemoglobin level is less than 10g/dL
   2. Your hemoglobin level has reached or exceeds 12g/dL and your dose is being reduced/interrupted to decrease the need for blood transfusions

D. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:**
   1. Your hemoglobin level is between 10g/dL and 12g/dL

E. **If you have anemia related to zidovudine (Retrovir) therapy, renewal also requires:**
   1. Your hemoglobin level is between 10g/dL and 12g/dL

F. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:**
   1. Your hemoglobin level is between 10g/dL and 12g/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Procrit, Epogen.

REFERENCES

- Procrit [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; July 2018.
- Epogen [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; July 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 02/11
Client Approval: 11/23
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EPOETIN ALFA-EPBX

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD) **AND** meet the following criterion?
   - The patient's hemoglobin level is less than 10g/dL

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **2,000U/mL: #12mL in 28 days.**
   - **3,000U/mL: #12mL in 28 days.**
   - **4,000U/mL: #12mL in 28 days.**
   - **10,000U/mL: #12mL in 28 days.**
   - **20,000U/mL: #12mL in 28 days.**
   - **40,000U/mL: #4mL in 28 days.**
   - **20,000U/2mL: #12mL in 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy and meet **ONE** of the following criteria?
   - The patient's hemoglobin level is less than 11g/dL
   - The patient's hemoglobin level has decreased at least 2g/dL below baseline level

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **2,000U/mL: #12mL in 28 days.**
   - **3,000U/mL: #12mL in 28 days.**
   - **4,000U/mL: #12mL in 28 days.**
   - **10,000U/mL: #12mL in 28 days.**
   - **20,000U/mL: #12mL in 28 days.**
   - **40,000U/mL: #4mL in 28 days.**
   - **20,000U/2mL: #12mL in 28 days.**

   If no, continue to #3.

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EPOETIN ALFA-EPBX

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of anemia related to zidovudine (Retrovir) therapy **AND** meet the following criterion?
   - The patient's hemoglobin level is less than 10g/dL

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **2,000U/mL: #12mL in 28 days.**
   - **3,000U/mL: #12mL in 28 days.**
   - **4,000U/mL: #12mL in 28 days.**
   - **10,000U/mL: #12mL in 28 days.**
   - **20,000U/mL: #12mL in 28 days.**
   - **40,000U/mL: #4mL in 28 days.**
   - **20,000U/2mL: #12mL in 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet **ALL** of the following criteria?
   - The patient's hemoglobin level is less than 10g/dL
   - The patient had a trial of or contraindication to ribavirin dose reduction

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
   - **2,000U/mL: #12mL in 28 days.**
   - **3,000U/mL: #12mL in 28 days.**
   - **4,000U/mL: #12mL in 28 days.**
   - **10,000U/mL: #12mL in 28 days.**
   - **20,000U/mL: #12mL in 28 days.**
   - **40,000U/mL: #4mL in 28 days.**
   - **20,000U/2mL: #12mL in 28 days.**

   If no, continue to #5.

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EPOETIN ALFA-EPBX

INITIAL CRITERIA (CONTINUED)

5. Is the patient undergoing elective, noncardiac, nonvascular surgery **AND** meet the following criterion?
   - The patient's hemoglobin level is less than 13g/dL

   If yes, **approve for 1 month by GPID or GPI-14 for the requested strength as follows:**
   - **2,000U/mL: #12mL in 28 days.**
   - **3,000U/mL: #12mL in 28 days.**
   - **4,000U/mL: #12mL in 28 days.**
   - **10,000U/mL: #12mL in 28 days.**
   - **20,000U/mL: #12mL in 28 days.**
   - **40,000U/mL: #4mL in 28 days.**
   - **20,000U/2mL: #12mL in 28 days.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EPOETIN ALFA-EPBX (Retacrit)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease (CKD)
      2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
      3. Anemia related to zidovudine (Retrovir) therapy (a type of drug to treat human immunodeficiency virus)
      4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
      6. You are undergoing elective, noncardiac, nonvascular surgery (surgery not relating to the heart or blood vessels)
   B. **If you have anemia due to chronic kidney disease, approval also requires:**
      1. Your hemoglobin level (a type of blood test) is less than 10g/dL
   C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires ONE of the following:**
      1. Your hemoglobin level is less than 11g/dL
      2. Your hemoglobin level has decreased at least 2g/dL below your baseline level

   (Initial denial text continued on next page)

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EPOETIN ALFA-EPBX

INITIAL CRITERIA (CONTINUED)

D. **If you have anemia related to zidovudine (Retrovir) therapy, approval also requires:**
   1. Your hemoglobin level is less than 10g/dL
E. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:**
   1. You have tried or have a contraindication (harmful for) to a lower ribavirin dose
   2. Your hemoglobin level is less than 10g/dL
F. **If you are undergoing elective, noncardiac, nonvascular surgery, approval also requires:**
   1. Your hemoglobin level is less than 13g/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EPOETIN ALFA-EPBX

RENEWAL CRITERIA

NOTE: Requests for patients undergoing elective, noncardiac, nonvascular surgery, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD)?

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient an adult (18 years of age or older) and meet **ONE** of the following criteria?
   - The patient's hemoglobin level is less than 10g/dL if not on dialysis
   - The patient's hemoglobin level is less than 11g/dL if on dialysis
   - The patient's hemoglobin level has reached 10g/dL (if not on dialysis) and the dose is being reduced/interrupted to decrease the need for blood transfusions
   - The patient's hemoglobin level has reached 11g/dL (if on dialysis) and the dose is being reduced/interrupted to decrease the need for blood transfusions

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **2,000U/mL: #12mL in 28 days.**
   - **3,000U/mL: #12mL in 28 days.**
   - **4,000U/mL: #12mL in 28 days.**
   - **10,000U/mL: #12mL in 28 days.**
   - **20,000U/mL: #12mL in 28 days.**
   - **40,000U/mL: #4mL in 28 days.**
   - **20,000U/2mL: #12mL in 28 days.**

   If no, continue to #3.

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EPOETIN ALFA-EPBX

RENEWAL CRITERIA (CONTINUED)

3. Is the request for a pediatric patient (less than 18 years of age) and meet **ONE** of the following criteria?
   - The patient's hemoglobin level is less than 10g/dL
   - The patient's hemoglobin level has reached or exceeds 12g/dL and the dose is being reduced/interrupted to decrease the need for blood transfusions

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **2,000U/mL: #12mL in 28 days.**
   - **3,000U/mL: #12mL in 28 days.**
   - **4,000U/mL: #12mL in 28 days.**
   - **10,000U/mL: #12mL in 28 days.**
   - **20,000U/mL: #12mL in 28 days.**
   - **40,000U/mL: #4mL in 28 days.**
   - **20,000U/2mL: #12mL in 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy **AND** meet the following criterion?
   - The patient's hemoglobin level is between 10g/dL and 12g/dL

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **2,000U/mL: #12mL in 28 days.**
   - **3,000U/mL: #12mL in 28 days.**
   - **4,000U/mL: #12mL in 28 days.**
   - **10,000U/mL: #12mL in 28 days.**
   - **20,000U/mL: #12mL in 28 days.**
   - **40,000U/mL: #4mL in 28 days.**
   - **20,000U/2mL: #12mL in 28 days.**

   If no, continue to #5.

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EPOETIN ALFA-EPBX

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of anemia related to zidovudine (Retrovir) therapy **AND** meet the following criterion?
   - The patient's hemoglobin level is between 10g/dL and 12g/dL

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **2,000U/mL: #12mL in 28 days.**
   - **3,000U/mL: #12mL in 28 days.**
   - **4,000U/mL: #12mL in 28 days.**
   - **10,000U/mL: #12mL in 28 days.**
   - **20,000U/mL: #12mL in 28 days.**
   - **40,000U/mL: #4mL in 28 days.**
   - **20,000U/2mL: #12mL in 28 days.**

   If no, continue to #6.

6. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa **AND** meet the following criterion?
   - The patient's hemoglobin level is between 10g/dL and 12g/dL

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
   - **2,000U/mL: #12mL in 28 days.**
   - **3,000U/mL: #12mL in 28 days.**
   - **4,000U/mL: #12mL in 28 days.**
   - **10,000U/mL: #12mL in 28 days.**
   - **20,000U/mL: #12mL in 28 days.**
   - **40,000U/mL: #4mL in 28 days.**
   - **20,000U/2mL: #12mL in 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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EPOETIN ALFA-EPBX

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **EPOETIN ALFA-EPBX (Retacrit)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease (CKD)
   2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia related to zidovudine (Retrovir) therapy (a type of drug to treat human immunodeficiency virus)
   4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

B. **If you are an adult (you are 18 years of age or older) with anemia due to chronic kidney disease, renewal also requires ONE of the following:**
   1. Your hemoglobin level (a type of blood test) is less than 10g/dL if you are not on dialysis (process of removing excess water, toxins from the blood)
   2. Your hemoglobin level is less than 11g/dL if you are on dialysis
   3. Your hemoglobin level has reached 10g/dL (if you are not on dialysis) and your dose is being reduced/interrupted to decrease the need for blood transfusions
   4. Your hemoglobin level has reached 11g/dL (if you are on dialysis) and your dose is being reduced/interrupted to decrease the need for blood transfusions

C. **If you are a pediatric patient (you are less than 18 years of age) with anemia due to chronic kidney disease, renewal also requires ONE of the following:**
   1. Your hemoglobin level is less than 10g/dL
   2. Your hemoglobin level has reached or exceeds 12g/dL and your dose is being reduced or interrupted to decrease the need for blood transfusions

D. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:**
   1. Your hemoglobin level is between 10g/dL and 12g/dL

E. **If you have anemia related to zidovudine (Retrovir) therapy, renewal also requires:**
   1. Your hemoglobin level is between 10g/dL and 12g/dL

F. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:**
   1. Your hemoglobin level is between 10g/dL and 12g/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EPOETIN ALFA-EPBX

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Retacrit.

REFERENCES

- Retacrit [Prescribing Information]. Lake Forest, IL: Pfizer Inc.; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 02/11
Client Approval: 11/23
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ERDAFITINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic urothelial carcinoma (i.e., bladder cancer) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a susceptible FGFR3 genetic alteration as detected by an FDA-approved companion diagnostic test
   - The patient has disease progression on or after at least one line of prior systemic therapy (e.g., cisplatin, Keytruda [pembrolizumab])

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **3mg: #3 per day.**
   - **4mg: #2 per day.**
   - **5mg: #1 per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ERDAFITINIB (Balversa)** requires the following rule(s) be met for approval:
   A. You have locally advanced or metastatic urothelial carcinoma (a type of bladder cancer that has spread to nearby tissue or other parts of the body)
   B. You are 18 years of age or older
   C. You have a susceptible (can be treated with the drug) fibroblast growth factor receptor 3 (FGFR3: a type of protein) genetic alteration (mutation) as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test
   D. You have disease progression (condition has worsened) on or after at least one line of prior systemic therapy (treatment that targets the entire body, such as cisplatin, Keytruda [pembrolizumab])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ERDAFITINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Balversa.

REFERENCES

- Balversa [Prescribing Information]. Horsham, PA: Janssen Products, LP; January 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/12/24
Created: 04/19
Client Approval: 01/24
P&T Approval: 04/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ERENUMAB-AOOE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of episodic migraines and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Aimovig is prescribed for the preventive treatment of migraines
   - Aimovig will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine prevention
   - The patient had a trial of ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 30 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of chronic migraines and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Aimovig is prescribed for the preventive treatment of migraines
   - Aimovig will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine prevention
   - The patient had a trial of ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox **[Note: For Botox, previous trial of only NDCs # 00023-1145-01 or 00023-3921-02 are allowable]**

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 30 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ERENUMAB-AOOE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ERENUMAB-AOOE (Aimovig)** requires the following rule(s) be met for approval:

A. You have migraines
B. **If you have episodic migraines (0-14 headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Aimovig is prescribed for the preventive treatment of migraines
   3. You will NOT use Aimovig concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine prevention
   4. You have tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol
C. **If you have chronic migraines (15 or more headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Aimovig is prescribed for the preventive treatment of migraines
   3. You will NOT use Aimovig concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine prevention
   4. You have tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox [Note: For Botox, previous trial of only NDCs # 00023-1145-01 or 00023-3921-02 are allowable]

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ERENUMAB-AOOE

RENEWAL CRITERIA

1. Is Aimovig being prescribed for the preventive treatment of migraines **AND** does the patient meet the following criterion?
   - Aimovig will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine prevention

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month with Aimovig therapy
   - The patient has experienced a reduction in migraine severity with Aimovig therapy
   - The patient has experienced a reduction in migraine duration with Aimovig therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 30 days.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ERENUMAB-AOOE (Aimovig)** requires the following rule(s) be met for renewal:
   A. Aimovig is being prescribed for preventive treatment of migraines.
   B. You will NOT use Aimovig concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine prevention
   C. You meet ONE of the following criteria:
      1. You have experienced less migraines or headache attacks by at least 2 days per month with Aimovig therapy
      2. You have experienced a lessening in migraine severity with Aimovig therapy
      3. You have experienced a lessening in migraine duration with Aimovig therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ERENUMAB-AOOE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Aimovig.

REFERENCE

- Aimovig [Prescribing Information]. Thousand Oaks, CA: Amgen/Novartis; October 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/23
Created: 05/18
Client Approval: 06/23
P&T Approval: 01/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ERGOTAMINE-CAFFEINE

GUIDELINES FOR USE

1. Is Migergot being used to abort or prevent vascular headaches (e.g., migraine, migraine variants, so-called 'histaminic cephalalgia') and the patient meets **ALL** of the following criteria?
   - The patient cannot swallow ergotamine/caffeine tablets
   - The patient had a trial of or contraindication to generic ergotamine/caffeine tablets AND two triptans (e.g., sumatriptan, rizatriptan)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #24 per 30 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ERGOTAMINE-CAFFEINE (Migergot)** requires the following rule(s) be met for approval:
   A. Migergot is being used to abort (stop) or prevent vascular headaches (such as migraines, migraine variants, so-called 'histaminic cephalalgia' [types of headaches])
   B. You cannot swallow ergotamine/caffeine tablets
   C. You had a trial of or contraindication (harmful for) to generic ergotamine/caffeine tablets AND two triptans (such as sumatriptan, rizatriptan)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Migergot.

REFERENCES

- Migergot [Prescribing Information]. South Plainfield, NJ: Cosette Pharmaceuticals, Inc., August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective:04/01/23
Created: 11/22
Client Approval: 02/23
P&T Approval: 10/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ERLOTINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test
   - Tarceva (erlotinib) will NOT be used concurrently with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (e.g., Gilotrif, Tagrisso, Iressa, Vizimpro)

   If yes, **approve for 12 months by GPID or GPI-14 as requested with the following quantity limits:**
   - **25mg: #2 per day.**
   - **100mg: #2 per day.**
   - **150mg: #3 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of locally advanced, unresectable, or metastatic pancreatic cancer and meet **ALL** of the following criteria?
   - The requested medication will be used in combination with gemcitabine
   - The medication will be used as a first line treatment

   If yes, **approve for 12 months by GPID or GPI-14 as requested with the following quantity limits:**
   - **25mg: #2 per day.**
   - **100mg: #2 per day.**
   - **150mg: #3 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ERLOTINIB (Tarceva)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Metastatic non-small cell lung cancer (type of lung cancer that has spread to other parts of the body)
      2. Locally advanced, unresectable, or metastatic pancreatic cancer (pancreas cancer that has spread or cannot be completely removed by surgery)

   (Denial text continued on next page)

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ERLOTINIB

GUIDELINES FOR USE (CONTINUED)

B. **If you have metastatic non-small cell lung cancer, approval also requires:**
   1. Your tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations (types of gene mutations or permanent change in the DNA that makes up a gene) as detected by an FDA (Food and Drug Administration)-approved test
   2. You will NOT be using Tarceva (erlotinib) concurrently (at the same time) with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (e.g., Gilotrif, Tagrisso, Iressa, Vizimpro)

C. **If you have locally advanced, unresectable, or metastatic pancreatic cancer, approval also requires:**
   1. The requested medication will be used in combination with gemcitabine
   2. The medication will be used as a first line treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tarceva.

REFERENCES

- Tarceva [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc.; October 2016.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 11/10
Client Approval: 05/22
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ETANERCEPT

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mg syringes: #4mL per 28 days.**
   - **25mg vials: #8 vials OR #4mL per 28 days.**
   - **50mg syringes/cartridges: #4mL per 28 days.**

   If no, continue to #2.

2. Does the patient have moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mg syringes: #4mL per 28 days.**
   - **25mg vials: #8 vials OR #4mL per 28 days.**
   - **50mg syringes/cartridges: #4mL per 28 days.**

   If no, continue to #3.

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ETANERCEPT

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mg syringes: #4mL per 28 days.**
   - **25mg vials: #8 vials OR #4mL per 28 days.**
   - **50mg syringes/cartridges: #4mL per 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to an NSAID (e.g., naproxen, ibuprofen, meloxicam)

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mg syringes: #4mL per 28 days.**
   - **25mg vials: #8 vials OR #4mL per 28 days.**
   - **50mg syringes/cartridges: #4mL per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient is 4 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient had a trial of or contraindication to ONE or more forms of conventional therapies, (e.g., PUVA [psoralen and ultraviolet light A], UVB [ultraviolet light B], topical corticosteroids [e.g., betamethasone dipropionate, clobetasol propionate], calcipotriene, acitretin, methotrexate, or cyclosporine)

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ETANERCEPT

INITIAL CRITERIA (CONTINUED)

6. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic and is switching to Enbrel
   - The patient has psoriasis covering 3% or more of body surface area (BSA)
   - The patient has psoriatic lesions affecting the hands, feet, genital area, or face

   If yes, **approve for a total of 6 months by GPID or GPI-14 and enter two approvals as follows:**
   - **FIRST APPROVAL: approve for 3 months for the requested strength:**
     - **25mg syringes: #8mL per 28 days.**
     - **25mg vials: #16 vials OR #8mL per 28 days.**
     - **50mg syringes/cartridges: #8mL per 28 days.**
   - **SECOND APPROVAL: approve for the requested strength for the next 3 months:**
     - **25mg syringes: #4mL per 28 days.**
     - **25mg vials: #8 vials OR #4mL per 28 days.**
     - **50mg syringes/cartridges: #4mL per 28 days.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ETANERCEPT (Enbrel)** requires the following rule(s) be met for approval:

   A. You have ONE of the following diagnoses:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
      4. Ankylosing spondylitis (AS: a type of joint condition)
      5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)

   B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
      3. You have tried or have a contraindication (harmful for) to at least 3 months of ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   (Initial denial text continued on next page)

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ETANERCEPT

INITIAL CRITERIA (CONTINUED)

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication (harmful for) to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have psoriatic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You have tried or have a contraindication (harmful for) to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

E. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication (harmful for) to an NSAID (non-steroidal anti-inflammatory drug, such as naproxen, ibuprofen, meloxicam)

F. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 4 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You have tried or have a contraindication (harmful for) to ONE or more forms of standard therapies, such as PUVA (psoralen and ultraviolet light A: a type of light therapy), UVB (ultraviolet light B: a type of light therapy), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), calcipotriene, acitretin, methotrexate, or cyclosporine
   4. You meet ONE of the following:
      a. You were previously stable on another biologic and are switching to Enbrel
      b. You have psoriasis covering 3% or more of body surface area (BSA)
      c. You have psoriatic lesions (rashes) affecting the hands, feet, genital area, or face

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ETANERCEPT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mg syringes: #4mL per 28 days.**
   - **25mg vials: #8 vials OR #4mL per 28 days.**
   - **50mg syringes/cartridges: #4mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mg syringes: #4mL per 28 days.**
   - **25mg vials: #8 vials OR #4mL per 28 days.**
   - **50mg syringes/cartridges: #4mL per 28 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mg syringes: #4mL per 28 days.**
   - **25mg vials: #8 vials OR #4mL per 28 days.**
   - **50mg syringes/cartridges: #4mL per 28 days.**

   If no, continue to #4.

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ETANERCEPT

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) **AND** meet the following criterion?
   - The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mg syringes: #4mL per 28 days.**
   - **25mg vials: #8 vials OR #4mL per 28 days.**
   - **50mg syringes/cartridges: #4mL per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?
   - The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mg syringes: #4mL per 28 days.**
   - **25mg vials: #8 vials OR #4mL per 28 days.**
   - **50mg syringes/cartridges: #4mL per 28 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ETANERCEPT (Enbrel)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
      4. Ankylosing spondylitis (AS: a type of joint condition)
      5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
      1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   (Renewal denial text continued on next page)

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ETANERCEPT

RENEWAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

D. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires**:
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

E. **If you have ankylosing spondylitis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy.

F. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Enbrel.

REFERENCES

- Enbrel [Prescribing Information]. Thousand Oaks, CA: Immunex Corporation; October 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24

Created: 02/03
Client Approval: 03/24

P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ETHACRYNIC ACID

GUIDELINES FOR USE

1. Does the patient have **ONE** of the following diagnoses?
   - Edema associated with congestive heart failure, cirrhosis of the liver, or renal disease (including nephrotic syndrome)
   - Ascites due to malignancy, idiopathic edema, or lymphedema

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a trial of or contraindication to **TWO** generic loop diuretics (e.g., furosemide, bumetanide, torsemide)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ETHACRYNIC ACID (Edecrin)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Edema (swelling caused by fluid build-up in the body) associated with congestive heart failure (a type of heart condition), cirrhosis (liver damage), or renal disease (including nephrotic syndrome [a type of kidney disorder])
      2. Ascites (accumulation of fluid in the abdominal cavity) due to malignancy (cancer), idiopathic (unknown cause) edema, or lymphedema (swelling in an arm or leg due to build-up of lymph fluid)
   B. You had a trial of or contraindication (harmful for) to TWO generic loop diuretics (such as furosemide, bumetanide, torsemide)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ETHACRYNIC ACID

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Edecrin.

REFERENCES

- Edecrin [Prescribing Information]. Greenville, NC: Bausch Health Companies, Inc., August 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 05/22
Client Approval: 05/22
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ETRASIMOD

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Velsipity will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication
   - The patient had a trial of or contraindication to ONE conventional therapy, such as corticosteroids (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz) [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance programs do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ETRASIMOD (Velsipity)** requires the following rule(s) be met for approval:
   A. You have moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   D. You will NOT use Velsipity concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)

   (Initial denial text continued on the next page)

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ETRASIMOD

INITIAL CRITERIA (CONTINUED)

E. You have tried or have a contraindication to (harmful for you to use) ONE standard therapy, such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
F. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ETRASIMOD

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?
   - Velsipity will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz) [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance programs do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ETRASIMOD (Velsipity)** requires the following rule(s) be met for renewal:
   A. You have moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   B. You will NOT use Velsipity concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   C. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

   NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ETRASIMOD

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Velsipity.

REFERENCES

- Velsipity [Prescribing Information]. New York, NY: Pfizer, Inc.; November 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/01/24
Created: 10/23
Client Approval: 04/24
P&T Approval: 04/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EVEROLIMUS-AFINITOR DISPERZ

GUIDELINES FOR USE

1. Does the patient have a diagnosis of tuberous sclerosis complex (TSC)-associated subependymal giant cell astrocytoma (SEGA) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient's diagnosis requires therapeutic intervention but cannot be curatively resected

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, continue to #2.

2. Does the patient have a diagnosis of tuberous sclerosis complex (TSC)-associated partial-onset seizures and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Afinitor Disperz will be used as adjunctive treatment

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EVEROLIMUS (Afinitor Disperz)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated subependymal giant cell astrocytoma (SEGA: a type of brain tumor)
      2. Tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated partial-onset seizures

   B. **If you have tuberous sclerosis complex (TSC)-subependymal giant cell astrocytoma (SEGA), approval also requires:**
      1. You are 1 year of age or older
      2. Your diagnosis requires therapeutic intervention but cannot be curatively resected (completely remove with surgery)

   C. **If you have tuberous sclerosis complex (TSC)-associated partial-onset seizures, approval also requires:**
      1. You are 2 years of age or older
      2. Afinitor Disperz will be used as adjunctive (add-on) treatment

   (Denial text continued on next page)

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EVEROLIMUS-AFINITOR DISPERZ

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Afinitor Disperz.

REFERENCES

- Afinitor/Afinitor Disperz [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. February 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/23
Created: 03/23
Client Approval: 03/23
P&T Approval: 04/18

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EVEROLIMUS-AFINITOR

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced hormone receptor (HR)-positive, HER2-negative breast cancer and meet **ALL** of the following criteria?
   - The patient is a postmenopausal woman
   - Afinitor will be used in combination with exemestane
   - The patient has failed or has a contraindication to treatment with Femara (letrozole) or Arimidex (anastrozole)

   If yes, **approve for 12 months for the requested strength by GPID or GPI-14 as follows:**
   - **2.5mg: #1 per day.**
   - **5mg: #1 per day.**
   - **7.5mg: #2 per day.**
   - **10mg: #2 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of progressive, neuroendocrine tumors (NET) with unresectable, locally advanced or metastatic disease **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following?
   - The patient has a neuroendocrine tumors of pancreatic origin (PNET)
   - The patient has well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin

   If yes, **approve for 12 months for the requested strength by GPID or GPI-14 as follows**
   - **2.5mg: #1 per day.**
   - **5mg: #1 per day.**
   - **7.5mg: #2 per day.**
   - **10mg: #2 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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EVEROLIMUS-AFINITOR

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months for the requested strength by GPID or GPI-14 as follows:**
   - **2.5mg: #1 per day.**
   - **5mg: #1 per day.**
   - **7.5mg: #2 per day.**
   - **10mg: #2 per day.**

   If no, continue to #5.

5. Does the patient have a diagnosis of tuberous sclerosis complex (TSC)-associated renal angiomyolipoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient does not require immediate surgery

   If yes, **approve for 12 months for the requested strength by GPID or GPI-14 as follows:**
   - **2.5mg: #1 per day.**
   - **5mg: #1 per day.**
   - **7.5mg: #2 per day.**
   - **10mg: #2 per day.**

   If no, continue to #6.

6. Does the patient have a diagnosis of tuberous sclerosis complex (TSC)-associated subependymal giant cell astrocytoma (SEGA) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient's diagnosis requires therapeutic intervention but cannot be curatively resected

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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EVEROLIMUS-AFINITOR

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **EVEROLIMUS (Afinitor)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Advanced hormone receptor-positive (HR: a type of protein), human epidermal growth factor receptor 2 (HER2: a type of protein)-negative breast cancer
   2. Progressive, neuroendocrine tumors (NET: a rare type of tumor) with unresectable (unable to remove by surgery), locally advanced (cancer that has spread from where it started to nearby tissue or lymph nodes) or metastatic disease (cancer that has spread to other parts of the body)
   3. Advanced renal cell carcinoma (RCC: type of kidney cancer)
   4. Tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated renal angiomyolipoma (type of kidney tumor)
   5. Tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated subependymal giant cell astrocytoma (SEGA: a type of brain tumor)

B. **If you have advanced hormone receptor-positive, HER2-negative breast cancer, approval also requires:**
   1. You are a postmenopausal woman
   2. Afinitor will be used in combination with Aromasin (exemestane)
   3. You have failed or have a contraindication (harmful for) to treatment with Femara (letrozole) or Arimidex (anastrozole)

C. **If you have progressive, neuroendocrine tumors (NET) with unresectable, locally advanced or metastatic disease, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. You have neuroendocrine tumors of pancreatic origin (PNET: tumor in the pancreas)
      b. You have well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal (GI: relates to the digestive system) or lung origin

D. **If you have advanced renal cell carcinoma, approval also requires:**
   1. You are 18 years of age or older

E. **If you have tuberous sclerosis complex (TSC)-associated renal angiomyolipoma, approval also requires:**
   1. You are 18 years of age or older
   2. You do not require immediate surgery

(Denial text continued on next page)

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EVEROLIMUS-AFINITOR

GUIDELINES FOR USE (CONTINUED)

F. **If you have tuberous sclerosis complex (TSC)-associated subependymal giant cell astrocytoma, approval also requires:**
   1. You are 1 year of age or older
   2. Your diagnosis requires therapeutic intervention but cannot be curatively resected (completely remove with surgery)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Afinitor.

REFERENCES

- Afinitor/Afinitor Disperz [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. February 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/23
Created: 05/11
Client Approval: 10/21
P&T Approval: 04/18

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FECAL MICROBIOTA CAPSULE

GUIDELINES FOR USE

1. Is the request for the prevention of recurrent *Clostridioides difficile* infection (CDI) **AND** the patient meets the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient previously received Vowst?

   If yes, continue to #4.
   If no, continue to #3.

3. Has the patient completed antibiotic treatment (e.g., vancomycin [Vancocin], fidaxomicin [Dificid]) for recurrent CDI (defined as at least 3 CDI episodes)?

   If yes, **approve for 30 days by HICL or GPI-10 for 1 fill with a quantity limit of #12 per 3 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient meet **ALL** of the following criteria?
   - The patient had treatment failure, defined as the presence of CDI diarrhea within 8 weeks of the first dose of Vowst, AND a positive stool test for *C. difficile*
   - The patient has not previously received more than 1 treatment course of Vowst AND the start of that treatment course was at least 12 days and not more than 8 weeks prior

   If yes, **approve for 30 days by HICL or GPI-10 for 1 fill with a quantity limit of #12 per 3 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FECAL MICROBIOTA CAPSULE

GUIDELINES FOR USE

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FECAL MICROBIOTA CAPSULE (Vowst)** requires the following rule(s) be met for approval:

A. You are using the requested medication for the prevention of recurrent *Clostridioides difficile* (*C. difficile*) infection (CDI: a bacterial infection)
B. You are 18 years of age or older
C. **If you have NOT previously received Vowst, approval also requires:**
   1. You have completed antibiotic (such as vancomycin [Vancocin], fidaxomicin [Dificid]) treatment for recurrent CDI (defined as at least 3 CDI episodes)
D. **If you have been previously treated with Vowst, approval also requires:**
   1. You had treatment failure, defined as the presence of CDI diarrhea within 8 weeks of the first dose of Vowst, AND a positive stool test for *C. difficile*
   2. You have not previously received more than 1 treatment course of Vowst AND the start of that treatment course was at least 12 days and not more than 8 weeks prior

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vowst.

REFERENCES

- Vowst [Prescribing Information]. Cambridge, MA: Seres Therapeutics, Inc.; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/01/23
Created: 05/23
Client Approval: 05/23
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FECAL MICROBIOTA SUSPENSION

GUIDELINES FOR USE

1. Is the request for the prevention of recurrent *Clostridioides difficile* infection (CDI) **AND** the patient meets the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient previously received Rebyota?

   If yes, continue to #4.
   If no, continue to #3.

3. Has the patient completed antibiotic treatment (e.g., vancomycin [Vancocin]) for recurrent CDI (defined as at least 3 CDI episodes) at least 24 hours prior?

   If yes, **approve for 30 days by HICL or GPI-10 for 1 fill with a quantity limit of #150 mL.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient meet **ALL** of the following criteria?
   - The patient had treatment failure, defined as the presence of CDI diarrhea within 8 weeks of first dose of Rebyota AND a positive stool test for *C. difficile*
   - The patient has not previously received more than 1 dose of Rebyota AND that dose was at least 7 days and not more than 8 weeks prior

   If yes, **approve for 30 days by HICL or GPI-10 for 1 fill with a quantity limit of #150 mL.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **FECAL MICROBIOTA SUSPENSION (Rebyota)** requires the following rule(s) be met for approval:
   A. You are using the requested medication for the prevention of recurrent *Clostridioides difficile* (*C. difficile*) infection (CDI: a bacterial infection)
   B. You are 18 years of age or older
   (Denial text continued on next page)

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FECAL MICROBIOTA SUSPENSION

GUIDELINES FOR USE (CONTINUED)

C. **If you have NOT previously received Rebyota, approval also requires:**
   1. You have completed antibiotic (such as vancomycin [Vancocin]) treatment for recurrent CDI (defined as at least 3 CDI episodes) at least 24 hours prior

D. **If you have been previously treated with Rebyota, approval also requires:**
   1. You had treatment failure, defined as the presence of CDI diarrhea within 8 weeks of the first dose of Rebyota AND a positive stool test for *C. difficile*
   2. You have not previously received more than 1 dose of Rebyota AND that dose was at least 7 days and not more than 8 weeks prior

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rebyota.

REFERENCES

- Rebyota [Prescribing Information]. Parsippany, NJ: Ferring Pharmaceuticals, Inc.; November 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/22/23
Created: 02/23
Client Approval: 05/23
P&T Approval: 01/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FEDRATINIB

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to Jakafi (ruxolitinib)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FEDRATINIB (Inrebic)** requires the following rule(s) be met for approval:
   - You have intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (type of bone marrow cancer)
   - You are 18 years of age or older
   - You previously had a trial of or contraindication (medical reason why you cannot use) to Jakafi (ruxolitinib)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FEDRATINIB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient shown symptom improvement by meeting **ONE** of the following criteria?
   - The patient has a spleen volume reduction of 35% or greater from baseline
   - The patient has a 50% or greater reduction in total symptom score (e.g., Myeloproliferative Neoplasm Symptom Assessment Form [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0)
   - The patient has a 50% or greater reduction in palpable spleen length

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FEDRATINIB (Inrebic)** requires the following rule(s) be met for renewal:
   A. You have intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (type of bone marrow cancer)
   B. You have shown symptom improvement by meeting ONE of the following:
      1. You have a spleen volume reduction of 35% or greater from baseline
      2. You have a 50% or greater reduction in total symptom score (such as Myeloproliferative Neoplasm Symptom Assessment Form [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0)
      3. You have a 50% or greater reduction in palpable (can be felt by external examination) spleen length

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FEDRATINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Inrebic.

REFERENCES

3. Inrebic [Prescribing Information]. Summit, NJ: Celgene Corporation; September 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 11/19
Client Approval: 11/21
P&T Approval: 10/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FENFLURAMINE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of seizures associated with Dravet syndrome and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient had a trial of or contraindication to TWO of the following: valproic acid derivative, clobazam, topiramate

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #11.8mL per day.** If no, continue to #2.

2. Does the patient have a diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient had a trial of or contraindication to valproic acid or derivatives
   - The patient had a trial of or contraindication to TWO of the following: Epidiolex, rufinamide, felbamate, clobazam, topiramate, lamotrigine, clonazepam

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #11.8mL per day.** If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FENFLURAMINE (Fintepla)** requires the following rule(s) be met for approval:
   A. You have seizures associated with ONE of the following:
      1. Dravet syndrome (a rare type of seizure)
      2. Lennox-Gastaut syndrome (LGS: a type of seizure disorder in young children)
   B. **If you have Dravet syndrome, approval also requires:**
      1. You are 2 years of age or older
      2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
      3. You had a trial of or contraindication (harmful for) to TWO of the following: valproic acid derivative, clobazam, topiramate

   (Initial denial text continued on next page)

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FENFLURAMINE

INITIAL CRITERIA (CONTINUED)

C. **If you have Lennox-Gastaut syndrome, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or given in consultation with a neurologist (a type of brain doctor)
   3. You had a trial of or contraindication (harmful for) to valproic acid or derivatives
   4. You had a trial of or contraindication (harmful for) to TWO of the following: Epidiolex, rufinamide, felbamate, clobazam, topiramate, lamotrigine, clonazepam

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

NOTE: For the diagnosis of Lennox-Gastaut syndrome (LGS), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of seizures associated with Dravet syndrome **AND** meet the following criterion?
   - The patient has shown continued clinical benefit (e.g., reduction of seizures, reduced length of seizures, seizure control maintained)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #11.8mL per day.** If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FENFLURAMINE (Fintepla)** requires the following rule(s) be met for approval:
   A. You have seizures associated with Dravet syndrome (a rare type of seizure)
   B. You have shown continued clinical benefit (such as reduction of seizures, reduced length of seizures, seizure control maintained) while on therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FENFLURAMINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fintepla.

REFERENCES

- Fintepla [Prescribing Information]. Emeryville, CA: Zogenix, Inc., March 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22

Created: 07/20
Client Approval: 05/22

P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FENTANYL NASAL SPRAY

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cancer?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient on a maintenance dose of controlled release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Avinza or the generic forms of any of these drugs)?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Has the patient tried, or does the patient have a contraindication to at least 1 immediate-release oral pain agent (morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these)?

   If yes, continue to #5.
   If no, continue to #4.

4. Does the patient have difficulty swallowing tablets or capsules?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Has the patient tried, or does the patient have a contraindication to generic fentanyl citrate lozenge?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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FENTANYL NASAL SPRAY

GUIDELINES FOR USE (CONTINUED)

6. Has the patient tried, or does the patient have a contraindication to Abstral, or Fentora?

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #15 per month.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FENTANYL NASAL SPRAY (Lazanda)** requires the following rule(s) to be met for approval:
   A. You have a diagnosis of cancer-related pain
   B. You are currently taking a maintenance dose of a controlled-release pain medication (such as MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Kadian, Avinza or the generic forms of any of these drugs)
   C. You had a trial of an oral immediate-release pain medication (such as morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these), unless you have difficulty swallowing tablets or capsules OR there is a medical reason why you cannot (contraindication)
   D. You had a trial of generic fentanyl citrate lozenge (which also requires a prior authorization), unless there is a medical reason why you cannot (contraindication)
   E. You had a trial of Abstral or Fentora (which also requires a prior authorization), unless there is a medical reason why you cannot (contraindication)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lazanda.

REFERENCES

- Lazanda [Prescribing Information]. Northbrook, IL: West Therapeutic Development, LLC; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 08/11
Client Approval: 04/20
P&T Approval: 11/14

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FENTANYL SUBLINGUAL SPRAY

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cancer?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient on a maintenance dose of controlled release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Avinza or the generic forms of any of these drugs)?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Has the patient tried or does the patient have a contraindication to at least one immediate-release oral pain agent (morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these)?

   If yes, continue to #5.
   If no, continue to #4.

4. Does the patient have difficulty swallowing tablets or capsules?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Has the patient tried or does the patient have a contraindication to generic fentanyl citrate lozenge?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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FENTANYL SUBLINGUAL SPRAY

GUIDELINES FOR USE (CONTINUED)

6. Has the patient tried or does the patient have a contraindication to Abstral or Fentora?

   If yes, **approve for 6 months by GPID or GPI-12 with a quantity limit of #120 per month.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FENTANYL SUBLINGUAL SPRAY (Subsys)** requires the following rule(s) be met for approval:
   A. You have cancer-related pain
   B. You are currently using the requested medication with a controlled-release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Kadian, Avinza or the generic forms of any of these drugs)
   C. You had a trial of an oral immediate-release pain medication (morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these), unless you have difficulty swallowing tablets or capsules OR there is a medical reason why you cannot (contraindication)
   D. You had a trial of generic fentanyl citrate lozenge (which also requires a prior authorization), unless there is a medical reason why you cannot (contraindication)
   E. You had a trial of Abstral or Fentora, all of which may also require a prior authorization, unless there is a medical reason why you cannot (contraindication)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Subsys.

REFERENCES

- Subsys [Prescribing Information]. Chandler, AZ: Insys Therapeutics; November 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 04/12
Client Approval: 04/20
P&T Approval: 11/14

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FENTANYL TRANSDERMAL PATCH

GUIDELINES FOR USE

1. Does the patient meet the definition of opioid tolerance (defined as those who are taking, for one week or longer, at least 60mg oral morphine per day, 25mcg transdermal fentanyl/hour, 30mg oral oxycodone/day, 25mg oral oxymorphone/day, 8mg oral hydromorphone/day, or an equianalgesic dose of another opioid)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the request form indicate that this medication will be used on an "as needed" or “PRN” basis?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #3.

3. Is the request for more than one strength of transdermal fentanyl patch OR does the patient have an active prior authorization(s) for a different strength of fentanyl patch?

   If yes, send to Clinical Pharmacist for review.
   If no, continue to #4.

4. Is the request for every 72 hours dosing?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength(s) with the following quantity limits:**
   - **FOR EVERY 72 HOUR DOSING (12, 25, 37.5, 50, 62.5, 75, 87.5mcg/hr): #10 patches per 30 days.**
   - **FOR 100mcg/hr: up to #20 patches per 30 days.**

   (NOTE: Please override both PA and step therapy [if applicable] restrictions by entering 'Y' for OVR_RES).

   If no, continue to #5.

CONTINUED ON NEXT PAGE

FENTANYL TRANSDERMAL PATCH

GUIDELINES FOR USE (CONTINUED)

5. Is the request for dosing every 48 hours?

   If yes, continue to #6.
   If no, send to Clinical Pharmacist for review.

6. Has the patient tried every 72 hours dosing?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength(s) with the following quantity limits:**
   - **FOR EVERY 48 HOUR DOSING (12, 25, 37.5, 50, 62.5, 75, 87.5mcg/hr): #15 patches per 30 days.**
   - **FOR 100mcg/hr: up to #30 patches per 30 days.**

   (NOTE: Please override both PA and step therapy [if applicable] restrictions by entering 'Y' for OVR_RES).

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FENTANYL TRANSDERMAL PATCH (Duragesic)** requires the following rule(s) be met for approval:
   A. You meet the definition of opioid tolerance. This is defined as those who are taking, for one week or longer, at least 60mg oral morphine per day, 25mcg transdermal fentanyl/hour, 30mg oral oxycodone/day, 25mg oral oxymorphone/day, 8mg oral hydromorphone/day, or an equianalgesic dose (equal pain-relieving dose) of another opioid
   B. The requested medication is not prescribed on an 'as needed' basis
   C. Requests for dosing every 48 hours requires a trial of transdermal (absorbed through the skin) fentanyl patch dosed every 72 hours

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FENTANYL TRANSDERMAL PATCH

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Duragesic.

REFERENCES

- Fentanyl Patch [Prescribing Information]. Morgantown, WV: Mylan Pharmaceuticals, Inc.; March 2015.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 02/03
Client Approval: 04/20
P&T Approval: 07/19

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FENTANYL TRANSMUCOSAL AGENTS

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cancer?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient on a maintenance dose of controlled release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Avinza or the generic forms of any of these drugs)?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Has the patient tried or does the patient have a contraindication to at least one immediate-release oral pain agent (morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these)?

   If yes, continue to #5.
   If no, continue to #4.

4. Does the patient have difficulty swallowing tablets or capsules?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the request for generic fentanyl citrate lozenge?

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength with a quantity limit of #120 per month.**
   If no, continue to #6.

CONTINUED ON NEXT PAGE

FENTANYL TRANSMUCOSAL AGENTS

GUIDELINES FOR USE (CONTINUED)

6. Has the patient tried or does the patient have a contraindication to generic fentanyl citrate lozenge?

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength with a quantity limit of #120 per month.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FENTANYL TRANSMUCOSAL AGENTS (Actiq, Fentora, Abstral)** requires the following rule(s) be met for approval:
   A. You have cancer-related pain
   B. You are currently using the requested medication with a controlled-release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Avinza or the generic forms of any of these drugs)
   C. You had a trial of an oral immediate-release pain medication (such as morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these), unless you have difficulty swallowing tablets or capsules OR there is a medical reason why you cannot (contraindication)
   D. You had a trial of generic fentanyl citrate lozenge (which also requires a prior authorization) unless there is a medical reason why you cannot (contraindication)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Actiq, Fentora, and Abstral.

REFERENCES

- Actiq [Prescribing Information]. North Wales, PA: Cephalon, Inc.; October 2019.
- Fentora [Prescribing Information]. North Wales, PA: Cephalon, Inc.; October 2019.
- Abstral [Prescribing Information]. Solana Beach, CA: Sentynl Therapeutics, Inc.; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 02/03
Client Approval: 04/20
P&T Approval: 11/14

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FERRIC MALTOL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of iron deficiency and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to an OTC oral iron preparation (e.g., ferrous sulfate, ferrous gluconate, ferrous fumarate)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FERRIC MALTOL (Accrufer)** requires the following rule(s) be met for approval:
   A. You have iron deficiency (low iron levels)
   B. You are 18 years of age or older
   C. You had a trial of an over-the-counter (OTC) oral iron preparation (e.g., ferrous sulfate, ferrous gluconate, ferrous fumarate), unless there is a medical reason why you cannot (contraindication)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Accrufer.

REFERENCES

- Accrufer [Prescribing Information]. Bourgoin-Jallieu, France: Patheon., October 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/21
Created:07/21
Client Approval: 08/21
P&T Approval: 07/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FEZOLINETANT

GUIDELINES FOR USE

INITIAL CRITERIA (FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe menopausal vasomotor symptoms (VMS) **AND** meet the following criterion?
   - The patient experiences 7 or more hot flashes per day

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FEZOLINETANT (Veozah)** requires the following rule(s) be met for approval:
   A. You have moderate to severe menopausal vasomotor symptoms (VMS: a type of symptom related to menopause)
   B. You experience 7 or more hot flashes per day

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FEZOLINETANT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe menopausal vasomotor symptoms (VMS) and meet **ALL** of the following criteria?
   - The patient has a continued need for VMS treatment (i.e., persistently symptomatic with hot flashes)
   - The patient had a reduction in VMS frequency OR severity due to Veozah (fezolinetant) treatment

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FEZOLINETANT (Veozah)** requires the following rule(s) be met for renewal:
   A. You have moderate to severe menopausal vasomotor symptoms (VMS: a type of symptom related to menopause)
   B. You have a continued need for VMS treatment (you still experience persistent hot flashes)
   C. You have had a reduction in VMS frequency OR severity due to treatment with Veozah (fezolinetant)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Veozah.

REFERENCES

- Veozah [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc.; May 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 05/23
Client Approval: 11/23
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FILGRASTIM

GUIDELINES FOR USE

1. Does the patient meet **ONE** of the following criteria?
   - The patient has a non-myeloid malignancy and is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
   - The patient has a diagnosis of acute myeloid leukemia (AML) and is undergoing induction or consolidation chemotherapy treatment
   - The patient has a non-myeloid malignancy, is undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT), and is experiencing neutropenia and/or neutropenia-related clinical sequelae (e.g., febrile neutropenia)
   - The requested medication will be used for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
   - The patient has a diagnosis of congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia
   - The requested medication will be used to increase survival in a patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

FILGRASTIM

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FILGRASTIM (Neupogen)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow) and are receiving myelosuppressive anti-cancer drugs (drugs that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever
   2. You have acute myeloid leukemia (AML: a type of blood cancer) and are undergoing induction or consolidation chemotherapy treatment (you are starting therapy so there is no sign of cancer cells or you have therapy to kill any remaining cancer cells in the body)
   3. You have a non-myeloid malignancy (cancer not affecting bone marrow), are undergoing myeloablative chemotherapy (high-dose drugs used to treat cancer) followed by bone marrow transplantation, and are experiencing neutropenia (a type of blood condition) and/or neutropenia-related clinical symptoms (such as febrile neutropenia [a type of blood condition with fever])
   4. You will be using Neupogen for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis (a type of blood cell is stimulated to be collected by a process where it is separated from the blood)
   5. You have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia (low levels of a type of white blood cell at birth, in cycles, or due to unknown cause)
   6. You will be using Neupogen to increase survival if you have been acutely exposed to myelosuppressive doses of radiation (doses that decrease bone marrow activity)
B. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
C. You had a trial of or contraindication (harmful for) to the preferred medication: Nivestym (filgrastim-aafi)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE

FILGRASTIM

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Neupogen.

REFERENCES

- Neupogen [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 08/21
Client Approval: 05/23
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FILGRASTIM-AAFI

GUIDELINES FOR USE

1. Does the patient meet **ONE** of the following criteria?
   - The patient has a non-myeloid malignancy and is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
   - The patient has a diagnosis of acute myeloid leukemia (AML) and is undergoing induction or consolidation chemotherapy treatment
   - The patient has a non-myeloid malignancy, is undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT), and is experiencing neutropenia and/or neutropenia-related clinical sequelae (e.g., febrile neutropenia)
   - The requested medication will be used for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
   - The patient has a diagnosis of congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia
   - The requested medication will be used to increase survival in a patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is therapy prescribed by or in consultation with a hematologist or oncologist?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

FILGRASTIM-AAFI

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FILGRASTIM-AAFI (Nivestym)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow) and are receiving myelosuppressive anti-cancer drugs (drugs that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever
   2. You have acute myeloid leukemia (AML: a type of blood cancer) and are undergoing induction or consolidation chemotherapy treatment (you are starting therapy so there is no sign of cancer cells or you have therapy to kill any remaining cancer cells in the body)
   3. You have a non-myeloid malignancy (cancer not affecting bone marrow), are undergoing myeloablative chemotherapy (high-dose drugs used to treat cancer) followed by bone marrow transplantation, and are experiencing neutropenia (a type of blood condition) and/or neutropenia-related clinical symptoms (such as febrile neutropenia [a type of blood condition with fever])
   4. You will be using Nivestym for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis (a type of blood cell is stimulated to be collected by a process where it is separated from the blood)
   5. You have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia (low amount of a type of white blood cell at birth, in cycles or due to unknown cause)
   6. You will be using Nivestym to increase survival if you have been acutely exposed to myelosuppressive doses of radiation (doses that decrease bone marrow activity)

B. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE

FILGRASTIM-AAFI

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nivestym and Neupogen.

REFERENCES

- Nivestym [Prescribing Information]. Lake Forest, IL: Pfizer; April 2021.
- Neupogen [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 10/22
Client Approval: 05/23
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FILGRASTIM-AYOW

GUIDELINES FOR USE

1. Does the patient meet **ONE** of the following criteria?
   - The patient has a nonmyeloid malignancy and is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
   - The patient has acute myeloid leukemia (AML) and is undergoing induction or consolidation chemotherapy treatment
   - The patient has a nonmyeloid malignancy, is undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT), and is experiencing neutropenia and/or neutropenia-related clinical sequelae (e.g., febrile neutropenia)
   - The requested medication will be used for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
   - The patient has a diagnosis of congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia
   - The requested medication will be used to increase survival in a patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

FILGRASTIM-AYOW

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FILGRASTIM-AYOW (Releuko)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. You have a nonmyeloid malignancy (a type of cancer) and are receiving myelosuppressive anti-cancer drugs (drugs that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever
   2. You have acute myeloid leukemia (AML: a type of blood cancer) and are undergoing induction or consolidation chemotherapy treatment (you are starting therapy so there is no sign of cancer cells or you have therapy to kill any remaining cancer cells in the body)
   3. You have a nonmyeloid malignancy (cancer not affecting bone marrow), are undergoing myeloablative chemotherapy (drugs used to treat cancer) followed by bone marrow transplantation, and are experiencing neutropenia (a type of blood condition) and/or neutropenia-related clinical symptoms (such as febrile neutropenia [a type of blood condition with fever])
   4. You will be using Releuko for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis (a type of blood cell is stimulated to be collected by a process where it is separated from the blood)
   5. You have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia (low amount of a type of white blood cell at birth, in cycles, or due to unknown cause)
   6. You will be using Releuko to increase survival if you have been acutely exposed to myelosuppressive doses of radiation (doses that decrease bone marrow activity)
B. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
C. You had a trial of or contraindication (harmful for) to the preferred medication: Nivestym (filgrastim-aafi)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FILGRASTIM-AYOW

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Releuko and Neupogen.

REFERENCES

- Releuko [Prescribing Information]. Piscataway, NJ: Kashiv BioSciences, LLC; October 2022.
- Neupogen [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 05/22
Client Approval: 05/23
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FILGRASTIM-SNDZ

GUIDELINES FOR USE

1. Does the patient meet **ONE** of the following criteria?
   - The patient has a non-myeloid malignancy and is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
   - The patient has a diagnosis of acute myeloid leukemia (AML) and is undergoing induction or consolidation chemotherapy treatment
   - The patient has a non-myeloid malignancy, is undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT), and is experiencing neutropenia and/or neutropenia-related clinical sequelae (e.g., febrile neutropenia)
   - The requested medication will be used for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
   - The patient has a diagnosis of congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia
   - The requested medication will be used to increase survival in a patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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FILGRASTIM-SNDZ

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FILGRASTIM-SNDZ (Zarxio)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow) and are receiving myelosuppressive anti-cancer drugs (drugs that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever
   2. You have acute myeloid leukemia (AML: a type of blood cancer) and are undergoing induction or consolidation chemotherapy treatment (you are starting therapy so there is no sign of cancer cells or you have therapy to kill any remaining cancer cells in the body)
   3. You have a non-myeloid malignancy (cancer not affecting bone marrow), are undergoing myeloablative chemotherapy (high-dose drugs used to treat cancer) followed by bone marrow transplantation, and are experiencing neutropenia (a type of blood condition) and/or neutropenia-related clinical symptoms (such as febrile neutropenia [a type of blood condition with fever])
   4. You will be using Zarxio for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis (a type of blood cell is stimulated to be collected by a process where it is separated from the blood)
   5. You have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia (low levels of a type of white blood cell at birth, in cycles, or due to unknown cause)
   6. You will be using Zarxio to increase survival if you have been acutely exposed to myelosuppressive doses of radiation (doses that decrease bone marrow activity)

B. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

C. You had a trial of or contraindication (harmful for) to the preferred medication: Nivestym (filgrastim-aafi)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FILGRASTIM-SNDZ

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zarxio and Neupogen.

REFERENCES

- Zarxio [Prescribing Information]. Princeton, NJ: Sandoz Inc.; March 2021.
- Neupogen [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 10/22
Client Approval: 05/23
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FINASTERIDE-TADALAFIL

GUIDELINES FOR USE

1. Has the patient received a 26-week course of Entadfi?

   If yes, do no approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #2.

2. Is the request for a male patient with a diagnosis of benign prostatic hyperplasia (BPH) who meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to TWO alpha blockers (e.g., terazosin, doxazosin, tamsulosin)
   - The patient had a trial of or contraindication to ONE 5-alpha-reductase inhibitor (e.g., finasteride, dutasteride)
   - The patient had a trial of or contraindication to tadalafil 2.5 mg or tadalafil 5 mg

   If yes, **approve for 26 weeks by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **FINASTERIDE-TADALAFIL (Entadfi)** requires the following rule(s) be met for approval:
   A. You are male and have benign prostatic hyperplasia (BPH: a type of prostate condition)
   B. You are 18 years of age or older
   C. You had a trial of or contraindication (harmful for) to TWO alpha blockers (such as terazosin, doxazosin, tamsulosin)
   D. You had a trial of or contraindication (harmful for) to ONE 5-alpha-reductase inhibitor (such as finasteride, dutasteride)
   E. You had a trial of or contraindication (harmful for) to tadalafil 2.5 mg or tadalafil 5 mg

   Requests will not be approved if you have received a 26-week course of Entadfi.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FINASTERIDE-TADALAFIL

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Entadfi.

REFERENCES

- Entadfi [Prescribing Information]. Miami, FL: Veru, Inc.; December 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/29/22
Created: 08/22
Client Approval: 08/22
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FINERENONE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to **BOTH** of the following:
     - A sodium-glucose cotransport-2 (SGLT2) inhibitor (e.g., Farxiga, Invokana, Jardiance, Steglatro)
     - Spironolactone OR eplerenone

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FINERENONE (Kerendia)** requires the following rule(s) be met for approval:
   A. You have chronic kidney disease (CKD) associated with type 2 diabetes (T2D)
   B. You are 18 years of age or older
   C. You had a trial of or contraindication to (medical reason why you cannot use) BOTH of the following:
      1. A sodium-glucose cotransport-2 (SGLT2) inhibitor (such as Farxiga, Invokana, Jardiance, Steglatro)
      2. Spironolactone OR eplerenone

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FINERENONE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kerendia.

REFERENCES

- Kerendia [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc., July 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/01/23

Created: 07/21
Client Approval: 03/23

P&T Approval: 04/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FINGOLIMOD

GUIDELINES FOR USE

1. Does the patient have the diagnosis of a relapsing form of multiple sclerosis to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease **AND** meet the following criterion?
   - The patient is 10 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have **ANY** of the following contraindications to Gilenya?
   - A recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure
   - A history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a functioning pacemaker
   - A baseline QTC interval 500 msec or above
   - Current treatment with Class Ia (quinidine, procainamide, or disopyramide) or Class III anti-arrhythmic drugs (amiodarone, dofetilide, dronedarone, ibutilide, or sotalol)

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**

DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **FINGOLIMOD (Gilenya)** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (immune system eats away at protective covering of nerves and you have new or increasing symptoms), to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease
B. You are 10 years of age or older.
C. You do not have any of the following contraindications (medical reason why you cannot use) to Gilenya:
   1. A recent (within past 6 months) occurrence of myocardial infarction (heart attack), unstable angina (chest pain), stroke, transient ischemic attack (short stroke-like attack), decompensated heart failure requiring hospitalization, or Class III/IV heart failure

(Denial text continued on next page)

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FINGOLIMOD

GUIDELINES FOR USE (CONTINUED)

2. A history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome (types of irregular heartbeats), unless you have a functioning pacemaker
3. A baseline QTC interval 500 msec or above (a measure of the speed of electrical conduction in the heart)
4. Current treatment with Class Ia (quinidine, procainamide, or disopyramide) or Class III anti-arrhythmic drugs (amiodarone, dofetilide, dronedarone, ibutilide, or sotalol)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gilenya.

REFERENCES

- Gilenya [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceutical Corporation; December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 11/10
Client Approval: 04/20
P&T Approval: 07/18

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FINGOLIMOD LAURYL SULFATE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease, and meet **ALL** of the following criteria?
   - The patient is 10 years of age or older
   - The patient had a trial of fingolimod capsules
   - The patient is unable to swallow fingolimod capsules
   - The patient had a trial of or contraindication to ONE agent indicated for the treatment of MS

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have **ANY** of the following contraindications to Tascenso ODT?
   - A recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure
   - A history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a functioning pacemaker
   - A baseline QTc interval of 500 msec or greater
   - Current treatment with Class Ia (quinidine, procainamide, or disopyramide) or Class III anti-arrhythmic drugs (amiodarone, dofetilide, dronedarone, ibutilide, or sotalol)

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**

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FINGOLIMOD LAURYL SULFATE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FINGOLIMOD LAURYL SULFATE (Tascenso ODT)** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (a type of nerve disorder), to include clinically isolated syndrome (a type of nerve disorder that occurs once), relapsing-remitting disease (symptoms or disease returns and goes away) and active secondary progressive disease (advanced disease)
B. You are 10 years of age or older
C. You had a trial of fingolimod capsules
D. You are unable to swallow fingolimod capsules
E. You had a trial of or contraindication (harmful for) to one other agent indicated for the treatment of multiple sclerosis
F. You do not have any of the following contraindications (harmful for) to Tascenso ODT:
    1. A recent (within past 6 months) occurrence of myocardial infarction (heart attack), unstable angina (chest pain), stroke, transient ischemic attack (short stroke-like attack), decompensated heart failure requiring hospitalization, or Class III/IV heart failure
    2. A history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome (types of irregular heartbeats), unless you have a functioning pacemaker
    3. A baseline QTc interval of 500 msec or greater (a measure of the speed of electrical conduction in the heart)
    4. Current treatment with Class Ia (quinidine, procainamide, or disopyramide) or Class III anti-arrhythmic drugs (amiodarone, dofetilide, dronedarone, ibutilide, or sotalol)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FINGOLIMOD LAURYL SULFATE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tascenso ODT.

REFERENCES

- Tascenso ODT [Prescribing Information]. San Jose, CA: Handa Neuroscience, LLC; December 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/16/23
Created: 11/22
Client Approval: 12/22
P&T Approval: 10/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FLIBANSERIN

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

1. Is Addyi (flibanserin) a covered benefit?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) (also referred to as female sexual interest/arousal disorder [FSIAD] per DSM-5), as defined by **ALL** of the following criteria?
   - Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
   - HSDD is not a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
   - HSDD symptom cause marked distress or interpersonal difficulty

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Have **ALL** of the following criteria been met?
   - The patient is a premenopausal female
   - The patient is 18 years of age or older
   - The patient had a previous trial of or contraindication to bupropion
   - The patient is not currently using Vyleesi (bremelanotide)

   If yes, **approve for 8 weeks by HICL or GPI-10 with a quantity limit of #1 tablet per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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FLIBANSERIN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FLIBANSERIN (Addyi)** requires the following rule(s) be met for approval:

A. You have acquired, generalized hypoactive sexual desire disorder (HSDD; lack or absence of sexual desire). This is also referred to as female sexual interest/arousal disorder per DSM-5 (a diagnostic tool for mental disorders), as defined by **ALL** of the following criteria:
   1. Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
   2. Hypoactive sexual desire disorder is not a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
   3. Hypoactive sexual desire disorder symptom causes marked distress or interpersonal difficulty

B. You are a premenopausal female

C. You are 18 years of age or older

D. You previously had a trial of bupropion, unless there is a medical reason why you cannot (contraindication)

E. You are not currently using Vyleesi (bremelanotide)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) (also referred to as female sexual interest/arousal disorder [FSIAD] per DSM-5), as defined by **ALL** of the following criteria?
   - Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
   - HSDD is not a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
   - HSDD symptom cause marked distress or interpersonal difficulty

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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FLIBANSERIN

RENEWAL CRITERIA (CONTINUED)

2. Does the patient meet **ALL** of the following criteria?
   - The patient is a premenopausal female
   - The patient is not currently using Vyleesi
   - The patient has demonstrated continued improvement in symptoms of HSDD/FSIAD (e.g., increased sexual desire, lessened distress)?

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 tablet per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline for **FLIBANSERIN (Addyi)** requires the following rule(s) be met for renewal:
   A. You have acquired, generalized hypoactive sexual desire disorder (HSDD; lack or absence of sexual desire). This is also referred to as female sexual interest/arousal disorder per DSM-5 (a diagnostic tool for mental disorders), as defined by **ALL** of the following criteria:
      1. Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
      2. Hypoactive sexual desire disorder is not a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
      3. Hypoactive sexual desire disorder symptom causes marked distress or interpersonal difficulty
   B. You are a premenopausal female
   C. You are 18 years of age or older
   D. You are not currently using Vyleesi (bremelanotide)
   E. You have demonstrated continued improvement in symptoms of hypoactive sexual desire disorder/female sexual interest and arousal disorder (such as increased sexual desire, lessened distress)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FLIBANSERIN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Addyi.

REFERENCES

- Addyi [Prescribing Information]. Raleigh, NC: Sprout Pharmaceuticals, Inc.; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 09/15
Client Approval: 04/20
P&T Approval: 07/19

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FLUOROURACIL CREAM

**** Please use the criteria for the specific drug requested ****

GUIDELINE FOR USE

CARAC

1. Does the patient have a diagnosis of actinic or solar keratosis of the face and anterior scalp **AND** meet the following criterion?
   - The patient had a trial of **TWO** generic topical agents indicated for AK (e.g., fluorouracil, imiquimod, diclofenac 3%)

   If yes, **approve for 1 month by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **FLUOROURACIL CREAM (Carac)** requires the following rule(s) be met for approval:
   A. You have actinic or solar keratosis (AK: rough, scaly patch on the skin caused by years of sun exposure) of the face and anterior (front) scalp
   B. You have previously tried TWO generic topical (applied to skin) agents for AK (such as fluorouracil, imiquimod, diclofenac 3%)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

FLUOROPLEX

1. Does the patient have a diagnosis of actinic or solar keratosis **AND** meet the following criterion?
   - The patient had a trial of **TWO** generic topical agents indicated for AK (e.g., fluorouracil, imiquimod, diclofenac 3%)

   If yes, **approve for 1 month by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FLUOROURACIL CREAM

GUIDELINES FOR USE (CONTINUED) - FLUOROPLEX

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FLUOROURACIL CREAM (Fluoroplex)** requires the following rule(s) be met for approval:

A. You have actinic or solar keratosis (AK: rough, scaly patch on the skin caused by years of sun exposure)
B. You have previously tried TWO generic topical (applied to skin) agents for AK (such as fluorouracil, imiquimod, diclofenac 3%)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Carac or Fluoroplex.

REFERENCES

- Carac [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC.; May 2017.
- Fluoroplex [Prescribing Information]. Exton, PA: Almirall, LLC.; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/21
Created: 08/18
Client Approval: 08/21
P&T Approval: 04/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FOSDENOPTERIN

GUIDELINES FOR USE

1. Does the patient have a diagnosis of molybdenum cofactor deficiency (MoCD) Type A?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FOSDENOPTERIN (Nulibry)** requires the following rule(s) be met for approval:
   A. You have molybdenum cofactor deficiency (MoCD) Type A (rare condition characterized by brain dysfunction)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nulibry.

REFERENCES

- Nulibry [Prescribing Information]. Boston, MA: Origin Biosciences, Inc.; February 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/21
Created: 05/21
Client Approval: 05/21
P&T Approval: 04/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FOSTAMATINIB

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic immune thrombocytopenia (cITP) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a hematologist or immunologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the patient received splenectomy?

   If yes, **approve for 3 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   APPROVAL TEXT: Renewal requires clinically significant prevention of bleeds while on therapy, attainment of platelet levels of 50-450 x 10^9/L, and proof of normal LFTs (liver function tests), total bilirubin, and ANC (absolute neutrophil count).

   If no, continue to #3.

3. Has the patient had a previous trial of or contraindication to **TWO** of the following treatments?
   - Corticosteroids
   - IVIG (intravenous immunoglobulin)
   - Rhogam
   - Rituxan (rituximab)
   - Thrombopoietin receptor agonist (i.e., Promacta (eltrombopag), Nplate (romiplostim))

   If yes, **approve for 3 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   APPROVAL TEXT: Renewal requires clinically significant prevention of bleeds while on therapy, attainment of platelet levels of 50-450 x 10^9/L, and proof of normal LFTs (liver function tests), total bilirubin, and ANC (absolute neutrophil count).

   If no, do not approve.
   DENIAL TEXT: See the initial denial text on the next page.

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FOSTAMATINIB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FOSTAMATINIB (Tavalisse)** requires the following rule(s) be met for approval:

A. You have chronic immune thrombocytopenia (cITP; Low levels of the blood cells that prevent bleeding)
B. You are 18 years of age or older
C. The requested medication is prescribed by or given in consultation with a hematologist (blood specialist) or immunologist (allergy/immune system doctor)
D. You had a splenectomy (surgical removal of spleen) **OR** a previous trial of or contraindication to (medical reason why you cannot use) at least **TWO** of the following treatments:
    1. Corticosteroids
    2. IVIG (intravenous immunoglobulin)
    3. Rhogam
    4. Rituxan (rituximab)
    5. Thrombopoietin receptor agonist such as Promacta (eltrombopag), Nplate (romiplostim)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic immune thrombocytopenia (cITP) and meet **ALL** of the following criteria?
    - The patient has had clinically significant prevention of bleeds while on therapy
    - The patient's AST and ALT levels have remained under 3 times the upper limits of normal per reference range
    - The patient's total bilirubin level has remained under 2 times the upper limits of normal per reference range
    - The patient's ANC has remained within normal limits per reference range
    - The patient's platelets have attained a level between 50 and 450 x 10^9/L

    If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
    If no, do not approve.
    DENIAL TEXT: See the renewal denial text at the end of the guideline on the next page.

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FOSTAMATINIB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FOSTAMATINIB (Tavalisse)** requires the following rule(s) be met for renewal:

A. You have chronic immune thrombocytopenia (cITP; Low levels of the blood cells that prevent bleeding)
B. You had clinically significant prevention of bleeds while on therapy
C. Your AST (aspartate transaminase) and ALT (alanine transaminase) levels (types of liver enzymes) have remained under 3 times the upper limits of normal per reference range
D. Your total bilirubin level has remained under 2 times the upper limits of normal per reference range
E. Your absolute neutrophil count (ANC; a measure of the number of neutrophils which are a type of white blood cell) has remained within normal limits per reference range
F. Your platelets have reached a level between 50 and 450 x 10(9)/L

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tavalisse.

REFERENCES

- Tavalisse [Prescribing Information]. South San Francisco, CA. Rigel Pharmaceuticals, Inc. April 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 08/18
Client Approval: 04/20
P&T Approval: 07/19

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FOSTEMSAVIR

GUIDELINES FOR USE

1. Does the patient have a diagnosis of human immunodeficiency virus type 1 (HIV-1) infection and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used in combination with other antiretroviral(s)
   - The patient is treatment experienced
   - The patient has multidrug-resistant HIV-1 infection
   - The patient is failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FOSTEMSAVIR (Rukobia)** requires the following rule(s) be met for approval:
   A. You have human immunodeficiency virus type 1 (HIV-1) infection (a virus that attacks the body's immune system and if untreated, can lead to AIDS [acquired immunodeficiency syndrome])
   B. You are 18 years of age or older
   C. The requested medication will be used in combination with other antiretroviral(s) (class of medication used to treat HIV)
   D. You are treatment experienced (previously treated)
   E. You have multidrug-resistant HIV-1 infection (your virus is resistant to more than one HIV medication)
   F. You are failing your current antiretroviral regimen due to resistance, intolerance, or safety considerations

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FOSTEMSAVIR

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rukobia.

REFERENCES

- Rukobia [Prescribing Information]. Research Triangle Park, NC: GlaxoSmithKline; July 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective:08/01/20
Created: 07/20
Client Approval: 07/20
P&T Approval:07/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FREMANEZUMAB-VFRM

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of episodic migraines and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Ajovy is prescribed for the preventive treatment of migraines
   - Ajovy will NOT be used concurrently with other CGRP inhibitors (e.g., Aimovig, Emgality, Vyepti, Nurtec ODT, Qulipta) for migraine prevention
   - The patient had a trial of ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol
   - The patient had a trial of TWO of the following preferred agents: Aimovig, Emgality, Nurtec ODT, Qulipta

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1.5mL per 30 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of chronic migraines and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Ajovy is prescribed for the preventive treatment of migraines
   - Ajovy will NOT be used concurrently with other CGRP inhibitors (e.g., Aimovig, Emgality, Vyepti, Nurtec ODT, Qulipta) for migraine prevention
   - The patient had a trial of ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox **[Note: For Botox, previous trial of only NDCs # 00023-1145-01 or 00023-3921-02 are allowable]**
   - The patient had a trial of TWO of the following preferred agents: Aimovig, Emgality, Nurtec ODT, Qulipta

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1.5mL per 30 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline

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FREMANEZUMAB-VFRM

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FREMANEZUMAB-VFRM (Ajovy)** requires the following rule(s) be met for approval:

A. You have migraines
B. **If you have episodic migraines (0-14 headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Ajovy is prescribed for the preventive treatment of migraines
   3. You will NOT use Ajovy concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Aimovig, Emgality, Vyepti, Nurtec ODT, Qulipta) for migraine prevention
   4. You have tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol
   5. You have tried TWO of the following: Aimovig, Emgality, Nurtec ODT, Qulipta
C. **If you have chronic migraines (15 or more headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Ajovy is prescribed for the preventive treatment of migraines
   3. You will NOT use Ajovy concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Aimovig, Emgality, Vyepti, Nurtec ODT, Qulipta) for migraine prevention
   4. You have tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox [**Note:** For Botox, previous trial of only NDCs 00023-1145-01 or 00023-3921-02 are allowable]
   5. You have tried TWO of the following: Aimovig, Emgality, Nurtec ODT, Qulipta

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FREMANEZUMAB-VFRM

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Is Ajovy being prescribed for the preventive treatment of migraines **AND** does the patient meet the following criterion?
   - Ajovy will NOT be used concurrently with other CGRP inhibitors (e.g., Aimovig, Emgality, Vyepti, Nurtec ODT, Qulipta) for migraine prevention

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month with Ajovy therapy
   - The patient has experienced a reduction in migraine severity with Ajovy therapy
   - The patient has experienced a reduction in migraine duration with Ajovy therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1.5mL per 30 days.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **FREMANEZUMAB-VFRM (Ajovy)** requires the following rule(s) be met for renewal:
   A. Ajovy is prescribed for the preventive treatment of migraines
   B. You will NOT use Ajovy concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Amovig, Emgality, Vyepti, Nurtec ODT, Qulipta) for migraine prevention
   C. You meet ONE of the following:
      1. You have experienced a reduction in migraine or headache frequency of at least 2 days per month with Ajovy therapy
      2. You have experienced a reduction in migraine severity with Ajovy therapy
      3. You have experienced a reduction in migraine duration with Ajovy therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FREMANEZUMAB-VFRM

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ajovy.

REFERENCES

- Ajovy [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; September 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 09/18
Client Approval: 02/22
P&T Approval: 01/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FRUQUINTINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (e.g., FOLFOX, FOLFIRI, CapeOx)
   - The patient has received previous treatment with an anti-VEGF therapy (e.g., Zaltrap [ziv-aflibercept], Cyramza [ramucirumab])

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **1mg: #84 per 28 days.**
   - **5mg: #21 per 28 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FRUQUINTINIB (Fruzaqla)** requires the following rule(s) be met for approval:
   A. You have metastatic colorectal cancer (mCRC: a type of digestive system cancer that has spread to other parts of the body)
   B. You are 18 years of age or older
   C. You had previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (such as FOLFOX, FOLFIRI, CapeOx)
   D. You had previous treatment with an anti-VEGF therapy (such as Zaltrap [ziv-aflibercept], Cyramza [ramucirumab])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FRUQUINTINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fruzaqla.

REFERENCES

- Fruzaqla [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; November 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 11/23
Client Approval: 11/23
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FUTIBATINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma (iCCA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has been previously treated for unresectable, locally advanced or metastatic iCCA
   - The patient has fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements
   - The patient will complete a comprehensive ophthalmological examination, including optical coherence tomography (OCT), prior to the initiation of Lytgobi and at the recommended scheduled intervals

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #5 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FUTIBATINIB (Lytgobi)** requires the following rule(s) be met for approval:
   A. You have unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma (iCCA) (a type of bile duct cancer inside the liver that is unable to be removed by surgery, has spread from where it started to nearby tissue/lymph nodes or to other parts of the body)
   B. You are 18 years of age or older
   C. You have been previously treated for unresectable, locally advanced or metastatic iCCA
   D. You have fibroblast growth factor receptor 2 (FGFR2: a type of protein) gene fusions or other rearrangements
   E. You will complete a comprehensive ophthalmological examination (eye exam), including optical coherence tomography (OCT: a type of eye imaging test), before starting Lytgobi and at the recommended scheduled times

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FUTIBATINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lytgobi.

REFERENCES

- Lytgobi [Prescribing Information]. Princeton, NJ: Taiho Pharmaceutical Co., Ltd., September 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/14/22
Created: 11/22
Client Approval: 11/22
P&T Approval: 10/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GALCANEZUMAB-GNLM

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of episodic migraines and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Emgality is prescribed for the preventive treatment of migraines
   - Emgality will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine prevention
   - The patient had a trial of ONE of the following preventive migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol

   If yes, **approve for a total of 6 months by entering TWO approvals as follows:**
   - **FIRST APPROVAL: approve for 1 month by GPID or GPI-14 for the requested Emgality 120mg/mL formulation with a quantity limit of #2mL per 30 days.**
   - **SECOND APPROVAL: approve for 5 months by GPID or GPI-14 for the requested Emgality 120mg/mL formulation with a quantity limit of #1mL per 30 days. (Please enter a start date of 23 days AFTER the start date of the first approval).**

   If no, continue to #2.

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GALCANEZUMAB-GNLM

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of chronic migraines and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Emgality is prescribed for the preventive treatment of migraines
   - Emgality will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine prevention
   - The patient had a trial of ONE of the following preventive migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox [**Note**: For Botox, previous trial of only NDCs 00023-1145-01 or 00023-3921-02 are allowable]

   If yes, **approve for a total of 6 months by entering TWO approvals as follows:**
   - **FIRST APPROVAL: approve for 1 month by GPID or GPI-14 for the requested Emgality 120mg/mL formulation with a quantity limit of #2mL per 30 days.**
   - **SECOND APPROVAL: approve for 5 months by GPID or GPI-14 for the requested Emgality 120mg/mL formulation with a quantity limit of #1mL per 30 days. (Please enter a start date of 23 days AFTER the start date of the first approval).**

   If no, continue to #3.

3. Is the request for the treatment of episodic cluster headache **AND** does the patient meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 3 months by GPID or GPI-14 for Emgality 100mg/mL with a quantity limit of #3mL per 30 days.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GALCANEZUMAB-GNLM (Emgality)** requires the following rule(s) be met for approval:
   A. You have migraines or episodic cluster headaches (very painful headaches that occur in patterns)

(Initial denial text continued on next page)

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GALCANEZUMAB-GNLM

INITIAL CRITERIA (CONTINUED)

B. **If you have episodic migraines (0-14 headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Emgality is prescribed for the preventive treatment of migraines
   3. You will NOT use Emgality concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine prevention
   4. You have tried ONE of the following preventive migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol

C. **If you have chronic migraines (15 or more headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Emgality is prescribed for the preventive treatment of migraines
   3. You will NOT use Emgality concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine prevention
   4. You have tried ONE of the following preventive migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox [**Note**: For Botox, previous trial of only NDCs 00023-1145-01 or 00023-3921-02 are allowable]

D. **If you have episodic cluster headaches, approval also requires:**
   1. You are 18 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GALCANEZUMAB-GNLM

RENEWAL CRITERIA

1. Is Emgality prescribed for the preventive treatment of migraines **AND** does the patient meet the following criterion?
   - Emgality will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine prevention

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month with Emgality therapy
   - The patient has experienced a reduction in migraine severity with Emgality therapy
   - The patient has experienced a reduction in migraine duration with Emgality therapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested Emgality 120mg/mL formulation with a quantity limit of #1mL per 30 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Is Emgality prescribed for the treatment of episodic cluster headache **AND** does the patient meet the following criterion?
   - The patient had improvement in episodic cluster headache frequency as compared to baseline

   If yes, **approve for 12 months by GPID or GPI-14 for Emgality 100mg/mL with a quantity limit of #3mL per 30 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **GALCANEZUMAB-GNLM (Emgality)** requires the following rule(s) be met for renewal:
   A. Emgality is being prescribed for preventive treatment of migraines OR for the treatment of episodic cluster headache (very painful headaches that occur in patterns)
   (Renewal denial text continued on next page)

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GALCANEZUMAB-GNLM

RENEWAL CRITERIA (CONTINUED)

B. **If you have migraines, renewal also requires:**
   1. You will NOT use Emgality concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine prevention
   2. You meet ONE of the following:
      a. You have experienced a reduction in migraine or headache frequency of at least 2 days per month with Emgality therapy
      b. You have experienced a reduction in migraine severity with Emgality therapy
      c. You have experienced a reduction in migraine duration with Emgality therapy

C. **If you have episodic cluster headaches, renewal also requires:**
   1. You had improvement in episodic cluster headache frequency as compared to baseline

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing information and/or Drug Monograph for Emgality.

REFERENCES

- Emgality [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; May 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/15/24
Created: 10/18
Client Approval: 03/24
P&T Approval: 01/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GANAXOLONE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of seizures and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient's seizures are associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #36 mL per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GANAXOLONE (Ztalmy)** requires the following rule(s) be met for approval:
   A. You have seizures
   B. You are 2 years of age or older
   C. Your seizures are associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD: a type of genetic disorder)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ztalmy.

REFERENCES

- Ztalmy [Prescribing Information]. Radnor, PA: Marinus Pharmaceuticals, Inc.; June 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/22
Created: 08/22
Client Approval: 09/22
P&T Approval: 07/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GEFITINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient has tumors with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test
   - Iressa (gefitinib) will NOT be used concurrently with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (e.g., Tarceva [erlotinib], Tagrisso [osimertinib], Gilotrif [afatinib], Vizimpro [dacomitinib])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GEFITINIB (Iressa)** requires the following rule(s) be met for approval:
   A. You have metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
   B. Your tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations (abnormal changes in a gene) as detected by an FDA (Food and Drug Administration)-approved test
   C. You will NOT be using Iressa (gefitinib) concurrently (at the same time) with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (such as Tarceva [erlotinib], Tagrisso [osimertinib], Gilotrif [afatinib], Vizimpro [dacomitinib])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Iressa.

REFERENCES

- Iressa [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals; February 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/22/23
Created: 07/15
Client Approval: 05/23
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GILTERITINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory acute myeloid leukemia (AML) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GILTERITINIB (Xospata)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory acute myeloid leukemia (AML: type of white blood cell cancer)
   B. You are 18 years of age or older
   C. You have FMS-like tyrosine kinase 3 (type of gene) mutation (change in the DNA gene) as detected by a Food and Drug Administration-approved test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xospata.

REFERENCES

- Xospata [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc.; November 2018

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 03/19
Client Approval: 03/21
P&T Approval: 01/19

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLASDEGIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of newly-diagnosed acute myeloid leukemia (AML) **AND** meet the following criterion?
   - The requested medication will be used in combination with low-dose cytarabine

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient is 75 years of age or older
   - The patient has comorbidities that prevent use of intensive induction chemotherapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with a quantity limit as follows:**
   - **Daurismo 25mg: #2 per day.**
   - **Daurismo 100mg: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GLASDEGIB (Daurismo)** requires the following rule(s) be met for approval:
   A. You have newly-diagnosed acute myeloid leukemia (AML: type of white blood cell cancer)
   B. The requested medication will be used in combination with low-dose cytarabine
   C. You are 75 years of age or older, **OR** you have comorbidities (having more than one disease) that prevents the use of intensive induction chemotherapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLASDEGIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Daurismo.

REFERENCES

- Daurismo [Prescribing Information]. New York, NY: Pfizer Inc.; November 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 01/19
Client Approval: 04/20
P&T Approval: 01/19

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLATIRAMER ACETATE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **20mg/mL: #1mL per day.**
   - **40mg/mL: #12mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GLATIRAMER ACETATE (Copaxone, Glatopa)** requires the following rule(s) be met for approval:
   1. You have a relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
   2. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLATIRAMER ACETATE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Copaxone and Glatopa.

REFERENCES

- Copaxone [Prescribing Information]. Overland Park, KS: Teva; January 2020.
- Glatopa [Prescribing Information]. Princeton, NJ: Sandoz Inc.; January 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21

Created: 02/14
Client Approval: 11/20

P&T Approval: 02/14

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C, genotype 1, 2, 3, 4, 5, or 6 **AND** meet the following criterion?
   - The patient is 3 years of age or older

   If yes, continue to #2.
   If no, continue to #15.

2. Does the patient have an HCV RNA level within the past 6 months?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ANY** of the following criteria?
   - The patient has moderate or severe liver impairment (decompensated cirrhosis: Child-Pugh B or C)
   - Mavyret will be used concurrently with any of the following medications: rifampin, atazanavir, carbamazepine, efavirenz, darunavir, lopinavir, ritonavir, atorvastatin, lovastatin, simvastatin, rosuvastatin (at doses greater than 10mg), cyclosporine (for patients requiring stable cyclosporine doses greater than 100mg/day), medications containing ethinyl estradiol, Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Vosevi (velpatasvir/sofosbuvir/voxilaprevir), or Zepatier (elbasvir/grazoprevir)
   - The patient has prior failure of a direct-acting antiviral (DAA) regimen that contains an NS5A inhibitor AND a NS3/4A protease inhibitor (e.g., Viekira Pak [ombitasvir/paritaprevir/ritonavir/dasabuvir], Viekira XR [ombitasvir/paritaprevir/ritonavir/dasabuvir extended release], Technivie [ombitasvir/paritaprevir/ritonavir], Vosevi [sofosbuvir/velpatasvir/voxilaprevir], Zepatier [elbasvir/grazoprevir]), or previous concurrent treatments containing an NS5A inhibitor AND NS3/4A protease inhibitor
   - The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #4.

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GUIDELINES FOR USE (CONTINUED)

4. Is the patient treatment experienced and meet **ALL** of the following criteria?
   - The patient is 12 to 17 years of age OR weighs at least 45 kg
   - The patient has genotype 1, 2, 4, 5, or 6
   - The patient does not have cirrhosis
   - The patient had prior exposure to an interferon-based regimen and/or Sovaldi (sofosbuvir)
   - The patient had NO exposure to NS3/4A protease inhibitors (e.g., simeprevir [Olysio], Zepatier [elbasvir/grazoprevir]) or NS5A inhibitors (e.g., Epclusa [velpatasvir/sofosbuvir], Harvoni [ledipasvir/sofosbuvir])

   If yes, **approve for 8 weeks for the requested strength by GPID or GPI-14 as follows:**
   - **100mg-40mg tablet: #3 per day.**
   - **50mg-20mg pellets: #5 per day.**

   If no, continue to #5.

5. Is the patient treatment experienced and meet **ALL** of the following criteria?
   - The patient is less than 18 years of age
   - The patient has genotype 1, 2, 4, 5, or 6
   - The patient has compensated cirrhosis
   - The patient had prior exposure to an interferon-based regimen and/or Sovaldi (sofosbuvir)
   - The patient had NO exposure to NS3/4A protease inhibitors (e.g., simeprevir [Olysio], Zepatier [elbasvir/grazoprevir]) or NS5A inhibitors (e.g., Epclusa [velpatasvir/sofosbuvir], Harvoni [ledipasvir/sofosbuvir])

   If yes, **approve for 12 weeks for the requested strength by GPID or GPI-14 as follows:**
   - **100mg-40mg tablet: #3 per day.**
   - **50mg-20mg pellets: #5 per day.**

   If no, continue to #6.

6. Is the patient treatment experienced and meet **ALL** of the following criteria?
   - The patient is less than 18 years of age
   - The patient had prior exposure to an NS3/4A protease inhibitor (e.g., simeprevir [Olysio], Zepatier [elbasvir/grazoprevir]) but NO exposure to NS5A inhibitors (e.g., Epclusa [velpatasvir/sofosbuvir], Harvoni [ledipasvir/sofosbuvir])

   If yes, **approve for 12 weeks for the requested strength by GPID or GPI-14 as follows:**
   - **100mg-40mg tablet: #3 per day.**
   - **50mg-20mg pellets: #5 per day.**

   If no, continue to #7.

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

7. Is the patient treatment experienced and meet **ALL** of the following criteria?
   - The patient is less than 18 years of age
   - The patient has genotype 3
   - The patient had exposure to an interferon-based regimen and/or Sovaldi (sofosbuvir)
   - The patient had NO exposure to NS3/4A protease inhibitors (e.g., simeprevir [Olysio], Zepatier [elbasvir/grazoprevir]) or NS5A inhibitors (e.g., Epclusa [velpatasvir/sofosbuvir], Harvoni [ledipasvir/sofosbuvir])

   If yes, **approve for 16 weeks for the requested strength by GPID or GPI-14 as follows:**
   - **100mg-40mg tablet: #3 per day.**
   - **50mg-20mg pellets: #5 per day.**

   If no, continue to #8.

8. Does the patient have a genotype 1, 4, 5, or 6 infection and meet **ONE** of the following criteria?
   - The patient has a contraindication to Epclusa AND Harvoni
   - The patient has failed a short trial of Epclusa or Harvoni (e.g., inability to tolerate, had adverse effect during therapy)

   If yes, continue to #10.
   If no, continue to #9.

9. Does the patient have a genotype 2 or 3 infection and meet **ONE** of the following criteria?
   - The patient has a contraindication to Epclusa
   - The patient has failed a short trial of Epclusa (e.g., inability to tolerate, had adverse effect during therapy)

   If yes, continue to #10.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

10. Is the patient treatment naive and meet **ONE** of the following criteria?
    - The patient is post-liver transplant
    - The patient is post-kidney transplant

    If yes, **approve for 12 weeks for the requested strength by GPID or GPI-14 as follows:**
    - **100mg-40mg tablet: #3 per day.**
    - **50mg-20mg pellets: #5 per day.**

    If no, continue to #11.

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

11. Is the patient treatment naive and meet **ONE** of the following criteria?
    - The patient does not have cirrhosis
    - The patient has compensated cirrhosis (Child-Pugh A)

    If yes, **approve for 8 weeks for the requested strength by GPID or GPI-14 as follows:**
    - **100mg-40mg tablet: #3 per day.**
    - **50mg-20mg pellets: #5 per day.**

    If no, continue to #12.

12. Is the patient treatment experienced and meet **ALL** of the following criteria?
    - The patient is less than 18 years of age
    - The patient is interferon-experienced

    If yes, **approve for 8 weeks for the requested strength by GPID or GPI-14 as follows:**
    - **100mg-40mg tablet: #3 per day.**
    - **50mg-20mg pellets: #5 per day.**

    If no, continue to #13.

13. Is the patient treatment experienced and meet **ONE** of the following criteria?
    - The patient is post-liver transplant
    - The patient is post-kidney transplant AND treatment experienced with a non-DAA (e.g., interferon/ribavirin)

    If yes, **approve for 12 weeks for the requested strength by GPID or GPI-14 as follows:**
    - **100mg-40mg tablet: #3 per day.**
    - **50mg-20mg pellets: #5 per day.**

    If no, continue to #14.

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

14. Is the patient treatment experienced and meets **ONE** of the following criteria?
    - The patient has failed prior treatment with a sofosbuvir-based regimen with no NS3/4 protease inhibitor (e.g., Epclusa [velpatasvir/sofosbuvir], Harvoni [ledipasvir/sofosbuvir], Sovaldi [sofosbuvir])
    - The patient has previously failed Mavyret AND Mavyret will be used with Sovaldi (sofosbuvir) and ribavirin
    - The patient has previously failed Vosevi (sofosbuvir/velpatasvir/voxilaprevir) AND Mavyret will be used with Sovaldi (sofosbuvir) and ribavirin
    - The patient is less than 18 years of age, has genotype 3, AND is interferon-experienced
    - The patient is less than 18 years of age AND had prior exposure to an NS5A inhibitor (e.g., Epclusa [velpatasvir/sofosbuvir], Harvoni [ledipasvir/sofosbuvir]) but NO exposure to NS3/4A protease inhibitors (e.g., simeprevir [Olysio], Zepatier [elbasvir/grazoprevir])

    If yes, **approve for 16 weeks for the requested strength by GPID or GPI-14 as follows:**
    - **100mg-40mg tablet: #3 per day.**
    - **50mg-20mg pellets: #5 per day.**

    If no, continue to #15.

15. Is the requested regimen recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment?

    If yes, **approve as indicated per guidance in AASLD/IDSA.**
    If no, do not approve.
    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **GLECAPREVIR/PIBRENTASVIR (Mavyret)** requires the following rule(s) be met for approval:
    A. The requested regimen is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment
    B. You have chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6 infection (liver inflammation caused by a type of virus)
    C. You are 3 years of age or older
    D. You have an HCV RNA level (amount of hepatitis C virus in your blood) within the past 6 months
    E. You do NOT have moderate or severe liver impairment (decompensated cirrhosis: Child-Pugh B or C [symptoms related to liver damage])
    (Denial text continued on next page)

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

F. You will NOT use Mavyret concurrently (at the same time) with any of the following medications: rifampin, atazanavir, carbamazepine, efavirenz, darunavir, lopinavir, ritonavir, atorvastatin, lovastatin, simvastatin, rosuvastatin (at doses greater than 10mg), cyclosporine (for patients requiring stable cyclosporine doses greater than 100mg/day), medications containing ethinyl estradiol, velpatasvir/sofosbuvir (Epclusa), ledipasvir/sofosbuvir (Harvoni), velpatasvir/sofosbuvir/voxilaprevir (Vosevi), or elbasvir/grazoprevir (Zepatier)
G. You do NOT have prior failure of a direct-acting antiviral (DAA) regimen that contains an NS5A inhibitor AND NS3/4A protease inhibitor (such as Technivie [ombitasvir/paritaprevir/ritonavir], Vosevi [velpatasvir/sofosbuvir/voxilaprevir], Viekira [ombitasvir/paritaprevir/ritonavir/dasabuvir], Zepatier [elbasvir/grazoprevir]) or you had no prior concurrent treatments containing an NS5A inhibitor AND a NS3/4A protease inhibitor
H. You do NOT have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)
I. **If you are treatment naive (never previously treated), approval also requires:**
    1. You had a short trial of (you stopped due to reasons such as inability [not able] to tolerate or adverse effects [side effects] during therapy) the preferred medication: Epclusa or Harvoni if you have genotype 1, 4, 5, or 6 infection, or a short trial of the preferred medication: Epclusa if you have genotype 2 or 3 infection, OR you have a contraindication (harmful for you to use) to the preferred medication(s)
    2. You meet ONE of the following:
        a. You received a liver transplant (replaced your liver) or kidney transplant (replaced your kidney)
        b. You do not have cirrhosis (liver damage or scarring)
        c. You have compensated cirrhosis (Child-Pugh A: no symptoms related to liver damage)
J. **If you are treatment experienced (failed prior treatment), approval also requires ONE of the following:**
    1. You are 12 to 17 years of age OR weigh at least 45 kg; have genotype 1, 2, 4, 5, or 6 infection; do not have cirrhosis (liver damage or scarring); had previous exposure to an interferon-based regimen and/or Sovaldi (sofosbuvir); AND no exposure to NS3/4A protease inhibitors (such as simeprevir [Olysio], Zepatier [elbasvir/grazoprevir]) or NS5A inhibitors (such as Epclusa [velpatasvir/sofosbuvir], Harvoni [ledipasvir/sofosbuvir])
    2. You are less than 18 years of age; have genotype 1, 2, 4, 5, or 6 infection; have compensated cirrhosis (Child-Pugh A: no symptoms related to liver damage); had previous exposure to an interferon-based regimen and/or Sovaldi (sofosbuvir); AND no exposure to NS3/4A protease inhibitors (such as simeprevir [Olysio], Zepatier [elbasvir/grazoprevir]) or NS5A inhibitors (such as Epclusa [velpatasvir/sofosbuvir], Harvoni [ledipasvir/sofosbuvir])

(Denial text continued on next page)

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

3. You are less than 18 years of age AND had previous exposure to an NS3/4A protease inhibitor (such as simeprevir [Olysio], Zepatier [elbasvir/grazoprevir]) but no exposure to NS5A inhibitors (such as Epclusa [velpatasvir/sofosbuvir], Harvoni [ledipasvir/sofosbuvir])
4. You are less than 18 years of age; have genotype 3 infection; had previous exposure to an interferon-based regimen and/or Sovaldi (sofosbuvir); AND had no exposure to NS3/4A protease inhibitors (such as simeprevir [Olysio], Zepatier [elbasvir/grazoprevir]) or NS5A inhibitors (such as Epclusa [velpatasvir/sofosbuvir], Harvoni [ledipasvir/sofosbuvir])
5. You are less than 18 years of age; had previous experience with interferon; and you had a short trial of (you stopped due to reasons such as inability [not able] to tolerate or adverse effects [side effects] during therapy) the preferred medication: Epclusa or Harvoni if you have a genotype 1, 4, 5, or 6 infection, or a short trial of the preferred medication: Epclusa if you have a genotype 2 or 3 infection, OR you have a contraindication to (harmful for you to use) the preferred medication(s)
6. You received a liver transplant (replaced your liver) AND you had a short trial of the preferred medication: Epclusa or Harvoni if you have a genotype 1, 4, 5, or 6 infection, or a short trial of the preferred medication: Epclusa if you have a genotype 2 or 3 infection, OR you have a contraindication to the preferred medication(s)
7. You received a kidney transplant (replaced your kidney); had previous experience with a non-direct acting antiviral (such as interferon/ribavirin); and you had a short trial of the preferred medication: Epclusa or Harvoni if you have a genotype 1, 4, 5, or 6 infection, or a short trial of the preferred medication: Epclusa if you have a genotype 2 or 3 infection, OR you have a contraindication to the preferred medication(s)
8. You failed prior treatment with sofosbuvir-based regimen with no NS3/4A protease inhibitor (such as Epclusa [velpatasvir/sofosbuvir], Harvoni [ledipasvir/sofosbuvir], or Sovaldi [sofosbuvir]) AND you had a short trial of the preferred medication: Epclusa or Harvoni if you have a genotype 1, 4, 5, or 6 infection, or a short trial of the preferred medication: Epclusa if you have a genotype 2 or 3 infection, OR you have a contraindication to the preferred medication(s)
9. You have previously failed Mavyret; Mavyret will be used with Sovaldi (sofosbuvir) and ribavirin; and you had a short trial of the preferred medication: Epclusa or Harvoni if you have a genotype 1, 4, 5, or 6 infection, or a short trial of the preferred medication: Epclusa if you have a genotype 2 or 3 infection, OR you have a contraindication to the preferred medication(s)

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

10. You have previously failed Vosevi (sofosbuvir/velpatasvir/voxilaprevir); Mavyret will be used with Sovaldi (sofosbuvir) and ribavirin; and you had a short trial of the preferred medication: Epclusa or Harvoni if you have a genotype 1, 4, 5, or 6 infection, or a short trial of the preferred medication: Epclusa if you have a genotype 2 or 3 infection, OR you have a contraindication to the preferred medication(s)
11. You are less than 18 years of age; have genotype 3; had previous experience with interferon; and you had a short trial of the preferred medication: Epclusa or Harvoni if you have a genotype 1, 4, 5, or 6 infection, or a short trial of the preferred medication: Epclusa if you have a genotype 2 or 3 infection, OR you have a contraindication to the preferred medication(s)
12. You are less than 18 years of age; had previous exposure to an NS5A inhibitor (such as Epclusa [velpatasvir/sofosbuvir], Harvoni [ledipasvir/sofosbuvir]) but no exposure to NS3/4A protease inhibitors (such as simeprevir [Olysio], Zepatier [elbasvir/grazoprevir]); and you had a short trial of the preferred medication: Epclusa or Harvoni if you have a genotype 1, 4, 5, or 6 infection, or a short trial of the preferred medication: Epclusa if you have a genotype 2 or 3 infection, OR you have a contraindication to the preferred medication(s)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mavyret.

REFERENCES

- Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed October 2023.
- Mavyret [Prescribing Information]. North Chicago, IL: Abbvie; October 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/15/24
Created: 09/17
Client Approval: 12/23
P&T Approval: 07/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLP-1 AGONIST

GUIDELINES FOR USE

1. Does the patient have a diagnosis of type 2 diabetes (ICD-10 group E08, E09, E11, E13)?

   If yes, **approve the requested agent for 12 months as follows:**
   - **Bydureon BCise: Approve by HICL or GPI-10 with a quantity limit of #3.4mL per 28 days.**
   - **Byetta: Approve by HICL or GPI-10 with a quantity limit of #0.08mL per day.**
   - **Mounjaro: Approve by GPID or GPI-14 with a quantity limit of #2mL per 28 days.**
   - **Ozempic: Approve by GPID or GPI-14 with a quantity limit of #3mL per 28 days.**
   - **Rybelsus: Approve by GPID or GPI-14 with a quantity limit of #1 per day.**
   - **Trulicity: Approve by HICL or GPI-10 with a quantity limit of #2mL per 28 days.**
   - **Victoza: Approve by GPID or GPI-14 with a quantity limit of #0.3mL per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GLP-1 AGONIST (Bydureon BCise, Byetta, Mounjaro, Ozempic, Rybelsus, Trulicity, Victoza)** requires the following rule(s) be met for approval:
   A. You have type 2 diabetes (a disorder with high blood sugar)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLP-1 AGONIST

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Bydureon BCise, Byetta, Mounjaro, Ozempic, Rybelsus, Trulicity, or Victoza.

REFERENCES

- Bydureon BCise [Prescribing Information]. Wilmington, DE: AstraZeneca Pharma.; May 2023.
- Byetta [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals, LP; December 2022.
- Mounjaro [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC; July 2023.
- Ozempic [Prescribing Information]. Plainsboro, NJ: Novo Nordisk Inc.; September 2023.
- Rybelsus [Prescribing Information]. Plainsboro, NJ: Novo Nordisk Inc.; December 2022.
- Trulicity [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; December 2022.
- Victoza [Prescribing Information]. Plainsboro, NJ: Novo Nordisk Inc.; July 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLYCEROL PHENYLBUTYRATE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a urea cycle disorder (UCD) and meet **ALL** of the following criteria?
   - Documentation of confirmation of UCD via enzymatic, biochemical or genetic testing
   - Ravicti will be used as adjunctive therapy along with dietary protein restriction
   - UCD cannot be managed by dietary protein restriction and/or amino acid supplementation alone
   - The patient does NOT have a deficiency of N-acetylglutamate synthetase deficiency (NAGS) or acute hyperammonemia
   - The patient has tried or has a contraindication to Buphenyl (sodium phenylbutyrate)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #17.5mL per day.** If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GLYCEROL PHENYLBUTYRATE (Ravicti)** requires the following rule(s) be met for approval:
   A. You have a urea cycle disorder (UCD: genetic disorder that causes buildup of ammonia in blood)
   B. There is documentation of confirmation of urea cycle disorder via enzymatic, biochemical or genetic testing (types of lab tests)
   C. Ravicti will be used as adjunctive (add-on) therapy along with dietary protein restriction
   D. Your disorder cannot be managed by dietary protein restriction and/or amino acid supplementation alone
   E. You do NOT have a deficiency of N-acetylglutamate synthetase (type of enzyme) or acute hyperammonemia (short and sudden high ammonia levels)
   F. You have tried or have a contraindication to (harmful for you to use) Buphenyl (sodium phenylbutyrate)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLYCEROL PHENYLBUTYRATE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of a urea cycle disorder (UCD) **AND** meet the following criterion?
   - The patient had a clinical benefit from baseline (e.g., normal fasting glutamine, low-normal fasting ammonia levels, or mental status clarity)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #17.5mL per day.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GLYCEROL PHENYLBUTYRATE (Ravicti)** requires the following rule(s) be met for renewal:
   A. You have a urea cycle disorder (genetic disorder that causes buildup of ammonia in blood)
   B. You had a clinical benefit from baseline (such as normal fasting glutamine, low-normal fasting ammonia levels, or mental status clarity).

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ravicti.

REFERENCES

- Ravicti [Prescribing Information]. Lake Forest, IL: Horizon Pharma USA, Inc; November 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 12/19/23
Created: 02/13
Client Approval: 12/23
P&T Approval: 07/19

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLYCOPYRRONIUM TOPICAL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of primary axillary hyperhidrosis and meet **ALL** of the following criteria?
   - The patient is 9 years of age or older
   - The patient had a trial of prescription strength aluminum chloride product (e.g., Drysol)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 packet per day.** If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GLYCOPYRRONIUM TOPICAL (Qbrexza)** requires the following rule(s) be met for approval:
   A. You have primary axillary hyperhidrosis (excessive underarm sweating)
   B. You are 9 years of age or older
   C. You had a trial of a prescription strength aluminum chloride product such as Drysol

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Qbrexza.

REFERENCES

- Qbrexza [Prescribing Information]. Menlo Park, CA. Dermira, Inc. June 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/20
Created: 11/18
Client Approval: 08/20
P&T Approval: 07/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GOLIMUMAB - SQ

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient is currently using or has a contraindication to methotrexate

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
   - The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 6 months of the 50 mg prefilled SmartJect autoinjector or syringe by GPID or GPI-14 with a quantity limit of #0.5 mL per 28 days.**

     If no, do not approve.
     DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Taltz (ixekizumab), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 6 months of the 50 mg prefilled SmartJect autoinjector or syringe by GPID or GPI-14 with a quantity limit of #0.5 mL per 28 days.**

     If no, continue to #4.

4. Does the patient have a diagnosis of moderate to severe ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 6 months of the 50 mg prefilled SmartJect autoinjector or syringe by GPID or GPI-14 with a quantity limit of #0.5 mL per 28 days.**

     If no, continue to #5.

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GOLIMUMAB - SQ

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to ONE conventional therapy (e.g., corticosteroids [e.g., budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Humira (adalimumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for a total of 6 months by GPID or GPI-14 and enter two authorizations as follows:**
     - **FIRST APPROVAL: Approve 1 month of the 100 mg/mL prefilled syringe OR SmartJect autoinjector with a quantity limit of #3 mL per 28 days.**
     - **SECOND APPROVAL: Approve 5 months of the 100 mg/mL prefilled syringe OR SmartJect autoinjector with a quantity limit of #1 mL per 28 days (Enter a start date that is 1 week AFTER the END date of the first approval).**

     If no, do not approve.

     INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

     Our guideline named **GOLIMUMAB-SQ (Simponi)** requires the following rule(s) be met for approval:
     A. You have ONE of the following:
        1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
        2. Psoriatic arthritis (PsA: a type of skin and joint condition)
        3. Moderate to severe ankylosing spondylitis (AS: a type of joint condition)
        4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

     (Initial denial text continued on next page)

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INITIAL CRITERIA (CONTINUED)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) at least 3 months of ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You are currently using or have a contraindication to (harmful for you to use) methotrexate
   5. You meet ONE of the following:
      a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
      b. You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Taltz (ixekizumab), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

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GOLIMUMAB - SQ

INITIAL CRITERIA (CONTINUED)

D. **If you have moderate to severe ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) an NSAID (non-steroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam)
   4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

E. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
   3. You have tried or have a contraindication to (harmful for you to use) ONE standard therapy, such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Humira (adalimumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GOLIMUMAB - SQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient is currently using or has a contraindication to methotrexate

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
   - The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months of the 50 mg prefilled SmartJect autoinjector or syringe by GPID or GPI-14 with a quantity limit of #0.5 mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Taltz (ixekizumab), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months of the 50 mg prefilled SmartJect autoinjector or syringe by GPID or GPI-14 with a quantity limit of #0.5 mL per 28 days.**

   If no, continue to #4.

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GOLIMUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months of the 50 mg prefilled SmartJect autoinjector or syringe by GPID or GPI-14 with a quantity limit of #0.5 mL per 28 days.**

     If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) **AND** meet the following criterion?
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Humira (adalimumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months of the 100 mg prefilled SmartJect autoinjector or syringe by GPID or GPI-14 with a quantity limit of #1 mL per 28 days.**

     If no, do not approve.
     DENIAL TEXT: See the renewal denial text at the end of the guideline.

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GOLIMUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GOLIMUMAB-SQ (Simponi)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe ankylosing spondylitis (AS: a type of joint condition)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You are currently using or have a contraindication to (harmful for you to use) methotrexate
   3. You mean ONE of the following:
      a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
      b. You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Taltz (ixekizumab), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

(Renewal denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

D. **If you have moderate to severe ankylosing spondylitis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (diagnostic test to determine the effectiveness of drug therapy) while on therapy
   2. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

E. **If you have moderate to severe Crohn's disease, renewal also requires:**
   1. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Humira (adalimumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Simponi.

REFERENCES

- Simponi [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 06/09
Client Approval: 03/24
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GUSELKUMAB

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient had a trial of or contraindication to ONE or more forms of conventional therapies (e.g., PUVA [psoralen and ultraviolet light A], UVB [ultraviolet light B], topical corticosteroids [e.g., betamethasone dipropionate, clobetasol propionate], calcipotriene, acitretin, methotrexate, or cyclosporine)

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic and switching to Tremfya
   - The patient has psoriasis covering 3% or more of body surface area (BSA)
   - The patient has psoriatic lesions affecting the hands, feet, genital area, or face

   If yes, **approve for 6 months by entering TWO approvals by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: approve for 1 month with a quantity limit of #1mL per 28 days.**
   - **SECOND APPROVAL: approve for 5 months with a quantity limit of #1mL per 56 days. (Please enter a start date of 3 WEEKS AFTER the START date of the first approval)**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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GUSELKUMAB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by entering TWO approvals by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: approve for 1 month with a quantity limit of #1mL per 28 days.**
   - **SECOND APPROVAL: approve for 5 months with a quantity limit of #1mL per 56 days. (Please enter a start date of 3 WEEKS AFTER the START date of the first approval)**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GUSELKUMAB (Tremfya)** requires the following rule(s) be met for approval:

   A. You have ONE of the following diagnoses:
      1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)

   B. **If you have moderate to severe plaque psoriasis, approval also requires:**
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
      3. You had a trial of or contraindication (harmful for) to ONE or more forms of standard therapies such as PUVA (psoralen and ultraviolet light A: a type of light therapy), UVB (ultraviolet light B: a type of light therapy), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), calcipotriene, acitretin, methotrexate, or cyclosporine
      4. You meet ONE of the following criteria:
         a. You were previously stable on another biologic and are switching to Tremfya
         b. You have psoriasis covering 3 percent or more of body surface area (BSA)
         c. You have psoriatic lesions (rashes) affecting the hands, feet, genital area, or face

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GUSELKUMAB

INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You had a trial of or contraindication (harmful for) to ONE DMARD (disease-modifying antirheumatic drug) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GUSELKUMAB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?
   - The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 56 days.** If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 56 days.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GUSELKUMAB (Tremfya)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following diagnoses:
      1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)

   B. **If you have moderate to severe plaque psoriasis, renewal also requires:**
      1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

   C. **If you have psoriatic arthritis, renewal also requires:**
      1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GUSELKUMAB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tremfya.

REFERENCES

- Tremfya [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; July 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 07/17
Client Approval: 03/24
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HYDROCORTISONE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of adrenocortical insufficiency and meet **ALL** of the following criteria?
   - The patient is less than 18 years of age
   - The patient is unable to take the tablet formulation of hydrocortisone (e.g., need for lower strength, difficulty swallowing)

   If yes, **approve for 6 months for all strengths by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HYDROCORTISONE (Alkindi Sprinkle)** requires the following rule(s) be met for approval:
   A. You have adrenocortical insufficiency (your body does not produce enough of certain hormones)
   B. You are less than 18 years of age
   C. You are unable to take the tablet form of hydrocortisone (for example you need a lower strength, or you have difficulty swallowing)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Alkindi Sprinkle.

REFERENCES

- Alkindi Sprinkle [Prescribing Information]. Baden-Wuerttemberg, Germany: Eton Pharmaceuticals, Inc.; October 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/21
Created: 02/21
Client Approval: 02/21
P&T Approval: 01/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HYDROMORPHONE ER

GUIDELINES FOR USE

1. Does the patient meet the definition of opioid tolerance (defined as those who are taking, for one week or longer, at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 25 mg oral oxymorphone/day, 8 mg oral hydromorphone/day, or an equianalgesic dose of another opioid)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the request form indicate that this medication will be used on an "as needed" or "PRN" basis?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #3.

3. Does the patient require a dosage of 16mg or less?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent (8mg, 12mg, 16mg) for #1 per day. (NOTE: Please override both PA and step therapy [if applicable] restrictions by entering 'Y' for OVR_RES).**

   If no, continue to #4.

4. Was this dosage recommended by a pain specialist?

   If yes, **approve for 12 months by GPID or GPI-14 (32mg) for #2 per day. (NOTE: Please override both PA and step therapy [if applicable] restrictions by entering 'Y' for OVR_RES).**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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HYDROMORPHONE ER

GUDIELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **HYDROMORPHONE ER (Exalgo)** requires the following rule(s) be met for approval:

A. You meet the definition of opioid tolerance. This is defined as those who are taking, for one week or longer, at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 25 mg oral oxymorphone/day, 8 mg oral hydromorphone/day, or an equianalgesic dose (equal pain relieving dose) of another opioid
B. The requested medication is not prescribed on an as-needed basis
C. Dosages above 16mg require recommendation from a pain specialist

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Exalgo.

REFERENCES

- Exalgo [Prescribing Information]. Hazelwood, MO: Mallinckrodt; February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 03/04/22
Created: 04/10
Client Approval: 02/22
P&T Approval: 07/19

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IBREXAFUNGERP

GUIDELINES FOR USE

1. Is the request for the treatment of vulvovaginal candidiasis (VVC) and the patient meets **ALL** of the following criteria?
   - The patient is a post-menarchal female
   - The patient had a trial of or contraindication to oral fluconazole AND an intravaginal azole (e.g., terconazole cream)

   If yes, **approve for 30 days by HICL or GPI-10 for one fill with a quantity limit of #4.**
   If no, continue to #2.

2. Is the request for the reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC) and the patient meets **ALL** of the following criteria?
   - The patient is a post-menarchal female
   - The patient had a trial of or contraindication to oral fluconazole (the patient had a breakthrough episode of VVC while taking fluconazole 150 mg weekly)
   - The patient is NOT currently on oteseconazole for RVVC

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Has the patient previously received Brexafemme?

   If yes, continue to #5.
   If no, continue to #4.

4. Has the patient had 3 or more episodes of VVC in the past 12 months?

   If yes, **approve for 6 months by HICL or GPI-10 for 6 fills total with a quantity limit of #4 per 30 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

GUIDELINES FOR USE (CONTINUED)

5. Does the patient meet **ALL** of the following criteria?
   - The patient has successfully completed a course of Brexafemme for prevention of RVVC
   - The patient is either being treated or has just completed treatment for a new recurrence of VVC

   If yes, **approve for 6 months by HICL or GPI-10 for 6 fills total with a quantity limit of #4 per 30 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IBREXAFUNGERP (Brexafemme)** requires the following rule(s) be met for approval:
   A. The request is for ONE of the following:
      1. Treatment of vulvovaginal candidiasis (VVC: vaginal yeast infection)
      2. Reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC: repeated vaginal yeast infection)
   B. **If you are using Brexafemme for the treatment of vulvovaginal candidiasis, approval also requires:**
      1. You are a post-menarchal (you have started having your period) female
      2. You have tried or have a contraindication to (harmful for) oral fluconazole AND an intravaginal azole (type of drug that is inserted into the vagina and used to treat yeast infections such as terconazole cream)
   C. **If you are using Brexafemme for the reduction in the incidence of recurrent vulvovaginal candidiasis, approval also requires:**
      1. You are a post-menarchal (you have started having your period) female
      2. You have tried or have a contraindication to (harmful for) oral fluconazole (you had a breakthrough episode of VVC while taking fluconazole 150 mg weekly)
      3. You are NOT currently on oteseconazole for RVVC
      4. You meet ONE of the following:
         a. You have not previously received Brexafemme AND you had 3 or more episodes of RVVC in the past 12 months
         b. You have been previously treated with Brexafemme and meet ALL of the following:
            i. You have successfully completed a course of Brexafemme for prevention of RVVC
            ii. You are either being treated or have just completed treatment for a new recurrence of VVC

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IBREXAFUNGERP

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Brexafemme.

REFERENCES

- Brexafemme [Prescribing Information]. Jersey City, NJ: Scynexis, Inc.; November 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/23
Created: 07/21
Client Approval: 02/23
P&T Approval: 07/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IBRUTINIB

GUIDELINES FOR USE

1. Is the request for Imbruvica (ibrutinib) 560 mg tablet?

   If yes, do not approve. (**Note:** This strength does not have an FDA-approved indication.)
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), or Waldenstrom's macroglobulinemia (WM) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **70 mg capsule: #1 per day.**
   - **140 mg capsule: #2 per day.**
   - **140 mg tablet: #1 per day.**
   - **280 mg tablet: #1 per day.**
   - **420 mg tablet: #1 per day.**
   - **70 mg/mL oral suspension: #7.2 mL per day.**

   If no, continue to #3.

3. Does the patient have a diagnosis of chronic graft versus host disease (cGVHD) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient has failed one or more lines of systemic therapy (e.g., prednisone, prednisolone, methylprednisolone)

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **70 mg capsule: #1 per day.**
   - **140 mg capsule: #2 per day.**
   - **140 mg tablet: #1 per day.**
   - **280 mg tablet: #1 per day.**
   - **420 mg tablet: #1 per day.**
   - **70 mg/mL oral suspension: #7.2 mL per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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IBRUTINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **IBRUTINIB (Imbruvica)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
   2. Small lymphocytic lymphoma (SLL: a type of blood cancer)
   3. Waldenstrom's macroglobulinemia (WM: a type of blood cancer)
   4. Chronic graft versus host disease (cGVHD: a type of immune disorder)

B. **If you have chronic lymphocytic leukemia, small lymphocytic lymphoma, or Waldenstrom's macroglobulinemia, approval also requires:**
   1. You are 18 years of age or older

C. **If you have chronic graft versus host disease, approval also requires:**
   1. You are 1 year of age or older
   2. You have failed one or more lines of systemic therapy (treatment spread through the blood, such as prednisone, prednisolone, methylprednisolone)

Note: Requests for Imbruvica (ibrutinib) 560mg tablet will not be approved. This strength does not have a Food and Drug Administration (FDA)-approved indication.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Imbruvica.

REFERENCES

- Imbruvica [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; May 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/23
Created: 01/14
Client Approval: 06/23
P&T Approval: 07/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ICATIBANT

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet ALL of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an allergist, immunologist or hematologist
   - The patient's diagnosis is confirmed via complement testing
   - The requested medication is being used for treatment of acute attacks of hereditary angioedema
   - The requested medication will NOT be used concurrently with other acute treatments for HAE attacks (e.g., Berinert, Ruconest, Kalbitor)

   If yes, **approve for 12 months by HICL or GPI-10, each fill of #18mL (6 syringes), up to 12 fills per year.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ICATIBANT (Firazyr, Sajazir)** requires the following rule(s) be met for approval:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with an allergist, immunologist (allergy doctor or immune system doctor) or hematologist (blood doctor)
   D. Your diagnosis is confirmed by complement testing (a type of lab test)
   E. The requested medication is being used for treatment of acute (sudden and severe) attacks of hereditary angioedema
   F. The requested medication will NOT be used concurrently (at the same time) with other acute treatments for HAE attacks (such as Berinert, Ruconest, Kalbitor)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ICATIBANT

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Firazyr and Sajazir.

REFERENCE

- Firazyr [Prescribing Information]. Lexington, MA: Shire Orphan Therapies; October 2021.
- Sajazir [Prescribing Information]. Cambridge, United Kingdom: Cycle Pharmaceuticals Ltd; June 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/22
Created: 09/11
Client Approval: 07/22
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IDELALISIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed chronic lymphocytic leukemia (CLL) **AND** meet the following criterion?
   - Zydelig will be used in combination with rituximab

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IDELALISIB (Zydelig)** requires the following rule(s) be met for approval:
   A. You have relapsed chronic lymphocytic leukemia (CLL: a type of blood cancer)
   B. Zydelig will be used in combination with rituximab

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Zydelig.

REFERENCES

- Zydelig [Prescribing Information]. Foster City, CA: Gilead Sciences, Inc.; February 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 08/14
Client Approval: 02/22
P&T Approval: 11/14

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ILOPROST

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have documentation (e.g., chart note, lab result, diagnostic test result, etc.) confirming a PAH diagnosis based on right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Has the patient had a trial of or contraindication to **TWO** of the following agents from different drug classes?
   - Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
   - Oral phosphodiesterase-5 inhibitor (e.g., Revatio [sildenafil], Adcirca [tadalafil])
   - Oral cGMP stimulator (e.g., Adempas [riociguat])
   - IV/SQ prostacyclin (e.g., Flolan [epoprostenol], Remodulin [treprostinil])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ILOPROST

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ILOPROST (Ventavis)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
C. There is documentation (such as chart note, lab result, diagnostic test result) showing you have pulmonary arterial hypertension based on ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 2 Wood units
D. You have tried or have a contraindication to (harmful for you to use) TWO of the following medications from different drug classes:
    1. Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
    2. Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
    3. Oral cGMP stimulator (such as Adempas [riociguat])
    4. Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ILOPROST

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ILOPROST (Ventavis)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Ventavis.

REFERENCES

- Ventavis [Prescribing Information]. Titusville, NJ: Actelion Pharmaceuticals US, Inc.; March 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 01/08
Client Approval: 02/24
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IMATINIB

GUIDELINES FOR USE

1. Does the patient have **ONE** of the following diagnoses?
   - Newly diagnosed Philadelphia positive chronic myeloid leukemia (Ph+ CML) in chronic phase
   - Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in blast crisis, accelerated phase, or chronic phase after failure of interferon-alpha therapy

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient received previous treatment with another tyrosine kinase inhibitor [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Iclusig (ponatinib)]?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Gleevec 400mg: #2 per day.**
   - **Gleevec 100mg: #6 per day.**

3. Does the patient have a diagnosis of relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Gleevec 400mg: #1 per day.**
   - **Gleevec 100mg: #6 per day.**

   If no, continue to #4.

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GUIDELINES FOR USE (CONTINUED)

4. Does the patient have newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) **AND** meet the following criterion?
   - The requested medication will be used in combination with chemotherapy

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Gleevec 400mg: #1 per day.**
   - **Gleevec 100mg: #6 per day.**

   If no, continue to #5.

5. Does the patient have a diagnosis of a myelodysplastic/myeloproliferative disease associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve Gleevec 400mg for 12 months by GPID or GPI-14 with a quantity limit of #1 tablet per day.**
   If no, continue to #6.

6. Does the patient have a diagnosis of aggressive systemic mastocytosis without D816V c-Kit mutation or with c-Kit mutational status unknown **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Gleevec 400mg: #1 per day.**
   - **Gleevec 100mg: #3 per day.**

   If no, continue to #7.

7. Does the patient have a diagnosis of hypereosinophilic syndrome and/or chronic eosinophilic leukemia **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Gleevec 400mg: #1 per day.**
   - **Gleevec 100mg: #3 per day.**

   If no, continue to #8.

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IMATINIB

GUIDELINES FOR USE (CONTINUED)

8. Does the patient have a diagnosis of unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Gleevec 400mg: #2 per day.**
   - **Gleevec 100mg: #6 per day.**

   If no, continue to #9.

9. Does the patient have a diagnosis of unresectable and/or metastatic malignant gastrointestinal stromal tumor (GIST) with a Kit (CD117) positive?

   If yes, continue to #11.
   If no, continue to #10.

10. Is the request for adjuvant treatment following complete gross resection of Kit (CD117) positive gastrointestinal stromal tumor (GIST) **AND** the patient meets the following criterion?
    - The patient is 18 years of age or older

    If yes, continue to #11.
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

11. Is the request for Gleevec 400mg twice daily?

    If yes, continue to #12.
    If no, **approve as follows:**
    - **For adjuvant GIST treatment: approve Gleevec 400mg for 36 months by GPID or GPI-14 with a quantity limit of #1 per day.**
    - **For unresectable and/or metastatic malignant GIST: approve Gleevec 400mg for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**

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IMATINIB

GUIDELINES FOR USE (CONTINUED)

12. Has patient tried Gleevec 400mg once daily or does the patient have GIST tumor expressing a KIT exon 9 mutation?

    If yes, **approve as follows:**
    - **For adjuvant GIST treatment: approve Gleevec 400mg for 36 months by GPID or GPI-14 with a quantity limit of #2 per day.**
    - **For unresectable and/or metastatic malignant GIST: approve Gleevec 400mg for 12 months by GPID or GPI-14 with a quantity limit of #2 per day.**

    If no, do not approve.
    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **IMATINIB (Gleevec)** requires the following rule(s) be met for approval:
    A. You have ONE of the following diagnoses:
        1. Newly diagnosed Philadelphia positive chronic myeloid leukemia (type of blood cell cancer that begins in bone marrow with an abnormal gene) in chronic phase
        2. Philadelphia chromosome positive chronic myeloid leukemia in blast crisis, accelerated phase, or chronic phase after failure of interferon-alpha therapy
        3. Relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (type of white blood cell cancer that has returned or did not respond to treatment)
        4. Newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (type of white blood cell cancer)
        5. Myelodysplastic/myeloproliferative disease (a group of diseases where the bone marrow makes too many white blood cells) associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements
        6. Aggressive systemic mastocytosis (a type of cell accumulates in internal tissues and organs) without D816V c-Kit mutation or with c-Kit mutational status unknown
        7. Hypereosinophilic syndrome and/or chronic eosinophilic leukemia (type of inflammatory cancer)
        8. Unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans (type of rare skin tumor that cannot be completely removed by surgery or returns/ spreads)
        9. Unresectable and/or metastatic malignant gastrointestinal stromal tumor (tumor in stomach/intestines that spreads or cannot be removed by surgery) with a Kit (CD117) positive
        10. Adjuvant (add-on) treatment after complete gross resection (surgical removal) of Kit (CD117) positive gastrointestinal stromal tumor

    (Denial text continued on next page)

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IMATINIB

GUIDELINES FOR USE (CONTINUED)

B. **If you are newly diagnosed with Philadelphia positive chronic myeloid leukemia in chronic phase, approval also requires:**
   1. You have NOT received previous treatment with another tyrosine kinase inhibitor such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Iclusig (ponatinib)

C. **If you have Philadelphia chromosome positive chronic myeloid leukemia in blast crisis, accelerated phase, or chronic phase after failure of interferon-alpha therapy, approval also requires:**
   1. You have NOT received previous treatment with another tyrosine kinase inhibitor such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Iclusig (ponatinib)

D. **If you have relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), approval also requires:**
   1. You are 18 years of age or older

E. **If you have newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), approval also requires:**
   1. The requested medication will be used in combination with chemotherapy

F. **If you have myelodysplastic/myeloproliferative disease associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements, approval also requires:**
   1. You are 18 years of age or older

G. **If you have aggressive systemic mastocytosis without D816V c-Kit mutation or with c-Kit mutational status unknown, approval also requires:**
   1. You are 18 years of age or older

H. **If you have hypereosinophilic syndrome and/or chronic eosinophilic leukemia, approval also requires:**
   1. You are 18 years of age or older

I. **If you have unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans, approval also requires:**
   1. You are 18 years of age or older

J. **If the request is for adjuvant treatment following complete gross resection of Kit (CD117) positive gastrointestinal stromal tumor (GIST), approval also requires:**
   1. You are 18 years of age or older

K. **If you have gastrointestinal stromal tumor, approval also requires:**
   1. For request of Gleevec 400mg twice daily, approval requires a trial of Gleevec 400mg once daily OR a GIST tumor expressing a KIT exon 9 (type of gene) mutation (a permanent change in your DNA that make up your gene)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE

IMATINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gleevec.

REFERENCES

- Gleevec [Prescribing Information] East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 11/11
Client Approval: 03/21
P&T Approval: 10/19

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IMIQUIMOD

GUIDELINES FOR USE

1. Does the patient have a diagnosis of actinic keratosis (AK) of the full face or balding scalp and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is immunocompetent
   - The patient had a trial of **TWO** generic topical agents indicated for AK (e.g., fluorouracil, imiquimod, diclofenac 3%)

   If yes, **approve the requested strength for 4 months by GPID or GPI-14 with the following quantity limits:**
   - **3.75% packet: #28 packets per 28 days.**
   - **2.5% or 3.75% pump: #7.5g per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of external genital or perianal warts and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient had a trial of or contraindication to generic imiquimod 5% topical cream

   If yes, **approve the requested strength for 2 months by GPID or GPI-14 with the following quantity limits:**
   - **3.75% packet: #28 packets per 28 days.**
   - **2.5% or 3.75% pump: #7.5g per 28 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IMIQUIMOD (Zyclara)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Actinic keratosis (AK: rough, scaly patch on the skin caused by years of sun exposure) of the full face or balding scalp
      2. External genital or perianal (around the anus) warts

   (Denial text continued on next page)

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IMIQUIMOD

GUIDELINES FOR USE (CONTINUED)

B. **If you have actinic keratosis of the full face or balding scalp, approval also requires:**
   1. You are 18 years of age or older
   2. You are immunocompetent (healthy immune system)
   3. You had a trial of TWO generic topical agents for AK (such as fluorouracil, imiquimod, diclofenac 3%)

C. **If you have external genital or perianal warts, approval also requires:**
   1. You are 12 years of age or older
   2. You have tried or have a contraindication (harmful for) to generic imiquimod 5% topical cream

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zyclara.

REFERENCES

- Zyclara [Prescribing Information]. Bridgewater, NJ: Bausch Health US, LLC; June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/12/23
Created: 08/97
Client Approval: 05/23
P&T Approval: 04/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INFIGRATINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable locally advanced or metastatic cholangiocarcinoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has been previously treated for unresectable locally advanced or metastatic cholangiocarcinoma
   - The patient has a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement, as detected by an FDA-approved test
   - The patient will complete a comprehensive ophthalmological examination, including optical coherence tomography (OCT), prior to initiation of therapy and at the recommended scheduled intervals

   If yes, **approve the requested dose pack for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **50mg: #42 per 28 days.**
   - **75mg: #63 per 28 days.**
   - **100mg: #21 per 28 days.**
   - **125mg: #42 per 28 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INFIGRATINIB (Truseltiq)** requires the following rule(s) be met for approval:
   A. You have unresectable locally advanced or metastatic cholangiocarcinoma (bile duct cancer that has grown outside the organ but has not yet spread to other parts of the body and cannot be removed by surgery, or bile duct cancer that has spread to other parts of the body)
   B. You are 18 years of age or older
   C. You have previously been treated for unresectable locally advanced or metastatic cholangiocarcinoma
   D. You have a fibroblast growth factor receptor 2 (FGFR2: type of protein) fusion or other rearrangement, as detected by a Food and Drug Administration (FDA)-approved test
   E. You will complete a comprehensive ophthalmological examination (eye exam), including optical coherence tomography (OCT: a type of eye imaging test), before starting the medication and at the recommended scheduled times
   (Denial text continued on next page)

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INFIGRATINIB

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Truseltiq.

REFERENCES

- Truseltiq [Prescribing Information]. Brisbane, CA: QED Therapeutics, Inc.; May 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/23
Created: 07/21
Client Approval: 11/22
P&T Approval: 10/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB-DYYB - SQ

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Zymfentra will be used following treatment with an intravenous infliximab agent (e.g., Remicade, Renflexis, Avsola)
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to ONE conventional therapy (e.g., corticosteroids [e.g., budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simponi SQ (golimumab subcutaneous)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #2 per 28 days.**
     If no, continue to #2.

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INFLIXIMAB-DYYB - SQ

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Zymfentra will be used following treatment with an intravenous infliximab agent (e.g., Remicade, Renflexis, Avsola)
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to ONE conventional therapy (e.g., corticosteroids [e.g., budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab), Stelara (ustekinumab), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Cimzia (certolizumab pegol)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #2 per 28 days.**
     If no, do not approve.
     DENIAL TEXT: See the initial denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

INFLIXIMAB-DYYB - SQ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INFLIXIMAB-DYYB - SQ (Zymfentra)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   2. Moderate to severe Crohn's disease (CD: a type of bowel disorder)

B. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 18 years of age or older
   2. Zymfentra will be used following treatment with an intravenous (injection into the vein) infliximab medication (such as Remicade, Renflexis, Avsola)
   3. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   4. You have tried or have a contraindication to (harmful for you to use) ONE conventional therapy, such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simponi SQ (golimumab subcutaneous)

C. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 18 years of age or older
   2. Zymfentra will be used following treatment with an intravenous (injection into the vein) infliximab medication (such as Remicade, Renflexis, Avsola)
   3. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   4. You have tried or have a contraindication to (harmful for you to use) ONE conventional therapy, such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Cimzia (certolizumab pegol)

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INFLIXIMAB-DYYB - SQ

INITIAL CRITERIA (CONTINUED)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE

INFLIXIMAB-DYYB - SQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) **AND** meet the following criterion?
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simponi SQ (golimumab subcutaneous)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2 per 28 days.**
     If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) **AND** meet the following criterion?
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab), Stelara (ustekinumab), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Cimzia (certolizumab pegol)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2 per 28 days.**
     If no, do not approve.

     RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

     Our guideline named **INFLIXIMAB-DYYB - SQ (Zymfentra)** requires the following rule(s) be met for renewal:
     A. You have ONE of the following:
        1. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
        2. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
     B. **If you have moderate to severe ulcerative colitis, renewal also requires:**
        1. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Simponi SQ (golimumab subcutaneous)

     (Renewal denial text continued on the next page)

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RENEWAL CRITERIA (CONTINUED)

C. **If you have moderate to severe Crohn's disease, renewal also requires:**
   1. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Cimzia (certolizumab pegol)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zymfentra.

REFERENCES

- Zymfentra [Prescribing Information]. Jersey City, New Jersey: Celltrion USA, Inc.; February 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 03/18/24
Created: 02/24
Client Approval: 03/24
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INGENOL

GUIDELINES FOR USE

Do not approve requests for Picato gel.

(NOTE: Picato discontinued due to safety concerns and increased risk of cancer.)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Picato.

Manufacturer provided FDA with notification of discontinuation in the manufacture of Picato. Discontinuation may be likely due to safety concerns; Picato is no longer authorized in the EU after concluding that Picato increases the risk of cancer.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/21

Created: 05/12
Client Approval: 08/21

P&T Approval: 04/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INHALED INSULIN

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient meet any **ONE** of the following criteria?
   - Chronic lung disease (i.e., asthma or chronic obstructive pulmonary disease)
   - Active lung cancer
   - Currently in diabetic ketoacidosis
   - Patient who smokes or who has quit smoking within the past 6 months

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #2.

2. Has baseline spirometry to measure FEV1 been performed?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INHALED INSULIN

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis type 1 diabetes and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is concurrently using a long-acting insulin
   - The patient had a trial of a preferred formulary rapid acting insulin: Humalog

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent with the following quantity limits:**
   - **Afrezza 90-4 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **Afrezza 90-8 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **Afrezza 90-12 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **Afrezza 90-4 Unit + 90-8 Unit Titration pack: #180 cartridges (1 kit) per 28 days.**
   - **Afrezza 90-8 Unit + 90-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.**
   - **Afrezza 30-4 Unit + 60-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **Afrezza 60-4 Unit + 30-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **Afrezza 60-8 Unit + 30-12 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **Afrezza 60-4 Unit + 60-8 Unit + 60-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.**

   APPROVAL TEXT: Renewal requires a follow-up spirometry after 6 months of treatment and annually thereafter, and concurrent use of a long acting insulin. Renewal will not be provided for patients with a FEV1 that has declined 20% or more from baseline.

   If no, continue to #4.

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INHALED INSULIN

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of type 2 diabetes and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of a preferred formulary rapid acting insulin: Humalog
   - The prescriber indicated that the patient is physically unable to or unwilling to administer injectable insulin

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent with the following quantity limits:**
   - **Afrezza 90-4 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **Afrezza 90-8 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **Afrezza 90-12 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **Afrezza 90-4 Unit + 90-8 Unit Titration pack: #180 cartridges (1 kit) per 28 days.**
   - **Afrezza 90-8 Unit + 90-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.**
   - **Afrezza 30-4 Unit + 60-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **Afrezza 60-4 Unit + 30-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **Afrezza 60-8 Unit + 30-12 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **Afrezza 60-4 Unit + 60-8 Unit + 60-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.**

   APPROVAL TEXT: Renewal requires a follow-up spirometry after 6 months of treatment and annually thereafter. Renewal will not be provided for patients with a FEV1 that has declined 20% or more from baseline.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INHALED INSULIN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INHALED INSULIN (Afrezza)** requires the following rule(s) be met for approval:

A. You have type 1 or type 2 diabetes
B. You are 18 years of age or older
C. You have a baseline spirometry (test to measure how well your lungs work) to measure FEV1 (forced expiratory volume)
D. **If you have type 1 diabetes, approval also requires:**
   1. You are using a long-acting insulin with the requested medication and that you have tried a formulary rapid acting insulin: Humalog
E. **If you have type 2 diabetes, approval also requires:**
   1. You tried a formulary rapid acting insulin: Humalog
   2. Your prescriber has indicated that you are physically unable or unwilling to use injectable insulin

Note: Afrezza will not be approved if you have any of the following conditions: chronic lung disease, active lung cancer, currently in diabetic ketoacidosis (condition where body breaks down fat too fast), or if you are currently smoking or who have quit smoking within the past 6 months

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of type 1 diabetes and currently on a long acting insulin?

   If yes, continue to #3.
   If no, continue to #2.

2. Does the patient have a diagnosis of type 2 diabetes?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RENEWAL CRITERIA (CONTINUED)

3. Was follow-up spirometry to measure FEV1 performed after 6 months of treatment and annually thereafter?

   If yes, continue to #4.
   If no, **approve for 1 month by GPID or GPI-14 (to allow for follow-up spirometry evaluation) with the following quantity limits:**
   - **Afrezza 90-4 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **Afrezza 90-8 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **Afrezza 90-12 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **Afrezza 90-4 Unit + 90-8 Unit Titration pack: #180 cartridges (1 kit) per 28 days.**
   - **Afrezza 90-8 Unit + 90-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.**
   - **Afrezza 30-4 Unit + 60-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **Afrezza 60-4 Unit + 30-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **Afrezza 60-8 Unit + 30-12 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **Afrezza 60-4 Unit + 60-8 Unit + 60-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.**

4. Has FEV1 declined 20% or more from baseline?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, **approve for 12 months by GPID or GPI-14 for the requested agent with the following quantity limits:**
   - **Afrezza 90-4 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **Afrezza 90-8 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **Afrezza 90-12 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **Afrezza 90-4 Unit + 90-8 Unit Titration pack: #180 cartridges (1 kit) per 28 days.**
   - **Afrezza 90-8 Unit + 90-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.**
   - **Afrezza 30-4 Unit + 60-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **Afrezza 60-4 Unit + 30-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **Afrezza 60-8 Unit + 30-12 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **Afrezza 60-4 Unit + 60-8 Unit + 60-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.**

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INHALED INSULIN

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INHALED INSULIN (Afrezza)** requires the following rule(s) be met for renewal:

A. You have type 1 or type 2 diabetes
B. You have documentation of follow up spirometry (test to measure how well your lungs work) to measure FEV1 (forced expiratory volume in one second) after 6 months of treatment and annually thereafter
C. Your FEV1 has NOT declined 20% or more from baseline
D. **If you have type 1 diabetes,** approval requires that you are using a long acting insulin at the same time with the requested medication

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Afrezza.

REFERENCES

- Afrezza [Prescribing Information]. Danbury, CT: Mankind Corporation. October 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 02/15
Client Approval: 04/20
P&T Approval: 07/17

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INOTERSEN

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy and meet **ALL** the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, cardiologist, hATTR specialist, or medical geneticist
   - The patient has documented diagnosis of hereditary TTR amyloidosis (hATTR) as confirmed by ONE of the following:
     - Biopsy of tissue/organ to confirm amyloid presence AND chemical typing to confirm presence of TTR protein
     - DNA genetic sequencing to confirm hATTR mutation
   - The patient has FAP stage 1 or 2 OR up to PND stage IIIb polyneuropathy
   - The patient had a trial of or contraindication to the preferred agent: Amvuttra

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #6mL per 28 days.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INOTERSEN (Tegsedi)** requires the following rule(s) be met for approval:
   A. You have hereditary transthyretin-mediated amyloidosis (hATTR: a rare genetic disorder) with polyneuropathy (widespread nerve pain/damage)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor), cardiologist (a type of heart doctor), hATTR specialist, or medical geneticist (doctor who treats gene disorders)
   D. You have a documented diagnosis of hereditary TTR amyloidosis (hATTR) as confirmed by ONE of the following:
      1. Biopsy (surgical removal of a sample) of tissue/organ to confirm amyloid (abnormal protein that can build up in any tissue or organ) presence AND chemical typing to confirm presence of TTR (transthyretin) protein
      2. DNA genetic sequencing (lab test for genes) to confirm hATTR mutation
   E. You have familial amyloidotic polyneuropathy (FAP) stage 1 or 2 OR up to polyneuropathy disability (PND) stage IIIb polyneuropathy
   F. You had a trial of or contraindication (harmful for) to the preferred medication: Amvuttra
   (Initial denial text continued on next page)

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INOTERSEN

INTIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy **AND** meet the following criterion?
   - The patient has not progressed to FAP stage 3 OR PND stage IV polyneuropathy as evidenced by functional decline (e.g., wheelchair-bound, bedridden)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6mL per 28 days.** If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INOTERSEN (Tegsedi)** requires the following rule(s) be met for renewal:
   A. You have hereditary transthyretin-mediated amyloidosis (hATTR: a rare genetic disorder) with polyneuropathy (widespread nerve pain/damage)
   B. You have not progressed to familial amyloidotic polyneuropathy (FAP) stage 3 OR polyneuropathy disability (PND) stage IV polyneuropathy as shown by functional decline such as being wheelchair-bound or bedridden

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tegsedi.

REFERENCES

- Tegsedi [Prescribing Information]. Carlsbad, CA: Ionis Pharmaceuticals, Inc.; June 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/22
Created: 10/18
Client Approval: 09/22
P&T Approval: 07/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INTERFERON ALFA-2B

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have **ONE** of the following diagnoses?
   - Hairy cell leukemia
   - Condylomata acuminata
   - AIDS-related Kaposi's sarcoma
   - Chronic hepatitis B
   - Non-Hodgkin's lymphoma
   - Malignant melanoma
   - Chronic phase, Philadelphia chromosome (Ph) positive chronic myelogenous leukemia (CML) patients who are minimally treated (within 1 year of diagnosis)
   - Follicular lymphoma
   - Angioblastoma
   - Carcinoid tumor
   - Chronic myeloid leukemia
   - Laryngeal papillomatosis
   - Multiple myeloma
   - Neoplasm of conjunctiva-neoplasm of cornea
   - Ovarian cancer
   - Polycythemia vera
   - Renal cell carcinoma
   - Skin cancer
   - Thrombocytosis
   - Vulvar vestibulitis

   If yes, **approve by HICL or GPI-10 for 24 weeks (6 months).**
   If no, continue to #2.

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INTERFERON ALFA-2B

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of chronic hepatitis C, genotype 1, 2, 3, 4, 5, or 6 and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (e.g., hepatologist)
   - The patient has a detectable pretreatment HCV RNA level/viral load of 50 IU/mL or higher
   - The requested medication will be used with ribavirin or the patient has a contraindication to ribavirin
   - The patient had a trial of or contraindication to peginterferon alfa-2a or peginterferon alfa-2b

   If yes, **approve by HICL or GPI-10 for 24 weeks (6 months).**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON ALFA-2B (Intron A)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Chronic hepatitis C (type of liver inflammation)
      2. Hairy cell leukemia (bone marrow cancer that makes too many white blood cells)
      3. Condylomata acuminate (genital warts)
      4. AIDS (acquired immunodeficiency syndrome)-related Kaposi's sarcoma (cancer in those with weak immune system that causes tumors of lymph nodes/skin)
      5. Chronic hepatitis B (type of liver inflammation)
      6. Non-Hodgkin's lymphoma (cancer that starts in your lymphatic system- the disease-fighting network in the body)
      7. Malignant melanoma (serious type of skin cancer)
      8. Chronic phase, Philadelphia chromosome (type of abnormal gene) positive chronic myelogenous leukemia (type of blood cell cancer that starts in bone marrow) who are minimally treated (within 1 year of diagnosis)
      9. Follicular lymphoma (type of lymphatic system cancer)
      10. Angioblastoma (certain blood-vessel tumors of the brain)
      11. Carcinoid (cancer) tumor
      12. Chronic myeloid leukemia (type of cancer that starts in immature white blood cells)
      13. Laryngeal papillomatosis (tumors form along the pathways for breathing/digestion)

   (Initial denial text continued on next page)

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INTERFERON ALFA-2B

INITIAL CRITERIA (CONTINUED)

14. Multiple myeloma (plasma cell cancer)
15. Neoplasm of conjunctiva-neoplasm of cornea (eye tumors)
16. Ovarian cancer
17. Polycythemia vera (cancer where bone marrow makes too many red blood cells)
18. Renal cell carcinoma (type of kidney cancer)
19. Skin cancer, thrombocytosis (your body makes too many platelets)
20. Thrombocytosis (high level of platelets (cells that helps blood clot and stop bleeding) in your blood)
21. Vulvar vestibulitis (type of pain around the female sex organ called the vulva)

B. **If you have chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6, approval also requires:**
   1. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions), infectious disease specialist (a doctor who specializes in the treatment of infections), or a physician specializing in the treatment of hepatitis (such as a hepatologist: a type of liver doctor)
   2. You have a detectable pretreatment HCV (hepatitis C virus) RNA level/viral load (amount of virus in your blood) of 50 IU/mL or higher
   3. The requested medication will be used with ribavirin or you have a contraindication (harmful for)
   4. You had a trial of or contraindication (harmful for) to peginterferon alfa-2a or peginterferon alfa-2b

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic hepatitis C **AND** meet the following criterion? Therapy is prescribed by or in consultation with a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (e.g., hepatologist)

   If yes, continue to #2.
   If no, **approve by HICL or GPI-10 for 24 weeks (6 months).**

2. Has the patient already received 24 weeks or more of interferon during this treatment?

   If yes, continue to #3.
   If no, **approve by HICL or GPI-10 for 24 weeks (6 months).**

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INTERFERON ALFA-2B

RENEWAL CRITERIA (CONTINUED)

3. Is the patient's HCV RNA undetectable (less than 50 IU/mL) at 24 weeks?

If yes, **approve by HICL or GPI-10 for 24 weeks (6 months).**
If no, do not approve.
RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INTERFERON ALFA-2B (Intron A)** requires the following rule(s) be met for renewal:

A. The request is for continuation of current therapy or renewal with Intron A therapy
B. **If you have chronic hepatitis C (type of liver inflammation), renewal also requires:**
   1. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions), infectious disease specialist (a doctor who specializes in the treatment of infections), or a physician specializing in the treatment of hepatitis (such as a hepatologist: a type of liver doctor)
   2. If you already received 24 weeks or more of interferon treatment, your HCV (hepatitis C virus) RNA level (amount of virus in your blood) is undetectable (less than 50 IU/mL) at 24 weeks

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Intron A.

REFERENCES

- Intron A [Prescribing Information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp.; November 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/15/22
Created: 02/14
Client Approval: 05/22
P&T Approval: 02/14

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INTERFERON FOR MS - AVONEX

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis, to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 as follows:**
   - **Avonex: #1 kit per 28 days or 2mL (#4 syringes) per 28 days.**
   - **Avonex Pen: #1 pen injector kit per 28 days or 2mL (#4 syringes) per 28 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON FOR MS - AVONEX** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Avonex.

REFERENCES

- Avonex [Prescribing Information]. Cambridge, MA: Biogen Inc.; July 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/01/22
Created: 10/22
Client Approval: 10/22
P&T Approval: 01/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INTERFERON FOR MS - BETASERON

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis, to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months for all NDCs or GPI-14 of Betaseron for #14 vials or kits per 28 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON FOR MS - BETASERON** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Betaseron.

REFERENCES

- Betaseron [Prescribing Information]. Whippany, NJ: Bayer; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/01/22
Created: 10/22
Client Approval: 10/22
P&T Approval: 01/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INTERFERON FOR MS - EXTAVIA

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to any TWO of the following preferred agents for MS: Avonex, Copaxone/Glatiramer/Glatopa, Gilenya, Plegridy, Rebif, Betaseron, dimethyl fumarate, Mavenclad, Mayzent, Vumerity, Aubagio, Kesimpta
     (Please note: other multiple sclerosis agents may also require prior authorization)

   If yes, **approve for 12 months for all NDCs or GPI-14 of Extavia for #14 vials or kits per 28 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON FOR MS - EXTAVIA** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older
   C. You had a trial of or contraindication (harmful for) to any TWO of the following preferred medications: Avonex, Copaxone/Glatiramer/Glatopa, Gilenya, Plegridy, Rebif, Betaseron, dimethyl fumarate, Mavenclad, Mayzent, Vumerity, Aubagio, Kesimpta
      (Please note: other multiple sclerosis medications may also require prior authorization)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INTERFERON FOR MS - EXTAVIA

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Extavia.

REFERENCES

- Extavia [Prescribing Information]. East Hanover, NJ: EMD Novartis; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/01/22
Created: 10/22
Client Approval: 10/22
P&T Approval: 01/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INTERFERON FOR MS - PLEGRIDY

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis, to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 as follows:**
   INITIAL REQUESTS:
   - **FIRST APPROVAL: Plegridy injection starter pack: approve for 1 month with a quantity limit of 1mL (#2 prefilled pens or syringes).**
   - **SECOND APPROVAL: Plegridy Pen/Syringe: approve for 11 months (total approval duration of 12 months) with a quantity limit of 1mL (#2 125mcg prefilled pens or syringes) per 28 days. (Please enter start date of 3 weeks AFTER the START date of the first approval.).**

   SUBSEQUENT REQUESTS:
   - **Plegridy Pen/Syringe: approve for 12 months with a quantity limit of 1mL (#2 125mcg prefilled pens or syringes) per 28 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON FOR MS - PLEGRIDY** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INTERFERON FOR MS - PLEGRIDY

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Plegridy.

REFERENCES

- Plegridy [Prescribing Information]. Cambridge, MA: Biogen Inc.; July 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/01/22
Created: 10/22
Client Approval: 10/22
P&T Approval: 01/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INTERFERON FOR MS - REBIF

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 as follows:**
   INITIAL REQUESTS:
   - **FIRST APPROVAL: Rebif Titration Pack/Rebif Rebidose Titration Pack: approve for 1 month with a quantity limit of 4.2mL (#12 syringes) per 28 days.**
   - **SECOND APPROAL: Rebif/Rebif Rebidose: approve for 11 months (total approval duration of 12 months) with a quantity limit of 6mL (#12 syringes) per 28 days. (Please enter start date of 3 weeks AFTER the START date of the first approval.).**

   SUBSEQUENT REQUESTS:
   - **Rebif/Rebif Rebidose: approve for 12 months with a quantity limit of 6mL (#12 syringes) per 28 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON FOR MS - REBIF** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INTERFERON FOR MS - REBIF

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rebif.

REFERENCES

- Rebif [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; July 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/01/22
Created: 10/22
Client Approval: 10/22
P&T Approval: 01/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INTERFERON GAMMA-1B, RECOMB

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic granulomatous disease (CGD) **AND** meet the following criterion?
   - The medication is prescribed by or given in consultation with a hematologist, infectious disease specialist, or immunologist

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT: Renewal requires the following: 1) patient has demonstrated clinical benefit compared to baseline (e.g. reduction in frequency and severity of serious infections), and 2) patient has not received hematopoietic cell transplantation.

   If no, continue to #2.

2. Does the patient have a diagnosis of severe malignant osteopetrosis (SMO) **AND** meet the following criterion?
   - The medication is prescribed by or given in consultation with an endocrinologist

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT: Renewal requires the following: 1) patient has demonstrated clinical benefit compared to baseline (e.g. reduction in frequency and severity of serious infections), and 2) patient has not received hematopoietic cell transplantation.

   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **INTERFERON GAMMA-1B, RECOMB (Actimmune)** requires the following rules be met for approval:
   A. You have ONE of the following diagnoses:
      1. Chronic granulomatous disease (CGD: inherited immune system disorder that occurs when a type of white blood cells that usually helps your body fight infections does not work properly)
      2. Severe malignant osteopetrosis (SMO: a bone disease that makes bone abnormally thick and prone to breakage/fracture)

   (Initial denial text continued on the next page)

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INTERFERON GAMMA-1B, RECOMB

INITIAL CRITERIA (CONTINUED)

B. **If you have chronic granulomatous disease, approval also requires:**
   1. The medication is prescribed by or given in consultation with a hematologist (blood doctor), infectious disease specialist (doctor that specializes in treating infections), or immunologist (doctor that specializes in treating and managing allergies, asthma and immunologic disorders)

C. **If you have severe malignant osteopetrosis, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (doctor that specializes in all things relating to our hormones)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic granulomatous disease (CGD) or severe malignant osteopetrosis (SMO) and meet **ALL** of the following criteria?
   - The patient has demonstrated clinical benefit compared to baseline (e.g., reduction in frequency and severity of serious infections)
   - The patient has not received hematopoietic cell transplantation

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON GAMMA-1B, RECOMB (Actimmune)** requires the following rules be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Chronic granulomatous disease (CGD: inherited immune system disorder that occurs when a type of white blood cells that usually helps your body fight infections does not work properly)
      2. Severe malignant osteopetrosis (SMO: a bone disease that makes bone abnormally thick and prone to breakage/fracture)
   B. You have shown clinical (medical) benefit compared to baseline (such as reduction in frequency and severity of serious infections)
   C. You have not received hematopoietic cell transplantation (transplant of stem cells from bone marrow, peripheral blood, or umbilical cord blood)

   (Renewal denial text continued on the next page)

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INTERFERON GAMMA-1B, RECOMB

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Actimmune.

REFERENCES

- Actimmune [Prescribing Information] Lake Forest, IL: Horizon Therapeutics USA, Inc., January 2020.

Library	Commercial	NSA
No	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20

Created: 09/05
Client Approval: 02/20

P&T Approval: 01/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IPTACOPAN

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist
   - Fabhalta will NOT be used concurrently with a C5 complement inhibitor (e.g., Soliris [eculizumab], Ultomiris [ravulizumab-cwvz]) or a C3 complement inhibitor (e.g., Empaveli [pegcetacoplan])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have documented confirmation (e.g., chart notes, lab results, diagnostic test results, etc.) of PNH by flow cytometry demonstrating **ALL** of the following?
   - The patient has at least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes)
   - PNH granulocyte clone size of at least 10 percent

   If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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IPTACOPAN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **IPTACOPAN (Fabhalta)** requires the following rule(s) be met for approval:

A. You have paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
D. You have documented confirmation (such as chart notes, lab results, diagnostic test results) of PNH through flow cytometry (a type of lab test) demonstrating ALL of the following:
    1. You have at least 2 different GPI-protein deficiencies (you are missing a certain type of protein, such as CD55, CD59) on at least 2 cell lineages (types of cells, such as erythrocytes [red blood cells], granulocytes [a type of white blood cell])
    2. PNH granulocyte clone size of at least 10 percent
E. You will NOT use Fabhalta concurrently (at the same time) with a C5 complement inhibitor (such as, Soliris [eculizumab], Ultomiris [ravulizumab-cwvz]) or a C3 complement inhibitor (such as, Empaveli [pegcetacoplan])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IPTACOPAN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) and meet **ALL** of the following criteria?
   - The patient experienced clinical benefit while on Fabhalta (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase [LDH] and hemoglobin levels) compared to baseline
   - Fabhalta will NOT be used concurrently with a C5 complement inhibitor (e.g., Soliris [eculizumab], Ultomiris [ravulizumab-cwvz]) or a C3 complement inhibitor (e.g., Empaveli [pegcetacoplan])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IPTACOPAN (Fabhalta)** requires the following rule(s) be met for renewal:
   A. You have paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
   B. You have had clinical benefit while on Fabhalta (such as, a reduction in the number of blood transfusions [adding blood to your body], improvement/stabilization of lactate dehydrogenase [LDH: a type of enzyme] levels and hemoglobin [type of protein in red blood cells] levels) compared to baseline
   C. You will NOT use Fabhalta concurrently (at the same time) with a C5 complement inhibitor (such as, Soliris [eculizumab], Ultomiris [ravulizumab-cwvz]) or a C3 complement inhibitor (such as, Empaveli [pegcetacoplan])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IPTACOPAN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fabhalta.

REFERENCES

- Fabhalta [Prescribing Information]. East Hanover, NJ: Novartis Pharma Corp; December 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 12/23
Client Approval: 02/24
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ISAVUCONAZONIUM

GUIDELINES FOR USE

1. Is this request for continuation of therapy after the patient was started on Cresemba in the hospital?

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
   - **74.5 mg: #150 per 30 days.**
   - **186 mg: #60 per 30 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of invasive aspergillosis and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older and weighs at least 16 kg (35.2 lb)
   - Therapy is prescribed by or in consultation with an infectious disease specialist
   - The patient had a trial of or contraindication to voriconazole

   If yes, **approve for 6 months total by GPID or GPI-14 for the requested strength as follows:**
   INITIAL REQUESTS:
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit as follows:**
     - **74.5 mg: #170 per 30 days for 1 fill.**
     - **186 mg: #68 per 30 days for 1 fill.**
   - **SECOND APPROVAL: Approve for 5 months with a quantity limit as follows (enter a start date of 3 days before the end date of the first approval):**
     - **74.5 mg: #150 per 30 days.**
     - **186 mg: #60 per 30 days.**

   SUBSEQUENT REQUESTS:
   - **Approve for 6 months for the requested strength with a quantity limit as follows:**
     - **74.5 mg: #150 per 30 days.**
     - **186 mg: #60 per 30 days.**

   If no, continue to #3.

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ISAVUCONAZONIUM

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of invasive mucormycosis and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older and weighs at least 16 kg (35.2 lb)
   - Therapy is prescribed by or in consultation with an infectious disease specialist

   If yes, **approve for 6 months total by GPID or GPI-14 for the requested strength as follows:**
   INITIAL REQUESTS:
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit as follows:**
     - **74.5 mg: #170 per 30 days for 1 fill.**
     - **186 mg: #68 per 30 days for 1 fill.**
   - **SECOND APPROVAL: Approve for 5 months with a quantity limit as follows (enter a start date of 3 days before the end date of the first approval):**
     - **74.5 mg: #150 per 30 days.**
     - **186 mg: #60 per 30 days.**

   SUBSEQUENT REQUESTS:
   - **Approve for 6 months for the requested strength with a quantity limit as follows:**
     - **74.5 mg: #150 per 30 days.**
     - **186 mg: #60 per 30 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ISAVUCONAZONIUM (Cresemba)** requires the following rule(s) be met for approval:
   A. You meet ONE of the following:
      1. This is a request for continuation of therapy after you were started on Cresemba in the hospital
      2. You have invasive aspergillosis (a type of fungal infection)
      3. You have invasive mucormycosis (a type of fungal infection)
   B. **If you have invasive aspergillosis, approval also requires:**
      1. You are 6 years of age or older and weigh at least 16 kilograms (35.2 pounds)
      2. Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)
      3. You have tried or have a contraindication to (harmful for you to use) voriconazole

   (Denial text continued on next page)

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ISAVUCONAZONIUM

GUIDELINES FOR USE (CONTINUED)

C. **If you have invasive mucormycosis, approval also requires:**
   1. You are 6 years of age or older and weigh at least 16 kilograms (35.2 pounds)
   2. Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cresemba.

REFERENCES

- Cresemba [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc; December 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/15/24
Created: 05/21
Client Approval: 12/23
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ISTRADEFYLLINE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Parkinson's disease (PD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is experiencing 'OFF' episodes
   - Nourianz will be used concurrently with levodopa/carbidopa
   - The patient had a previous trial of, failure of, or contraindication to **TWO** Parkinson's agents from **TWO** different therapeutic classes: dopamine agonists (e.g., ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (e.g., selegiline, rasagiline), or catechol-O-methyl transferase inhibitors (e.g., entacapone, tolcapone)

   If yes, **approve for lifetime by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ISTRADEFYLLINE (Nourianz)** requires the following rule(s) be met for approval:
   A. You have Parkinson's disease (a nerve system disorder that affects movement)
   B. You are 18 years of age or older
   C. You are experiencing 'OFF' episodes (times when medication wears off and you have movement problems)
   D. Nourianz will be used along with levodopa/carbidopa
   E. You had a previous trial of or contraindication to (medical reason why you cannot use) **TWO** Parkinson's agents from **TWO** different drug classes:
      1. Dopamine agonists (such as ropinirole, pramipexole, rotigotine)
      2. Monoamine oxidase-inhibitors (such as selegiline, rasagiline)
      3. Catechol-O-methyl transferase inhibitors (such as entacapone, tolcapone)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ISTRADEFYLLINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nourianz.

REFERENCES

- Nourianz [Prescribing Information]. Bedminster, NJ: Kyowa Kirin, Inc.; September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 11/19
Client Approval: 04/20
P&T Approval: 10/19

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ITRACONAZOLE - TOLSURA

GUIDELINES FOR USE

1. Does the patient have a diagnosis of **ONE** of the following types of fungal infections?
   - Blastomycosis, pulmonary and extrapulmonary
   - Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis
   - Aspergillosis, pulmonary and extrapulmonary, **AND** the patient is intolerant to or refractory to amphotericin B therapy

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with an infectious disease specialist
   - The patient had a previous trial of a generic itraconazole formulation
   - Tolsura is prescribed due to subclinical response to other formulations of itraconazole suspected to be due to poor bioavailability

   If yes, **approve for a total of 12 months by GPID or GPI-14 as follows:**
   INITIAL REQUESTS
   - **FIRST APPROVAL: approve for 1 fill with a quantity limit of #126 per 30 days.**
   - **SECOND APPROVAL: approve for 11 months with a quantity limit of #120 per 30 days.**

   SUBSEQUENT REQUESTS
   - **Approve for 12 months with a quantity limit of #120 per 30 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ITRACONAZOLE - TOLSURA

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ITRACONAZOLE (Tolsura)** requires the following rule(s) be met for approval:

A. You have **ONE** of the following fungal infections:
   1. Blastomycosis, pulmonary and extrapulmonary (type of fungal infection affecting in and outside of the lungs)
   2. Histoplasmosis (type of fungal infection), including chronic cavitary pulmonary (affecting the lungs) disease and disseminated, nonmeningeal (not affecting spinal cord and brain membranes) histoplasmosis
   3. Aspergillosis, pulmonary and extrapulmonary (type of fungal infection in and outside of the lungs), **AND** you are intolerant to or refractory to (not responsive to) amphotericin B therapy

B. You are 18 years of age or older

C. Therapy is prescribed by or given in consultation with an infectious disease specialist

D. You had a previous trial of a generic itraconazole formulation

E. Tolsura is prescribed because you had a poor clinical response to other formulations of itraconazole due to poor bioavailability (amount of drug in the body that has an effect)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tolsura.

REFERENCES

- Tolsura [Prescribing Information]. Greenville, NC: Mayne Pharma; September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/21
Created: 03/19
Client Approval: 05/21
P&T Approval: 04/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IVACAFTOR

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cystic fibrosis (CF) and meet **ALL** of the following criteria?
   - The patient is 1 month of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist or cystic fibrosis expert
   - The patient is NOT homozygous for the F508del mutation in the CFTR gene

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is there documentation (e.g., chart notes, lab results, diagnostic test results, etc.) that the patient has **ONE** of the following mutations in the CFTR gene?

711+3A→G	*F311del*	*I148T*	*R75Q*	*S589N*
2789+5G→A	*F311L*	*I175V*	*R117C*	*S737F*
3272-26A→G	*F508C*	*I807M*	*R117G*	*S945L*
3849+10kbC→T	*F508C; S1251N*	*I1027T*	*R117H*	*S977F*
A120T	*F1052V*	*I1139V*	*R117L*	*S1159F*
A234D	*F1074L*	*K1060T*	*R117P*	*S1159P*
A349V	*G178E*	*L206W*	*R170H*	*S1251N*
A455E	*G178R*	*L320V*	*R347H*	*S1255P*
A1067T	*G194R*	*L967S*	*R347L*	*T338I*
D110E	*G314E*	*L997F*	*R352Q*	*T1053I*
D110H	*G551D*	*L1480P*	*R553Q*	*V232D*
D192G	*G551S*	*M152V*	*R668C*	*V562I*
D579G	*G576A*	*M952I*	*R792G*	*V754M*
D924N	*G970D*	*M952T*	*R933G*	*V1293G*
D1152H	*G1069R*	*P67L*	*R1070Q*	*W1282R*
D1270N	*G1244E*	*Q237E*	*R1070W*	*Y1014C*
E56K	*G1249R*	*Q237H*	*R1162L*	*Y1032C*
E193K	*G1349D*	*Q359R*	*R1283M*	
E822K	*H939R*	*Q1291R*	*S549N*	
E831X	*H1375P*	*R74W*	*S549R*	

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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IVACAFTOR

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **IVACAFTOR (Kalydeco)** requires the following rule(s) be met for approval:

A. You have cystic fibrosis (CF: a type of lung disorder)
B. You are 1 month of age or older
C. Therapy is prescribed by or in consultation with a pulmonologist (lung doctor) or cystic fibrosis expert
D. You are NOT homozygous (have two copies of the same gene) for the F508del mutation (an abnormal change) in the CFTR (cystic fibrosis transmembrane conductance regulator) gene
E. You have documentation (such as chart notes, lab results, diagnostic test results) of ONE of the following mutations in the CFTR (cystic fibrosis transmembrane conductance regulator) gene:

711+3A→G	*F311del*	*I148T*	*R75Q*	*S589N*
2789+5G→A	*F311L*	*I175V*	*R117C*	*S737F*
3272-26A→G	*F508C*	*I807M*	*R117G*	*S945L*
3849+10kbC→T	*F508C; S1251N*	*I1027T*	*R117H*	*S977F*
A120T	*F1052V*	*I1139V*	*R117L*	*S1159F*
A234D	*F1074L*	*K1060T*	*R117P*	*S1159P*
A349V	*G178E*	*L206W*	*R170H*	*S1251N*
A455E	*G178R*	*L320V*	*R347H*	*S1255P*
A1067T	*G194R*	*L967S*	*R347L*	*T338I*
D110E	*G314E*	*L997F*	*R352Q*	*T1053I*
D110H	*G551D*	*L1480P*	*R553Q*	*V232D*
D192G	*G551S*	*M152V*	*R668C*	*V562I*
D579G	*G576A*	*M952I*	*R792G*	*V754M*
D924N	*G970D*	*M952T*	*R933G*	*V1293G*
D1152H	*G1069R*	*P67L*	*R1070Q*	*W1282R*
D1270N	*G1244E*	*Q237E*	*R1070W*	*Y1014C*
E56K	*G1249R*	*Q237H*	*R1162L*	*Y1032C*
E193K	*G1349D*	*Q359R*	*R1283M*	
E822K	*H939R*	*Q1291R*	*S549N*	
E831X	*H1375P*	*R74W*	*S549R*	

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IVACAFTOR

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cystic fibrosis (CF) and improvement in clinical status compared to baseline as shown by **ONE** of the following?
   - The patient has improved, maintained, or demonstrated a less than expected decline in FEV1
   - The patient has improved, maintained, or demonstrated a less than expected decline in BMI
   - The patient has experienced a reduction in rate of pulmonary exacerbations

   If yes, **approve for lifetime by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IVACAFTOR (Kalydeco)** requires the following rule(s) be met for renewal:
   A. You have cystic fibrosis (CF: a type of lung disorder)
   B. You have shown improvement in clinical (medical) status compared to baseline as shown by ONE of the following:
      1. You have improved, maintained, or demonstrated a less than expected decline in forced expiratory volume (FEV1: amount of air you can exhale in 1 second)
      2. You have improved, maintained, or demonstrated a less than expected decline in body mass index (BMI: a tool for evaluating body fat)
      3. You have experienced a reduction in rate of pulmonary exacerbations (you have less attacks of breathing problems)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kalydeco.

REFERENCES

- Kalydeco [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Incorporated; May 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/01/23
Created: 02/12
Client Approval: 05/23
P&T Approval: 01/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IVOSIDENIB

GUIDELINES FOR USE

1. Does the patient have a new diagnosis of acute myeloid leukemia (AML) and meet **ALL** of the following criteria?
   - Tibsovo will be used in combination with azacitidine or as monotherapy
   - The patient's cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient is 75 years of age or older
   - The patient is 18 years of age or older AND has comorbidities that prevent the use of intensive induction chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of relapsed or refractory acute myeloid leukemia (AML) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #4.

4. Does the patient have a diagnosis of relapsed or refractory myelodysplastic syndromes (MDS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #5.

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IVOSIDENIB

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of locally advanced or metastatic cholangiocarcinoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test
   - The patient's cancer has been previously treated

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IVOSIDENIB (Tibsovo)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Newly diagnosed acute myeloid leukemia (AML: a type of blood cancer)
      2. Relapsed or refractory acute myeloid leukemia (AML: a type of blood cancer that has returned or has not responded to treatment)
      3. Relapsed or refractory myelodysplastic syndromes (MDS: a type of blood cancer that has returned or has not respond to treatment)
      4. Locally advanced or metastatic cholangiocarcinoma (bile duct cancer that has spread from where it started to nearby tissue/lymph nodes or to other parts of the body)
   B. **If you have a new diagnosis of acute myeloid leukemia, approval also requires:**
      1. Tibsovo will be used in combination with azacitidine or as monotherapy (one drug treatment)
      2. Your cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation (a type of enzyme mutation that can be treated with Tibsovo), as detected by a Food and Drug Administration (FDA)-approved test
      3. You meet ONE of the following:
         a. You are 75 years of age or older
         b. You are 18 years of age or older AND have comorbidities (additional diseases) that prevent the use of intensive induction chemotherapy (a type of therapy to treat cancer)
   C. **If you have relapsed or refractory acute myeloid leukemia, approval also requires:**
      1. You are 18 years of age or older
      2. Your cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation (a type of enzyme mutation that can be treated with Tibsovo), as detected by a Food and Drug Administration (FDA)-approved test

   (Denial text continued on next page)

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IVOSIDENIB

GUIDELINES FOR USE (CONTINUED)

D. **If you have relapsed or refractory myelodysplastic syndromes, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation (a type of enzyme mutation that can be treated with Tibsovo), as detected by a Food and Drug Administration (FDA)-approved test

E. **If you have locally advanced or metastatic cholangiocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has an isocitrate dehydrogenase-1 (IDH1) mutation (type of enzyme mutation), as detected by a Food and Drug Administration (FDA)-approved test
   3. Your cancer has been previously treated

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tibsovo.

REFERENCES

- Tibsovo [Prescribing Information]. Cambridge, MA: Agios Pharmaceuticals; October 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/13/23
Created: 11/18
Client Approval: 10/23
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IXAZOMIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma and meet **ALL** of the following criteria?
   - Ninlaro (ixazomib) will be used in combination with lenalidomide and dexamethasone
   - The patient has received at least one prior therapy for the treatment of multiple myeloma such as bortezomib, carfilzomib, thalidomide, lenalidomide, melphalan or stem cell transplantation

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IXAZOMIB (Ninlaro)** requires the following rule(s) be met for approval:
   A. You have multiple myeloma (plasma cell cancer)
   B. The requested medication will be used in combination with lenalidomide and dexamethasone
   C. You have received at least one prior therapy such as bortezomib, carfilzomib, thalidomide, lenalidomide, melphalan or stem cell transplantation

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ninlaro.

REFERENCES

- Ninlaro [Prescribing Information]. Cambridge, MA: Takeda Pharmaceutical Company Limited; February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 12/15
Client Approval: 04/20
P&T Approval: 02/16

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IXEKIZUMAB

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient had a trial of or contraindication to ONE or more forms of conventional therapies, (e.g., PUVA [psoralen and ultraviolet light A], UVB [ultraviolet light B], topical corticosteroids [e.g., betamethasone dipropionate, clobetasol propionate], calcipotriene, acitretin, methotrexate, or cyclosporine)

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic and is switching to Taltz
   - The patient has psoriasis covering 3% or more of body surface area (BSA)
   - The patient has psoriatic lesions affecting the hands, feet, genital area, or face

   If yes, **approve for a total of 6 months by HICL or GPI-10 as follows:**
   - **For patients who are 6 years to 17 years of age, enter TWO approvals:**
     - **FIRST APPROVAL: Approve for 1 month with a quantity limit of 2mL per 28 days.**
     - **SECOND APPROVAL: Approve for 5 months with a quantity limit of 1mL per 28 days (Start date is 3 WEEKS AFTER the START date of the first approval).**
   - **For patients who are 18 years of age or older, enter THREE approvals:**
     - **FIRST APPROVAL: Approve for 1 month with a quantity limit of 3mL per 28 days.**
     - **SECOND APPROVAL: Approve for 2 months with a quantity limit of 2mL per 28 days (Start date is 3 WEEKS AFTER the START date of the first approval).**
     - **THIRD APPROVAL: Approve for 3 months with a quantity limit of 1mL per 28 days (Start date is 1 WEEK BEFORE the END date of the second approval).**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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IXEKIZUMAB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #4.
   If no, continue to #5.

4. Does the patient have coexistent moderate to severe plaque psoriasis (PsO)?

   If yes, **approve for a total of 6 months by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of 3mL per 28 days.**
   - **SECOND APPROVAL: Approve for 2 months with a quantity limit of 2mL per 28 days (Start date is 3 WEEKS AFTER the START date of the first approval).**
   - **THIRD APPROVAL: Approve for 3 months with a quantity limit of 1mL per 28 days (Start date is 1 WEEK BEFORE the END date of the second approval).**

   If no, **approve for a total of 6 months by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of 2mL per 28 days.**
   - **SECOND APPROVAL: Approve for 5 months with a quantity limit of 1mL per 28 days (Start date is 3 WEEKS AFTER the START date of the first approval).**

5. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)

   If yes, **approve for a total of 6 months by entering TWO approvals by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of 2mL per 28 days.**
   - **SECOND APPROVAL: Approve for 5 months with a quantity limit of 1mL per 28 days (Start date is 3 WEEKS AFTER the START date of the first approval).**

   If no, continue to #6.

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IXEKIZUMAB

INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic (e.g., Cosentyx [secukinumab], Cimzia [certolizumab]) and is switching to the requested drug
   - The patient has C-reactive protein (CRP) levels above the upper limit of normal
   - The patient has sacroiliitis on magnetic resonance imaging (MRI)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of 1mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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IXEKIZUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **IXEKIZUMAB (Taltz)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)

B. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You had a trial of or contraindication (harmful for) to ONE or more forms of standard therapies, such as PUVA (psoralen and ultraviolet light A: a type of light therapy), UVB (ultraviolet light B: a type of light therapy), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), calcipotriene, acitretin, methotrexate, or cyclosporine
   4. You meet ONE of the following:
      a. You were previously stable on another biologic and are switching to Taltz
      b. You have psoriasis covering 3% or more of body surface area (BSA)
      c. You have psoriatic lesions (rashes) affecting the hands, feet, genital area, or face

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You had a trial of or contraindication (harmful for) to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

(Initial denial text continued on next page)

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IXEKIZUMAB

INITIAL CRITERIA (CONTINUED)

D. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You had a trial of or contraindication (harmful for) to an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

E. **If you have non-radiographic axial spondyloarthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You had a trial of or contraindication (harmful for) to an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
   4. You meet ONE of the following:
      a. You were previously stable on another biologic (such as Cosentyx [secukinumab], Cimzia [certolizumab]) and are switching to the requested drug
      b. You have C-reactive protein (CRP; a measure of how much inflammation you have) levels above the upper limit of normal
      c. You have sacroiliitis (type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IXEKIZUMAB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?
   - The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of 1mL per 28 days.** If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of 1mL per 28 days.** If no, continue to #3.

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) or non-radiographic axial spondyloarthritis (nr-axSpA) **AND** meet the following criterion?
   - The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of 1mL per 28 days.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IXEKIZUMAB (Taltz)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Ankylosing spondylitis (AS: a type of joint condition)
      4. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
   B. **If you have moderate to severe plaque psoriasis, renewal also requires:**
      1. You achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50% or more

   (Renewal denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

D. **If you have ankylosing spondylitis OR non-radiographic axial spondyloarthritis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Taltz.

REFERENCES

- Taltz [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; September 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24

Created: 04/16
Client Approval: 03/24

P&T Approval: 04/23

EPINEPHRINE

Generic	Brand	HICL	GCN	Exception/Other
EPINEPHRINE	AUVI-Q			NDC-9 000245831 NDC-9 000245833 NDC-9 608420022 NDC-9 608420023

GUIDELINES FOR USE

1. Is there a FDA confirmed shortage of ALL other epinephrine auto-injector products for the emergency treatment of anaphylaxis [Adrenaclick, epinephrine auto-injector (generic Adrenaclick), EpiPen, EpiPen Jr.]?

   If yes, **Approve for 1 fill only**.
   If no, continue to #2.

2. Is the patient unable to use alternative mechanisms of epinephrine delivery [e.g., Adrenaclick, epinephrine auto-injector (generic Adrenaclick), EpiPen, EpiPen Jr.] despite documented training with a healthcare professional, due to significant functional impairment requiring the need for an auto-injector with audio cues for self-administration?

   If yes, **Approve for 1 fill only**.
   If no, continue to #3.

3. Is the patient caregiver unable to use alternative mechanisms of epinephrine delivery [e.g., Adrenaclick, epinephrine auto-injector (generic Adrenaclick), EpiPen, EpiPen Jr.] despite documented training with a healthcare professional, due to significant functional impairment and requires an auto-injector with audio cues for appropriate administration?

   If yes, **Approve for 1 fill only**.
   If no, **do not approve, but please ensure member receives one of the alternative mechanisms of delivery**.

DENIAL TEXT: Our guideline for **EPINEPHRINE** requires either a Food and Drug Administration (FDA) confirmed shortage of all other epinephrine auto-injector products for the emergency treatment of anaphylaxis [Adrenaclick, epinephrine auto-injector (generic Adrenaclick), EpiPen, EpiPen Jr.], or despite documented training with a healthcare professional the patient or patients' caregiver must be unable to use alternative mechanisms of epinephrine delivery [Adrenaclick, epinephrine auto-injector (generic Adrenaclick), EpiPen, EpiPen Jr.] due to significant functional impairment and requires an auto-injector with audio cues for appropriate administration .

RATIONALE
To prevent inappropriate utilization of epinephrine auto-injectors when there are other preferred epinephrine auto-injector dosage forms.

FDA APPROVED INDICATIONS
Epinephrine auto-injectors contain epinephrine, which is vasopressor indicated for the emergency treatment

of type I allergic reactions, including anaphylaxis.

REFERENCES

- Kaléo, Inc. A u v i - Q package insert. R i c h m o n d , VA. M a y 2016.

NALOXONE HCL

Generic	Brand	HICL	GCN	Exception/Other
NALOXONE HCL	EVZIO		36342, 42502	

GUIDELINES FOR USE

1. Is there a FDA confirmed shortage of ALL other naloxone products for the emergency treatment of opioid overdose [naloxone vials and syringes (with or without a nasal adaptor) and naloxone nasal spray (Narcan)]?

   If yes, **Approve for 1 fill only**.
   If no, continue to #2.

2. Is the caregiver unable to use alternative mechanisms of naloxone delivery (e.g., naloxone nasal spray, injectable naloxone pre-filled syringe or vial) due to deficits requiring the need for an auto-injector with audio cues for administration and precluding the use of nasally administered naloxone?

   If yes, **Approve for 1 fill only**.
   If no, **do not approve, but please ensure member receives one of the alternative mechanisms of delivery**.

DENIAL TEXT: Our guideline for **NALOXONE HCL** auto-injector with audio cues (Evzio) requires either a Food and Drug Administration (FDA) confirmed shortage of all other naloxone products for the emergency treatment of opioid overdose [naloxone vials and syringes (with or without a nasal adaptor) and naloxone nasal spray (Narcan)], or the caregiver must be unable to use alternative mechanisms of naloxone delivery (e.g., naloxone nasal spray, injectable naloxone pre-filled syringe or vial) due to deficits requiring the need for an auto-injector with audio cues for administration and precluding the use of nasally administered naloxone.

RATIONALE
To prevent inappropriate utilization of naloxone auto-injector with audio cues when there are other preferred naloxone dosage forms.

FDA APPROVED INDICATIONS
Naloxone HCl is an opioid antagonist indicated for the emergency treatment of known or suspected opiate overdose, as manifested by respiratory and/or central nervous system depression.

REFERENCES

- Kaleo, Inc. Evzio package insert. Richmond, VA. April 2014.

METFORMIN ER (FORTAMET & GENERIC FORTAMET)

Generic	Brand	HICL	GCN	Exception/Other
METFORMIN ER	FORTAMET		54018 54019	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of type 2 diabetes mellitus?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient tried and failed therapy with, or does the patient have a contraindication to ALL of the following other metformin products (including each separate supplier)?

   Immediate release Metformin
   Glucophage (brand)
   Metformin (generic Glucophage) manufactured by Amneal, Aurobindo, Heritage Pharma, Major, Mylan, Solco, Sun, Zydus
   Riomet (brand solution)
   Extended release Metformin
   Glucophage XR (brand)
   Metformin ER (generic Glucophage XR) manufactured by Actavis, Amneal, Apotex, Major, Sun, Tagi, Teva)

   If yes, **Approve for 12 months by GCN with a quantity limit of #60 tablets per 30 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: Our guideline for **Fortamet and its generic** requires a diagnosis of type 2 Diabetes Mellitus AND a trial showing intolerance to every other metformin product marketed in the United States (except for Glumetza and its generic).

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METFORMIN ER (FORTAMET & GENERIC FORTAMET)

RATIONALE

To prevent inappropriate utilization of Fortamet and its generic due to its exorbitant cost without any shown therapeutic benefit. A usual course of Fortamet costs around $24,000 per year, while generic Glucophage XR (metformin ER) costs around $100 per year.

FDA APPROVED INDICATIONS

Fortamet is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

REFERENCES

- Shionogi Inc. Fortamet package insert. Florham Park, NJ. 2013.

METFORMIN ER (GLUMETZA & GENERIC GLUMETZA)

Generic	Brand	HICL	GCN	Exception/Other
METFORMIN ER	GLUMETZA		61267 61273	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of type 2 diabetes mellitus?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient tried and failed therapy with, or does the patient have a contraindication to ALL of the following other metformin products (including each separate supplier)?

   Immediate release Metformin
   Glucophage (brand)
   Metformin (generic Glucophage) manufactured by Amneal, Aurobindo, Heritage Pharma, Major, Mylan, Solco, Sun, Zydus
   Riomet (brand solution)
   Extended release Metformin
   Glucophage XR (brand)
   Metformin ER (generic Glucophage XR) manufactured by Actavis, Amneal, Apotex, Major, Sun, Tagi, Teva)
   Fortamet (brand)
   Metformin ER Osmotic (generic Fortamet)

   If yes, **Approve for 12 months by GCN with a quantity limit of #60 tablets per 30 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: Our guideline for **Glumetza and its generic** requires a diagnosis of type 2 Diabetes Mellitus AND a trial showing intolerance to every other metformin product marketed in the United States.

CONTINUED ON NEXT PAGE

METFORMIN ER (GLUMETZA & GENERIC GLUMETZA)

RATIONALE

To prevent inappropriate utilization of Glumetza and its generic due to its exorbitant cost without any shown therapeutic benefit. A usual course of Glumetza costs around $24,000 per year, while generic Glucophage XR (metformin ER) costs around $100 per year.

FDA APPROVED INDICATIONS

Glumetza is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

REFERENCES

- Valeant Pharmaceuticals International. Glumetza package insert. Bridgewater, NJ. 2016.

CUSTOM
PRIOR AUTHORIZATION GUIDELINES

DULAGLUTIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DULAGLUTIDE	TRULICITY			GPI-10 (2717001500)	

GUIDELINES FOR USE

CRITERIA

1. Does the patient have a documented diagnosis of Type 2 Diabetes Mellitus?

   If yes, **approve the requested drug for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT:

Our guideline named **DULAGLUTIDE (Trulicity)** requires that you have a documented diagnosis of Type 2 Diabetes Mellitus.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Trulicity.

Created: 03/23
Effective: 07/01/23

CUSTOM
PRIOR AUTHORIZATION GUIDELINES

EXENATIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EXENATIDE	BYDUREON, BYDUREON BCISE, BYETTA			GPI-10 (2717002000)	

GUIDELINES FOR USE

CRITERIA

1. Does the patient have a documented diagnosis of Type 2 Diabetes Mellitus?

   If yes, **approve the requested drug for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT:

Our guideline named **EXENATIDE (Bydureon, Bydureon Bcise, Byetta)** requires that you have a documented diagnosis of Type 2 Diabetes Mellitus.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Bydureon/BCise/Byetta.

Created: 03/23
Effective: 07/01/23

CUSTOM
PRIOR AUTHORIZATION GUIDELINES

LIRAGLUTIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LIRAGLUTIDE	VICTOZA			GPI-10 (2717005000)	

GUIDELINES FOR USE

CRITERIA

1. Does the patient have a documented diagnosis of Type 2 Diabetes Mellitus?

   If yes, **approve the requested drug for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT:

Our guideline named **LIRAGLUTIDE (Victoza)** requires that you have a documented diagnosis of Type 2 Diabetes Mellitus.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Victoza.

Created: 03/23
Effective: 07/01/23

CUSTOM
PRIOR AUTHORIZATION GUIDELINES

LIXISENATIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LIXISENATIDE	ADLYXIN			GPI-10 (2717005600)	

GUIDELINES FOR USE

CRITERIA

1. Does the patient have a documented diagnosis of Type 2 Diabetes Mellitus?

   If yes, **approve the requested drug for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT:

Our guideline named **LIXISENATIDE (Adlyxin)** requires that you have a documented diagnosis of Type 2 Diabetes Mellitus.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Adlyxin.

Created: 03/23
Effective: 07/01/23

CUSTOM
PRIOR AUTHORIZATION GUIDELINES

SEMAGLUTIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SEMAGLUTIDE	OZEMPIC, RYBELSUS			GPI-10 (2717007000)	

GUIDELINES FOR USE

CRITERIA

1. Does the patient have a documented diagnosis of Type 2 Diabetes Mellitus?

   If yes, **approve the requested drug for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT:

Our guideline named **SEMAGLUTIDE (Ozempic, Rybelsus)** requires that you have a documented diagnosis of Type 2 Diabetes Mellitus.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ozempic/Rybelsus.

Created: 03/23
Effective: 07/01/23

CUSTOM
PRIOR AUTHORIZATION GUIDELINES

TIRZEPATIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TIRZEPATIDE	MOUNJARO			GPI-10 (2717308000)	

GUIDELINES FOR USE

CRITERIA

1. Does the patient have a documented diagnosis of Type 2 Diabetes Mellitus?

   If yes, **approve the requested drug for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT:

Our guideline named **TIRZEPATIDE (Mounjaro)** requires that you have a documented diagnosis of Type 2 Diabetes Mellitus.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mounjaro.

Created: 03/23
Effective: 07/01/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LACOSAMIDE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of partial-onset seizures and meet **ALL** of the following criteria?
   - The patient weighs at least 50 kgs (110 lbs.)
   - The patient had a trial of or contraindication to THREE generic antiepileptic medications (e.g., carbamazepine, divalproex sodium, valproic acid, oxcarbazepine, levetiracetam IR or ER, gabapentin, zonisamide, topiramate, lamotrigine)
   - The patient is unable to tolerate lacosamide immediate-release

   If yes, **approve for 12 months by GPID or GPI-14 as follows:**
   INITIAL REQUESTS:
   - **FIRST APPROVAL: Approve for 1 month for all strengths with the following quantity limits:**
     - **100 mg: #4 per day.**
     - **150 mg: #2 per day.**
     - **200 mg: #2 per day.**
   - **SECOND APPROVAL: Approve for 11 months for the requested strength with the following quantity limits (please enter a start date of 3 days before the end of the first approval):**
     - **100 mg: #1 per day.**
     - **150 mg: #2 per day.**
     - **200 mg: #2 per day.**

   SUBSEQUENT REQUESTS:
   - **Approve for 12 months for the requested strength with the following quantity limits:**
     - **100 mg: #1 per day.**
     - **150 mg: #2 per day.**
     - **200 mg: #2 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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LACOSAMIDE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LACOSAMIDE (Motpoly XR)** requires the following rule(s) be met for approval:

A. You have a diagnosis of partial-onset seizures (a type of seizure)
B. You are at least 50 kilograms (110 pounds)
C. You had a trial of or contraindication (harmful for) to THREE generic anti-seizure medications (such as carbamazepine, divalproex sodium, valproic acid, oxcarbazepine, levetiracetam immediate-release or extended-release, gabapentin, zonisamide, topiramate, or lamotrigine)
D. You are not able to tolerate lacosamide immediate-release

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Motpoly XR.

REFERENCES

- Motpoly XR [Prescribing Information]. Piscataway, NJ: Aucta Pharmaceuticals, Inc.; May 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 12/01/23
Created: 11/23
Client Approval: 11/23
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LANADELUMAB-FLYO

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with an allergist, immunologist or hematologist
   - The patient's diagnosis of HAE is confirmed via documentation (e.g., chart note, lab result, diagnostic test result, etc.) of complement testing
   - Takhzyro is being used for prophylaxis against HAE attacks
   - The patient is NOT on concurrent treatment with alternative prophylactic agent for HAE (e.g., Cinryze, Haegarda, danazol, berotralstat)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4mL per 28 days.**
   APPROVAL TEXT: Prescriber may consider a dosing interval of every 4 weeks if the patient is well-controlled for more than six months.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LANADELUMAB-FLYO (Takhzyro)** requires the following rule(s) be met for approval:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. You are 2 years of age or older
   C. Therapy is prescribed by or in consultation with an allergist, immunologist (allergy or immune system doctor) or hematologist (blood doctor)
   D. Your diagnosis is confirmed by documentation (such as chart note, lab result, diagnostic test result) of complement testing (a type of blood test)
   E. Takhzyro is being used for prevention of hereditary angioedema attacks
   F. You will NOT be using Takhzyro concurrently (at the same time) with an alternative preventive agent for HAE (such as Cinryze, Haegarda, danazol, berotralstat)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LANADELUMAB-FLYO

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet **ALL** of the following criteria?
   - The patient has experienced improvement (i.e., reductions in attack frequency or attack severity) compared to baseline in HAE attacks
   - The patient is NOT on concurrent treatment with alternative prophylactic agent for HAE (e.g., Cinryze, Haegarda, danazol, berotralstat)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4mL per 28 days.**
   APPROVAL TEXT: Prescriber may consider a dosing interval of every 4 weeks if the patient is well-controlled for more than six months.

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LANADELUMAB-FLYO (Takhzyro)** requires the following rule(s) be met for renewal:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. You have experienced improvement (reductions in attack frequency or attack severity) compared to baseline in hereditary angioedema attacks
   C. You will NOT be using Takhzyro concurrently (at the same time) with an alternative preventive agent for HAE (such as Cinryze, Haegarda, danazol, berotralstat)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LANADELUMAB-FLYO

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Takhzyro.

REFERENCES

- Takhzyro [Prescribing Information]. Lexington, MA: Dyax Corp.; February 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/23
Created: 09/18
Client Approval: 03/23
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LAPATINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced or metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient's breast cancer is human epidermal growth factor receptor 2 (HER2) positive
   - The requested medication will be used in combination with Xeloda (capecitabine)
   - The patient has received prior therapy with Herceptin (trastuzumab), an anthracycline (e.g., daunorubicin, doxorubicin, epirubicin, idarubicin), AND a taxane (e.g., paclitaxel, docetaxel)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #5 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient's breast cancer is human epidermal growth factor receptor 2 (HER2) positive
   - The patient's tumor is hormone receptor-positive
   - The requested medication will be used in combination with Femara (letrozole)
   - The patient is a postmenopausal woman

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LAPATINIB (Tykerb)** requires the following rule(s) be met for approval:
   A. You have advanced or metastatic breast cancer (breast cancer that has progressed or has spread to other parts of your body)
   B. Your breast cancer is human epidermal growth factor receptor 2 (HER2: gene/protein in breast cancer) positive
   C. **If you have advanced or metastatic breast cancer, approval also requires:**
      1. The requested medication will be used in combination with Xeloda (capecitabine)
      2. You have previously received treatment with Herceptin (trastuzumab), an anthracycline (such as daunorubicin, doxorubicin, epirubicin, idarubicin), AND a taxane (such as paclitaxel, docetaxel)
   D. **If you have metastatic breast cancer, approval also requires:**
      1. Your tumor is hormone receptor-positive
      2. The requested medication will be used in combination with Femara (letrozole)
      3. You are a postmenopausal woman

   (Denial text continued on the next page)

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LAPATINIB

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tykerb.

REFERENCES

- Tykerb [Package Insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 04/10
Client Approval: 03/21
P&T Approval: 08/13

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LAROTRECTINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a solid tumor and meet **ALL** of the following criteria?
   - The tumor has a neurotrophic receptor tyrosine kinase (*NTRK*) gene fusion without a known acquired resistance mutation
   - The tumor is metastatic or surgical resection is likely to result in severe morbidity
   - There are no satisfactory alternative treatments, or the patient has progressed following treatment

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the request for Vitrakvi oral capsules?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Vitrakvi 25mg: #6 capsules per day.**
   - **Vitrakvi 100mg: #2 capsules per day.**

   If no, continue to #3.

3. Is the request for Vitrakvi oral solution and the patient meets **ONE** of the following criteria?
   - The request is for a pediatric patient
   - The patient is unable to take Vitrakvi capsules due to difficulty swallowing or dysphagia
   - The patient has other medical need for the oral solution

   If yes, **approve for 12 months by GPID or GPI-14 as follows:**
   - **Vitrakvi 20mg/mL oral solution: #10mL per day.**

   If no, do not approve Vitrakvi oral suspension. **Please enter a proactive PA for Vitrakvi capsules and approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Vitrakvi 25mg: #6 capsules per day.**
   - **Vitrakvi 100mg: #2 capsules per day.**

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LAROTRECTINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LAROTRECTINIB (Vitrakvi)** requires the following rule(s) be met for approval:

A. You have a solid tumor (abnormal mass of tissue that usually does not contain cysts or liquid)
B. Your tumor has a neurotrophic receptor tyrosine kinase (*NTRK)* gene fusion without a known acquired resistance mutation (you have a type of enzyme that doesn't have a mutation)
C. Your tumor is metastatic (spreads to other parts of body) or surgical resection (removal) is likely to result in severe morbidity (illness)
D. There are no satisfactory alternative treatments, or your tumor has gotten worse after treatment
E. **Requests for Vitrakvi oral solution also require ONE of the following:**
    1. You are a pediatric patient (less than 18 years of age)
    2. You are unable to take Vitrakvi capsules due to difficulty swallowing (or dysphagia)
    3. You have other medical need for the oral solution

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vitrakvi.

REFERENCES

- Vitrakvi [Prescribing Information]. Stamford, CT: Loxo Oncology, Inc: December 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 03/19
Client Approval: 04/20
P&T Approval: 01/19

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LASMIDITAN

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the acute treatment of migraine and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to **ONE** triptan (e.g., sumatriptan, rizatriptan)

   If yes, **approve for 6 months for the requested strength by GPID OR GPI-14 as follows:**
   - **50mg: #8 per 30 days.**
   - **100mg: #8 per 30 days.**

   APPROVAL TEXT: Renewal requires that the request is for acute treatment of migraines and the patient has experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (e.g., Migraine Assessment of Current Therapy [Migraine-ACT]) OR the patient has experienced clinical improvement as defined by ONE of the following: 1) ability to function normally within 2 hours of dose, 2) headache pain disappears within 2 hours of dose, or 3) therapy works consistently in majority of migraine attacks.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LASMIDITAN (Reyvow)** requires the following rule(s) be met for approval:
   A. You are being treated for acute (quick onset) migraine
   B. You are 18 years of age or older
   C. You have previously tried ONE triptan (such as sumatriptan, rizatriptan), unless there is a medical reason why you cannot (contraindication)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LASMIDITAN

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Is the request for the acute treatment of migraine and the patient meets **ONE** of the following criteria?
   - The patient has experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (e.g., Migraine Assessment of Current Therapy [Migraine-ACT])
   - The patient has experienced clinical improvement as defined by **ONE** of the following:
     - Ability to function normally within 2 hours of dose
     - Headache pain disappears within 2 hours of dose
     - Therapy works consistently in majority of migraine attacks

   If yes, **approve for 12 months for the requested strength by GPID or GPI-14 as follows:**
   - **50mg: #8 per 30 days.**
   - **100mg: #8 per 30 days.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LASMIDITAN (Reyvow)** requires the following rule(s) be met for renewal:
   A. You are being treated for acute (quick onset) migraine
   B. You meet ONE of the following:
      1. You have experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (assessment tool used to help guide treatment such as Migraine Assessment of Current Therapy [MIGRAINE-ACT])
      2. You have experienced clinical improvement as defined by ONE of the following:
         a. Ability to function normally within 2 hours of dose
         b. Headache pain disappears within 2 hours of dose
         c. Treatment works consistently in majority of migraine attacks

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LASMIDITAN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Reyvow.

REFERENCES

- Reyvow [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC, January 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 12/12/20

Created: 02/20
Client Approval: 12/20

P&T Approval: 01/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEDIPASVIR/SOFOSBUVIR

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C, genotype 1, 4, 5, or 6 **AND** meet the following criterion?
   - The patient is 3 years of age or older

   If yes, continue to #2.
   If no, continue to #14.

2. Does the patient have an HCV RNA level within the past 6 months?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ANY** of the following criteria?
   - Harvoni will be used concurrently with any of the following medications: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, Priftin (rifapentine), rosuvastatin, Olysio (simeprevir), Sovaldi (sofosbuvir), Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir), Aptivus (tipranavir)/ritonavir, Mavyret (pibrentasvir/glecaprevir), Epclusa (velpatasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)
   - The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #4.

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LEDIPASVIR/SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

4. Is the patient treatment naïve and meets **ALL** of the following criteria?
   - The patient has genotype 1
   - The patient does not have cirrhosis
   - The patient has HCV RNA level of less than 6 million IU/mL
   - The patient does not have HIV infection

   If yes, continue to #6.
   If no, continue to #5.

5. Is the patient treatment naïve and meets **ALL** of the following criteria?
   - The patient has genotype 4
   - The patient does not have cirrhosis
   - The patient has HCV RNA level of less than 6 million IU/mL

   If yes, continue to #6.
   If no, continue to #7.

6. Is the request for Harvoni 45mg-200mg pellets **AND** the patient is unable to swallow tablets?

   If yes, **approve 45mg-200mg pellets for 8 weeks by GPID or GPI-14 with a quantity limit of #2 per day.**

   If no, **approve for 8 weeks by GPID or GPI-14 for the requested strength as follows:**
   - **90mg-400mg tablet: #1 per day.**
   - **45mg-200mg tablet: #1 per day.**
   - **33.75mg-150mg pellets: #1 per day.**

7. Is the patient treatment naïve and meets **ONE** of the following criteria?
   - The patient does not have cirrhosis
   - The patient has compensated cirrhosis

   If yes, continue to #12.
   If no, continue to #8.

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LEDIPASVIR/SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

8. Is the patient treatment experienced and meets **ONE** of the following criteria?
   - The patient is post-liver transplant AND does not have decompensated cirrhosis
   - The patient is post-kidney transplant, treatment experienced with non-DAA (e.g., interferon), AND does not have decompensated cirrhosis
   - The patient is less than 18 years of age, interferon-experienced, AND does not have decompensated cirrhosis
   - The patient is less than 18 years of age, has genotype 4, 5, or 6, does not have decompensated cirrhosis, AND had prior exposure to an interferon and an HCV protease inhibitor regimen (e.g., Mavyret [glecaprevir/pibrentasvir], simeprevir [Olysio], paritaprevir [Technivie], Vosevi [velpatasvir/sofosbuvir/voxilaprevir])
   - The patient is less than 18 years of age, has genotype 1, does not have cirrhosis, AND had prior exposure to an interferon and an HCV protease inhibitor regimen (e.g., Mavyret [glecaprevir/pibrentasvir], simeprevir [Olysio], paritaprevir [Technivie], Vosevi [velpatasvir/sofosbuvir/voxilaprevir])

   If yes, continue to #12.
   If no, continue to #9.

9. Is the patient treatment experienced and meets **ALL** of the following criteria?
   - The patient is less than 18 years of age
   - The patient has genotype 1
   - That patient had prior exposure to an interferon and an HCV protease inhibitor regimen (e.g., Mavyret [glecaprevir/pibrentasvir], simeprevir [Olysio], paritaprevir [Technivie], Vosevi [velpatasvir/sofosbuvir/voxilaprevir])
   - The patient has compensated cirrhosis

   If yes, continue to #13.
   If no, continue to #10.

10. Does the patient have decompensated cirrhosis and meet **ONE** of the following criteria?
    - Harvoni will be used with ribavirin
    - The patient is post-liver transplant, treatment naïve, AND Harvoni will be used with ribavirin

    If yes, continue to #12.
    If no, continue to #11.

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LEDIPASVIR/SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

11. Does the patient have decompensated cirrhosis and meet **ONE** of the following criteria?
    - The patient has a contraindication to ribavirin (ribavirin ineligible)
    - The patient failed prior treatment with sofosbuvir based regimen (e.g., Epclusa [sofosbuvir/velpatasvir]) AND Harvoni will be used with ribavirin
    - The patient is post-liver transplant, treatment experienced, AND Harvoni will be used with ribavirin

    If yes, continue to #13.
    If no, continue to #14.

12. Is the request for Harvoni 45mg-200mg pellets **AND** the patient is unable to swallow tablets?

    If yes, **approve 45mg-200mg pellets for 12 weeks by GPID or GPI-14 with a quantity limit of #2 per day.**

    If no, **approve for 12 weeks by GPID or GPI-14 for the requested strength as follows:**
    - **90mg-400mg tablet: #1 per day.**
    - **45mg-200mg tablet: #1 per day.**
    - **33.75mg-150mg pellets: #1 per day.**

13. Is the request for 45mg-200mg pellets **AND** the patient is unable to swallow tablets?

    If yes, **approve 45mg-200mg pellets for 24 weeks by GPID or GPI-14 with a quantity limit of #2 per day.**

    If no, **approve for 24 weeks by GPID or GPI-14 for the requested strength as follows:**
    - **90-400mg tablet: #1 per day.**
    - **45-200mg tablet: #1 per day.**
    - **33.75-150mg pellets: #1 per day.**

14. Is the requested regimen recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment?

    If yes, **approve as indicated per guidance in AASLD/IDSA.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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LEDIPASVIR/SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LEDIPASVIR/SOFOSBUVIR (Harvoni)** requires the following rule(s) be met for approval:

A. The requested regimen is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment
B. You have chronic hepatitis C, genotype 1, 4, 5, or 6 (liver inflammation caused by a type of virus)
C. You are 3 years of age or older
D. You have an HCV RNA level (amount of hepatitis C virus in your blood) within the past 6 months
E. You will NOT use Harvoni concurrently (at the same time) with any of the following medications: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, Priftin (rifapentine), rosuvastatin, Olysio (simeprevir), Sovaldi (sofosbuvir), Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir), Aptivus (tipranavir)/ritonavir, Mavyret (pibrentasvir/glecaprevir), Epclusa (velpatasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)
F. You do NOT have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)
G. **If the request is for Harvoni 45mg/200 mg pellets, approval also requires:**
    1. You are unable to swallow tablets
H. **If you are treatment naïve (never previously treated), approval also requires:**
    1. You do not have cirrhosis OR you have compensated cirrhosis (no symptoms related to liver damage)

(Denial text continued on next page)

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LEDIPASVIR/SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

I. **If you are treatment experienced (failed prior treatment), approval also requires ONE of the following:**
   1. You have received a liver transplant (replaced your liver) AND you do not have decompensated cirrhosis (symptoms related to liver damage)
   2. You have received a kidney transplant (replaced your kidney), you do not have decompensated cirrhosis, AND you have received prior treatment with a non-direct acting antiviral (such as interferon)
   3. You are less than 18 years of age, you do not have decompensated cirrhosis, AND you are treatment experienced with an interferon
   4. You are less than 18 years of age with genotype 4, 5, or 6, you do not have decompensated cirrhosis, AND you had prior exposure to an interferon and an HCV protease inhibitor regimen (such as Mavyret [glecaprevir/pibrentasvir], simeprevir [Olysio], paritaprevir [Technivie], Vosevi [velpatasvir/sofosbuvir/voxilaprevir])
   5. You are less than 18 years of age with genotype 1, you do not have decompensated cirrhosis, AND you had prior exposure to an interferon and an HCV protease inhibitor regimen (such as Mavyret [glecaprevir/pibrentasvir], simeprevir [Olysio], paritaprevir [Technivie], Vosevi [velpatasvir/sofosbuvir/voxilaprevir])

J. **If you have decompensated cirrhosis (symptoms related to liver damage), approval also requires ONE of the following:**
   1. You will be using Harvoni with ribavirin unless you have a contraindication to (harmful for you to use) ribavirin
   2. You have received a liver transplant, you are treatment naïve (never previously treated), AND Harvoni will be used with ribavirin
   3. You have failed prior treatment with sofosbuvir based regimen (such as Epclusa [sofosbuvir/velpatasvir]) AND Harvoni will be used with ribavirin
   4. You have received a liver transplant (replaced your liver), you are treatment experienced, AND Harvoni will be used with ribavirin

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LEDIPASVIR/SOFOSBUVIR

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Harvoni.

REFERENCES

- Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed November 28, 2023.
- Harvoni [Prescribing Information]. Foster City, CA: Gilead Sciences; March 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/15/24
Created: 11/14
Client Approval: 12/23
P&T Approval: 07/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEFAMULIN

GUIDELINES FOR USE

1. Does the patient have a diagnosis of community-acquired bacterial pneumonia (CABP) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Infection is caused by any of the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is therapy prescribed by or given in consultation with an Infectious Disease (ID) specialist?

   If yes, **approve Xenleta 600mg tablet for one fill by GPID or GPI-14 with a quantity limit of #10 per 5 days.**
   If no, continue to #3.

3. Have antimicrobial susceptibility tests been performed that meet **ALL** of the following criteria?
   - The results from the infection site culture indicate pathogenic organism(s) with **resistance** to at least **TWO** standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)
   - The results from the infection site culture indicate pathogenic organism(s) with susceptibility to Xenleta

   If yes, **approve Xenleta 600mg tablet for one fill by GPID or GPI-14 with a quantity limit of #10 per 5 days.**
   If no, continue to #4.

4. Does the patient meet **ALL** of the following criteria?
   - Antimicrobial susceptibility results are unavailable
   - The patient has had a trial of or contraindication to at least **TWO** standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)

   If yes, **approve Xenleta 600mg tablet for one fill by GPID or GPI-14 with a quantity limit of #10 per 5 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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LEFAMULIN

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LEFAMULIN (Xenleta)** requires the following rule(s) be met for approval:

A. You have community-acquired bacterial pneumonia (type of lung infection)
B. You are 18 years of age or older
C. The infection is caused by any of the following susceptible microorganisms (bacteria that the drug can kill): *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*
D. You meet **ONE** of the following criteria:
   1. The requested medication is prescribed by or given in consultation with an Infectious Disease (ID) specialist
   2. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is available, and the infection site culture results indicate pathogenic (disease-causing) organism(s) with a) resistance to at least **TWO** standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone), **AND** b) susceptibility to Xenleta
   3. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is unavailable, and you had a trial of at least **TWO** standard of care agents (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid) for community-acquired bacterial pneumonia, unless there is a medical reason why you cannot (contraindication)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xenleta.

REFERENCES

- Xenleta [Prescribing Information]. Ireland DAC: Nabriva Therapeutics US, Inc.; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 08/19
Client Approval: 04/20
P&T Approval: 07/19

STANDARD COMMERCIAL AND NSA DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LENACAPAVIR

GUIDELINES FOR USE

1. Does the patient have a diagnosis of human immunodeficiency virus type 1 (HIV-1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is treatment-experienced
   - The patient's HIV-1 is multidrug resistant and has failed current antiretroviral regimen due to resistance, intolerance, or safety considerations

   If yes, **approve for 12 months by GPID or GPI-14 for all dosage forms as follows:**
   - **300mg tablet: #5 per 6 months.**
   - **463.5mg/1.5mL vial: #3 mL per 6 months.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LENACAPAVIR (Sunlenca)** requires the following rule(s) be met for approval:
   A. You have human immunodeficiency virus type 1 (HIV-1: a type of immune disorder)
   B. You are 18 years of age or older
   C. You are treatment-experienced
   D. You have a multidrug resistant (not responding to treatment) HIV-1 infection and have failed your current antiretroviral regimen (HIV treatment) due to resistance, intolerance (side effects), or safety considerations

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LENACAPAVIR

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sunlenca.

REFERENCES

- Sunlenca [Prescribing Information]. Foster City, CA: Gilead Sciences, Inc.; December 2022.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 06/01/23
Created: 01/23
Client Approval: 05/23
P&T Approval: 01/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LENALIDOMIDE

GUIDELINES FOR USE

1. Is the patient 18 years of age or older?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a diagnosis of multiple myeloma (MM)?

   If yes, continue to #3.
   If no, continue to #5.

3. Will Revlimid (lenalidomide) be used as induction treatment for multiple myeloma (MM)?

   If yes, **approve for 12 months by HICL or GPI-10 for #21 every 28 days.**
   If no, continue to #4.

4. Will Revlimid (lenalidomide) be used as maintenance treatment for multiple myeloma (MM)?

   If yes, **approve for 12 months by HICL or GPI-10 for #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Does the patient have a diagnosis of anemia due to a myelodysplastic syndrome (MDS) **AND** meet the following criterion?
   - The patient's myelodysplastic syndrome (MDS) is associated with a deletion 5q abnormality

   If yes, **approve for 12 months by HICL or GPI-10 for #1 per day.**
   If no, continue to #6.

6. Does the patient have a diagnosis of mantle cell lymphoma (MCL) **AND** meet the following criterion?
   - The patient has relapsed or progressed after two prior therapies, one of which included Velcade (bortezomib)

   If yes, **approve for 12 months by HICL or GPI-10 for #21 per 28 days.**
   If no, continue to #7.

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LENALIDOMIDE

GUIDELINES FOR USE (CONTINUED)

7. Does the patient have a diagnosis of follicular lymphoma (FL) and meet **ALL** of the following criteria?
   - The patient has previously been treated for follicular lymphoma (FL)
   - The requested medication is being taken in combination with a rituximab product

   If yes, **approve for 12 months by HICL or GPI-10 for #21 per 28 days for 12 fills.**
   If no, continue to #8.

8. Does the patient have a diagnosis of marginal zone lymphoma (MZL) and meet **ALL** the following criterion?
   - The patient has previously been treated for marginal zone lymphoma (MZL)
   - The requested medication is being taken in combination with a rituximab product

   If yes, **approve for 12 months by HICL or GPI-10 for #21 per 28 days for 12 fills.**
   If no, do not approve.

   DENIAL TEXT: Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LENALIDOMIDE (Revlimid)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Multiple myeloma (a type of blood cancer)
      2. Anemia due to a myelodysplastic syndrome (a type of blood cancer)
      3. Mantle cell lymphoma (a type of blood cell)
      4. Follicular lymphoma (a type of blood cancer)
      5. Marginal zone lymphoma (a type of blood cancer)
   B. You are 18 years of age or older
   C. **If you have anemia due to a myelodysplastic syndrome, approval also requires:**
      1. You have a deletion 5q (type of gene) abnormality
   D. **If you have mantle cell lymphoma, approval also requires:**
      1. You have relapsed or progressed (disease has returned or worsened) after two prior therapies, one of which included Velcade (bortezomib) (Note: Velcade may be covered under the medical benefit and/or require prior authorization).
   E. **If you have follicular lymphoma, approval also requires:**
      1. You have previously been treated for follicular lymphoma
      2. The requested medication is being taken in combination with a rituximab product (type of cancer drug)

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LENALIDOMIDE

GUIDELINES FOR USE (CONTINUED)

F. **If you have marginal zone lymphoma, approval also requires:**
   1. You have previously been treated for marginal zone lymphoma
   2. The requested medication is being taken in combination with a rituximab product

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Revlimid.

REFERENCES

- Revlimid [Prescribing Information]. Summit, NJ: Celgene Corporation; August 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 08/12
Client Approval: 03/22
P&T Approval: 07/19

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LENIOLISIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of activated phosphoinositide 3-kinase delta (PI3Kdelta) syndrome (APDS) **AND** meet the following criterion?
   - The patient is 12 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LENIOLISIB (Joenja)** requires the following rule(s) be met for approval:
   A. You have activated phosphoinositide 3-kinase delta (PI3Kdelta) syndrome (APDS: a type of mutation that impacts the immune system)
   B. You are 12 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Joenja.

REFERENCES

- Joenja [Prescribing Information]. Leiden, The Netherlands: Pharming Technologies B.V.; March 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 04/23
Client Approval: 05/23
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LENVATINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of differentiated thyroid cancer (DTC) and meet **ALL** of the following criteria; (**NOTE**: Differentiated thyroid cancer (DTC) can be classified as papillary (PTC), follicular (FTC), or Hurthle cell)?
   - The thyroid cancer is locally recurrent or metastatic
   - The thyroid cancer is progressive
   - The thyroid cancer is refractory to radioactive iodine therapy

   If yes, **approve for 12 months by GPID or GPI-14 based on the following daily dose requirements:**
   - **10 mg daily dose: #1 per day.**
   - **14 mg daily dose: #2 per day.**
   - **20 mg daily dose: #2 per day.**
   - **24 mg daily dose: #3 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of advanced renal cell cancer (RCC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Lenvima will be used as a first-line treatment
   - Lenvima will be used in combination with pembrolizumab (Keytruda)

   If yes, **approve for 12 months by GPID or GPI-14 based on the following daily dose requirements:**
   - **8 mg daily dose: #2 per day.**
   - **10 mg daily dose: #1 per day.**
   - **14 mg daily dose: #2 per day.**
   - **20 mg daily dose: #2 per day.**

   If no, continue to #3.

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LENVATINIB

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of advanced renal cell cancer (RCC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Lenvima will be used in combination with everolimus
   - The patient has tried one anti-angiogenic therapy (e.g., Sutent [sunitinib], Votrient [pazopanib], Inlyta [axitinib], Nexavar [sorafenib])

   If yes, **approve for 12 months by GPID or GPI-14 based on the following daily dose requirements:**
   - **8 mg daily dose: #2 per day.**
   - **10 mg daily dose: #1 per day.**
   - **14 mg daily dose: #2 per day.**
   - **18 mg daily dose: #3 per day.**

   If no, continue to #4.

4. Does the patient have a diagnosis of unresectable hepatocellular carcinoma (HCC) **AND** meet the following criterion?
   - Lenvima is being used as a first-line treatment

   If yes, **approve for 12 months by GPID or GPI-14 based on the following daily dose requirements:**
   - **4 mg every other day: #1 per 2 days.**
   - **4 mg daily dose: #1 per day.**
   - **8 mg daily dose: #2 per day.**
   - **12 mg daily dose: #3 per day.**

   If no, continue to #5.

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LENVATINIB

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of advanced endometrial carcinoma (EC) and meet **ALL** of the following criteria?
   - Lenvima is used in combination with pembrolizumab (Keytruda)
   - The patient's cancer is mismatch repair proficient (pMMR), as determined by an FDA-approved test, or is not microsatellite instability-high (MSI-H)
   - The patient has experienced disease progression following prior systemic therapy
   - The patient is not a candidate for curative surgery or radiation

   If yes, **approve for 12 months by GPID or GPI-14 based on the following daily dose requirements:**
   - **8 mg daily dose: #2 per day.**
   - **10 mg daily dose: #1 per day.**
   - **14 mg daily dose: #2 per day.**
   - **20 mg daily dose: #2 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LENVATINIB (Lenvima)** requires the following rule(s) be met for approval:
   A. You have **ONE** of the following diagnoses:
      1. Differentiated thyroid cancer (DTC: cancer cells look/act like normal thyroid cells)
      2. Advanced renal cell cancer (RCC: kidney cancer)
      3. Unresectable hepatocellular carcinoma (HCC: liver cancer that cannot be removed by surgery)
      4. Advanced endometrial carcinoma (EC: type of cancer that starts in the uterus)

   B. **If you have differentiated thyroid cancer, approval also requires:**
      1. Your thyroid cancer is locally recurrent (re-appears in the same spot) or metastatic (has spread to other parts of the body)
      2. Your thyroid cancer is progressive (getting worse)
      3. Your thyroid cancer is refractory (has not responded) to radioactive iodine therapy

   (Denial text continued on next page)

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LENVATINIB

GUIDELINES FOR USE (CONTINUED)

C. **If you have advanced renal cell cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. Lenvima will be used as first-line treatment in combination with pembrolizumab (Keytruda)
      b. Lenvima is used in combination with everolimus AND you have tried one prior anti-angiogenic therapy (treatment that stop tumors from growing their own blood vessels, such as Sutent [sunitinib], Votrient [pazopanib], Inlyta [axitinib], Nexavar [sorafenib])

D. **If you have unresectable hepatocellular carcinoma, approval also requires:**
   1. Lenvima is being used as a first-line treatment

E. **If you have advanced endometrial carcinoma, approval also requires:**
   1. Lenvima is used in combination with pembrolizumab (Keytruda)
   2. Your cancer is mismatch repair proficient (pMMR), as determined by a Food and Drug Administration (FDA)-approved test, or is not microsatellite instability-high (MSI-H) (markers of the cancer to help determine what treatment options are appropriate)
   3. You have experienced disease progression (worsening) following prior systemic therapy (treatment that targets the entire body)
   4. You are not a candidate for curative surgery or radiation

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lenvima.

REFERENCES

- Lenvima [Prescribing Information]. Nutley, NJ: Eisai, Inc.; November 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/09/23
Created: 2/15
Client Approval: 09/23
P&T Approval: 10/21

STANDARD COMMERCIAL AND NSA DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LETERMOVIR

GUIDELINES FOR USE

1. Is the request for prophylaxis of cytomegalovirus (CMV) infection and disease in an allogeneic hematopoietic stem cell transplant (HSCT) recipient and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is a CMV-seropositive recipient [R+] of an allogeneic HSCT
   - Prevymis will be initiated between Day 0 and Day 28 post-transplant (before or after engraftment)

   If yes, continue to #2.
   If no, continue to #4.

2. Will the patient receive Prevymis beyond 100 days post-transplant?

   If yes, continue to #3.

   If no, **approve for 100 days by GPID or GPI-14 for all strengths as follows:**
   - **240mg tablet: #1 per day.**
   - **480mg tablet: #1 per day.**
   - **240mg/12mL vial: #12mL per day.**
   - **480mg/24mL vial: #24mL per day.**

3. Is the patient at risk for late CMV infection and disease, **AND** will not receive Prevymis beyond 200 days post-transplant?

   If yes, **approve for 200 days by GPID or GPI-14 for all strengths as follows:**
   - **240mg tablet: #1 per day.**
   - **480mg tablet: #1 per day.**
   - **240mg/12mL vial: #12mL per day.**
   - **480mg/24mL vial: #24mL per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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LETERMOVIR

GUIDELINES FOR USE (CONTINUED)

4. Is the request for prophylaxis of cytomegalovirus (CMV) disease in a kidney transplant recipient and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is a kidney transplant recipient at high risk (i.e., donor is CMV seropositive, recipient is CMV seronegative [D+/R-])
   - Prevymis will be initiated between Day 0 and Day 7 post-transplant
   - The patient will not receive Prevymis beyond 200 days post-transplant

   If yes, **approve for 200 days by GPID or GPI-14 for all strengths as follows:**
   - **240mg tablet: #1 per day.**
   - **480mg tablet: #1 per day.**
   - **240mg/12mL vial: #12mL per day.**
   - **480mg/24mL vial: #24mL per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LETERMOVIR (Prevymis)** requires the following rule(s) be met for approval:

   A. The request is for ONE of the following:
      1. Prophylaxis (prevention) of cytomegalovirus (CMV: a type of virus) infection and disease in an allogeneic hematopoietic stem cell transplant (HSCT: cells transplanted from a matching donor) recipient
      2. Prophylaxis of cytomegalovirus (CMV) disease in a kidney transplant recipient

   B. **If the request is for prophylaxis of cytomegalovirus infection and disease in an allogeneic hematopoietic stem cell transplant recipient, approval also requires:**
      1. You are 18 years of age or older
      2. You are a CMV-seropositive recipient [R positive] of an allogeneic HSCT
      3. Prevymis will be started between Day 0 and Day 28 post-transplant (before or after engraftment [a type of transplant])
      4. You meet ONE of the following:
         a. You are NOT at risk for late CMV infection and disease, AND you will not receive Prevymis beyond 100 days post (after)-transplant
         b. You are at risk for late CMV infection and disease, AND you will not receive Prevymis beyond 200 days post (after)-transplant

   (Denial text continued on next page)

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LETERMOVIR

GUIDELINES FOR USE (CONTINUED)

C. **If the request is for prophylaxis of cytomegalovirus disease in a kidney transplant recipient, approval also requires:**
   1. You are 18 years of age or older
   2. You are a kidney transplant recipient at high risk (donor is CMV seropositive, recipient is CMV seronegative [D positive/R negative])
   3. Prevymis will be started between Day 0 and Day 7 post (after)-transplant
   4. You will not receive Prevymis beyond 200 days post-transplant

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Prevymis.

REFERENCES

- Prevymis [Prescribing Information]. Rahway, NJ: Merck Sharp & Dohme LLC; August 2023.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 09/18/23
Created: 02/18
Client Approval: 09/23
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEUPROLIDE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for gender dysphoria?

   If yes, **approve for 12 months by HICL or GPI-10 and override quantity limits.**
   If no, continue to #2.

2. Does the patient have a diagnosis of advanced prostate cancer?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2 kits per 28 days.**
   If no, continue to #3.

3. Is the request for a female patient who has a diagnosis of central precocious puberty (CPP) and meets **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a pediatric endocrinologist
   - The patient has elevated levels of follicle-stimulating hormone (FSH) (level >4.0 mIU/mL) and luteinizing hormone (LH) (level > 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 8 years of age at the onset of CPP
   - There is documentation of pubertal staging using the Tanner scale for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, continue to #4.

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LEUPROLIDE

INITIAL CRITERIA (CONTINUED)

4. Is the request for a male patient who has a diagnosis of central precocious puberty (CPP) and meets **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a pediatric endocrinologist
   - The patient has elevated levels of follicle-stimulating hormone (FSH) (level >5.0 mIU/mL) and luteinizing hormone (LH) (level > 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 9 years of age at the onset of CPP
   - There is documentation of pubertal staging using the Tanner scale for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEUPROLIDE** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
      2. Advanced prostate cancer (prostate cancer that has spread to nearby tissue or organs)
      3. Central precocious puberty (CPP: early sexual development in girls and boys)

   B. **If you are female and have central precocious puberty, approval also requires:**
      1. You are 2 years of age or older
      2. Therapy is prescribed by or in consultation with a pediatric endocrinologist (hormone doctor)
      3. You have high levels of follicle-stimulating hormone (FSH) (level greater than 4.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
      4. You are/were younger than 8 years of age when your condition started
      5. There is documentation of pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

   C. **If you are male and have central precocious puberty, approval also requires:**
      1. You are 2 years of age or older
      2. Therapy is prescribed by or in consultation with a pediatric endocrinologist (hormone doctor)
      3. You have high levels of follicle-stimulating hormone (FSH) (level greater than 5.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
      4. You are/were younger than 9 years of age when your condition started

   (Initial denial text continued on next page)

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LEUPROLIDE

INITIAL CRITERIA (CONTINUED)

5. There is documentation of pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

NOTE: For the diagnoses of gender dysphoria or advanced prostate cancer, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of central precocious puberty (CPP) and meet **ALL** of the following criteria?
   - The Tanner scale staging at initial diagnosis of CPP has stabilized or regressed during three separate medical visits in the previous year
   - The patient has not reached the actual age which corresponds to their current pubertal age

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEUPROLIDE** requires the following rule(s) be met for renewal:
   A. You have central precocious puberty (CPP: early sexual development in girls and boys)
   B. Your Tanner scale staging (scale of physical measurements of development based on external sex characteristics) at initial diagnosis of CPP has stabilized or regressed (lowered) during three separate medical visits in the previous year
   C. You have not reached the actual age which corresponds to your current pubertal age

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LEUPROLIDE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Leuprolide.

REFERENCES

- Leuprolide acetate [Prescribing Information]. Princeton, NJ: Sandoz Inc.; Aug 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/23/23
Created: 09/18
Client Approval: 01/23
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEUPROLIDE-ELIGARD

GUIDELINES FOR USE

1. Is the requested medication being used for gender dysphoria?

   If yes, **approve for 12 months by HICL or GPI-10 and override quantity limits.**
   If no, continue to #2.

2. Does the patient have a diagnosis of advanced prostate cancer?

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **7.5mg: #1 per month.**
   - **22.5mg: #1 per 3 months.**
   - **30mg: #1 per 4 months.**
   - **45mg: #1 per 6 months.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEUPROLIDE-ELIGARD** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
      2. Advanced prostate cancer (prostate cancer that has spread to nearby tissue or organs)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEUPROLIDE-ELIGARD

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Eligard.

REFERENCES

- Eligard [Prescribing Information]. Fort Collins, CO: Tolmar Pharmaceuticals, Inc.; April 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/23/23

Created: 09/18
Client Approval: 01/23

P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVAMLODIPINE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hypertension and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - The patient had a trial of or contraindication to TWO generic dihydropyridine calcium channel blockers (e.g., amlodipine, felodipine, nicardipine)
   - The patient had a trial of or contraindication to TWO other antihypertensive agents in another class (e.g., hydrochlorothiazide, lisinopril, losartan)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEVAMLODIPINE (Conjupri)** requires the following rule(s) be met for approval:
   A. You have hypertension (high blood pressure)
   B. You are 6 years of age or older
   C. You have tried or have a contraindication (harmful for) to TWO generic dihydropyridine calcium channel blockers (such as amlodipine, felodipine, nicardipine)
   D. You have tried or have a contraindication (harmful for) to TWO other antihypertensive agents in another class (such as hydrochlorothiazide, lisinopril, losartan)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Conjupri.

REFERENCES

- Conjupri [Prescribing Information]. Hong Kong: CSPC Ouyi Pharmaceutical Co., Ltd.; December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/01/22
Created: 10/20
Client Approval: 05/22
P&T Approval: 10/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVETIRACETAM

GUIDELINES FOR USE

1. Does the patient have a diagnosis of partial-onset seizures and meet **ALL** of the following criteria?
   - The patient is 4 years of age or older
   - The patient is unable to swallow levetiracetam tablets
   - The patient had a trial of levetiracetam oral solution

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **250mg: #4 per day.**
   - **500mg: #4 per day.**
   - **750mg: #4 per day.**
   - **1000mg: #2 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of myoclonic seizures in juvenile myoclonic epilepsy and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Spritam will be used as adjunctive therapy
   - The patient is unable to swallow levetiracetam tablets
   - The patient had a trial of levetiracetam oral solution

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **250mg: #4 per day**
   - **500mg: #4 per day**
   - **750mg: #4 per day**
   - **1000mg: #2 per day**

   If no, continue to #3.

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LEVETIRACETAM

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of primary generalized tonic-clonic seizures and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Spritam will be used as adjunctive therapy
   - The patient is unable to swallow levetiracetam tablets
   - The patient had a trial of levetiracetam oral solution

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **250mg: #4 per day.**
   - **500mg: #4 per day.**
   - **750mg: #4 per day.**
   - **1000mg: #2 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEVETIRACETAM (Spritam)** requires the following rules be met for approval:
   A. You have ONE of the following diagnoses:
      1. Partial-onset seizures (type of seizure)
      2. Myoclonic seizures in juvenile myoclonic epilepsy (type of seizure in childhood)
      3. Primary generalized tonic-clonic seizures (type of seizure)
   B. **If you have partial-onset seizures, approval also requires:**
      1. You are 4 years of age or older
      2. You are unable to swallow levetiracetam tablets
      3. You had a trial of levetiracetam oral solution
   C. **If you have myoclonic seizures in juvenile myoclonic epilepsy, approval also requires:**
      1. You are 12 years of age or older
      2. Spritam will be used as adjunctive (add-on) therapy
      3. You are unable to swallow levetiracetam tablets
      4. You had a trial of levetiracetam oral solution
   D. **If you have primary generalized tonic-clonic seizures, approval also requires:**
      1. You are 6 years of age or older
      2. Spritam will be used as adjunctive (add-on) therapy
      3. You are unable to swallow levetiracetam tablets
      4. You had a trial of levetiracetam oral solution

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LEVETIRACETAM

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Spritam.

REFERENCES

- Spritam [Prescribing Information]. Blue Ash, OH: Aprecia Pharmaceuticals LLC; January 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/23

Created: 11/22
Client Approval: 02/23

P&T Approval: 10/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVODOPA

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Parkinson's disease and meet **ALL** of the following criteria?
   - Inbrija is being used for intermittent treatment of OFF episodes associated with Parkinson's disease
   - The patient is currently being treated with carbidopa/levodopa
   - Therapy is prescribed by or given in consultation with a neurologist
   - The patient is **NOT** currently taking more than 1600mg of levodopa per day
   - The physician has optimized drug therapy as evidenced by **BOTH** of the following:
     - Change in levodopa/carbidopa dosing strategy or formulation
     - Trial of or contraindication to at least **TWO** Parkinson's disease agents from **TWO** different classes of the following: dopamine agonist (e.g., ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (e.g., selegiline, rasagiline), catechol-o-methyl transferase (COMT) inhibitors (e.g., entacapone, tolcapone), adenosine receptor antagonist A2A (e.g., istradefylline)

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #10 capsules per day.**
   APPROVAL TEXT: Renewal requires that the patient has experienced improvement with motor fluctuations during OFF episodes with the use of Inbrija (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEVODOPA INHALATION (Inbrija)** requires the following rule(s) be met for approval:
   A. You have Parkinson's disease (a nerve system disorder that affects movement)
   B. Inbrija is being used for intermittent treatment of OFF episodes (times when you have symptoms return due to medication wearing off) associated with Parkinson's disease
   C. You are currently being treated with carbidopa/levodopa
   D. The requested medication is prescribed by or given in consultation with a neurologist (nerve doctor)
   (Initial denial text continued on next page)

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LEVODOPA

INITIAL CRITERIA (CONTINUED)

E. You are **NOT** currently taking more than 1600mg of levodopa per day
F. Your doctor has optimized drug therapy as evidenced by **BOTH** of the following:
   1. Change in levodopa/carbidopa dosing strategy or formulation
   2. Trial of or contraindication to (medical reason why you cannot use) at least **TWO** Parkinson's agents from **TWO** different classes of the following: dopamine agonist (such as ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (such as selegiline, rasagiline), catechol-O-methyl transferase (COMT) inhibitors (such as entacapone, tolcapone), adenosine receptor antagonist A_{2A} (such as istradefylline)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Parkinson's disease **AND** meet the following criterion?
   - The patient had improvement with motor fluctuations during OFF episodes with the use of Inbrija (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #10 capsules per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEVODOPA INHALATION (Inbrija)** requires the following rule(s) be met for renewal approval:
   A. You have Parkinson's disease (a nerve system disorder that affects movement)
   B. You had improvement with motor fluctuations during OFF episodes (times when you have symptoms return due to medication wearing off) with the use of Inbrija. Improvements can be in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LEVODOPA

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Inbrija.

REFERENCES

- Inbrija [Prescribing Information]. Ardsley, NY: Acorda Therapeutics, Inc., September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 05/19
Client Approval: 04/20
P&T Approval: 10/19

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVOKETOCONAZOLE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Cushing's syndrome and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient is not a candidate for surgery or surgery has not been curative
   - The patient has tried or has a contraindication to oral ketoconazole

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, do not approve.
   INTIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEVOKETOCONAZOLE (Recorlev)** requires the following rule(s) be met for approval:
   A. You have Cushing's syndrome (a type of hormone disorder)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   D. You are not a candidate for surgery or surgery has not been curative
   E. You have tried or have a contraindication (harmful for) to oral ketoconazole

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LEVOKETOCONAZOLE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Cushing's syndrome and meet **ALL** of the following criteria?
   - The patient continues to have improvement of Cushing's syndrome (e.g., clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of disease)
   - The patient maintains tolerability to Recorlev

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEVOKETOCONAZOLE (Recorlev)** requires the following rule(s) be met for renewal:
   A. You have Cushing's syndrome (a type of hormone disorder)
   B. You continue to have improvement of Cushing's syndrome (such as clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of your disease)
   C. You continue to tolerate treatment with Recorlev

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Recorlev.

REFERENCES

- Recorlev [Prescribing Information]. Chicago, IL: Xeris Pharmaceuticals, Inc.; January 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/01/22
Created: 01/22
Client Approval: 01/22
P&T Approval: 01/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVOTHYROXINE-ERMEZA

GUIDELINES FOR USE

1. Does the patient have a diagnosis of congenital or acquired hypothyroidism?

   If yes, continue to #3.
   If no, continue to #2.

2. Does the patient have a diagnosis of thyrotropin-dependent well-differentiated thyroid cancer **AND** meet the following criterion?
   - The requested medication will be used as an adjunct to surgery and radioiodine therapy

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ALL** of the following criteria?
   - The patient had a trial and failure of Thyquidity
   - The patient had a trial and failure of generic levothyroxine tablets
   - The patient is unable to swallow levothyroxine tablets or capsules

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **LEVOTHYROXINE-ERMEZA** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Congenital (present from birth) or acquired hypothyroidism (low thyroid function)
      2. Thyrotropin (a type of thyroid hormone)-dependent well-differentiated thyroid cancer
   B. You had a trial and failure (drug did not work) of Thyquidity
   C. You had a trial and failure (drug did not work) of generic levothyroxine tablets
   D. You are unable to swallow levothyroxine tablets or capsules
   E. **If you have thyrotropin-dependent well-differentiated thyroid cancer, approval also requires:**
      1. The requested medication will be used as an adjunct (add-on) to surgery and radioiodine therapy (a type of radiation therapy)

   (Denial text continued on next page)

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LEVOTHYROXINE-ERMEZA

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ermeza.

REFERENCES

- Ermeza [Prescribing Information]. Morgantown, WV: Mylan Specialty L.P.; April 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/23

Created: 02/23
Client Approval: 02/23

P&T Approval: 01/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVOTHYROXINE-TIROSINT

GUIDELINES FOR USE

1. Does the patient have a diagnosis of congenital or acquired hypothyroidism?

   If yes, continue to #3.
   If no, continue to #2.

2. Does the patient have a diagnosis of thyrotropin-dependent well-differentiated thyroid cancer **AND** meet the following criterion?
   - The requested medication is being used as an adjunct to surgery and radioiodine therapy

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - The patient had a trial and failure of generic levothyroxine tablets
   - There is documentation of rationale for not using generic levothyroxine tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEVOTHYROXINE-TIROSINT** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Congenital (present from birth) or acquired hypothyroidism (low thyroid function)
      2. Thyrotropin (a type of thyroid hormone)-dependent well-differentiated thyroid cancer
   B. You are 6 years of age or older
   C. You had a trial and failure (drug did not work) of generic levothyroxine tablets
   D. There is documentation of rationale (reason) for not using generic levothyroxine tablets
   E. **If you have thyrotropin-dependent well-differentiated thyroid cancer, approval also requires:**
      1. The requested medication will be used as an adjunct (add-on) to surgery and radioiodine therapy (a type of radiation therapy)

   (Denial text continued on next page)

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LEVOTHYROXINE-TIROSINT

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tirosint.

REFERENCES

- Tirosint [Prescribing Information]. Pambio-Noranco, Switzerland: IBSA Institut Biochimique SA; June 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/23
Created: 07/21
Client Approval: 12/22
P&T Approval:10/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVOTHYROXINE-TIROSINT-SOL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of congenital or acquired hypothyroidism?

   If yes, continue to #3.
   If no, continue to #2.

2. Does the patient have a diagnosis of thyrotropin-dependent well-differentiated thyroid cancer **AND** meet the following criterion?
   - The requested medication is being used as an adjunct to surgery and radioiodine therapy

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ALL** of the following criteria?
   - The patient had a trial and failure of Thyquidity
   - The patient had a trial and failure of or contraindication to generic levothyroxine tablets
   - There is documentation of rationale for not using Thyquidity and generic levothyroxine tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2mL per day.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **LEVOTHYROXINE-TIROSINT-SOL** requires the following rule(s) be met for approval:

   A. You have ONE of the following diagnoses:
      1. Congenital (present from birth) or acquired hypothyroidism (low thyroid function)
      2. Thyrotropin (a type of thyroid hormone)-dependent well-differentiated thyroid cancer
   B. You had a trial and failure (drug did not work) of Thyquidity
   C. You had a trial and failure (drug did not work) of or contraindication (harmful for) to generic levothyroxine tablets
   D. There is documentation of rationale (reason) for not using Thyquidity and generic levothyroxine tablets

   (Denial text continued on the next page)

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LEVOTHYROXINE-TIROSINT-SOL

GUIDELINES FOR USE (CONTINUED)

E. **If you have thyrotropin-dependent well-differentiated thyroid cancer, approval also requires:**
   1. The requested medication will be used as an adjunct (add-on) to surgery and radioiodine therapy (a type of radiation therapy)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tirosint-Sol.

REFERENCES

- Tirosint-Sol [Prescribing Information]. Pambio-Noranco, Switzerland: IBSA Institut Biochimique SA; January 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/23
Created: 07/21
Client Approval: 12/22
P&T Approval:10/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

L-GLUTAMINE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of sickle cell disease (SCD) and meet **ALL** of the following criteria?
   - The medication is prescribed by or given in consultation with a hematologist
   - The patient had a trial of or contraindication to hydroxyurea

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient between the ages of 5 to 17 years old?

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #180 packets per 30 days.**
   Approval Text: Renewal requires that the patient has maintained or experienced a reduction in acute complications of sickle-cell disease (SCD) (e.g., number of sickle cell crises, hospitalizations, ACS).

   If no, continue to #3.

3. Is the patient 18 years of age or older and meets **ONE** of the following criteria?
   - The patient had at least 2 sickle cell crises in the past year (A sickle cell crises is defined as a visit to an emergency room/medical facility for sickle cell disease-related pain which was treated with a parenterally administered narcotic or parenterally administered ketorolac, the occurrence of chest syndrome, priapism, or splenic sequestration)
   - The patients is having sickle-cell associated symptoms (e.g., pain or anemia) which are interfering with activities of daily living
   - The patients has a history of or has recurrent acute chest syndrome (ACS)

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #180 packets per 30 days.**
   Approval Text: Renewal requires that the patient has maintained or experienced a reduction in acute complications of sickle-cell disease (SCD) (e.g., number of sickle cell crises, hospitalizations, ACS).

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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L-GLUTAMINE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **L-GLUTAMINE (ENDARI)** requires the following rule(s) be met for approval:

A. You have sickle cell disease (type of red blood cell disorder)
B. You are 5 years of age or older
C. The medication is prescribed by or given in consultation with a hematologist (blood doctor specialist)
D. The patient had a trial of or contraindication to hydroxyurea
E. **If you are 18 years of age or older, approval also requires ONE of the following:**
    1. You had at least 2 sickle cell crises in the past year (A sickle cell crises is defined as a visit to an emergency room/medical facility for sickle cell disease-related pain which was treated with a parenterally administered given into the vein, narcotic or parenterally administered ketorolac, the occurrence of chest syndrome, priapism (prolonged erection of penis), or splenic sequestration [suppressing of spleen])
    2. You are having sickle-cell associated symptoms such as pain or anemia (your blood doesn't have enough healthy red blood cells and you're tired) which are interfering with activities of daily living
    3. You have a history of or have recurrent acute chest syndrome (ACS: chest pain, cough, fever, low oxygen level)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of sickle cell disease **AND** meet the following criterion?
    - The patient has maintained or experienced a reduction in acute complications of sickle-cell disease (SCD) (e.g., number of sickle cell crises, hospitalizations, ACS)

    If yes, **approve for lifetime by GPID or GPI-10 with a quantity limit of #180 packets per 30 days.**
    If no, do not approve.
    DENIAL TEXT: See the renewal denial text at the end of the guideline.

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L-GLUTAMINE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **L-GLUTAMINE (Endari)** requires the following rule(s) bet met for renewal:

A. You have sickle cell disease (type of red blood cell disorder)
B. You have maintained or experienced a reduction in acute complications of sickle-cell disease such as number of sickle cell crises, hospitalizations, acute chest syndrome (ACS: chest pain, cough, fever, low oxygen level)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Endari

REFERENCES

- Endari [Prescribing Information]. Torrance, CA: Emmaus Medical, Inc. October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20
Created: 09/17
Client Approval: 02/20
P&T Approval: 01/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LIXISENATIDE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of type 2 diabetes and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist, cardiologist, nephrologist, family practice, internal medicine, or another healthcare provider who is specialized in diabetic management
   - The patient had a trial of metformin (IR/ER), a sulfonylurea (e.g., glipizide, glimepiride), pioglitazone, or a preferred combination product containing any of the above agents (e.g., glipizide-metformin, pioglitazone-metformin)
   - The patient had a trial of a preferred GLP-1 agonist (e.g., Byetta [exenatide], Bydureon [exenatide microspheres], Victoza [liraglutide])
   - Adlyxin will NOT be used together with a DPP-4 inhibitor (e.g., Januvia [sitagliptin], alogliptin, saxagliptin)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6mL per 28 days.** If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LIXISENATIDE (Adlyxin)** requires the following rule(s) be met for approval:
   A. You have type 2 diabetes (a disorder with high blood sugar)
   B. You are 18 years of age or older
   C. Adlyxin is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), cardiologist (a type of heart doctor), nephrologist (a type of kidney doctor), family practice, internal medicine, or another healthcare provider who specializes in diabetic management
   D. You have tried metformin (immediate-release/ extended-release), a sulfonylurea (such as glipizide, glimepiride), pioglitazone, or a preferred combination product containing any of the above medications (such as glipizide-metformin, pioglitazone-metformin)
   E. You have tried a preferred GLP-1 agonist (such as Byetta [exenatide], Bydureon [exenatide microspheres], Victoza [liraglutide])
   F. Adlyxin will NOT be used together with a DPP-4 inhibitor (such as Januvia [sitagliptin], alogliptin, saxagliptin)
   (Initial denial text continued on the next page)

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LIXISENATIDE

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LIXISENATIDE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of type 2 diabetes and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist, cardiologist, nephrologist, family practice, internal medicine, or another healthcare provider who specializes in diabetic management
   - Adlyxin will NOT be used together with a DPP-4 inhibitor (e.g., Januvia [sitagliptin], alogliptin, saxagliptin)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6mL per 28 days.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LIXISENATIDE (Adlyxin)** requires the following rule(s) be met for approval:
   A. You have type 2 diabetes (a disorder with high blood sugar)
   B. Adlyxin is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), cardiologist (a type of heart doctor), nephrologist (a type of kidney doctor), family practice, internal medicine, or another healthcare provider who specializes in diabetic management
   C. Adlyxin will NOT be used together with a DPP-4 inhibitor (such as Januvia [sitagliptin], alogliptin, saxagliptin)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Adlyxin.

REFERENCES

- Adlyxin [Prescribing Information]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC, September 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 11/22
Client Approval: 10/23
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LOFEXIDINE

GUIDELINES FOR USE

1. Is the requested medication being used to mitigate opioid withdrawal symptoms to facilitate abrupt opioid discontinuation and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is in a setting with close patient monitoring for a duration of Lucemyra (lofexidine) treatment not to exceed 18 days
   - Treatment with Lucemyra is being administered as part of an opioid discontinuation plan that includes other withdrawal symptom management medications (e.g., stool softeners, sleep aids) and psychosocial support is in place to help prevent relapse

   If yes, **approve for 1 fill by HICL or GPI-10 with a quantity limit of #264 per 18 days.**
   If no, do not approve.
   DENIAL TEXT: Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline name **LOFEXIDINE (Lucemyra)** requires the following rule(s) be met for approval:
   A. Lucemyra is being used to lessen opioid withdrawal symptoms to help abrupt opioid discontinuation
   B. You are 18 years of age or older
   C. You are in a setting with close patient monitoring of Lucemyra (lofexidine) treatment for a maximum of 18 days
   D. Treatment with Lucemyra is being administered as part of an opioid discontinuation plan that includes other withdrawal symptom management medications (such as stool softeners, sleep aids) and psychosocial support is in place to help prevent relapse

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LOFEXIDINE

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Lucemyra.

REFERENCES

- Lucemyra [Prescribing Information]. Louisville, KY. US Worldmeds, LLC. November 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 08/18
Client Approval: 04/20
P&T Approval: 07/18

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LOMITAPIDE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of homozygous familial hypercholesterolemia (HoFH) as determined by meeting **ONE** of the following criteria?
   - Simon Broome diagnostic criteria (definite)
   - Dutch Lipid Network criteria with a score of at least 8
   - A clinical diagnosis based on a history of an untreated LDL-cholesterol level greater than 500 mg/dL, in combination with either:
     (1) xanthoma before 10 years of age **OR**
     (2) evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The requested medication is prescribed by or given in consultation with a cardiologist, endocrinologist, or lipidologist
   - The patient has a LDL-cholesterol level greater than or equal to 70 mg/dL

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient has been taking a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks
   - The patient has been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks given that the patient cannot tolerate a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)

   If yes, continue to #4.
   If no, continue to #5.

4. Will the patient continue statin treatment as described above in combination with Juxtapid?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

LOMITAPIDE

GUIDELINES FOR USE (CONTINUED)

5. Does the patient meet **ONE** of the following criteria?
   - The patient has an absolute contraindication to statin therapy (e.g., active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction)
   - The patient has complete statin intolerance as defined by severe and intolerable adverse effects (e.g., creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group) that have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient meet **ONE** of the following criteria?
   - The patient has had a previous trial of Repatha (evolocumab)
   - The patient lacks functioning LDL receptors

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Juxtapid 5mg: #45 per 30 days.**
   - **Juxtapid 10mg: #30 per 30 days.**
   - **Juxtapid 20mg: #90 per 30 days.**
   - **Juxtapid 30mg: #30 per 30 days.**
   - **Juxtapid 40mg: #30 per 30 days.**
   - **Juxtapid 60mg: #30 per 30 days.**

   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **LOMITAPIDE (Juxtapid)** requires the following rule(s) be met for approval:
   A. You have homozygous familial hypercholesterolemia (type of inherited high cholesterol)
   (Denial text continued on next page)

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LOMITAPIDE

GUIDELINES FOR USE (CONTINUED)

B. Your diagnosis of homozygous familial hypercholesterolemia (type of inherited high cholesterol) was determined by meeting **ONE** of the following criteria:
   1. Simon Broome diagnostic criteria
   2. Dutch Lipid Network criteria with a score of at least 8
   3. A clinical diagnosis based on a history of an untreated LDL (low density lipoprotein) - cholesterol level greater than 500 mg/dL, in combination with either (1) xanthoma (condition where fatty growth develops under the skin) before 10 years of age **OR** (2) evidence of heterozygous familial hypercholesterolemia (type of inherited high cholesterol) in both parents

C. The requested medication is prescribed by or given in consultation with a cardiologist (heart doctor), endocrinologist (hormone doctor), or lipidologist (cholesterol management doctor)

D. You have an LDL (low density lipoprotein) - cholesterol level greater than or equal to 70 mg/dL while on maximally tolerated statin (drug used for cholesterol) treatment

E. You previously had a trial of Repatha (evolocumab) unless you do not have functional LDL (low density lipoprotein) receptors

F. **If you are statin tolerant, approval also requires:**
   1. You meet **ONE** of the following criteria:
      a. You have been taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks
      b. You have been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks given you cannot tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
   2. You will continue statin (drug used for cholesterol) treatment in combination with Juxtapid

G. **If you are statin intolerant, approval also requires ONE of the following:**
   1. You have an absolute contraindication to (medical reason why you cannot use) statin therapy (drug used for cholesterol) such as active decompensated liver disease (you have symptoms related to liver damage), nursing female, pregnancy or plans to become pregnant, or hypersensitivity (allergic) reaction
   2. You have complete statin intolerance as defined by severe and intolerable adverse effects such as creatine kinase elevation (a measurement of how much muscle damage you have) greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis (muscle breakdown), severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group. These must have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LOMITAPIDE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Juxtapid.

REFERENCES

- Juxtapid [Prescribing Information]. Cambridge, MA: Aegerion Pharmaceuticals, Inc.; December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 01/13
Client Approval: 04/20
P&T Approval: 04/18

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LOMUSTINE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Hodgkin's lymphoma?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of primary and metastatic brain tumors **AND** meet the following criterion?
   - The patient has previously received appropriate surgical and/or radiotherapeutic procedures

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Will the patient be using this medication as a part of the PCV regimen (procarbazine, lomustine, and vincristine)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **LOMUSTINE (Gleostine)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Hodgkin's lymphoma (type of immune system cancer)
      2. Primary and metastatic brain tumors (tumor that has spread to other parts of body)
   B. **If you have primary and metastatic brain tumors, approval also requires:**
      1. You have previously received appropriate surgical and/or radiotherapeutic procedures
      2. The requested medication will be used as a part of the PCV regimen (procarbazine, lomustine, and vincristine)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LOMUSTINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gleostine.

REFERENCES

- Gleostine [Prescribing Information]. NextSource Biotechnology, LLC: Miami, FL; December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/23
Created: 02/18
Client Approval: 11/22
P&T Approval: 01/18

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LONAFARNIB

GUIDELINES FOR USE

1. Is the patient 1 year of age or older **AND** meets the following criterion?
   - The patient has a body surface area (BSA) of 0.39m(2) or above

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a diagnosis of Hutchinson-Gilford progeria syndrome (HGPS)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have a diagnosis of processing-deficient progeroid laminopathies with **ONE** of the following?
   - Heterozygous LMNA mutation with progerin-like protein accumulation
   - Homozygous or compound heterozygous ZMPSTE24 mutations

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **LONAFARNIB (Zokinvy)** requires the following rule(s) be met for approval:
   A. You have Hutchinson-Gilford progeria syndrome (HGPS) OR processing-deficient progeroid laminopathies (rare genetic disorders that cause premature aging in children)
   B. You are 1 year of age or older
   C. You have a body surface area (BSA) of 0.39 meters squared or more
   D. **If you have processing-deficient progeroid laminopathies, approval also requires you have ONE of the following:**
      1. Heterozygous LMNA (type of gene) mutation with progerin-like protein accumulation
      2. Homozygous or compound heterozygous ZMPSTE24 (type of gene) mutations

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LONAFARNIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zokinvy.

REFERENCES

- Zokinvy [Prescribing Information]. Palo Alto, CA: Eiger BioPharmaceuticals, Inc.; November 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/21
Created: 02/21
Client Approval:02/21
P&T Approval: 01/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LONAPEGSOMATROPIN-TCGD

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature (ISS)

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) and meet **ALL** of the following criteria?
   - The patient is 1 to 17 years of age AND weighs at least 11.5 kg
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient has a height velocity that is less than the 25th percentile for age
   - The patient has a low peak growth hormone (less than 10 ng/mL) on TWO growth hormone stimulation tests, OR has an insulin-like growth factor 1 (IGF-1) that is at least 2 SD below the mean for the same age and gender

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Skytrofa 3mg, 3.6mg, 4.3mg, 5.2mg, 6.3mg, 13.3mg: #1 cartridge per 7 days.**
   - **Skytrofa 7.6mg, 9.1mg, 11mg: #2 cartridges per 7 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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LONAPEGSOMATROPIN-TCGD

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LONAPEGSOMATROPIN-TCGD (Skytrofa)** requires the following rule(s) be met for approval:

A. You have growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
B. You are 1 to 17 years of age and weigh at least 11.5 kilograms (25.3 pounds)
C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
D. Your epiphyses (end part of long bone) are NOT closed as confirmed by a radiograph (type of imaging test) of the wrist and hand
E. You meet ONE of the following:
    1. Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender
    2. Your height velocity is less than the 25th percentile for your age
    3. You have a low peak growth hormone level (less than 10 ng/mL) on TWO growth hormone stimulation tests, OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations below the mean for your age and gender
F. Request for Skytrofa will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LONAPEGSOMATROPIN-TCGD

RENEWAL CRITERIA

1. Is the requested medication being used for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature (ISS)

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) and meet **ALL** of the following criteria?
   - The patient is 1 to 17 years of age AND weighs at least 11.5 kg
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand), OR the patient has not completed prepubertal growth

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient has an annual growth velocity of at least 2 cm compared with what was observed from the previous year
   - The patient has an annual growth velocity of at least 1 cm compared with what was observed from the previous year if close to the terminal phase of puberty

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Skytrofa 3mg, 3.6mg, 4.3mg, 5.2mg, 6.3mg, 13.3mg: #1 cartridge per 7 days.**
   - **Skytrofa 7.6mg, 9.1mg, 11mg: #2 cartridges per 7 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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LONAPEGSOMATROPIN-TCGD

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LONAPEGSOMATROPIN-TCGD (Skytrofa)** requires the following rule(s) be met for renewal:

A. You have growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
B. You are 1 to 17 years of age and weigh at least 11.5 kilograms (25.3 pounds)
C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
D. Your epiphyses (end part of long bone) are NOT closed as confirmed by a radiograph (type of imaging test) of the wrist and hand, OR you have not completed prepubertal growth
E. You meet ONE of the following:
    1. Your annual growth velocity (rate of growth) is at least 2 cm compared with what was observed from the previous year
    2. Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are close to the terminal (final) phase of puberty
F. Request for Skytrofa will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Skytrofa.

REFERENCES

- Skytrofa [Prescribing Information]. Princeton, NJ: Ascendis Pharma US, Inc.; October 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/26/24
Created: 10/21
Client Approval: 02/24
P&T Approval: 01/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LORCASERIN

GUIDELINES FOR USE

Do not approve requests for Belviq or Belviq XR.

(**NOTE:** Safety concerns [increased risk of cancer] have prompted market withdrawal of Belviq and Belviq XR.)

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Belviq/Belviq XR.

FDA requested removal from the market as Belviq/Belviq XR displayed an increased risk of cancer in a safety trial. Manufacturer complied with FDA request and product has been discontinued.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/21

Created: 01/13
Client Approval: 08/21

P&T Approval: 04/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LORLATINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumors are anaplastic lymphoma kinase (ALK) - positive as detected by an FDA-approved test

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Lorbrena 25mg: #3 per day.**
   - **Lorbrena 100mg: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LORLATINIB (Lorbrena)** requires the following rule(s) be met for approval:
   A. You have metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
   B. You are 18 years of age or older
   C. Your tumors are anaplastic lymphoma kinase (ALK: type of enzyme) - positive which is shown by an FDA (Federal and Drug Administration) approved test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LORLATINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lorbrena.

REFERENCES

- Lorbrena [Prescribing Information]. New York, NY: Pfizer, Inc.; March 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 03/19
Client Approval: 03/21
P&T Approval: 04/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LOTEPREDNOL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of dry eye disease **AND** meet the following criterion?
   - The patient had a trial of or contraindication to one generic loteprednol ophthalmic **AND** one non-loteprednol ophthalmic corticosteroid (e.g., fluorometholone, dexamethasone, prednisolone)

   If yes, **approve for 2 weeks by GPID or GPI-14 with a quantity limit of #8.3mL (1 bottle) per 14 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LOTEPREDNOL (Eysuvis)** requires the following rule(s) be met for approval:
   A. You have dry eye disease
   B. You previously tried one generic loteprednol ophthalmic product **AND** one non-loteprednol ophthalmic (eye) corticosteroid (such as fluorometholone, dexamethasone, prednisolone) unless there is a medical reason why you cannot (contraindication)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Eysuvis.

REFERENCES

- Eysuvis [Prescribing Information]. Watertown, MA: Kala Pharmaceuticals, Inc.; October 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/21
Created: 02/21
Client Approval: 02/21
P&T Approval: 01/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LOTILANER

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Demodex blepharitis **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 6 weeks by HICL or GPI-10 with a quantity limit of #10mL for 1 fill.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LOTILANER (Xdemvy)** requires the following rule(s) be met for approval:
   A. You have Demodex blepharitis (a type of inflammatory eye condition)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xdemvy.

REFERENCES

- Xdemvy [Prescribing Information]. Irvine, CA: Tarsus Pharmaceuticals, Inc.; July 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 12/01/23
Created: 10/23
Client Approval: 11/23
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LUMACAFTOR-IVACAFTOR

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

1. Does the patient have a diagnosis of cystic fibrosis (CF) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist or CF expert
   - There is documentation that the patient is homozygous for the F508del-CFTR gene mutation

   If yes, **approve by GPID or GPI-14 for 24 weeks for all of the formulations and strengths with the following quantity limits:**
   - **75-94 mg granule packets: #2 per day.**
   - **100-125 mg granule packets: #2 per day.**
   - **150-188 mg granule packets: # 2 per day.**
   - **100-125 mg tablets: #4 per day.**
   - **200-125 mg tablets: #4 per day.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LUMACAFTOR-IVACAFTOR (Orkambi)** requires the following rule(s) be met for approval:
   A. You have cystic fibrosis (a type of lung disorder)
   B. You are 1 year of age or older
   C. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
   D. There is documentation that you are homozygous (have 2 copies of the same gene) for the F508del-CFTR (type of gene: cystic fibrosis transmembrane conductance regulator) mutation

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LUMACAFTOR-IVACAFTOR

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cystic fibrosis (CF) and improvement in clinical status as shown by **ONE** of the following?
   - The patient has improved, maintained, or demonstrated less than expected decline in FEV1 (forced expiratory volume)
   - The patient has improved, maintained, or demonstrated less than expected decline in BMI (body mass index)
   - The patient has experienced a reduction in rate of pulmonary exacerbations

   If yes, **approve by GPID or GPI-14 for lifetime for all of the formulations and strengths with the following quantity limits:**
   - **75-94 mg granule packets: #2 per day.**
   - **100-125 mg granule packets: #2 per day.**
   - **150-188 mg granule packets: #2 per day.**
   - **100-125 mg tablets: #4 per day.**
   - **200-125 mg tablets: #4 per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LUMACAFTOR-IVACAFTOR (Orkambi)** requires the following rule(s) be met for renewal:
   A. You have cystic fibrosis (a type of lung disorder)
   B. You have shown improvement in clinical (medical) status compared to baseline as shown by ONE of the following:
      1. You have improved, maintained, or demonstrated less than expected decline in FEV1 (forced expiratory volume: amount of air you can exhale in 1 second)
      2. You have improved, maintained, or demonstrated less than expected decline in BMI (body mass index)
      3. You have experienced a reduction in rate of pulmonary exacerbations (worsening in lung condition)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LUMACAFTOR-IVACAFTOR

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orkambi.

REFERENCES

- Orkambi [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Incorporated, September 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/22
Created: 07/15
Client Approval: 09/22
P&T Approval: 10/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LUSUTROMBOPAG

GUIDELINES FOR USE

1. Does the patient have a diagnosis of thrombocytopenia and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist, gastroenterologist, hepatologist, immunologist, endocrinologist, or surgeon
   - The patient has chronic liver disease
   - The patient is scheduled to undergo a procedure 8 to 14 days following initiation of Mulpleta (lusutrombopag) therapy
   - The patient has a platelet count of less than $50x10^9$ cells/L measured within the last 30 days
   - The patient is not receiving other thrombopoietin receptor agonist therapy (e.g., avatrombopag, romiplostim, eltrombopag)

   If yes, **approve for 1 fill by HICL or GPI-10 with a quantity limit of #7 tablets.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LUSUTROMBOPAG (Mulpleta)** requires the following rule(s) be met for approval:
   A. You have thrombocytopenia (a type of blood disorder)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor), gastroenterologist (a doctor who treats digestive conditions), hepatologist (a type of liver doctor), immunologist (a type of immune system doctor), endocrinologist (a type of hormone doctor), or surgeon
   D. You have chronic liver disease
   E. You are scheduled to undergo a procedure 8 to 14 days after starting Mulpleta (lusutrombopag) therapy
   F. You have a platelet count of less than $50x10^9$ cells/L measured within the last 30 days
   G. You are not receiving other thrombopoietin receptor agonist therapy, such as avatrombopag, romiplostim, eltrombopag

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LUSUTROMBOPAG

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mulpleta.

REFERENCES

- Mulpleta [Prescribing Information]. Florham Park, NJ: Shionogi & Co, Ltd. May 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 11/18
Client Approval: 02/22
P&T Approval: 01/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MACITENTAN

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have documentation (e.g., chart note, lab result, diagnostic test result, etc.) confirming a PAH diagnosis based on right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MACITENTAN (Opsumit)** requires the following rule(s) be met for approval:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   C. There is documentation (such as, chart note, lab result, diagnostic test result) showing you have pulmonary arterial hypertension based on ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      3. Pulmonary vascular resistance (PVR) greater than 2 Wood units

   (Initial denial text continued on next page)

CONTINUED ON NEXT PAGE

MACITENTAN

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MACITENTAN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MACITENTAN (Opsumit)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Opsumit.

REFERENCES

- Opsumit [Prescribing Information]. Titusville, NJ: Actelion Pharmaceuticals US, Inc.; June 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 10/22
Client Approval: 02/24
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MACITENTAN-TADALAFIL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has WHO Functional Class II-III symptoms
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - Opsynvi will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - Opsynvi will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have documentation (e.g., chart note, lab result, diagnostic test result, etc.) confirming a PAH diagnosis based on right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **MACITENTAN-TADALAFIL (Opsynvi)** requires the following rule(s) be met for approval:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   B. You are 18 years of age or older
   (*Initial denial text continued on the next page*)

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MACITENTAN-TADALAFIL

INITIAL CRITERIA (CONTINUED)

C. You have WHO Functional Class II-III symptoms (a way to classify how limited physical activity)
D. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
E. There is documentation (such as chart note, lab result, diagnostic test result) showing you have pulmonary arterial hypertension based on ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary arterial hypertension) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary arterial hypertension) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary arterial hypertension) greater than 2 Wood units
F. You will NOT use Opsynvi concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
G. You will NOT use Opsynvi concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MACITENTAN-TADALAFIL

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
   - Opsynvi will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - Opsynvi will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MACITENTAN-TADALAFIL (Opsynvi)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
   B. You will NOT use Opsynvi concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   C. You will NOT use Opsynvi concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Opsynvi.

REFERENCES

- Opsynvi [Prescribing Information]. Titusville, NJ: Actelion Pharmaceuticals US, Inc.; March 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/15/24
Created: 04/24
Client Approval: 04/24
P&T Approval: 04/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MARALIXIBAT

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cholestatic pruritus associated with Alagille syndrome (ALGS) and meet **ALL** of the following criteria?
   - The patient is 3 months of age or older
   - Livmarli will NOT be used concurrently with another IBAT inhibitor (e.g., Bylvay [odevixibat])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3mL per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of cholestatic pruritus associated with progressive familial intrahepatic cholestasis (PFIC) and meet **ALL** of the following criteria?
   - The patient is 5 years of age or older
   - Livmarli will NOT be used concurrently with another IBAT inhibitor (e.g., Bylvay [odevixibat])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4mL per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MARALIXIBAT (Livmarli)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Cholestatic pruritus (itching caused by liver disease) associated with Alagille syndrome (ALGS: a type of genetic disorder)
      2. Cholestatic pruritus (itching caused by liver disease) associated with progressive familial intrahepatic cholestasis (PFIC: a type of genetic disorder)

   B. **If you have cholestatic pruritus associated with Alagille syndrome, approval also requires:**
      1. You are 3 months of age or older
      2. You will NOT use Livmarli concurrently (at the same time) with an ileal bile acid transporter (IBAT) inhibitor (such as Bylvay [odevixibat])

   (Denial text continued on next page)

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MARALIXIBAT

GUIDELNES FOR USE (CONTINUED)

C. **If you have cholestatic pruritus associated with progressive familial intrahepatic cholestasis, approval also requires:**
   1. You are 5 years of age or older
   2. You will NOT use Livmarli concurrently (at the same time) with an ileal bile acid transporter (IBAT) inhibitor (such as Bylvay [odevixibat])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Livmarli.

REFERENCES

- Livmarli [Prescribing Information]. Foster City, CA: Mirum Pharmaceuticals, Inc.; March 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/15/24
Created: 10/21
Client Approval: 03/24
P&T Approval: 04/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MARIBAVIR

GUIDELINES FOR USE

1. Does the patient have a diagnosis of post-transplant cytomegalovirus (CMV) infection and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient is refractory to prior therapy with ganciclovir, valganciclovir, cidofovir or foscarnet

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MARIBAVIR (Livtencity)** requires the following rule(s) be met for approval:
   A. You have a post-transplant cytomegalovirus (CMV) infection (a type of viral infection)
   B. You are 12 years of age or older
   C. You are refractory to prior therapy with ganciclovir, valganciclovir, cidofovir or foscarnet

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Livtencity.

REFERENCES

- Livtencity [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; November 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective:01/01/22
Created: 12/21
Client Approval: 12/21
P&T Approval: 10/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MAVACAMTEN

GUIDELINES FOR USE

NITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of symptomatic obstructive hypertrophic cardiomyopathy (HCM) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has New York Heart Association (NYHA) class II-III symptoms
   - The patient has a left ventricular outflow track (LVOT) gradient of 50 mmHg or higher
   - Therapy is prescribed by or in consultation with a cardiologist
   - The patient had a trial of or contraindication to beta-blockers (e.g., metoprolol, carvedilol) AND non-dihydropyridine calcium channel blockers (e.g., verapamil, diltiazem)

   If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MAVACAMTEN (Camzyos)** requires the following rule(s) be met for approval:
   A. You have symptomatic obstructive hypertrophic cardiomyopathy (HCM: a type of heart condition)
   B. You are 18 years of age or older
   C. You have New York Heart Association (NYHA) class II-III (classification system for heart failure) symptoms
   D. You have a left ventricular outflow track gradient (a predictor of heart failure and cardiovascular death) of 50 mmHg or higher
   E. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor)
   F. You had a trial of or contraindication (harmful for) to beta-blockers (such as metoprolol, carvedilol) AND non-dihydropyridine calcium channel blockers (such as verapamil, diltiazem)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MAVACAMTEN

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of symptomatic obstructive hypertrophic cardiomyopathy (HCM) **AND** meet the following criterion?
   - The patient has experienced continued clinical benefit (e.g., reduction of symptoms, NYHA classification improvement)

   If yes, **approve for 12 months by HICL or GPI-10 with quantity limit of #1 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MAVACAMTEN (Camzyos)** requires the following rule(s) be met for renewal:
   A. You have symptomatic obstructive hypertrophic cardiomyopathy (HCM: a type of heart condition)
   B. You have experienced continued clinical benefit (such as reduction of symptoms, NYHA classification improvement)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Camzyos.

REFERENCES

- Camzyos [Prescribing Information]. Brisbane, CA: MyoKardia, Inc.; April 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective:06/01/22
Created: 05/22
Client Approval: 05/22
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MEBENDAZOLE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of *Enterobius vermicularis* (pinworm) infection and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient had a trial of or contraindication to pyrantel pamoate (OTC)

   If yes, **approve for 1 month by GPID or GPI-14 with a quantity limit of #2**.
   If no, continue to #2.

2. Does the patient have a diagnosis of *Trichuris trichiura* (whipworm) or *Ascaris lumbricoides* (common roundworm) infection and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - There is documentation (e.g., chart notes, lab results, diagnostic test results) confirming the diagnosis of *Trichuris trichiura* (whipworm) or *Ascaris lumbricoides* (common roundworm) infection
   - The patient had a trial of or contraindication to albendazole (Albenza)

   If yes, **approve for 1 month by GPID or GPI-14 with a quantity limit of #6**.
   If no, continue to #3.

3. Does the patient have a diagnosis of *Ancylostoma duodenale* (common hookworm) or *Necator americanus* (American hookworm) infection and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - There is documentation (e.g., chart notes, lab results, diagnostic test results) confirming the diagnosis of *Ancylostoma duodenale* (common hookworm) or *Necator americanus* (American hookworm) infection
   - The patient had a trial of or contraindication to albendazole (Albenza) or pyrantel pamoate (OTC)

   If yes, **approve for 1 month by GPID or GPI-14 with a quantity limit of #6.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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MEBENDAZOLE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MEBENDAZOLE (Emverm)** requires the following rule(s) be met for approval:

A. You have a diagnosis of *Enterobius vermicularis* (pinworm), *Trichuris trichiura* (whipworm), *Ascaris lumbricoides* (common roundworm), *Ancylostoma duodenale* (common hookworm), or *Necator americanus* (American hookworm) infection
B. You are 2 years of age or older
C. **If you have *Enterobius vermicularis* (pinworm) infection, approval also requires:**
   1. You had a trial of or contraindication (harmful for) to over-the-counter (OTC) pyrantel pamoate
D. **If you have Trichuris trichiura (whipworm) or Ascaris lumbricoides (common roundworm) infection, approval also requires:**
   1. There is documentation (such as chart notes, lab results, diagnostic test results) confirming your diagnosis of *Trichuris trichiura* (whipworm) or *Ascaris lumbricoides* (common roundworm) infection
   2. You had a trial of or contraindication (harmful for) to albendazole (Albenza)
E. **If you have Ancylostoma duodenale (common hookworm) or Necator americanus (American hookworm) infection, approval also requires:**
   1. There is documentation (such as chart notes, lab results, diagnostic test results) confirming your diagnosis of *Ancylostoma duodenale* (common hookworm) or *Necator americanus* (American hookworm) infection
   2. You had a trial of or contraindication (harmful for) to albendazole (Albenza) OR over-the-counter (OTC) pyrantel pamoate

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Emverm.

REFERENCES

- Emverm [Prescribing Information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; August 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/11/23
Created: 03/16
Client Approval: 08/23
P&T Approval: 07/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MECAMYLAMINE HYDROCHLORIDE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of moderately severe to severe essential (or primary) hypertension or uncomplicated malignant hypertension?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient tried or does the patient have a contraindication to three of the following: angiotensin converting enzyme (ACE) inhibitor or ACE-I combination, angiotensin receptor blocker (ARB) or ARB combination, Beta Blocker, or Calcium Channel Blocker?
   PAC NOTE: These drugs include: benazepril, benazepril-HCTZ, captopril, captopril-HCTZ, enalapril, enalapril-HCTZ, fosinopril, fosinopril-HCTZ, lisinopril, lisinopril-HCTZ, quinapril, ramipril, moexipril, moexipril-HCTZ, perindopril erbumine, quinapril, quinapril-HCTZ, trandolapril, trandolapril/verapamil, losartan, losartan-HCTZ, irbesartan, irbesartan-HCTZ, olmesartan, olmesartan-HCTZ, olmesartan-amlodipine-HCTZ, valsartan, valsartan-HCTZ, diltiazem HCL, diltiazem sustained release (generics only), verapamil, verapamil sustained release (generics only), atenolol, atenolol-chlorthalidone, bisoprolol, bisoprolol-HCTZ, carvedilol, metoprolol tartrate, nadolol, acebutolol, betaxolol, labetalol, metoprolol succinate, metoprolol-HCTZ, pindolol, propranolol, propranolol-HCTZ, sotalol, timolol maleate, or nebivolol.

   If yes, **approve for 12 months by GPID or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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MECAMYLAMINE HYDROCHLORIDE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MECAMYLAMINE HYDROCHLORIDE (Vecamyl)** requires the following rule(s) be met for approval:

A. The requested medication will be used for the management of moderately severe to severe essential (or primary) hypertension or in uncomplicated cases of malignant hypertension
B. You have had a trial of at least three of the following, unless there is a medical reason why you cannot (contraindication): angiotensin converting enzyme inhibitor (ACE-I) or ACE-I combination, angiotensin receptor blocker (ARB) or ARB combination, Beta Blocker, or Calcium Channel Blocker, such as benazepril, benazepril-HCTZ, captopril, captopril-HCTZ, enalapril, enalapril-HCTZ, fosinopril, fosinopril-HCTZ, lisinopril, lisinopril-HCTZ, quinapril, ramipril, moexipril, moexipril-HCTZ, perindopril erbumine, quinapril, quinapril-HCTZ, trandolapril, trandolapril/verapamil, losartan, losartan-HCTZ, irbesartan, irbesartan-HCTZ, olmesartan, olmesartan-HCTZ, olmesartan-amlodipine-HCTZ, valsartan, valsartan-HCTZ, diltiazem HCL, diltiazem sustained release (generics only), verapamil, verapamil sustained release (generics only), atenolol, atenolol-chlorthalidone, bisoprolol, bisoprolol-HCTZ, carvedilol, metoprolol tartrate, nadolol, acebutolol, betaxolol, labetalol, metoprolol succinate, metoprolol-HCTZ, pindolol, propranolol, propranolol-HCTZ, sotalol, timolol maleate, or nebivolol.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vecamyl.

REFERENCES

- Vecamyl [Prescribing Information]. Fort Collins, CO: Manchester Pharmaceuticals; July 2015.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 05/13
Client Approval: 04/20
P&T Approval: 08/13

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MECASERMIN

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have **ONE** of the following diagnoses?
   - Severe primary IGF-1 deficiency
   - Growth hormone (GH) gene deletion (not growth hormone-deficient short stature) **AND** have neutralizing antibodies to GH

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient is 2 years to less than 18 years of age
   - The requested medication is prescribed by or given in consultation with a pediatric endocrinologist or a pediatric nephrologist
   - Height standard deviation score ≤ -3.0
   - Basal IGF-1 standard deviation score ≤ -3.0
   - Normal or elevated growth hormone (GH), [serum growth hormone level of ≥ 10ngm/mL to at least two stimuli (insulin, levodopa, arginine, clonidine, or glucagon)]
   - The patient's epiphyses (bone growth plates) open (as confirmed by radiograph of the wrist and hand)

   If yes, **approve by HICL or GPI-10 for 6 months up to a maximum dose of 9 vials per month.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MECASERMIN (Increlex)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Severe primary insulin growth-like factor 1 deficiency (IGF-1: hormone levels that promote normal bone and tissue growth and development are extremely low or undetectable in the blood)
      2. Growth hormone gene deletion (not growth hormone-deficient short stature) and developed neutralizing antibodies to growth hormone

   (Initial denial text continued on the next page)

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MECASERMIN

INITIAL CRITERIA (CONTINUED)

B. You are 2 years to less than 18 years of age
C. The requested medication is prescribed by or given in consultation with a pediatric endocrinologist (hormone doctor) or pediatric nephrologist (kidney doctor)
D. You have a height standard deviation score less than or equal to -3.0, basal IGF-1 (insulin growth-like factor 1) standard deviation score less than or equal to -3.0, and normal or elevated growth hormone [serum growth hormone level of greater than or equal to 10ngm/mL to at least 2 stimuli (insulin, levodopa, arginine, clonidine or glucagon)]
E. Your bone growth plates (epiphyses) are open (as confirmed by radiograph of the wrist and hand)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Has the patient shown a response in the first 6 months of IGF-1 therapy (i.e., increase in height, increase in height velocity)?

If yes, **approve by HICL or GPI-10 for 12 months up to a maximum dose of 9 vials per month.**
If no, do not approve.
RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MECASERMIN (Increlex)** requires the following rule(s) be met for renewal:
A. You have shown a response in the first 6 months of insulin growth-like factor-1 (IGF-1) therapy (increase in height, increase in height velocity)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MECASERMIN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Increlex.

REFERENCES

- Increlex [Prescribing Information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20

Created: 02/06
Client Approval: 03/20

P&T Approval: 04/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MECHLORETHAMINE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of stage IA or IB mycosis fungoides-type cutaneous T-cell lymphoma (CTCLs)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient tried prior skin-directed therapy (such as corticosteroids, carmustine, topical retinoids [Targretin, Tazorac], imiquimod, or local radiation therapy)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **MECHLORETHAMINE (Valchlor)** requires the following rule(s) be met for approval:
   A. You have stage IA or IB mycosis fungoides-type cutaneous T-cell lymphoma (type of immune system cancer)
   B. You had prior skin-directed therapy such as corticosteroids, carmustine, topical retinoids (Targretin, Tazorac), imiquimod, or local radiation therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Valchlor.

REFERENCES

- Valchlor [Prescribing Information]. Iselin, NJ: Helsinn Therapeutics (U.S.), Inc.; January 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/23
Created: 11/13
Client Approval: 03/23
P&T Approval: 11/13

STANDARD COMMERCIAL AND NSA DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MEPOLIZUMAB

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a physician specializing in pulmonary medicine or allergy medicine
   - The patient has a documented (e.g., chart notes, lab results, diagnostic test results, etc.) blood eosinophil level of at least 150 cells/mcL within the past 12 months
   - The patient is concurrently treated with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast,], theophylline, or an oral corticosteroid [e.g., prednisone])
   - Nucala will NOT be used concurrently with Xolair (omalizumab), Dupixent (dupilumab), Tezspire (tezepelumab-ekko), or another anti-IL-5 biologic (e.g., Cinqair [reslizumab], Fasenra [benralizumab]) when these are used for the treatment of asthma

     If yes, continue to #2.
     If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced at least ONE asthma exacerbation requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months
   - The patient has experienced at least ONE serious asthma exacerbation requiring hospitalization or an emergency room visit within the past 12 months

     If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #1 vial/syringe per 28 days.**

     If no, continue to #3.

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MEPOLIZUMAB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have poor symptom control despite current therapy as evidenced by at least **THREE** of the following within the past 4 weeks?
   - Daytime asthma symptoms more than twice per week
   - Any night waking due to asthma
   - Use of a short-acting inhaled beta2-agonist (SABA) reliever (e.g., albuterol) for symptoms more than twice per week
   - Any activity limitation due to asthma

   If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #1 vial/syringe per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an otolaryngologist or allergist/immunologist
   - Nucala will be used as add-on maintenance treatment
   - The patient had a previous 56-day trial of ONE intranasal corticosteroid (e.g., mometasone nasal spray)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 vial/syringe per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome, **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 vials/syringes per 28 days.**

   If no, continue to #6.

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MEPOLIZUMAB

INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of hypereosinophilic syndrome (HES) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has had HES for 6 months or more without an identifiable non-hematologic secondary cause

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 vials/syringes per 28 days.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MEPOLIZUMAB (Nucala)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Severe asthma with an eosinophilic phenotype (a type of lung condition with inflammation)
      2. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus passages with small growths in the nose)
      3. Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome (inflammation of blood vessels with high levels of a type of white blood cell)
      4. Hypereosinophilic syndrome (HES: a type of blood disorder)

   B. **If you have severe asthma with an eosinophilic phenotype, approval also requires:**
      1. You are 6 years of age or older
      2. Therapy is prescribed by or in consultation with a physician specializing in pulmonary (relating to lungs/breathing) medicine or allergy medicine
      3. You have a documented (such as chart notes, lab results, diagnostic test results) blood eosinophil (a type of white blood cell) level of at least 150 cells/mcL within the past 12 months
      4. You are being treated at the same time with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)

   (Initial denial text continued on next page)

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MEPOLIZUMAB

INITIAL CRITERIA (CONTINUED)

5. You meet ONE of the following:
   a. You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months, OR at least ONE serious asthma exacerbation requiring a hospitalization or an emergency room visit within the past 12 months
   b. You have poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks:
      i. Daytime asthma symptoms more than twice per week
      ii. Any night waking due to asthma
      iii. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
      iv. Any activity limitation due to asthma
6. You will NOT use Nucala concurrently (at the same time) with Xolair (omalizumab), Dupixent (dupilumab), Tezspire (tezepelumab-ekko), or another anti-IL-5 (interleukin-5) biologic (such as Cinqair [reslizumab], Fasenra [benralizumab]) when these are used for the treatment of asthma

C. **If you have chronic rhinosinusitis with nasal polyps, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an otolaryngologist (ear, nose, and throat doctor) or an allergist/immunologist (a type of allergy or immune system doctor)
   3. Nucala will be used as add-on maintenance treatment
   4. You had a previous 56-day trial of ONE intranasal corticosteroid (such as mometasone nasal spray)

D. **If you have eosinophilic granulomatosis with polyangiitis, approval also requires:**
   1. You are 18 years of age or older

E. **If you have hypereosinophilic syndrome, approval also requires:**
   1. You are 12 years of age or older
   2. You have had HES for 6 months or more without an identifiable non-hematologic (not present in the blood) secondary cause

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MEPOLIZUMAB

RENEWAL CRITERIA

NOTE: For the diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA, Churg-Strauss syndrome) OR hypereosinophilic syndrome (HES), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype and meet **ALL** of the following criteria?
   - The patient will continue to use an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline, or an oral corticosteroid [e.g., prednisone])
   - Nucala will NOT be used concurrently with Xolair (omalizumab), Dupixent (dupilumab), Tezspire (tezepelumab-ekko), or another anti-IL-5 biologic (e.g., Cinqair [reslizumab], Fasenra [benralizumab]) when these are used for the treatment of asthma

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient shown a clinical response as evidenced by **ONE** of the following?
   - Reduction in asthma exacerbation from baseline
   - Decreased utilization of rescue medications (e.g., albuterol)
   - Increase in percent predicted FEV1 from pretreatment baseline
   - Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 vial/syringe per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) **AND** meet the following criterion?
   - The patient has had a clinical benefit compared to baseline (e.g., improvements in nasal congestion, sense of smell, size of polyps)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 vial/syringe per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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MEPOLIZUMAB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MEPOLIZUMAB (Nucala)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Severe asthma with an eosinophilic phenotype (a type of lung condition with inflammation)
   2. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus passages with small growths in the nose)

B. **If you have severe asthma with an eosinophilic phenotype, renewal also requires:**
   1. You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)
   2. You will NOT use Nucala concurrently (at the same time) with Xolair (omalizumab), Dupixent (dupilumab), Tezspire (tezepelumab-ekko), or another anti-IL-5 (interleukin-5) biologic (such as Cinqair [reslizumab], Fasenra [benralizumab]) when these are used for the treatment of asthma
   3. You have shown a clinical response as evidenced by ONE of the following:
      a. Reduction in asthma exacerbation (worsening of symptoms) from baseline (before starting Nucala)
      b. Decreased use of rescue medications (such as albuterol)
      c. Increase in percent predicted FEV1 (type of lung test) from pre-treatment baseline (before starting Nucala)
      d. Reduction in the severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

C. **If you have chronic rhinosinusitis with nasal polyposis, renewal also requires:**
   1. You have had a clinical benefit compared to baseline (before starting Nucala) (such as improvements in nasal congestion, sense of smell, size of polyps)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MEPOLIZUMAB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nucala.

REFERENCES

- Nucala [Prescribing Information]. Philadelphia, PA: GlaxoSmithKline, LLC.; March 2023.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 11/15
Client Approval: 03/24
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METHOTREXATE - JYLAMVO

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute lymphoblastic leukemia (ALL) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Jylamvo will be used as part of a combination chemotherapy maintenance regimen
   - The patient is unable to swallow generic methotrexate tablets

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, continue to #2.

2. Does the patient have a diagnosis of mycosis fungoides (cutaneous T-cell lymphoma) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is unable to swallow generic methotrexate tablets

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, continue to #3.

3. Does the patient have a diagnosis of relapsed or refractory non-Hodgkin lymphoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Jylamvo will be used as part of a metronomic combination chemotherapy regimen
   - The patient is unable to swallow generic methotrexate tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #20mL per 28 days.**
   If no, continue to #4.

4. Does the patient have a diagnosis of rheumatoid arthritis and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is unable to swallow generic methotrexate tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #40mL per 28 days.**
   If no, continue to #5.

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METHOTREXATE - JYLAMVO

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of severe psoriasis and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is unable to swallow generic methotrexate tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #60mL per 28 days.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **METHOTREXATE - JYLAMVO** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Acute lymphoblastic leukemia (ALL: a type of blood cancer)
      2. Mycosis fungoides (cutaneous T-cell lymphoma) (a type of blood cancer affecting the skin)
      3. Relapsed or refractory non-Hodgkin lymphoma (a type of blood cancer that has returned or did not respond to treatment)
      4. Rheumatoid arthritis (a type of joint condition)
      5. Severe psoriasis (a type of skin condition)
   B. **If you have acute lymphoblastic leukemia, approval also requires:**
      1. You are 18 years of age or older
      2. Jylamvo will be used as part of a combination chemotherapy maintenance regimen (a type of therapy to treat cancer)
      3. You cannot swallow generic methotrexate tablets
   C. **If you have mycosis fungoides (cutaneous T-cell lymphoma), approval also requires:**
      1. You are 18 years of age or older
      2. You cannot swallow generic methotrexate tablets
   D. **If you have relapsed or refractory non-Hodgkin lymphoma, approval also requires:**
      1. You are 18 years of age or older
      2. Jylamvo will be used as part of a metronomic combination chemotherapy regimen (a type of therapy to treat cancer where lower doses are given over a long period to reduce side effects)
      3. You cannot swallow generic methotrexate tablets

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METHOTREXATE - JYLAMVO

GUIDELINES FOR USE (CONTINUED)

E. **If you have rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. You cannot swallow generic methotrexate tablets

F. **If you have severe psoriasis, approval also requires:**
   1. You are 18 years of age or older
   2. You cannot swallow generic methotrexate tablets

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Jylamvo.

REFERENCES

- Jylamvo [Prescribing Information]. Scotch Plains, NJ: Therakind Limited; November 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 11/23
Client Approval: 11/23
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METHOXY PEG-EPOETIN BETA

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient 18 years of age or older and meets **ALL** of the following criteria?
   - The patient had a trial of the preferred agent: Retacrit
   - The patient has a hemoglobin level of less than 10g/dL

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.6mL per 28 days.**

   If no, continue to #3.

3. Is the patient between 5 and 17 years of age and meets **ALL** of the following criteria?
   - The patient is on hemodialysis
   - The patient is converting from another erythropoiesis-stimulating agent (ESA) (i.e., epoetin alfa, darbepoetin alfa) after the hemoglobin level has been stabilized with the ESA

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.6mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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METHOXY PEG-EPOETIN BETA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **METHOXY PEG-EPOETIN BETA (Mircera)** requires the following rule(s) be met for approval:

A. You have anemia (low amount of healthy red blood cells) associated with chronic kidney disease
B. **If you are 18 years of age or older, approval also requires**:
   1. You have tried the preferred medication: Retacrit
   2. You have a hemoglobin level (type of blood test) of less than 10g/dL
C. **If you are between 5 and 17 years of age, approval also requires:**
   1. You are on hemodialysis (process of removing excess water, toxins from the blood)
   2. You are changing from another erythropoiesis-stimulating agent (ESA; epoetin alfa, darbepoetin alfa) after the hemoglobin level has been stabilized with the ESA

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient 18 years of age or older and meets **ONE** of the following criteria?
   - The patient has a hemoglobin level of less than 11g/dL if on dialysis
   - The patient has a hemoglobin level that has reached 11g/dL (if on dialysis) and the dose is being reduced/interrupted to decrease the need for blood transfusions
   - The patient has a hemoglobin level of less than 10g/dL if not on dialysis
   - The patient has a hemoglobin level that has reached 10g/dL (if not on dialysis) and the dose is being reduced/interrupted to decrease the need for blood transfusions

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.6mL per 28 days.**

   If no, continue to #3.

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METHOXY PEG-EPOETIN BETA

RENEWAL CRITERIA (CONTINUED)

3. Is the patient between 5 and 17 years of age and meets **ALL** of the following criteria?
   - The patient is currently receiving dialysis treatment
   - The patient has a hemoglobin level of less than 11g/dL OR the patient has a hemoglobin level that has reached 11g/dL and the dose is being reduced/interrupted to decrease the need for blood transfusions

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.6mL per 28 days.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **METHOXY PEG-EPOETIN BETA (Mircera)** requires the following rule(s) be met for renewal:
   A. You have anemia (low amount of healthy red blood cells) associated with chronic kidney disease
   B. **If you are 18 years of age or older, renewal also requires ONE of the following:**
      1. You have a hemoglobin level (type of blood test) of less than 11g/dL if you are on dialysis (process of removing excess water, toxins from the blood)
      2. The patient has a hemoglobin level that has reached 11g/dL (if you are on dialysis) and your dose is being reduced/interrupted to decrease the need for blood transfusions
      3. You have a hemoglobin level (type of blood test) of less than 10g/dL if you are not on dialysis
      4. You have a hemoglobin level that has reached 10g/dL (if you are not on dialysis) and your dose is being reduced/interrupted to decrease the need for blood transfusions
   C. **If you are between 5 and 17 years of age, renewal also requires:**
      1. You are currently receiving dialysis treatment (process of removing excess water, toxins from the blood)
      2. You have ONE of the following:
         a. A hemoglobin level (type of blood test) of less than 11g/dL
         b. A hemoglobin level that has reached 11g/dL and your dose is being reduced/interrupted to decrease the need for blood transfusions

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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METHOXY PEG-EPOETIN BETA

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mircera.

REFERENCES

- Mircera [Prescribing Information]. St. Gallen, Switzerland: Vifor, August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/17/23
Created: 02/11
Client Approval: 03/23
P&T Approval: 01/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METHYLNALTREXONE

GUIDELINES FOR USE

1. Is the request for methylnaltrexone (Relistor) tablets or injection for a patient with constipation due to an opioid (such as morphine or methadone) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has chronic non-cancer pain (including chronic pain related to prior cancer or its treatment who do not require frequent opioid dosage escalation)
   - The patient has been taking opioids for at least four weeks
   - The patient has a previous trial of or contraindication to naloxegol (Movantik)

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following listed agents and quantity limits:**
   - **Relistor 12mg vial: #1 vial per day.**
   - **Relistor 12mg syringe: #1 syringe per day.**
   - **Relistor 150mg tablets: #3 tablets per day.**

   If no, continue to #2.

2. Is the request for methylnaltrexone (Relistor) injection for a patient with constipation due to an opioid (such as morphine or methadone) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has advanced (terminal) illness or pain caused by active cancer who require opioid dosage escalation for palliative care

   If yes, **approve Relistor injection for 6 months by GPID or GPI-14 with the following quantity limits:**
   - **Relistor 12 mg vial: #1 vial per day.**
   - **Relistor 12 mg syringe: #1 syringe per day.**
   - **Relistor 8 mg syringe: #1 syringe per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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METHYLNALTREXONE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **METHYLNALTREXONE (Relistor)** requires the following rule(s) be met for approval:

A. You have opioid (type of pain medication)-induced constipation with chronic non-cancer pain, OR you have an advanced illness or pain caused by active cancer and you require opioid dosage increase for palliative care (treatment of symptoms)
B. You are 18 years of age or older
C. **If you have advanced (terminal) illness, or pain caused by active cancer and** you require opioid dosage increase for palliative care (treatment of symptoms), only Relistor injection may be approved
D. **If you have chronic non-cancer pain, approval also requires:**
    1. You have been taking opioids for at least four weeks
    2. You had a previous trial of naloxegol (Movantik), unless there is a medical reason why you cannot (contraindication)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Relistor.

REFERENCES

- Relistor [Prescribing Information]. Bridgewater, NJ: Salix Pharmaceuticals. November 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 11/08
Client Approval: 04/20
P&T Approval: 08/16

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METHYLTESTOSTERONE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) who meets **ONE** of the following criteria?
   - The patient has a previously approved prior authorization for testosterone or has been receiving any form of testosterone replacement therapy
   - The patient has AT LEAST ONE of the following laboratory values confirming low testosterone levels:
     - At least TWO total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
     - Free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)

   If yes, continue to #2.
   If no, continue to #5.

2. Is the patient 40 years of age or older?

   If yes, continue to #3.
   If no, continue to #4.

3. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Has the patient had a trial of or contraindication to **TWO** preferred agents: intramuscular testosterone cypionate and intramuscular testosterone enanthate?

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 with a quantity limit of #5 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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METHYLTESTOSTERONE

INITIAL CRITERIA (CONTINUED)

5. Is the request for a male patient with a diagnosis of delayed puberty not secondary to a pathological disorder who meets the following criterion?
   - The patient had a trial of or contraindication to intramuscular testosterone enanthate

   If yes, **approve the requested agent for 6 months by GPID or GPI-14 with a quantity limit of #5 per day.**

   If no, continue to #6.

6. Is the request for a female patient with a diagnosis of metastatic breast cancer who meets the following criterion?
   - The patient had a trial of or contraindication to intramuscular testosterone enanthate

   If yes, continue to #7.
   If no, continue to #8.

7. Does the patient meet **ONE** of the following criteria?
   - The patient is postmenopausal
   - The patient is premenopausal who benefited from an oophorectomy AND is considered to have a hormone-responsive tumor

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 with a quantity limit of #20 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

8. Is the requested agent for gender dysphoria as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb) **AND** the patient meets the following criterion?
   - The patient is 16 years of age or older

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 and override quantity limits.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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METHYLTESTOSTERONE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **METHYLTESTOSTERONE (Testred, Android, Methitest)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   2. Delayed puberty not due to a pathological disorder (not due to disease) in a male
   3. Metastatic breast cancer (cancer that has spread to other parts of the body) in a female
   4. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

B. If you are a male with primary or secondary hypogonadism, approval also requires:
   1. You meet ONE of the following:
      a. You have a previously approved prior authorization for testosterone, or you have been receiving any form of testosterone replacement therapy
      b. You have ONE of the following lab values showing you have low testosterone levels:
         i. At least TWO total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
         ii. Free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)
   2. You have tried or have a contraindication to (harmful for you to use) TWO preferred medications: intramuscular [injected into the muscle] testosterone cypionate, intramuscular testosterone enanthate
   3. If you are 40 years of age or older, approval also requires that your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

C. **If you are a male with delayed puberty not secondary to a pathological disorder, approval also requires:**
   1. You have tried or have a contraindication to (harmful for you to use) intramuscular (injected into the muscle) testosterone enanthate

D. **If you are a female with metastatic breast cancer, approval also requires:**
   1. You have tried or have a contraindication to (harmful for you to use) intramuscular (injected into the muscle) testosterone enanthate
   2. You meet ONE of the following:
      a. You are postmenopausal (after menopause)
      b. You are premenopausal (before menopause), you have benefited from an oophorectomy (surgical removal of the ovaries), and your tumor is hormone-responsive

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METHYLTESTOSTERONE

INITIAL CRITERIA (CONTINUED)

E. **If you have gender dysphoria, approval also requires:**
   1. Only agents supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria may be approved
   2. You are 16 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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METHYLTESTOSTERONE

RENEWAL CRITERIA

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) who meets **ALL** of the following criteria?
   - The patient has improved symptoms compared to baseline and tolerance to treatment
   - The patient's serum testosterone level and hematocrit concentration have normalized compared to baseline

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient 40 years of age or older?

   If yes, continue to #3.
   If no, **approve the requested agent for 12 months by GPID or GPI-14 with a quantity limit of #5 per day.**

3. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 with a quantity limit of #5 per day.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Is the request for a male patient with a diagnosis of delayed puberty not secondary to a pathological disorder who meets the following criterion?
   - The patient has not received more than two 6-month courses of testosterone replacement therapy

   If yes, **approve the requested agent for 6 months by GPID or GPI-14 with a quantity limit of #5 per day.**

   If no, continue to #5.

5. Is the request for a female patient with a diagnosis of metastatic breast cancer?

   If yes, continue to #6.
   If no, continue to #7.

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METHYLTESTOSTERONE

RENEWAL CRITERIA (CONTINUED)

6. Does the patient meet **ONE** of the following criteria?
   - The patient is postmenopausal
   - The patient is premenopausal who benefited from an oophorectomy AND is considered to have a hormone-responsive tumor

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 with a quantity limit of #20 per day.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

7. Is the requested agent for gender dysphoria as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 and override quantity limits.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.***

   Our guideline named **METHYLTESTOSTERONE (Testred, Android, Methitest)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
      2. Delayed puberty not due to a pathological disorder (not due to disease) in a male
      3. Metastatic breast cancer (cancer that has spread to other parts of the body) in a female
      4. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
   B. **If you are a male with primary or secondary hypogonadism, renewal also requires:**
      1. You have shown improvement in your symptoms compared to baseline and tolerance to treatment
      2. Your serum testosterone level and hematocrit concentration (types of blood tests) have normalized compared to baseline
      3. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

   (Renewal denial text continues on next page)

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METHYLTESTOSTERONE

RENEWAL CRITERIA (CONTINUED)

C. **If you are a male with delayed puberty not secondary to a pathological disorder, renewal also requires:**
   1. You have NOT received more than two 6-month courses of testosterone replacement therapy

D. **If you are a female with metastatic breast cancer, renewal also requires:**
   1. You meet ONE of the following:
      a. You are postmenopausal (after menopause)
      b. You are premenopausal (before menopause), you have benefited from an oophorectomy (surgical removal of the ovaries), and your tumor is hormone-responsive

E. **If you have gender dysphoria, renewal also requires:**
   1. Only agents supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria may be approved

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Testred, Android, and Methitest.

REFERENCES

- Android [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals; April 2015.
- Methitest [Prescribing Information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; May 2019.
- Testred [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals; April 2015.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 02/23
Client Approval: 02/24
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METOCLOPRAMIDE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute and recurrent diabetic gastroparesis **AND** meet the following criterion?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to metoclopramide ODT

   If yes, **approve for 3 months by GPID or GPI-14 with a quantity limit of #9.8 mL (1 bottle) per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **METOCLOPRAMIDE (Gimoti)** requires the following rule(s) be met for approval:
   A. You have acute (short duration) and recurrent (occurring repeatedly) diabetic gastroparesis (disorder that causes delayed emptying of food from the stomach)
   B. You are 18 years of age or older
   C. You have previously tried or have a contraindication (medical reason why you cannot take) to metoclopramide ODT (orally disintegrating tablet)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gimoti.

REFERENCES

- Gimoti [Prescribing Information]. Solana Beach, CA: Evoke Pharma, Inc.; June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21
Created: 11/20
Client Approval: 11/20
P&T Approval: 10/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METRONIDAZOLE

GUIDELINES FOR USE

1. Is the request for the treatment of trichomoniasis and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to generic metronidazole tablets
   - The patient is unable to swallow metronidazole tablets

   If yes, **approve for 30 days by GPID or GPI-14 with a quantity limit of #400mL per 10 days for 1 fill.**

   If no, continue to #2.

2. Is the request for the treatment of acute intestinal amebiasis (amoebic dysentery) or amebic liver abscess, and the patient meets **ALL** of the following criteria?
   - The patient had a trial of or contraindication to generic metronidazole tablets
   - The patient is unable to swallow metronidazole tablets

   If yes, **approve for 30 days by GPID or GPI-14 with a quantity limit of #400mL per 10 days for 1 fill.**

   If no, continue to #3.

3. Is the request for the treatment of serious infections caused by susceptible anaerobic bacteria (e.g., *Bacteroides* species, *Clostridium* species, *Peptococcus* species) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to generic metronidazole tablets
   - The patient is unable to swallow metronidazole tablets

   If yes, **approve for 30 days by GPID or GPI-14 with a quantity limit of #400mL per 10 days for 1 fill.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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METRONIDAZOLE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **METRONIDAZOLE (Likmez)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Trichomoniasis (a type of infection caused by a parasite)
   2. Acute intestinal amebiasis (amoebic dysentery: a type of infection of the intestines) OR amebic liver abscess (a collection of pus in the liver caused by a parasite)
   3. Serious infections caused by susceptible anaerobic bacteria, such as *Bacteroides* species, *Clostridium* species, *Peptococcus* species (infections caused by types of bacteria that can be treated with Likmez)

B. You have tried or have a contraindication to (harmful for you to use) generic metronidazole tablets

C. You are unable to swallow metronidazole tablets

D. **For the treatment of trichomoniasis or serious infections caused by susceptible anaerobic bacteria, approval also requires:**
   1. You are 18 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Likmez.

REFERENCES

- Likmez [Prescribing Information]. Hauppauge, NY: Saptalis Pharmaceuticals LLC; September 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/01/24
Created: 11/23
Client Approval: 01/24
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIDOSTAURIN

GUIDELINES FOR USE

1. Does the patient have newly diagnosed acute myeloid leukemia (AML) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is FLT3 mutation-positive as detected by an FDA-approved diagnostic test
   - The requested medication will be used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation
   - The requested medication will not be used as a single-agent induction therapy for the treatment of patients with AML

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #56 per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #224 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIDOSTAURIN (Rydapt)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Newly diagnosed acute myeloid leukemia (AML: a type of blood cancer)
      2. Aggressive systemic mastocytosis (ASM: a type of blood disorder)
      3. Systemic mastocytosis with associated hematological neoplasm (SM-AHN: type of blood cancer)
      4. Mast cell leukemia (MCL: type of blood cell cancer)

   (Denial text continued on next page)

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MIDOSTAURIN

GUIDELINES FOR USE (CONTINUED)

B. **If you have newly diagnosed acute myeloid leukemia, approval also requires:**
   1. You are 18 years of age or older
   2. You are FLT3 (type of gene) mutation-positive as detected by a Food and Drug Administration (FDA)-approved diagnostic test
   3. The requested medication will be used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation (cancer drugs)
   4. The requested medication will not be used by itself to start treatment (single-agent induction therapy)

C. **If you have aggressive systemic mastocytosis, systemic mastocytosis with associated hematological neoplasm, or mast cell leukemia, approval also requires:**
   1. You are 18 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Rydapt.

REFERENCES

- Rydapt [Prescribing Information]. East Hanover, New Jersey: Novartis Pharmaceuticals; November 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 08/17
Client Approval: 03/22
P&T Approval: 07/17

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIFEPRISTONE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of endogenous Cushing's syndrome (CS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's hypercortisolism is NOT a result of chronic glucocorticoids (e.g., prednisone)
   - The patient also has a diagnosis of type 2 diabetes mellitus OR glucose intolerance
   - The patient has failed surgical treatment for Cushing's syndrome OR is not a candidate for surgery

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the diagnosis of endogenous Cushing's syndrome been confirmed by **ONE** of the following tests?
   - 24-hour urine free cortisol (2 or more tests to confirm)
   - Overnight 1mg dexamethasone test
   - Late-night salivary cortisol (2 or more tests to confirm)

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **MIFEPRISTONE (Korlym)** requires the following rule(s) be met for approval:
   A. You have endogenous Cushing's syndrome (CS: a type of hormone disorder)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   (Initial denial text continued on the next page)

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MIFEPRISTONE

INITIAL CRITERIA (CONTINUED)

D. Your diagnosis is confirmed by ONE of the following:
   1. 24-hour urine free cortisol (a type of test that measures the amount of cortisol in the urine) (at least 2 or more tests to confirm)
   2. Overnight 1mg dexamethasone test (a type of diagnostic test)
   3. Late-night salivary cortisol (a type of test that measures the amount of cortisol in the saliva at night) (at least 2 or more tests to confirm)

E. Your hypercortisolism (high levels of cortisol) is NOT due to chronic glucocorticoids (long-term use of a class of drugs that consists of steroids, such as prednisone)

F. You also have type 2 diabetes mellitus (a disorder with high blood sugar) OR glucose intolerance (a condition that results in high blood sugar)

G. You have failed surgical treatment (surgery did not work) for Cushing's syndrome OR you are NOT a candidate for surgery

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIFEPRISTONE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of endogenous Cushing's syndrome (CS) and meet **ALL** of the following criteria?
   - The patient continues to have improvement of glucose tolerance or stable glucose tolerance (e.g., reduced A1C, improved fasting glucose, etc.)
   - The patient continues to have tolerability to Korlym
   - The patient continues to NOT be a candidate for surgical treatment OR has failed surgery

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIFEPRISTONE (Korlym)** requires the following rule(s) be met for renewal:
   A. You have endogenous Cushing's syndrome (CS: a type of hormone disorder)
   B. You continue to have improvement of glucose tolerance or stable glucose tolerance (such as reduced hemoglobin A1C level [a type of lab test], improved fasting glucose)
   C. You continue to tolerate Korlym
   D. You are NOT a candidate for surgery OR have failed surgery (surgery did not work) for Cushing's syndrome

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Korlym.

REFERENCE

- Korlym [Prescribing Information]. Menlo Park, CA: Corcept Therapeutics Incorporated; November 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/12/24
Created: 04/12
Client Approval: 01/24
P&T Approval: 07/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIGALASTAT

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Fabry disease and meet **ALL** of the following criteria?
   - The patient is 18 years or older
   - Therapy is prescribed by or in consultation with a nephrologist, cardiologist, or specialist physician in genetics or inherited metabolic disorders
   - The patient has an amenable galactosidase alpha (GLA) gene variant based on in vitro assay data as interpreted by clinical genetics professional as pathogenic or likely pathogenic (i.e., patient does not have a benign amenable GLA variant)
   - Galafold will NOT be used concurrently with another Fabry disease therapy (e.g., Fabrazyme [agalsidase beta], Elfabrio [pegunigalsidase alfa-iwxj])
   - The patient is symptomatic OR has evidence of injury from GL-3 to the kidney, heart, or central nervous system recognized by laboratory, histological, or imaging findings (e.g., decreased GFR for age, persistent albuminuria, cerebral white matter lesions on brain MRI, cardiac fibrosis on contrast cardiac MRI)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the request for a female patient who meets the following criterion?
   - The patient has a galactosidase alpha (GLA) gene mutation via genetic testing

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #14 per 28 days.**
   If no, continue to #3.

3. Is the request for a male patient who meets **ONE** of the following criteria?
   - The patient has an alpha galactosidase A (a-Gal -A) deficiency as indicated by an enzyme assay
   - The patient has a galactosidase alpha (GLA) gene mutation via genetic testing

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #14 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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MIGALASTAT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MIGALASTAT (Galafold)** requires the following rule(s) be met for approval:

A. You have Fabry disease (a rare genetic disease)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a nephrologist (kidney doctor), cardiologist (heart doctor), or specialist in genetics or inherited metabolic disorders
D. You have an amenable (responsive) galactosidase alpha (GLA: a type of gene) gene variant based on in vitro assay data (data collected from lab test tubes or cultures) that is interpreted by clinical genetics professional as the cause of disease (pathogenic or likely pathogenic)
E. You will NOT use Galafold concurrently (taking at the same time) with another Fabry disease medication (such as Fabrazyme [agalsidase beta], Elfabrio [pegunigalsidase alfa-iwxj])
F. You are symptomatic OR have evidence of injury from globotriaosylceramide (GL-3: a type of fat) to the kidney, heart, or central nervous system recognized by laboratory, histological, or imaging findings. Evidence of injury includes decreased GFR (measurement of how well your kidneys are working) for age, persistent albuminuria (buildup of a type of protein), cerebral white matter lesions on brain MRI (magnetic resonance imaging: a type of imaging lab), cardiac fibrosis (scarring of the heart) on contrast cardiac MRI
G. **If you are a female, approval also requires:**
    1. You have a galactosidase alpha (GLA: a type of gene) gene mutation via genetic testing
H. **If you are a male patient, approval also requires ONE of the following:**
    1. You do not have enough alpha galactosidase A (a-Gal-A: a type of protein) as indicated by an enzyme assay (a type of lab test)
    2. You have a galactosidase alpha (GLA: a type of gene) gene mutation via genetic testing

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIGALASTAT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Fabry disease **AND** meet the following criterion?
   - Galafold will NOT be used concurrently with another Fabry disease therapy (e.g., Fabrazyme [agalsidase beta], Elfabrio [pegunigalsidase alfa-iwxj])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient demonstrated improvement, maintenance, or stabilization in ONE of the following while on therapy?
   - Symptoms (e.g., pain, hypohidrosis/anhidrosis, exercise intolerance, GI symptoms, angiokeratomas, abnormal cornea, tinnitus/hearing loss)
   - Imaging (e.g., brain/cardiac MRI, DEXA, renal ultrasound)
   - Laboratory or histological testing (e.g., GL-3 in plasma/urine, renal biopsy)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #14 per 28 days.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIGALASTAT (Galafold)** requires the following rule(s) be met for renewal:
   A. You have Fabry disease (rare genetic disease)
   B. You will NOT use Galafold concurrently (taking at the same time) with another Fabry disease therapy (such as Fabrazyme [agalsidase beta], Elfabrio [pegunigalsidase alfa-iwxj])
   C. You have demonstrated improvement, maintenance, or stabilization in ONE of the following while on therapy:
      1. Symptoms such as pain, hypohidrosis/anhidrosis (little to no sweat), exercise intolerance, gastrointestinal (GI) symptoms, angiokeratomas (dark red/purple raised spots), abnormal cornea, tinnitus (ringing in the ears), or hearing loss
      2. Imaging such as brain/cardiac MRI (magnetic resonance imaging: a type of imaging lab), DEXA (test to measure bone density), or renal (kidney) ultrasound
      3. Laboratory or histological (viewed by microscope) testing such as globotriaosylceramide (GL-3: a type of fat) in plasma/urine, renal biopsy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MIGALASTAT

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Galafold.

REFERENCES

- Galafold [Prescribing Information]. Cranbury, NJ: Amicus Therapeutics; June 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/23
Created: 11/18
Client Approval: 08/23
P&T Approval: 07/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIGLUSTAT-OPFOLDA

GUIDELINES FOR USE

1. Does the patient have a diagnosis of late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient weighs at least 40 kgs (88 lbs.)
   - The patient is not improving on their current enzyme replacement therapy (ERT) (e.g., Lumizyme [alglucosidase alfa])
   - Opfolda will be used in combination with Pombiliti (cipaglucosidase alfa-atga)

   If yes, **approve for lifetime by GPID or GPI-14 with a quantity limit of #8 per 28 days.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIGLUSTAT-OPFOLDA** requires the following rule(s) be met for approval:
   A. You have late-onset Pompe disease (a type of genetic disorder) due to lysosomal acid alpha-glucosidase (GAA: a type of enzyme) deficiency
   B. You are 18 years of age or older
   C. You weigh at least 40 kilograms (88 pounds)
   D. You are not improving on your current enzyme replacement therapy (ERT) such as Lumizyme (alglucosidase alfa)
   E. Opfolda will be used in combination with Pombiliti (cipaglucosidase alfa-atga)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIGLUSTAT-OPFOLDA

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Opfolda.

REFERENCES

- Opfolda [Prescribing Information]. Philadelphia, PA: Amicus Therapeutics US, LLC; September 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 12/01/23
Created: 11/23
Client Approval: 11/23
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIGLUSTAT-ZAVESCA

GUIDELINES FOR USE

1. Does the patient have a diagnosis of mild to moderate type 1 (non-neuronopathic) Gaucher disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used as monotherapy
   - Enzyme replacement therapy is not a therapeutic option for this patient (e.g., due to allergy, hypersensitivity, poor venous access)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #90 per 30 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIGLUSTAT-ZAVESCA** requires the following rule(s) be met for approval:
   A. You have mild to moderate type 1 Gaucher disease (a type of genetic condition)
   B. You are 18 years of age or older
   C. The requested medication will be used as monotherapy (used alone)
   D. Enzyme replacement therapy is not a therapeutic option for you (due to reasons such as allergy, hypersensitivity, poor access to your veins)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zavesca.

REFERENCES

- Zavesca [Package Insert]. Titusville, NJ: Actelion Pharmaceuticals US, Inc.; August 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/23/23
Created: 05/05
Client Approval: 10/23
P&T Approval: 08/12

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MILTEFOSINE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Leishmaniasis and meet **ALL** of the following criteria?
   - The patient has **ONE** of the following types of infections:
     - Visceral leishmaniasis caused by *Leishmania donovani*
     - Cutaneous leishmaniasis caused by any of the following: *Leishmania braziliensis, Leishmania guyanensis*, or *Leishmania panamensis*
     - Mucosal leishmaniasis caused by *Leishmania braziliensis*
   - Leishmaniasis species is identified via **ONE** of the following CDC recommended tests:
     - Stained slides (using tissue from biopsy specimens, impression smears or dermal scrapings
     - Culture medium
     - Polymerase chain reaction (PCR)
     - Serologic testing (e.g., rK39 Rapid Test)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #84 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline for **MILTEFOSINE (Impavido)** requires the following rule(s) be met for approval:
   A. You have Leishmaniasis (type of parasite disease) with ONE of the following types of infection:
      1. Visceral leishmaniasis (affects your organs) caused by *Leishmania donovani (type of parasite)*
      2. Cutaneous leishmaniasis (affects your skin layers) caused by any of the following types of parasites:
         a. *Leishmania braziliensis*
         b. *Leishmania guyanensis*
         c. *Leishmania panamensis*
      3. Mucosal leishmaniasis (affects inside mouth, throat and nose) caused by *Leishmania braziliensis*
   B. Species identification must be confirmed via ONE of the following CDC (Center for Disease Control and Prevention) recommended tests:
      1. Stained slides (using tissue from biopsy specimens, impression smears or dermal scrapings
      2. Culture medium
      3. Polymerase chain reaction (lab method to make copies of genes)
      4. Serologic testing (testing your blood and body fluids such as rK39 Rapid Test)

   (Denial text continued on next page)

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MILTEFOSINE

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Impavido.

REFERENCES

- Impavido [Prescribing Information]. Orlando, FL: Profounda, Inc.; May 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/01/21
Created: 04/16
Client Approval: 10/21
P&T Approval: 05/16

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIPOMERSEN SODIUM

GUIDELINES FOR USE

1. Is the requested medication prescribed by or given in consultation with a cardiologist, endocrinologist, or lipidologist?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has been taking a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks
   - The patient has been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks given that the patient cannot tolerate a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)

   If yes, continue to #3.
   If no, continue to #4.

3. Will the patient continue statin treatment as described above in combination with Kynamro?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient meet **ONE** of the following criteria?
   - The patient has an absolute contraindication to statin therapy (e.g., active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction)
   - The patient has complete statin intolerance as defined by severe and intolerable adverse effects (e.g., creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group) that have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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MIPOMERSEN SODIUM

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a LDL-cholesterol level greater than or equal to 70 mg/dL while on maximally tolerated statin treatment?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient meet **ONE** of the following criteria?
   - The patient has had a previous trial of Repatha (evolocumab)
   - The patient lacks functioning LDL receptors

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Does the patient have a diagnosis of homozygous familial hypercholesterolemia (HoFH) as determined by meeting **ONE** of the following criteria?
   - Simon Broome diagnostic criteria (definite)
   - Dutch Lipid Network criteria with a score of at least 8
   - A clinical diagnosis based on a history of an untreated LDL-cholesterol level greater than 500 mg/dL, in combination with either (1) xanthoma before 10 years of age **OR** (2) evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4mL (4 syringes) per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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MIPOMERSEN SODIUM

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MIPOMERSEN SODIUM (Kynamro)** requires the following rule(s) be met for approval:

A. You have homozygous familial hypercholesterolemia (type of inherited high cholesterol) which was determined by meeting **ONE** of the following criteria:
   1. Simon Broome diagnostic criteria (definite)
   2. Dutch Lipid Network criteria with a score of at least 8
   3. A clinical diagnosis based on a history of an untreated LDL (low density lipoprotein)-cholesterol level greater than 500 mg/dL, in combination with either (1) xanthoma (fatty growths underneath the skin) before 10 years of age **OR** (2) evidence of heterozygous familial hypercholesterolemia (type of inherited high cholesterol) in both parents

B. The medication is prescribed by or recommended by a cardiologist (heart doctor), endocrinologist (hormone doctor), or lipidologist (cholesterol management specialist)

C. You have an LDL (low density lipoprotein)-cholesterol level greater than or equal to 70 mg/dL while on maximally tolerated drug treatment

D. You previously had a trial of Repatha (evolocumab) unless you do not have functional LDL (low density lipoprotein) receptors

E. **If you are statin tolerant, approval also requires:**
   1. You meet ONE of the following:
      i. You have been taking a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks, **OR**
      ii. You have been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks and you cannot tolerate a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
   2. You will continue statin treatment in combination with Kynamro

F. **If you are statin intolerant, approval also requires ONE of the following:**
   1. You have an absolute contraindication to (medical reason why you cannot use) statin therapy such as active decompensated liver disease (you have symptoms related to liver damage), nursing female, pregnancy or plans to become pregnant or hypersensitivity reaction
   2. You have complete statin intolerance as defined by severe and intolerable adverse effects such as creatine kinase elevation (a measure of how much muscle damage you have) greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis (muscle breakdown), severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group. These must have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin

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MIPOMERSEN SODIUM

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kynamro.

REFERENCES

- Kynamro [Prescribing Information]. Chicago, IL: Kastle Therapeutics; January 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 03/13
Client Approval: 04/20
P&T Approval: 04/18

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIRABEGRON SUSPENSION

GUIDELINES FOR USE

1. Does the patient have a diagnosis of neurogenic detrusor overactivity (NDO) and meet **ALL** of the following criteria?
   - The patient is 3 years of age or older
   - The patient had a trial of or contraindication to ONE anticholinergic (e.g., oxybutynin, solifenacin)
   - The patient is unable to swallow Myrbetriq tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #10mL per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIRABEGRON SUSPENSION (Myrbetriq)** requires the following rule(s) be met for approval:
   A. You have neurogenic detrusor overactivity (NDO: a type of bladder control condition)
   B. You are 3 years of age or older
   C. You had a trial of or contraindication (harmful for) to ONE anticholinergic (such as oxybutynin, solifenacin)
   D. You are unable to swallow Myrbetriq tablets

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Myrbetriq.

REFERENCES

- Myrbetriq [Prescribing Information]. Northbrook, IL: Astellas Pharma, Inc.; April 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 11/21
Client Approval: 11/21
P&T Approval: 10/21

STANDARD COMMERCIAL AND NSA DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIRIKIZUMAB-MRKZ

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Omvoh will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication
   - The patient had a trial of or contraindication to ONE conventional therapy, such as corticosteroids (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz) [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance programs do not qualify]

     If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
     - **<u>FIRST APPROVAL:</u> Approve Omvoh 300mg/15mL vial for 3 months with a quantity limit of #15mL per 28 days.**
     - **<u>SECOND APPROVAL:</u> Approve Omvoh 100mg/mL pen for 3 months with a quantity limit of #2mL per 28 days. (Please enter a start date of 3 DAYS BEFORE the END date of the first approval.).**

     If no, do not approve.
     DENIAL TEXT: See the initial denial text at the end of the guideline.

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MIRIKIZUMAB-MRKZ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MIRIKIZUMAB-MRKZ (Omvoh)** requires the following rule(s) be met for approval:

A. You have moderate to severe ulcerative colitis (UC: a type of digestive disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
D. You will NOT use Omvoh concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
E. You have tried or have a contraindication to (harmful for you to use) ONE standard therapy, such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
F. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE

MIRIKIZUMAB-MRKZ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?
   - Omvoh will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz) [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance programs do not qualify]

   If yes, **approve Omvoh 100mg/mL pen for 12 months by GPID or GPI-14 with a quantity limit of #2mL per 28 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIRIKIZUMAB-MRKZ (Omvoh)** requires the following rule(s) be met for renewal:
   A. You have moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   B. You will NOT use Omvoh concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   C. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

   NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MIRIKIZUMAB-MRKZ

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Omvoh.

REFERENCES

- Omvoh [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; October 2023.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 05/01/24
Created: 11/23
Client Approval: 04/24
P&T Approval: 04/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MITAPIVAT

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hemolytic anemia and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has pyruvate kinase (PK) deficiency

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MITAPIVAT (Pyrukynd)** requires the following rule(s) be met for approval:
   A. You have hemolytic anemia (a type of blood condition)
   B. You are 18 years of age or older
   C. You have pyruvate kinase (PK: a type of enzyme) deficiency

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hemolytic anemia with and meet **ALL** of the following criteria?
   - The patient has pyruvate kinase (PK) deficiency
   - The patient has had clinical benefit while on Pyrukynd

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial at the end of the guideline.

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MITAPIVAT

GUIDELINES FOR USE (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MITAPIVAT (Pyrukynd)** requires the following rule(s) be met for renewal:
A. You have hemolytic anemia (a type of blood condition)
B. You have pyruvate kinase (PK: a type of enzyme) deficiency
C. You have had clinical benefit while on Pyrukynd

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pyrukynd.

REFERENCES

- Pyrukynd [Prescribing Information]. Cambridge, MA: Agios Pharmaceuticals, Inc.; February 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 05/22
Client Approval: 05/22
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MOBOCERTINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test
   - The patient's disease progressed on or after platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MOBOCERTINIB (Exkivity)** requires the following rule(s) be met for approval:
   A. You have locally advanced or metastatic (cancer that has spread from where it started to nearby tissue or has spread to other parts of the body) non-small cell lung cancer (NSCLC: type of lung cancer)
   B. You are 18 years of age or older
   C. You have epidermal growth factor receptor (EGFR) exon 20 insertion mutations (type of gene mutation), as detected by a Food and Drug Administration (FDA)-approved test
   D. Your disease progressed (disease has gotten worse) on or after platinum-based chemotherapy such as cisplatin, carboplatin, oxaliplatin

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Exkivity.

REFERENCES

- Exkivity [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals America, Inc., September 2021.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MOBOCERTINIB

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22

Created: 11/21
Client Approval: 11/21

P&T Approval: 10/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MOMELOTINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF (post-polycythemia vera [PV] and post-essential thrombocythemia [ET]), and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has anemia

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MOMELOTINIB (Ojjaara)** requires the following rule(s) be met for approval:
   A. You have intermediate or high-risk myelofibrosis (MF: a type of blood cancer), including primary MF (MF that developed on its own) or secondary MF (MF that developed from another blood disorder, such as post-polycythemia vera [PV: a type of blood cancer] or post-essential thrombocythemia [ET: a type of blood disease])
   B. You are 18 years of age or older
   C. You have anemia (a type of blood condition)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ojjaara.

REFERENCES

- Ojjaara [Prescribing Information]. Durham, NC: GlaxoSmithKline; September 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 12/01/23
Created: 10/23
Client Approval: 11/23
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MONOMETHYL FUMARATE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to dimethyl fumarate AND **ONE** of the following agents: Avonex, Betaseron, Copaxone/Glatiramer/Glatopa, Plegridy, Rebif, Aubagio, Vumerity, Kesimpta (**Please note:** other MS agents may also require prior authorization)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MONOMETHYL FUMARATE (Bafiertam)** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: immune system eats away at the protective covering of the nerves), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older
   C. You have previously tried or have a contraindication to (medical reason why you cannot take) dimethyl fumarate AND ONE of the following: Avonex, Betaseron, Copaxone/Glatiramer/Glatopa, Plegridy, Rebif, Aubagio, Vumerity, Kesimpta
   (**Please note:** Other multiple sclerosis medications may also require prior authorization)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MONOMETHYL FUMARATE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Bafiertam.

REFERENCES

- Bafiertam [Prescribing Information]. High Point, NC: Banner Life Sciences LLC; May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21

Created: 11/20
Client Approval: 11/20

P&T Approval: 10/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NAFARELIN

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for gender dysphoria?

   If yes, **approve for 12 months by HICL or GPI-10 and override quantity limits.**
   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe pain associated with endometriosis and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The diagnosis is confirmed via surgical or direct visualization (e.g., pelvic ultrasound) OR histopathological confirmation (e.g., laparoscopy or laparotomy) in the last 10 years
   - Therapy is prescribed by or in consultation with an obstetrician/gynecologist
   - The patient had a trial of or contraindication to a nonsteroidal anti-inflammatory drug (NSAID) AND a progestin-containing contraceptive preparation (e.g., combination hormonal contraceptive preparation, progestin-only contraceptive preparation)
   - The requested medication will NOT be used concurrently with another GnRH-modulating agent (e.g., elagolix, relugolix, Lupron Depot)
   - The patient has NOT received more than 6 months of treatment with Synarel per lifetime

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #96mL per 6 months.**
   If no, continue to #3.

3. Is the request for a female patient who has a diagnosis of central precocious puberty (CPP) and meets **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a pediatric endocrinologist
   - The patient has elevated levels of follicle-stimulating hormone (FSH) (level >4.0 mIU/mL) and luteinizing hormone (LH) (level > 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 8 years of age at the onset of CPP
   - There is documentation of pubertal staging using the Tanner scale for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #32mL per month.**
   If no, continue to #4.

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NAFARELIN

INITIAL CRITERIA (CONTINUED)

4. Is the request for a male patient who has a diagnosis of central precocious puberty (CPP) and meets **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a pediatric endocrinologist
   - The patient has elevated levels of follicle-stimulating hormone (FSH) (level >5.0 mIU/mL) and luteinizing hormone (LH) (level > 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 9 years of age at the onset of CPP
   - The patient has documentation of pubertal staging using the Tanner scale for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #32mL per month.** If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NAFARELIN (Synarel)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
      2. Moderate to severe pain from endometriosis (condition affecting the uterus)
      3. Central precocious puberty (CPP: early sexual development in girls and boys)
   B. **If you have moderate to severe pain from endometriosis, approval also requires:**
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with an obstetrician/gynecologist (a type of women's health doctor)
      3. Your diagnosis is confirmed by surgical or direct visualization (such as pelvic ultrasound [type of imaging]) or histopathological (tissue) confirmation (such as laparoscopy [type of surgery] or laparotomy [type of surgery]) in the last 10 years
      4. You have tried or have a contraindication (harmful for) to a nonsteroidal anti-inflammatory drug (NSAID) AND a progestin-containing contraceptive preparation (such as combination hormonal contraceptive preparation, progestin-only contraceptive preparation)
      5. You are NOT using Synarel concurrently (at the same time) with another gonadotropin-releasing hormone (GnRH)-modulating agent (such as elagolix, relugolix, Lupron Depot)
      6. You have NOT received more than 6 months of treatment with Synarel per lifetime

   (Initial denial text continued on next page)

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NAFARELIN

INITIAL CRITERIA (CONTINUED)

C. **If you are female and have central precocious puberty, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a pediatric endocrinologist (hormone doctor)
   3. You have high levels of follicle-stimulating hormone (FSH) (level greater than 4.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   4. You are/were younger than 8 years of age when your condition started
   5. There is documentation of pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

D. **If you are male and have central precocious puberty, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a pediatric endocrinologist (hormone doctor)
   3. You have high levels of follicle-stimulating hormone (FSH) (level greater than 5.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   4. You are/were younger than 9 years of age when your condition started
   5. There is documentation of pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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NAFARELIN

GUIDELINES FOR USE (CONTINUED0

RENEWAL CRITERIA

NOTE: For the diagnoses of gender dysphoria or pain from endometriosis, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of central precocious puberty (CPP) and meet **ALL** of the following criteria?
   - The Tanner scale staging at initial diagnosis of CPP has stabilized or regressed during three separate medical visits in the previous year
   - The patient has not reached the actual age which corresponds to their current pubertal age

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #32mL per month.** If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NAFARELIN (Synarel)** requires the following rule(s) be met for renewal:
   A. You have central precocious puberty (CPP: early sexual development in girls and boys)
   B. Your Tanner scale staging (scale of physical measurements of development based on external sex characteristics) at initial diagnosis of CPP has stabilized or regressed (lowered) during three separate medical visits in the previous year
   C. You have not reached the actual age which corresponds to your current pubertal age

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Synarel.

REFERENCES

- Synarel [Prescribing Information]. New York, NY: Pfizer Inc.; May 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/23/23
Created: 09/18
Client Approval: 01/23
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NEDOSIRAN

GUIDELINES FOR USE

1. Does the patient have a diagnosis of primary hyperoxaluria type 1 (PH1) and meet **ALL** of the following criteria?
   - The patient is 9 years of age and older
   - The patient has relatively preserved kidney function (e.g., eGFR is greater than or equal to 30mL/min/1.73m(2))

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **80mg/0.5mL: #1mL per 30 days.**
   - **128mg/0.8mL: #0.8mL per 30 days.**
   - **160mg/mL: #1mL per 30 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NEDOSIRAN (Rivfloza)** requires the following rule(s) be met for approval:
   A. You have primary hyperoxaluria type 1 (PH1: a type of rare genetic disorder)
   B. You are 9 years of age and older
   C. You have relatively preserved kidney function (such as an estimated glomerular filtration rate [eGFR: a tool for evaluating kidney function] of at least 30mL/min/1.73m(2))

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rivfloza.

REFERENCES

- Rivfloza [Prescribing Information]. Plainsboro, NJ: Novo Nordisk Inc.; September 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/12/24
Created: 01/24
Client Approval: 01/24
P&T Approval: 04/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NERATINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of early stage (stage I-III) breast cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a HER2-overexpressed/amplified (HER2-positive) tumor
   - The requested medication will be used as a single agent for extended adjuvant therapy following Herceptin- (trastuzumab-) based therapy
   - The medication is being requested within 2 years after completing last trastuzumab dose

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #180 per 30 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of advanced or metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a HER2-overexpressed/amplified (HER2-positive) tumor
   - The requested medication will be used in combination with capecitabine
   - The patient has received two or more prior anti-HER2 based regimens in the metastatic setting

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #180 per 30 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NERATINIB (Nerlynx)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Early stage (stage I-III) breast cancer
      2. Advanced or metastatic breast cancer
   B. **If you have early stage (stage I-III) breast cancer, approval also requires:**
      1. You are 18 years of age or older
      2. You have a HER2-overexpressed/amplified (HER2-positive) tumor
      3. The requested medication will be used as a single agent for extended adjuvant therapy following Herceptin- (trastuzumab-) based therapy
      4. The medication is being requested within 2 years of completing the last trastuzumab dose

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NERATINIB

GUIDELINES FOR USE (CONTINUED)

C. **If you have advanced or metastatic breast cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have a HER2-overexpressed/amplified (HER2-positive) tumor
   3. The requested medication will be used in combination with capecitabine
   4. You have received two or more prior anti-HER2 based regimens in the metastatic setting

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nerlynx.

REFERENCES

- Nerlynx [Prescribing Information]. Los Angeles, CA: Puma Biotechnology; July 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 07/17
Client Approval: 03/21
P&T Approval: 04/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NILOTINIB

GUIDELINES FOR USE

1. Does the patient have a newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase **AND** meet the following criterion?
   - The patient is 1 year of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase or accelerated phase and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is resistant or intolerant to prior therapy that included imatinib (Gleevec)
   - The patient had a mutational analysis prior to initiation AND Tasigna is appropriate per the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile *(Please see header CML-5 of the current NCCN guidelines)*

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase or accelerated phase and meet **ALL** of the following criteria?
   - The patient is 1 to 17 years of age
   - The patient is resistant or intolerant to prior therapy with other tyrosine kinase inhibitors (TKI) [e.g., Gleevec (imatinib), Sprycel (dasatinib), Bosulif (bosutinib)]
   - The patient had a mutational analysis prior to initiation AND Tasigna is appropriate per the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile *(Please see header CML-5 of the current NCCN guidelines)*

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NILOTINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NILOTINIB (Tasigna)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML: a type of blood cell cancer) in chronic phase
   2. Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia in chronic or accelerated phase

B. **If you have newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, approval also requires:**
   1. You are 1 year of age or older

C. **If you have Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase or accelerated phase, approval also requires:**
   1. If you are 18 years of age or older, you are resistant or intolerant to prior therapy including Gleevec (imatinib)
   2. If you are 1 to 17 years of age, you are resistant or intolerant to prior therapy with other tyrosine kinase inhibitors (TKI) such as Gleevec (imatinib), Sprycel (dasatinib), Bosulif (bosutinib)
   3. You had a mutational analysis prior to initiation of therapy AND Tasigna is appropriate per the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1; a type of abnormal gene) profile

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tasigna.

REFERENCES

- Tasigna [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 05/12
Client Approval: 02/22
P&T Approval: 01/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NIMODIPINE SOLUTION

GUIDELINES FOR USE

1. Does the patient have a history of subarachnoid hemorrhage (SAH) from a ruptured intracranial berry aneurysm within the past 21 days and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is unable to swallow nimodipine capsules

   If yes, **approve once for the requested strength by GPID or GPI-14 up to a maximum 21 day supply with the following quantity limits:**
   - **Nymalize 30mg/10mL: #120mL per day.**
   - **Nymalize 60mg/20mL: #120mL per day.**
   - **Nymalize 30mg/5mL: #60mL per day.**
   - **Nymalize 60mg/10mL: #60mL per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NIMODIPINE SOLUTION (Nymalize)** requires the following rule(s) be met for approval:
   A. You have a history of subarachnoid hemorrhage (SAH: bleeding in the space surrounding your brain) from a ruptured intracranial berry aneurysm (an area of an artery wall in your brain ballooned and burst) within the past 21 days
   B. You are 18 years of age or older
   C. You are unable to swallow nimodipine oral capsules

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NIMODIPINE SOLUTION

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nymalize.

REFERENCES

- Nymalize [Prescribing Information]. Atlanta, GA: Arbor Pharmaceuticals, Inc: April 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/26/21
Created: 08/13
Client Approval: 07/21
P&T Approval: 07/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NINTEDANIB

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of idiopathic pulmonary fibrosis (IPF) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist
   - The patient has a usual interstitial pneumonia (UIP) pattern as evidenced by high-resolution computed tomography (HRCT) alone or via a combination of surgical lung biopsy and HRCT
   - The patient does NOT have other known causes of interstitial lung disease (for example, connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis, systemic sclerosis, rheumatoid arthritis, radiation, sarcoidosis, bronchiolitis obliterans organizing pneumonia, human immunodeficiency virus infection, viral hepatitis, or cancer)
   - The patient has a predicted forced vital capacity (FVC) of at least 50% at baseline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) and meet **ALL** of the following criteria?
   - The patient has a diagnosis of Systemic Sclerosis (SSc) according to American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist or rheumatologist
   - The patient has at least 10% fibrosis on a chest high resolution computed tomography (HRCT)
   - The patient has a baseline forced vital capacity (FVC) of at least 40% of predicted value
   - The patient does NOT have other etiologies of interstitial lung disease (ILD) [e.g., heart failure/fluid overload, drug-induced lung toxicity (cyclophosphamide, methotrexate, ACE-inhibitors), recurrent aspiration (such as from GERD), pulmonary vascular disease, pulmonary edema, pneumonia, chronic pulmonary thromboembolism, alveolar hemorrhage or ILD caused by another rheumatic disease, such as mixed connective tissue disease (MCTD)]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #3.

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NINTEDANIB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype (PF-ILD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist or rheumatologist
   - The patient's lung function and respiratory symptoms OR chest imaging have worsened/progressed despite treatment with medications used in clinical practice for ILD (not attributable to comorbidities e.g., infection, heart failure)
   - The patient has ≥ 10% fibrosis on a chest high resolution computed tomography (HRCT) (e.g., defined as reticular abnormality with traction bronchiectasis with or without honeycombing)
   - The patient has a baseline forced vital capacity (FVC) at least 45% of predicted value

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NINTEDANIB (Ofev)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Idiopathic pulmonary fibrosis (IPF: scarring of the lungs with an unknown cause)
      2. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
      3. Chronic fibrosing interstitial lung disease (ILDs) with a progressive phenotype (PF-ILD: scarring of the lungs caused by different underlying diseases or conditions that worsens over time)
   B. **If you have idiopathic pulmonary fibrosis, approval also requires:**
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor)
      3. You have a usual interstitial pneumonia pattern as evidenced by high-resolution computed tomography (HRCT: type of imaging test) alone or via a combination of surgical lung biopsy and HRCT
      4. You do NOT have other known causes of interstitial lung disease, such as connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis (lung inflammation from inhaled substances), systemic sclerosis (an immune system disorder), rheumatoid arthritis (joint pain and inflammation), radiation, sarcoidosis (growth of inflammatory cells in the body), bronchiolitis obliterans organizing pneumonia (type of lung infection), human immunodeficiency virus infection, viral hepatitis (type of liver inflammation), or cancer
      5. You have a predicted forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 50 percent at baseline

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NINTEDANIB

INITIAL CRITERIA (CONTINUED)

C. **If you have systemic sclerosis-associated interstitial lung disease, approval also requires:**
   1. You have systemic sclerosis (SSc) according to the American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
   2. You are 18 years of age or older
   3. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a type of immune system doctor)
   4. You have at least 10 percent fibrosis (tissue scarring) on a chest high resolution computed tomography (HRCT: type of imaging testing)
   5. You have a baseline forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 40 percent of predicted value
   6. Other causes of interstitial lung disease have been ruled out. Other causes may include heart failure/fluid overload, drug-induced lung toxicity [cyclophosphamide, methotrexate, ACE-inhibitors (class of blood pressure medications)], recurrent aspiration (inhaling) such as from GERD (acid reflux), pulmonary vascular disease (affecting blood vessels in lungs), pulmonary edema (excess fluid in the lungs), pneumonia (type of lung infection), chronic pulmonary thromboembolism (blood clot in lungs), alveolar hemorrhage (bleeding of a part of the lungs) or interstitial lung disease caused by another rheumatic (inflammatory) disease, such as mixed connective tissue disease (MCTD)

D. **If you have chronic fibrosing interstitial lung disease with progressive phenotype, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a type of immune system doctor)
   3. Your lung function and respiratory (breathing) symptoms OR chest imaging have worsened/progressed despite treatment with medications used in clinical practice for interstitial lung disease (not caused by comorbidities such as infection, heart failure)
   4. You have at least 10 percent fibrosis (tissue scarring) on a chest high resolution computed tomography (HRCT: type of imaging testing)
   5. You have a baseline forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 45 percent of predicted value

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NINTEDANIB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of idiopathic pulmonary fibrosis (IPF), systemic sclerosis-associated interstitial lung disease (SSc-ILD), or chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype (PF-ILD) **AND** meet the following criterion?
   - The patient has experienced a clinically meaningful improvement or maintenance in annual rate of decline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NINTEDANIB (Ofev)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Idiopathic pulmonary fibrosis (IPF: scarring of the lungs with an unknown cause)
      2. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
      3. Chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype (PF-ILD: scarring of the lungs caused by different underlying diseases or conditions that worsens over time)
   B. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ofev.

REFERENCES

- Ofev [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; October 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/28/23
Created: 02/15
Client Approval: 07/23
P&T Approval: 04/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NIRAPARIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is in complete or partial response to first-line platinum based-chemotherapy (e.g., cisplatin, carboplatin)
   - The requested medication will be used for maintenance treatment

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is in complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin)
   - The requested medication will be used for maintenance treatment
   - The patient's cancer has deleterious or suspected deleterious germline *BRCA*-mutation (*gBRCAmut*) based on an FDA-approved companion diagnostic for Zejula
   - The requested medication will be used as monotherapy
   - The requested medication will be started no later than 8 weeks after the patient's most recent platinum-containing regimen
   - The patient has completed at least 2 or more lines of platinum-based chemotherapy (e.g., cisplatin, carboplatin)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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NIRAPARIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NIRAPARIB (Zejula)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Advanced epithelial ovarian (cancer that forms on the surface of the ovary), fallopian tube, or primary peritoneal cancer (type of abdominal cancer)
   2. Recurrent (returning) epithelial ovarian (cancer that forms on the surface of the ovary), fallopian tube, or primary peritoneal cancer (type of abdominal cancer)

B. **If you have advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You are in complete or partial response to first-line platinum based-chemotherapy (such as cisplatin, carboplatin)
   3. The requested medication will be used for maintenance treatment (treatment to prevent cancer from coming back after it has disappeared after initial therapy)

C. **If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You are in complete or partial response to platinum-based chemotherapy (such as cisplatin, carboplatin)
   3. The requested medication will be used for maintenance treatment (treatment to prevent cancer from coming back after it has disappeared after initial therapy)
   4. Your cancer has deleterious or suspected deleterious germline *BRCA*-mutation (*gBRCAmut*: a type of gene mutation [abnormal change]) based on a Food and Drug Administration (FDA)-approved companion diagnostic for Zejula
   5. The requested medication will be used as monotherapy (used by itself for treatment)
   6. The requested medication is started no later than 8 weeks after your most recent platinum-containing regimen (such as cisplatin, carboplatin)
   7. You have completed at least two lines of platinum-based chemotherapy (such as cisplatin, carboplatin)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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NIRAPARIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zejula.

REFERENCES

- Zejula [Prescribing Information]. Durham, NC: GlaxoSmithKline; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/23
Created: 08/17
Client Approval: 08/23
P&T Approval: 07/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NIRAPARIB-ABIRATERONE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) and meet **ALL** of the following criteria?
   - The patient's cancer has a deleterious or suspected deleterious BRCA mutation (BRCAm) based on an FDA-approved test for Akeega
   - Akeega will be used in combination with an oral corticosteroid (e.g., prednisone, prednisolone, methylprednisolone)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., less than 50 ng/dL)
   - Akeega will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **NIRAPARIB-ABIRATERONE (Akeega)** requires the following rule(s) be met for approval:
   A. You have metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)
   B. Your cancer has a deleterious (harmful) or suspected deleterious BRCA mutation (BRCAm: abnormal change in gene) based on a Food and Drug Administration (FDA)-approved test for Akeega
   C. Akeega will be used in combination with an oral corticosteroid (such as prednisone, prednisolone, methylprednisolone)
   (Denial text continued on the next page)

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NIRAPARIB-ABIRATERONE

GUIDELINES FOR USE (CONTINUED)

D. You meet ONE of the following:
   1. You had a bilateral orchiectomy (both testicles have been surgically removed)
   2. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
   3. Akeega will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Akeega.

REFERENCES

- Akeega [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; August 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 12/01/23
Created: 10/23
Client Approval: 11/23
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NIROGACESTAT

GUIDELINES FOR USE

1. Does the patient have a diagnosis of progressing desmoid tumors and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient requires systemic treatment

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **50mg: #6 per day.**
   - **100mg: #2 per day.**
   - **150mg: #2 per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NIROGACESTAT (Ogsiveo)** requires the following rule(s) be met for approval:
   A. You have progressing desmoid tumors (noncancerous growths in the connective tissue)
   B. You are 18 years of age or older
   C. You require systemic treatment (therapy that targets the entire body)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ogsiveo.

REFERENCES

- Ogsiveo [Prescribing Information]. Stamford, CT: SpringWorks Therapeutics, Inc.; April 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/06/24
Created: 12/23
Client Approval: 04/24
P&T Approval: 07/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NITISINONE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a documented diagnosis of hereditary tyrosinemia type 1 (HT-1) and meet **ALL** of the following criteria?
   - The patient has elevated urinary or plasma succinylacetone (SA) levels OR a mutation in the fumarylacetoacetate hydrolase (FAH) gene
   - Therapy is prescribed by or in consultation with a prescriber specializing in inherited metabolic diseases
   - The patient has been counseled on maintaining dietary restriction of tyrosine and phenylalanine

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the request for Nityr tablets; brand Orfadin 2mg, 5mg, 10 mg, 20 mg capsules; or Orfadin suspension **AND** the patient meets the following criterion?
   - The patient had a trial of or contraindication to generic nitisinone capsule

   If yes, **approve the requested drug for 6 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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NITISINONE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NITISINONE (Orfadin, Nityr)** requires the following rule(s) be met for approval:

A. You have hereditary tyrosinemia type 1 (HT-1: a type of genetic disorder where you cannot breakdown an important component in proteins)
B. Your diagnosis is confirmed by elevated urinary or plasma succinylacetone levels (a chemical that is present in hereditary tyrosinemia) OR a mutation in the fumarylacetoacetate hydrolase gene
C. Therapy is prescribed by or in consultation with a prescriber specializing in inherited metabolic diseases
D. You have been counseled on maintaining dietary restriction of tyrosine and phenylalanine
E. **If you are requesting Nityr tablets; brand Orfadin 2mg, 5mg, 10 mg, 20 mg capsules; or Orfadin oral suspension, approval also requires:**
    1. You have tried or have a contraindication (harmful for) to generic nitisinone capsules

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary tyrosinemia type 1 **AND** meet the following criterion?
    - The patients urinary or plasma succinylacetone (SA) levels have decreased from baseline while on treatment with nitisinone.

    If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the requested formulation.**
    If no, do not approve.
    DENIAL TEXT: See the renewal denial text at the end of the guideline.

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NITISINONE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NITISINONE (Orfadin, Nityr)** requires the following rule(s) be met for renewal:

A. You have hereditary tyrosinemia type 1 (HT-1: a type of genetic disorder where you cannot breakdown an important component in proteins)
B. Your urinary or plasma succinylacetone levels (a chemical that is present in hereditary tyrosinemia) have decreased from baseline while on treatment with nitisinone

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orfadin and Nityr.

REFERENCES

- Orfadin [Prescribing Information]. Waltham, MA: Sobi, Inc.; May 2019.
- Nityr [Prescribing Information]. Cambridge, UK: Cycle Pharmaceuticals Ltd.; September 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/17/23
Created: 08/16
Client Approval: 03/23
P&T Approval: 07/18

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OBETICHOLIC ACID

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary biliary cholangitis as confirmed by at least **TWO** of the following criteria?
   - An alkaline phosphatase level of at least 1.5 times the upper limit of normal
   - The presence of antimitochondrial antibodies at a titer of 1:40 or higher
   - Histologic evidence of non-suppurativa destructive cholangitis and destruction of interlobular bile ducts

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient is at least 18 years of age and older
   - The patient does not have cirrhosis OR has compensated cirrhosis with no evidence of portal hypertension
   - The medication is prescribed by or in consultation with a gastroenterologist or hepatologist
   - The requested agent will be used in combination with ursodeoxycholic acid (e.g., Ursodiol, Urso 250, Urso Forte) in adults with an inadequate response to ursodeoxycholic acid at a dosage of 13-15mg/kg/day for at least 1 year, OR as monotherapy in adults unable to tolerate ursodeoxycholic acid
   - The patient does not have complete biliary obstruction

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OBETICHOLIC ACID

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OBETICHOLIC ACID (Ocaliva)** requires the following rule(s) be met for approval:

A. You have primary biliary cholangitis (type of liver disease), as confirmed by TWO of the following criteria:
   1. An alkaline phosphatase level (indicator of possible liver/gallbladder problems) of at least 1.5 times the upper limit of normal
   2. The presence of antimitochondrial antibodies (indicator of body attacking its own cells) at a titer (concentration) of 1:40 or higher
   3. Histologic evidence of non-suppurative destructive cholangitis and destruction of interlobular bile ducts (you have lab data that shows you have certain symptoms of liver disease)
B. You are 18 years of age and older
C. You do not have cirrhosis (liver damage) OR have compensated cirrhosis (a type of liver condition) with no evidence of portal hypertension (high blood pressure in the major vein that leads to the liver)
D. The medication is prescribed by or in consultation with a gastroenterologist (digestive system doctor) or hepatologist (liver doctor)
E. You meet ONE of the following:
   1. You have had an inadequate response to ursodeoxycholic acid (such as Ursodiol, Urso 250, Urso Forte) at a dosage of 13-15 mg/kg/day for at least 1 year and the requested medication will be used in combination with ursodeoxycholic acid
   2. You are unable to tolerate ursodeoxycholic acid and the requested medication will be used as monotherapy (only drug used for treatment)
F. You do not have complete biliary obstruction (blockage of bile ducts)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OBETICHOLIC ACID

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of primary biliary cholangitis and meets **ALL** of the following criteria?
   - The patient's alkaline phosphatase levels are less than 1.67-times the upper limit of normal OR have decreased by at least 15% from baseline while on treatment with obeticholic acid
   - The patient has not developed complete biliary obstruction

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OBETICHOLIC ACID (Ocaliva)** requires the following rule(s) be met for renewal:
   A. You have primary biliary cholangitis (type of liver disease)
   B. Your alkaline phosphatase levels (indicator of possible liver/gallbladder problems) are less than 1.67-times the upper limit of normal or have decreased by at least 15% from baseline while on treatment with obeticholic acid
   C. You have not developed complete biliary obstruction (blockage of bile ducts)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ocaliva.

REFERENCES

- Ocaliva [Prescribing Information]. New York, NY: Intercept Pharmaceuticals, Inc. May 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 08/16
Client Approval: 11/21
P&T Approval: 10/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OCTREOTIDE - IM

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acromegaly and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks
   - The patient had an inadequate response to surgery or radiotherapy, OR surgery or radiotherapy is not an option for this patient

   If yes, **approve the requested strength for 3 months by GPID or GPI-14 with the following quantity limit:**
   - **10 mg: #6 mL per 28 days.**
   - **20 mg: #12 mL per 28 days.**
   - **30 mg: #6 mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of severe diarrhea and flushing episodes associated with metastatic carcinoid tumor and meet **ALL** of the following criterion?
   - The patient had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks

   If yes, **approve for 2 months by HICL or GPI-12 with a quantity limit of #6 mL per 28 days.**
   If no, continue to #3.

3. Does the patient have a diagnosis of profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumor (VIPoma) and meet **ALL** of the following criterion?
   - The patient had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks

   If yes, **approve for 2 months by HICL or GPI-12 with a quantity limit of #6 mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See initial denial text at the end of the guideline.

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OCTREOTIDE - IM

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OCTREOTIDE - IM (Sandostatin LAR Depot)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Acromegaly (a type of hormone disorder)
   2. Severe diarrhea and flushing episodes associated with metastatic carcinoid tumor (a type of slow growing cancer that has spread to different parts of the body)
   3. Profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumor (a type of cancer that starts from hormone producing cells)

B. You had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks

C. **If you have acromegaly, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   2. You had an inadequate response (drug did not work) to surgery or radiotherapy (radiation to treat cancer), OR surgery or radiotherapy is not an option for you

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acromegaly and meet **ALL** of the following criteria?
   - The patient has a reduction, normalization or maintenance of IGF-1 levels based on age and gender
   - The patient has shown an improvement or sustained remission of clinical symptoms of acromegaly

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limit:**
   - **10 mg: #6 mL per 28 days.**
   - **20 mg: #12 mL per 28 days.**
   - **30 mg: #6 mL per 28 days.**

   If no, continue to #2.

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OCTREOTIDE - IM

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of severe diarrhea and flushing episodes associated with metastatic carcinoid tumor **AND** meet the following criterion?
   - The patient has improvement or sustained remission of clinical symptoms

   If yes, **approve for 12 months by HICL or GPI-12 with a quantity limit of #6 mL per 28 days.**
   If no, continue to #3.

3. Does the patient have a diagnosis of profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumor (VIPoma) **AND** meet the following criterion?
   - The patient has improvement or sustained remission of clinical symptoms

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 mL per 28 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OCTREOTIDE - IM (Sandostatin LAR Depot)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Acromegaly (a type of hormone disorder)
      2. Severe diarrhea and flushing episodes associated with metastatic carcinoid tumor (a type of slow growing cancer that has spread to different parts of the body)
      3. Profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumor (a type of cancer that starts from hormone producing cells)
   B. **If you have acromegaly, renewal also requires:**
      1. You have a reduction, normalization or maintenance of insulin-like growth factor (IGF-1: a growth hormone) levels based on age and gender
      2. You have shown an improvement or sustained remission (symptoms have gone away) of clinical symptoms of acromegaly
   C. **If you have severe diarrhea and flushing episodes associated with metastatic carcinoid tumor OR profuse watery diarrhea associated with vasoactive intestinal peptide-secreting tumor, renewal also requires:**
      1. You have an improvement or sustained remission (symptoms have gone away) of clinical symptoms

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OCTREOTIDE - IM

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sandostatin LAR Depot.

REFERENCES

- Sandostatin LAR Depot [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation.; March 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/23
Created: 08/22
Client Approval: 02/23
P&T Approval: 07/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OCTREOTIDE - ORAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acromegaly and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has responded to and tolerated treatment with octreotide or lanreotide

   If yes, **approve for 3 months by GPID or GPI-14 with a quantity limit of #4 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OCTREOTIDE - ORAL (Mycapssa)** requires the following rule(s) be met for approval:
   A. You have acromegaly (a type of hormone disorder)
   B. Therapy is prescribed by or in consultation with an endocrinologist (doctor who specializes in hormones)
   C. You have responded to and tolerated treatment with octreotide or lanreotide

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OCTREOTIDE - ORAL

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acromegaly and meet **ALL** of the following criteria?
   - The patient has a reduction, normalization, or maintenance of IGF-1 levels based on age and gender
   - The patient has shown an improvement or sustained remission of clinical symptoms of acromegaly

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #4 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OCTREOTIDE - ORAL (Mycapssa)** requires the following rule(s) be met for renewal:
   A. You have acromegaly (a type of hormone disorder)
   B. You have had a reduction, normalization, or maintenance of insulin-like growth factor 1 (IGF-1: a type of hormone) levels based on your age and gender
   C. You have shown an improvement or sustained remission (symptoms have gone away) of clinical symptoms of acromegaly

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mycapssa.

REFERENCES

- Mycapssa [Prescribing Information]. Scotland, UK: MW Encap Ltd., March 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/22
Created: 08/20
Client Approval: 09/22
P&T Approval: 07/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OCTREOTIDE - SQ

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acromegaly and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient had a trial of or contraindication to ONE generic octreotide product (e.g., octreotide acetate)
   - The patient had an inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #16.8mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of severe diarrhea and flushing episodes associated with metastatic carcinoid tumor and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to ONE generic octreotide product (e.g., octreotide acetate)

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #16.8mL per 28 days.**
   If no, continue to #3.

3. Does the patient have a diagnosis of profuse watery diarrhea associated with vasoactive intestinal peptide tumor (VIPoma) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to ONE generic octreotide product (e.g., octreotide acetate)

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #16.8mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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OCTREOTIDE - SQ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OCTREOTIDE - SQ (Bynfezia)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Acromegaly (a type of hormone disorder)
   2. Severe diarrhea and flushing episodes associated with metastatic carcinoid tumor (a type of slow growing cancer that has spread to different parts of the body)
   3. Profuse watery diarrhea associated with vasoactive intestinal peptide tumor (VIPoma: a type of cancer that starts from hormone producing cells)

B. **If you have acromegaly, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   3. You had a trial of or contraindication (harmful for) to ONE generic octreotide product (such as octreotide acetate)
   4. You had an inadequate response to or cannot be treated with **ALL** of the following:
      a. Surgical resection (removal by surgery)
      b. Pituitary irradiation (radiation therapy directed at the pituitary)
      c. Bromocriptine mesylate at maximally tolerated doses

C. **If you have severe diarrhea and flushing episodes associated with metastatic carcinoid tumor, approval also requires:**
   1. You are 18 years of age or older
   2. You had a trial of or contraindication (harmful for) to ONE generic octreotide product (such as octreotide acetate)

D. **If you have profuse watery diarrhea associated with vasoactive intestinal peptide tumor (VIPoma), approval also requires:**
   1. You are 18 years of age or older
   2. You had a trial of or contraindication (harmful for) to ONE generic octreotide product (such as octreotide acetate)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OCTREOTIDE - SQ

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acromegaly and meet **ALL** of the following criteria?
   - The patient has a reduction, normalization or maintenance of IGF-1 levels based on age and gender
   - The patient has shown an improvement or sustained remission of clinical symptoms of acromegaly

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #16.8mL per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of severe diarrhea and flushing episodes associated with metastatic carcinoid tumor **AND** meet the following criterion?
   - The patient has improvement or sustained remission of clinical symptoms

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #16.8mL per 28 days.**
   If no, continue to #3.

3. Does the patient have a diagnosis of profuse watery diarrhea associated with vasoactive intestinal peptide tumor (VIPoma) **AND** meet the following criterion?
   - The patient has improvement or sustained remission of clinical symptoms

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #16.8mL per 28 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OCTREOTIDE - SQ (Bynfezia)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Acromegaly (a type of hormone disorder)
      2. Severe diarrhea and flushing episodes associated with metastatic carcinoid tumor (a type of slow growing cancer that has spread to different parts of the body)
      3. Profuse watery diarrhea associated with vasoactive intestinal peptide tumor (VIPoma: a type of cancer that starts from hormone producing cells)

   (Renewal denial text continued on next page)

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OCTREOTIDE - SQ

RENEWAL CRITERIA (CONTINUED)

B. **If you have acromegaly, renewal also requires:**
   1. You have a reduction, normalization or maintenance of insulin-like growth factor (IGF-1: a growth hormone) levels based on age and gender
   2. You have shown an improvement or sustained remission (symptoms have gone away) of clinical symptoms of acromegaly

C. **If you have severe diarrhea and flushing episodes associated with metastatic carcinoid tumor OR profuse watery diarrhea associated with vasoactive intestinal peptide tumor, renewal also requires:**
   1. You have an improvement or sustained remission (symptoms have gone away) of clinical symptoms

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Bynfezia.

REFERENCES

- Bynfezia [Prescribing Information]. Cranbury, NJ: Sun Pharmaceuticals Industries Inc., January 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/22
Created: 08/20
Client Approval: 09/22
P&T Approval: 07/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ODEVIXIBAT

GUIDELINES FOR USE

1. Does the patient have a diagnosis of pruritus associated with progressive familial intrahepatic cholestasis (PFIC) and meet **ALL** of the following criteria?
   - The patient is 3 months of age or older
   - Bylvay will **NOT** be used concurrently with another IBAT inhibitor (e.g., Livmarli [maralixibat])

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **200mcg pellets: #30 per day.**
   - **400mcg capsule: #15 per day.**
   - **600mcg pellets: #10 per day.**
   - **1200mcg capsule: #5 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of cholestatic pruritus associated with Alagille syndrome (ALGS) and meet **ALL** of the following criteria?
   - The patient is 12 months of age or older
   - Bylvay will **NOT** be used concurrently with another IBAT inhibitor (e.g., Livmarli [maralixibat])

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **200mcg pellets: #36 per day.**
   - **400mcg capsule: #18 per day.**
   - **600mcg pellets: #12 per day.**
   - **1200mcg capsule: #6 per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ODEVIXIBAT (Bylvay)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Pruritus (itching) associated with progressive familial intrahepatic cholestasis (PFIC: an inherited liver condition)
      2. Cholestatic pruritus (itching caused by liver disease) associated with Alagille syndrome (ALGS: a type of genetic disorder)

   (Denial text continued on next page)

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ODEVIXIBAT

GUIDELINES FOR USE (CONTINUED)

B. **If you have pruritus associated with progressive familial intrahepatic cholestasis, approval also requires:**
   1. You are 3 months of age or older
   2. You will **NOT** use Bylvay concurrently (at the same time) with an ileal bile acid transporter (IBAT) inhibitor (such as Livmarli [maralixibat])

C. **If you have cholestatic pruritus associated with Alagille syndrome, approval also requires:**
   1. You are 12 months of age or older
   2. You will **NOT** use Bylvay concurrently (at the same time) with an ileal bile acid transporter (IBAT) inhibitor (such as Livmarli [maralixibat])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Bylvay.

REFERENCES

- Bylvay [Prescribing Information]. Boston, MA: Albireo Pharma, Inc.; June 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 10/21
Client Approval: 02/24
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OFATUMUMAB-SQ

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve the requested drug for a total of 12 months by GPID or GPI-10 as follows:**
   INITIAL REQUEST:
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #1.2mL per 28 days.**
   - **SECOND APPROVAL: Approve for 11 months with a quantity limit of #0.4mL per 28 days (Enter a start date 3 weeks AFTER THE START DATE of the first approval).**

   SUBSEQUENT/CONTINUATION REQUEST:
   - **Approve for 12 months with a quantity limit of #0.4mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OFATUMUMAB-SQ (Kesimpta)** requires the following rules be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OFATUMUMAB-SQ

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kesimpta.

REFERENCES

- Kesimpta [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21

Created: 09/20
Client Approval: 11/20

P&T Approval: 04/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OLANZAPINE/SAMIDORPHAN

GUIDELINES FOR USE

1. Does the patient meet **ONE** of the following criteria?
   - The patient has a diagnosis of schizophrenia
   - The patient has a diagnosis of bipolar I disorder and meets ONE of the following:
     - Lybalvi is being used for acute treatment of manic or mixed episodes as monotherapy or as adjunct to lithium or valproate
     - Lybalvi is being used as maintenance monotherapy treatment

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a psychiatrist
   - The patient is at high risk for weight gain
   - The patient had a trial and failure of or contraindication to BOTH of the following:
     - TWO generic antipsychotics (e.g., aripiprazole, quetiapine, risperidone, etc.)
     - ONE of the following preferred brand agents: Vraylar, Latuda or Rexulti

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **OLANZAPINE/SAMIDORPHAN (Lybalvi)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Schizophrenia (type of mental health disorder)
      2. Bipolar I disorder (type of mood disorder)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a psychiatrist (a type of mental health doctor)
   D. You are at high risk for weight gain
   E. You had a trial and failure of or contraindication (harmful for) to BOTH of the following:
      1. TWO generic antipsychotics (such as aripiprazole, quetiapine, risperidone)
      2. ONE of the following preferred brand agents: Vraylar, Latuda or Rexulti

   (Denial text continued on next page)

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OLANZAPINE/SAMIDORPHAN

GUIDELINES FOR USE (CONTINUED)

F. **If you have bipolar I disorder, approval also requires ONE of the following:**
   1. Lybalvi is being used for acute treatment of manic or mixed episodes as monotherapy or as adjunct to lithium or valproate
   2. Lybalvi is being used as maintenance monotherapy treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lybalvi.

REFERENCES

- Lybalvi [Prescribing Information]. Waltham, MA: Alkermes, Inc., May 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/11/21
Created: 09/21
Client Approval: 09/21
P&T Approval: 10/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OLAPARIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced epithelial ovarian, fallopian tube or primary peritoneal cancer, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Lynparza will be used for maintenance treatment
   - The patient is in complete or partial response to first-line platinum-based chemotherapy (e.g., paclitaxel, docetaxel, cisplatin, carboplatin)
   - The patient's diagnosis is confirmed by an FDA-approved companion diagnostic for Lynparza

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient's cancer has a deleterious or suspected deleterious germline or somatic BRCA mutation
   - The patient's cancer is associated with a homologous recombination deficiency (HRD)-positive status as defined by either a deleterious or suspected deleterious BRCA mutation, and/or genomic instability, AND Lynparza will be used in combination with bevacizumab

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a deleterious or suspected deleterious germline or somatic BRCA mutation, as confirmed by an FDA-approved companion diagnostic for Lynparza
   - The patient is in complete or partial response to their most recent platinum based-chemotherapy (e.g., paclitaxel, docetaxel, cisplatin, carboplatin)
   - The patient has completed two or more lines of platinum-based chemotherapy (e.g., paclitaxel, docetaxel, cisplatin, carboplatin)
   - Lynparza will be used as monotherapy for maintenance treatment

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #4.

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OLAPARIB

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of HER2-negative high risk early breast cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Lynparza will be used as adjuvant treatment
   - The patient's cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) as confirmed by an FDA-approved companion diagnostic for Lynparza
   - The patient has been treated with neoadjuvant or adjuvant chemotherapy (e.g., doxorubicin, paclitaxel)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #5.

5. Does the patient have a diagnosis of HER2-negative metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) as confirmed by an FDA-approved companion diagnostic for Lynparza
   - The patient has been treated with chemotherapy (e.g., doxorubicin, docetaxel) in the neoadjuvant, adjuvant, or metastatic setting

   If yes, continue to #6.
   If no, continue to #7.

6. Does the patient meet **ONE** of the following criteria?
   - The patient does not have hormone receptor (HR)-positive breast cancer
   - The patient has a hormone receptor (HR)-positive breast cancer and has been treated with a prior endocrine therapy or is considered inappropriate for endocrine therapy (e.g., tamoxifen, Arimidex [anastrozole])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

7. Does the patient have a diagnosis of metastatic pancreatic adenocarcinoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Lynparza will be used for maintenance treatment
   - The patient's cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) as confirmed by an FDA-approved companion diagnostic for Lynparza
   - The patient's disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen (e.g., paclitaxel, docetaxel, cisplatin, carboplatin)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #8.

8. Does the patient have a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #9.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

9. Does the patient meet **BOTH** of the following criteria?
   - The patient's cancer has a deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutation as confirmed by an FDA-approved companion diagnostic for Lynparza
   - The patient's disease has progressed following prior treatment with enzalutamide (Xtandi) or abiraterone (Yonsa, Zytiga)

   If yes, continue to #11.
   If no, continue to #10.

10. Does the patient meet **BOTH** of the following criteria?
    - Lynparza will be used in in combination with abiraterone (Yonsa, Zytiga) AND prednisone or prednisolone
    - The patient's cancer has a deleterious or suspected deleterious BRCA mutation (BRCAm) as confirmed by an FDA-approved companion diagnostic for Lynparza

    If yes, continue to #11.
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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OLAPARIB

GUIDELINES FOR USE (CONTINUED)

11. Does the patient meet **ONE** of the following criteria?
    - The patient previously had a bilateral orchiectomy
    - The patient has a castrate testosterone level (i.e., less than 50 ng/dL)
    - Lynparza will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

    If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
    If no, do not approve.

    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **OLAPARIB (Lynparza)** requires the following rule(s) be met for approval:
    A. You have ONE of the following diagnoses:
        1. Recurrent (returning) or advanced epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer (types of reproductive system cancers)
        2. HER2 ((human epidermal growth factor receptor 2: a type of protein)-negative high risk early breast cancer (a type of breast cancer)
        3. HER2-negative metastatic breast cancer (a type of breast cancer that has spread to other parts of the body)
        4. Metastatic pancreatic adenocarcinoma (a type of pancreas cancer that has spread to other parts of the body)
        5. Homologous recombination repair (HRR) gene-mutated (type of mutation) metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and does not respond to hormone therapy)
        6. BRCA-mutated (type of mutation) metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and does not respond to hormone therapy)

    (Denial text continued on next page)

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GUIDELINES FOR USE (CONTINUED)

B. **If you have advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Lynparza will be used for maintenance treatment
   3. You are in complete or partial response to first-line platinum-based chemotherapy (such as paclitaxel, docetaxel, cisplatin, carboplatin)
   4. Your diagnosis is confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   5. You meet ONE of the following:
      a. Your cancer has a deleterious or suspected deleterious germline or somatic BRCA mutation (a type of gene mutation)
      b. Your cancer is associated with a homologous recombination deficiency (HRD: type of gene mutation) positive status as defined by either a deleterious or suspected deleterious BRCA mutation (type of gene mutation), and/or genomic instability (high rate of gene mutation), AND Lynparza will be used in combination with bevacizumab

C. **If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a deleterious or suspected deleterious germline or somatic BRCA mutation (a type of gene mutation), as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   3. You are in complete or partial response to your most recent platinum-based chemotherapy (such as paclitaxel, docetaxel, cisplatin, carboplatin)
   4. You have completed at least two or more lines of platinum-based chemotherapy such as paclitaxel, docetaxel, cisplatin, carboplatin
   5. Lynparza will be used as monotherapy (used alone) for maintenance treatment

D. **If you have HER2-negative high risk early breast cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Lynparza will be used as adjuvant (add-on) treatment
   3. Your cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm: a type of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   4. You have been treated with neoadjuvant or adjuvant chemotherapy (cancer treatment given before main treatment or as add-on therapy such as doxorubicin, paclitaxel)

(Denial text continued on next page)

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OLAPARIB

GUIDELINES FOR USE (CONTINUED)

E. **If you have HER2-negative metastatic breast cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm: a type of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   3. You have been treated with chemotherapy (such as doxorubicin, docetaxel) in the neoadjuvant (given before main treatment), adjuvant (add-on to main treatment), or metastatic setting (to treat disease that has spread to other parts of the body)
   4. You meet ONE of the following:
      a. You do not have hormone receptor (HR)-positive breast cancer
      b. You have hormone receptor (HR)-positive breast cancer and you have been treated with a prior endocrine (hormone) therapy (such as tamoxifen, Arimidex [anastrozole]) or endocrine therapy is considered inappropriate for you

F. **If you have metastatic pancreatic adenocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. Lynparza will be used for maintenance treatment
   3. Your cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm: a type of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   4. Your disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen (such as paclitaxel, docetaxel, cisplatin, carboplatin)

G. **If you have homologous recombination repair gene-mutated metastatic castration-resistant prostate cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutation (type of mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   3. Your disease has worsened following prior treatment with enzalutamide (Xtandi) or abiraterone (Yonsa or Zytiga)
   4. You meet ONE of the following:
      a. You previously had a bilateral orchiectomy (both testicles have been surgically removed)
      b. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
      c. Lynparza will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

(Denial text continued on next page)

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OLAPARIB

GUIDELINES FOR USE (CONTINUED)

H. **If you have BRCA-mutated metastatic castration-resistant prostate cancer, approval also requires, approval also requires:**
   1. You are 18 years of age or older
   2. Lynparza will be used in in combination with abiraterone (Yonsa or Zytiga) AND prednisone or prednisolone
   3. Your cancer has a deleterious or suspected deleterious BRCA mutation (BRCAm: a type of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   4. You meet ONE of the following:
      a. You previously had a bilateral orchiectomy (both testicles have been surgically removed)
      b. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
      c. Lynparza will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lynparza.

REFERENCES

- Lynparza Tablets [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals. September 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/23/23
Created: 12/14
Client Approval: 10/23
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OLUTASIDENIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory acute myeloid leukemia (AML) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OLUTASIDENIB (Rezlidhia)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory acute myeloid leukemia (AML: a type of blood cancer that has returned or did not respond to treatment)
   B. You are 18 years of age or older
   C. You have a susceptible (can be treated with the drug) isocitrate dehydrogenase-1 (IDH1: a type of enzyme) mutation as detected by a Food and Drug Administration (FDA)-approved test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rezlidhia.

REFERENCES

- Rezlidhia [Prescribing Information]. Greenville, NC: Forma Therapeutics, Inc., December 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/23
Created: 01/23
Client Approval: 02/23
P&T Approval: 01/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMACETAXINE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic or accelerated phase chronic myeloid leukemia (CML) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a resistance or intolerance to TWO or more tyrosine kinase inhibitors (e.g., Gleevec, Sprycel, Tasigna, Bosulif, Iclusig)

   If yes, **approve for 12 months by HICL.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OMACETAXINE (Synribo)** requires the following rule(s) be met for approval:
   A. You have chronic or accelerated phase chronic myeloid leukemia (CML: type of blood cell cancer)
   B. You are 18 years of age or older
   C. You had a resistance or intolerance to TWO or more tyrosine kinase inhibitors (such as Gleevec, Sprycel, Tasigna, Bosulif, Iclusig)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Synribo.

REFERENCES

- Synribo [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; November 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/11/22
Created: 12/12
Client Approval: 03/22
P&T Approval: 05/13

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMADACYCLINE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of community-acquired bacterial pneumonia (CABP) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Infection is caused by any of the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumophila, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*

   If yes, continue to #2.
   If no, continue to #5.

2. Is therapy prescribed by or given in consultation with an Infectious Disease (ID) specialist?

   If yes, **approve Nuzyra 150mg tablet for one fill by GPID or GPI-14 with a quantity limit of #26 tablets per 13 days.**
   If no, continue to #3.

3. Have antimicrobial susceptibility tests been performed that meet **ALL** of the following criteria?
   - The results from the infection site culture indicate pathogenic organism(s) with **resistance** to at least **TWO** standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone)
   - The results from the infection site culture indicate pathogenic organism(s) with susceptibility to Nuzyra

   If yes, **approve Nuzyra 150mg tablet for one fill by GPID or GPI-14 with a quantity limit of #26 tablets per 13 days.**
   If no, continue to #4.

4. Does the patient meet **ALL** of the following criteria?
   - Antimicrobial susceptibility results are unavailable
   - The patient has had a trial of or contraindication to at least **TWO** standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone)

   If yes, **approve Nuzyra 150mg tablet for one fill by GPID or GPI-14 with a quantity limit of #26 tablets per 13 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OMADACYCLINE

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of an acute bacterial skin or skin structure infection (ABSSSI) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Infection is caused by any of the following susceptible microorganisms: *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates), *Staphylococcus lugdunensis, Streptococcus pyogenes, Streptococcus anginosus grp.* (includes *S. anginosus, S. intermedius,* and *S. constellatus), Enterococcus faecalis, Enterobacter cloacae,* or *Klebsiella pneumoniae*

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Is therapy prescribed by or given in consultation with an Infectious Disease (ID) specialist?

   If yes, **approve Nuzyra 150mg tablet for one fill by GPID or GPI-14 with a quantity limit of #30 tablets per 14 days.**
   If no, continue to #7.

7. Have antimicrobial susceptibility tests been performed that meet **ALL** of the following criteria?
   - The results from the infection site culture indicate pathogenic organism(s) with **resistance** to at least **TWO** standard of care agents for ABSSSI (e.g., linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, cefazolin)
   - The results from the infection site culture indicate pathogenic organism(s) with susceptibility to Nuzyra

   If yes, **approve Nuzyra 150mg tablet for one fill by GPID or GPI-14 with a quantity limit of #30 tablets per 14 days.**
   If no, continue to #8.

8. Does the patient meet **ALL** of the following criteria?
   - Antimicrobial susceptibility results are unavailable
   - The patient has had a trial of or contraindication to at least **TWO** standard of care agents for ABSSSI (e.g., linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, cefazolin)

   If yes, **approve Nuzyra 150mg tablet for one fill by GPID or GPI-14 with a quantity limit of #30 tablets per 14 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OMADACYCLINE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OMADACYCLINE (Nuzyra)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Community-acquired bacterial pneumonia (CABP: type of lung infection)
   2. Acute (severe and sudden) bacterial skin or skin structure infection (ABSSSI)

B. **If you have community-acquired bacterial pneumonia, approval also requires:**
   1. You are 18 years of age or older
   2. The infection is caused by any of the following bacteria: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumoniae, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*
   3. You meet ONE of the following criteria:
      a. The requested medication is prescribed by or given in consultation with an Infectious Disease (ID) specialist
      b. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is available, and the infection site culture results indicate pathogenic (disease-causing) organism(s) with 1) resistance to at least TWO standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone), AND 2) Nuzyra will work against the bacteria
      c. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is unavailable, and you have had a trial of or contraindication (medical reason why you cannot use) to at least TWO standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone)

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OMADACYCLINE

GUIDELINES FOR USE (CONTINUED)

C. **If you have acute bacterial skin or skin structure infection (ABSSSI), approval also requires:**
   1. You are 18 years of age or older
   2. The infection is caused by any of the following bacteria: *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates), *Staphylococcus lugdunensis, Streptococcus pyogenes, Streptococcus anginosus grp. (*Includes *S. anginosus, S. intermedius,* and *S. constellatus), Enterococcus faecalis, Enterobacter cloacae,* or *Klebsiella pneumoniae*
   3. You meet ONE of the following criteria:
      a. The requested medication is prescribed by or given in consultation with an Infectious Disease (ID) specialist
      b. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is available, and the infection site culture results indicate pathogenic (disease-causing) organism(s) with 1) resistance to at least TWO standard of care agents for acute bacterial skin or skin structure infection (such as linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, cefazolin), AND 2) Nuzyra will work against the bacteria
      c. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is unavailable, and you had a trial of or contraindication to at least TWO standard of care agents for acute bacterial skin or skin structure infection (such as linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, cefazolin)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nuzyra.

REFERENCES

- Nuzyra [Prescribing Information]. Boston, MA: Paratek Pharmaceuticals, Inc.; February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 03/19
Client Approval: 04/20
P&T Approval: 01/19

STANDARD COMMERCIAL AND NSA DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMALIZUMAB

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe persistent asthma and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a physician specializing in pulmonary medicine or allergy medicine
   - The patient has a positive skin prick or blood test (e.g., ELISA, FEIA) to a perennial aeroallergen
   - The patient has a documented (e.g., chart notes, lab results, diagnostic test results, etc.) baseline IgE serum level of at least 30 IU/mL
   - The patient is concurrently treated with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline, or an oral corticosteroid [e.g., prednisone])
   - Xolair will NOT be used concurrently with Dupixent (dupilumab), Tezspire (tezepelumab-ekko), or an anti-IL-5 biologic (e.g., Nucala [mepolizumab], Cinqair [reslizumab], Fasenra [benralizumab]) when these are used for the treatment of asthma

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced at least ONE asthma exacerbation requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months
   - The patient has experienced at least ONE serious asthma exacerbation requiring hospitalization or an emergency room visit within the past 12 months

   If yes, **approve for 4 months by GPID or GPI-14 for the requested agent as follows:**
   - **150mg vial: #6 vials per 28 days.**
   - **75mg/0.5mL syringe/autoinjector: #5mL per 28 days.**
   - **150mg/mL syringe/autoinjector: #5mL per 28 days.**
   - **300mg/2mL syringe/autoinjector: #4mL per 28 days.**

   If no, continue to #3.

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OMALIZUMAB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have poor symptom control despite current therapy as evidenced by at least **THREE** of the following within the past 4 weeks?
   - Daytime asthma symptoms more than twice per week
   - Any night waking due to asthma
   - Use of a short-acting inhaled beta2-agonist (SABA) reliever (e.g., albuterol) for symptoms more than twice per week
   - Any activity limitation due to asthma

   If yes, **approve for 4 months by GPID or GPI-14 for the requested agent as follows:**
   - **150mg vial: #6 vials per 28 days.**
   - **75mg/0.5mL syringe/autoinjector: #5mL per 28 days.**
   - **150mg/mL syringe/autoinjector: #5mL per 28 days.**
   - **300mg/2mL syringe/autoinjector: #4mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of nasal polyps and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an otolaryngologist or allergist/immunologist
   - Xolair will be used as add-on maintenance treatment
   - The patient had a previous 56-day trial of ONE intranasal corticosteroid (e.g., mometasone nasal spray)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #8 vials/mL per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of an IgE-mediated food allergy and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - Xolair will be used in conjunction with food allergen avoidance

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 vials/mL per 28 days.**

   If no, continue to #6.

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OMALIZUMAB

INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of chronic spontaneous urticaria (CSU; also called chronic idiopathic urticaria [CIU]) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with an allergist, dermatologist, or immunologist
   - The patient still experiences hives or angioedema on most days of the week for at least 6 weeks
   - The patient had a trial of and is maintained on, OR has a contraindication to, a second generation H1 anti-histamine (i.e., Zyrtec [cetirizine], Xyzal [levocetirizine], Claritin [loratadine], Clarinex [desloratadine], or Allegra [fexofenadine])

   If yes, **approve for 6 months by GPID or GPI-14 for the requested agent as follows:**
   - **150mg vial: #2 vials per 28 days.**
   - **150mg/mL syringe/autoinjector: #2mL per 28 days.**
   - **300mg/2mL syringe/autoinjector: #2mL per 28 days.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OMALIZUMAB (Xolair)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Moderate to severe persistent asthma (a type of lung condition)
      2. Nasal polyps (a type of nose condition)
      3. IgE-mediated food allergy (your body's reaction to a food allergy)
      4. Chronic spontaneous urticaria (also called chronic idiopathic urticaria) [severe itching with unknown cause]

   B. **If you have moderate to severe persistent asthma, approval also requires:**
      1. You are 6 years of age or older
      2. Therapy is prescribed by or in consultation with a physician specializing in pulmonary (relating to lungs/breathing) medicine or allergy medicine
      3. You have a positive skin prick or blood test, such as ELISA or FEIA (types of blood tests to identify allergies), to a perennial aeroallergen (airborne particles that cause allergies year-round)
      4. You have a documented (such as chart notes, lab results, diagnostic test results) baseline IgE (type of antibody produced by the immune system) serum (blood) level of 30 IU/mL or higher

   (Initial denial text continued on next page)

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OMALIZUMAB

INITIAL CRITERIA (CONTINUED)

5. You are being treated at the same time with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)
6. You meet ONE of the following:
    a. You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months, OR at least ONE serious asthma exacerbation requiring a hospitalization or an emergency room visit within the past 12 months
    b. You have poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks:
        i. Daytime asthma symptoms more than twice per week
        ii. Any night waking due to asthma
        iii. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
        iv. Any activity limitation due to asthma
7. You will NOT use Xolair concurrently (at the same time) with Dupixent (dupilumab), Tezspire (tezepelumab-ekko), or an anti-IL-5 (interleukin-5) biologic (such as Nucala [mepolizumab], Cinqair [reslizumab], Fasenra [benralizumab]) when these are used for the treatment of asthma

C. **If you have nasal polyps, approval also requires:**
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with an otolaryngologist (ear, nose, and throat doctor) or an allergist/immunologist (a type of allergy or immune system doctor)
3. Xolair will be used as add-on maintenance treatment
4. You had a previous 56-day trial of ONE intranasal corticosteroid (such as mometasone nasal spray)

D. **If you have an IgE-mediated food allergy, approval also requires:**
1. You are 1 year of age or older
2. Xolair will be used in conjunction (together) with food allergen avoidance (not eating or coming into contact with any food that causes an allergic reaction)

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OMALIZUMAB

INITIAL CRITERIA (CONTINUED)

E. **If you have chronic spontaneous urticaria (chronic idiopathic urticaria), approval also requires:**
   1. You are 12 years of age or older
   2. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
   3. You still experience hives or angioedema (a type of swelling) on most days of the week for at least 6 weeks
   4. You have tried and are maintained on (continue to use on a regular basis), OR you have a contraindication to (harmful for you to use), a second generation H1 antihistamine (type of allergy medication) (Zyrtec [cetirizine], Xyzal [levocetirizine], Claritin [loratadine], Clarinex [desloratadine] or Allegra [fexofenadine])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OMALIZUMAB

RENEWAL CRITERIA

NOTE: For the diagnosis of an IgE-mediated food allergy, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe persistent asthma and meet **ALL** of the following criteria?
   - The patient will continue to use an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline, or an oral corticosteroid [e.g., prednisone])
   - Xolair will NOT be used concurrently with Dupixent (dupilumab), Tezspire (tezepelumab-ekko), or an anti-IL-5 biologic (e.g., Nucala [mepolizumab], Cinqair [reslizumab], Fasenra [benralizumab]) when these are used for the treatment of asthma

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient shown a clinical response as evidenced by **ONE** of the following?
   - Reduction in asthma exacerbation from baseline
   - Decreased utilization of rescue medications (e.g., albuterol)
   - Increase in percent predicted FEV1 from pretreatment baseline
   - Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent as follows:**
   - **150mg vial: #6 vials per 28 days.**
   - **75mg/0.5mL syringe/autoinjector: #5mL per 28 days.**
   - **150mg/mL syringe/autoinjector: #5mL per 28 days.**
   - **300mg/2mL syringe/autoinjector: #4mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient have a diagnosis of nasal polyps **AND** meet the following criterion?
   - The patient has had a clinical benefit compared to baseline (e.g., improvements in nasal congestion, sense of smell, size of polyps)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 vials/mL per 28 days.**

   If no, continue to #4.

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OMALIZUMAB

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of chronic spontaneous urticaria (CSU; also called chronic idiopathic urticaria [CIU]) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an allergist, dermatologist, or immunologist
   - The patient is maintained on, OR has a contraindication to, a second generation H1 anti-histamine (i.e., Zyrtec [cetirizine], Xyzal [levocetirizine], Claritin [loratadine], Clarinex [desloratadine], or Allegra [fexofenadine])

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent as follows:**
   - **150mg vial: #2 vials per 28 days.**
   - **150mg/mL syringe/autoinjector: #2mL per 28 days.**
   - **300mg/2mL syringe/autoinjector: #2mL per 28 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OMALIZUMAB (Xolair)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Moderate to severe persistent asthma (a type of lung condition)
      2. Nasal polyps (a type of nose condition)
      3. Chronic spontaneous urticaria (also called chronic idiopathic urticaria) [severe itching with unknown cause]
   B. **If you have moderate to severe persistent asthma, renewal also requires:**
      1. You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)
      2. You will NOT use Xolair concurrently (at the same time) with Dupixent (dupilumab), Tezspire (tezepelumab-ekko), or an anti-IL-5 (interleukin-5) biologic (such as Nucala [mepolizumab], Cinqair [reslizumab], Fasenra [benralizumab]) when these are used for the treatment of asthma
      3. You have shown a clinical response as evidenced by ONE of the following:
         a. Reduction in asthma exacerbation (worsening of symptoms) from baseline
         b. Decreased use of rescue medications (such as albuterol)
         c. Increase in percent predicted FEV1 (type of lung test) from pre-treatment baseline
         d. Reduction in the severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

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OMALIZUMAB

RENEWAL CRITERIA (CONTINUED)

C. **If you have nasal polyps, renewal also requires:**
   1. You have had a clinical benefit compared to baseline (before starting Xolair) (such as improvements in nasal congestion, sense of smell, size of polyps)

D. **If you have chronic spontaneous urticaria (chronic idiopathic urticaria), renewal also requires:**
   1. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
   2. You are maintained on (continue to use on a regular basis), OR you have a contraindication to (harmful for you to use), a second generation H1 antihistamine (type of allergy medication) (Zyrtec [cetirizine], Xyzal [levocetirizine], Claritin [loratadine], Clarinex [desloratadine] or Allegra [fexofenadine])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xolair.

REFERENCES

- Xolair [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; February 2024.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 03/18/24
Created: 08/03
Client Approval: 03/24
P&T Approval: 04/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMAVELOXOLONE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Friedreich's ataxia **AND** meet the following criterion?
   - The patient is 16 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OMAVELOXOLONE (Skyclarys)** requires the following rule(s) be met for approval:
   A. You have Friedreich's ataxia (a type of nervous system and movement disorder)
   B. You are 16 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Skyclarys.

REFERENCES

- Skyclarys [Prescribing Information]. Plano, TX: Reata Pharmaceuticals, Inc.; February 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 04/23
Client Approval: 05/23
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPICAPONE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Parkinson's disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is experiencing “OFF” episodes
   - The patient is currently being treated with carbidopa/levodopa
   - The patient had a previous trial of, failure of, or contraindication to **TWO** Parkinson's disease agents from **TWO** different classes of the following:
     - Dopamine agonist (e.g., ropinirole, pramipexole, rotigotine)
     - Monoamine oxidase-inhibitors (MAO-I) (e.g., selegiline, rasagiline)
     - Adenosine receptor antagonist A2A (e.g., istradefylline)
     - Catechol-O-methyltransferase (COMT) inhibitors (e.g., entacapone, tolcapone)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OPICAPONE (Ongentys)** requires the following rule(s) be met for approval:
   A. You have Parkinson's disease (PD: a nerve system disorder that affects movement)
   B. You are 18 years of age or older
   C. You are experiencing 'OFF' episodes (times when you have symptoms return due to medication wearing off)
   D. You are currently being treated with carbidopa/levodopa
   E. You have tried or failed or have a contraindication (medical reason why you cannot use) to TWO Parkinson's disease medications from TWO different classes of medications:
      1. Dopamine agonist (such as ropinirole, pramipexole, rotigotine)
      2. Monoamine oxidase-inhibitors (MAO-I) (such as selegiline, rasagiline)
      3. Adenosine receptor antagonist A2A (such as istradefylline)
      4. Catechol-O-methyltransferase (COMT) inhibitors (such as entacapone, tolcapone)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPICAPONE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ongentys.

REFERENCES

- Ongentys [Prescribing Information]. San Diego, CA: Neurocrine Biosciences, Inc.; April 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21
Created: 09/20
Client Approval: 11/20
P&T Approval: 10/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OSILODROSTAT

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Cushing's disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - Pituitary surgery is not an option or has not been curative for the patient
   - The patient had a trial of or contraindication to oral ketoconazole

   If yes, **approve for 6 months for all strengths by GPID or GPI-14 with the following quantity limits:**
   - **1mg: #8 per day.**
   - **5mg: #12 per day.**
   - **10mg: #6 per day.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OSILODROSTAT (Isturisa)** requires the following rule(s) be met for approval:
   A. You have Cushing's disease (a type of hormone disorder)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   D. Pituitary (major hormone gland) surgery is not an option or has not cured your condition
   E. You had a trial of or contraindication (harmful for) to oral ketoconazole

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OSILODROSTAT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Cushing's disease and meet **ALL** the following criteria?
   - The patient continues to have improvement of Cushing's disease (e.g., clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of disease)
   - The patient maintains tolerability to Isturisa

   If yes, **approve for 12 months for all strengths by GPID or GPI-14 with the following quantity limits:**
   - **1mg: #8 per day.**
   - **5mg: #12 per day.**
   - **10mg: #6 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OSILODROSTAT (Isturisa)** requires the following rule(s) be met for renewal:
   A. You have Cushing's disease (a type hormone disorder)
   B. You continue to have improvement of Cushing's disease (such as clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of disease)
   C. You continue to tolerate treatment with Isturisa

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Isturisa.

REFERENCES

- Isturisa [Prescribing Information]. Lebanon, NJ: Recordati Rare Diseases, Inc.; March 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/23
Created: 08/20
Client Approval: 06/23
P&T Approval: 07/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OSIMERTINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Tagrisso will be used as adjuvant therapy after tumor resection
   - The patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test
   - Tagrisso will NOT be used concurrently with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (e.g., Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib], Vizimpro [dacomitinib])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Tagrisso will NOT be used concurrently with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (e.g., Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib], Vizimpro [dacomitinib])

   If yes, continue to #3.
   If no, continue to #5.

3. Does the patient's tumor have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test, **AND** Tagrisso will be used as first-line treatment?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #4.

4. Does the patient's tumor have an epidermal growth factor receptor (EGFR) T790M mutation, as detected by an FDA-approved test, **AND** the patient meets the following criterion?
   - The patient's disease has progressed while on or after epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor therapy (e.g., Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OSIMERTINIB

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Tagrisso will be used in combination with pemetrexed and platinum-based chemotherapy (e.g., cisplatin, carboplatin) as first-line treatment
   - The patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test
   - Tagrisso will NOT be used concurrently with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (e.g., Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib], Vizimpro [dacomitinib])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OSIMERTINIB (Tagrisso)** requires the following rule(s) be met for approval:
   A. You have non-small cell lung cancer (NSCLC: a type of lung cancer)
   B. **If you have non-small cell lung cancer, approval also requires:**
      1. You are 18 years of age or older
      2. Tagrisso will be used as adjuvant therapy (add-on treatment) after tumor resection (surgical removal of a tumor)
      3. Your tumor has epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
      4. You will NOT use Tagrisso concurrently (at the same time) with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (such as Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib], Vizimpro [dacomitinib])

   (Denial text continued on next page)

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OSIMERTINIB

GUIDELINES FOR USE (CONTINUED)

C. **If you have metastatic non-small cell lung cancer (cancer that has spread to other parts of the body), approval also requires:**
   1. You are 18 years of age or older
   2. You will NOT use Tagrisso concurrently (at the same time) with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (such as Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib], Vizimpro [dacomitinib])
   3. You meet ONE of the following:
      a. Your tumor has epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test, AND Tagrisso will be used as first-line treatment (initial treatment)
      b. Your tumor has an epidermal growth factor receptor (EGFR) T790M mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test, AND your disease has progressed (worsening of disease) while on or after EGFR tyrosine kinase-inhibitor therapy (such as Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

D. **If you have locally advanced or metastatic non-small cell lung cancer (cancer that has spread from where it started to nearby tissue or lymph nodes or other parts of the body), approval also requires:**
   1. You are 18 years of age or older
   2. Tagrisso will be used in combination with pemetrexed and platinum-based chemotherapy (such as cisplatin, carboplatin) as first-line treatment (initial treatment)
   3. Your tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
   4. You will NOT use Tagrisso concurrently (at the same time) with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (such as Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib], Vizimpro [dacomitinib])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OSIMERTINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tagrisso.

REFERENCES

- Tagrisso [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 03/18/24
Created: 11/15
Client Approval: 03/24
P&T Approval: 04/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OTESECONAZOLE

GUIDELINES FOR USE

1. Is the request for the reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC) and the patient meets **ALL** of the following criteria?
   - The patient is female
   - The patient is NOT of reproductive potential (defined as a biological female who is postmenopausal or has another reason for permanent infertility [e.g., tubal ligation, hysterectomy, salpingo-oophorectomy])
   - The patient is NOT currently on ibrexafungerp for RVVC

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient previously received Vivjoa?

   If yes, continue to #4.
   If no, continue to #3.

3. Has the patient had 3 or more episodes of VVC in the past 12 months?

   If yes, **approve for 3 months by HICL or GPI-10 with a quantity limit of #18 per 12 weeks.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient meet **ALL** of the following criteria?
   - The patient has successfully completed a course of Vivjoa for prevention of RVVC
   - The patient is either being treated or has just completed treatment for a new recurrence of VVC

   If yes, **approve for 3 months by HICL or GPI-10 with a quantity limit of #18 per 12 weeks.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OTESECONAZOLE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OTESECONAZOLE (Vivjoa)** requires the following rule(s) be met for approval:

A. You have recurrent vulvovaginal candidiasis (RVVC: a repeating vaginal fungal infection)
B. You are female
C. You are not able to reproduce, which means you are a biological female and are postmenopausal (after menopause) or you have another reason for permanent infertility (such as tubal ligation [having tubes tied], hysterectomy [removal of the uterus], salpingo-oophorectomy [removal of an ovary and its fallopian tube])
D. You are NOT currently on ibrexafungerp for RVVC
E. **If you have not previously received Vivjoa, approval also requires:**
   1. You had 3 or more episodes of RVVC in the past 12 months
F. **If you have previously received Vivjoa, approval also requires:**
   1. You have successfully completed a course of Vivjoa for prevention of RVVC
   2. You are either being treated or have just completed treatment for a new recurrence of VVC

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vivjoa.

REFERENCES

- Vivjoa [Prescribing Information]. Durham, NC: Mycovia Pharmaceuticals, Inc.; April 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/23
Created: 07/22
Client Approval: 02/23
P&T Approval: 01/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OXYMETAZOLINE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of blepharoptosis and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an ophthalmologist or optometrist
   - The patient has been evaluated for surgical intervention
   - The patient had a trial of TWO ophthalmic alpha-adrenergic agonists (e.g., apraclonidine, tetrahydrozoline, naphazoline)

   If yes, **approve for 3 months by HICL or GPI-10 with a quantity limit of #1 droperette per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OXYMETAZOLINE (Upneeq)** requires the following rule(s) be met for approval:
   A. You have blepharoptosis (drooping of the upper eyelid)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or optometrist (a type of eye doctor)
   D. You have been evaluated for surgical intervention
   E. You had a trial of TWO ophthalmic alpha-adrenergic agonists (such as apraclonidine, tetrahydrozoline, naphazoline)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OXYMETAZOLINE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of blepharoptosis **AND** meet the following criterion?
   - The patient continues to have benefit from Upneeq

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 droperette per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OXYMETAZOLINE (Upneeq)** requires the following rule(s) be met for renewal:
   A. You have blepharoptosis (drooping of the upper eyelid)
   B. You continue to have benefit from Upneeq

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Upneeq.

REFERENCES

- Upneeq [Prescribing Information]. Bridgewater, NJ: RVL Pharmaceuticals, Inc.; June 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 11/21
Client Approval: 02/22
P&T Approval: 10/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OZANIMOD

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of ONE sphingosine-1-phosphate receptor modulator (e.g., Gilenya [fingolimod], Mayzent [siponimod])
   - The patient had a trial of ONE agent indicated for the treatment of multiple sclerosis (**Please note:** other MS agents may also require prior authorization)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Zeposia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication
   - The patient had a trial of or contraindication to ONE conventional therapy (e.g., corticosteroids [e.g., budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz) [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance programs do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial text at the end of the guideline.

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OZANIMOD

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OZANIMOD (Zeposia)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. A relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
   2. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have a relapsing form of multiple sclerosis, approval also requires:**
   1. You are 18 years of age or older
   2. You have tried ONE sphingosine-1-phosphate receptor modulator (such as Gilenya [fingolimod], Mayzent [siponimod])
   3. You have tried ONE medication indicated for the treatment of multiple sclerosis (**Please note**: The following medications are preferred and may also require prior authorization: Avonex, Copaxone/Glatiramer/Glatopa, Gilenya, Plegridy, Rebif, Betaseron, dimethyl fumarate, Mavenclad, Mayzent, Vumerity, Aubagio, Kesimpta)

C. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Zeposia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE standard therapy, such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

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OZANIMOD

INITIAL CRITERIA (CONTINUED)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OZANIMOD

RENEWAL CRITERIA

NOTE: For the diagnosis of multiple sclerosis, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?
   - Zeposia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz) [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance programs do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OZANIMOD (Zeposia)** requires the following rule(s) be met for renewal:
   A. You have moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   B. You will NOT use Zeposia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   C. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

   NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OZANIMOD

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zeposia.

REFERENCES

- Zeposia [Prescribing Information]. Summit, NJ: Celgene Corporation; August 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/01/24
Created: 06/20
Client Approval: 04/24
P&T Approval: 04/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PACRITINIB

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of intermediate- or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocytopenia) myelofibrosis and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a platelet count below 50,000/uL

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do no approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PACRITINIB (Vonjo)** requires the following rule(s) be met for approval:
   A. You have intermediate- or high-risk primary or secondary (post-polycythemia vera [type of blood cell disorder] or post-essential thrombocythemia [type of blood cell disorder]) myelofibrosis (type of bone marrow cancer)
   B. You are 18 years of age or older
   C. You have a platelet count below 50,000/uL

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of intermediate- or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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PACRITINIB

RENEWAL CRITERIA (CONTINUED)

2. Has the patient shown symptom improvement by meeting **ONE** of the following criteria?
   - The patient has a spleen volume reduction of 35% or greater from baseline
   - The patient has a 50% or greater reduction in total symptom score (e.g., Myeloproliferative Neoplasm Symptom Assessment Form [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0)
   - The patient has a 50% or greater reduction in palpable spleen length

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PACRITINIB (Vonjo)**requires the following rule(s) be met for renewal:
   A. You have intermediate- or high-risk primary or secondary (post-polycythemia vera [type of blood cell disorder] or post-essential thrombocythemia [type of blood cell disorder]) myelofibrosis (type of bone marrow cancer)
   B. You have shown symptom improvement by meeting ONE of the following:
      1. You have a spleen volume reduction of 35% or greater from baseline
      2. You have a 50% or greater reduction in total symptom score (such as Myeloproliferative Neoplasm Symptom Assessment Form [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0)
      3. You have a 50% or greater reduction in palpable (can be felt by external examination) spleen length

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vonjo.

REFERENCES

- Vonjo [Prescribing Information]. Seattle, WA: CTI BioPharma Corp.; February 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 03/22
Client Approval:03/22
P&T Approval: 10/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PALBOCICLIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced or metastatic breast cancer **AND** meet the following criterion?
   - The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Will Ibrance be used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) and the patient meets **ALL** of the following criteria?
   - The patient has NOT received prior endocrine-based therapy (e.g., anastrozole, letrozole, tamoxifen)
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Kisqali (ribociclib), Verzenio (abemaciclib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #21 per 28 days.**
   If no, continue to #3.

3. Will Ibrance be used in combination with fulvestrant (Faslodex) **AND** the patient meets the following criterion?
   - The patient has experienced disease progression following endocrine therapy (e.g., anastrozole, letrozole, tamoxifen)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the patient a male or a postmenopausal female?

   If yes, continue to #5.
   If no, continue to #6.

5. Has the patient had a trial of or contraindication to **ONE** of the following preferred agents: Kisqali (ribociclib), Verzenio (abemaciclib)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #21 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PALBOCICLIB

GUIDELINES FOR USE (CONTINUED)

6. Has the patient had a trial of or contraindication to the preferred agent: Verzenio (abemaciclib)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PALBOCICLIB (Ibrance)** requires the following rule(s) be met for approval:
   A. You have advanced or metastatic breast cancer (cancer that has worsened or has spread to other parts of the body)
   B. Your cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (a type of protein)
   C. **If you are requesting Ibrance in combination with an aromatase inhibitor (such as anastrozole, letrozole, exemestane), approval also requires:**
      1. You have not received prior endocrine (hormone)-based therapy (such as anastrozole, letrozole, tamoxifen)
      2. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Kisqali (ribociclib), Verzenio (abemaciclib)
   D. **If you are requesting Ibrance in combination with fulvestrant (Faslodex), approval also requires:**
      1. Your disease has worsened after endocrine (hormone) therapy (such as anastrozole, letrozole, tamoxifen)
      2. You meet ONE of the following:
         a. If you are a male or a postmenopausal female, you have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Kisqali (ribociclib), Verzenio (abemaciclib)
         b. If you are a female and not postmenopausal, you have tried or have a contraindication to (harmful for you to use) the preferred medication: Verzenio (abemaciclib)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PALBOCICLIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ibrance.

REFERENCES

- Ibrance [Prescribing Information]. New York, NY: Pfizer Laboratories; September 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 05/15
Client Approval: 11/23
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PALOVAROTENE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of fibrodysplasia ossificans progressiva (FOP) and meet **ONE** of the following criteria?
   - The patient is a female and 8 years of age or older
   - The patient is a male and 10 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PALOVAROTENE (Sohonos)** requires the following rule(s) be met for approval:
   A. You have fibrodysplasia ossificans progressiva (FOP: a type of rare genetic tissue disorder)
   B. You meet ONE of the following:
      1 You are female and 8 years of age or older
      2. You are male and 10 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sohonos.

REFERENCES

- Sohonos [Prescribing Information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; August 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 12/01/23
Created: 10/23
Client Approval: 11/23
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PARATHYROID HORMONE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hypocalcemia secondary to hypoparathyroidism and meets the following criteria?
   - Previous trial of activated vitamin D (calcitriol) and calcium
   - Patient's hypoparathyroidism is **not** due to a calcium sensing receptor (CSR) mutation
   - Patient's hypoparathyroidism is **not** considered acute post-surgical hypoparathyroidism (surgery in past 30 days)
   - Therapy is prescribed by or given in consultation with an endocrinologist

   If yes, **approve for 12 months by HICL or GPI-10 for quantity of #2 cartridges per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline for **PARATHYROID HORMONE** requires the following rule(s) be met for approval:
   A. You have hypocalcemia secondary to hypoparathyroidism (low blood calcium due to low levels of a type of hormone)
   B. You have previously tried activated vitamin D (calcitriol) and calcium
   C. Your hypoparathyroidism (low levels of a type of hormone) is not due to a calcium sensing receptor (CSR) mutation (changes in your DNA that make up your gene)
   D. Your hypoparathyroidism is not considered acute post-surgical hypoparathyroidism (not sudden and severe due to surgery in past 30 days)
   E. Therapy is prescribed by or given in consultation with an endocrinologist (hormone specialist)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PARATHYROID HORMONE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Natpara.

REFERENCES

- Natpara [Prescribing Information]. Bedminster, NJ: NPS Pharmaceuticals, Inc. December 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 04/15
Client Approval: 04/20
P&T Approval: 05/15

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PASIREOTIDE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Cushing's disease (CD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with an endocrinologist
   - The patient has undergone pituitary surgery or pituitary surgery is not an option for this patient
   - The patient had a trial of or contraindication to oral ketoconazole

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PASIREOTIDE (Signifor)** requires the following rule(s) be met for approval:
   A. You have Cushing's disease (CD: a condition in which the pituitary gland releases too much of a hormone called adrenocorticotropic hormone [ACTH])
   B. You are 18 years of age or older
   C. Therapy is prescribed by or given in consultation with an endocrinologist (doctor who specializes in hormones)
   D. You have undergone pituitary (a major hormone gland) surgery OR pituitary surgery is not an option
   E. You have previously tried oral ketoconazole, unless there is a medical reason you are cannot (contraindication)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PASIREOTIDE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Cushing's disease (CD) and meet **ALL** of the following criteria?
   - The patient continues to have improvement of Cushing's disease (e.g., clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of disease)
   - The patient maintains tolerability to Signifor

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PASIREOTIDE (Signifor)** requires the following rule(s) be met for renewal:
   A. You have Cushing's disease (CD: a condition in which the pituitary gland releases too much of a hormone called adrenocorticotropic hormone [ACTH])
   B. You continue to have improvement of Cushing's disease (such as clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of your disease)
   C. You continue to tolerate treatment with Signifor

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Signifor.

REFERENCES

- Signifor [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/20
Created: 05/13
Client Approval: 08/20
P&T Approval: 07/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PATIROMER

GUIDELINES FOR USE

1. Is the patient being treated for hyperkalemia **AND** meet the following criterion?
   - Therapy is prescribed by or given in consultation with a nephrologist or cardiologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The requested medication is being used as an emergency treatment for life-threatening hyperkalemia
   - The patient is currently receiving dialysis

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #3.

3. Has the patient attempted **ONE** of the following approaches in an effort to reduce the modifiable risks for hyperkalemia?
   - Limit to taking no more than one of the following drugs at any given time:
     - Angiotensin converting enzyme inhibitor (ACE-I)
     - Angiotensin receptor blocker (ARB)
   - Consideration of dose reduction of renin-angiotensin-aldosterone system (RAAS) inhibitors (e.g., ACE-I's, ARB's, aldosterone antagonists)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have an estimated glomerular filtration rate (eGFR) below 30 mL/min/1.73 m^2 **AND** meet the following criterion?
   - The patient has tried loop diuretics (e.g., bumetanide, ethacrynic acid, furosemide, torsemide) for the treatment of hyperkalemia

   If yes, continue to #6.
   If no, continue to #5.

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PATIROMER

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have an estimated glomerular filtration rate (eGFR) of 30 mL/min/1.73 m^2 or above and have tried **ONE** of the following for the treatment of hyperkalemia?
   - The patient has tried loop diuretic (e.g., bumetanide, ethacrynic acid, furosemide, torsemide)
   - The patient has tried thiazide diuretic (e.g., chlorthalidone, hydrochlorothiazide, metolazone)

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Has the patient had a previous trial of Lokelma (sodium zirconium cyclosilicate)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #30 packets per 30 days.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **PATIROMER (Veltassa)** requires the following rule(s) be met for approval:
   A. You have hyperkalemia (high levels of potassium in blood)
   B. Therapy is prescribed by or given in consultation with a nephrologist (kidney doctor) or cardiologist (heart doctor)
   C. The requested medication is NOT being used as an emergency treatment for life-threatening hyperkalemia (high levels of potassium in blood)
   D. You are NOT currently receiving dialysis
   E. You have tried ONE of the following to lower the risks for hyperkalemia:
      1. Limit to taking no more than one of the following drugs at any given time:
         i. Angiotensin converting enzyme inhibitor (ACE-I such as lisinopril, benazepril)
         ii. Angiotensin receptor blocker (ARB such as valsartan, losartan)
      2. Lowering the dose of renin-angiotensin-aldosterone system (RAAS) inhibitors (such as ACE-I's, ARB's, aldosterone antagonists like spironolactone) has been considered
   F. **If your estimated glomerular filtration rate (eGFR) is below 30 mL/min/1.73 m(2), approval also requires:**
      1. You have tried to treat hyperkalemia with loop diuretics such as bumetanide, ethacrynic acid, furosemide, torsemide

   (Denial text continued on next page)

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PATIROMER

GUIDELINES FOR USE (CONTINUED)

G. **If your estimated glomerular filtration rate (eGFR) is 30 mL/min/1.73 m(2) or above approval also requires:**
   1. You have tried to treat hyperkalemia with a loop diuretic such as bumetanide, ethacrynic acid, furosemide, torsemide, OR a thiazide diuretic such as chlorthalidone, hydrochlorothiazide, metolazone

H. You have previously tried Lokelma (sodium zirconium cyclosilicate)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Veltassa.

REFERENCES

- Veltassa [Prescribing Information]. Redwood City, CA: Relypsa, Inc.; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 2/16
Client Approval: 04/20
P&T Approval: 01/19

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PAZOPANIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of advanced soft tissue sarcoma (STS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received prior chemotherapy (e.g., anthracycline treatment)
   - The patient does NOT have a diagnosis of adipocytic soft tissue sarcoma (STS) or gastrointestinal stromal tumors (GIST)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PAZOPANIB (Votrient)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Advanced renal cell carcinoma (RCC: a type of kidney cancer)
      2. Advanced soft tissue sarcoma (STS: cancer that starts in soft tissues [muscle, tendons, fat, lymph vessels, blood vessels, nerves])
   B. **If you have advanced renal cell carcinoma, approval also requires:**
      1. You are 18 years of age or older
   C. **If you have advanced soft tissue sarcoma, approval also requires:**
      1. You are 18 years of age or older
      2. You have received prior chemotherapy (a type of cancer therapy such as anthracycline treatment)
      3. You do NOT have adipocytic soft tissue sarcoma (STS: a type of fat cell cancer) or gastrointestinal stromal tumors (GIST: a type of digestive tumor)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PAZOPANIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Votrient.

REFERENCES

- Votrient [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/06/23
Created: 05/11
Client Approval: 10/23
P&T Approval: 08/16

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEANUT ALLERGEN POWDER-DNFP

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a peanut allergy and meet **ALL** of the following criteria?
   - The patient is 4 to 17 years of age
   - Therapy is prescribed by or in consultation with an allergist or immunologist
   - The patient has a clinical history of allergic reaction to peanuts
   - Palforzia will be used in conjunction with a peanut-avoidance diet
   - Palforzia will NOT be used concurrently with a peanut-specific immunotherapy (e.g., Viaskin Peanut)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the patient completed a purposeful food challenge and has a documentation (e.g., chart notes, lab results, diagnostic test results, etc.) of **ONE** of the following criteria?
   - The patient tested positive on a skin prick test with a wheal diameter of at least 3 mm within the past 24 months
   - The patient has a peanut-specific immunoglobulin E level of at least 0.35 kUA/L within the past 24 months

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **300 mg powder packet/sachet: #1 per day.**
   - **All other strengths: No quantity limit.**

   If no, continue to #3.

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PEANUT ALLERGEN POWDER-DNFP

INITIAL CRITERIA (CONTINUED)

3. Has the patient NOT completed a purposeful food challenge and has a documentation (e.g., chart notes, lab results, diagnostic test results, etc.) of **ONE** of the following criteria?
   - The patient tested positive on a skin prick test with a wheal diameter of at least 8 mm within the past 24 months
   - The patient has a peanut-specific immunoglobulin E level of at least 14 kUA/L within the past 24 months

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **300 mg powder packet/sachet: #1 per day.**
   - **All other strengths: No quantity limit.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEANUT ALLERGEN POWDER-DNFP (Palforzia)** requires the following rule(s) be met for approval:
   A. You have a peanut allergy
   B. You are 4 to 17 years of age
   C. Therapy is prescribed by or in consultation with an allergist (allergy doctor) or immunologist (immune system doctor)
   D. You have a clinical history of an allergic reaction to peanuts
   E. Palforzia will be used together with a peanut-avoidance diet
   F. Palforzia will NOT be used concurrently (at the same time) with peanut-specific immunotherapy (such as Viaskin Peanut)
   G. You meet ONE of the following:
      1. If you have completed a purposeful food challenge (a type of test): you have documentation (such as chart notes, lab results, diagnostic test results) of a positive skin prick test (a skin test to check for peanut allergy) with a wheal diameter of at least 3 mm within the past 24 months, OR you had a peanut-specific immunoglobulin E (IgE: a blood test that indicates an allergy to peanuts) level of at least 0.35 kUA/L within the past 24 months
      2. If you have NOT completed a purposeful food challenge: you have documentation (such as chart notes, lab results, diagnostic test results) of a positive skin prick test (a skin test to check for peanut allergy) with a wheal diameter of at least 8 mm within the past 24 months, OR you had a peanut-specific immunoglobulin E (IgE: a blood test that indicates an allergy to peanuts) level of at least 14 kUA/L within the past 24 months

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PEANUT ALLERGEN POWDER-DNFP

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a peanut allergy and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an allergist or immunologist
   - Palforzia will be used in conjunction with a peanut-avoidance diet
   - Palforzia will NOT be used concurrently with a peanut-specific immunotherapy (e.g., Viaskin Peanut)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient completed a purposeful food challenge?

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient have a documentation (e.g., chart notes, lab results, diagnostic test results, etc.) of a persistent peanut allergy and meets **ONE** of the following criteria?
   - The patient tested positive on a skin prick test with a wheal diameter of at least 3 mm within the past 24 months
   - The patient has a peanut-specific immunoglobulin E level of at least 0.35 kUA/L within the past 24 months

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **300 mg powder packet/sachet: #1 per day.**
   - **All other strengths: No quantity limit.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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PEANUT ALLERGEN POWDER-DNFP

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a documentation (e.g., chart notes, lab results, diagnostic test results, etc.) of a persistent peanut allergy and meets **ONE** of the following criteria?
   - The patient tested positive on a skin prick test with a wheal diameter of at least 8 mm within the past 24 months
   - The patient has a peanut-specific immunoglobulin E level of at least 14 kUA/L within the past 24 months

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **300 mg powder packet/sachet: #1 per day.**
   - **All other strengths: No quantity limit.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEANUT ALLERGEN POWDER-DNFP (Palforzia)** requires the following rule(s) be met for renewal:

   A. You have an allergy to peanuts
   B. Therapy is prescribed by or in consultation with an allergist (allergy doctor) or immunologist (immune system doctor)
   C. Palforzia will be used together with a peanut-avoidance diet
   D. Palforzia will NOT be used concurrently (at the same time) with peanut-specific immunotherapy (such as Viaskin Peanut)
   E. You meet ONE of the following:
      1. If you have undergone a purposeful food challenge (a type of test): you have documentation (such as chart notes, lab results, diagnostic test results) of a persistent peanut allergy based on a positive skin prick test (a skin test to check for peanut allergy) with a wheal diameter of at least 3 mm, OR peanut-specific immunoglobulin E (IgE: a blood test that indicates an allergy to peanuts) level of at least 0.35 kUA/L within the past 24 months
      3. If you have NOT undergone a purposeful food challenge: you have documentation (such as chart notes, lab results, diagnostic test results) of a persistent peanut allergy based on a positive skin prick test (a skin test to check for peanut allergy) with a wheal diameter of at least 8 mm, OR you had a peanut-specific immunoglobulin E (IgE: a blood test that indicates an allergy to peanuts) level of at least 14 kUA/L within the past 24 months

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEANUT ALLERGEN POWDER-DNFP

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Palforzia.

REFERENCES

- Palforzia [Prescribing Information]. Brisbane, CA: Aimmune Therapeutics, Inc.; March 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/23

Created: 02/20
Client Approval: 06/23

P&T Approval: 07/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGCETACOPLAN - SQ

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist
   - Empaveli will NOT be used concurrently with C5 complement inhibitor therapy (e.g., Soliris [eculizumab], Ultomiris [ravulizumab-cwvz]) or Factor B inhibitor (e.g., Fabhalta [iptacopan])
   - The patient has tried and failed (as evidenced by hemoglobin levels less than 10.5 g/dL directly following at least 3 months of stable dosing) Soliris (eculizumab) or Ultomiris (ravulizumab-cwvz)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have documented confirmation (e.g., chart notes, lab results, diagnostic test results, etc.) of PNH by flow cytometry demonstrating **ALL** of the following?
   - The patient has at least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes)
   - PNH granulocyte clone size of at least 10 percent

   If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #200mL per 30 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PEGCETACOPLAN - SQ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PEGCETACOPLAN - SQ (Empaveli)** requires the following rule(s) be met for approval:

A. You have paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
D. You have documented confirmation (such as chart notes, lab results, diagnostic test results) of PNH through flow cytometry (a type of lab test) demonstrating ALL of the following:
    1. You have at least 2 different GPI-protein deficiencies (you are missing a certain type of protein, such as CD55, CD59) on at least 2 cell lineages (types of cells, such as erythrocytes [red blood cells], granulocytes [a type of white blood cell])
    2. PNH granulocyte clone size of at least 10 percent
E. You will NOT use Empaveli concurrently (at the same time) with a C5 complement inhibitor (such as, Soliris [eculizumab], Ultomiris [ravulizumab-cwvz]) or a Factor B inhibitor (such as, Fabhalta [iptacopan])
F. You have tried and failed (as shown by hemoglobin [type of protein in red blood cells] levels less than 10.5 g/dL immediately following at least 3 months of stable dosing) Soliris (eculizumab) or Ultomiris (ravulizumab-cwvz)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEGCETACOPLAN - SQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) and meet **ALL** of the following criteria?
   - The patient experienced a clinical benefit while on Empaveli (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase [LDH] and hemoglobin levels) compared to baseline (baseline defined as patient condition post treatment with Soliris [eculizumab] or Ultomiris [ravulizumab-cwvz])
   - Empaveli will NOT be used concurrently with a C5 complement inhibitor therapy (e.g., Soliris [eculizumab], Ultomiris [ravulizumab-cwvz]) or Factor B inhibitor (e.g., Fabhalta [iptacopan])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #200mL per 30 days.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGCETACOPLAN - SQ (Empaveli)** requires the following rule(s) be met for renewal:
   A. You have paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
   B. You have had clinical benefit while on Empaveli (such as, a reduction in the number of blood transfusions [adding blood to your body], improvement/stabilization of lactate dehydrogenase [LDH: a type of enzyme] levels and hemoglobin [type of protein in red blood cells] levels) compared to baseline (baseline is defined as your condition after treatment with Soliris [eculizumab] or Ultomiris [ravulizumab-cwvz])
   C. You will NOT use Empaveli concurrently (at the same time) with a C5 complement inhibitor (such as, Soliris [eculizumab], Ultomiris [ravulizumab-cwvz]) or a Factor B inhibitor (such as, Fabhalta [iptacopan])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Empaveli.

REFERENCES

- Empaveli [Prescribing Information]. Waltham, MA: Apellis Pharmaceuticals, Inc.; September 2023.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGCETACOPLAN - SQ

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24

Created: 05/21
Client Approval: 02/24

P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM

GUIDELINES FOR USE

1. Is the request to increase survival in a patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome) **AND** does the patient meet the following criterion?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, continue to #4.
   If no, continue to #2.

2. Does the patient have a non-myeloid malignancy and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the request for Neulasta Onpro kit **AND** the patient meets the following criterion?
   - The patient has a barrier to access (e.g., travel barriers, or the patient is unable to return to the clinic for Neulasta injections)

   If yes, **approve Neulasta Onpro for 12 months by GPID or GPI-14.**
   If no, continue to #4.

4. Has the patient had a trial of or contraindication to the preferred agent: Nyvepria (pegfilgrastim-apgf)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PEGFILGRASTIM

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PEGFILGRASTIM (Neulasta, Neulasta Onpro)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. You will be using Neulasta to increase survival if you have been acutely exposed to myelosuppressive doses of radiation (radiation that affects your blood and bone marrow)
   2. You have a non-myeloid malignancy (cancer not affecting bone marrow)

B. **If you have a non-myeloid malignancy, approval also requires:**
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   2. You are receiving myelosuppressive anti-cancer medications associated with a significant incidence of severe neutropenia (medications that affect the bone marrow and cause low levels of a type of white blood cell) with fever
   3. You meet ONE of the following:
      a. The request is for Neulasta AND you had a trial of or contraindication (harmful for) to the preferred medication: Nyvepria (pegfilgrastim-apgf)
      b. The request is for Neulasta Onpro AND you have a barrier to access (such as travel barriers, or you are unable to return to the clinic for Neulasta injections)

C. **If the request is to increase survival if you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:**
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   2. You had a trial of or contraindication (harmful for) to the preferred medication: Nyvepria (pegfilgrastim-apgf)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEGFILGRASTIM

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Neulasta.

REFERENCES

- Neulasta [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; February 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 08/21
Client Approval: 05/23
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM - APGF

GUIDELINES FOR USE

1. Does the patient have a non-myeloid malignancy and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Is the request to increase survival in a patiently acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome) **AND** does the patient meet the following criterion?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGFILGRASTIM - APGF (NYVEPRIA)** requires the following rule(s) be met for approval:
   A. The request is for ONE of the following:
      1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
      2. You will be using Nyvepria to increase survival if you have been acutely exposed to myelosuppressive doses of radiation (radiation that affects your blood and bone marrow)
   B. **If you have a non-myeloid malignancy, approval also requires:**
      1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
      2. You are receiving myelosuppressive anti-cancer medications associated with a significant incidence of severe neutropenia (medications that affect the bone marrow and cause low levels of a type of white blood cell) with fever
   C. **If the request is to increase survival if you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:**
      1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM-APGF

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nyvepria and Neulasta.

REFERENCES

- Nyvepria [Prescribing Information]. New York, NY: Pfizer; April 2021.
- Neulasta [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; February 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 10/22
Client Approval: 05/23
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM - BMEZ

GUIDELINES FOR USE

1. Does the patient have a non-myeloid malignancy and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
   - The patient had a trial of or contraindication to the preferred agent: Nyvepria (pegfilgrastim-apgf)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Is the request to increase survival in a patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome) and does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nyvepria (pegfilgrastim-apgf)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGFILGRASTIM - BMEZ (Ziextenzo)** requires the following rule(s) be met for approval:
   A. The request is for ONE of the following:
      1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
      2. You will be using Ziextenzo to increase survival if you have been acutely exposed to myelosuppressive doses of radiation (radiation that affects your blood and bone marrow)

   B. **If you have a non-myeloid malignancy, approval also requires:**
      1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
      2. You are receiving myelosuppressive anti-cancer medications associated with a significant incidence of severe neutropenia (medications that affect the bone marrow and cause low levels of a type of white blood cell) with fever
      3. You had a trial of or contraindication (harmful for) to the preferred medication: Nyvepria (pegfilgrastim-apgf)

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PEGFILGRASTIM-BMEZ

GUIDELINES FOR USE (CONTINUED)

C. **If the request is to increase survival if you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:**
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   2. You had a trial of or contraindication (harmful for) to the preferred medication: Nyvepria (pegfilgrastim-apgf)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ziextenzo and Neulasta.

REFERENCES

- Ziextenzo [Prescribing Information]. Princeton, NJ: Sandoz Inc.; March 2021.
- Neulasta [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; February 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 10/22
Client Approval: 05/23
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM - CBQV

GUIDELINES FOR USE

1. Does the patient have a non-myeloid malignancy and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
   - The patient had a trial of or contraindication to the preferred agent: Nyvepria (pegfilgrastim-apgf)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Is the requested medication for increasing survival in a patient acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome) and does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nyvepria (pegfilgrastim-apgf)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGFILGRASTIM - CBQV (Udenyca, Udenyca Onbody)** requires the following rule(s) be met for approval:
   A. The request is for ONE of the following:
      1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
      2. Increase survival if you have been acutely exposed to myelosuppressive doses of radiation (radiation that affects your blood and bone marrow)
   B. **If you have a non-myeloid malignancy, approval also requires:**
      1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
      2. You are receiving myelosuppressive anti-cancer medications associated with a significant incidence of severe neutropenia (medications that affect the bone marrow and cause low levels of a type of white blood cell) with fever
      3. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nyvepria (pegfilgrastim-apgf)

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PEGFILGRASTIM-CBQV

GUIDELINES FOR USE (CONTINUED)

C. **If the request is to increase survival if you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:**
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nyvepria (pegfilgrastim-apgf)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Udenyca and Neulasta.

REFERENCES

- Udenyca [Prescribing Information]. Redwood City, CA: Coherus BioSciences, Inc.; December 2023.
- Neulasta [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; February 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/12/24
Created: 10/22
Client Approval: 01/24
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM-FPGK

GUIDELINES FOR USE

1. Does the patient have a non-myeloid malignancy and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient is receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia
   - The patient had a trial of or contraindication to the preferred agent: Nyvepria (pegfilgrastim-apgf)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Is the request to increase survival in a patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome) and does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nyvepria (pegfilgrastim-apgf)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGFILGRASTIM-FPGK (Stimufend)** requires the following rule(s) be met for approval:
   A. The request is for ONE of the following:
      1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
      2. You will be using Stimufend to increase survival if you have been acutely exposed to myelosuppressive doses of radiation (radiation that affects your blood and bone marrow)

   B. **If you have a non-myeloid malignancy, approval also requires:**
      1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
      2. You are receiving myelosuppressive anti-cancer medications associated with a clinically significant incidence of neutropenia (medications that affect the bone marrow and cause low levels of a type of white blood cell) with fever
      3. You had a trial of or contraindication (harmful for) to the preferred medication: Nyvepria (pegfilgrastim-apgf)

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PEGFILGRASTIM-FPGK

GUIDELINES FOR USE (CONTINUED)

C. **If the request is to increase survival if you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:**
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   2. You had a trial of or contraindication (harmful for) to the preferred medication: Nyvepria (pegfilgrastim-apgf)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Stimufend and Neulasta.

REFERENCES

- Stimufend [Prescribing Information]. Lake Zurich, IL: Fresenius Kabi USA, LLC, September 2022.
- Neulasta [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; February 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 12/22
Client Approval: 05/23
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM-JMDB

GUIDELINES FOR USE

1. Does the patient have a non-myeloid malignancy and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
   - The patient had a trial of or contraindication to the preferred agent: Nyvepria (pegfilgrastim-apgf)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Is the request to increase survival in a patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome) and does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nyvepria (pegfilgrastim-apgf)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGFILGRASTIM - JMDB (Fulphila)** requires the following rule(s) be met for approval:
   A. The request is for ONE of the following:
      1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
      2. You will be using Fulphila to increase survival if you have been acutely exposed to myelosuppressive doses of radiation (radiation that affects your blood and bone marrow)

   B. **If you have a non-myeloid malignancy, approval also requires:**
      1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
      2. You are receiving myelosuppressive anti-cancer medications associated with a significant incidence of severe neutropenia (medications that affect the bone marrow and cause low levels of a type of white blood cell) with fever
      3. You had a trial of or contraindication (harmful for) to the preferred medication: Nyvepria (pegfilgrastim-apgf)

   (Denial text continued on next page)

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PEGFILGRASTIM-JMDB

GUIDELINES FOR USE (CONTINUED)

C. **If the request is to increase survival if you have been acutely exposed to myelosuppressive doses of radiation, approval also requires**:
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   2. You had a trial of or contraindication (harmful for) to the preferred medication: Nyvepria (pegfilgrastim-apgf)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fulphila and Neulasta.

REFERENCES

- Fulphila [Prescribing Information]. Zurich, Switzerland: Mylan GmbH; March 2021.
- Neulasta [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; February 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23

Created: 10/22
Client Approval: 05/23

P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM-PBBK

GUIDELINES FOR USE

1. Does the patient have a non-myeloid malignancy and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
   - The patient had a trial of or contraindication to the preferred agent: Nyvepria (pegfilgrastim-apgf)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Is the request to increase survival in a patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome) and does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Nyvepria (pegfilgrastim-apgf)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGFILGRASTIM-PBBK (Fylnetra)** requires the following rule(s) be met for approval:
   A. The request is for ONE of the following:
      1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
      2. You will be using Fylnetra to increase survival if you have been acutely exposed to myelosuppressive doses of radiation (radiation that affects your blood and bone marrow)

   B. **If you have a non-myeloid malignancy, approval also requires:**
      1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
      2. You are receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia (medications that affect the bone marrow and cause low levels of a type of white blood cell) with fever
      3. You had a trial of or contraindication (harmful for) to the preferred agent: Nyvepria (pegfilgrastim-apgf)

   (Denial text continued on next page)

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GUIDELINES FOR USE (CONTINUED)

C. **If the request is to increase survival if you have been acutely exposed to myelosuppressive doses of radiation, approval also requires**:
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   2. You had a trial of or contraindication (harmful for) to the preferred agent: Nyvepria (pegfilgrastim-apgf)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fylnetra and Neulasta.

REFERENCES

- Fylnetra [Prescribing Information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC, May 2022.
- Neulasta [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; February 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 10/22
Client Approval: 05/23
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGINTERFERON ALFA 2A OR 2B

GUIDELINES FOR USE

1. Is the request for the treatment of chronic hepatitis C virus infection (HCV)?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #2.

2. Is the request for Pegasys?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have chronic hepatitis B **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a gastroenterologist, infectious disease specialist, a physician specializing in the treatment of hepatitis (e.g., a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the patient between 3 to 17 years of age and meet **ALL** of the following criteria?
   - The patient does NOT have cirrhosis
   - The patient has serum HBeAg-positive chronic hepatitis B
   - The patient has evidence of viral replication with elevated serum alanine aminotransferase (ALT)

   If yes, **approve for 24 weeks by HICL or GPI-10 with a quantity limit of #4 per 28 days.**
   If no, continue to #5.

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PEGINTERFERON ALFA 2A OR 2B

GUIDELINES FOR USE (CONTINUED)

5. Is the patient 18 years of age or older and meet **ALL** of the following criteria?
   - The patient has serum HBeAg-positive or HBeAg-negative chronic hepatitis B
   - The patient has compensated liver disease with evidence of viral replication and liver inflammation

   If yes, **approve for 24 weeks by HICL or GPI-10 with a quantity limit of #4 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGINTERFERON ALFA-2A or 2B (Pegasys, PegIntron)** requires the following rule(s) be met for approval:
   A. You have chronic hepatitis B (a type of liver infection)
   B. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive condition), infectious disease specialist (a doctor who specializes in the treatment of infections), a doctor specializing in the treatment of hepatitis such as a hepatologist (liver doctor), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
   C. **If you are between 3 to 17 years of age, approval also requires:**
      1. You do NOT have cirrhosis (liver damage)
      2. Your blood test shows you have HBeAg (marker of active virus multiplying in the body)-positive chronic hepatitis B
      3. You have evidence of viral replication (virus is multiplying in the body) with elevated serum alanine aminotransferase (ALT: a type of liver enzyme test)
   D. **If you are 18 years of age or older, approval also requires:**
      1. Your blood test shows you have HBeAg (marker of active virus multiplying in the body)-positive or HBeAg-negative chronic hepatitis B
      2. You have compensated liver disease (a type of liver condition) with evidence of viral replication and liver inflammation

   Note: Pegasys and PegIntron will not be approved for the treatment of hepatitis C.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEGINTERFERON ALFA 2A OR 2B

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pegasys/PegIntron.

REFERENCES

- Pegasys [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; March 2021.
- Pegintron [Prescribing Information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp., January 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/01/23

Created: 02/14
Client Approval: 04/23

P&T Approval: 01/17

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEG-INTERFERON ALFA-2B

GUIDELINES FOR USE

1. Is the patient currently taking the requested medication?

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient received 5 years of therapy with Sylatron?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, **approve for 12 months by HICL or GPI-10.**

3. Does the patient have a diagnosis of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **PEG-INTERFERON ALFA-2B (Sylatron)** requires the following rule(s) be met for approval:
   A. You meet ONE of the following:
      1. You are currently taking Sylatron and have NOT received 5 years of treatment with Sylatron
      2. You have melanoma (skin cancer) with the presence of cancer cells in your lymph nodes (microscopic or gross nodal involvement), within 84 days of surgical removal of the cancer

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEG-INTERFERON ALFA-2B

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sylatron.

REFERENCES

- Sylatron [Prescribing Information]. Whitehouse Station, NJ: Merck & Co.; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/20
Created: 05/11
Client Approval: 08/20
P&T Approval: 07/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGVALIASE-PQPZ

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of phenylketonuria and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management, as confirmed by a measurement in the last 30 days
   - The patient has had a trial of Kuvan (sapropterin)
   - The patient is not concurrently receiving Kuvan (sapropterin)

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **2.5mg/0.5mL: #1mL (2 syringes) per 7 days.**
   - **10mg/0.5mL: #0.5mL (1 syringe) per day.**
   - **20mg/mL: #3mL (3 syringes) per day.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGVALIASE-PQPZ (Palynziq)** requires the following rules be met for approval:
   A. You have phenylketonuria (PKU: a type of birth defect that causes buildup of a chemical called phenylalanine)
   B. You are 18 years of age or older
   C. You have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management, as confirmed by a measurement in the last 30 days
   D. You have tried Kuvan (sapropterin)
   E. You are NOT receiving Kuvan (sapropterin) at the same time as Palynziq (pegvaliase)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEGVALIASE-PQPZ

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of phenylketonuria **AND** meet the following criterion?
   - The patient has demonstrated a reduction in phenylalanine levels, compared to baseline, by at least 20% or to a level below 600 micromol/L

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **2.5mg/0.5mL: #1mL (2 syringes) per 7 days.**
   - **10mg/0.5mL: #0.5mL (1 syringe) per day.**
   - **20mg/mL: #3mL (3 syringes) per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGVALIASE-PQPZ (Palynziq)** requires the following rules be met for renewal:
   A. You have phenylketonuria (PKU: a type of birth defect that causes buildup of a chemical called phenylalanine)
   B. Your phenylalanine levels have dropped by at least 20% from baseline or to a level under 600 micromol/L

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Palynziq.

REFERENCES

- Palynziq [Prescribing Information]. Novato, CA: BioMarin Pharmaceutical, Inc.; November 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/23
Created: 08/18
Client Approval: 03/23
P&T Approval: 07/18

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEMIGATINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable locally advanced or metastatic cholangiocarcinoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has been previously treated for unresectable locally advanced or metastatic cholangiocarcinoma
   - The patient has a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test
   - The patient will complete a comprehensive ophthalmological examination, including optical coherence tomography (OCT), prior to initiation of therapy and at the recommended scheduled intervals

   If yes, **approve for 12 months by HICL or GPI-10 for #14 per 21 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of relapsed or refractory myeloid/lymphoid neoplasms (MLNs) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a fibroblast growth factor receptor 1 (FGFR1) rearrangement
   - The patient will complete a comprehensive ophthalmological examination, including optical coherence tomography (OCT), prior to initiation of therapy and at the recommended scheduled intervals

   If yes, **approve for 12 months by HICL or GPI-10 for #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEMIGATINIB (Pemazyre)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Unresectable locally advanced or metastatic cholangiocarcinoma (bile duct cancer that has spread to nearby tissue and lymph nodes and cannot be removed by surgery, or it has spread to other parts of the body)
      2. Relapsed or refractory myeloid/lymphoid neoplasms (a type of blood cancer that has returned or did not respond to treatment)

   (Denial text continued on next page)

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PEMIGATINIB

GUIDELINES FOR USE (CONTINUED)

B. **If you have unresectable locally advanced or metastatic cholangiocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have previously been treated for unresectable locally advanced or metastatic cholangiocarcinoma
   3. You have a fibroblast growth factor receptor 2 (FGFR2: a type of protein) fusion or other rearrangement as detected by a Food and Drug Administration (FDA)-approved test
   4. You will complete a comprehensive ophthalmological examination (eye exam), including optical coherence tomography (OCT: a type of eye imaging test), before starting the medication and at the recommended scheduled times

C. **If you have relapsed or refractory myeloid/lymphoid neoplasms, approval also requires:**
   1. You are 18 years of age or older
   2. You have a fibroblast growth factor receptor 1 (FGFR1: a type of protein) rearrangement
   3. You will complete a comprehensive ophthalmological examination (eye exam), including optical coherence tomography (OCT: a type of eye imaging test), before starting the medication and at the recommended scheduled times

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pemazyre.

REFERENCES

- Pemazyre [Prescribing Information]. Wilmington, DE: Incyte Corporation; August 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/23
Created: 07/20
Client Approval: 11/22
P&T Approval: 10/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PENICILLAMINE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for D-Penamine and the patient has an active prior authorization approval for Depen?
   [Note: D-Penamine is temporarily available to address a critical drug shortage of Depen. Patients previously approved for Depen will be allowed access without additional criteria during this shortage.]

   If yes, **approve D-Penamine for 12 months by GPID or GPI-14 for the requested indication as follows:**
   - **Wilson's Disease: #16 per day.**
   - **Active Rheumatoid Arthritis: #12 per day.**
   - **Cystinuria: #32 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of Wilson's disease and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hepatologist or gastroenterologist
   - The patient has a Leipzig score of 4 or greater
   - The patient is willing to follow a diet avoiding high copper foods (e.g., shellfish, nuts, chocolate, mushrooms, organ meat)

   If yes, continue to #3.
   If no, continue to #5.

3. Is the request for Depen or D-Penamine?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested drug as follows:**
   - **Depen: #8 per day.**
   - **D-Penamine: #16 per day.**

   If no, continue to #4.

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PENICILLAMINE

INITIAL CRITERIA (CONTINUED)

4. Is the request for Cuprimine and the patient had a trial of or contraindication to Depen (penicillamine) or D-Penamine (penicillamine)?

   If yes, **approve Cuprimine for 12 months by GPID or GPI-14 with a quantity limit of #8 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Does the patient have a diagnosis of cystinuria and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a nephrologist
   - The patient has a daily cystine output that is greater than 300mg per 24 hours following urine cystine excretion testing
   - The patient has failed to respond to an adequate trial of or has a contraindication to conventional therapy which includes ALL of the following: increased fluid intake, modest reductions in sodium and protein intake, and urinary alkalinization

   If yes, continue to #6.
   If no, continue to #9.

6. Does the patient have nephrolithiasis and meet **ONE** of the following criteria?
   - The patient's stone analysis shows a presence of cystine
   - The patient's urinalysis shows pathognomonic hexagonal cystine crystals
   - The patient has a family history of cystinuria AND a positive cyanide-nitroprusside screening

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Is the request for Depen or D-Penamine?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested drug as follows:**
   - **Depen: #16 per day.**
   - **D-Penamine: #32 per day.**

   If no, continue to #8.

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PENICILLAMINE

INITIAL CRITERIA (CONTINUED)

8. Is the request for Cuprimine and has the patient had a trial of or contraindication to Depen (penicillamine) or D-Penamine (penicillamine) **AND** Thiola (tiopronin)?

   If yes, **approve Cuprimine for 12 months by GPID or GPI-14 with a quantity of #16 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

9. Does the patient have a diagnosis of active rheumatoid arthritis and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient does not have a history or other evidence of renal insufficiency
   - The patient has failed to respond to an adequate trial of at least 3 months of conventional therapy including at least ONE of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #10.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

10. Is the request for Depen or D-Penamine?

    If yes, **approve for 12 months by GPID or GPI-14 for the requested drug as follows:**
    - **Depen: #6 per day.**
    - **D-Penamine: #12 per day.**

    If no, continue to #11.

11. Is the request for Cuprimine and has the patient had a trial of or contraindication to Depen (penicillamine) or D-Penamine (penicillamine)?

    If yes, **approve Cuprimine for 12 months by GPID or GPI-14 with a quantity of #6 per day.**
    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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PENICILLAMINE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PENICILLAMINE (Cuprimine, Depen, D-Penamine)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Wilson's disease (a genetic disorder that leads to copper accumulation in the organs)
   2. Cystinuria (a type of genetic metabolic disorder)
   3. Active rheumatoid arthritis (a type of joint condition)

B. I**f you have Wilson's disease, approval also requires:**
   1. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor) or gastroenterologist (a type of digestive system doctor)
   2. You have a Leipzig score of 4 or greater (a type of diagnostic score)
   3. You are willing to follow a diet avoiding high copper foods (such as shellfish, nuts, chocolate, mushrooms, organ meat)
   4. If you are requesting Cuprimine, you had a trial of or have a contraindication (harmful for) to Depen (penicillamine) or D-Penamine (penicillamine)

C. **If you have cystinuria, approval also requires:**
   1. Therapy is prescribed by or in consultation with a nephrologist (kidney doctor)
   2. You have a daily cystine output greater than 300mg per 24 hours after urine cystine excretion testing
   3. You have failed to respond to an adequate trial of or has a contraindication (harmful for) to conventional therapy which includes ALL of the following:
      a. Increased fluid intake
      b. Modest reductions in sodium and protein intake
      c. Urinary alkalinization (a process that makes urine basic)
   4. You have nephrolithiasis (kidney stones) and ONE of the following:
      a. Your kidney stone analysis shows that there is a presence of cystine (an amino acid)
      b. Your urine analysis shows that there are hexagonal cystine crystals in your urine that are pathognomonic (signs relating to the disease)
      c. You have a family history of cystinuria and positive test results in the cyanide-nitroprusside screen (a test to determine the amount of cysteine in your body)
   5. If you are requesting Cuprimine, you had a trial of or have a contraindication (harmful for) to Depen (penicillamine) or D-Penamine (penicillamine) AND Thiola (tiopronin)

(Initial denial text continued on next page)

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PENICILLAMINE

INITIAL CRITERIA (CONTINUED)

D. **If you have active rheumatoid arthritis, approval requires:**
   1. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   2. You do not have a history or other evidence of renal insufficiency (kidney problems)
   3. You have failed to respond to an adequate trial of at least 3 months of conventional therapy including at least ONE of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. If you are requesting Cuprimine, you had a trial of or have a contraindication (harmful for) to Depen (penicillamine) or D-Penamine (penicillamine)

E. **If you have an active prior authorization approval for Depen, D-Penamine** will be approved without meeting additional criteria during the period of Depen shortage.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Wilson's disease **AND** meet the following criterion?
   - The patient has achieved a free serum copper of less than 10 mcg/dL

   If yes, **approve for lifetime by GPID or GPI-14 for the requested drug as follows:**
   - **Depen: #8 per day.**
   - **Cuprimine: #8 per day.**
   - **D-Penamine: #16 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of cystinuria **AND** meet the following criterion?
   - The patient has achieved a cystine excretion of less than 200 mg/day

   If yes, **approve for lifetime by GPID or GPI-14 for the requested drug as follows:**
   - **Depen: #16 per day.**
   - **D-Penamine: #32 per day.**
   - **Cuprimine: #16 per day.**

   If no, continue to #3.

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PENICILLAMINE

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of active rheumatoid arthritis and meet **ALL** of the following criteria?
   - The patient does not have a history of or other evidence of renal insufficiency
   - The patient has experienced or maintained improvement in tender joint count or swollen joint count while on therapy compared to baseline

   If yes, **approve for lifetime by GPID or GPI-14 for the requested drug as follows:**
   - **Depen: #6 per day.**
   - **D-Penamine: #12 per day.**
   - **Cuprimine: #6 per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PENICILLAMINE (Cuprimine, Depen, D-Penamine)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Wilson's disease (a genetic disorder that leads to copper accumulation in the organs)
      2. Cystinuria (a type of genetic metabolic disorder)
      3. Active rheumatoid arthritis (a type of joint condition)
   B. **If you have Wilson's disease, approval also requires:**
      1. You have achieved a free serum copper of less than 10 mcg/dLl
   C. **If you have cystinuria, approval also requires:**
      1. You have achieved a cystine excretion of less than 200 mg/day
   D. **If you have active rheumatoid arthritis, approval also requires:**
      1. You do not have a history of or other evidence of renal insufficiency (kidney problems)
      2. You have experienced or maintained improvement in tender joint count or swollen joint count while on therapy compared to baseline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PENICILLAMINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cuprimine/Depen/Thiola EC.

REFERENCES

- Cuprimine [Prescribing Information]. Bridgewater, NJ: Bausch Health Companies Inc.; October 2020.
- Thiola [Prescribing Information]. San Antonio, TX: Mission Pharmacal; March 2021.
- Depen [Prescribing Information]. Somerset, NJ: Meda Pharmaceuticals; January 2019.
- FDA Website: Penicillamine (Depen) Titratable Tablets Drug Shortage. Available at: https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Penicillamine%20(Depen)%20Titratable%20Tablets&st=c. Accessed on January 21, 2019

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/08/23

Created: 05/16
Client Approval: 04/23

P&T Approval: 10/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PENTOSAN POLYSULFATE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of interstitial cystitis/bladder pain syndrome ongoing for at least six weeks?

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   APPROVAL TEXT: Renewal requires that the patient has experienced clinical improvement from baseline secondary to treatment.

   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **PENTOSAN POLYSULFATE (Elmiron)** requires the following rule(s) be met for approval:
   A. You have a diagnosis of interstitial cystitis/bladder (painful bladder condition) pain syndrome ongoing for at least six weeks

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Has the patient experienced clinical improvement from baseline secondary to treatment?

   If yes, **approve for lifetime by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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PENTOSAN POLYSULFATE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PENTOSAN POLYSULFATE (Elmiron)** requires the following rule(s) be met for renewal:
A. You have experienced clinical improvement from baseline secondary to treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Elmiron.

REFERENCES

- Elmiron [Prescribing Information]. Titusville, New Jersey: Janssen Pharmaceuticals, Inc. September 2018

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20
Created: 02/20
Client Approval: 02/20
P&T Approval: 01/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PERFLUOROHEXYLOCTANE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of dry eye disease (DED) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an ophthalmologist or optometrist
   - The patient has at least one positive diagnostic test (e.g., tear breakup time, tear film osmolarity, ocular surfacing staining, Schirmer test, etc.)
   - The patient had a trial of or contraindication to ONE ocular lubricant (e.g., carboxymethylcellulose [Refresh, Celluvisc, TheraTears, etc.], polyvinyl alcohol [LiquiTears, Refresh Classic, etc.], or wetting agent [Systane, Lacri-Lube, etc.])
   - The patient had a trial of or contraindication to BOTH of the following preferred agents: Restasis (cyclosporine ophthalmic emulsion) AND Xiidra (lifitegrast ophthalmic solution)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #0.43 mL per day.** If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PERFLUOROHEXYLOCTANE (MIEBO)** requires the following rule(s) be met for approval:
   A. You have dry eye disease
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with an ophthalmologist or optometrist (types of eye doctor)
   D. You have at least one positive diagnostic test (such as tear breakup time, tear film osmolarity, ocular surfacing staining, Schirmer test)
   E. You had a trial of or contraindication (harmful for) to ONE ocular lubricant (such as carboxymethylcellulose [Refresh, Celluvisc, TheraTears], polyvinyl alcohol [LiquiTears, Refresh Classic], or wetting agent [Systane, Lacri-Lube])
   F. You had a trial of or contraindication to (harmful for) BOTH of the following preferred medications: Restasis (cyclosporine eye drop) AND Xiidra (lifitegrast eye drop)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PERFLUOROHEXYLOCTANE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of dry eye disease (DED) **AND** meet the following criterion?
   - The patient has demonstrated improvement of dry eye disease

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.43 mL per day.** If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PERFLUOROHEXYLOCTANE (MIEBO)** requires the following rule(s) be met for renewal:
   A. You have dry eye disease
   B. You have demonstrated improvement of dry eye disease

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Miebo.

REFERENCES

- Miebo [Prescribing Information]. Bridgewater, NJ: Bausch & Lomb Americas Inc.; May 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/23
Created: 06/23
Client Approval: 06/23
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEXIDARTINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of symptomatic tenosynovial giant cell tumor (TGCT) and meet **ALL** of the following criteria?
   - TGCT is associated with severe morbidity or functional limitations
   - TGCT is **NOT** amenable to improvement with surgery
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEXIDARTINIB (Turalio)** requires the following rules be met for approval:
   A. You have symptomatic tenosynovial giant cell tumor (TGCT: type of non-cancerous growth in or around a joint causing tissue damage and reducing function)
   B. TGCT is associated with severe morbidity (disease) or functional limitations
   C. TGCT is NOT responsive to improvement with surgery
   D. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Turalio.

REFERENCES

- Turalio [Prescribing Information]. Basking Ridge, NJ: Daiichi Sankyo, Inc.; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 08/19
Client Approval: 03/21
P&T Approval: 07/19

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PHENOXYBENZAMINE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of pheochromocytoma and meet **ALL** of the following criteria?
   - The requested medication is used for the treatment of pheochromocytoma prior to pheochromocytoma resection/removal
   - Therapy is prescribed by or in consultation with an endocrinologist, an endocrine surgeon, or a hematologist - oncologist
   - The patient has had a previous trial of or contraindication to an alpha-1 selective adrenergic receptor blocker (e.g., doxazosin, terazosin, or prazosin)

   If yes, **approve for one fill by HICL or GPI-10 with a quantity limit of #10 capsules per day for 21 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PHENOXYBENZAMINE (Dibenzyline)** requires the following rules be met for approval:
   A. You have pheochromocytoma (tumor in your adrenal gland)
   B. The requested drug is used to treat pheochromocytoma before pheochromocytoma surgery to remove the tumor
   C. The requested drug is prescribed by an endocrinologist (hormone doctor), an endocrine surgeon (surgeon specializing in removal of glands such as adrenal glands), or a hematologist/oncologist (cancer doctor)
   D. You must have tried an alpha-1 selective adrenergic receptor blocker (such as doxazosin, terazosin, or prazosin), unless there is a medical reason why you cannot (contraindication)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PHENOXYBENZAMINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Dibenzyline.

REFERENCES

- Dibenzyline [Prescribing Information]. Concordia Pharmaceuticals Inc.; February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 08/18
Client Approval: 04/20
P&T Approval: 07/18

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PILOCARPINE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of presbyopia and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an ophthalmologist or optometrist
   - The patient is not using corrective lenses OR corrective lenses are insufficient to completely correct patient's vision
   - The patient had a trial of or contraindication to generic pilocarpine ophthalmic solution
   - Vuity will NOT be used concurrently with another pilocarpine eyedrop

   If yes, **approve for 3 months by GPID or GPI-14 with a quantity limit of #10mL per 30 days.** If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PILOCARPINE (Vuity)** requires the following rule(s) be met for approval:
   A. You have presbyopia (not able to focus on nearby objects)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or optometrist (a type of eye doctor)
   D. You are not using corrective lenses OR corrective lenses are insufficient to completely correct your vision
   E. You have tried or have a contraindication (harmful for) to generic pilocarpine ophthalmic (eye) solution
   F. You will NOT use Vuity concurrently (at the same time) with another pilocarpine eyedrop

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PILOCARPINE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of presbyopia and meet **ALL** of the following criteria?
   - The patient is not using corrective lenses OR corrective lenses are insufficient to completely correct patient's vision
   - Vuity will NOT be used concurrently with another pilocarpine eyedrop
   - The patient continues to have benefit from Vuity

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #10mL per 30 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PILOCARPINE (Vuity)** requires the following rule(s) be met for renewal:
   A. You have presbyopia (not able to focus on nearby objects)
   B. You are not using corrective lenses OR corrective lenses are insufficient to completely correct your vision
   C. You will NOT use Vuity concurrently (at the same time) with another pilocarpine eyedrop
   D. You continue to have benefit from Vuity

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vuity.

REFERENCES

- Vuity [Prescribing Information]. North Chicago, IL: AbbVie Inc.; March 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 11/21
Client Approval: 11/23
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PIMAVANSERIN

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Parkinson's disease psychosis and meets **ALL** of the following criteria?
   - Patient is 18 years of age or older
   - Medication is prescribed by or given in consultation with a physician specializing in one of the following areas: neurology, geriatric medicine, or behavioral health (such as psychiatrist)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **Nuplazid 34mg capsules: #30 capsules per 30 days.**
   - **Nuplazid 17mg tablets: #60 tablets per 30 days.**
   - **Nuplazid 10mg tablets: #30 tablets per 30 days.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named drug named **PIMAVANSERIN (Nuplazid)** requires you to meet the following rule(s) for approval:
   A. You have a diagnosis of psychosis associated with Parkinson's disease (a mental disorder that causes you to have false beliefs or to hear or see things that are not really there and is related to a movement disorder)
   B. You are at least 18 years old; and
   C. The drug is prescribed by a doctor specializing in one of the following areas: neurology (brain doctor), geriatric medicine (specialty that focuses on health care of elderly people), or behavioral health (such as a psychiatrist).

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PIMAVANSERIN

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. During the past 12 months of therapy, has the patient experienced an improvement in psychosis symptoms from baseline and demonstrates a continued need for treatment?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **Nuplazid 34mg capsules: #30 capsules per 30 days.**
   - **Nuplazid 17mg tablets: #60 tablets per 30 days.**
   - **Nuplazid 10mg tablets: #30 tablets per 30 days.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PIMAVANSERIN (Nuplazid)** requires that you have experienced an improvement in psychosis symptoms (mental issues such as false beliefs or hearing or seeing things that are not really there) from baseline during the past 12 months of therapy and you show a continued need for treatment.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nuplazid.

REFERENCES

- Nuplazid [Prescribing Information]. San Diego, CA. Arcadia Pharmaceuticals Inc.; May 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 04/16
Client Approval: 04/20
P&T Approval: 05/16

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PIRFENIDONE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of idiopathic pulmonary fibrosis (IPF) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist
   - The patient does NOT have other known causes of interstitial lung disease (e.g., connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis, systemic sclerosis, rheumatoid arthritis, radiation, sarcoidosis, bronchiolitis obliterans organizing pneumonia, human immunodeficiency virus (HIV) infection, viral hepatitis, or cancer)
   - The patient has a usual interstitial pneumonia (UIP) pattern as evidenced by high-resolution computed tomography (HRCT) alone or via a combination of surgical lung biopsy and HRCT
   - The patient has a predicted forced vital capacity (FVC) of at least 50% at baseline
   - The patient does NOT currently smoke cigarettes

   If yes, **enter two authorizations for a total of 12 months as follows:**
   FIRST APPROVAL: Approve for 1 month by GPID or GPI-14 for all dosage strengths with the following quantity limits:
   - **267mg: #9 per day.**
   - **534mg: #3 per day.**
   - **801mg: #3 per day.**

   SECOND APPROVAL: Approve for 11 months by HICL or GPI-10 with a quantity limit of #3 per day (enter a start date of 2 days before the end of the first approval).

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PIRFENIDONE (Esbriet)** requires the following rule(s) be met for approval:
   A. You have idiopathic pulmonary fibrosis (IPF: a type of lung condition)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor)
   (Initial denial text continued on next page)

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PIRFENIDONE

INITIAL CRITERIA (CONTINUED)

D. You do NOT have other known causes of interstitial lung disease. Other causes may include connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis (type of lung infection), systemic sclerosis (chronic hardening and tightening of the skin and connective tissues), rheumatoid arthritis (a type of joint condition), radiation, sarcoidosis (a type of inflammatory disorder), bronchiolitis obliterans organizing pneumonia (infection affecting the small airways of the lung), human immunodeficiency virus infection (HIV: a type of immune disorder), viral hepatitis (a type of liver inflammation), or cancer
E. You have a usual interstitial pneumonia (type of lung infection) pattern as evidenced by high-resolution computed tomography (HRCT: type of imaging test) alone or via a combination of surgical lung biopsy (removal of cells or tissue from the body for examination) and HRCT
F. You have a predicted forced vital capacity (FVC: amount of air exhaled from lungs) of at least 50% at baseline
G. You do NOT currently smoke cigarettes

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of idiopathic pulmonary fibrosis (IPF) **AND** meet the following criterion?
   - The patient has experienced a clinically meaningful improvement or maintenance in annual rate of decline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PIRFENIDONE (Esbriet)** requires the following rule(s) be met for renewal:
   A. You have idiopathic pulmonary fibrosis (IPF: a type of lung condition)
   B. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PIRFENIDONE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Esbriet.

REFERENCES

- Esbriet [Prescribing Information]. South San Francisco, CA: Genentech USA, Inc.; February 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/23
Created: 02/15
Client Approval: 11/22
P&T Approval: 10/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PIRTOBRUTINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory mantle cell lymphoma (MCL) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least TWO lines of systemic therapy including a Bruton's tyrosine kinase (BTK) inhibitor (e.g., Imbruvica [ibrutinib], Calquence [acalabrutinib], Brukinsa [zanubrutinib])

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **50 mg: #3 per day.**
   - **100 mg: #2 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least TWO prior lines of therapy, including a Bruton's tyrosine kinase (BTK) inhibitor (e.g., Imbruvica [ibrutinib], Calquence [acalabrutinib], Brukinsa [zanubrutinib]) AND a B-cell lymphoma-2 (BCL-2) inhibitor (e.g., Venclexta [venetoclax])

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **50 mg: #3 per day.**
   - **100 mg: #2 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PIRTOBRUTINIB

GUIDELINES FOR USE (CONTINUED FOR USE)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PIRTOBRUTINIB (Jaypirca)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Relapsed or refractory mantle cell lymphoma (MCL: type of white blood cell cancer)
   2. Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) (types of blood cancers)

B. **If you have relapsed or refractory mantle cell lymphoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have previously received at least TWO lines of systemic therapy (treatment that targets the entire body) for mantle cell lymphoma, including a BTK inhibitor (Bruton's tyrosine kinase inhibitor such as Imbruvica [ibrutinib], Calquence [acalabrutinib], Brukinsa [zanubrutinib])

C. **If you have chronic lymphocytic leukemia or small lymphocytic lymphoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have previously received at least TWO prior lines of therapy (treatment that targets the entire body), including a BTK inhibitor (Bruton's tyrosine kinase inhibitor such as Imbruvica [ibrutinib], Calquence [acalabrutinib], Brukinsa [zanubrutinib]) AND a BCL-2 inhibitor (B-cell lymphoma-2 inhibitor such as Venclexta [venetoclax])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Jaypirca.

REFERENCES

- Jaypirca [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; December 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 05/23
Client Approval: 12/23
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PITOLISANT

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy and narcolepsy is confirmed by **ONE** of the following criteria?
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less **AND** 2 or more early-onset rapid eye movement (REM) sleep test periods (SOREMPs)
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less **AND** one early-onset rapid eye movement (REM) sleep test period (SOREMP) **AND** additionally one SOREMP (within approximately 15 minutes) on a polysomnography the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness (EDS)
   - The patient has low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ALL** of the following criteria?
   - The patient has excessive daytime sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient had a trial of or contraindication to one generic typical stimulant (e.g., amphetamine sulfate, methylphenidate, etc.) **AND** solriamfetol, armodafinil, or modafinil

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PITOLISANT

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of cataplexy with narcolepsy and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient has tried **TWO** of the following: venlafaxine, fluoxetine or a TCA (e.g., clomipramine, imipramine)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PITOLISANT (Wakix)** requires the following rule(s) be met for approval:
   A. You have one of the following:
      1. Excessive daytime sleepiness (EDS) with narcolepsy (sleep disorder with extreme drowsiness)
      2. Narcolepsy as demonstrated by cataplexy (sleep disorder with extreme drowsiness with sudden and uncontrollable muscle weakness)
   B. **If you have excessive daytime sleepiness with narcolepsy, approval also requires:**
      1. You have narcolepsy that is confirmed by **ONE** of the following:
         a. A Multiple Sleep Latency Test showing a both an average sleep latency of 8 minutes or less **AND** 2 or more early-onset rapid eye movement (REM) sleep test periods
         b. A Multiple Sleep Latency Test (MSLT) showing both an average sleep latency of 8 minutes or less **AND** one early-onset rapid eye movement (REM) sleep test period (SOREMP) **AND** additionally one SOREMP (within approximately 15 minutes) on a polysomnography (type of sleep test) the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness
         c. You have low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing you have low levels of a chemical that helps with staying awake)
      2. You have excessive daytime sleepiness (EDS) lasting for at least 3 months and Epworth Sleepiness Scale (type of sleepiness test) score of more than 10
      3. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
      4. You had a trial of one generic typical stimulant (such as amphetamine sulfate, methylphenidate, etc.) AND solriamfetol, armodafinil, or modafinil, unless there is a medical reason why you cannot (contraindication)

   (Initial denial text continued on next page)

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PITOLISANT

INITIAL CRITERIA (CONTINUED)

C. **If you have cataplexy with narcolepsy, approval also requires:**
   1. Wakix is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   2. You have tried TWO of the following: venlafaxine, fluoxetine, or a TCA (tricyclic antidepressant such as clomipramine, imipramine)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy or cataplexy with narcolepsy and meet **ONE** of the following criteria?
   - The patient has demonstrated 25% or more improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline
   - The patient has shown improvement in cataplexy symptoms compared to baseline
   - The patient has demonstrated improvement in sleep latency from baseline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PITOLISANT (Wakix)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Excessive daytime sleepiness (EDS) with narcolepsy (sleep disorder with extreme drowsiness)
      2. Narcolepsy as demonstrated by cataplexy (sleep disorder with extreme drowsiness with sudden and uncontrollable muscle weakness)
   B. You meet ONE of the following:
      1. You have demonstrated 25% or more improvement in Epworth Sleepiness Scale (type of sleepiness test) scores compared to baseline
      2. You have shown improvement in cataplexy (sudden and uncontrollable muscle weakness) symptoms compared to baseline
      3. You have demonstrated improvement in sleep latency (the amount of time it takes to fall asleep) from baseline

   (Renewal denial text continued on next page)

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PITOLISANT

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Wakix.

REFERENCES

- Wakix [Prescribing Information]. Plymouth Meeting, PA: Harmony Biosciences, LLC; October 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/23

Created: 10/19
Client Approval: 11/22

P&T Approval: 10/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PLASMINOGEN

GUIDELINES FOR USE

1. Does the patient have a diagnosis of plasminogen deficiency type 1 (hypoplasminogenemia)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PLASMINOGEN (Ryplazim)** requires the following rule(s) be met for approval:
   A. You have a diagnosis of plasminogen deficiency type 1 (hypoplasminogenemia: a type of genetic condition)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ryplazim.

REFERENCES

- Ryplazim [Prescribing Information]. Laval, Quebec, Canada: Prometic Bioproduction, Inc.; June 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 01/22
Client Approval: 02/22
P&T Approval: 01/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

POMALIDOMIDE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma (MM) and meet ALL of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used in combination with dexamethasone
   - The patient has received at least two prior therapies including Revlimid (lenalidomide) and a proteasome inhibitor (e.g., Velcade [bortezomib], Kyprolis [carfilzomib], or Ninlaro [ixazomib])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #21 per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of Kaposi sarcoma (KS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient meets ONE of the following criteria:
     - The patient has AIDS-related Kaposi sarcoma after failing highly active antiretroviral therapy (HAART)
     - The patient is HIV-negative

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **POMALIDOMIDE (Pomalyst)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Multiple myeloma (MM: cancer that forms in your white blood cells)
      2. Kaposi sarcoma (KS: cancer that forms from the cells in your lymph or blood vessels)
   B. **If you have multiple myeloma, approval also requires:**
      1. You are 18 years of age or older
      2. The requested medication is used in combination with dexamethasone
      3. You have tried at least two drugs including Revlimid (lenalidomide) and a proteasome inhibitor (type of cancer drug such as Velcade [bortezomib], Kyprolis [carfilzomib], or Ninlaro [ixazomib])

   (Denial text continued on next page)

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POMALIDOMIDE

GUIDELINES FOR USE (CONTINUED)

C. **If you have Kaposi sarcoma, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. You have acquired immunodeficiency syndrome (AIDS)-related Kaposi sarcoma after failing highly active antiretroviral therapy (HAART: medications used to treat human immunodeficiency virus [HIV])
      b. You are human immunodeficiency virus (HIV)-negative

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pomalyst.

REFERENCES

- Pomalyst [Prescribing Information]. Summit, NJ: Celgene Corporation; May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 02/13
Client Approval: 06/20
P&T Approval: 07/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PONATINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic myeloid leukemia (CML) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a mutational analysis prior to initiation AND Iclusig is appropriate per the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile *(Please see header CML-5 of the current NCCN guidelines)*

   If yes, continue to #2.
   If no, continue to #5.

2. Does the patient have T315I-positive CML (chronic phase, accelerated phase, or blast phase)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #3.

3. Does the patient have chronic phase (CP) chronic myeloid leukemia (CML) **AND** meet the following criterion?
   - The patient has a resistance or intolerance to at least TWO prior kinase inhibitors [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #4.

4. Does the patient have accelerated phase (AP) or blast phase (BP) chronic myeloid leukemia (CML) **AND** meet the following criterion?
   - There are no other kinase inhibitors [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)] indicated for the patient

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PONATINIB

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient meet **ONE** of the following criteria?
   - The patient's cancer is positive for the T315I mutation
   - There are no other kinase inhibitors [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)] indicated for the patient
   - The patient is newly diagnosed AND Iclusig will be used in combination with chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **PONATINIB (Iclusig)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Chronic myeloid leukemia (CML: type of blood cancer)
      2. Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL: a type of white blood cell cancer)
   B. **If you have chronic myeloid leukemia, approval also requires:**
      1. You are 18 years of age or older
      2. You had a mutational analysis (a type of test) before starting therapy AND Iclusig is appropriate per the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1; a type of abnormal gene) profile
      3. You meet ONE of the following:
         a. You have T315I-positive (a genetic mutation) CML (chronic phase, accelerated phase, or blast phase)
         b. You have chronic phase CML AND have a resistance to or are not able to safely use at least TWO prior kinase inhibitor treatments such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)
         c. You have accelerated phase or blast phase CML AND there are no other kinase inhibitors, such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib), that can be used for your disease

   (Denial text continued on next page)

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PONATINIB

GUIDELINES FOR USE (CONTINUED)

C. **If you have Philadelphia chromosome positive acute lymphoblastic leukemia, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. Your cancer is positive for the T315I mutation (a type of abnormal gene)
      b. There are no other kinase inhibitors [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)] indicated for the patient
      c. You are newly diagnosed AND Iclusig will be used in combination with chemotherapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Iclusig.

REFERENCES

- Iclusig [Prescribing Information]. Cambridge, MA: ARIAD Pharmaceuticals, Inc.; March 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/15/24
Created: 01/13
Client Approval: 03/24
P&T Approval: 04/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PONESIMOD

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS), including clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease, **AND** meet the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial and failure of ONE sphingosine-1-phosphate receptor modulator (e.g., Gilenya, Mayzent) **AND** ONE other agent indicated for the treatment of MS

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PONESIMOD (Ponvory)** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (type of disease where body attacks its own nerves and symptoms return after treatment) to include clinically isolated syndrome (occurs once), relapsing-remitting disease (periods of symptoms and no symptoms), and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older
   C. You had a trial of one sphingosine-1-phosphate receptor modulator (such as Gilenya or Mayzent) AND one other agent indicated for the treatment of multiple sclerosis (**Please note**: Other multiple sclerosis agents may also require prior authorization)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ponvory.

REFERENCES

- Ponvory [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; March 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 03/21
Client Approval: 03/21
P&T Approval: 01/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

POSACONAZOLE

GUIDELINES FOR USE

1. Is the request for continuation of therapy after the patient was started on posaconazole in the hospital?

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, continue to #2.

2. Is the request for the treatment of invasive aspergillosis and the patient meets **ALL** of the following criteria?
   - The patient is 13 years of age or older
   - The request is for posaconazole (Noxafil) tablets

   If yes, **approve for 12 weeks by GPID or GPI-14.**
   If no, continue to #3.

3. Is the request for prophylaxis of invasive aspergillus or candida infections **AND** the patient meets the following criterion?
   - The patient is at high risk of developing these infections due to being severely immunocompromised, such as HSCT recipients with GVHD or has a hematologic malignancy with prolonged neutropenia from chemotherapy

   If yes, continue to #4.
   If no, continue to #7.

4. Is the request for posaconazole (Noxafil) tablets and the patient meets **ONE** of following criteria?
   - The patient is 18 years of age or older
   - The patient is 2 years of age or older AND weighs greater than 40 kg

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, continue to #5.

5. Is the request for posaconazole (Noxafil) oral suspension and the patient meets **ALL** of the following criteria?
   - The patient is 13 years of age or older
   - The patient is unable to swallow tablets

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, continue to #6.

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POSACONAZOLE

GUIDELINES FOR USE (CONTINUED)

6. Is the request for posaconazole (Noxafil) PowderMix and the patient meets **ALL** of the following criteria?
   - The patient is 2 to less than 18 years of age AND weighs less than 40 kg
   - The patient is unable to swallow tablets

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Does the patient have a diagnosis of oropharyngeal candidiasis (OPC) and meet **ALL** of the following criteria?
   - The patient is 13 years of age or older
   - The patient had a trial of or contraindication to fluconazole OR itraconazole
   - The request is for posaconazole (Noxafil) oral suspension

   If yes, **approve for 3 months by GPID or GPI-14.**
   If no, continue to #8.

8. Does the patient have a diagnosis of esophageal candidiasis and meet **ALL** of the following criteria?
   - The patient is 13 years of age or older
   - The patient had a trial and failure of or contraindication to two of the following: fluconazole, itraconazole solution, or voriconazole

   If yes, **approve for 3 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **POSACONAZOLE (Noxafil)** requires the following rule(s) be met for approval:
   A. The request is for ONE of the following:
      1. Continuation of therapy after hospital discharge
      2. Treatment of invasive aspergillosis (type of fungal infection)
      3. Prophylaxis (prevention) of invasive aspergillus or candida infections (types of fungal infection)
      4. Oropharyngeal candidiasis (fungal infection of the throat)
      5. Esophageal candidiasis (fungal infection in the tube connecting the throat and stomach)

   (Denial text continued on next page)

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POSACONAZOLE

GUIDELINES FOR USE (CONTINUED)

B. **If the request is for treatment of invasive aspergillosis, approval also requires:**
   1. You are 13 years of age or older
   2. You are requesting Noxafil (posaconazole) tablets

C. **If the request is for prophylaxis of invasive aspergillus or candida infections, approval also requires:**
   1. You are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplantation (HSCT: bone marrow transplant) recipient with graft versus host disease (GVHD: a type of immune disorder) or you have hematologic malignancies (cancer affecting the blood) with prolonged neutropenia (low levels of a type of white blood cell) from chemotherapy (cancer treatment)
   2. If the request is for posaconazole (Noxafil) tablets, you meet ONE of the following:
      a. You are 18 years of age or older
      b. You are 2 years of age or older AND weigh greater than 40 kg
   3. If the request is for posaconazole (Noxafil) suspension, you meet ALL of the following:
      a. You are 13 years of age or older
      b. You are unable to swallow tablets
   4. If the request is for posaconazole (Noxafil) PowderMix, you meet the following:
      a. You are 2 to 18 years of age AND weigh less than 40 kg
      b. You are unable to swallow tablets

D. **If the request is for oropharyngeal candidiasis, approval also requires:**
   1. You are 13 years of age or older
   2. You had a trial of or contraindication (harmful for) to fluconazole OR itraconazole
   3. You are requesting Noxafil (posaconazole) oral suspension

E. **If the request is for esophageal candidiasis, approval also requires:**
   1. You are 13 years of age or older
   2. You had a trial and failure of or contraindication (harmful for) to TWO of the following: fluconazole, itraconazole solution, or voriconazole

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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POSACONAZOLE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Noxafil.

REFERENCES

- Noxafil [Prescribing Information]. Whitehouse Station, NJ: Merck & Co., Inc.; January 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/23

Created: 11/07
Client Approval: 11/22

P&T Approval: 10/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PRALSETINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced or metastatic *RET* fusion-positive thyroid cancer?

   If yes, do not approve. (**NOTE**: This indication has been withdrawn and no longer approved by FDA.)
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a *RET* fusion-positive tumor, as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **PRALSETINIB (Gavreto)** requires the following rule(s) be met for approval:
   A. You have metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
   B. You are 18 years of age or older
   C. You have a rearranged during transfection (*RET*) fusion-positive (a type of gene mutation) tumor that has been detected by a Food and Drug Administration (FDA)-approved test

   NOTE: Advanced or metastatic rearranged during transfection (RET) fusion-positive thyroid cancer indication has been withdrawn and no longer approved by FDA.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PRALSETINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gavreto.

REFERENCES

- Gavreto [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; March 2024.
- Withdrawn Cancer Accelerated Approvals website. Available at: https://www.fda.gov/drugs/resources-information-approved-drugs/withdrawn-cancer-accelerated-approvals. Accessed 4/15/2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/01/24
Created: 10/20
Client Approval: 04/24
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PYRIMETHAMINE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the patient being treated for acute toxoplasmosis **AND** meets the following criterion?
   - The medication is prescribed by or given in consultation with an infectious disease specialist

   If yes**, approve for 6 weeks by GPID or GPI-10. Please enter two authorizations as follows:**
   - **Approve one fill for #8 per day.**
   - **Approve for 6 weeks with a quantity limit of #3 per day.**

   APPROVAL TEXT: Renewal requires that the patient has persistent clinical disease (headache, neurological symptoms, or fever) and persistent radiographic disease (one or more mass lesions on brain imaging).

   If no, continue to #2.

2. Is the patient being treated for chronic maintenance of toxoplasmosis and meets **ALL** of the following criteria?
   - The patient is infected with human immunodeficiency virus (HIV)
   - The patient has successfully completed treatment for acute toxoplasmosis for at least 6 weeks treatment duration
   - The medication is prescribed by or given in consultation with an infectious disease specialist

   If yes, **approve for 6 months by GPID or GPI-10 with a quantity limit of #2 per day.**
   APPROVAL TEXT: Renewal requires that the patient's CD4 count is less than 200 cells/mm(3) and the patient is currently taking ART (anti-retroviral therapy).

   If no, continue to #3.

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PYRIMETHAMINE

INITIAL CRITERIA (CONTINUED)

3. Is the patient being treated for primary prophylaxis of toxoplasmosis and meets **ALL** of the following criteria?
   - The patient is infected with human immunodeficiency virus (HIV)
   - The medication is prescribed by or given in consultation with an infectious disease specialist
   - The patient had a previous trial of or contraindication to Bactrim (SMX/TMP)
   - The patient is positive for *Toxoplasma gondii* IgG
   - The patient has a CD4 count of less than 100 cells/mm(3)

   If yes, **approve for 6 months by GPID or GPI-10 with a quantity limit of #3 per day.**
   APPROVAL TEXT: Renewal requires that the patient's CD4 count is less than 200 cells/mm(3) and the patient is currently taking ART (anti-retroviral therapy).

   If no, continue to #4.

4. Does the patient have a diagnosis of congenital toxoplasmosis **AND** meet the following criterion?
   - The medication is prescribed by or given in consultation with a neonatologist or pediatric infectious disease specialist

   If yes, **approve for 12 months by GPID or GPI-10.**
   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline for **PYRIMETHAMINE (Daraprim)** requires the following rule(s) be met for approval:
   A. The request is ONE of the following:
      1. Acute treatment of toxoplasmosis (sudden and severe type of parasite infection)
      2. Chronic maintenance therapy for toxoplasmosis
      3. Primary prophylaxis of toxoplasmosis (prevention of a type of parasite infection)
      4. Congenital toxoplasmosis (the infection was passed on to you as a baby from your mother)
   B. **If you are being treated for acute toxoplasmosis, approval also requires:**
      1. The medication is prescribed by or given in consultation with an infectious disease specialist (doctor that specializes in treating infections)

   (Initial denial text continued on next page)

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PYRIMETHAMINE

INITIAL CRITERIA (CONTINUED)

C. **If you are being treated for chronic maintenance for toxoplasmosis, approval also requires:**
   1. You are also infected with human immunodeficiency virus (HIV: a virus that weakens your immune system with a parasite infection)
   2. You have successfully completed treatment for acute toxoplasmosis for at least 6 weeks treatment duration
   3. The medication is prescribed by or given in consultation with an infectious disease specialist (doctor that specializes in treating infections)

D. **If you are being treated for primary prophylaxis of toxoplasmosis, approval also requires:**
   1. You are also infected with human immunodeficiency virus (HIV)
   2. The medication is prescribed by or given in consultation with an infectious disease specialist (doctor that specializes in treating infections)
   3. You had a previous trial of Bactrim (sulfamethoxazole and trimethoprim), unless there is a medication reason why cannot (contraindication)
   4. You tested positive for *Toxoplasma gondii* (a type of parasite) Immunoglobulins (IgG) (i.e., you had a current or past infection with *Toxoplasma gondii)*
   5. Your CD4 count (an indicator of how weak your immune system is) is less than 100 cells/mm(3)

E. **If you have congenital toxoplasmosis, approval also requires:**
   1. The medication is prescribed by or given in consultation with a neonatologist (doctor that specializes in sick and premature newborn infants) or pediatric (children and adolescents) infectious disease specialist

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

NOTE: For the diagnosis of congenital toxoplasmosis, please refer to Initial Criteria section.

1. Is the patient being treated for acute toxoplasmosis **AND** meets the following criterion?
   - The patient has persistent clinical disease (headache, neurological symptoms, or fever) and persistent radiographic disease (one or more mass lesions on brain imaging)

   If yes, **approve for 6 weeks by GPID or GPI-10 with a quantity limit of #3 per day.**
   If no, continue to #2.

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PYRIMETHAMINE

RENEWAL CRITERIA (CONTINUED)

2. Is the patient being treated for chronic maintenance of toxoplasmosis OR primary prophylaxis of toxoplasmosis and meets **ALL** of the following criteria?
   - The patient is infected with human immunodeficiency virus (HIV)
   - The patient has a CD4 count of less than 200 cells/mm(3)
   - The patient is currently taking ART (anti-retroviral therapy)

   If yes, **approve for 6 months by GPID or GPI-10 as follows:**
   - **Chronic maintenance of toxoplasmosis: #2 per day.**
   - **Primary prophylaxis of toxoplasmosis: #3 per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline for **PYRIMETHAMINE (Daraprim)** requires the following rule(s) be met for renewal:
   A. The request is ONE of the following:
      1. Acute treatment of toxoplasmosis (sudden and severe type of parasite infection)
      2. Chronic maintenance therapy for toxoplasmosis
      3. Primary prophylaxis of toxoplasmosis (prevention of a type of parasite infection)
   B. **If you are being treated for acute toxoplasmosis, renewal also requires:**
      1. You have persistent clinical disease (headache, neurological symptoms, or fever) and persistent radiographic disease (one or more mass lesions on brain imaging)
   C. **If you are being treated for chronic maintenance of toxoplasmosis OR primary prophylaxis for toxoplasmosis, renewal also requires:**
      1. You are also infected with human immunodeficiency virus (HIV: a virus that weakens your immune system with a parasite infection)
      2. Your CD4 count (an indicator of how weak your immune system is) is less than 200 cells/mm(3)
      3. You are currently taking ART (anti-retroviral therapy)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PYRIMETHAMINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Daraprim.

REFERENCES

- Daraprim [Prescribing Information]. New York, NY: Vyera Pharmaceuticals LLC., August 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20
Created: 10/15
Client Approval: 02/20
P&T Approval: 01/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

QUIZARTINIB

GUIDELINES FOR USE

1. Does the patient have newly diagnosed acute myeloid leukemia (AML) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is FLT3 internal tandem duplication (ITD)-positive as detected by a Food and Drug Administration (FDA)-approved test

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Will Vanflyta be used in combination with standard cytarabine and anthracycline (e.g., daunorubicin, idarubicin) for induction therapy, followed by use with cytarabine as consolidation therapy?

   If yes, **approve for 6 months for all strengths by GPID or GPI-14 with the following quantity limits:**
   - **17.7 mg: #28 per fill for a total of 6 fills.**
   - **26.5 mg: #14 per fill for a total of 6 fills.**

   If no, continue to #3.

3. Will Vanflyta be used as maintenance monotherapy following consolidation chemotherapy?

   If yes, **approve for 34 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **QUIZARTINIB (Vanflyta)** requires the following rule(s) be met for approval:
   A. You have newly diagnosed acute myeloid leukemia (AML: a type of blood cancer)
   B. You are 18 years of age or older
   C. Your cancer is FMS-like tyrosine kinase 3 internal tandem duplication (FLT3-ITD: a type of mutation) positive as detected by a Food and Drug Administration (FDA)-approved test
   (Denial text continued on the next page)

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QUIZARTINIB

GUIDELINES FOR USE (CONTINUED)

D. You meet ONE of the following:
   1. Vanflyta will be used in combination with standard cytarabine and anthracycline (such as daunorubicin, idarubicin) as induction therapy (a type of therapy to treat cancer), followed by use with cytarabine as consolidation therapy (type of therapy to treat cancer)
   2. Vanflyta will be used as maintenance monotherapy (one drug treatment) following consolidation chemotherapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vanflyta.

REFERENCES

- Vanflyta [Prescribing Information]. Basking Ridge, NJ: Daiichi Sankyo, Inc.; July 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 12/01/23
Created: 11/23
Client Approval: 11/23
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RANOLAZINE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic angina and meet **ALL** the following criteria?
   - The patient had a trial of or contraindication to ranolazine ER tablets
   - The patient is unable to swallow ranolazine ER tablets
   - The patient had a trial of or contraindication to a nitrate (e.g., nitroglycerin, isosorbide mononitrate, isosorbide dinitrate)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **500mg: #2 per day.**
   - **1000mg: #2 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RANOLAZINE (Aspruzyo Sprinkle)** requires the following rule(s) be met for approval:
   A. You have chronic angina (a type of heart condition)
   B. You had a trial of or contraindication (harmful for) to ranolazine ER (extended release) tablets
   C. You are unable to swallow ranolazine ER tablets
   D. You had a trial of or contraindication (harmful for) to a nitrate (such as nitroglycerin, isosorbide mononitrate, isosorbide dinitrate)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RANOLAZINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Aspruzyo Sprinkle.

REFERENCES

- Aspruzyo Sprinkle [Prescribing Information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; March 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/22

Created: 08/22
Client Approval: 09/22

P&T Approval: 07/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

REGORAFENIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic colorectal cancer (CRC) and meet **ALL** of the following criteria?
   - The patient has received previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (e.g., FOLFOX, FOLFIRI, FOLFOXIRI, CapeOx, infusional 5-FU/LV, capecitabine)
   - The patient has received previous treatment with an anti-VEGF therapy (e.g., Avastin [bevacizumab], Zaltrap [ziv-aflibercept])

   If yes, continue to #2.
   If no, continue to #4.

2. Is the colorectal cancer RAS wild-type (mutation negative)?

   If yes, continue to #3.
   If no, **approve for 12 months by HICL or GPI-10 with a quantity limit of #84 per 28 days.**

3. Has the patient received previous treatment with an anti-EGFR therapy (e.g., Erbitux [cetuximab], Vectibix [panitumumab])?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #84 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a diagnosis of locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST) **AND** meet the following criterion?
   - The patient has received previous treatment with Gleevec (imatinib) and Sutent (sunitinib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #84 per 28 days.**
   If no, continue to #5.

5. Does the patient have a diagnosis of hepatocellular carcinoma (HCC) **AND** meet the following criterion?
   - The patient has received previous treatment with Nexavar (sorafenib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #84 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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REGORAFENIB

GUIDELINE FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **REGORAFENIB (Stivarga)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic colorectal cancer (CRC: a type of digestive cancer that has spread to other parts of the body)
   2. Locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST: a type of digestive tumor that has spread from where it started to nearby tissue or lymph nodes, unable to remove by surgery, or has spread to other parts of the body)
   3. Hepatocellular carcinoma (HCC: a type of liver cancer)

B. **If you have metastatic colorectal cancer, approval also requires:**
   1. You had previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy such as FOLFOX, FOLFIRI, FOLFOXIRI, CapeOx, infusional 5-FU/LV, capecitabine
   2. You had previous treatment with an anti-VEGF therapy such as Avastin (bevacizumab), Zaltrap (ziv-aflibercept)
   3. If you have RAS wild-type (a type of unmutated gene) metastatic colorectal cancer, approval also requires you had previous treatment with an anti-EGFR therapy such as Erbitux (cetuximab), Vectibix (panitumumab)

C. **If you have locally advanced, unresectable, or metastatic gastrointestinal stromal tumor, approval also requires:**
   1. You had previous treatment with Gleevec (imatinib) and Sutent (sunitinib)

D. **If you have hepatocellular carcinoma, approval also requires:**
   1. You had previous treatment with Nexavar (sorafenib)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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REGORAFENIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Stivarga.

REFERENCES

- Stivarga [Prescribing Information]. Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc, December 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22

Created: 10/12
Client Approval: 03/22

P&T Approval: 07/17

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RELUGOLIX

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced prostate cancer **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for a total of 12 months as follows:**
   FOR INITIAL REQUESTS:
   - **FIRST APPROVAL: Approve for 1 month by HICL or GPI-10 with a quantity limit of #30 per 28 days.**
   - **SECOND APPROVAL: Approve for 11 months by HICL or GPI-10 with a quantity limit of #1 per day (Please enter a start date of 3 WEEKS AFTER the START date of the first approval).**

   FOR SUBSEQUENT/MAINTENANCE REQUESTS:
   - **Approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RELUGOLIX (Orgovyx)** requires the following rule(s) be met for approval:
   A. You have advanced prostate cancer
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orgovyx.

REFERENCES

- Orgovyx [Prescribing Information]. Brisbane, CA: Myovant Sciences, Inc.; December 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/21
Created: 02/21
Client Approval: 02/21
P&T Approval: 01/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RELUGOLIX-ESTRADIOL-NORETHINDRONE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Has the patient received a total of 24 months cumulative treatment with Myfembree?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #2.

2. Is the request for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) and the patient meets **ALL** the following criteria?
   - The patient is 18 years of age or older
   - The patient is a premenopausal woman
   - Therapy is prescribed by or in consultation with an obstetrician or gynecologist (OB/GYN)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #3.

3. Is the request for the management of moderate to severe pain associated with endometriosis and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is a premenopausal woman
   - Therapy is prescribed by or in consultation with an obstetrician or gynecologist (OB/GYN)
   - The patient's diagnosis is confirmed via surgical or direct visualization (e.g., pelvic ultrasound) or histopathological confirmation (e.g., laparoscopy or laparotomy) in the last 10 years
   - Myfembree will NOT be used concurrently with another GnRH-modulating agent (e.g., Orilissa, Lupron Depot, Synarel)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day**.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RELUGOLIX-ESTRADIOL-NORETHINDRONE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RELUGOLIX-ESTRADIOL-NORETHINDRONE (Myfembree)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
   2. Management of moderate to severe pain associated with endometriosis (condition affecting the uterus)

B. **If the request is for management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids), approval also requires:**
   1. You are 18 years of age or older
   2. You are a premenopausal (before menopause) woman
   3. Therapy is prescribed by or in consultation with an obstetrician or gynecologist (OB/GYN: a type of women's health doctor)
   4. You have not received a total of 24 months cumulative (total) treatment with Myfembree

C. **If the request is for management of moderate to severe pain associated with endometriosis, approval also requires:**
   1. You are 18 years of age or older
   2. You are a premenopausal (before menopause) woman
   3. Therapy is prescribed by or in consultation with an obstetrician or gynecologist (OB/GYN: a type of women's health doctor)
   4. Your diagnosis of endometriosis is confirmed via surgical or direct visualization (such as pelvic ultrasound [type of imaging]) or histopathological (tissue) confirmation (such as laparoscopy [type of surgery] or laparotomy [type of surgery]) in the last 10 years
   5. Myfembree will NOT be used concurrently (at the same time) with another GnRH-modulating agent (such as Orilissa, Lupron Depot, Synarel)
   6. You have not received a total of 24 months cumulative (total) treatment with Myfembree

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RELUGOLIX-ESTRADIOL-NORETHINDRONE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Has the patient received a total of 24 months cumulative treatment with Myfembree?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #2.

2. Is the request for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) **AND** the patient meets the following criterion?
   - The patient has had improvement of heavy menstrual bleeding

   If yes, **approve for 18 months (or up to 24 months cumulative lifetime treatment duration) by HICL or GPI-10 with a quantity limit of #1 per day.**

   If no, continue to #3.

3. Is the request for the management of moderate to severe pain associated with endometriosis and the patient meets **ALL** of the following criteria?
   - The patient has had improvement in pain related to endometriosis
   - Myfembree will NOT be used concurrently with another GnRH-modulating agent (e.g., Orilissa, Lupron Depot, Synarel)

   If yes, **approve for 18 months (or up to 24 months cumulative lifetime treatment duration) by HICL or GPI-10 with a quantity limit of #1 per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **RELUGOLIX-ESTRADIOL-NORETHINDRONE (Myfembree)** requires the following rule(s) be met for renewal:
   A. The request is for ONE of the following:
      1. Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
      2. Management of moderate to severe pain associated with endometriosis (condition affecting the uterus)

   (Renewal denial text continued on next page)

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RELUGOLIX-ESTRADIOL-NORETHINDRONE

RENEWAL CRITERIA (CONTINUED)

B. **If the request is for management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids), renewal also requires:**
   1. You had improvement of heavy menstrual bleeding on therapy
   2. You have not received a total of 24 months cumulative (total) treatment with Myfembree

C. **If the request is for management of moderate to severe pain associated with endometriosis, renewal also requires:**
   1. You have had improvement in pain related to endometriosis while on therapy
   2. Myfembree will NOT be used concurrently (at the same time) with another GnRH-modulating agent (such as Orilissa, Lupron Depot, Synarel)
   3. You have not received a total of 24 months cumulative (total) treatment with Myfembree

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Myfembree.

REFERENCES

- Myfembree [Prescribing Information]. Brisbane, CA: Myovant Sciences, Inc., August 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/12/22
Created: 06/21
Client Approval: 08/22
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

REPOTRECTINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has *ROS1*-positive tumors

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **REPOTRECTINIB (Augtyro)** requires the following rule(s) be met for approval:
   A. You have locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
   B. You are 18 years of age or older
   C. You have *ROS1*-positive (abnormal change in a type of gene) tumors

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Augtyro.

REFERENCES

- Augtyro [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; November 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 11/23
Client Approval: 11/23
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RESMETIROM

GUIDELINES FOR USE

INITIAL CRITERA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of non-alcoholic steatohepatitis (NASH) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient does not have cirrhosis
   - Therapy is prescribed by or in consultation with a hepatologist or gastroenterologist
   - The patient is enrolled in or has already completed a lifestyle intervention (e.g., dietary, exercise, psychology)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the NASH diagnosis been confirmed by biopsy or noninvasive testing (e.g., elastography), obtained within the past 12 months, which demonstrates **ALL** of the following?
   - The patient has liver fibrosis stage 2 or 3
   - The patient has a non-alcoholic fatty liver disease (NAFLD) Activity Score (NAS) of at least 4

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RESMETIROM (Rezdiffra)** requires the following rule(s) be met for approval:
   A. You have non-alcoholic steatohepatitis (NASH: a type of liver disease)
   B. You are 18 years of age or older
   C. You do not have cirrhosis (liver damage and scarring)
   D. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor) or gastroenterologist (doctor who treats digestive conditions)
   E. You are enrolled in or have already completed a lifestyle intervention (such as dietary, exercise, psychology)
   (Initial denial text continued on next page)

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RESMETIROM

INITIAL CRITERIA (CONTINUED)

F. Your diagnosis has been confirmed by biopsy (removal of cells or tissue from the body for examination) or noninvasive testing (such as elastography [type of imaging test]) within the past 12 months which demonstrates ALL of the following:
   1. You have liver fibrosis stage 2 or 3 (scoring system to measure liver damage)
   2. You have a non-alcoholic fatty liver disease (NAFLD) Activity Score (NAS: a scoring system used to measure disease activity and severity) of at least 4

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RESMETIROM

RENEWAL CRITERIA

1. Does the patient have a diagnosis of non-alcoholic steatohepatitis (NASH)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient a non-responder as defined by meeting **ALL** of the following criteria?
   - The patient's NAFLD Activity Score (NAS) has not decreased by at least 2 points from baseline
   - The patient has had no reduction in fibrosis stage

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #3.

3. Has the patient experienced NASH resolution as defined by meeting **ALL** of the following criteria?
   - The patient has an NAFLD Activity Score (NAS) of less than or equal to 3
   - The patient has liver fibrosis stage 0 to 1

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RESMETIROM (Rezdiffra)** requires the following rule(s) be met for renewal:
   A. You have non-alcoholic steatohepatitis (NASH: a type of liver disease)
   B. You do NOT meet any of the following:
      1. You are a non-responder (defined as NAFLD [non-alcoholic fatty liver disease] Activity Score [NAS: a scoring system used to measure disease activity and severity] not decreasing by at least 2 points from baseline [before start of treatment] AND no reduction [no improvement] in liver fibrosis stage [scoring system to measure liver damage])
      2. You have experienced NASH resolution (defined as NAFLD Activity Score [NAS] of less than or equal to 3 AND liver fibrosis stage 0 to 1)

   (Renewal denial text continued on next page)

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RESMETIROM

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rezdiffra.

REFERENCES

- Rezdiffra [Prescribing Information]. West Conshohocken, PA: Madrigal Pharmaceuticals; March 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/15/24
Created: 03/24
Client Approval: 03/24
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RIBOCICLIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced or metastatic breast cancer **AND** meet the following criterion?
   - The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline

2. Will Kisqali be used in combination with an aromatase inhibitor (e.g., anastrozole, exemestane, letrozole) **AND** the patient meets the following criterion?
   - The patient has NOT received prior endocrine-based therapy (e.g., letrozole, anastrozole, tamoxifen) for advanced or metastatic breast cancer

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **200mg: #0.75 per day.**
   - **400mg: #1.5 per day.**
   - **600mg: #2.25 per day.**

   If no, continue to #3.

3. Will Kisqali be used in combination with Faslodex (fulvestrant), **AND** the patient is a male or a postmenopausal female?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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RIBOCICLIB

GUIDELINES FOR USE (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   - The patient has NOT received prior endocrine-based therapy (e.g., letrozole, anastrozole, tamoxifen) for advanced or metastatic breast cancer
   - The patient has experienced disease progression on endocrine therapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **200mg: #0.75 per day.**
   - **400mg: #1.5 per day.**
   - **600mg: #2.25 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RIBOCICLIB (Kisqali)** requires the following rule(s) be met for approval:
   A. You have advanced or metastatic breast cancer (breast cancer that has progressed or has spread to other parts of the body)
   B. Your cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (a type of protein)
   C. **If you are requesting Kisqali in combination with an aromatase inhibitor (such as anastrozole, exemestane, letrozole), approval also requires:**
      1. You have NOT received prior endocrine (hormone)-based therapy (such as letrozole, anastrozole, tamoxifen) for advanced or metastatic breast cancer
   D. **If you are requesting Kisqali in combination with (Faslodex) fulvestrant, approval also requires:**
      1. You are a male or a postmenopausal (after menopause) female
      2. You meet ONE of the following:
         a. You have NOT received prior endocrine (hormone)-based therapy (such as letrozole, anastrozole, tamoxifen) for advanced or metastatic breast cancer
         b. You have experienced disease progression (your condition worsened) on endocrine (hormone) therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RIBOCICLIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kisqali.

REFERENCES

- Kisqali [Prescribing Information]. East Hanover, NJ. Novartis; August 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 12/01/23
Created: 05/17
Client Approval: 11/23
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RIBOCICLIB-LETROZOLE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced or metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative
   - The patient has NOT received prior endocrine-based therapy (e.g., letrozole, anastrozole, tamoxifen) for advanced or metastatic breast cancer

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **200mg-2.5mg: #1.75 per day.**
   - **400mg-2.5mg: #2.5 per day.**
   - **600mg-2.5mg: #3.25 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RIBOCICLIB-LETROZOLE (Kisqali/Femara Co-Pack)** requires the following rule(s) be met for approval:
   A. You have advanced or metastatic breast cancer (breast cancer that has progressed or has spread to other parts of the body)
   B. Your cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (a type of protein)
   C. You have NOT received prior endocrine (hormone)-based therapy (such as letrozole, anastrozole, tamoxifen) for advanced or metastatic breast cancer

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RIBOCICLIB-LETROZOLE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kisqali/Femara Co-Pack.

REFERENCES

- Kisqali/Femara Co-Pack [Prescribing Information]. East Hanover, NJ. Novartis; August 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 12/01/23
Created: 03/23
Client Approval: 11/23
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RIFAXIMIN

**** Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

XIFAXAN 550MG TABLETS

1. Is the patient being treated for the reduction in risk of overt hepatic encephalopathy (HE) recurrence and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hepatologist
   - The patient had a trial of lactulose or is currently on lactulose monotherapy

   If yes, **approve for 12 months for Xifaxan 550mg by GPID or GPI-14 with a quantity limit of #2 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of irritable bowel syndrome with diarrhea (IBS-D) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to tricyclic anti-depressants (e.g., amitriptyline, nortriptyline) or dicyclomine

   If yes, **approve for 8 weeks for Xifaxan 550mg by GPID or GPI-14 for 1 fill of #42.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RIFAXIMIN

INITIAL CRITERIA - XIFAXAN 550MG TABLETS (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RIFAXIMIN (Xifaxan 550 mg tablets)** requires the following rules be met for approval:

A. The request is for ONE of the following:
   1. Reduction of risk of overt hepatic encephalopathy (HE: a type of brain condition caused by liver damage) recurrence
   2. Irritable bowel syndrome with diarrhea (IBS-D: a type of bowel disease)

B. **For reduction in risk of overt hepatic encephalopathy recurrence, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor)
   3. You have tried lactulose or you are currently taking lactulose monotherapy (one drug treatment)

C. **If you have irritable bowel syndrome with diarrhea, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
   3. You have tried or have a contraindication (harmful for you to use) to tricyclic anti-depressants (such as amitriptyline, nortriptyline) or dicyclomine

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RIFAXIMIN

INITIAL CRITERIA (CONTINUED)

XIFAXAN 200MG TABLETS

1. Does the patient have a diagnosis of travelers' diarrhea (TD) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient had a trial of or contraindication to oral azithromycin, ciprofloxacin, ofloxacin, or levofloxacin

   If yes, **approve for 3 days for Xifaxan 200mg by GPID or GPI-14 for 1 fill of #9.**
   If no, continue to #2.

2. Is the request for the treatment of overt hepatic encephalopathy (HE) **AND** the patient meets the following criterion?
   - The requested medication will be used in combination with lactulose

   If yes, **approve for 10 days for Xifaxan 200mg by GPID or GPI-14 with a quantity limit of #6 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of *Clostridium difficile* infection (CDI) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an infectious disease specialist
   - The patient had at least one previous occurrence of Clostridium difficile infection
   - The patient has been treated with vancomycin for the current *Clostridium difficile* infection

   If yes, **approve for 20 days for Xifaxan 200mg by GPID or GPI-14 with a quantity limit of #6 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RIFAXIMIN

INITIAL CRITERIA - XIFAXAN 200MG TABLETS (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RIFAXIMIN (Xifaxan 200 mg tablets)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Travelers' diarrhea
   2. *Clostridium difficile* infection (a type of bacterial infection)
   3. Treatment of overt hepatic encephalopathy (HE: a type of brain condition caused by liver damage)

B. **If you have traveler's diarrhea, approval also requires:**
   1. You are 12 years of age or older
   2. You have tried or have a contraindication (harmful for you to use) to oral azithromycin, ciprofloxacin, ofloxacin, or levofloxacin

C. **For the treatment of overt hepatic encephalopathy, approval also requires:**
   1. The requested medication will be used in combination with lactulose

D. **If you have *Clostridium difficile* infection, approval also requires:**
   1. Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)
   2. You had at least one previous occurrence of *Clostridium difficile* infection
   3. You have been treated with vancomycin for the current *Clostridium difficile* infection

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RIFAXIMIN

RENEWAL CRITERIA

1. Is the request for renewal of Xifaxan 550mg tablet?

   If yes, continue to #2.
   If no, please refer to initial criteria above for Xifaxan 200mg request.

2. Is the patient being treated for the reduction in risk of overt hepatic encephalopathy (HE) recurrence?

   If yes, **approve for 12 months for Xifaxan 550mg by GPID or GPI-14 with a quantity limit of #2 per day.**

   If no, continue to 3.

3. Does the patient have a diagnosis of irritable bowel syndrome with diarrhea (IBS-D) and meet **ALL** of the following criteria?
   - The patient's last treatment course of Xifaxan has been at least 6 weeks ago
   - The patient has experienced at least 30 percent decrease in abdominal pain (on a 0-10 point pain scale)
   - The patient has experienced at least 50 percent reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7)

   If yes, **approve for 12 months for Xifaxan 550mg by GPID or GPI-14 for up to 2 fills of #42 each fill, separated by at least 8 weeks (total of 2 fills in 12 months).**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RIFAXIMIN

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RIFAXIMIN (Xifaxan 550 mg tablets)** requires the following rule(s) be met for renewal:

A. The request is for ONE of the following:
   1. Reduction of risk of overt hepatic encephalopathy (HE: a type of brain condition caused by liver damage) recurrence
   2. Irritable bowel syndrome with diarrhea (IBS-D: a type of bowel disease)

B. **If you have irritable bowel syndrome with diarrhea, renewal also requires:**
   1. Your last treatment course of Xifaxan has been at least 6 weeks ago
   2. You have experienced at least 30 percent decrease in abdominal pain (on a 0-10 point pain scale)
   3. You have experienced at least 50 percent reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information for Xifaxan.

REFERENCES

- Xifaxan [Prescribing Information]. Bridgewater, NJ: Salix Pharmaceuticals; October 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 12/01/23
Created: 02/05
Client Approval: 11/23
P&T Approval: 01/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RILONACEPT

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has genetic testing for gain-of-function mutations in the *NLRP3* gene OR has inflammatory markers (i.e., elevated CRP, ESR, serum amyloid A protein (SAA) or S100 proteins)
   - The patient has TWO of the following: urticarial-like rash (neutrophilic dermatitis), cold-triggered episodes, sensorineural hearing loss, musculoskeletal symptoms, chronic aseptic meningitis, skeletal abnormalities
   - Arcalyst will NOT be used concurrently with other IL-1 inhibitors (e.g., Ilaris [canakinumab], Kineret [anakinra])

   If yes, **enter TWO approvals by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL:**
     - **Approve for 1 month with a quantity limit of #5 per 28 days.**
   - **SECOND APPROVAL:**
     - **Approve for lifetime with a quantity limit of #4 per 28 days (enter a start date of 3 days BEFORE the END of the first approval).**

   If no, continue to #2.

2. Does the patient have a diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) and meet **ALL** of the following criteria?
   - The patient has genetic testing for gain-of-function mutations in the *IL1RN* gene OR has inflammatory markers (i.e., elevated CRP, ESR)
   - The patient has ONE of the following: pustular psoriasis-like rashes, osteomyelitis, absence of bacterial osteomyelitis, nail changes (i.e., onychomadesis)
   - Arcalyst will NOT be used concurrently with other IL-1 inhibitors (e.g., Ilaris [canakinumab], Kineret [anakinra])

   If yes, **approve for lifetime by HICL or GPI-10 with a quantity limit of #8 per 28 days.**
   If no, continue to #3.

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RILONACEPT

GUIDELINES FOR USE (CONTINUED)

3. Is the request for the treatment or reduction in risk of recurrent pericarditis (RP) and the patient meets **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient had an episode of acute pericarditis
   - The patient has been symptom-free for an interval of 4 to 6 weeks
   - The patient has TWO of the following: chest pain consistent with pericarditis, pericardial friction rub, ECG showing diffuse ST-segment elevation or PR-segment depression, and new or worsening pericardial effusion
   - The patient had a trial of or contraindication to two NSAIDs (e.g., ibuprofen, indomethacin) AND colchicine
   - Arcalyst will NOT be used concurrently with other IL-1 inhibitors (e.g., Ilaris [canakinumab], Kineret [anakinra])

   If yes, **approve for 12 months by HICL or GPI-10 as follows:**
   INITIAL REQUESTS:
   - **FIRST APPROVAL:**
     - **Approve for 1 month with a quantity limit of #5 per 28 days.**
   - **SECOND APPROVAL:**
     - **Approve for 11 months with a quantity limit of #4 per 28 days (enter a start date of 3 days BEFORE the END of the first approval).**

   SUBSEQUENT REQUESTS:
   - **Approve for 12 months with a quantity limit of #4 per 28 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RILONACEPT (Arcalyst)** requires the following rule(s) be met for approval:
   A. You meet ONE of the following:
      1. You have Cryopyrin-Associated Periodic Syndromes (CAPS) including Familial Cold Autoinflammatory Syndrome (FCAS: an inherited inflammatory disorder that is triggered with cold) or Muckle-Wells Syndrome (MWS: a disorder characterized by periodic episodes of skin rash, fever, and joint pain)
      2. You have Deficiency of Interleukin-1 Receptor Antagonist (DIRA: a type of immune system disorder)
      3. Arcalyst will be used for the treatment or reduction in risk of recurrent pericarditis (RP: a type of heart condition that returns)

   (Denial text continued on next page)

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GUIDELINE FOR USE (CONTINUED)

B **If you have Cryopyrin-Associated Periodic Syndromes including Familial Cold Autoinflammatory Syndrome or Muckle-Wells Syndrome, approval also requires:**
1. You are 12 years of age or older
2. You had genetic testing for gain-of-function mutations (abnormal change in gene) in the *NLRP3* gene (a type of gene) OR you have inflammatory markers (elevated C-reactive protein [CRP: sign of inflammation], erythrocyte sedimentation rate [ESR: a type of blood test], serum amyloid A protein [SAA: a type of protein] or S100 proteins [a type of protein])
3. You have TWO of the following: urticarial-like rash (neutrophilic dermatitis: a type of skin condition), cold-triggered episodes, sensorineural hearing loss (SNHL: a type of hearing loss), musculoskeletal symptoms (symptoms related to the skin and bones), chronic aseptic meningitis (inflammation of the brain and spinal cord), and skeletal (bone) abnormalities
4. Arcalyst will NOT be used concurrently (at the same time) with other IL-1 inhibitors (such as Ilaris [canakinumab], Kineret [anakinra])

C. **If you have Deficiency of Interleukin-1 Receptor Antagonist, approval also requires:**
1. You had genetic testing for gain-of-function mutations (abnormal change in gene) in the *IL1RN* gene (a type of gene) OR you have inflammatory markers (elevated C-reactive protein [CRP: sign of inflammation], erythrocyte sedimentation rate [ESR: a type of blood test])
2. You have ONE of the following: pustular psoriasis-like rashes (a type of skin condition), osteomyelitis (bone infection), absence of bacterial osteomyelitis, nail changes (onychomadesis: fungal infection of toenail)
3. Arcalyst will NOT be used concurrently (at the same time) with other IL-1 inhibitors (such as Ilaris [canakinumab], Kineret [anakinra])

D. **If the request is for the treatment or reduction in risk of recurrent pericarditis, approval also requires:**
1. You are 12 years of age or older
2. You had an episode of acute pericarditis (a type of short-term heart condition)
3. You have been symptom-free for 4 to 6 weeks
4. You have TWO of the following: chest pain consistent with pericarditis, pericardial friction rub (a type of heart condition), electrocardiogram (ECG: a type of lab test) showing diffuse ST-segment elevation or PR-segment depression (an abnormal heart test), and new or worsening pericardial effusion (a type of heart condition)
5. You had a trial of or contraindication to (harmful for) two NSAIDS (non-steroidal anti-inflammatory drugs such as ibuprofen, indomethacin) AND colchicine
6. Arcalyst will NOT be used concurrently with other IL-1 inhibitors (such as Ilaris [canakinumab], Kineret [anakinra])

(Denial text continued on next page)

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RILONACEPT

GUIDELINE FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Arcalyst.

REFERENCES

- Arcalyst [Prescribing Information]. London, UK: Kiniksa Pharmaceuticals; May 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/23
Created: 08/23
Client Approval: 08/23
P&T Approval: 07/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RILUZOLE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) and meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has had a trial of riluzole tablets
   - The patient is unable to take riluzole tablet formulation

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Exservan: #2 per day.**
   - **Tiglutik: #20mL per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RILUZOLE (Exservan, Tiglutik)** requires the following rule(s) be met for approval:
   A. You have amyotrophic lateral sclerosis (ALS: nervous system disease that weakens muscles and affects physical function)
   B. You are 18 years of age or older
   C. You have tried riluzole tablets
   D. You are unable to take riluzole tablet formulation

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Exservan or Tiglutik.

REFERENCES

- Exservan. [Prescribing Information]. Warren, NJ: Aquestive Therapeutics; April 2020.
- Tiglutik. [Prescribing Information]. Berwyn, PA: ITF Pharma, Inc.; September 2018.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RILUZOLE

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/01/21
Created: 11/18
Client Approval: 05/21
P&T Approval: 01/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RIMEGEPANT

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the acute treatment of migraines and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Nurtec ODT will NOT be used concurrently with other CGRP inhibitors (e.g., Zavzpret [zavegepant], Ubrelvy [ubrogepant]) for the acute treatment of migraines
   - The patient had a trial of or contraindication to ONE triptan (e.g., Imitrex [sumatriptan], Maxalt [rizatriptan])

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #18 per 30 days.**
   If no, continue to #2.

2. Is the request for the preventive treatment of episodic migraines and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Nurtec ODT will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Qulipta [atogepant]) for migraine prevention
   - The patient had a trial of or contraindication to ONE of the following preventive migraine treatments: divalproex sodium/sodium valproate, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #16 per 30 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RIMEGEPANT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RIMEGEPANT (Nurtec ODT)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Acute (quick onset) treatment of migraines
   2. Preventive treatment of episodic migraines

B. **If the request is for the acute treatment of migraines, approval also requires:**
   1. You are 18 years of age or older
   2. You will NOT use Nurtec ODT concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Zavzpret [zavegepant], Ubrelvy [ubrogepant]) for the acute treatment of migraines
   3. You have tried or have a contraindication to (harmful for you to use) ONE triptan (such as Imitrex [sumatriptan], Maxalt [rizatriptan])

C. **If the request is for the preventive treatment of episodic migraines, approval also requires:**
   1. You are 18 years of age or older
   2. You will NOT use Nurtec ODT concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Qulipta [atogepant]) for migraine prevention
   3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preventive migraine treatments: divalproex sodium/sodium valproate, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RIMEGEPANT

RENEWAL CRITERIA

1. Is the request for the acute treatment of migraines **AND** the patient meets the following criterion?
   - Nurtec ODT will NOT be used concurrently with other CGRP inhibitors (e.g., Zavzpret [zavegepant], Ubrelvy [ubrogepant]) for the acute treatment of migraines

   If yes, continue to #2.
   If no, continue to #4.

2. Has the patient experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (e.g., Migraine Assessment of Current Therapy [Migraine-ACT])?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #18 per 30 days.**
   If no, continue to #3.

3. Has the patient experienced clinical improvement defined as **ONE** of the following criteria?
   - Ability to function normally within 2 hours of dose
   - Headache pain disappears within 2 hours of dose
   - Therapy works consistently in majority of migraine attacks

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #18 per 30 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Is the request for the preventive treatment of episodic migraines **AND** the patient meets the following criterion?
   - Nurtec ODT will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Qulipta [atogepant]) for migraine prevention

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

5. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month
   - The patient has experienced a reduction in migraine severity
   - The patient has experienced a reduction in migraine duration

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #16 per 30 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RIMEGEPANT

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RIMEGEPANT (Nurtec ODT)** requires the following rule(s) be met for renewal:

A. The request is for ONE of the following:
   1. Acute (quick onset) treatment of migraines
   2. Preventive treatment of episodic migraines

B. **If the request is for the acute treatment of migraines, renewal also requires:**
   1. You will NOT use Nurtec ODT concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Zavzpret [zavegepant], Ubrelvy [ubrogepant]) for the acute treatment of migraines
   2. You meet ONE of the following:
      a. You have experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (assessment tool used to help guide treatment such as migraine assessment of current therapy [MIGRAINE-ACT])
      b. You have experienced clinical improvement as defined by ONE of the following:
         i. Ability to function normally within 2 hours of dose
         ii. Headache pain disappears within 2 hours of dose
         iii. Treatment works consistently in a majority of migraine attacks

C. **If the request is for the preventive treatment of episodic migraines, renewal also requires:**
   1. You will NOT use Nurtec ODT concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Qulipta [atogepant]) for migraine prevention
   2. You meet ONE of the following:
      a. You have experienced a reduction in migraine or headache frequency of at least 2 days per month
      b. You have experienced a reduction in migraine severity
      c. You have experienced a reduction in migraine duration

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RIMEGEPANT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nurtec ODT.

REFERENCES

- Nurtec ODT [Prescribing Information]. New York, NY: Pfizer Inc.; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 03/20
Client Approval: 03/24
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RIOCIGUAT

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - Adempas will NOT be used concurrently with nitrates or nitric oxide donors (e.g., amyl nitrate), phosphodiesterase inhibitors (e.g., Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (e.g., dipyridamole, theophylline)

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient have documentation (e.g., chart note, lab result, diagnostic test result, etc.) confirming a PAH diagnosis based on right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have a diagnosis of persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The patient has persistent or recurrent disease after surgical treatment OR is not a candidate for surgery OR has inoperable CTEPH
   - The patient has NYHA-WHO Functional Class II to IV symptoms
   - Adempas will NOT be used concurrently with nitrates or nitric oxide donors (e.g., amyl nitrate), phosphodiesterase inhibitors (e.g., Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (e.g., dipyridamole, theophylline)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RIOCIGUAT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RIOCIGUAT (Adempas)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH: a type of heart and lung condition) (World Health Organization [WHO] Group 4)
   2. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

B. **If you have pulmonary arterial hypertension, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   3. There is documentation (such as, chart note, lab result, diagnostic test result) showing you have pulmonary arterial hypertension based on ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR) greater than 2 Wood units
   4. You will NOT use Adempas concurrently (at the same time) with nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)

C. **If you have chronic thromboembolic pulmonary hypertension, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   3. You have persistent or recurrent disease after surgical treatment (condition continues to exist or returns after surgery) OR you are not a candidate for surgery OR you have inoperable (not able to operate on) chronic thromboembolic pulmonary hypertension
   4. You have NYHA-WHO Functional Class II to IV symptoms (a way to classify how limited you are during physical activity)
   5. You will NOT use Adempas concurrently (at the same time) with nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)

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RIOCIGUAT

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RIOCIGUAT

RENEWAL CRITERIA

1. Does the patient have ONE of the following diagnoses?
   - Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4)
   - Pulmonary arterial hypertension (PAH) (WHO Group 1)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Will Adempas be taken concurrently with nitrates or nitric oxide donors (e.g., amyl nitrate), phosphodiesterase inhibitors (e.g., Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (e.g., dipyridamole, theophylline)?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RIOCIGUAT (Adempas)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH: a type of heart and lung condition) (World Health Organization [WHO] Group 4)
      2. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   B. You will NOT use Adempas concurrently (at the same time) with nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RIOCIGUAT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Adempas.

REFERENCES

- Adempas [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; September 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 11/13
Client Approval: 02/24
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RIPRETINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced gastrointestinal stromal tumor (GIST) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received prior treatment with 3 or more kinase inhibitors (e.g. sunitinib, avapritinib, regorafenib), including imatinib

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RIPRETINIB (Qinlock)** requires ALL of the following rule(s) be met for approval:
   A. You have advanced gastrointestinal stromal tumor (GIST: a type of cancer in your digestive tract)
   B. You are 18 years of age or older
   C. You have received prior treatment with 3 or more kinase inhibitors (class of drugs), including imatinib

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Qinlock.

REFERENCES

- Qinlock [Prescribing Information]. Waltham, MA: Deciphera Pharmaceuticals, May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 07/20
Client Approval: 03/21
P&T Approval: 07/20

STANDARD COMMERCIAL AND NSA DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RISANKIZUMAB-RZAA

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient had a trial of or contraindication to one or more forms of conventional therapies (e.g., PUVA [psoralen and ultraviolet light A], UVB [ultraviolet light B], topical corticosteroids [e.g., betamethasone dipropionate, clobetasol propionate], calcipotriene, acitretin, methotrexate, or cyclosporine)

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic and is switching to Skyrizi
   - The patient has psoriasis covering 3% or more of body surface area (BSA)
   - The patient has psoriatic lesions affecting the hands, feet, face, or genital area

   If yes, **approve the requested strength and dosage form for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL:
   - **150mg/1.66mL Kit: Approve for 1 month with a quantity limit of #1 kit (2 syringes) per 28 days.**
   - **150mg/mL pen/syringe: Approve for 1 month with a quantity limit of #1mL per 28 days.**

   SECOND APPROVAL:
   - **150mg/1.66mL Kit: Approve for 5 months with a quantity limit of #1 kit (2 syringes) per 84 days (Please enter a start date of 3 WEEKS AFTER the START date of the first approval).**
   - **150mg/mL pen/syringe: Approve for 5 months with a quantity limit of #1mL per 84 days. (Please enter a start date of 3 WEEKS AFTER the START date of the first approval).**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RISANKIZUMAB-RZAA

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve the requested strength and dosage form for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL:
   - **150mg/1.66mL Kit: Approve for 1 month with a quantity limit of #1 kit (2 syringes) per 28 days.**
   - **150mg/mL pen/syringe: Approve for 1 month with a quantity limit of #1mL per 28 days.**

   SECOND APPROVAL:
   - **150mg/1.66mL Kit: Approve for 5 months with a quantity limit of #1 kit (2 syringes) per 84 days (Please enter a start date of 3 WEEKS AFTER the START date of the first approval).**
   - **150mg/mL pen/syringe: Approve for 5 months with a quantity limit of #1mL per 84 days. (Please enter a start date of 3 WEEKS AFTER the START date of the first approval).**

   If no, continue to #4.

4. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to ONE conventional agent, such as corticosteroids (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RISANKIZUMAB-RZAA

INITIAL CRITERIA (CONTINUED)

5. Is the prescriber requesting an intravenous infusion induction dose of **Skyrizi 600mg/10mL?**

If yes, approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:
FIRST APPROVAL:
- **600mg/10mL: Approve for 3 months with a quantity limit of #10mL per 28 days.**

SECOND APPROVAL (approve the requested strength):
- **180mg/1.2mL: Approve for 3 months with a quantity limit of #1.2 mL per 56 days (Please enter start date of 11 WEEKS AFTER the START date of the first approval).**
- **360mg/2.4mL: Approve for 3 months with a quantity limit of #2.4 mL per 56 days (Please enter start date of 11 WEEKS AFTER the START date of the first approval).**

If no, **approve a maintenance dose for 6 months by GPID or GPI-14 for the requested strength as follows:**
- **180mg/1.2mL: #1.2mL per 56 days.**
- **360mg/2.4mL: #2.4mL per 56 days.**

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RISANKIZUMAB-RZAA (Skyrizi)** requires the following rules be met for approval:
A. You have ONE of the following diagnoses:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)

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RISANKIZUMAB-RZAA

INITIAL CRITERIA (CONTINUED)

B. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You have tried or have a contraindication (harmful for) to one or more forms of standard therapies, such as PUVA (psoralen and ultraviolet light A: a type of light therapy), UVB (ultraviolet light B: a type of light therapy), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), calcipotriene, acitretin, methotrexate, or cyclosporine
   4. You meet ONE of the following:
      a. You were previously stable on another biologic and are switching to Skyrizi
      b. You have psoriasis covering 3 percent or more of body surface area (BSA)
      c. You have psoriatic lesions (rashes) affecting the hands, feet, genital area, or face

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You have tried or have a contraindication (harmful for) to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
   3. You had a trial of or contraindication (harmful for) to ONE standard therapy, such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RISANKIZUMAB-RZAA

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?
   - The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

   If yes, **approve the requested strength and dosage form for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **150mg/1.66mL Kit: #1 kit (2 syringes) per 84 days.**
   - **150mg/mL pen/syringe: #1mL per 84 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve the requested strength and dosage form for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **150mg/1.66mL Kit: #1 kit (2 syringes) per 84 days.**
   - **150mg/mL pen/syringe: #1mL per 84 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD)?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **180mg/1.2mL: #1.2mL per 56 days.**
   - **360mg/2.4mL: #2.4mL per 56 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RISANKIZUMAB-RZAA

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RISANKIZUMAB-RZAA (Skyrizi)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)

B. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Skyrizi.

REFERENCES

- Skyrizi [Prescribing Information]. North Chicago, IL: AbbVie, Inc.; December 2022.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 05/19
Client Approval: 03/24
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RISDIPLAM

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of spinal muscular atrophy (SMA) and meet **ALL** of the following criteria?
   - Diagnosis of spinal muscular atrophy (SMA) is confirmed by documentation of gene mutation analysis indicating mutations or deletions of both alleles of the survival motor neuron 1 (SMN1) gene (e.g., homozygous deletions of SMN1, homozygous mutations of SMN1, compound heterozygous mutations in SMN1 [i.e., deletion of SMN1 on one allele and point mutation of SMN1 on the other allele])
   - Therapy is prescribed by or given in consultation with a neuromuscular specialist or spinal muscular atrophy (SMA) specialist at a SMA Specialty Center

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient presymptomatic **AND** meets the following criterion?
   - There is documentation of up to (i.e., no more than) three copies of survival motor neuron 2 (SMN2) based on newborn screening

   If yes, **approve for 12 months by HICL or GPI-10 for #240mL per 30 days.**
   APPROVAL TEXT: Renewal requires that the patient has improved, maintained, or demonstrated less than expected decline in motor function assessments compared to baseline, OR in other muscle function.

   If no, continue to #3.

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RISDIPLAM

INITIAL CRITERIA (CONTINUED)

3. Is the patient symptomatic and meets **ALL** of the following criteria?
   - The onset of spinal muscular atrophy (SMA) symptoms occurred before 20 years of age
   - There is documentation of a baseline motor function assessment by a neuromuscular specialist or SMA specialist
   - For patients who have received prior gene therapy: the patient had less than expected clinical benefit with gene therapy

   If yes, **approve for 12 months by HICL or GPI-10 for #240mL per 30 days.**
   APPROVAL TEXT: Renewal requires that the patient has improved, maintained, or demonstrated less than expected decline in motor function assessments compared to baseline, OR in other muscle function.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RISDIPLAM (Evrysdi)** requires the following rule(s) be met for approval:
   A. You have spinal muscular atrophy (SMA: genetic disorder where your muscles become weak and break down)
   B. Your diagnosis of spinal muscular atrophy (SMA) is confirmed by documentation of a gene mutation analysis indicating mutations or deletions of both alleles of the survival motor neuron 1 (SMN1: type of protein in spinal cord) gene (such as homozygous deletions of SMN1, homozygous mutations of SMN1, compound heterozygous mutations in SMN1 [deletion of SMN1 on one allele and point mutation of SMN1 on the other allele])
   C. The requested medication is prescribed by or given in consultation with a neuromuscular (nerve and muscle) specialist or spinal muscular atrophy (SMA) specialist at a SMA Specialty Center
   D. **If you are presymptomatic (symptoms have not yet appeared), approval also requires:**
      1. There is documentation showing you have up to three copies of survival motor neuron 2 (SMN2: type of protein in spinal cord) based on screening done when you were a newborn
   E. **If you are symptomatic (symptoms have appeared), approval also requires:**
      1. The onset of spinal muscular atrophy (SMA) symptoms occurred before 20 years of age
      2. There is documentation showing you had a baseline motor function assessment by a neuromuscular (nerve and muscle) specialist or SMA specialist
      3. If you previously had gene therapy, you had less than expected clinical benefit

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RISDIPLAM

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of spinal muscular atrophy (SMA) and meet **ONE** of the following criteria?
   - The patient has improved, maintained, or demonstrated less than expected decline in motor function assessments compared to baseline (e.g., HINE, HFMSE, CHOP-INTEND)
   - The patient has improved, maintained, or demonstrated less than expected decline in other muscle function (e.g., pulmonary)

   If yes, **approve for 12 months by HICL or GPI-10 for #240mL per 30 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RISDIPLAM (Evrysdi)** requires the following rule(s) be met for renewal:
   A. You have spinal muscular atrophy (SMA: genetic disorder where your muscles become weak and break down)
   B. You meet ONE of the following:
      1. You have improved, maintained, or demonstrated less than expected decline in motor function assessments compared to baseline. Some types of motor assessment tests include Hammersmith Infant Neurological Examination (HINE), Hammersmith Functional Motor Scale - Expanded (HFMSE) and Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
      2. You have improved, maintained, or demonstrated less than expected decline in other muscle function such as pulmonary (lung/breathing) function

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RISDIPLAM

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Evrysdi.

REFERENCES

- Evrysdi [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; August 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/07/20
Created: 08/20
Client Approval: 08/20
P&T Approval: 04/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RITLECITINIB

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of severe alopecia areata and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has had at least 50% scalp hair loss as measured by the Severity of Alopecia Tool (SALT) for more than 6 months
   - The patient is NOT utilizing other systemic biologics for alopecia areata or other JAK inhibitors for any indication (e.g., Xeljanz [tofacitinib IR or XR], Rinvoq [upadacitinib])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the patient had a trial of or contraindication to **TWO** of the following (from different categories)?
   - Intralesional corticosteroid (e.g., triamcinolone acetonide)
   - Topical corticosteroid (e.g., fluocinolone acetonide, betamethasone dipropionate, clobetasol propionate)
   - Minoxidil (e.g., minoxidil 5% solution)
   - Short contact Anthralin
   - Topical immunotherapy (e.g., squaric acid dibutylester [SADBE], diphencyprone [DPCP])
   - Systemic treatment (e.g., psoralen plus UV-A [PUVA], cyclosporine, methotrexate, steroids such as prednisone)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the patient 12 to 17 years of age?

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #4.

4. Is the patient 18 years of age or older **AND** meet the following criterion?
   - The patient had a trial of or contraindication to the preferred agent: Olumiant (baricitinib)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RITLECITINIB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RITLECITINIB (Litfulo)** requires the following rule(s) be met for approval:

A. You have severe alopecia areata (a type of hair loss)
B. You are 12 years of age or older
C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
D. You have had at least 50% scalp hair loss as measured by the Severity of Alopecia Tool (SALT: a type of disease evaluation tool) for more than 6 months
E. You are NOT using other systemic biologics for alopecia areata or other JAK (Janus kinase) inhibitors for any indication (such as Xeljanz [tofacitinib immediate-release or extended-release], Rinvoq [upadacitinib])
F. You had a trial of or contraindication (harmful for) to TWO of the following (from different categories):
    1. Intralesional corticosteroid (such as triamcinolone acetonide)
    2. Topical corticosteroid (such as fluocinolone acetonide, betamethasone dipropionate, clobetasol propionate)
    3. Minoxidil (such as minoxidil 5% solution)
    4. Short contact Anthralin
    5. Topical immunotherapy (such as squaric acid dibutylester [SADBE], diphencyprone [DPCP])
    6. Systemic treatment (such as psoralen plus UV-A [PUVA], cyclosporine, methotrexate, steroids such as prednisone)
G. **If you are 18 years of age or older, approval also requires:**
    1. You have tried or have a contraindication (harmful for) to the preferred medication: Olumiant (baricitinib)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RITLECITINIB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of severe alopecia areata and meet **ALL** of the following criteria?
   - The patient has had improvement while on therapy (e.g., scalp hair coverage)
   - The patient is NOT utilizing other systemic biologics for alopecia areata or other JAK inhibitors for any indication (e.g., Xeljanz [tofacitinib IR or ER], Rinvoq [upadacitinib])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient 12 to 17 years of age?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #3.

3. Is the patient 18 years of age or older **AND** meet the following criterion?
   - The patient had a trial of or contraindication to the preferred agent: Olumiant (baricitinib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RITLECITINIB (Litfulo)** requires the following rule(s) be met for renewal:
   A. You have severe alopecia areata (a type of hair loss)
   B. You are 12 years of age or older
   C. You have had improvement while on therapy (such as scalp hair coverage)
   D. You are NOT using other systemic biologics for alopecia areata or other JAK (Janus kinase) inhibitors for any indication (such as Xeljanz [tofacitinib immediate-release or extended-release], Rinvoq [upadacitinib])
   E. **If you are 18 years of age or older, approval also requires:**
      1. You had a trial of or contraindication (harmful for) to the preferred medication: Olumiant (baricitinib)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RITLECITINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Litfulo.

REFERENCES

- Litfulo [Prescribing Information]. New York, NY: Pfizer; June 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/14/23
Created: 07/23
Client Approval: 08/23
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROFLUMILAST - CREAM

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of plaque psoriasis and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has psoriasis covering 2 percent to 20 percent of body surface area (BSA) (excluding scalp, palms, and soles)
   - Zoryve will NOT be used concurrently with other systemic immunomodulating agents (e.g., Stelara [ustekinumab], Otezla [apremilast]), topical corticosteroids (e.g., betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (e.g., calcitriol, tazarotene)

   If yes, continue to #2.
   If no, do no approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the patient had a trial of or contraindication to **TWO** of the following (from different categories)?
   - High potency topical corticosteroid (e.g., triamcinolone acetonide 0.5% cream or ointment, halobetasol propionate 0.01% lotion) or a super-high potency topical corticosteroid (e.g., fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
   - Topical vitamin D analog (e.g., calcipotriene cream, calcitriol ointment)
   - Topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus)
   - Topical retinoid (e.g., tazarotene cream/gel)
   - Anthralin

   If yes, **approve for 2 months by GPID or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.***

   Our guideline named **ROFLUMILAST - CREAM (Zoryve)** requires the following rule(s) be met for approval:
   A. You have plaque psoriasis (a type of skin condition)
   B. You are 6 years of age or older
   C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   (Initial denial text continued on next page)

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ROFLUMILAST - CREAM

INITIAL CRITERIA (CONTINUED)

D. You have psoriasis covering 2 percent to 20 percent of body surface area (BSA) (excluding scalp, palms, and soles)
E. You will NOT use Zoryve concurrently (at the same time) with other systemic immunomodulating agents (such as Stelara [ustekinumab], Otezla [apremilast]), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (such as calcitriol, tazarotene)
F. You have tried or have a contraindication to (harmful for you to use) TWO of the following (from different categories):
    1. High potency topical corticosteroid (such as triamcinolone acetonide 0.5% cream or ointment, halobetasol propionate 0.01% lotion) or a super-high potency topical corticosteroid (such as fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
    2. Topical vitamin D analog (such as calcipotriene cream, calcitriol ointment)
    3. Topical calcineurin inhibitor (such as tacrolimus, pimecrolimus)
    4. Topical retinoid (such as tazarotene cream/gel)
    5. Anthralin

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROFLUMILAST - CREAM

RENEWAL CRITERIA

1. Does the patient have a diagnosis of plaque psoriasis and meet **ALL** of the following criteria?
   - The patient has achieved or maintained clear or minimal disease
   - Zoryve will NOT be used concurrently with other systemic immunomodulating agents (e.g., Stelara [ustekinumab], Otezla [apremilast]), topical corticosteroids (e.g., betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (e.g., calcitriol, tazarotene)

   If yes, **approve for 12 months by GPID or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ROFLUMILAST - CREAM (Zoryve)** requires the following rule(s) be met for renewal:
   A. You have plaque psoriasis (a type of skin condition)
   B. You have achieved or maintained clear or minimal disease
   C. You will NOT use Zoryve concurrently (at the same time) with other systemic immunomodulating agents (such as Stelara [ustekinumab], Otezla [apremilast]), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (such as calcitriol, tazarotene)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zoryve.

REFERENCES

- Zoryve [Prescribing Information]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; October 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/15/24
Created: 08/22
Client Approval: 12/23
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROFLUMILAST - FOAM

GUIDELINES FOR USE

1. Does the patient have a diagnosis of seborrheic dermatitis and meet **ALL** of the following criteria?
   - The patient is 9 years of age or older
   - The patient's seborrheic dermatitis covers 20 percent of their body surface area (BSA) (may involve scalp, face, trunk, or intertriginous areas)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient had a trial of or contraindication to **TWO** of the following (from different categories)?
   - High potency topical corticosteroid (e.g., triamcinolone acetonide 0.5% cream or ointment, halobetasol propionate 0.01% lotion) or a super-high potency topical corticosteroid (e.g., fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
   - Topical antifungal (e.g., ketoconazole, ciclopirox)
   - Topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus)

   If yes, **approve for 8 weeks by GPID or GPI-10.**
   If no, continue to #3.

3. Has the patient had a prior successful treatment with roflumilast foam?

   If yes, **approve for 8 weeks by GPID or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **ROFLUMILAST - FOAM (Zoryve)** requires the following rule(s) be met for approval:
   A. You have seborrheic dermatitis (a type of skin condition)
   B. You are 9 years of age or older
   C. Your seborrheic dermatitis covers 20 percent of your body surface area (BSA) (may involve scalp, face, trunk [the central part of your body], or intertriginous areas [between skin folds])
   (Denial text continued on the next page)

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ROFLUMILAST - FOAM

GUIDELINES FOR USE (CONTINUED)

D. You meet ONE of the following:
   1. You have tried or have a contraindication to (harmful for you to use) TWO of the following (from different categories):
      a. High potency topical corticosteroid (such as triamcinolone acetonide 0.5% cream or ointment, halobetasol propionate 0.01% lotion) or a super-high potency topical corticosteroid (such as fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
      b. Topical antifungal (such as ketoconazole, ciclopirox)
      c. Topical calcineurin inhibitor (such as tacrolimus, pimecrolimus)
   2. You previously had a successful treatment with roflumilast foam

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zoryve.

REFERENCES

- Zoryve [Prescribing Information]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; December 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/15/24
Created: 12/23
Client Approval: 12/23
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROPEGINTERFERON ALFA-2B-NJFT

GUIDELINES FOR USE

1. Does the patient have a diagnosis of polycythemia vera **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.** If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ROPEGINTERFERON ALFA-2B-NJFT (Besremi)** requires the following rule(s) be met for approval:
   A. You have polycythemia vera (a type of blood cancer)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Besremi.

REFERENCES

- Besremi [Prescribing Information]. Burlington, MA: PharmaEssentia, Corp., November 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 01/22
Client Approval: 02/22
P&T Approval: 01/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RUCAPARIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a deleterious BRCA mutation (germline and/or somatic)
   - The patient is in complete or partial response to platinum-based chemotherapy
   - The requested medication will be used for maintenance treatment

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a deleterious BRCA mutation (germline and/or somatic) based on an FDA-approved companion diagnostic for Rubraca
   - The patient has been treated with an androgen receptor-directed therapy and a taxane-based chemotherapy

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient previously had a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., < 50 ng/dL)
   - The requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., leuprolide, goserelin, histrelin)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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RUCAPARIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RUCAPARIB (Rubraca)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer (types of reproductive system cancers that has returned)
   2. Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)

B. **If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a deleterious BRCA mutation (germline and/or somatic) (a type of gene mutation that is passed on from parent to child and/or acquired during life)
   3. You are in complete or partial response to platinum-based chemotherapy (a type of therapy to treat cancer)
   4. The requested medication will be used for maintenance treatment

C. **If you have metastatic castration-resistant prostate cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a deleterious BRCA mutation (germline and/or somatic) (a type of gene mutation that is passed on from parent to child and/or acquired during life) based on a Food and Drug Administration (FDA)-approved companion diagnostic for Rubraca
   3. You have been treated with an androgen receptor-directed therapy and a taxane-based chemotherapy (types of therapy to treat cancer)
   4. You meet ONE of the following:
      a. You previously received a bilateral orchiectomy (removal of testicles)
      b. You have a castrate level of testosterone (blood testosterone levels are less than 50 ng/dL)
      c. The requested medication will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as leuprolide, goserelin, histrelin)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RUCAPARIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rubraca.

REFERENCES

- Rubraca [Prescribing Information]. Boulder, CO: Clovis Oncology, Inc.; December 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/23/23

Created: 12/16
Client Approval: 01/23

P&T Approval: 01/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RUXOLITINIB

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 6 months by GPID or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of polycythemia vera and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has had a trial of or contraindication to hydroxyurea

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of steroid-refractory acute graft-versus-host disease **AND** meet the following criterion?
   - The patient is 12 years of age or older

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #4.

4. Does the patient have a diagnosis of chronic graft-versus-host disease and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has had a failure of one or two lines of systemic therapy

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RUXOLITINIB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RUXOLITINIB (Jakafi)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Intermediate or high-risk myelofibrosis, (type of bone marrow cancer such as primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis)
   2. Polycythemia vera (a type of blood cancer)
   3. Steroid -refractory acute graft-versus-host disease (a type of short-term immune disorder that did not respond to a type of treatment)
   4. Chronic graft-versus-host disease (a type of long-term immune disorder)

B. **If you have intermediate or high-risk myelofibrosis, such as primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis, approval also requires:**
   1. You are 18 years of age or older

C. **If you have polycythemia vera, approval also requires:**
   1. You are 18 years of age or older
   2. You had a trial of hydroxyurea, unless you have a contraindication (harmful for)

D. **If you have steroid-refractory acute graft-versus-host disease, approval also requires:**
   1. You are 12 years of age or older

E. **If you have chronic graft-versus-host disease, approval also requires:**
   1. You are 12 years of age or older
   2. You had a failure of one or two lines of systemic therapy (treatment that targets the entire body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RUXOLITINIB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

NOTE: For the diagnoses of polycythemia vera, acute graft-versus-host disease, or chronic graft-versus-host disease, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient shown symptom improvement by meeting **ONE** of the following criteria?
   - The patient has a 50% or greater reduction in total symptom score (e.g., Myeloproliferative Neoplasm Symptom Assessment Form [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0)
   - The patient has a 50% or greater reduction in palpable spleen length
   - The patient has a spleen volume reduction of 35% or greater from baseline

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **RUXOLITINIB (Jakafi)** requires the following rule(s) be met for renewal:
   A. You have intermediate or high-risk myelofibrosis, (type of bone marrow cancer such as primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis)
   B. You have shown symptom improvement by meeting ONE of the following:
      1. You have a 50 percent or greater reduction in total symptom score (such as Myeloproliferative Neoplasm Symptom Assessment Form [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0)
      2. You have a 50 percent or greater reduction in palpable (can be felt by external examination) spleen length
      3. You have a spleen volume reduction of 35 percent or greater from baseline

   (Renewal denial text continued on next page)

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RUXOLITINIB

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Jakafi.

REFERENCES

- Jakafi [Prescribing Information]. Wilmington, DE. Incyte Corporation; September 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 12/11
Client Approval: 11/21
P&T Approval: 10/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RUXOLITINIB TOPICAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of mild to moderate atopic dermatitis and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient is NOT immunocompromised
   - The patient had a trial of or contraindication to a topical corticosteroid (e.g., halobetasol, triamcinolone, fluocinonide) OR a topical non-steroidal immunomodulating agent (e.g., Elidel [pimecrolimus], Protopic [tacrolimus])

   If yes, continue to #2.
   If no, continue to #3.

2. Will Opzelura be used concurrently with **ANY** of the following?
   - Other non-steroid topicals (e.g., Elidel [pimecrolimus], Protopic [tacrolimus], Eucrisa [crisaborole])
   - Systemic therapeutic biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
   - Other JAK inhibitors (e.g., Rinvoq [upadacitinib], Cibinqo [abrocitinib])
   - Potent immunosuppressants (e.g., azathioprine, cyclosporine)

   If yes, do not approve.
   DENIAL TEXT: See the initial denial at the end of the guideline.

   If no, **approve for 3 months by GPID or GPI-10 with a quantity limit of #60 grams per 30 days.**

3. Does the patient have a diagnosis of nonsegmental vitiligo and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has depigmented areas covering 10 percent or less of total body surface area
   - The patient had a trial of or contraindication to a topical corticosteroid (e.g., halobetasol, triamcinolone, fluocinonide) OR a topical calcineurin inhibitor (e.g., Elidel [pimecrolimus], Protopic [tacrolimus])

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text on the next page.

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RUXOLITINIB TOPICAL

INITIAL CRITERIA (CONTINUED)

4. Will Opzelura be used concurrently with **ANY** of the following?
   - Other non-steroid topicals (e.g., Elidel [pimecrolimus], Protopic [tacrolimus], Eucrisa [crisaborole])
   - Systemic therapeutic biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
   - Other JAK inhibitors (e.g., Rinvoq [upadacitinib], Cibinqo [abrocitinib])
   - Potent immunosuppressants (e.g., azathioprine, cyclosporine)

   If yes, do not approve.
   If no, **approve for 6 months by GPID or GPI-10 with a quantity limit of #60 grams per 30 days.**

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RUXOLITINIB TOPICAL (Opzelura)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Mild to moderate atopic dermatitis (a type of skin condition)
      2. Nonsegmental vitiligo (a type of skin condition)

   B. **If you have mild to moderate atopic dermatitis, approval also requires:**
      1. You are 12 years of age or older
      2. You are NOT immunocompromised (low immune system)
      3. You have tried or have a contraindication to (harmful for you to use) a topical corticosteroid (such as halobetasol, triamcinolone, fluocinonide) OR a topical non-steroidal immunomodulating agent (such as Elidel [pimecrolimus], Protopic [tacrolimus])
      4. You are NOT using Opzelura together with ANY of the following:
         a. Other non-steroidal topicals (such as Protopic [tacrolimus], Elidel [pimecrolimus], Eucrisa [crisaborole])
         b. Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
         c. Other JAK (Janus kinase)inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
         d. Potent immunosuppressants (such as azathioprine, cyclosporine)

   (Initial denial text continued on next page)

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RUXOLITINIB TOPICAL

INITIAL CRITERIA (CONTINUED)

C. **If you have nonsegmental vitiligo, approval also requires:**
   1. You are 12 years of age or older
   2. You have depigmented (lightening of the skin) areas covering 10 percent or less of total body surface area
   3. You have tried or have a contraindication to (harmful for you to use) a topical corticosteroid (such as halobetasol, triamcinolone, fluocinonide) OR a topical calcineurin inhibitor (such as Elidel [pimecrolimus], Protopic [tacrolimus])
   4. You are NOT using Opzelura together with ANY of the following:
      a. Other non-steroidal topicals (such as Protopic [tacrolimus], Elidel [pimecrolimus], Eucrisa [crisaborole])
      b. Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
      c. Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
      d. Potent immunosuppressants (such as azathioprine, cyclosporine)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RUXOLITINIB TOPICAL

RENEWAL CRITERIA

1. Does the patient have a diagnosis of mild to moderate atopic dermatitis **AND** meet the following criterion?
   - The patient has experienced or maintained improvement in pruritus, relapsing-remitting dermatitis, or facial/interdigital involvement

   If yes, continue to #3.
   If no, continue to #2.

2. Does the patient have a diagnosis of nonsegmental vitiligo **AND** meet the following criterion?
   - The patient has experienced or maintained clinically meaningful repigmentation

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Will Opzelura be used concurrently with **ANY** of the following?
   - Other non-steroid topicals (e.g., Elidel [pimecrolimus], Protopic [tacrolimus], Eucrisa [crisaborole])
   - Systemic therapeutic biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
   - Other JAK inhibitors (e.g., Rinvoq [upadacitinib], Cibinqo [abrocitinib])
   - Potent immunosuppressants (e.g., azathioprine, cyclosporine)

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, **approve for 12 months by GPID or GPI-10 with a quantity limit of #60 grams per 30 days.**

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RUXOLITINIB TOPICAL

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RUXOLITINIB TOPICAL (Opzelura)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Mild to moderate atopic dermatitis (a type of skin condition)
   2. Nonsegmental vitiligo (a type of skin condition)

B. **If you have mild to moderate atopic dermatitis, renewal also requires:**
   1. You have experienced or maintained improvement in pruritus (itchiness), relapsing-remitting (disease returns and goes away) dermatitis, or facial/interdigital (between the fingers or toes) involvement
   2. You are NOT using Opzelura together with ANY of the following:
      a. Other non-steroidal topicals (such as Protopic [tacrolimus], Elidel [pimecrolimus], Eucrisa [crisaborole])
      b. Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
      c. Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
      d. Potent immunosuppressants (such as azathioprine, cyclosporine)

C. **If you have nonsegmental vitiligo, renewal also requires:**
   1. You have experienced or maintained clinically meaningful repigmentation (recoloration of the skin after loss in color)
   2. You are NOT using Opzelura together with ANY of the following:
      a. Other non-steroidal topicals (such as Protopic [tacrolimus], Elidel [pimecrolimus], Eucrisa [crisaborole])
      b. Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
      c. Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
      d. Potent immunosuppressants (such as azathioprine, cyclosporine)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RUXOLITINIB TOPICAL

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Opzelura.

REFERENCES

- Opzelura [Prescribing Information]. Wilmington, DE: Incyte, Corp., September 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 12/01/23
Created: 09/21
Client Approval: 11/23
P&T Approval: 10/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SACROSIDASE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of genetically determined sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID), and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a gastroenterologist or medical geneticist
   - The patient's diagnosis is confirmed by ONE of the following:
     - Small bowel biopsy
     - Sucrose breath test
     - Genetic test

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SACROSIDASE (Sucraid)** requires the following rule be met for approval:
   A. You have a genetically determined sucrase deficiency , which is part of congenital sucrase-isomaltase deficiency (a type of genetic digestive condition)
   B. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions) or medical geneticist (doctor who treats gene disorders)
   C. Your diagnosis is confirmed by ONE of the following:
      1. Small bowel biopsy (removal of cells or tissue from the body for examination)
      2. Sucrose breath test
      3. Genetic test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SACROSIDASE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of genetically determined sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID) **AND** meet the following criterion?
   - The patient has experienced or maintained improvement on treatment

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SACROSIDASE (Sucraid)** requires the following rule(s) be met for renewal:
   A. You have a genetically determined sucrase deficiency which is part of congenital sucrase-isomaltase deficiency (a type of genetic digestive condition)
   B. You have experienced or maintained improvement on treatment

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sucraid.

REFERENCES

- Sucraid [Prescriber Information]. Vero Beach, FL: QOL Medical, LLC.; August 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 05/12
Client Approval: 05/22
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SARGRAMOSTIM

GUIDELINES FOR USE

1. Therapy is prescribed by or given in consultation with a hematologist or oncologist?

   If yes, **approve by HICL or GPI-10 for 3 months or requested duration of treatment up to 1 year.**
   If no, continue to #2.

2. Is the request for **ONE** of the following indications?
   - To shorten time to neutrophil recovery and to reduce the incidence of severe, life-threatening, or fatal infections following induction chemotherapy in a patient with acute myeloid leukemia (AML) AND the patient is 55 years of age or older
   - For the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis, the patient is undergoing autologous transplantation AND the patient is 18 years of age or older
   - For the acceleration of myeloid reconstitution following autologous bone marrow or peripheral blood progenitor cell transplantation, in patients with non-Hodgkin's lymphoma (NHL), acute lymphoblastic leukemia (ALL) or Hodgkin's lymphoma AND the patient is 2 years of age or older
   - For the acceleration of myeloid reconstitution following allogeneic bone marrow transplantation from HLA-matched related donors AND the patient is 2 years of age or older
   - For the treatment of delayed neutrophil recovery or graft failure after autologous or allogeneic bone marrow transplantation AND the patient is 2 years of age or older
   - To increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS])

   If yes, **approve by HICL or GPI-10 for 3 months or requested duration of treatment up to 1 year.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SARGRAMOSTIM (Leukine)** requires the following rule(s) be met for approval:
   A. The requested medication is prescribed by or given in consultation with a hematologist (blood specialist) or oncologist (cancer/tumor doctor), **OR** you meet **ONE** of the following:
      1. You have acute myeloid leukemia (AML: type of blood and bone marrow cancer) and are using the requested medication to shorten time to neutrophil (a type of white blood cell) recovery and to reduce the incidence of severe, life-threatening, or fatal infections following induction chemotherapy AND you are 55 years of age or older

   (Denial text continued on next page)

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SARGRAMOSTIM

GUIDELINES FOR USE (CONTINUED)

2. You are undergoing autologous transplantation (your own blood-forming stem cells are collected) and using the requested medication for the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis (to collect blood sample and separate white blood cells in a lab test) AND you are 18 years of age or older
3. You have non-Hodgkin's lymphoma (NHL: type of cancer), acute lymphoblastic leukemia (ALL: type of white blood cell cancer) or Hodgkin's lymphoma (type of cancer) and are using the requested medication for the acceleration of myeloid reconstitution following autologous bone marrow or peripheral blood progenitor cell transplantation (to help your blood and bone marrow recover) AND you are 2 years of age or older
4. The requested medication is being used for the acceleration of myeloid reconstitution following allogeneic bone marrow transplantation from HLA-matched related donors (to help your blood and bone marrow recover after using a lab test to match you to the correct donors) AND you are 2 years of age or older
5. The requested medication is being used for the treatment of delayed neutrophil recovery or graft failure after autologous or allogeneic bone marrow transplantation AND you are 2 years of age or older
6. You are acutely exposed to myelosuppressive doses (doses that suppress bone marrow activity) of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]) and using the requested medication to increase your survival

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Leukine.

REFERENCES

- Leukine [Prescribing Information]. Lexington, MA: Partner Therapeutics, Inc.; April 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 02/03
Client Approval: 04/20
P&T Approval: 04/18

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SARILUMAB

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following?
   - The patient had a trial of or contraindication to THREE of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Actemra (tocilizumab)
   - The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2.28mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SARILUMAB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of polymyalgia rheumatica (PMR) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had an inadequate response to corticosteroids (e.g., prednisone) or cannot tolerate a corticosteroid taper

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2.28mL per 28 days.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SARILUMAB (Kevzara)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Polymyalgia rheumatica (PMR: an inflammatory disorder causing muscle pain and stiffness)
   B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
      3. You have tried or have a contraindication to (harmful for you to use) at least 3 months of treatment with ONE DMARD (disease modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
      4. You meet ONE of the following:
         a. You have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Actemra (tocilizumab)
         b. You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib] due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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SARILUMAB

INITIAL CRITERIA (CONTINUED)

C. **If you have polymyalgia rheumatica, approval also requires:**
   1. You are 18 years of age or older
   2. You had an inadequate response (drug did not work) to corticosteroids (such as prednisone) or cannot tolerate a corticosteroid taper

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SARILUMAB

RENEWAL CRITERIA

NOTE: For the diagnosis of polymyalgia rheumatica, please refer to the initial criteria section.

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

     If yes, continue to #2.
     If no, do not approve.
     DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following?
   - The patient had a trial of or contraindication to THREE of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Actemra (tocilizumab)
   - The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2.28mL per 28 days.**

     If no, do not approve.
     DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SARILUMAB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SARILUMAB (Kevzara)** requires the following rule(s) be met for renewal:

A. You have moderate to severe rheumatoid arthritis (RA: a type of joint condition)
B. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy.
C. You meet ONE of the following:
    1. You have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz), Actemra (tocilizumab)
    2. You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kevzara.

REFERENCE

- Kevzara [Prescribing Information]. Bridgewater, NJ: Sanofi-Aventis US LLC; February 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 11/16
Client Approval: 03/24
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SATRALIZUMAB-MWGE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a neurologist
   - Diagnosis is confirmed by a positive serologic test for anti-aquaporin-4 (AQP4) antibodies
   - The patient is NOT concurrently using rituximab, inebilizumab or eculizumab

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have **ONE** of the following core clinical characteristics?
   - Optic neuritis
   - Acute myelitis
   - Area postrema syndrome
   - Acute brainstem syndrome
   - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
   - Symptomatic cerebral syndrome with NMOSD-typical brain lesions

   If yes, **approve for a total of 12 months by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: Approve for 30 days with a quantity limit of #2mL per 28 days.**
   - **SECOND APPROVAL: Approve for 11 months with a quantity limit of #1mL per 28 days (Enter a start date 2 days before the end date of the first approval).**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SATRALIZUMAB-MWGE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SATRALIZUMAB-MWGE (ENSPRYNG)** requires the following rule(s) be met for approval:

A. You have neuromyelitis optica spectrum disorder (NMOSD: a rare immune system disease that affects the central nervous system and causes inflammation in the optic nerve and spinal cord)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a neurologist (doctor who specializes in the brain, spinal cord, and nerves)
D. Your diagnosis is confirmed by a positive serologic (blood) test for anti-aquaporin-4 (AQP4: type of protein) antibodies
E. You are not concurrently (at the same time) using rituximab, inebilizumab, or eculizumab
F. You have at least ONE of the following core clinical characteristics:
    1. Optic neuritis (inflammation that damages an eye nerve)
    2. Acute myelitis (sudden and severe inflammation of the spinal cord)
    3. Area postrema syndrome (attacks of uncontrollable nausea, vomiting, or hiccups)
    4. Acute brainstem syndrome (problems with vision, hearing, swallowing and muscle weakness in the head)
    5. Symptomatic narcolepsy (sudden attacks of sleep) or acute diencephalic clinical syndrome (rare disorder caused by a tumor above the brainstem) with NMOSD-typical diencephalic MRI lesions
    6. Symptomatic cerebral syndrome with NMOSD-typical brain lesions

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SATRALIZUMAB-MWGE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) and meet **ALL** of the following criteria?
   - The patient had a reduction in relapse frequency from baseline
   - The patient is NOT concurrently using rituximab, inebilizumab or eculizumab

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 28 days.** If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SATRALIZUMAB-MWGE (ENSPRYNG)** requires the following rule(s) be met for renewal:
   A. You have neuromyelitis optica spectrum disorder (NMOSD: a rare disorder that affects the central nervous system and causes inflammation in the optic nerve and spinal cord)
   B. You had a reduction in relapse frequency from baseline
   C. You are not concurrently (at the same time) using rituximab, inebilizumab, or eculizumab

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Enspryng.

REFERENCES

- Enspryng [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; March 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 08/20
Client Approval: 05/22
P&T Approval: 04/22

STANDARD COMMERCIAL AND NSA DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SECUKINUMAB

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) without psoriatic arthritis involvement and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, genital area, or face
   - Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy) for the treatment of plaque psoriasis
   - The patient has a contraindication or intolerance to both immunosuppressant and PUVA (phototherapy) for the treatment of plaque psoriasis
   - The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to THREE of the preferred agents: Enbrel (etanercept), Taltz (ixekizumab), Stelara (ustekinumab)
   - The patient is 18 years of age or older AND had a trial of or contraindication to FOUR of the following preferred agents: Taltz (ixekizumab), Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz) [**NOTE**: Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve the requested strength by GPID or GPI-14 for a total of 6 months as follows:**
   <u>FIRST APPROVAL</u>: Approve for 1 month with the following quantity limits:
   - **75mg/0.5mL: #2mL per 28 days.**
   - **150mg/mL: #4mL per 28 days.**
   - **300mg/2mL: #8mL per 28 days.**

   <u>SECOND APPROVAL</u>: Approve for 5 months with the following quantity limits (enter a start date of 3 DAYS BEFORE the END date of the first approval):
   - **75mg/0.5mL: #0.5mL per 28 days.**
   - **150mg/mL: #1mL per 28 days.**
   - **300mg/2mL: #2mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - The patient had a trial of or a contraindication to ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication

   If yes, continue to #5.
   If no, continue to #8.

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

5. Does the patient meet **ONE** of the following criteria?
   - The patient is 2 to 5 years of age AND had a trial of or contraindication to the preferred agent: Enbrel (etanercept)
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to BOTH of the preferred agents: Enbrel (etanercept), Stelara (ustekinumab)
     [**NOTE**: Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve the requested strength by GPID or GPI-14 for a total of 6 months as follows:**
     FIRST APPROVAL: Approve for 1 month with the following quantity limits:
     - **75mg/0.5mL: #2mL per 28 days.**
     - **150mg/mL: #4mL per 28 days.**

     SECOND APPROVAL: Approve for 5 months with the following quantity limits (enter a start date of 3 DAYS BEFORE the END date of the first approval):
     - **75mg/0.5mL: #0.5mL per 28 days.**
     - **150mg/mL: #1mL per 28 days.**

     If no, continue to #6.

6. Is the patient 18 years of age or older **AND** meets the following criterion?
   - The patient had a trial of or contraindication to THREE of the following preferred agents: Taltz (ixekizumab), Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [**NOTE**: Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, continue to #7.
     If no, do not approve.
     DENIAL TEXT: See the initial denial text at the end of the guideline.

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

7. Does the patient have coexistent moderate to severe plaque psoriasis (PsO)? (**Note:** For psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis, use the dosing and administration recommendations for plaque psoriasis.)

   If yes, **approve the requested strength by GPID or GPI-14 for a total of 6 months as follows:**
   FIRST APPROVAL: Approve for 1 month with the following quantity limits:
   - **150mg/mL: #4mL per 28 days.**
   - **300mg/2mL: #8mL per 28 days.**

   SECOND APPROVAL: Approve for 5 months with the following quantity limits (enter a start date of 3 DAYS BEFORE the END date of the first approval):
   - **150mg/mL: #1mL per 28 days.**
   - **300mg/2mL: #2mL per 28 days.**

   If no, continue to #9.

8. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication
   - The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Taltz (ixekizumab), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, continue to #9.
   If no, continue to #13.

9. Is the request for Cosentyx subcutaneous pen or syringe?

   If yes, continue to #10.
   If no, continue to #12.

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

10. Is the request for a maintenance dosage of 300mg with or without a loading dose?

    If yes, continue to #11.
    If no, **approve the 150mg/mL strength by GPID or GPI-14 for a total of 6 months as follows:**
    - **Approve for 1 month with a quantity limit of #4mL per 28 days.**
    - **Approve for 5 months with a quantity limit of #1mL per 28 days. (Enter a start date of 3 DAYS BEFORE the END date of the first approval.)**

11. Has the patient tried the 150mg maintenance dosing schedule **AND** continues to have active ankylosing spondylitis or active psoriatic arthritis?

    If yes, **approve the requested strength by GPID or GPI-14 for a total of 6 months as follows:**
    FIRST APPROVAL: Approve for 1 month with the following quantity limits:
    - **150mg/mL: #4mL per 28 days.**
    - **300mg/2mL: #2mL per 28 days.**

    SECOND APPROVAL: Approve for 5 months with the following quantity limit (enter a start date of 3 DAYS BEFORE the END date of the first approval):
    - **300mg/2mL: #2mL per 28 days.**

    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.
    PAC NOTE: Please enter proactive PAs for the 150mg/mL strength by GPID or GPI-14 for a total of 6 months as follows:
    - **Approve for 1 month with a quantity limit of #4mL per 28 days.**
    - **Approve for 5 months with a quantity limit of #1mL per 28 days. (Enter a start date of 3 DAYS BEFORE the END date of the first approval.)**

12. Is the request for Cosentyx 125mg/5mL intravenous solution?

    If yes, **approve the 125mg/5mL strength by GPID or GPI-14 for a total of 6 months as follows:**
    - **Approve for 1 month with a fill count of #1.**
    - **Approve for 5 months with a quantity limit of #15mL per 28 days. (Enter a start date of 3 DAYS BEFORE the END date of the first approval.)**

    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

13. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Therapy is prescribed by or in consultation with a rheumatologist
    - Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication
    - The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)
    - The patient had a trial of or contraindication to TWO of the following preferred agents: Taltz (ixekizumab), Cimzia (certolizumab), Rinvoq (upadacitinib)
      [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

      If yes, continue to #14.
      If no, continue to #15.

14. Does the patient have **ONE** of the following objective signs of inflammation?
    - C-reactive protein (CRP) levels above the upper limit of normal
    - Sacroiliitis on magnetic resonance imaging (MRI)

      If yes, **approve the requested strength by GPID or GPI-14 for a total of 6 months as follows:**
      <u>FIRST APPROVAL:</u>
      - **150mg/mL: Approve for 1 month with a quantity limit of #4mL per 28 days.**
      - **125mg/5mL: Approve for 1 month with a fill count of #1.**

      <u>SECOND APPROVAL</u>: Approve for 5 months with the following quantity limits (enter a start date of 3 DAYS BEFORE the END date of the first approval):
      - **150mg/mL: #1mL per 28 days.**
      - **125mg/5mL: #15mL per 28 days.**

      If no, do not approve.
      DENIAL TEXT: See the initial denial text at the end of the guideline.

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

15. Does the patient have a diagnosis of enthesitis-related arthritis (ERA) and meet **ALL** of the following criteria?
    - The patient is 4 years of age or older
    - Therapy is prescribed by or in consultation with a rheumatologist
    - The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam), sulfasalazine, or methotrexate

    If yes, **approve the requested strength by GPID or GPI-14 for a total of 6 months as follows:**
    FIRST APPROVAL: Approve for 1 month with the following quantity limits:
    - **75mg/0.5mL: #2mL per 28 days.**
    - **150mg/mL: #4mL per 28 days.**

    SECOND APPROVAL: Approve for 5 months with the following quantity limits (enter a start date of 3 DAYS BEFORE the END date of the first approval):
    - **75mg/0.5mL: #0.5mL per 28 days.**
    - **150mg/mL: #1mL per 28 days.**

    If no, continue to #16.

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

16. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Therapy is prescribed by or in consultation with a dermatologist
    - Cosentyx will NOT be used together with other systemic biologics (e.g., Humira [adalimumab]) for the treatment of HS or other IL-17 inhibitors (e.g., Taltz [ixekizumab]) for any indication
    - The patient had a trial of or contraindication to TWO topical therapies (e.g., clindamycin, resorcinol, chlorhexidine, zinc pyrithione, benzoyl peroxide) or oral antibiotics (e.g., tetracycline, dapsone)
    - The patient had a trial of or contraindication to ONE of the following preferred agents: Humira (adalimumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
      [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

      If yes, **approve the requested strength by GPID or GPI-14 for a total of 4 months as follows:**
      <u>FIRST APPROVAL</u>: Approve for 1 month with the following quantity limits:
      - **150mg/mL: #8mL per 28 days.**
      - **300mg/2mL: #8mL per 28 days.**

      <u>SECOND APPROVAL</u>: Approve for 3 months with the following quantity limits (enter a start date of 3 DAYS BEFORE the END date of the first approval):
      - **150mg/mL: #4mL per 28 days.**
      - **300mg/2mL: #4mL per 28 days.**

      If no, do not approve.
      DENIAL TEXT: See the initial denial text at the end of the guideline.

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SECUKINUMAB (Cosentyx)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
   5. Enthesitis-related arthritis (ERA: a type of joint condition)
   6. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)

B. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You have psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   5. You meet ONE of the following:
      a. You have had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
      b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
      c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

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INITIAL CRITERIA (CONTINUED)

6. You meet ONE of the following:
   a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) THREE of the preferred medications: Enbrel (etanercept), Taltz (ixekizumab), Stelara (ustekinumab)
   b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) FOUR of the following preferred medications: Taltz (ixekizumab), Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

C. **If you have psoriatic arthritis, approval also requires:**
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
3. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
4. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
5. Requests for the 300mg maintenance dosage in psoriatic arthritis without coexisting plaque psoriasis requires that you have tried the 150mg maintenance dosing schedule AND continue to have active psoriatic arthritis
6. You meet ONE of the following:
   a. You are 2 to 5 years of age AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Enbrel (etanercept)
   b. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) BOTH of the preferred medications: Enbrel (etanercept), Stelara (ustekinumab)
   c. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications: Taltz (ixekizumab), Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz IR/XR (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

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INITIAL CRITERIA (CONTINUED)

D. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) an NSAID (such as ibuprofen, naproxen, meloxicam)
   5. Requests for the 300mg maintenance dosage requires that you have tried the 150mg maintenance dosage schedule AND continue to have active ankylosing spondylitis
   6. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Taltz (ixekizumab), Xeljanz IR/XR (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

E. **If you have non-radiographic axial spondyloarthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) an NSAID (such as ibuprofen, naproxen, meloxicam)
   5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Taltz (ixekizumab), Cimzia (certolizumab), Rinvoq (upadacitinib)
   6. You have ONE of the following signs of inflammation:
      a. C-reactive protein (CRP: a measure of how much inflammation is in the body) levels above the upper limit of normal
      b. Sacroiliitis (type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI)

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

F. **If you have enthesitis-related arthritis, approval also requires:**
   1. You are 4 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) an NSAID (such as ibuprofen, naproxen, meloxicam), sulfasalazine, or methotrexate

G. **If you have moderate to severe hidradenitis suppurativa, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You will NOT use Cosentyx together with other systemic biologics (such as Humira [adalimumab]) for the treatment of hidradenitis suppurativa or other interleukin-17 (IL-17) inhibitors (such as Taltz [ixekizumab]) for any indication
   4. You have tried or have a contraindication to (harmful for you to use) TWO topical therapies (such as clindamycin, resorcinol, chlorhexidine, zinc pyrithione, benzoyl peroxide) or oral antibiotics (such as, tetracycline, dapsone)
   5. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Humira (adalimumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SECUKINUMAB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy
   - Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to THREE of the preferred agents: Enbrel (etanercept), Taltz (ixekizumab), Stelara (ustekinumab)
   - The patient is 18 years of age or older AND had a trial of or contraindication to FOUR of the following preferred agents: Taltz (ixekizumab), Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve the requested strength by GPID or GPI-14 for 12 months with the following quantity limits:**
   - **75mg/0.5mL: #0.5mL per 28 days.**
   - **150mg/mL: #1mL per 28 days.**
   - **300mg/2mL: #2mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication

   If yes, continue to #4.
   If no, continue to #5.

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SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   - The patient is 2 to 5 years of age AND had a trial of or contraindication to the preferred agent: Enbrel (etanercept)
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to BOTH of the preferred agents: Enbrel (etanercept), Stelara (ustekinumab)
   - The patient is 18 years of age or older AND had a trial of or contraindication to THREE of the following preferred agents: Taltz (ixekizumab), Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve the requested strength by GPID or GPI-14 for 12 months with the following quantity limits:**
     - **75mg/0.5mL: #0.5mL per 28 days.**
     - **150mg/mL: #1mL per 28 days.**
     - **300mg/2mL: #2mL per 28 days.**
     - **125mg/5mL: #15mL per 28 days.**

     If no, do not approve.
     DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1 - 10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy
   - Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Taltz (ixekizumab), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve the requested strength by GPID or GPI-14 for 12 months with the following quantity limits:**
     - **150mg/mL: #1mL per 28 days.**
     - **300mg/2mL: #2mL per 28 days.**
     - **125mg/5mL: #15mL per 28 days.**

     If no, continue to #6.

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SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1 - 10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy
   - Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Taltz (ixekizumab), Cimzia (certolizumab), Rinvoq (upadacitinib)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve the requested strength by GPID or GPI-14 for 12 months with the following quantity limits:**
     - **150mg/mL: #1mL per 28 days.**
     - **125mg/5mL: #15mL per 28 days.**

     If no, continue to #7.

7. Does the patient have a diagnosis of enthesitis-related arthritis (ERA) **AND** meet the following criterion?
   - The patient has experienced or maintained an improvement in global assessment of disease activity, functional ability, number of joints with active arthritis, OR number of joints with limited range of motion

     If yes, **approve the requested strength by GPID or GPI-14 for 12 months with the following quantity limits:**
     - **75mg/0.5mL: #0.5mL per 28 days.**
     - **150mg/mL: #1mL per 28 days.**

     If no, continue to #8.

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SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

8. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) and meet **ALL** of the following criteria?
   - The patient has shown improvement on therapy
   - Cosentyx will NOT be used together with other systemic biologics (e.g., Humira [adalimumab]) for the treatment of HS or other IL-17 inhibitors (e.g., Taltz [ixekizumab]) for any indication
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Humira (adalimumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve the requested strength by GPID or GPI-14 for 12 months with the following quantity limits:**
     - **150mg/mL: #4mL per 28 days.**
     - **300mg/2mL: #4mL per 28 days.**

     If no, do not approve.

     RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

     Our guideline named **SECUKINUMAB (Cosentyx)** requires the following rule(s) be met for renewal:

     A. You have ONE of the following:
        1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
        2. Psoriatic arthritis (PsA: a type of skin and joint condition)
        3. Ankylosing spondylitis (AS: a type of joint condition)
        4. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
        5. Enthesitis-related arthritis (ERA: a type of joint condition)
        6. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)

     (Renewal denial text continued on next page)

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SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

B. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
   2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   3. You meet ONE of the following:
      a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) THREE of the preferred medications: Enbrel (etanercept), Taltz (ixekizumab), Stelara (ustekinumab)
      b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) FOUR of the following preferred medications: Taltz (ixekizumab), Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   3. You meet ONE of the following:
      a. You are 2 to 5 years of age AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Enbrel (etanercept)
      b. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) BOTH of the preferred medications: Enbrel (etanercept), Stelara (ustekinumab)
      c. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications: Taltz (ixekizumab), Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate-release or extended-release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

(Renewal denial text continued on next page)

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SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

D. **If you have ankylosing spondylitis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1 - 10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
   2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Taltz (ixekizumab), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

E. **If you have non-radiographic axial spondyloarthritis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1 - 10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
   2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Taltz (ixekizumab), Cimzia (certolizumab), Rinvoq (upadacitinib)

F. **If you have enthesitis-related arthritis, renewal also requires:**
   1. You have experienced or maintained an improvement in global assessment of disease activity, functional ability, number of joints with active arthritis, OR number of joints with limited range of motion

(Renewal denial text continued on next page)

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SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

G. **If you have moderate to severe hidradenitis suppurativa, renewal also requires:**
   1. You have shown improvement on therapy
   2. You will NOT use Cosentyx together with other systemic biologics (such as Humira [adalimumab]) for the treatment of hidradenitis suppurativa or other interleukin-17 (IL-17) inhibitors (such as Taltz [ixekizumab]) for any indication
   3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Humira (adalimumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cosentyx.

REFERENCES

- Cosentyx [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. October 2023.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 05/01/24
Created: 02/15
Client Approval: 04/24
P&T Approval: 04/24

STANDARD COMMERCIAL AND NSA DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SELEXIPAG

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have documentation (e.g., chart note, lab result, diagnostic test result, etc.) confirming a PAH diagnosis based on right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SELEXIPAG

INITIAL CRITERIA (CONTINUED)

3. Has the patient had a trial of or contraindication to **TWO** of the following agents from different drug classes?
   - Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
   - Oral phosphodiesterase-5 inhibitor (e.g., Revatio [sildenafil], Adcirca [tadalafil])
   - Oral cGMP stimulator (e.g., Adempas [riociguat])
   - IV/SQ prostacyclin (e.g., Flolan [epoprostenol], Remodulin [treprostinil])

   If yes, **approve for 12 months by GPID or GPI-14 as follows (enter both approvals):**
   - **FIRST APPROVAL: Approve Uptravi 200-800mcg Titration Pack with a quantity limit of #200 per 28 days for 1 fill.**
   - **SECOND APPROVAL: Approve the requested strength as follows:**
     - **200mcg tablet: #8 per day.**
     - **400mcg, 600mcg, 800mcg, 1,000mcg, 1,200mcg, 1,400mcg, 1,600mcg tablet: #2 per day.**
     - **1,800mcg vial: #2 per day.**

   (NOTE: Uptravi vial is a non-self-administered [NSA] agent and may not be covered by some plans.)

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SELEXIPAG (Uptravi)** requires the following rule(s) be met for approval:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   C. There is documentation (such as, chart note, lab result, diagnostic test result) showing you have pulmonary arterial hypertension based on ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      3. Pulmonary vascular resistance (PVR) greater than 2 Wood units

   (Initial denial text continued on next page)

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SELEXIPAG

INITIAL CRITERIA (CONTINUED)

D. You have tried or have a contraindication to (harmful for you to use) TWO of the following medications from different drug classes:
   1. Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
   2. Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
   3. Oral cGMP stimulator (such as Adempas [riociguat])
   4. Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SELEXIPAG

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1)?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **200mcg tablet: #8 per day.**
   - **400mcg, 600mcg, 800mcg, 1,000mcg, 1,200mcg, 1,400mcg, 1,600mcg tablet: #2 per day.**
   - **1,800mcg vial: #2 per day.**

   (NOTE: Uptravi vial is a non-self-administered [NSA] agent and may not be covered by some plans.)

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SELEXIPAG (Uptravi)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Uptravi.

REFERENCES

- Uptravi [Prescribing Information]. Titusville, NJ: Actelion Pharmaceuticals US, Inc.; July 2022.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 01/16
Client Approval: 02/24
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SELINEXOR

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma (MM) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used in combination with bortezomib (Velcade) **AND** dexamethasone
   - The patient has received at least one prior therapy

   If yes, **approve all of the following for 12 months by GPID or GPI-14:**
   - **40 mg once weekly dose: #4 per 28 days.**
   - **60 mg once weekly dose: #4 per 28 days.**
   - **80 mg once weekly dose: #8 per 28 days.**
   - **100 mg once weekly dose: #8 per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of relapsed or refractory multiple myeloma (RRMM) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used in combination with dexamethasone
   - The patient has received at least four prior therapies for the treatment of RRMM
   - The patient's RRMM is refractory to **ALL** of the following:
     - Two proteasome inhibitors (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])
     - Two immunomodulatory agents (e.g., lenalidomide [Revlimid], pomalidomide [Pomalyst])
     - One anti-CD38 monoclonal antibody (e.g., daratumumab [Darzalex])

   If yes, **approve all of the following for 12 months by GPID or GPI-14:**
   - **60 mg once weekly dose: #4 per 28 days.**
   - **80 mg once weekly: #8 per 28 days.**
   - **100 mg once weekly dose: #8 per 28 days.**
   - **80 mg twice weekly (160 mg total per week) dose: #32 per 28 days.**

   If no, continue to #3.

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SELINEXOR

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least two lines of systemic therapy

   If yes, **approve all of the following for 12 months by GPID or GPI-14:**
   - **40 mg once weekly dose: #4 per 28 days.**
   - **60 mg once weekly dose: #4 per 28 days.**
   - **40 mg twice weekly (80 mg total per week) dose: #8 per 28 days.**
   - **60 mg twice weekly (120 mg total per week) dose: #24 per 28 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SELINEXOR (Xpovio)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Multiple myeloma (MM: a type of blood cancer)
      2. Relapsed or refractory multiple myeloma (RRMM: a type of blood cancer that returned or did not respond to treatment)
      3. Relapsed or refractory diffuse large B-cell lymphoma (DLBCL: a type of blood cancer), including DLBCL arising from follicular lymphoma

   B. You are 18 years of age or older
   C. **If you have multiple myeloma, approval also requires:**
      1. The requested medication will be used in combination with bortezomib (Velcade) and dexamethasone
      2. You have received at least one therapy before Xpovio

   D. **If you have relapsed or refractory multiple myeloma, approval also requires:**
      1. The requested medication will be used in combination with dexamethasone
      2. You have received at least four prior therapies for the treatment of RRMM)
      3. Your RRMM is refractory (non-responsive) to **ALL** of the following:
         a. Two proteasome inhibitors (such as bortezomib [Velcade], carfilzomib [Kyprolis])
         b. Two immunomodulatory agents (such as lenalidomide [Revlimid], pomalidomide [Pomalyst])
         c. One anti-CD38 monoclonal antibody (such as daratumumab [Darzalex])

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SELINEXOR

GUIDELINES FOR USE (CONTINUED)

E. **If you have relapsed or refractory diffuse large B-cell lymphoma, approval also requires:**
   1. You have received at least two lines of systemic therapy (treatment that spreads throughout the body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xpovio.

REFERENCES

- Xpovio [Prescribing Information]. Newton, MA: Karyopharm Therapeutics Inc.; July 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/23
Created: 07/19
Client Approval: 06/23
P&T Approval: 01/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SELPERCATINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a *RET* gene fusion, as detected by an FDA-approved test

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **40mg: #6 per day.**
   - **80mg: #4 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of advanced or metastatic medullary thyroid cancer (MTC) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient's cancer has a *RET*-mutation, as detected by an FDA-approved test
   - The patient requires systemic therapy

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **40mg: #6 per day.**
   - **80mg: #4 per day.**

   If no, continue to #3.

3. Does the patient have a diagnosis of advanced or metastatic thyroid cancer and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient's cancer has a *RET* gene fusion, as detected by an FDA-approved test
   - The patient requires systemic therapy
   - The thyroid cancer is refractory to radioactive iodine therapy (if radioactive iodine is appropriate)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **40mg: #6 per day.**
   - **80mg: #4 per day.**

   If no, continue to #4.

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SELPERCATINIB

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of locally advanced or metastatic solid tumors and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumor has a *RET* gene fusion
   - The tumor has progressed on or following prior systemic treatment OR the patient has no satisfactory alternative treatment options

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **40mg: #6 per day.**
   - **80mg: #4 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SELPERCATINIB (Retevmo)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Locally advanced or metastatic non-small cell lung cancer (a type of lung cancer that has spread to nearby tissue or lymph nodes, or has spread to other parts of the body)
      2. Advanced or metastatic medullary thyroid cancer (a type of thyroid cancer that has progressed or has spread to other parts of the body)
      3. Advanced or metastatic thyroid cancer (thyroid cancer that has progressed or has spread to other parts of the body)
      4. Locally advanced or metastatic solid tumors (abnormal mass that has spread to nearby tissue or lymph nodes, or has spread to other parts of the body)
   B. **If you have locally advanced or metastatic non-small cell lung cancer, approval also requires:**
      1. You are 18 years of age or older
      2. Your cancer has a rearranged during transfection (*RET:* type of gene) gene fusion, as detected by a Food and Drug Administration (FDA) approved test
   C. **If you have advanced or metastatic medullary thyroid cancer, approval also requires:**
      1. You are 12 years of age or older
      2. Your cancer has a rearranged during transfection (*RET*: type of gene) mutation, as detected by a Food and Drug Administration (FDA) approved test
      3. You require systemic therapy (treatment that travels through the entire body)

   (Denial text continued on next page)

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SELPERCATINIB

GUIDELINES FOR USE (CONTINUED)

D. **If you have advanced or metastatic thyroid cancer, approval also requires:**
   1. You are 12 years of age or older
   2. You require systemic therapy (treatment that travels through the entire body)
   3. Your cancer has a rearranged during transfection (*RET*: type of gene) gene fusion, as detected by a Food and Drug Administration (FDA) approved test
   4. Your thyroid cancer is refractory (has not responded) to radioactive iodine therapy, if radioactive iodine is appropriate

E. **If you have locally advanced or metastatic solid tumors, approval also requires:**
   1. You are 18 years of age or older
   2. Your tumor has a rearranged during transfection (*RET*: type of gene) gene fusion
   3. Your tumor has progressed on or following prior systemic treatment OR you have no satisfactory alternative treatment options

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Retevmo.

REFERENCES

- Retevmo [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC; September 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/17/22
Created: 07/20
Client Approval: 09/22
P&T Approval: 10/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SELUMETINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of neurofibromatosis type 1 (NF1) and meet **ALL** of the following criteria?
   - The patient is 2 to 17 years of age
   - The patient has symptomatic, inoperable plexiform neurofibromas (PN)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **Koselugo 10mg: #10 per day.**
   - **Koselugo 25mg: #4 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SELUMETINIB (Koselugo)** requires the following rule(s) be met for approval:
   A. You have neurofibromatosis type 1 (NF1: a genetic disorder that causes light brown skin spots and non-cancerous tumors to form on nerve tissue)
   B. You are 2 to 17 years of age
   C. You have symptomatic, inoperable (not treatable by surgery) plexiform neurofibromas (PN: tumors that grow from nerves anywhere in the body)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Koselugo.

REFERENCES

- Koselugo [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; April 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/20
Created: 07/20
Client Approval: 08/20
P&T Approval: 07/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SEMAGLUTIDE - WEGOVY

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke)?

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is overweight (BMI is at least 27 kg/m[2])
   - Wegovy will be used in combination with a reduced calorie diet and increased physical activity
   - Wegovy will NOT be used concurrently with another GLP-1 receptor agonist (e.g., Victoza [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have established cardiovascular disease as evidenced by **ONE** of the following?
   - Prior myocardial infarction
   - Prior stroke (ischemic or hemorrhagic stroke)
   - Symptomatic peripheral arterial disease (PAD), as evidenced by intermittent claudication with ankle-brachial index (ABI) less than 0.85 (at rest), peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL: #2 mL per 28 days.**
   - **1.7 mg/0.75 mL, 2.4 mg/0.75 mL: #3 mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SEMAGLUTIDE - WEGOVY

INITIAL CRITERIA (CONTINUED)

4. Is the request for weight loss or weight management?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Is weight loss or weight management a covered benefit?
   (**NOTE:** If weight loss/weight management is NOT a covered benefit - Denied claim would have this POS message - '*Benefit exclusion if only indicated for weight loss. ')*

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the '*Benefit exclusion of weight loss*' initial denial text at the end of the guideline.

6. Does the patient meet **ALL** of the following criteria?
   - There is evidence of active enrollment in an exercise and caloric reduction program OR a weight loss/behavioral modification program
   - Wegovy will NOT be used concurrently with another GLP-1 receptor agonist (e.g., Victoza [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])

   If yes, continue to #7.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Is the patient 18 years of age or older and meets **ONE** of the following criteria?
   - The patient has a body mass index (BMI) of at least 30 kg/m(2)
   - The patient has a BMI of at least 27 kg/m(2) AND at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, hyperlipidemia)

   If yes, **approve for 29 weeks by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL: #2 mL per 28 days.**
   - **1.7 mg/0.75 mL, 2.4 mg/0.75 mL: #3 mL per 28 days.**

   If no, continue to #8.

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SEMAGLUTIDE - WEGOVY

INITIAL CRITERIA (CONTINUED)

8. Is the patient 12 to 17 years of age **AND** meets the following criterion?
   - The patient has an initial BMI at the 95th percentile or greater standardized for age and sex (See table below)

BMI Cut-offs for Obesity by Age and Sex

Age (in years)	Male	Female
	95th Percentile BMI Value	95th Percentile BMI Value
12	24.2	25.2
12.5	24.7	25.7
13	25.1	26.3
13.5	25.6	26.8
14	26.0	27.2
14.5	26.4	27.7
15	26.8	28.1
15.5	27.2	28.5
16	27.5	28.9
16.5	27.9	29.3
17	28.2	29.6
17.5	28.6	30.0

If yes, **approve for 29 weeks by GPID or GPI-14 for all strengths with the following quantity limits:**
- **0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL: #2 mL per 28 days.**
- **1.7 mg/0.75 mL, 2.4 mg/0.75 mL: #3 mL per 28 days.**

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SEMAGLUTIDE - WEGOVY** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. To reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction [heart attack], or non-fatal stroke [a type of brain damage])
   2. Weight loss or weight management

(Initial denial text continued on the next page)

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SEMAGLUTIDE - WEGOVY

INITIAL CRITERIA (CONTINUED)

B. **If you will use Wegovy to reduce the risk of major adverse cardiovascular events, approval also requires:**
   1. You are 18 years of age or older
   2. You are overweight (your BMI [body mass index: a tool for evaluating body fat] is at least 27 kg/m[2])
   3. Wegovy will be used in combination with a reduced calorie diet and increased physical activity
   4. You will NOT use Wegovy concurrently (at the same time) with another GLP-1 receptor agonist (a type of drug for type 2 diabetes such as Victoza [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])
   5. You have established cardiovascular disease as evidenced by ONE of the following:
      a. Prior myocardial infarction (heart attack)
      b. Prior stroke (ischemic [stroke caused by blood clot] or hemorrhagic [stroke caused by broken blood vessel in the brain])
      c. Symptomatic peripheral arterial disease (PAD), as evidenced by intermittent claudication (pain caused by too little blood flow) with ankle-brachial index (ABI: a type of test to check blood flow) less than 0.85 (at rest), peripheral arterial revascularization procedure (surgery to restore blood flow in blocked arteries/veins), or amputation due to atherosclerotic disease (buildup of fat)

C. **If you will use Wegovy for weight loss or weight management, approval also requires:**
   1. There is evidence of your active enrollment in an exercise and caloric reduction program OR a weight loss/behavioral modification program
   2. You will NOT use Wegovy concurrently (at the same time) with another GLP-1 receptor agonist (a type of drug for type 2 diabetes such as Victoza [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])
   3. You meet ONE of the following:
      a. You are 18 years of age or older and meet ONE of the following:
         i. You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
         ii. You have a BMI of at least 27 kg/m(2) AND at least one weight-related comorbidity (disease) such as hypertension (high blood pressure), type 2 diabetes mellitus (a disorder with high blood sugar), or hyperlipidemia (high cholesterol)
      b. You are 12 to 17 years of age and meet the following:
         i. You have an initial body mass index (BMI: a tool for evaluating body fat) in the 95th percentile or greater standardized for age and sex

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SEMAGLUTIDE - WEGOVY

INITIAL CRITERIA (CONTINUED)

USE THIS DENIAL TEXT FOR BENEFIT EXCLUSION OF WEIGHT LOSS [Answer is NO to question 5].

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SEMAGLUTIDE - WEGOVY** requires the following rule(s) be met for approval:

A. The request is to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction [heart attack], or non-fatal stroke [a type of brain damage])
B. You are 18 years of age or older
C. You are overweight (your BMI [body mass index: a tool for evaluating body fat] is at least 27 kg/m[2])
D. Wegovy will be used in combination with a reduced calorie diet and increased physical activity
E. You will NOT use Wegovy concurrently (at the same time) with another GLP-1 receptor agonist (a type of drug for type 2 diabetes such as Victoza [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])
F. You have established cardiovascular disease as evidenced by ONE of the following:
    1. Prior myocardial infarction (heart attack)
    2. Prior stroke (ischemic [stroke caused by blood clot] or hemorrhagic [stroke caused by broken blood vessel in the brain])
    3. Symptomatic peripheral arterial disease (PAD), as evidenced by intermittent claudication (pain caused by too little blood flow) with ankle-brachial index (ABI: a type of test to check blood flow) less than 0.85 (at rest), peripheral arterial revascularization procedure (surgery to restore blood flow in blocked arteries/veins), or amputation due to atherosclerotic disease (buildup of fat)

NOTE: Your plan does not cover Wegovy when it is only used for weight loss or weight management.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SEMAGLUTIDE - WEGOVY

RENEWAL CRITERIA

1. Is the request to reduce the risk of cardiovascular death, heart attack, and stroke, and the patient meets **ALL** of the following criteria?
   - The patient has cardiovascular disease (e.g., prior myocardial infarction, prior stroke, symptomatic peripheral arterial disease [PAD])
   - Wegovy will be used in addition to a reduced calorie diet and increased physical activity
   - Wegovy will NOT be used concurrently with another GLP-1 receptor agonist (e.g., Victoza [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL: #2 mL per 28 days.**
   - **1.7 mg/0.75 mL, 2.4 mg/0.75 mL: #3 mL per 28 days.**

   If no, continue to #2.

2. Is the request for weight loss or weight management?

   If yes, continue to #3.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Is weight loss or weight management a covered benefit?
   (**NOTE**: If weight loss/weight management is NOT a covered benefit - Denied claim would have this POS message - '*Benefit exclusion if only indicated for weight loss.')*

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the *"Benefit exclusion of weight loss"* renewal denial text at the end of the guideline.

4. Will Wegovy be used concurrently with another GLP-1 receptor agonist (e.g., Victoza [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #5.

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RENEWAL CRITERIA (CONTINUED)

5. Does the patient meet **ONE** of the following criteria?
   - The patient is 18 years of age or older AND has achieved or maintained at least a 5 percent weight loss of baseline body weight
   - The patient is 12 to 17 years of age AND has achieved or maintained at least a 5 percent weight loss of baseline body mass index (BMI)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL: #2 mL per 28 days.**
   - **1.7 mg/0.75 mL, 2.4 mg/0.75 mL: #3 mL per 28 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SEMAGLUTIDE - WEGOVY** requires the following rule(s) be met for renewal:

   A. The request is for ONE of the following:
      1. To reduce the risk of cardiovascular death, heart attack, and stroke (a type of brain damage)
      2. Weight loss or weight management

   B. **If you will use Wegovy to reduce the risk of cardiovascular death, heart attack, and stroke, renewal also requires:**
      1. You have cardiovascular disease (such as prior heart attack, prior stroke, symptomatic peripheral arterial disease [PAD])
      2. Wegovy will be used in addition to a reduced calorie diet and increased physical activity
      3. You will NOT use Wegovy concurrently (at the same time) with another GLP-1 receptor agonist (a type of drug for type 2 diabetes such as Victoza [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])

   C. **If you will use Wegovy for weight loss or weight management, renewal also requires:**
      1. You will NOT use Wegovy concurrently (at the same time) with another GLP-1 receptor agonist (a type of drug for type 2 diabetes such as Victoza [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])
      2. You meet ONE of the following:
         a. You are 18 years of age or older AND have achieved or maintained at least a 5 percent weight loss of baseline body weight
         b. You are 12 to 17 years of age AND have achieved or maintained at least a 5 percent weight loss of baseline body mass index (BMI: a tool for evaluating body fat)

(Renewal denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

USE THIS DENIAL TEXT FOR BENEFIT EXCLUSION OF WEIGHT LOSS [Answer is NO to question 3].

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SEMAGLUTIDE - WEGOVY** requires the following rule(s) be met for renewal:

A. The request is to reduce the risk of cardiovascular death, heart attack, and stroke (a type of brain damage)
B. You have cardiovascular disease (such as prior heart attack, prior stroke, symptomatic peripheral arterial disease [PAD])
C. Wegovy will be used in addition to a reduced calorie diet and increased physical activity
D. You will NOT use Wegovy concurrently (at the same time) with another GLP-1 receptor agonist (a type of drug for type 2 diabetes such as Victoza [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])

NOTE: Your plan does not cover Wegovy when it is only used for weight loss or weight management.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Wegovy.

REFERENCES

- Wegovy [Prescribing Information]. Plainsboro, NJ: Novo Nordisk, Inc.; March 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 03/27/24
Created: 03/24
Client Approval: 03/24
P&T Approval: 04/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SETMELANOTIDE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for chronic weight management in obesity, and does the patient meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - The patient's obesity is due to **ONE** of the following deficiencies:
     - Pro-opiomelanocortin (POMC)
     - Proprotein convertase subtilisin/kexin type 1 (PCSK1)
     - Leptin receptor (LEPR)
   - Confirmed genetic testing demonstrates variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS)

   If yes, **approve for 16 weeks by HICL or GPI-10 with a quantity limit of #0.3 mL per day.**

   If no, continue to #2.

2. Is the request for chronic weight management in obesity, and does the patient meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - The patient's obesity is due to Bardet-Biedl syndrome (BBS)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.3 mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SETMELANOTIDE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SETMELANOTIDE (Imcivree)** requires the following rule(s) be met for approval:

A. The request is for chronic weight management
B. You are 6 years of age or older
C. You have a diagnosis of obesity (a condition where you have higher than normal body fat) that is caused by ONE of the following:
    1. Bardet-Biedl syndrome (BBS: a genetic disorder)
    2. A deficiency in ONE of the following:
        a. Pro-opiomelanocortin (POMC: type of gene)
        b. Proprotein convertase subtilisin/kexin type 1 (PCSK1: type of gene)
        c. Leptin receptor (LEPR: type of gene)
D. **If your obesity is caused by a POMC, PCSK1, or LEPR deficiency, approval also requires:**
    1. Confirmed genetic testing shows variants (changes) in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic (causing disease), likely pathogenic, or of uncertain significance (VUS)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SETMELANOTIDE

RENEWAL CRITERIA

1. Is the request for chronic weight management in obesity caused by a deficiency in pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR), and the patient meets **ONE** of the following criteria?
   - The patient is 18 years of age or older AND has lost at least 5% of baseline body weight
   - The patient is 6 to 17 years of age AND has lost at least 5% of baseline body mass index (BMI)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #0.3 mL per day.**
   If no, continue to #2.

2. Is the request for chronic weight management in obesity caused by Bardet-Biedl syndrome, and the patient meets **ONE** of the following criteria?
   - The patient is 18 years of age or older AND has lost at least 5% of baseline body weight
   - The patient is 6 to 17 years of age AND has lost at least 5% of baseline body mass index (BMI)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.3 mL per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SETMELANOTIDE (Imcivree)** requires the following rule(s) be met for approval:
   A. You have a diagnosis of obesity (a condition where you have higher than normal body fat) that is caused by ONE of the following:
      1. Bardet-Biedl syndrome (BBS: a genetic disorder)
      2. A deficiency in ONE of the following:
         a. Pro-opiomelanocortin (POMC: type of gene)
         b. Proprotein convertase subtilisin/kexin type 1 (PCSK1: type of gene)
         c. Leptin receptor (LEPR: type of gene)

   B. You meet ONE of the following:
      1. You are 18 years of age or older AND have lost at least 5% of your baseline body weight
      2. You are 6 to 17 years of age AND have lost at least 5% of your baseline body mass index (BMI: a tool for evaluating body fat)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SETMELANOTIDE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Imcivree.

REFERENCES

- Imcivree [Prescribing Information]. Boston, MA: Rhythm Pharmaceuticals, Inc.; June 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/23

Created: 02/21
Client Approval: 06/23

P&T Approval: 01/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SILDENAFIL IV

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The requested medication will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - The requested medication will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have documentation (e.g., chart note, lab result, diagnostic test result, etc.) confirming a PAH diagnosis based on right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #37.5mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SILDENAFIL IV

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SILDENAFIL IV (Revatio)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
D. There is documentation (such as, chart note, lab result, diagnostic test result) showing you have pulmonary arterial hypertension based on ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 2 Wood units
E. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
F. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SILDENAFIL IV

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
   - The requested medication will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - The requested medication will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes**, approve for 12 months by GPID or GPI-14 with a quantity limit of #37.5mL per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SILDENAFIL IV (Revatio)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   B. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   C. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Revatio.

REFERENCES

- Revatio [Prescribing Information]. New York, NY: Pfizer Inc.; January 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 01/08
Client Approval: 02/24
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SILDENAFIL SUSPENSION

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
   - The patient is 1 to 17 years of age
   - The request is for Revatio (sildenafil) suspension
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The requested medication will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - The requested medication will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])
   - The patient is unable to swallow pills and has tried crushed sildenafil tablets

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient have documentation (e.g., chart note, lab result, diagnostic test result, etc.) confirming a PAH diagnosis based on right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than or equal to 3 Wood units (WU)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #14.93mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SILDENAFIL SUSPENSION

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The requested medication will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - The requested medication will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have documentation (e.g., chart note, lab result, diagnostic test result, etc.) confirming a PAH diagnosis based on right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Is the request for **Revatio (sildenafil)** suspension **AND** the patient meets the following criterion?
   - The patient is unable to swallow pills and has tried crushed sildenafil tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #26.13mL per day.**
   If no, continue to #6.

6. Is the request for **Liqrev** suspension and the patient meets **ALL** of the following criteria?
   - The patient is unable to swallow Revatio (sildenafil) tablet
   - The patient had a trial of generic sildenafil powder for suspension

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #8.13mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SILDENAFIL SUSPENSION

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SILDENAFIL SUSPENSION (Revatio, Liqrev)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. **If you are 1 to 17 years of age, approval also requires:**
   1. You are requesting Revatio (sildenafil) suspension
   2. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   3. There is documentation (such as, chart note, lab result, diagnostic test result) showing you have pulmonary arterial hypertension based on ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units
   4. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   5. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])
   6. You are unable to swallow pills AND you have tried crushed sildenafil tablets
C. **If you are 18 years of age or older, approval also requires:**
   1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   2. There is documentation (such as, chart note, lab result, diagnostic test result) showing you have pulmonary arterial hypertension based on ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR) greater than 2 Wood units
   3. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   4. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

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SILDENAFIL SUSPENSION

INITIAL CRITERIA (CONTINUED)

5. If you are requesting Revatio (sildenafil) suspension, you are unable to swallow pills AND you have tried crushed sildenafil tablets
6. If you are requesting Liqrev suspension, you are unable to swallow Revatio (sildenafil) tablets AND you have tried generic sildenafil powder for suspension

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SILDENAFIL SUSPENSION

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
   - The requested medication will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - The requested medication will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient 1 to 17 years of age **AND** meets the following criterion?
   - The request is for Revatio (sildenafil) suspension

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #14.93mL per day.**
   If no, continue to #3.

3. Is the patient 18 years of age or older?

   If yes**, approve for 12 months by GPID or GPI-14 for the requested agent with the following quantity limits:**
   - **Revatio (sildenafil): #26.13mL per day.**
   - **Liqrev (sildenafil): #8.13mL per day.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SILDENAFIL SUSPENSION

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SILDENAFIL SUSPENSION (Revatio, Liqrev)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. **If you are 1 to 17 years of age, approval also requires:**
   1. You are requesting Revatio (sildenafil) suspension
   2. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   3. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])
C. **If you are 18 years of age or older, approval also requires:**
   1. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   2. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Revatio and Liqrev.

REFERENCES

- Revatio [Prescribing Information]. New York, NY: Pfizer Inc.; January 2023.
- Liqrev [Prescribing Information]. Farmville, NC: CMP Pharma Inc.; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 01/08
Client Approval: 02/24
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SILDENAFIL TABLET

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
   - The patient is 1 to 17 years of age
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The requested medication will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - The requested medication will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient have documentation (e.g., chart note, lab result, diagnostic test result, etc.) confirming a PAH diagnosis based on right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than or equal to 3 Wood units (WU)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #6 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

SILDENAFIL TABLET

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The requested medication will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - The requested medication will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have documentation (e.g., chart note, lab result, diagnostic test result, etc.) confirming a PAH diagnosis based on right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #12 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **SILDENAFIL TABLET (Revatio)** requires the following rule(s) be met for approval:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
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SILDENAFIL TABLET

INITIAL CRITERIA (CONTINUED)

B. **If you are 18 years of age or older, approval also requires:**
   1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   2. There is documentation (such as, chart note, lab result, diagnostic test result) showing you have pulmonary arterial hypertension based on ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR) greater than 2 Wood units
   3. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   4. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

C. **If you are 1 to 17 years of age, approval also requires:**
   1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   2. There is documentation (such as, chart note, lab result, diagnostic test result) showing you have pulmonary arterial hypertension based on ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units
   3. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   4. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SILDENAFIL TABLET

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
   - The requested medication will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - The requested medication will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient 1 to 17 years of age?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #6 per day.**
   If no, continue to #3.

3. Is the patient 18 years of age or older?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #12 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SILDENAFIL TABLET (Revatio)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   B. You are 1 year of age or older
   C. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   D. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SILDENAFIL TABLET

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Revatio.

REFERENCES

- Revatio [Prescribing Information]. New York, NY: Pfizer Inc.; January 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 01/08
Client Approval: 02/24
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SIPONIMOD

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have a CYP2C9 *1/*1, *1/*2, or *2/*2 genotype?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Mayzent 0.25mg starter pack for 2 mg maintenance dose: #12 tablets (1 pack) per fill.**
   - **Mayzent 2mg: #1 per day.**

   If no, continue to #3.

3. Does the patient have a CYP2C9 *1/*3 or *2/*3 genotype?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Mayzent 0.25mg starter pack for 1 mg maintenance dose: #7 tablets (1 pack) per fill.**
   - **Mayzent 0.25mg: #4 per day.**
   - **Mayzent 1mg: #1 per day.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SIPONIMOD (Mayzent)** requires the following rule(s) be met for approval:
   A. You have relapsing forms of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (symptoms occur once), relapsing-remitting disease (symptoms return and go away), or active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older
   C. You have CYP2C9 (type of enzyme) *1/*1, *1/*2, *2/*2, *1/*3, or *2/*3 genotype
   (Initial denial text continued on next page)

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SIPONIMOD

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of relapsing forms of multiple sclerosis (MS) to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease and meet **ALL** of the following criteria?
   - The patient has demonstrated a clinical benefit compared to pre-treatment baseline
   - The patient does not have lymphopenia

   If yes, continue to #2.
   If no, do not approve
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient have a CYP2C9 *1/*1, *1/*2, or *2/*2 genotype?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Mayzent 0.25mg starter pack for 2 mg maintenance dose: #12 tablets (1 pack) per fill.**
   - **Mayzent 2mg: #1 per day.**

   If no, continue to #3.

3. Does the patient have a CYP2C9 *1/*3 or *2/*3 genotype?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Mayzent 0.25mg starter pack for 1 mg maintenance dose: #7 tablets (1 pack) per fill.**
   - **Mayzent 0.25mg: #4 per day.**
   - **Mayzent 1mg: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SIPONIMOD

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SIPONIMOD (Mayzent)** requires the following rule(s) be met for renewal:

A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (symptoms occur once), relapsing-remitting disease (symptoms return and go away), or active secondary progressive disease (advanced disease)
B. You have demonstrated a clinical benefit compared to pre-treatment baseline
C. You do not have lymphopenia (low levels of a type of white blood cell)
D. You have CYP2C9 (type of enzyme) *1/*1, *1/*2, *2/*2, *1/*3, or *2/*3 genotype

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mayzent.

REFERENCES

- Mayzent [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/11/22
Created: 04/19
Client Approval: 03/22
P&T Approval: 10/19

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SIROLIMUS TOPICAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of facial angiofibroma associated with tuberous sclerosis **AND** meet the following criterion?
   - The patient is 6 years of age or older

   If yes, **approve for 12 weeks by GPID or GPI-10.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SIROLIMUS TOPICAL (Hyftor)** requires the following rule(s) be met for approval:
   A. You have facial angiofibroma (a skin condition) associated with tuberous sclerosis (a rare type of tumor disorder)
   B. You are 6 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of facial angiofibroma associated with tuberous sclerosis?

   If yes, **approve for 12 months by GPID or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial at the end of the guideline.

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SIROLIMUS TOPICAL

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SIROLIMUS TOPICAL (Hyftor)** requires the following rule(s) be met for renewal:

A. You have facial angiofibroma (a skin condition) associated with tuberous sclerosis (a rare type of tumor disorder)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Hyftor.

REFERENCES

- Hyftor [Prescribing Information]. Bethesda, MD: Nobelpharma America, LLC.; March 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/29/22
Created: 08/22
Client Approval: 08/22
P&T Approval: 07/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOD PHENYLBUTYRATE-TAURURSODIOL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) and meet **ALL** the following?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist or ALS specialist or being seen at an ALS Specialty Center or Care Clinic

   If yes, **approve for a total of 6 months by HICL or GPI-10. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve for 21 days with a quantity limit of #1 per day.**
   - **SECOND APPROVAL: Approve for the remaining days with a quantity limit of #2 per day.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOD PHENYLBUTYRATE-TAURURSODIOL (Relyvrio)** requires the following rule(s) be met for approval:
   A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor) or ALS specialist or being seen at an ALS Specialty Center or Care Clinic

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOD PHENYLBUTYRATE-TAURURSODIOL

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) and meet **ALL** of the following criteria?
   - The patient does not require invasive ventilation
   - The patient has improved or maintained baseline functional ability measured by functional assessments (e.g., Amyotrophic Lateral Sclerosis Functional Rating Scale [ALSFRS])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOD PHENYLBUTYRATE-TAURURSODIOL (Relyvrio)** requires the following rule(s) be met for renewal:
   A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
   B. You do not require invasive ventilation (inserting a breathing tube into your throat)
   C. You have improved or maintained baseline functional ability measured by functional assessments (e.g., Amyotrophic Lateral Sclerosis Functional Rating Scale [ALSFRS: a tool for evaluating functional status])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Relyvrio.

REFERENCES

- Relyvrio [Prescribing Information]. Cambridge, MA: Amylyx Pharmaceuticals, Inc., September 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/24/22
Created: 10/22
Client Approval: 10/22
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SODIUM OXYBATE-LUMRYZ

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the patient concurrently on a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #2.

2. Does the patient have a diagnosis of cataplexy in narcolepsy and meet **ALL** of the following criteria?
   - The patient is 7 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient had a trial of TWO of the following: venlafaxine (Effexor), fluoxetine (Prozac), TCA (tricyclic antidepressant, e.g., amitriptyline [Elavil], clomipramine [Anafranil], imipramine [Tofranil])
   - The patient had a trial of generic sodium oxybate

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) in narcolepsy and the narcolepsy diagnosis is confirmed by **ONE** of the following criteria?
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND two or more early-onset REM sleep periods (SOREMPs)
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND one or more early-onset REM sleep periods (SOREMPS) AND additionally one early-onset SOREMP (within approx. 15 minutes or less) on a polysomnography the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of EDS [**Note to pharmacist:** Multiple Sleep Latency Test (MSLT) is a guideline-supported instrument for assessing the severity and likelihood of narcolepsy, which consists of five 20-minute nap periods spread throughout *a single test* day at 2-hour intervals]
   - The patient has low Orexin/Hypocretin levels on CSF assay

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

4. Does the patient meet **ALL** of the following criteria?
   - The patient is 7 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient has excessive daytime sleepiness (EDS) persisting for 3 or more months
   - The patient has an Epworth Sleepiness Scale (ESS) score of more than 10
   - The patient had a trial, failure, or contraindication to generic sodium oxybate

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Is the patient 7 to 17 years of age **AND** meets the following criterion?
   - The patient had a trial, failure, or contraindication to a generic typical stimulant (e.g., amphetamine [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, continue to #6.

6. Is the patient 18 years of age or older **AND** meets the following criterion?
   - The patient had a trial, failure, or contraindication to one agent from EACH of the following categories:
     - Generic typical stimulant (e.g., amphetamine [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])
     - Armodafinil (Nuvigil) OR modafinil (Provigil)

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SODIUM OXYBATE-LUMRYZ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SODIUM OXYBATE (LUMRYZ)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Cataplexy in narcolepsy (sudden and uncontrollable muscle weakness or paralysis associated with a sleep disorder)
   2. Excessive daytime sleepiness (EDS) in narcolepsy (sleep disorder)

B. You are NOT concurrently (at the same time) on a sedative hypnotic agent (drugs that make you sleepy), such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant]

C. **If you have cataplexy in narcolepsy, approval also requires:**
   1. You are 7 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   3. You had a trial of generic sodium oxybate
   4. You had a trial of TWO of the following: venlafaxine (Effexor), fluoxetine (Prozac), TCA (tricyclic antidepressant, such as amitriptyline [Elavil], clomipramine [Anafranil], imipramine [Tofranil])

D. **If you have excessive daytime sleepiness (EDS) in narcolepsy, approval also requires:**
   1. You are 7 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   3. Your diagnosis of narcolepsy is confirmed by ONE of the following:
      a. A Multiple Sleep Latency Test (MLST) showing both an average sleep latency of 8 minutes or less AND 2 or more early-onset rapid eye movement (REM) sleep test periods
      b. A Multiple Sleep Latency Test (MSLT) showing an average sleep latency of 8 minutes or less AND one early-onset rapid eye movement (REM) sleep test period (SOREMP) AND additionally one SOREMP (within approximately 15 minutes) on a polysomnography (type of sleep test) the night before the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness
      c. You have low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing you have low levels of a chemical that helps with staying awake)

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SODIUM OXYBATE-LUMRYZ

INITIAL CRITERIA (CONTINUED)

4. You have excessive daytime sleepiness (EDS) persisting for 3 or more months
5. You have an Epworth Sleepiness Scale (ESS: questionnaire used to assess daytime sleepiness) score of more than 10
6. You had a trial, failure (drug did not work), or contraindication (harmful for) to generic sodium oxybate
7. If you are 7 to 17 years old, you had a trial, failure (drug did not work), or contraindication (harmful for) to a generic typical stimulant (such as amphetamine [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])
8. If you are 18 years or older, you had a trial, failure (drug did not work), or contraindication (harmful for) to one agent from EACH of the following categories:
   a. Generic typical stimulant (such as amphetamine [Evekeo], dextroamphetamine [Dexedrine], or methylphenidate [Ritalin])
   b. Armodafinil (Nuvigil) or modafinil (Provigil)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Is the patient concurrently on a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of narcolepsy and meet **ONE** of the following criteria?
   - The patient has demonstrated improvement of cataplexy symptoms compared to baseline
   - The patient has maintained an improvement in Epworth Sleepiness Scale (ESS) scores by at least 25% compared to baseline
   - The patient has demonstrated improvement in sleep latency from baseline

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SODIUM OXYBATE-LUMRYZ

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SODIUM OXYBATE (LUMRYZ)** requires the following rule(s) be met for renewal:

A. You have narcolepsy (uncontrollable daytime sleepiness)
B. You are NOT concurrently (at the same time) on a sedative hypnotic agent (drugs that make you sleepy), such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant]
C. You meet ONE of the following:
   1. You have demonstrated improvement in cataplexy symptoms (sudden and uncontrollable muscle weakness) compared to baseline
   2. You have maintained improvement in Epworth Sleepiness Scale (ESS: questionnaire used to assess daytime sleepiness) scores by at least 25% compared to baseline
   3. You have demonstrated improvement in sleep latency (the amount of time it takes you to fall asleep)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lumryz.

REFERENCES

- Lumryz [Prescribing Information]. Chesterfield, MO: Avadel CNS Pharmaceuticals, LLC; May 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/28/23
Created: 05/23
Client Approval: 08/23
P&T Approval: 10/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SODIUM OXYBATE-XYREM

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of idiopathic hypersomnia (IH) and the diagnosis is confirmed by **ALL** of the following criteria?
   - The patient does NOT have cataplexy
   - The patient has a Multiple Sleep Latency Test (MSLT) showing less than two sleep-onset REM sleep periods (SOREMP) OR no SOREMPs if REM sleep latency on polysomnogram is 15 minutes or less
   - The patient has one or more MSLT mean sleep latency of 8 minutes or less, OR total 24-hour sleep is 660 minutes or more on 24-hour polysomnography or by wrist actigraphy in association with a sleep log
   - The patient has had insufficient sleep syndrome ruled out, AND there is no better explanation by another sleep/medical/psychiatric disorder or use of drugs/medications, AND the patient has experienced daily periods of an irrepressible need to sleep or daytime lapses into sleep for at least 3 months

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - Xyrem (sodium oxybate) will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Restoril [temazepam])
   - The patient had a trial and failure of or contraindication to armodafinil (Nuvigil) OR modafinil (Provigil)

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of cataplexy in narcolepsy and meet **ALL** of the following criteria?
   - The patient is 7 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - Xyrem (sodium oxybate) will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Restoril [temazepam])
   - The patient has tried TWO of the following: venlafaxine (Effexor), fluoxetine (Prozac), a TCA (tricyclic antidepressant, e.g., amitriptyline [Elavil], clomipramine [Anafranil], imipramine [Tofranil])

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #18mL per day.**
   If no, continue to #4.

4. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) in narcolepsy and the narcolepsy diagnosis is confirmed by **ONE** of the following criteria?
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND two or more early-onset REM sleep periods (SOREMPs)
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND one or more early-onset REM sleep periods (SOREMPS) AND additionally one early-onset SOREMP (within approx. 15 minutes or less) on a polysomnography the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of EDS [**Note to pharmacist:** Multiple Sleep Latency Test (MSLT) is a guideline-supported instrument for assessing the severity and likelihood of narcolepsy, which consists of five 20-minute nap periods spread throughout *a single test* day at 2-hour intervals]
   - The patient has low orexin/hypocretin levels on CSF assay

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SODIUM OXYBATE-XYREM

INITIAL CRITERIA (CONTINUED)

5. Does the patient meet **ALL** of the following criteria?
   - The patient is 7 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient has EDS persisting for 3 or more months
   - The patient has an Epworth Sleepiness Scale (ESS) score of more than 10
   - Xyrem (sodium oxybate) will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Restoril [temazepam])

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Is the patient 7 to 17 years of age **AND** meet the following criterion?
   - The patient had a trial and failure of or contraindication to one generic stimulant indicated for excessive daytime sleepiness (EDS) in narcolepsy (e.g., amphetamine sulfate [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])

   If yes, continue to #8.
   If no, continue to #7.

7. Is the patient 18 years of age or older **AND** meet the following criterion?
   - The patient had a trial and failure of or contraindication to one agent from EACH of the following categories:
     - Generic typical stimulant (e.g., amphetamine sulfate [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])
     - Armodafinil (Nuvigil) OR modafinil (Provigil)

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

8. Is the request for generic sodium oxybate?

   If yes, **approve for 6 months for generic only by GPID or GPI-14 with a quantity limit of #18mL per day.**

   If no, continue to #9.

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SODIUM OXYBATE-XYREM

INITIAL CRITERIA (CONTINUED)

9. Is the request for brand Xyrem **AND** the patient meets the following criterion?
   - The patient had a trial and failure of or contraindication to generic sodium oxybate

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #18mL per day.**
   If no, do not approve. **(NOTE: Please enter a proactive PA for 6 months for generic sodium oxybate by GPID or GPI-14 with a quantity limit of #18mL per day.)**

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SODIUM OXYBATE (Xyrem)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Idiopathic hypersomnia (IH: a type of sleep disorder)
      2. Cataplexy in narcolepsy (sudden and uncontrollable muscle weakness or paralysis associated with a sleep disorder)
      3. Excessive daytime sleepiness (EDS) in narcolepsy (sleep disorder)
   B. Xyrem (sodium oxybate) will NOT be used concurrently (at the same time) with a sedative hypnotic agent (drugs that make you sleepy), such as Lunesta (eszopiclone), Ambien (zolpidem), or Restoril (temazepam)
   C. **If you have idiopathic hypersomnia, approval also requires:**
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
      3. Your diagnosis is confirmed by ALL of the following:
         a. You do NOT have cataplexy (sudden and uncontrollable muscle weakness or paralysis associated with a sleep disorder)
         b. You have a Multiple Sleep Latency Test (MSLT) showing less than two sleep-onset REM (rapid eye movement) sleep periods (SOREMP) OR no SOREMPs if REM sleep latency on polysomnogram (type of sleep test) is 15 minutes or less
         c. You have one or more MSLT mean sleep latency of 8 minutes or less, OR total 24-hour sleep is 660 minutes or more on 24-hour polysomnography or by wrist actigraphy (device that monitors movement) in association with a sleep log
         d. You have had insufficient sleep syndrome ruled out, AND there is no better explanation by another sleep/medical/psychiatric disorder or use of drugs/medications, AND you have experienced daily periods of an irrepressible need to sleep or daytime lapses into sleep for at least 3 months

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INITIAL CRITERIA (CONTINUED)

4. You have tried and failed or have a contraindication (harmful for) to armodafinil (Nuvigil) OR modafinil (Provigil)
5. If you are requesting brand Xyrem, you have tried and failed or have a contraindication (harmful for) to generic sodium oxybate

D. **If you have cataplexy in narcolepsy, approval also requires:**
1. You are 7 years of age or older
2. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
3. You have tried TWO of the following: venlafaxine (Effexor), fluoxetine (Prozac), a tricyclic anti-depressant (such as amitriptyline [Elavil], clomipramine [Anafranil], imipramine [Tofranil])

E. **If you have excessive daytime sleepiness in narcolepsy, approval also requires:**
1. You are 7 years of age or older
2. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
3. You have EDS persisting for 3 or more months
4. You have an Epworth Sleepiness Scale (tool to measure sleepiness) score of more than 10
5. Your diagnosis of narcolepsy is confirmed by ONE of the following:
   a. A Multiple Sleep Latency Test (MSLT) showing both an average sleep latency of 8 minutes or less AND two or more early-onset rapid eye movement (REM) sleep test periods
   b. A Multiple Sleep Latency Test showing an average sleep latency of 8 minutes or less AND one early-onset rapid eye movement (REM) sleep test period (SOREMP) AND additionally one SOREMP (within approximately 15 minutes) on a polysomnography (type of sleep test) the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness
   c. You have low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing low levels of a chemical that help with staying awake)
6. If you are 7 to 17 years old, you have tried and failed or have a contraindication (harmful for) to one generic stimulant indicated for EDS in narcolepsy (such as amphetamine [Evekeo], dextroamphetamine [Dexedrine], or methylphenidate [Ritalin])
7. If you are 18 years or older, you have tried and failed or have a contraindication (harmful for) to one agent from EACH of the following categories:
   a. Generic typical stimulant (such as amphetamine sulfate [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])
   b. Armodafinil (Nuvigil) OR modafinil (Provigil)
   c. If you are requesting brand Xyrem, you have tried and failed or have a contraindication (harmful for) to generic sodium oxybate

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SODIUM OXYBATE-XYREM

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of narcolepsy **AND** meet the following criterion?
   - Xyrem (sodium oxybate) will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Restoril [temazepam])

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has demonstrated improvement of cataplexy symptoms compared to baseline
   - The patient has maintained an improvement in Epworth Sleepiness Scale (ESS) scores by at least 25% compared to baseline
   - The patient has demonstrated improvement in sleep latency from baseline

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #18mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient have a diagnosis of idiopathic hypersomnia (IH) **AND** meet the following criterion?
   - Xyrem (sodium oxybate) will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Restoril [temazepam])

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Does the patient meet **ONE** of the following criteria?
   - The patient has demonstrated improvement of idiopathic hypersomnia symptoms compared to baseline
   - The patient has maintained an improvement in Epworth Sleepiness Scale (ESS) scores by at least 25% compared to baseline

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #18mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SODIUM OXYBATE-XYREM

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SODIUM OXYBATE (Xyrem)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Narcolepsy (uncontrollable daytime sleepiness)
   2. Idiopathic hypersomnia (IH: a type of sleep disorder)

B. Xyrem (sodium oxybate) will NOT be used concurrently (at the same time) with a sedative hypnotic agent (drugs that make you sleepy), such as Lunesta [eszopiclone], Ambien [zolpidem], or Restoril [temazepam]

C. **If you have narcolepsy, renewal also requires ONE of the following:**
   1. You have demonstrated improvement in cataplexy symptoms (sudden and uncontrollable muscle weakness) compared to baseline
   2. You have maintained improvement in Epworth Sleepiness Scale (tool to measure sleepiness) scores by at least 25% compared to baseline
   3. You have demonstrated improvement in sleep latency (the amount of time it takes to fall asleep)

D. **If you have idiopathic hypersomnia, renewal also requires ONE of the following:**
   1. You have demonstrated improvement of idiopathic hypersomnia symptoms compared to baseline
   2. You have maintained an improvement in Epworth Sleepiness Scale (tool to measure sleepiness) scores by at least 25% compared to baseline

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xyrem.

REFERENCES

- Xyrem [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/12/23
Created: 11/13
Client Approval: 05/23
P&T Approval: 10/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SODIUM PHENYLBUTYRATE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a urea cycle disorder (UCD) and meet **ALL** of the following criteria?
   - There is documentation (e.g., chart notes, lab results, diagnostic test results, etc.) of confirmation of UCD via enzymatic, biochemical or genetic testing
   - The requested medication will be used as adjunctive therapy along with dietary protein restriction
   - The patient cannot be managed by dietary protein restriction or amino acid supplementation alone

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the request for Buphenyl (sodium phenylbutyrate)?

   If yes, **approve the requested formulation for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Buphenyl tablets: #40 per day.**
   - **Buphenyl powder: #25 grams per day.**

   If no, continue to #3.

3. Is the request for Pheburane, and the patient meets **ALL** of the following criteria?
   - The patient had a trial of or contraindication to generic sodium phenylbutyrate powder
   - The patient is unable to swallow Buphenyl (sodium phenylbutyrate) tablet

   If yes, **approve Pheburane for 12 months by GPID or GPI-14 with a quantity limit of #20 grams per day.**

   If no, continue to #4.

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SODIUM PHENYLBUTYRATE

INITIAL CRITERIA (CONTINUED)

4. Is the request for Olpruva, and the patient meets **ALL** of the following criteria?
   - The patient had a trial of or contraindication to generic sodium phenylbutyrate powder
   - The patient is unable to swallow Buphenyl (sodium phenylbutyrate) tablet

   If yes, **approve the requested strength of Olpruva for 12 months by GPID or GPI-14 as follows:**
   - **2 grams: #12 per day.**
   - **3 grams: #12 per day.**
   - **4 grams: #15 per day.**
   - **5 grams: #12 per day.**
   - **6 grams: #9 per day.**
   - **6.67 grams: #9 per day.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SODIUM PHENYLBUTYRATE (Buphenyl, Pheburane, Olpruva)** requires the following rule(s) be met for approval:

   A. You have a urea cycle disorder (a genetic disorder that causes high ammonia levels in the blood)
   B. There is documentation (such as chart notes, lab results, diagnostic test results) confirming you have a urea cycle disorder via enzymatic, biochemical or genetic testing (types of lab tests)
   C. The requested medication will be used as adjunctive (add-on) therapy along with dietary protein restriction
   D. Your condition cannot be managed by dietary protein restriction or amino acid supplementation alone
   E. **If your request is for Pheburane or Olpruva, approval also requires:**
      1. You have tried or have a contraindication (harmful for) to generic sodium phenylbutyrate powder
      2. You are unable to swallow Buphenyl (sodium phenylbutyrate) tablet

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SODIUM PHENYLBUTYRATE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of a urea cycle disorder (UCD) **AND** meet the following criterion?
   - The patient has experienced a clinical benefit from baseline (e.g., normal fasting glutamine, low-normal fasting ammonia levels, mental status clarity)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the request for Buphenyl or Pheburane?

   If yes, **approve the requested medication for 12 months by GPID or GPI-14 as follows:**
   - **Buphenyl tablet: #40 per day.**
   - **Buphenyl powder: #25 grams per day.**
   - **Pheburane: #20 grams per day.**

   If no, continue to #3.

3. Is the request for Olpruva?

   If yes, **approve the requested strength of Olpruva for 12 months by GPID or GPI-14 as follows:**
   - **2 grams: #12 per day.**
   - **3 grams: #12 per day.**
   - **4 grams: #15 per day.**
   - **5 grams: #12 per day.**
   - **6 grams: #9 per day.**
   - **6.67 grams: #9 per day.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SODIUM PHENYLBUTYRATE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SODIUM PHENYLBUTYRATE (Buphenyl, Pheburane, Olpruva)** requires the following rule(s) be met for renewal:

A. You have a urea cycle disorder (a genetic disorder that causes high ammonia levels in the blood)
B. You have experienced a clinical benefit from baseline (for example you have normal fasting glutamine levels, low-normal fasting ammonia levels, mental status clarity)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Buphenyl, Olpruva, or Pheburane.

REFERENCES

- Buphenyl [Prescribing Information]. Deerfield, IL: Horizon Therapeutics USA, Inc.; April 2023.
- Olpruva [Prescribing Information]. Newton, MA: Acer Therapeutics Inc.; December 2022.
- Pheburane [Prescribing Information]. Bryn Mawr, PA: Medunik USA, Inc.; June 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/23
Created: 08/19
Client Approval: 06/23
P&T Approval: 07/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SODIUM/CALCIUM/MAG/POT OXYBATE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the patient concurrently on a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #2.

2. Does the patient have a diagnosis of idiopathic hypersomnia (IH) and the diagnosis is confirmed by **ALL** of the following criteria?
   - The patient does not have cataplexy
   - The patient has a Multiple Sleep Latency Test (MSLT) showing less than 2 sleep-onset REM sleep periods (SOREMP) OR no SOREMPs if REM sleep latency on polysomnogram is 15 minutes or less
   - The patient has 1 or more MSLT mean sleep latency of 8 minutes or less, OR total 24-hour sleep is 660 minutes or more on 24-hour polysomnography or by wrist actigraphy in association with a sleep log
   - The patient has had insufficient sleep syndrome ruled out, AND there is no better explanation by another sleep/medical/psychiatric disorder or use of drugs/medications, AND the patient has experienced daily periods of irrepressible need to sleep or daytime lapses into sleep for at least 3 months

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient had a trial and failure of or contraindication to armodafinil OR modafinil

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #18mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of cataplexy in narcolepsy and meet **ALL** of the following criteria?
   - The patient is 7 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient has tried TWO of the following: venlafaxine, fluoxetine, or a TCA (e.g., amitriptyline, clomipramine, imipramine)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #18mL per day.**
   If no, continue to #5.

5. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) in narcolepsy and the narcolepsy diagnosis is confirmed by **ONE** of the following criteria?
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND two or more early-onset REM sleep periods (SOREMPs)
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND one or more early-onset REM sleep periods (SOREMPS) AND additionally one early-onset SOREMP (within approx. 15 minutes or less) on a polysomnography the night preceding the MSLT, with the polysomnography has ruled out non-narcolepsy causes of EDS [**Note to pharmacist**: Multiple Sleep Latency Test (MSLT) is a guideline-supported instrument for assessing the severity and likelihood of narcolepsy, which consists of five 20-minute nap periods spread throughout a single test day at 2-hour intervals]
   - The patient has low Orexin/Hypocretin levels on CSF assay

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

6. Does the patient meet **ALL** of the following criteria?
   - The patient is 7 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient has EDS persisting for 3 months or more and an Epworth Sleepiness Scale (ESS) score greater than 10
   - The patient meets ONE of the following:
     - The patient is 7 to 17 years of age AND had a trial and failure of or contraindication to one generic stimulant indicated for EDS in narcolepsy (e.g., amphetamine, dextroamphetamine, or methylphenidate)
     - The patient is 18 years of age or older AND had a trial and failure of or contraindication to one agent from EACH of the following categories:
       - Generic typical stimulant (e.g., amphetamine sulfate, dextroamphetamine, methylphenidate)
       - Armodafinil OR modafinil

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #18mL per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SODIUM/CALCIUM/MAG/POT OXYBATE (Xywav)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Idiopathic hypersomnia (IH: a type of sleep disorder)
      2. Cataplexy in narcolepsy (sudden and uncontrollable muscle weakness or paralysis associated with a sleep disorder)
      3. Excessive daytime sleepiness (EDS) in narcolepsy (a type of sleep disorder)
   B. You are not concurrently on a sedative hypnotic agent (drugs that make you sleepy), such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant]

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INITIAL CRITERIA (CONTINUED)

C. **If you have idiopathic hypersomnia, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   3. Your diagnosis is confirmed by ALL of the following:
      a. You do not have cataplexy (sudden and uncontrollable muscle weakness or paralysis associated with a sleep disorder)
      b. You have a Multiple Sleep Latency Test (MSLT) showing less than 2 sleep-onset REM sleep periods (SOREMP) OR no SOREMPs if REM sleep latency on polysomnogram (type of sleep test) is 15 minutes or less
      c. You have 1 or more MSLT mean sleep latency of 8 minutes or less, OR total 24-hour sleep is 660 minutes or more on 24-hour polysomnography or by wrist actigraphy (device that monitors movement) in association with a sleep log
      d. You have had insufficient sleep syndrome ruled out, AND there is no better explanation by another sleep/medical/psychiatric disorder or use of drugs/medications, AND you have experienced daily periods of irrepressible need to sleep or daytime lapses into sleep for at least 3 months
   4. You tried and failed or have a contraindication (harmful for) to armodafinil OR modafinil

D. **If you have cataplexy in narcolepsy, approval also requires:**
   1. You are 7 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   3. You have tried TWO of the following: venlafaxine, fluoxetine, or tricyclic anti-depressants (such as amitriptyline, clomipramine, imipramine)

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SODIUM/CALCIUM/MAG/POT OXYBATE

INITIAL CRITERIA (CONTINUED)

E. **If you have excessive daytime sleepiness in narcolepsy, approval also requires:**
   1. You are 7 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   3. You have EDS persisting for 3 or more months and an Epworth Sleepiness Scale (tool to measure your sleepiness) score of more than 10
   4. Your diagnosis of narcolepsy is confirmed by ONE of the following:
      a. A Multiple Sleep Latency Test showing a both an average sleep latency of 8 minutes or less AND 2 or more early-onset rapid eye movement (REM) sleep test periods
      b. A Multiple Sleep Latency Test (MSLT) showing both an average sleep latency of 8 minutes or less AND one early-onset rapid eye movement (REM) sleep test period (SOREMP) AND additionally one SOREMP (within approximately 15 minutes) on a polysomnography (type of sleep test) the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness
      c. You have low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing you have low levels of a chemical that helps with staying awake)
   5. If you are 7 to 17 years old, you tried and failed or have a contraindication (harmful for) to one generic stimulant indicated for EDS in narcolepsy (such as amphetamine, dextroamphetamine, or methylphenidate)
   6. If you are 18 years or older, you tried and failed or have a contraindication (harmful for) to one agent from EACH of the following categories:
      a. Generic typical stimulant (such as amphetamine sulfate, methylphenidate, etc.)
      b. Armodafinil OR modafinil

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Is the patient concurrently on a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

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SODIUM/CALCIUM/MAG/POT OXYBATE

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of narcolepsy and meet **ONE** of the following criteria?
   - The patient has demonstrated improvement of cataplexy symptoms compared to baseline
   - The patient has maintained an improvement in Epworth Sleepiness Scale (ESS) scores by at least 25% compared to baseline
   - The patient has demonstrated improvement in sleep latency from baseline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #18mL per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of idiopathic hypersomnia (IH) and meet **ONE** of the following criteria?
   - The patient has demonstrated improvement of idiopathic hypersomnia symptoms compared to baseline
   - The patient has maintained an improvement in Epworth Sleepiness Scale (ESS) scores by at least 25% compared to baseline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #18mL per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SODIUM/CALCIUM/MAG/POT OXYBATE (Xywav)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Narcolepsy (uncontrollable daytime sleepiness)
      2. Idiopathic hypersomnia (IH: a type of sleep disorder)
   B. You are not concurrently (at the same time) on a sedative hypnotic agent (drugs that make you sleepy), such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant]
   C. **If you have narcolepsy, renewal also requires you meet ONE of the following:**
      1. You have demonstrated improvement in cataplexy symptoms (sudden and uncontrollable muscle weakness) compared to baseline
      2. You have maintained an improvement in Epworth Sleepiness Scale (tool to measure sleepiness) scores by at least 25% compared to baseline
      3. You have demonstrated improvement in sleep latency (the amount of time it takes you to fall asleep)

   (Renewal denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

D. **If you have idiopathic hypersomnia, renewal also requires you meet ONE of the following**:
   1. You have demonstrated improvement of idiopathic hypersomnia symptoms compared to baseline
   2. You have maintained an improvement in Epworth Sleepiness Scale (tool to measure sleepiness) scores by at least 25% compared to baseline

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xywav.

REFERENCES

- Xywav [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; October 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/23

Created: 11/20
Client Approval: 11/22

P&T Approval: 10/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOFOSBUVIR

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C with genotype 1, 2, 3, or 4 **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, continue to #5.

2. Does the patient have an HCV RNA level within the past 6 months?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ANY** of the following criteria?
   - The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
   - Sovaldi will be used concurrently with any of the following medications: carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, Priftin (rifapentine), Aptivus (tipranavir)/ritonavir, Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Vosevi (velpatasvir/sofosbuvir/voxilaprevir), or Zepatier (elbasvir/grazoprevir)
   - Sovaldi is being used with a direct acting antiviral (e.g., Olysio [simeprevir], Daklinza [daclatasvir]) AND is concurrently taking amiodarone

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #4.

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

4. Is the request for combination therapy of Sovaldi with Mavyret (glecaprevir/pibrentasvir) and the patient meets **ALL** of the following criteria?
   - The patient does not have decompensated cirrhosis
   - The patient has previously failed treatment with Mavyret (glecaprevir/pibrentasvir) OR Vosevi (sofosbuvir/velpatasvir/voxilaprevir)
   - Sovaldi will be used in combination with Mavyret (glecaprevir/pibrentasvir) AND ribavirin

   If yes, **approve for 16 weeks for the requested strength by GPID or GPI-14 as follows:**
   - **400mg tablets: #1 per day.**
   - **200mg tablets: #1 per day.**
   - **200mg pellets: #2 per day.**
   - **150mg pellets: #1 per day.**

   If no, continue to #5.

5. Is the requested regimen recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment?

   If yes, **approve as indicated per guidance in AASLD/IDSA.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOFOSBUVIR (Sovaldi)** requires the following rule(s) be met for approval:

A. The requested regimen is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment
B. You have chronic hepatitis C, genotype 1, 2, 3, or 4 infection (liver inflammation caused by a type of virus)
C. You are 18 years of age or older
D. You have an HCV RNA level (amount of hepatitis C virus in your blood) within the past 6 months
E. You will NOT use Sovaldi concurrently (at the same time) with any of the following medications: carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, Priftin (rifapentine), Aptivus (tipranavir)/ritonavir, Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Vosevi (velpatasvir/sofosbuvir/voxilaprevir), or Zepatier (elbasvir/grazoprevir)
F. You are NOT using Sovaldi with a direct acting antiviral (such as Olysio [simeprevir], Daklinza [daclatasvir]) AND concurrently taking amiodarone
G. You do NOT have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
H. **If Sovaldi will be used with Mavyret (glecaprevir/pibrentasvir), approval also requires:**
    1. You do not have decompensated cirrhosis (symptoms related to liver damage)
    2. You have previously failed treatment with Mavyret (glecaprevir/pibrentasvir) OR Vosevi (sofosbuvir/velpatasvir/voxilaprevir)
    3. Sovaldi will be used in combination with Mavyret (glecaprevir/pibrentasvir) AND ribavirin

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOFOSBUVIR

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sovaldi.

REFERENCES

- Sovaldi [Prescribing Information]. Foster City, CA: Gilead Sciences; March 2020.
- Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, and Managing. Available online at http://www.hcvguidelines.org/full-report-view Accessed October 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/15/24
Created: 01/14
Client Approval: 12/23
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOFOSBUVIR/VELPATASVIR

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C, genotype 1, 2, 3, 4, 5, or 6 **AND** meet the following criterion?
   - The patient is 3 years of age or older

   If yes, continue to #2.
   If no, continue to #10.

2. Does the patient have an HCV RNA level within the past 6 months?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ANY** of the following criteria?
   - Epclusa will be used concurrently with any of the following medications: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, Priftin (rifapentine), efavirenz-containing HIV regimens, rosuvastatin at doses above 10mg, Aptivus (tipranavir)/ritonavir, topotecan, Sovaldi (sofosbuvir, as a single agent), Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), Mavyret (pibrentasvir/glecaprevir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)
   - The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #4.

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GUIDELINES FOR USE (CONTINUED)

4. Is the patient treatment naïve and meets **ONE** of the following criteria?
   - The patient does not have cirrhosis
   - The patient has genotype 1, 2, 4, 5, or 6 AND has compensated cirrhosis
   - The patient has genotype 3 without NS5A RAS Y93H polymorphism AND has compensated cirrhosis
   - The patient has genotype 3 with NS5A RAS Y93H polymorphism, has compensated cirrhosis, AND Epclusa will be used with ribavirin
   - The patient is post-liver transplant AND has compensated cirrhosis
   - The patient is post-liver transplant, has decompensated cirrhosis (moderate or severe hepatic impairment; Child-Turcotte-Pugh class B or C), AND Epclusa will be used with ribavirin
   - The patient is less than 18 years of age AND has compensated cirrhosis

   If yes, **approve for 12 weeks by GPID or GPI-14 for the requested strength as follows:**
   - **400mg-100mg tablets: #1 per day.**
   - **200mg-50mg tablets: #1 per day.**
   - **200mg-50mg pellets: #2 per day.**
   - **150mg-37.5mg pellets: #1 per day.**

   If no, continue to #5.

5. Is the patient treatment experienced and meets **ONE** of the following criteria?
   - The patient is post-liver transplant AND does not have decompensated cirrhosis
   - The patient is post-kidney transplant, treatment experienced with a non-DAA (e.g., interferon), AND does not have decompensated cirrhosis
   - The patient is less than 18 years of age, interferon-experienced, AND does not have decompensated cirrhosis

   If yes, **approve for 12 weeks by GPID or GPI-14 for the requested strength as follows:**
   - **400mg-100mg tablets: #1 per day.**
   - **200mg-50mg tablets: #1 per day.**
   - **200mg-50mg pellets: #2 per day.**
   - **150mg-37.5mg pellets: #1 per day.**

   If no, continue to #6.

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SOFOSBUVIR/VELPATASVIR

GUIDELINES FOR USE (CONTINUED)

6. Is the patient treatment experienced and meets **ALL** of the following criteria?
   - The patient is less than 18 years of age
   - The patient had prior exposure to an interferon-based regimen and/or Sovaldi (sofosbuvir)
   - The patient had NO exposure to NS3/4A (e.g., simeprevir [Olysio], Zepatier [elbasvir/grazoprevir) or NS5A protease inhibitors (e.g., Epclusa [velpatasvir/sofosbuvir], Harvoni [ledipasvir/sofosbuvir])
   - The patient does not have decompensated cirrhosis OR the patient has decompensated cirrhosis and Epclusa will be used with ribavirin

   If yes, **approve for 12 weeks by GPID or GPI-14 for the requested strength as follows:**
   - **400mg-100mg tablets: #1 per day.**
   - **200mg-50mg tablets: #1 per day.**
   - **200mg-50mg pellets: #2 per day.**
   - **150mg-37.5mg pellets: #1 per day.**

   If no, continue to #7.

7. Is the patient treatment experienced **AND** meets the following criterion?
   - The patient is post-liver transplant, has decompensated cirrhosis (moderate or severe hepatic impairment; Child-Turcotte-Pugh class B or C), AND Epclusa will be used with ribavirin

   If yes, **approve for 24 weeks by GPID or GPI-14 for the requested strength as follows:**
   - **400mg-100mg tablets: #1 per day.**
   - **200mg-50mg tablets: #1 per day.**
   - **200mg-50mg pellets: #2 per day.**
   - **150mg-37.5mg pellets: #1 per day.**

   If no, continue to #8.

8. Does the patient have decompensated cirrhosis (moderate or severe hepatic impairment; Child-Turcotte-Pugh class B or C) **AND** meets the following criterion?
   - Epclusa will be used with ribavirin

   If yes, **approve for 12 weeks by GPID or GPI-14 for the requested strength as follows:**
   - **400mg-100mg tablets: #1 per day.**
   - **200mg-50mg tablets: #1 per day.**
   - **200mg-50mg pellets: #2 per day.**
   - **150mg-37.5mg pellets: #1 per day.**

   If no, continue to #9.

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SOFOSBUVIR/VELPATASVIR

GUIDELINES FOR USE (CONTINUED)

9. Does the patient have decompensated cirrhosis (moderate or severe hepatic impairment; Child-Turcotte-Pugh class B or C) and meets **ONE** of the following criteria?
   - The patient has a contraindication to ribavirin (ribavirin ineligible)
   - The patient has failed prior treatment with a sofosbuvir-based regimen (e.g., Harvoni [ledipasvir)/sofosbuvir]) or NS5A inhibitor-based regimen (e.g., Zepatier [elbasvir/grazoprevir]) AND Epclusa will be used with ribavirin

   If yes, **approve for 24 weeks by GPID or GPI-14 for the requested strength as follows:**
   - **400mg-100mg tablets: #1 per day.**
   - **200mg-50mg tablets: #1 per day.**
   - **200mg-50mg pellets: #2 per day.**
   - **150mg-37.5mg pellets: #1 per day.**

   If no, continue to #10.

10. Is the requested regimen recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment?

    If yes, **approve as indicated per guidance in AASLD/IDSA.**
    If no, do not approve.
    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **SOFOSBUVIR/VELPATASVIR (Epclusa)** requires the following rule(s) be met for approval:
    A. The requested regimen is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment
    B. You have chronic hepatitis C with genotype 1, 2, 3, 4, 5, or 6 (liver inflammation caused by a type of virus)
    C. You are 3 years of age or older
    D. You have an HCV RNA level (amount of hepatitis C virus in your blood) within the past 6 months
    E. You will NOT use Epclusa concurrently (at the same time) with any of the following medications: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, Priftin (rifapentine), efavirenz-containing HIV (human immunodeficiency virus) regimens, rosuvastatin at doses above 10mg, Aptivus (tipranavir)/ritonavir, topotecan, Sovaldi (sofosbuvir, as a single agent), Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), Mavyret (pibrentasvir/glecaprevir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)

    (Denial text continued on next page)

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GUIDELINES FOR USE (CONTINUED)

F. You do NOT have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)
G. **If you are treatment naïve (never previously treated), approval also requires ONE of the following**:
    1. You do not have cirrhosis (liver damage and scarring)
    2. You have genotype 1, 2, 4, 5, or 6 AND you have compensated cirrhosis (no symptoms related to liver damage)
    3. You have genotype 3 without NS5A RAS Y93H polymorphism (a type of HCV [hepatitis C virus] strain) AND you have compensated cirrhosis
    4. You have genotype 3 with NS5A RAS Y93H polymorphism, have compensated cirrhosis, AND Epclusa will be used with ribavirin
    5. You received a liver transplant (replaced your liver) AND you have compensated cirrhosis
    6. You received a liver transplant, have decompensated cirrhosis (moderate or severe hepatic impairment; Child-Turcotte-Pugh class B or C: symptoms related to liver damage), AND Epclusa will be used with ribavirin
    7. You are less than 18 years of age AND you have compensated cirrhosis
H. **If you are treatment experienced (failed prior treatment), approval also requires ONE of the following:**
    1. You received a liver transplant (replaced your liver) AND you do not have decompensated cirrhosis (symptoms related to liver damage)
    2. You received a kidney transplant (replaced your kidney), had prior treatment with a non-direct acting antiviral (such as interferon), AND you do not have decompensated cirrhosis
    3. You are less than 18 years of age, are treatment experienced with an interferon, AND you do not have decompensated cirrhosis
    4. You are less than 18 years of age, had prior exposure to interferon-based regimen and/or Sovaldi (sofosbuvir), had no exposure to NS3/4A (such as simeprevir [Olysio], Zepatier [elbasvir/grazoprevir) or NS5A protease inhibitors (such as Epclusa [velpatasvir/sofosbuvir], AND you do not have decompensated cirrhosis
    5. You are less than 18 years of age, had prior exposure to interferon-based regimen and/or Sovaldi (sofosbuvir), had no exposure to NS3/4A (such as simeprevir [Olysio], Zepatier [elbasvir/grazoprevir) or NS5A protease inhibitors (such as Epclusa [velpatasvir/sofosbuvir], have decompensated cirrhosis, AND Epclusa will be used with ribavirin
    6. You received a liver transplant, have decompensated cirrhosis (moderate or severe hepatic impairment; Child-Turcotte-Pugh class B or C), AND Epclusa will be used with ribavirin

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SOFOSBUVIR/VELPATASVIR

GUIDELINES FOR USE (CONTINUED)

l. **If you have decompensated cirrhosis (moderate or severe hepatic impairment; Child-Turcotte-Pugh class B or C: symptoms related to liver damage), approval also requires ONE of the following:**
   1. You will be using Epclusa with ribavirin unless you have a contraindication to (harmful for you to use) ribavirin
   2. You have failed prior treatment with a sofosbuvir-based regimen (such as Harvoni [ledipasvir)/sofosbuvir]) or NS5A inhibitor-based regimen (such as Zepatier [elbasvir/grazoprevir]) AND Epclusa will be used with ribavirin

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Epclusa.

REFERENCES

- Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed November 27, 2023.
- Epclusa [Prescribing Information]. Foster City, CA: Gilead Sciences; April 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/15/24
Created: 07/16
Client Approval: 12/23
P&T Approval: 07/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C, genotype 1, 2, 3, 4, 5, or 6 **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, continue to #7.

2. Does the patient have an HCV RNA level within the past 6 months?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ANY** of the following criteria?
   - Vosevi will be used concurrently with any of the following medications: amiodarone, rifampin, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifabutin, Priftin (rifapentine), HIV regimen containing atazanavir, lopinavir, Aptivus (tipranavir)/ritonavir, or efavirenz, rosuvastatin, pitavastatin, pravastatin (at doses above 40mg), cyclosporine, methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, sulfasalazine, topotecan, Sovaldi (sofosbuvir; as a single agent), Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), or Mavyret (pibrentasvir/glecaprevir)
   - The patient has moderate or severe hepatic impairment (decompensated cirrhosis; Child-Pugh B or C)
   - The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #4.

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GUIDELINES FOR USE (CONTINUED)

4. Is the patient treatment naive and meets **ALL** of the following criteria?
   - The patient has genotype 3
   - The patient has compensated cirrhosis
   - The patient has NS5A RAS Y93H polymorphism

   If yes, **approve for 12 weeks by HICL or GPI-10 for #1 per day.**
   If no, continue to #5.

5. Is the patient treatment experienced and meets **ONE** of the following criteria?
   - The patient failed prior treatment with a sofosbuvir based regimen (e.g., Epclusa [sofosbuvir/velpatasvir])
   - The patient failed prior treatment with Mavyret (glecaprevir/pibrentasvir)
   - The patient is post-liver transplant AND treatment experienced with a DAA (e.g., Epclusa [sofosbuvir/velpatasvir], Harvoni [ledipasvir/sofosbuvir])
   - The patient is a post-kidney transplant AND treatment experienced with a DAA (e.g., Epclusa [sofosbuvir/velpatasvir], Harvoni [ledipasvir/sofosbuvir])

   If yes, **approve for 12 weeks by HICL or GPI-10 for #1 per day.**
   If no, continue to #6.

6. Is the patient treatment experienced and meets **ALL** of the following criteria?
   - The patient failed prior treatment with Vosevi
   - Vosevi will be used with ribavirin

   If yes, **approve for 24 weeks by HICL or GPI-10 for #1 per day.**
   If no, continue to #7.

7. Is the requested regimen recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment?

   If yes, **approve as indicated per guidance in AASLD/IDSA.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR (Vosevi)** requires the following rule(s) be met for approval:

A. The requested regimen is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment
B. You have chronic hepatitis C, with genotype 1, 2, 3, 4, 5 or 6 (liver inflammation caused by a type of virus)
C. You are 18 years of age or older
D. You have an HCV RNA level (amount of hepatitis C virus in your blood) within the past 6 months
E. You will NOT use Vosevi concurrently (at the same time) with any of the following medications: amiodarone, rifampin, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifabutin, Priftin (rifapentine), HIV (human immunodeficiency virus) regimen containing atazanavir, lopinavir, Aptivus (tipranavir)/ritonavir, or efavirenz, rosuvastatin, pitavastatin, pravastatin (at doses above 40mg), cyclosporine, methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, sulfasalazine, topotecan, Sovaldi (sofosbuvir, as a single agent), Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), or Mavyret (pibrentasvir/glecaprevir)
F. You do NOT have moderate or severe hepatic impairment (decompensated cirrhosis; Child-Pugh B or C: symptoms related to liver damage)
G. You do NOT have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)
H. **If you are treatment naive (never previously treated), approval also requires**:
    1. You have genotype 3
    2. You have compensated cirrhosis (no symptoms related to liver damage)
    3. You have NS5A RAS Y93H polymorphism (a type of HCV [hepatitis C virus] strain)
I. **If you are treatment experienced (failed prior treatment), approval also requires ONE of the following**:
    1. You have failed prior treatment with a sofosbuvir based regimen (such as Epclusa [sofosbuvir/velpatasvir])
    2. You have failed prior treatment with Mavyret (glecaprevir/pibrentasvir)
    3. You received a liver transplant (replaced your liver) AND you have received prior treatment with a direct-acting antiviral (such as Epclusa [sofosbuvir/velpatasvir], Harvoni [ledipasvir/sofosbuvir])
    4. You received a kidney transplant (replaced your kidney) AND you have received prior treatment with a direct-acting antiviral (such as Epclusa [sofosbuvir/velpatasvir], Harvoni [ledipasvir/sofosbuvir])
    5. You have failed prior treatment with Vosevi AND Vosevi will be used with ribavirin

(Denial text continued on next page)

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GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vosevi.

REFERENCES

- Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed November 30, 2023.
- Vosevi [Prescribing Information]. Foster City, CA: Gilead Sciences; November 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/15/24
Created: 08/17
Client Approval: 12/23
P&T Approval: 07/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOLIFENACIN SUSPENSION

GUIDELINES FOR USE

1. Does the patient have a diagnosis of neurogenic detrusor overactivity and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient had a trial of or contraindication to TWO of the following:
     - Anticholinergics (e.g., oxybutynin)
     - Beta-3 agonists (e.g., mirabegron)
   - The patient is unable to swallow oral solifenacin tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #10mL per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOLIFENACIN SUSPENSION (Vesicare LS)** requires the following rule(s) be met for approval:
   A. You have neurogenic detrusor overactivity (type of bladder dysfunction)
   B. You are 2 years of age or older
   C. You had a trial of or contraindication (harmful for) to TWO of the following:
      1. Anticholinergics (such as oxybutynin)
      2. Beta-3 agonists (such as mirabegron)
   D. You are unable to swallow oral solifenacin tablets

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vesicare LS.

REFERENCES

- Vesicare LS [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc., June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 05/21
Client Approval: 11/21
P&T Approval: 10/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOLRIAMFETOL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy **AND** the narcolepsy is confirmed by **ONE** of the following criteria?
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less **AND** 2 or more early-onset rapid eye movement (REM) sleep test periods (SOREMPs)
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less **AND** one early-onset rapid eye movement (REM) sleep test period (SOREMP) **AND** additionally one SOREMP (within approximately 15 minutes) on a polysomnography the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness (EDS)
   - The patient has low orexin (aka hypocretin) levels on a cerebrospinal fluid (CSF) assay

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ALL** of the following criteria?
   - Excessive Daytime Sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10
   - Therapy is prescribed by or given in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient had a trial of or contraindication to one amphetamine derivative (e.g., amphetamine sulfate, methylphenidate, etc.) **AND** modafinil or armodafinil

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   APPROVAL TEXT: Renewal requires the patient has demonstrated 25% or more improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOLRIAMFETOL

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with obstructive sleep apnea (OSA) **AND** that OSA is confirmed by **ONE** of the following criteria?
   - Polysomnography
   - Home sleep apnea testing devices
   - Hospital-based bedside monitoring

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient meet **ALL** of the following criteria?
   - Excessive Daytime Sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10
   - The patient had a trial of or contraindication to modafinil or armodafinil
   - The patient is on ongoing treatment to address the obstructive causes of OSA, for at least one month since initiation, and has been counseled on weight-loss intervention (if BMI > 30)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   APPROVAL TEXT: Renewal requires the patient has demonstrated 25% or more improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOLRIAMFETOL (Sunosi)** requires the following rule(s) be met for approval:
   A. You have excessive daytime sleepiness (EDS) with narcolepsy (a sleep disorder); or obstructive sleep apnea (OSA: a disorder where airflow is blocked during sleep).

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INITIAL CRITERIA (CONTINUED)

B. **If you have excessive daytime sleepiness (EDS) with narcolepsy, approval also requires:**
   1. Your diagnosis of narcolepsy is confirmed by **ONE** of the following:
      i. You have a Multiple Sleep Latency Test (MSLT) showing an average sleep latency of 8 minutes or less **AND** two (2) or more early-onset rapid eye movement (REM) sleep test periods (SOREMPs)
      ii. You have a Multiple Sleep Latency Test (MSLT) showing an average sleep latency of 8 minutes or less **AND** one (1) early-onset rapid eye movement (REM) sleep test period (SOREMP) **AND** one (1) SOREMP (within about 15 minutes) on a sleep study (polysomnography) the night before the MSLT, with the sleep study ruling out non-narcolepsy causes of excessive daytime sleepiness (EDS)
      iii. You have low orexin levels on a cerebrospinal fluid (CSF) assay (a test to determine the amount of a type of chemical for wakefulness in your brain)
   2. You have had Excessive Daytime Sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10
   3. Therapy is prescribed by or given in consultation with a neurologist (brain doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   4. You have tried one amphetamine derivative (e.g., amphetamine sulfate, methylphenidate, etc.) **AND** modafinil or armodafinil, unless there is a medical reason why you cannot (contraindication)

C. **If you have excessive daytime sleepiness (EDS) with obstructive sleep apnea (OSA), approval also require:**
   1. Your diagnosis of OSA is confirmed by a sleep study (polysomnography), home sleep apnea testing devices, or hospital-based bedside monitoring
   2. You have had Excessive Daytime Sleepiness (EDS) for at least 3 months and your Epworth Sleepiness Scale (ESS) score is more than 10
   3. You have tried modafinil or armodafinil, unless there is a medical reason why you cannot (contraindication)
   4. You have been on a treatment for the obstructive causes of OSA, for at least one month since initiation, and you have been counseled on weight-loss intervention [if your BMI (Body Mass Index: a measure of body fat based on height and weight) is greater than 30]

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOLRIAMFETOL

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy or obstructive sleep apnea (OSA) **AND** meet the following criterion?
   - The patient has demonstrated 25% or more improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #30 per 30 days.** If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOLRIAMFETOL (Sunosi)** requires the following rule(s) be met for renewal:
   A. You have excessive daytime sleepiness (EDS) with narcolepsy (a sleep disorder); or obstructive sleep apnea (OSA: a disorder where airflow is blocked during sleep).
   B. You have sustained improvement in Epworth Sleepiness Scale (ESS) scores by at least 25% compared to baseline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Sunosi.

REFERENCES

- Sunosi [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; June 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 07/19
Client Approval: 04/20
P&T Approval: 10/19

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMAPACITAN-BECO

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature (ISS)

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) and meet **ALL** of the following criteria?
   - The patient is 2.5 to 17 years of age
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - The patient had a trial of or contraindication to the preferred agent: Skytrofa (lonapegsomatropin-tcgd)

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient has a height velocity that is less than the 25th percentile for age
   - The patient has a low peak growth hormone (less than 10 ng/mL) on TWO growth hormone stimulation tests, OR has an insulin-like growth factor 1 (IGF-1) that is at least 2 SD below the mean for the same age and gender

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOMAPACITAN-BECO

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of growth hormone deficiency (GHD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6mL per 28 days.** If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMAPACITAN-BECO (Sogroya)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
      2. Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

   B. **If you have growth failure due to an inadequate secretion of endogenous growth hormone, approval also requires:**
      1. You are 2.5 to 17 years of age
      2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
      3. Your epiphyses (end part of long bone) are NOT closed as confirmed by a radiograph (type of imaging test) of the wrist and hand
      4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Skytrofa (lonapegsomatropin-tcgd)
      5. You meet ONE of the following:
         a. Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender
         b. Your height velocity is less than the 25th percentile for your age
         c. You have a low peak growth hormone level (less than 10 ng/mL) on TWO growth hormone stimulation tests, OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations below the mean for your age and gender

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SOMAPACITAN-BECO

INITIAL CRITERIA (CONTINUED)

C. **If you have growth hormone deficiency, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   3. You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

D. Request for Sogroya will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMAPACITAN-BECO

RENEWAL CRITERIA

1. Is the requested medication being used for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature (ISS)

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) and meet **ALL** of the following criteria?
   - The patient is 2.5 to 17 years of age
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand), OR the patient has not completed prepubertal growth

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   - The patient has an annual growth velocity of at least 2 cm compared with what was observed from the previous year
   - The patient has an annual growth velocity of at least 1 cm compared with what was observed from the previous year if close to the terminal phase of puberty

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Does the patient have a diagnosis of growth hormone deficiency (GHD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has achieved or maintained a response to therapy as evidenced by clinical treatment goals (e.g., improved body composition, lipid panel, bone health)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SOMAPACITAN-BECO

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMAPACITAN-BECO (Sogroya)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
   2. Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

B. **If you have growth failure due to an inadequate secretion of endogenous growth hormone, renewal also requires:**
   1. You are 2.5 to 17 years of age
   2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by a radiograph (type of imaging test) of the wrist and hand, OR you have not completed prepubertal growth
   4. You meet ONE of the following:
      a. Your annual growth velocity (rate of growth) is at least 2 cm compared with what was observed from the previous year
      b. Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are close to the terminal (final) phase of puberty

C. **If you have growth hormone deficiency, renewal also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   3. You have achieved or maintained a response to therapy as evidenced by clinical treatment goals (such as improved body composition, lipid [fat] panel, bone health)

D. Renewal request for Sogroya will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMAPACITAN-BECO

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sogroya.

REFERENCES

- Sogroya [Prescribing Information]. Plainsboro, NJ: Novo Nordisk Inc.; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 05/23
Client Approval: 02/24
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROGON-GHLA

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature (ISS)

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) and meet **ALL** of the following criteria?
   - The patient is 3 to 17 years of age
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - The patient had a trial of or contraindication to the preferred agent: Skytrofa (lonapegsomatropin-tcgd)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient has a height velocity that is less than the 25th percentile for age
   - The patient has a low peak growth hormone (less than 10 ng/mL) on TWO growth hormone stimulation tests, OR has an insulin-like growth factor 1 (IGF-1) that is at least 2 SD below the mean for the same age and gender

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOMATROGON-GHLA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROGON-GHLA (Ngenla)** requires the following rule(s) be met for approval:

A. You have growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
B. You are 3 to 17 years of age
C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
D. Your epiphyses (end part of long bone) are NOT closed as confirmed by a radiograph (type of imaging test) of the wrist and hand
E. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Skytrofa (lonapegsomatropin-tcgd)
F. You meet ONE of the following:
    1. Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender
    2. Your height velocity is less than the 25th percentile for your age
    3. You have a low peak growth hormone level (less than 10 ng/mL) on TWO growth hormone stimulation tests, OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations below the mean for your age and gender
G. Request for Ngenla will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROGON-GHLA

RENEWAL CRITERIA

1. Is the requested medication being used for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature (ISS)

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) and meet **ALL** of the following criteria?
   - The patient is 3 to 17 years of age
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand), OR the patient has not completed prepubertal growth

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient has an annual growth velocity of at least 2 cm compared with what was observed from the previous year
   - The patient has an annual growth velocity of at least 1 cm compared with what was observed from the previous year if close to the terminal phase of puberty

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SOMATROGON-GHLA

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROGON-GHLA (Ngenla)** requires the following rule(s) be met for renewal:

A. You have growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
B. You are 3 to 17 years of age
C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
D. Your epiphyses (end part of long bone) are NOT closed as confirmed by a radiograph (type of imaging test) of the wrist and hand, OR you have not completed prepubertal growth
E. You meet ONE of the following:
    1. Your annual growth velocity (rate of growth) is at least 2 cm compared with what was observed from the previous year
    2. Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are close to the terminal (final) phase of puberty
F. Renewal request for Ngenla will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ngenla.

REFERENCES

- Ngenla [Prescribing Information]. Ringaskiddy, Cork, Ireland: Pfizer Ireland Pharmaceuticals; June 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 08/23
Client Approval: 02/24
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - GENOTROPIN

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) and meet **ALL** of the following criteria?
   - The request is for a pediatric patient
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Therapy is prescribed by or in consultation with an endocrinologist

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient has a height velocity less than the 25th percentile for age
   - The patient has a low peak growth hormone (less than 10ng/mL) on two GH stimulation tests OR has an insulin-like growth factor 1 (IGF-1) that is at least 2 SD below the mean for the same age and gender

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths**.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOMATROPIN - GENOTROPIN

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of growth failure associated with Turner syndrome and meet **ALL** of the following criteria?
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #5.

5. Does the patient have a diagnosis of growth failure due to Prader-Willi syndrome (PWS) and meet **ALL** of the following criteria?
   - The patient has a confirmed genetic diagnosis of PWS
   - Therapy is prescribed by or in consultation with an endocrinologist

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #6.

6. Does the patient have a diagnosis of growth failure born small for gestational age (SGA) and meet **ALL** of the following criteria?
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - The patient has no catch-up growth by age 2 years
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #7.

7. Does the patient have a diagnosis of growth hormone deficiency and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOMATROPIN - GENOTROPIN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROPIN (Genotropin)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
   2. Growth failure associated with Turner syndrome (TS: a type of gene condition)
   3. Growth failure due to Prader-Willi syndrome (PWS: a type of gene condition)
   4. Growth failure born small for gestational age (SGA)
   5. Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

B. **If you have growth failure due to an inadequate secretion of endogenous growth hormone, approval also requires:**
   1. You are a pediatric patient
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. You meet ONE of the following criteria:
      a. Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender
      b. Your height velocity is less than the 25th percentile for your age
      c. You have a low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations below the mean for your age and gender

C. **If you have growth failure associated with Turner syndrome, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

D. **If you have growth failure due to Prader-Willi syndrome (PWS), approval also requires:**
   1. You have a confirmed genetic diagnosis of Prader-Willi syndrome
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

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SOMATROPIN - GENOTROPIN

INITIAL CRITERIA (CONTINUED)

E. **If you have growth failure born small for gestational age (SGA), approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. You had no catch-up growth by age 2 years
   4. Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

F. **If you have growth hormone deficiency, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   3. You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

G. Request for Genotropin will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN - GENOTROPIN

RENEWAL CRITERIA

1. Is the request for treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) and meet **ALL** of the following criteria?
   - The request is for a pediatric patient
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand or the patient has not completed prepubertal growth)
   - Therapy is prescribed by or in consultation with an endocrinologist

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   - The patient has an annual growth velocity of at least 2 cm compared with what was observed from the previous year
   - The patient is near the terminal phase of puberty and has an annual growth velocity of at least 1 cm compared with what was observed from the previous year

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Does the patient have **ONE** of the following diagnoses?
   - Short stature associated with Turner syndrome
   - Growth failure born small for gestational age (SGA)

   If yes, continue to #5.
   If no, continue to #6.

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SOMATROPIN - GENOTROPIN

RENEWAL CRITERIA (CONTINUED)

5. Does the patient meet **ALL** of the following criteria?
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has a growth velocity of at least 2 cm compared with what was observed from the previous year OR the patient has not reached 50th percentile for patient's predicted adult height

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

6. Does the patient have a diagnosis of growth failure due to Prader-Willi syndrome (PWS) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has improvement in body composition

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #7.

7. Does the patient have a diagnosis of growth hormone deficiency and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **SOMATROPIN (Genotropin)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
      2. Growth failure associated with Turner syndrome (TS: a type of gene condition)
      3. Growth failure due to Prader-Willi syndrome (PWS: a type of gene condition)
      4. Growth failure born small for gestational age (SGA)
      5. Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

   (Renewal denial text continued on next page)

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SOMATROPIN - GENOTROPIN

RENEWAL CRITERIA (CONTINUED)

B. **If you have growth failure due to an inadequate secretion of endogenous growth hormone, renewal also requires:**
   1. You are a pediatric patient
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   3. Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth)
   4. You meet ONE of the following:
      a. Your annual growth velocity is at least 2 cm compared with what was observed from the previous year
      b. Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

C. **If you have short stature associated with Turner syndrome or growth failure born small for gestational age, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is at least 2 cm compared with what was observed from the previous year OR you have not reached 50th percentile for your predicted adult height

D. **If you have growth failure due to Prader-Willi syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have experienced improvement in body composition

E. **If you have growth hormone deficiency, renewal also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

F. Request for Genotropin will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN - GENOTROPIN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Genotropin.

REFERENCES

- Genotropin [Prescribing Information]. New York, NY: Pharmacia & Upjohn Co.; April 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 10/22
Client Approval: 11/23
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - HUMATROPE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) and meet **ALL** of the following criteria?
   - The request is for a pediatric patient
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient had a trial, failure, or contraindication to ONE of the following preferred agents: Norditropin (somatropin), Genotropin (somatropin)

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient has a height velocity less than the 25th percentile for age
   - The patient has a low peak growth hormone (less than 10ng/mL) on two GH stimulation tests OR has an insulin-like growth factor 1 (IGF-1) that is at least 2 SD below the mean for the same age and gender

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOMATROPIN - HUMATROPE

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of short stature associated with Turner syndrome and meet **ALL** of the following criteria?
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient had a trial, failure, or contraindication to ONE of the following preferred agents: Norditropin (somatropin), Genotropin (somatropin)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #5.

5. Does the patient have a diagnosis of short stature or growth failure with short stature homeobox-containing (SHOX) gene deficiency and meet **ALL** of the following criteria?
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #6.

6. Does the patient have a diagnosis of growth failure born small for gestational age (SGA) and meet **ALL** of the following criteria?
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - The patient has no catch-up growth by age 2 to 4 years
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient had a trial, failure, or contraindication to ONE of the following preferred agents: Norditropin (somatropin), Genotropin (somatropin)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #7.

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SOMATROPIN - HUMATROPE

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of growth hormone deficiency and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency
   - The patient had a trial, failure, or contraindication to ONE of the following preferred agents: Norditropin (somatropin), Genotropin (somatropin)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN (Humatrope)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
      2. Short stature associated with Turner syndrome (TS: a type of gene condition)
      3. Short stature or growth failure with short stature homeobox-containing gene (SHOX) deficiency (you're missing a certain gene, causing short height)
      4. Growth failure born small for gestational age (SGA)
      5. Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

   (Initial denial text continued on next page)

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SOMATROPIN - HUMATROPE

INITIAL CRITERIA (CONTINUED)

B. **If you have growth failure due to an inadequate secretion of endogenous growth hormone, approval also requires:**
   1. You are a pediatric patient
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   3. You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
   4. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   5. You meet ONE of the following criteria:
      a. Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender
      b. Your height velocity is less than the 25th percentile for your age
      c. You have a low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations below the mean for your age and gender

C. **If you have short stature associated with Turner syndrome, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

D. **If you have short stature or growth failure with SHOX gene deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

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SOMATROPIN - HUMATROPE

INITIAL CRITERIA (CONTINUED)

E. **If you have growth failure born small for gestational age, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. You had no catch-up growth by age 2 to 4 years
   5. Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

F. **If you have growth hormone deficiency, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   3. You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
   4. You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

G. Request for Humatrope will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN – HUMATROPE

RENEWAL CRITERIA

1. Is the request for treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) and meet ALL of the following criteria?
   - The request is for a pediatric patient
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand or the patient has not completed prepubertal growth)
   - Therapy is prescribed by or in consultation with an endocrinologist

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   - The patient has an annual growth velocity of at least 2 cm compared with what was observed from the previous year
   - The patient is near the terminal phase of puberty and has an annual growth velocity of at least 1 cm compared with what was observed from the previous year

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Does the patient have **ONE** of the following diagnoses?
   - Short stature associated with Turner syndrome
   - Short stature or growth failure with SHOX deficiency
   - Growth failure born small for gestational age (SGA)

   If yes, continue to #5.
   If no, continue to #6.

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SOMATROPIN - HUMATROPE

RENEWAL CRITERIA (CONTINUED)

5. Does the patient meet **ALL** of the following criteria?
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has a growth velocity of at least 2 cm compared with what was observed from the previous year OR the patient has not reached 50th percentile for patient's predicted adult height

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

6. Does the patient have a diagnosis of growth hormone deficiency and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **SOMATROPIN (Humatrope)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
      2. Short stature associated with Turner syndrome (TS: a type of gene condition)
      3. Short stature or growth failure with short stature homeobox-containing gene (SHOX) deficiency (you're missing a certain gene, causing short height)
      4. Growth failure born small for gestational age (SGA)
      5. Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

   (Renewal denial text continued on next page)

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SOMATROPIN - HUMATROPE

RENEWAL CRITERIA (CONTINUED)

B. **If you have growth failure due to an inadequate secretion of endogenous growth hormone, renewal also requires:**
   1. You are a pediatric patient
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   3. Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth)
   4. You meet ONE of the following:
      a. Your annual growth velocity is at least 2 cm compared with what was observed from the previous year
      b. Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

C. **If you have short stature associated with Turner syndrome, short stature or growth failure with SHOX deficiency, or growth failure born small for gestational age, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is at least 2 cm compared with what was observed from the previous year OR you have not reached 50th percentile for your predicted adult height

D. **If you have growth hormone deficiency, renewal also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

E. Request for Humatrope will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Humatrope.

REFERENCES

- Humatrope [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 10/22
Client Approval: 11/23
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - NORDITROPIN

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the associated criteria?
   For pediatric growth hormone deficiency (GHD), approval requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - The patient meets at least ONE of the following criteria for short stature:
     - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
     - Height velocity less than the 25th percentile for age
     - Documented low peak growth hormone (less than 10ng/mL) on two GH stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 SD below the mean for age and gender

   For short stature associated with Turner syndrome, approval requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - The patient's height is greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

   For short stature associated with Noonan syndrome, approval requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - The patient's height is greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

   (Initial criteria continued on next page)

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SOMATROPIN - NORDITROPIN

INITIAL CRITERIA (CONTINUED)

For short stature in pediatric patients born small for gestational age (SGA), approval requires ALL of the following:

- Therapy is prescribed by or in consultation with an endocrinologist
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- Patient with no catch-up growth by age 2 to 4 years
- The patient's height is greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

For adult growth hormone deficiency, approval requires ALL of the following:

- Therapy is prescribed by or in consultation with an endocrinologist
- The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, Surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

For growth failure due to Prader-Willi syndrome (PWS), approval requires ALL of the following:

- Confirmed genetic diagnosis of PWS
- Therapy is prescribed by or in consultation with an endocrinologist

If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
If no, do not approve.
INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROPIN (Norditropin Flexpro)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)
   2. Short stature associated with Turner syndrome (TS: a type of gene condition)
   3. Short stature associated with Noonan syndrome (a type of gene condition)
   4. Short stature born small for gestational age (SGA) in a pediatric patient
   5. Adult growth hormone deficiency
   6. Growth failure due to Prader-Willi syndrome (PWS: a type of gene condition)

This medication will not be approved for treatment of ANY of the following conditions:

1. Athletic enhancement
2. Anti-aging purposes
3. Idiopathic short stature (short height due to unknown cause)

(Initial denial text continued on next page)

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INITIAL CRITERIA (CONTINUED)

B. **If you have pediatric growth hormone deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. You meet at least ONE of the following criteria for short stature:
      a. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
      b. Your height velocity is less than the 25th percentile for your age
      c. You have documented low peak growth hormone (less than 10ng/mL) on two GH (growth hormone) stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 standard deviations below the mean for your age and gender

C. **If you have short stature associated with Turner syndrome, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

D. **If you have short stature associated with Noonan syndrome, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

E. **If you are a child with short stature born small for gestational age, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. You had no catch-up growth by age 2 to 4 years
   4. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

F. **If you have adult growth hormone deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

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SOMATROPIN - NORDITROPIN

INITIAL CRITERIA (CONTINUED)

G. **If you have growth failure due to Prader-Willi syndrome, approval also requires:**
   1. You have confirmed genetic diagnosis of Prader-Willi syndrome
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Is the request for treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the associated criteria?
   For pediatric growth hormone deficiency (GHD), renewal requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand or the patient has not completed prepubertal growth)
   - The patient meets ONE of the following:
     - Annual growth velocity of 2 cm or more compared with what was observed from the previous year
     - Annual growth velocity of 1 cm or more compared with what was observed from the previous year for patients who are near the terminal phase of puberty

   For short stature associated with Noonan syndrome, renewal requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height

   (Renewal criteria continued on next page)

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SOMATROPIN - NORDITROPIN

RENEWAL CRITERIA (CONTINUED)

For short stature associated with Turner syndrome, renewal requires ALL of the following:
- Therapy is prescribed by or in consultation with an endocrinologist
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height

For short stature in pediatric patients born small for gestational age (SGA), renewal requires ALL of the following:
- Therapy is prescribed by or in consultation with an endocrinologist
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height

For adult growth hormone deficiency, renewal requires:
- Therapy is prescribed by or in consultation with an endocrinologist

For growth failure due to Prader-Willi syndrome (PWS), renewal requires ALL of the following:
- Therapy is prescribed by or in consultation with an endocrinologist
- Improvement in body composition

If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
If no, do not approve.
RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROPIN (Norditropin Flexpro)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   3. Short stature associated with Noonan syndrome (a type of genetic disorder causing abnormal body development)
   4. Short stature born small for gestational age (SGA) in a pediatric patient
   5. Adult growth hormone deficiency
   6. Growth failure due to Prader-Willi syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)

This medication will not be approved for treatment of **ANY** of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (unknown cause for short height)

(Renewal denial text continued on next page)

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SOMATROPIN - NORDITROPIN

RENEWAL CRITERIA (CONTINUED)

B. **If you have pediatric growth hormone deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth
   3. You meet ONE of the following:
      a. Your annual growth velocity is 2 cm or more compared with what was observed from the previous year
      b. Your annual growth velocity is 1 cm or more compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

C. **If you have short stature associated with Noonan syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

D. **If you have short stature associated with Turner syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

E. **If you are a child with short stature born small for gestational age, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

F. **If you have adult growth hormone deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

G. **If you have growth failure due to Prader-Willi syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You had improvement in body composition

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN - NORDITROPIN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Norditropin.

REFERENCES

- Norditropin [Prescribing Information]. Plainsboro, NJ: Novo Nordisk; March 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/01/22
Created: 10/22
Client Approval: 10/22
P&T Approval: 04/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - NUTROPIN

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) and meet **ALL** of the following criteria?
   - The request is for a pediatric patient
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient had a trial, failure, or contraindication to ONE of the following preferred agents: Norditropin (somatropin), Genotropin (somatropin)

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient has a height velocity less than the 25th percentile for age
   - The patient has a low peak growth hormone (less than 10ng/mL) on two GH stimulation tests OR has an insulin-like growth factor 1 (IGF-1) that is at least 2 SD below the mean for the same age and gender

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOMATROPIN - NUTROPIN

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of growth failure secondary to chronic kidney disease (CKD) and meet **ALL** of the following criteria?
   - The patient has NOT undergone a renal transplantation
   - Therapy is prescribed by or in consultation with a nephrologist
   - The patient's height or growth velocity is at least 2 standard deviations (SD) below the mean for children of the same age and gender

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #5.

5. Does the patient have a diagnosis of short stature associated with Turner syndrome and meet **ALL** of the following criteria?
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient had a trial, failure, or contraindication to ONE of the following preferred agents: Norditropin (somatropin), Genotropin (somatropin)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #6.

6. Does the patient have a diagnosis of growth hormone deficiency and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency
   - The patient had a trial, failure, or contraindication to ONE of the following preferred agents: Norditropin (somatropin), Genotropin (somatropin)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOMATROPIN - NUTROPIN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **SOMATROPIN (Nutropin AQ)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
   2. Growth failure secondary to chronic kidney disease (CKD: long-term kidney disease)
   3. Short stature associated with Turner syndrome (TS: a type of gene condition)
   4. Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

B. **If you have growth failure due to an inadequate secretion of endogenous growth hormone, approval also requires:**
   1. You are a pediatric patient
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   3. You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
   4. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   5. You meet ONE of the following criteria:
      a. Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender
      b. Your height velocity is less than the 25th percentile for your age
      c. You have a low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations below the mean for your age and gender

C. **If you have growth failure secondary to chronic kidney disease, approval also requires:**
   1. You have NOT undergone a renal (kidney) transplantation
   2. Therapy is prescribed by or in consultation with a nephrologist (kidney doctor)
   3. Your height or growth velocity is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

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SOMATROPIN - NUTROPIN

INITIAL CRITERIA (CONTINUED)

D. **If you have short stature associated with Turner syndrome, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

E. **If you have growth hormone deficiency, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   3. You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
   4. You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

F. Request for Nutropin AQ will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN - NUTROPIN

RENEWAL CRITERIA

1. Is the request for treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) and meet **ALL** of the following criteria?
   - The request is for a pediatric patient
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand or the patient has not completed prepubertal growth)
   - Therapy is prescribed by or in consultation with an endocrinologist

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   - The patient has an annual growth velocity of at least 2 cm compared with what was observed from the previous year
   - The patient is near the terminal phase of puberty and has an annual growth velocity of at least 1 cm compared with what was observed from the previous year

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Does the patient have a diagnosis of growth failure secondary to chronic kidney disease (CKD) and meet **ALL** of the following criteria?
   - The patient has not undergone a renal transplantation
   - The patient has a growth velocity of at least 2 cm compared with what was observed from the previous year OR the patient has not reached 50th percentile for patient's predicted adult height

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #5.

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SOMATROPIN - NUTROPIN

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of short stature associated with Turner syndrome and meet **ALL** of the following criteria?
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has a growth velocity of at least 2 cm compared with what was observed from the previous year OR the patient has not reached 50th percentile for patient's predicted adult height

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #6.

6. Does the patient have a diagnosis of growth hormone deficiency and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN (Nutropin AQ)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
      2. Growth failure secondary to chronic kidney disease (CKD: long-term kidney disease)
      3. Short stature associated with Turner syndrome (TS: a type of gene condition)
      4. Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)
   B. **If you have growth failure due to an inadequate secretion of endogenous growth hormone, renewal also requires:**
      1. You are a pediatric patient
      2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
      3. Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth)
      4. You meet ONE of the following:
         a. Your annual growth velocity is at least 2 cm compared with what was observed from the previous year
         b. Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

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SOMATROPIN - NUTROPIN

RENEWAL CRITERIA (CONTINUED)

C. **If you have growth failure secondary to chronic kidney disease, renewal also requires:**
   1. You have not had a renal (kidney) transplantation
   2. Your growth velocity is at least 2 cm compared with what was observed from the previous year OR you have not reached 50th percentile for your predicted adult height

D. **If you have short stature associated with Turner syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is at least 2 cm compared with what was observed from the previous year OR you have not reached 50th percentile for your predicted adult height

E. **If you have growth hormone deficiency, renewal also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

F. Request for Nutropin AQ will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nutropin AQ.

REFERENCES

- Nutropin AQ [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; December 2016.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 10/22
Client Approval: 12/23
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - OMNITROPE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) and meet **ALL** of the following criteria?
   - The request is for a pediatric patient
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient had a trial, failure, or contraindication to ONE of the following preferred agents: Norditropin (somatropin), Genotropin (somatropin)

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient has a height velocity less than the 25th percentile for age
   - The patient has a low peak growth hormone (less than 10ng/mL) on two GH stimulation tests OR has an insulin-like growth factor 1 (IGF-1) that is at least 2 SD below the mean for the same age and gender

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOMATROPIN - OMNITROPE

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of growth failure due to Prader-Willi syndrome (PWS) and meet **ALL** of the following criteria?
   - The request is for a pediatric patient
   - Therapy is prescribed by or in consultation with an endocrinologist
   - There is confirmed genetic diagnosis of PWS
   - The patient had a trial, failure, or contraindication to ONE of the following preferred agents: Norditropin (somatropin), Genotropin (somatropin)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #5.

5. Does the patient have a diagnosis of growth failure born small for gestational age (SGA) and meet **ALL** of the following criteria?
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - The patient has no catch-up growth by age 2 years
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient had a trial, failure, or contraindication to ONE of the following preferred agents: Norditropin (somatropin), Genotropin (somatropin)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #6.

6. Does the patient have a diagnosis of growth failure associated with Turner syndrome and meet **ALL** of the following criteria?
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient had a trial, failure, or contraindication to ONE of the following preferred agents: Norditropin (somatropin), Genotropin (somatropin)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #7.

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SOMATROPIN - OMNITROPE

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of growth hormone deficiency and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency
   - The patient had a trial, failure, or contraindication to ONE of the following preferred agents: Norditropin (somatropin), Genotropin (somatropin)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN (Omnitrope)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
      2. Growth failure due to Prader-Willi syndrome (PWS: a type of gene condition)
      3. Growth failure born small for gestational age (SGA)
      4. Growth failure associated with Turner syndrome (TS: a type of gene condition)
      5. Growth hormone deficiency (GH: a type of hormone disorder with low growth hormone)

   (Initial denial text continued on next page)

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SOMATROPIN - OMNITROPE

INITIAL CRITERIA (CONTINUED)

B. **If you have growth failure due to an inadequate secretion of endogenous growth hormone, approval also requires:**
   1. You are a pediatric patient
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   3. You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
   4. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   5. You meet ONE of the following criteria:
      a. Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender
      b. Your height velocity is less than the 25th percentile for your age
      c. You have a low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations below the mean for your age and gender

C. **If you have growth failure due to Prader-Willi syndrome, approval also requires:**
   1. You are a pediatric patient
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   3. You have a confirmed genetic diagnosis of Prader-Willi Syndrome
   4. You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)

D. **If you have growth failure born small for gestational age, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You had no catch-up growth by age 2 years
   3. You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
   4. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   5. Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

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SOMATROPIN - OMNITROPE

INITIAL CRITERIA (CONTINUED)

E. **If you have growth failure associated with Turner syndrome, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

F. **If you have growth hormone deficiency, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   3. You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
   4. You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

G. Request for Omnitrope will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN - OMNITROPE

RENEWAL CRITERIA

1. Is the request for treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) and meet **ALL** of the following criteria?
   - The request is for a pediatric patient
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand or the patient has not completed prepubertal growth)
   - Therapy is prescribed by or in consultation with an endocrinologist

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   - The patient has an annual growth velocity of at least 2 cm compared with what was observed from the previous year
   - The patient is near the terminal phase of puberty and has an annual growth velocity of at least 1 cm compared with what was observed from the previous year

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Does the patient have a diagnosis of growth failure due to Prader-Willi syndrome and meet **ALL** of the following criteria?
   - The request is for a pediatric patient
   - Therapy is prescribed by or in consultation with an endocrinologist
   - There is improvement in body composition

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #5.

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SOMATROPIN - OMNITROPE

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have **ONE** of the following diagnoses?
   - Growth failure born small for gestational age (SGA)
   - Growth failure associated with Turner syndrome

   If yes, continue to #6.
   If no, continue to #7.

6. Does the patient meet **ALL** of the following criteria?
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has a growth velocity of at least 2 cm compared with what was observed from the previous year OR the patient has not reached 50th percentile for patient's predicted adult height

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

7. Does the patient have a diagnosis of growth hormone deficiency and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **SOMATROPIN (Omnitrope)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
      2. Growth failure due to Prader-Willi syndrome (PWS: a type of gene condition)
      3. Growth failure born small for gestational age (SGA)
      4. Growth failure associated with Turner syndrome (TS: a type of gene condition)
      5. Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

   (Renewal denial text continued on next page)

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SOMATROPIN – OMNITROPE

RENEWAL CRITERIA (CONTINUED)

B. **If you have growth failure due to an inadequate secretion of endogenous growth hormone, renewal also requires:**
   1. You are a pediatric patient
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   3. Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth)
   4. You meet ONE of the following:
      a. Your annual growth velocity is at least 2 cm compared with what was observed from the previous year
      b. Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

C. **If you have growth failure due to Prader-Willi syndrome, renewal also requires:**
   1. You are a pediatric patient
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   3. You have experienced improvement in body composition

D. **If you have growth failure born small for gestational age or growth failure associated with Turner syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is at least 2 cm compared with what was observed from the previous year OR you have not reached 50th percentile for your predicted adult height

E. **If you have growth hormone deficiency, renewal also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

F. Request for Omnitrope will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN – OMNITROPE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Omnitrope.

REFERENCES

- Omnitrope [Prescribing Information]. Princeton, NJ: Sandoz, Inc.; June 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 10/22
Client Approval: 11/23
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - SAIZEN

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) and meet **ALL** of the following criteria?
   - The request is for a pediatric patient
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient had a trial, failure, or contraindication to ONE of the following preferred agents: Norditropin (somatropin), Genotropin (somatropin)

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient has a height velocity that is less than the 25th percentile for age
   - The patient has a low peak growth hormone (less than 10ng/mL) on two GH stimulation tests OR has an insulin-like growth factor 1 (IGF-1) that is at least 2 SD below the mean for the same age and gender

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOMATROPIN - SAIZEN

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of growth hormone deficiency and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency
   - The patient had a trial, failure, or contraindication to ONE of the following preferred agents: Norditropin (somatropin), Genotropin (somatropin)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.

   INITIAL DENIAL TEXT: Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN (Saizen)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
      2. Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)
   B. **If you have growth failure due to an inadequate secretion of endogenous growth hormone, approval also requires:**
      1. You are a pediatric patient
      2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
      3. You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
      4. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
      5. You meet ONE of the following criteria:
         a. Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender
         b. Your height velocity is less than the 25th percentile for your age
         c. You have a low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations below the mean for your age and gender

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SOMATROPIN - SAIZEN

INITIAL CRITERIA (CONTINUED)

C. **If you have growth hormone deficiency, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   3. You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency
   4. You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)

D. Request for Saizen will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN - SAIZEN

RENEWAL CRITERIA

1. Is the request for treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) and meet **ALL** of the following criteria?
   - The request is for a pediatric patient
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand or the patient has not completed prepubertal growth)
   - Therapy is prescribed by or in consultation with an endocrinologist

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   - The patient has an annual growth velocity of at least 2 cm compared with what was observed from the previous year
   - The patient is near the terminal phase of puberty and has an annual growth velocity of at least 1 cm compared with what was observed from the previous year

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Does the patient have a diagnosis of growth hormone deficiency and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SOMATROPIN - SAIZEN

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROPIN (Saizen)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
   2. Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

B. **If you have growth failure due to an inadequate secretion of endogenous growth hormone, renewal also requires:**
   1. You are a pediatric patient
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   3. Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth)
   4. You meet ONE of the following:
      a. Your annual growth velocity is at least 2 cm compared with what was observed from the previous year
      b. Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

C. **If you have growth hormone deficiency, renewal also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

D. Request for Saizen will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Saizen

REFERENCES

- Saizen [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 10/22
Client Approval: 11/23
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - SEROSTIM

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a patient with a diagnosis of HIV wasting/cachexia who meets **ALL** of the following criteria?
   - The requested medication is NOT prescribed for athletic enhancement or anti-aging purposes
   - Therapy is prescribed by or in consultation with ONE of the following specialists: gastroenterologist, nutritional support specialist, or infectious disease specialist
   - The patient is on HIV anti-retroviral therapy
   - The patient has inadequate response to previous therapy (i.e., exercise training, nutritional supplements, appetite stimulants, or anabolic steroids)
   - The patient has an inadequate response to previous pharmacological therapy including one of the following: cyproheptadine, Marinol (dronabinol), or Megace (megestrol acetate)
   - Alternative causes of wasting have been ruled out; alternative causes include:
     - Altered metabolism (from metabolic and hormonal abnormalities) including testosterone deficiency or peripheral growth hormone resistance
     - Diarrhea
     - Inadequate energy (caloric) intake
     - Malignancies
     - Opportunistic infections
   - The patient meets **ONE** of the following criteria for weight loss:
     - 10% unintentional weight loss over 12 months
     - 7.5% unintentional weight loss over 6 months
     - 5% body cell mass (BCM) loss within 6 months
     - BCM less than 35% (men) AND a body mass index (BMI) less than 27 kg per meter squared
     - BCM less than 23% (women) of total body weight AND a body mass index (BMI) less than 27 kg per meter squared
     - BMI less than 18.5 kg per meter squared

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOMATROPIN - SEROSTIM

INITIAL CRITERIA (CONTINUED)

2. Is the patient hypogonadal as defined by **ONE** of the following?
   - Total serum testosterone level of less than 300ng/dL (10.4 nmol/L)
   - A low total serum testosterone level as indicated by a lab result, with a reference range, obtained within 90 days
   - A free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)

   If yes, continue to #3.
   If no, **approve for 12 weeks by GPID or GPI-14 for all strengths.**

3. For patients who are hypogonadal, does the patient meet the following criterion?
   - The patient has tried testosterone therapy (e.g., testosterone cypionate, AndroGel, Androderm, Axiron, Delatestryl, Fortesta, Striant, Testim, Testopel, Vogelxo, Natesto)

   If yes, **approve for 12 weeks by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN (Serostim)** requires the following rule(s) be met for approval:
   A. You have HIV (human immunodeficiency virus) wasting/cachexia (extreme weight loss and muscle loss)
   B. The requested medication is NOT prescribed for athletic enhancement or anti-aging purposes
   C. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions), nutritional support specialist OR infectious disease specialist (doctor who specializes in the treatment of infections)
   D. You are on HIV (human immunodeficiency virus) anti-retroviral therapy
   E. You have had an inadequate response to previous therapy such as exercise training, nutritional supplements, appetite stimulants or anabolic steroids
   F. You have had an inadequate response to previous pharmacological (drug) therapy including one of the following: cyproheptadine, Marinol (dronabinol), or Megace (megestrol acetate)
   (Initial denial text continued on next page)

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SOMATROPIN - SEROSTIM

INITIAL CRITERIA (CONTINUED)

G. Alternative causes of wasting have been ruled out. Alternative causes may include:
   1. Altered metabolism (from metabolic and hormonal abnormalities) including testosterone deficiency or peripheral growth hormone resistance
   2. Diarrhea
   3. Inadequate energy (caloric) intake
   4. Malignancies (tumors)
   5. Opportunistic infections (an infection that can occur because of a weakened immune system)

H. You meet ONE of the following criteria for weight loss:
   1. 10% unintentional weight loss over 12 months
   2. 7.5% unintentional weight loss over 6 months
   3. 5% body cell mass (BCM) loss within 6 months
   4. BCM less than 35% (men) and a body mass index (BMI) less than 27 kg per meter squared
   5. BCM less than 23% (women) of total body weight and a body mass index (BMI) less than 27 kg per meter squared
   6. BMI less than 18.5 kg per meter squared

I. **If you are hypogonadal (you have low testosterone levels), approval also requires:**
   1. You meet one of the following criteria for low testosterone:
      a. Total serum testosterone level of less than 300ng/dL (10.4nmol/L)
      b. A low total serum testosterone level as indicated by a lab result, with a reference range, obtained within 90 days
      c. A free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)
   2. You have tried testosterone therapy (examples include testosterone cypionate, AndroGel, Androderm, Axiron, Delatestryl, Fortesta, Striant, Testim, Testopel, Vogelxo, Natesto)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN - SEROSTIM

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Has the patient received more than 24 weeks of therapy within the plan year?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Is the request for a patient with HIV wasting/cachexia who meets **ALL** of the following criteria?
   - The requested agent is NOT prescribed for athletic enhancement or anti-aging purposes
   - The patient has shown clinical benefit in muscle mass and weight as indicated by a 10% or greater increase in weight or BCM from baseline (**Note:** Current and baseline weight must be documented including dates of measurement)
   - The patient is on HIV anti-retroviral therapy

   If yes, **approve for 12 weeks by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **SOMATROPIN (Serostim)** requires the following rule(s) be met for renewal:
   A. You have HIV (human immunodeficiency virus) wasting/cachexia (severe muscle and weight loss)
   B. You have NOT received more than 24 weeks of therapy within the plan year
   C. The requested agent is NOT prescribed for athletic enhancement or anti-aging purposes
   D. You have shown clinical benefit in muscle mass and weight as indicated by at least a 10 percent increase in weight or BCM (body cell mass) from baseline (Note: current and baseline weight must be documented including dates of measurement)
   E. You are on HIV anti-retroviral therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN - SEROSTIM

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Serostim.

REFERENCES

- Serostim [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; June 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/23
Created: 10/22
Client Approval: 11/22
P&T Approval: 04/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - ZOMACTON

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) and meet **ALL** of the following criteria?
   - The request is for a pediatric patient
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient had a trial, failure, or contraindication to ONE of the following preferred agents: Norditropin (somatropin), Genotropin (somatropin)

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient has a height velocity that is less than the 25th percentile for age
   - The patient has a low peak growth hormone (less than 10ng/mL) on two GH stimulation tests OR has an insulin-like growth factor 1 (IGF-1) that is at least 2 SD below the mean for the same age and gender

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of short stature associated with Turner syndrome and meet **ALL** of the following criteria?
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient had a trial, failure, or contraindication to ONE of the following preferred agents: Norditropin (somatropin), Genotropin (somatropin)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #5.

5. Does the patient have a diagnosis of short stature born small for gestational age (SGA) and meet **ALL** of the following criteria?
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - The patient has no catch-up growth by age 2 to 4 years
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient had a trial, failure, or contraindication to ONE of the following preferred agents: Norditropin (somatropin), Genotropin (somatropin)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #6.

6. Does the patient have a diagnosis of short stature or growth failure with short stature homeobox-containing (SHOX) gene deficiency and meet **ALL** of the following criteria?
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, continue to #7.

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SOMATROPIN - ZOMACTON

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of growth hormone deficiency and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency
   - The patient had a trial, failure, or contraindication to ONE of the following preferred agents: Norditropin (somatropin), Genotropin (somatropin)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN (Zomacton)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
      2. Short stature associated with Turner syndrome (TS: a type of gene condition)
      3. Short stature born small for gestational age (SGA)
      4. Short stature or growth failure with short stature homeobox-containing gene (SHOX) deficiency (you're missing a certain gene, causing short height)
      5. Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

   (Initial denial text continued on next page)

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INITIAL CRITERIA (CONTINUED)

B. **If you have growth failure due to an inadequate secretion of endogenous growth hormone, approval also requires:**
   1. You are a pediatric patient
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   3. You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
   4. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   5. You meet ONE of the following criteria:
      a. Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender
      b. Your height velocity is less than the 25th percentile for your age
      c. You have a low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations below the mean for your age and gender

C. **If you have short stature associated with Turner syndrome, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

D. **If you have short stature born small for gestational age**, **approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. You had no catch-up growth by age 2 to 4 years
   5. Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

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INITIAL CRITERIA (CONTINUED)

E. **If you have short stature or growth failure with SHOX deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender

F. **If you have growth hormone deficiency, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   3. You have tried, failed (drug did not work), or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Norditropin (somatropin), Genotropin (somatropin)
   4. You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

G. Request for Zomacton will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN - ZOMACTON

RENEWAL CRITERIA

1. Is the request for treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) and meet **ALL** of the following criteria?
   - The request is for a pediatric patient
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand or the patient has not completed prepubertal growth)
   - Therapy is prescribed by or in consultation with an endocrinologist

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   - The patient has an annual growth velocity of at least 2 cm compared with what was observed from the previous year
   - The patient is near the terminal phase of puberty and has an annual growth velocity of at least 1 cm compared with what was observed from the previous year

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Does the patient have **ONE** of the following diagnoses?
   - Short stature associated with Turner syndrome
   - Short stature born small for gestational age (SGA)
   - Short stature or growth failure with SHOX deficiency

   If yes, continue to #5.
   If no, continue to #6.

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SOMATROPIN - ZOMACTON

RENEWAL CRITERIA (CONTINUED)

5. Does the patient meet **ALL** of the following criteria?
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Therapy is prescribed by or in consultation with an endocrinologist
     The patient has a growth velocity of at least 2 cm compared with what was observed from the previous year OR the patient has not reached 50th percentile for patient's predicted adult height

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

6. Does the patient have a diagnosis of growth hormone deficiency and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **SOMATROPIN (Zomacton)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Growth failure due to an inadequate secretion (release) of endogenous (from your own body) growth hormone (GH)
      2. Short stature associated with Turner syndrome (TS: a type of gene condition)
      3. Short stature born small for gestational age (SGA)
      4. Short stature or growth failure with short stature homeobox-containing gene (SHOX) deficiency (you're missing a certain gene, causing short height)
      5. Growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

   (Renewal denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

B. **If you have growth failure due to an inadequate secretion of endogenous growth hormone, renewal also requires:**
   1. You are a pediatric patient
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   3. Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth)
   4. You meet ONE of the following:
      a. Your annual growth velocity is at least 2 cm compared with what was observed from the previous year
      b. Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

C. **If you have short stature associated with Turner syndrome, short stature born small for gestational age, or short stature or growth failure with SHOX deficiency, renewal also requires**:
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is at least 2 cm compared with what was observed from the previous year OR you have not reached 50th percentile for your predicted adult height

D. **If you have growth hormone deficiency, renewal also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

E. Request for Zomacton will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zomacton

REFERENCES

- Zomacton [Prescribing Information]. Parisppany, NJ: Ferring Pharmaceuticals Inc.; July 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 10/22
Client Approval: 11/23
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - ZORBTIVE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a patient with a diagnosis of short bowel syndrome who meets **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The requested medication is NOT prescribed for athletic enhancement or anti-aging purposes
   - The patient is currently on specialized nutritional support (such as high carbohydrate, low-fat diet, adjusted for individual requirements and preferences)

   If yes, **approve for 4 weeks by GPID or GPI-14 for #1 vial per day (max dose not to exceed 8mg per day).**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN (Zorbtive)** requires the following rule(s) be met for approval:
   A. You have short bowel syndrome (the body cannot absorb fluids and nutrients due to a lack of a functional small intestine)
   B. Therapy is prescribed by or in consultation with a gastroenterologist (digestive system doctor)
   C. The requested medication is NOT prescribed for athletic enhancement or anti-aging purposes
   D. You are currently on specialized nutritional support such as high carbohydrate, low-fat diet, adjusted for individual requirements and preferences

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN - ZORBTIVE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of short bowel syndrome?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient been on the medication for 4 weeks?

   If yes, do not approve. [**Note**: The patient should only be approved for one 4 weeks fill in a lifetime.]
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, **approve by GPID or GPI-14 for the remainder of therapy with a maximum of 4 weeks of therapy. (Please subtract any previous fills; maximum cumulative approval is for 4 weeks.).**

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN (Zorbtive)** requires the following rule(s) be met for renewal:
   A. You have short bowel syndrome (the body cannot absorb fluids and nutrients due to a lack of a functional small intestine)
   B. You have not been on the requested medication for 4 weeks

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN - ZORBTIVE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zorbtive.

REFERENCES

- Zorbtive [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/01/22
Created: 10/22
Client Approval: 10/22
P&T Approval: 04/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SONIDEGIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced basal cell carcinoma (BCC) and meet the following criteria?
   - The patient is 18 years of age or older
   - This is a recurrence of BCC after the patient has already had surgery or radiation therapy or the patient is not a candidate for surgery or radiation therapy

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at end of the guideline.

2. Has the patient obtained the following tests prior to initiating therapy?
   - Baseline serum creatinine kinase (CK) level
   - Baseline serum creatinine
   - Pregnancy status of females of reproductive potential

   If yes, **approve for 12 months by HICL or GPI 10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **SONIDEGIB (Odomzo)** requires the following rule(s) be met for approval:
   A. You have locally advanced basal cell carcinoma (BCC: type of skin cancer).
   B. You are 18 years of age or older
   C. This is a recurrence (disease returns) of basal cell carcinoma after surgery or radiation therapy OR you are not a candidate for surgery or radiation therapy
   D. Baseline serum creatine kinase (CK: type of lab test) and serum creatinine levels have been obtained before starting therapy
   E. If you are a female of reproductive potential, you must verify your pregnancy status before starting therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SONIDEGIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Odomzo.

REFERENCES

- Odomzo [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals, Corp. May 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 10/15
Client Approval: 12/21
P&T Approval: 01/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SORAFENIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of unresectable hepatocellular carcinoma?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) that is refractory to radioactive iodine treatment?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SORAFENIB (Nexavar)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Advanced renal cell carcinoma (RCC: type of kidney cancer)
      2. Unresectable hepatocellular carcinoma (liver cancer that cannot be removed with surgery)
      3. Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) that is refractory to radioactive iodine treatment (thyroid cancer that has returned or spread, is getting worse and is not responding to a type of treatment)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SORAFENIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Nexavar.

REFERENCES

- Nexavar [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc. July 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/18/22
Created: 05/11
Client Approval: 06/22
P&T Approval: 02/14

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOTATERCEPT-CSRK

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age and older
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have documentation (e.g., chart note, lab result, diagnostic test result, etc.) confirming a PAH diagnosis based on right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Has the patient been on background PAH therapy (for at least 3 months) with at least TWO of the following agents from different drug classes?
   - Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
   - Oral phosphodiesterase-5 inhibitor (e.g., Revatio [sildenafil], Adcirca [tadalafil])
   - Oral cGMP stimulator (e.g., Adempas [riociguat])
   - IV/SQ prostacyclin (e.g., Flolan [epoprostenol], Remodulin [treprostinil])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per 21 days.**
   If no, continue to #4.

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SOTATERCEPT-CSRK

INITIAL CRITERIA (CONTINUED)

4. Is the patient on ONE agent from one of the following drug classes, **AND** has a contraindication or intolerance to ALL of the other drug classes?
   - Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
   - Oral phosphodiesterase-5 inhibitor (e.g., Revatio [sildenafil], Adcirca [tadalafil])
   - Oral cGMP stimulator (e.g., Adempas [riociguat])
   - IV/SQ prostacyclin (e.g., Flolan [epoprostenol], Remodulin [treprostinil])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per 21 days.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOTATERCEPT-CSRK (Winrevair)** requires the following rule(s) be met for approval:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   B. You are 18 years of age and older
   C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   D. There is documentation (such as chart note, lab result, diagnostic test result) showing you have pulmonary arterial hypertension based on ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      3. Pulmonary vascular resistance (PVR) greater than 2 Wood units

   (Initial denial text continued on next page)

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SOTATERCEPT-CSRK

INITIAL CRITERIA (CONTINUED)

E. You meet ONE of the following:
   1. You have been on background PAH therapy (for at least 3 months) with at least TWO of the following medications from different drug classes:
      a. Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
      b. Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
      c. Oral cGMP stimulator (such as Adempas [riociguat])
      d. Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil])
   2. You are on ONE medication from one of the following drug classes, AND you have a contraindication to (harmful for you to use) or intolerance (side effect) to ALL of the other drug classes:
      a. Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
      b. Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
      c. Oral cGMP stimulator (such as Adempas [riociguat])
      d. Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOTATERCEPT-CSRK

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per 21 days.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOTATERCEPT-CSRK (Winrevair)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Winrevair.

REFERENCES

- Winrevair [Prescribing Information]. Rahway, NJ: Merck Sharp & Dohme LLC; March 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/22/24
Created: 04/24
Client Approval: 04/24
P&T Approval: 04/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOTORASIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a KRAS G12C-mutation, as determined by an FDA-approved test
   - The patient has received at least one prior systemic therapy

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **120mg: #8 per day.**
   - **320mg: #3 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOTORASIB (Lumakras)** requires the following rule(s) be met for approval:
   A. You have locally advanced or metastatic non-small cell lung cancer (NSCLC) (type of lung cancer that has grown outside the organ it started in but has not spread to other parts of the body or lung cancer that has spread to other parts of the body)
   B. You are 18 years of age or older
   C. You have a KRAS G12C-mutation (type of gene mutation), as determined by a Food and Drug Administration (FDA)-approved test
   D. You have received at least one prior systemic therapy (treatment that spreads throughout the body through the bloodstream)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOTORASIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lumakras.

REFERENCES

- Lumakras [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; January 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/17/23
Created: 07/21
Client Approval: 03/23
P&T Approval: 07/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SPARSENTAN

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a nephrologist
   - The patient's diagnosis is confirmed by a biopsy
   - The patient is at risk of rapid disease progression (e.g., urine protein-to-creatinine ratio [UPCR] 1.5 g/g or greater)
   - The patient has proteinuria of at least 1 g/day
   - The patient has an eGFR of at least 30 mL/min/1.73 m(2)
   - The patient had a trial of or contraindication to an ACE inhibitor (e.g., lisinopril, enalapril) or an ARB (e.g., losartan, valsartan) for at least 12 weeks
   - Filspari will NOT be used concurrently with an ACE inhibitor (e.g., lisinopril, enalapril), an ARB (e.g., losartan, valsartan), an endothelin receptor antagonist (e.g., ambrisentan, bosentan), or aliskiren

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SPARSENTAN (Filspari)** requires the following rule(s) be met for approval:
   A. You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
   D. Your diagnosis is confirmed by a biopsy (removal of cells or tissue for examination)
   E. You are at risk of rapid disease progression (such as urine protein-to-creatinine-ratio [UPCR: test that measures the amount of protein in urine] of 1.5 g/g or greater)
   F. You have proteinuria (increased levels of protein in the urine) of at least 1 g/day
   G. You have an eGFR (a tool for evaluating kidney function) of at least 30 mL/min/1.73 m(2)
   (Initial denial text continued on next page)

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SPARSENTAN

INITIAL CRITERIA (CONTINUED)

H. You had a trial of or contraindication (harmful for) to an angiotensin converting enzyme inhibitor (ACE-I: such as lisinopril, enalapril) or an angiotensin receptor blocker (ARB: such as losartan, valsartan) for at least 12 weeks
I. Filspari will NOT be used concurrently (at the same time) with ACE-I (such as lisinopril, enalapril), an ARB (such as losartan, valsartan), an endothelin receptor antagonist (such as ambrisentan, bosentan), or aliskiren

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) and meet **ONE** of the following criteria?
   - The patient has had a reduction in proteinuria
   - The patient has improved, or stable kidney function compared to baseline

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Will Filspari be used concurrently with an ACE inhibitor (e.g., lisinopril, enalapril), an ARB (e.g., losartan, valsartan), an endothelin receptor antagonist (e.g., ambrisentan, bosentan), or aliskiren?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**

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SPARSENTAN

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SPARSENTAN (Filspari)** requires the following rule(s) be met for renewal:

A. You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
B. You meet ONE of the following:
   1. You had a reduction in proteinuria (increased levels of protein in the urine)
   2. You have improvement or stable kidney function compared to baseline
C. Filspari will NOT be used concurrently (at the same time) with angiotensin converting enzyme inhibitor (ACE-I: such as lisinopril, enalapril), an angiotensin receptor blocker (ARB: such as losartan, valsartan), an endothelin receptor antagonist (such as ambrisentan, bosentan), or aliskiren

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Filspari.

REFERENCES

- Filspari [Prescribing Information]. San Diego, CA: Travere Therapeutics, Inc.; February 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 03/23
Client Approval: 05/23
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SPESOLIMAB-SBZO - SQ

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a generalized pustular psoriasis (GPP) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient weighs at least 40 kg (88 lbs)

   If yes, **approve for 12 months by GPID or GPI-14 as follows:**
   INITIAL REQUESTS:
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #4 for 1 fill.**
   - **SECOND APPROVAL: Approve for 11 months with a quantity limit of #2 per 28 days. (Please enter a START date of 3 days before the END date of the first approval.)**

   SUBSEQUENT REQUESTS:
   - **Approve for 12 months with a quantity limit of #2 per 28 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SPESOLIMAB-SBZO - SQ (Spevigo)** requires the following rule(s) be met for approval:
   A. You have a diagnosis of generalized pustular psoriasis (GPP: a type of skin condition).
   B. You are 12 years of age or older.
   C. You weigh at least 40 kilograms (88 pounds).

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SPESOLIMAB-SBZO - SQ

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Spevigo.

REFERENCES

- Spevigo [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; March 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/22/24
Created: 04/24
Client Approval: 04/24
P&T Approval: 07/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

STIRIPENTOL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of seizures associated with Dravet syndrome and meet **ALL** of the following criteria?
   - The patient is 6 months of age or older AND weighs 7kg or more
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient is currently being treated with clobazam
   - The patient had a trial of or contraindication to TWO of the following: valproic acid derivatives, clobazam, topiramate

   If yes, **approve for 12 months by GPID or GPI-14 for the requested drug with the following quantity limits:**
   - **250mg capsule: #12 per day.**
   - **500mg capsule: #6 per day.**
   - **250mg powder packet: #12 per day.**
   - **500mg powder packet: #6 per day.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **STIRIPENTOL (Diacomit)** requires the following rule(s) be met for approval:
   A. You have seizures associated with Dravet syndrome (a rare type of seizure)
   B. You are 6 months of age or older AND weighs 7kg or more
   C. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
   D. You are currently being treated with clobazam (a type of seizure drug)
   E. You had a trial of or contraindication (harmful for) to TWO of the following: valproic acid derivatives, clobazam, topiramate

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STIRIPENTOL

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of seizures associated with Dravet syndrome **AND** meet the following criterion?
   - The patient is currently being treated with clobazam

   If yes, **approve for 12 months by GPID or GPI-14 for the requested drug with the following quantity limits:**
   - **250mg capsule: #12 per day.**
   - **500mg capsule: #6 per day.**
   - **250mg powder packet: #12 per day.**
   - **500mg powder packet: #6 per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **STIRIPENTOL (Diacomit)** requires the following rule(s) be met for renewal:
   A. You have seizures associated with Dravet syndrome (a rare type of seizure)
   B. You are currently being treated with clobazam (type of seizure drug)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Diacomit.

REFERENCES

- Diacomit [Prescribing Information]. Beauvais, France: Biocodex, July 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/29/22
Created: 05/19
Client Approval: 08/22
P&T Approval: 10/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SUNITINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of gastrointestinal stromal tumor (GIST) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to imatinib mesylate (Gleevec)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of unresectable locally advanced or metastatic pancreatic neuroendocrine carcinoma (pNET) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumor is progressive and well-differentiated

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #4.

4. Is the request for adjuvant treatment of renal cell carcinoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is at high risk of recurrent renal cell carcinoma (RCC) following nephrectomy

   If yes, **approve for 12 months by HICL or GPI-10, with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See denial text at the end of the guideline.

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SUNITINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SUNITINIB (Sutent)** requires the following rule(s) be met for approval:

A. The requested medication is being used for ONE of the following:
   1. Advanced renal cell carcinoma (RCC: type of kidney cancer)
   2. Gastrointestinal stromal tumor (GIST: type of growth in the digestive system)
   3. Unresectable locally advanced or metastatic pancreatic neuroendocrine carcinoma (pNET: type of pancreas cancer)
   4. Adjuvant (add-on) treatment of renal cell carcinoma.

B. **If you have advanced renal cell carcinoma (RCC), approval also requires:**
   1. You are 18 years of age or older

C. **If you have gastrointestinal stromal tumor (GIST), approval also requires:**
   1. You are 18 years of age or older
   2. You had a trial of imatinib mesylate (Gleevec), unless there is a medical reason why you cannot (contraindication)

D. **If you have unresectable locally advanced or metastatic pancreatic neuroendocrine carcinoma (pNET), approval also requires:**
   1. You are 18 years of age or older
   2. Your tumor is progressive (getting worse) and well-differentiated

E. **If the request is for adjuvant treatment of renal cell carcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. You are at high risk of recurrent renal cell carcinoma (RCC) following nephrectomy (surgical removal of kidney)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sutent.

REFERENCES

- Sutent [Prescriber Information]. New York, NY. Pfizer, Inc. August 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/06/21
Created: 05/11
Client Approval: 08/21
P&T Approval: 01/18

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TADALAFIL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Benign Prostatic Hyperplasia (BPH)?

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient tried or had a contraindication to at least **TWO** preferred formulary agents, including **ONE** agent from **EACH** of the following classes?
   - 5-alpha-reductase inhibitors: (e.g., finasteride or dutasteride)
   - Alpha blockers: (e.g., doxazosin, terazosin, tamsulosin, or alfuzosin)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **Cialis 2.5mg OR 5mg: #30 per 30 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of erectile dysfunction?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Is erectile dysfunction a covered benefit?

   If yes, continue to #5.
   If no, guideline does not apply.

5. Has the patient tried generic sildenafil (Viagra)?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **Cialis 2.5mg OR 5mg: #30 per 30 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TADALAFIL

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TADALAFIL (Cialis)** requires the following rule(s) be met for approval:

A. You have benign prostatic hyperplasia (BPH: your prostate is too big causing difficulty urinating) OR erectile dysfunction (difficulty getting/keeping an erection)
B. **If you have benign prostatic hyperplasia (BPH), approval also requires:**
   1. You previously tried at least two preferred formulary alternatives, including one medication from each of the following classes:
      a. 5-alpha-reductase inhibitors: (such as finasteride or dutasteride)
      b. Alpha blockers: (such as doxazosin, terazosin, tamsulosin, or alfuzosin)
C. **If you have erectile dysfunction, approval also requires**:
   1. You have previously tried generic sildenafil (Viagra)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cialis.

REFERENCES

- Cialis [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company. February 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/07/20
Created: 11/14
Client Approval: 08/20
P&T Approval: 01/18

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TADALAFIL-ADCIRCA, ALYQ

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The requested medication will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - The requested medication will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have documentation (e.g., chart note, lab result, diagnostic test result, etc.) confirming a PAH diagnosis based on right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.***

   Our guideline named **TADALAFIL-ADCIRCA, ALYQ (Adcirca/Alyq)** requires the following rule(s) be met for approval:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   (*Initial denial text continued on the next page)*

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TADALAFIL-ADCIRCA, ALYQ

INITIAL CRITERIA (CONTINUED)

C. There is documentation (such as, chart note, lab result, diagnostic test result) showing you have pulmonary arterial hypertension based on ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
   1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
   3. Pulmonary vascular resistance (PVR) greater than 2 Wood units

D. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)

E. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TADALAFIL-ADCIRCA, ALYQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
   - The requested medication will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - The requested medication will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes**, approve for 12 months by GPID or GPI-14 with a quantity limit of #2 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TADALAFIL-ADCIRCA, ALYQ (Adcirca/Alyq)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   B. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   C. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Adcirca/Alyq.

REFERENCES

- Adcirca [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; September 2020.
- Alyq [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; September 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 01/08
Client Approval: 02/24
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TADALAFIL-TADLIQ

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - Tadliq will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - Tadliq will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])
   - The patient is unable to swallow tadalafil tablets

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have documentation (e.g., chart note, lab result, diagnostic test result, etc.) confirming a PAH diagnosis based on right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #10mL per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TADALAFIL-TADLIQ (Tadliq)** requires the following rule(s) be met for approval:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   (*Initial denial text continued on the next page)*

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TADALAFIL-TADLIQ

INITIAL CRITERIA (CONTINUED)

C. There is documentation (such as, chart note, lab result, diagnostic test result) showing you have pulmonary arterial hypertension based on ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
   1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
   3. Pulmonary vascular resistance (PVR) greater than 2 Wood units

D. You will NOT use Tadliq concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)

E. You will NOT use Tadliq concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

F. You are unable to swallow tadalafil tablets

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TADALAFIL-TADLIQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
   - Tadliq will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - Tadliq will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #10mL per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TADALAFIL-TADLIQ (Tadliq)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   B. You will NOT use Tadliq concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   C. You will NOT use Tadliq concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tadliq.

REFERENCES

- Tadliq [Prescribing Information]. Farmville, NC: CMP Pharma, Inc.; October 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 01/08
Client Approval: 02/24
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TAFAMIDIS

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a documented diagnosis of cardiomyopathy associated with wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) as confirmed by **ONE** of the following?
   - Bone scan (scintigraphy) strongly positive for myocardial uptake of 99mTcPYP/DPD *(**Note:** Strongly positive defined as heart to contralateral lung [H/CL] ratio of at least 1.5 or Grade 2 or greater localization to the heart using the Perugini Grade 1-3 scoring system)*
   - Biopsy of tissue of affected organ(s) (cardiac and possibly non-cardiac sites) to confirm amyloid presence **AND** chemical typing to confirm presence of transthyretin (TTR) protein

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a cardiologist, transthyretin amyloidosis (ATTR) specialist, or medical geneticist
   - The patient has New York Heart Association (NYHA) class I, II, or III heart failure

   If yes, **approve for 12 months for both of the following drugs:**
   - **Vyndaqel (tafamidis meglumine): Approve by HICL or GPI-10 with a quantity limit of #4 per day.**
   - **Vyndamax (tafamidis): Approve by HICL or GPI-10 with a quantity limit of #1 per day.**

   APPROVAL TEXT: Renewal requires that the patient has not progressed to New York Heart Association (NYHA) Class IV heart failure.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TAFAMIDIS

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TAFAMIDIS (Vyndaqel, Vyndamax)** requires the following rule(s) be met for approval:

A. You have cardiomyopathy associated with wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM: heart disease caused by a build-up of a type of protein) which is confirmed by ONE of the following:
   1. Bone scan (scintigraphy) strongly positive for myocardial uptake of 99mtcpyp/DPD (a type of test that shows your heart absorbs a chemical for imaging)(Note: Strongly positive defined as heart to contralateral lung [H/Cl] ratio of at least 1.5 or grade 2 or greater localization to the heart using the Perugini grade 1-3 scoring system
   2. Biopsy of tissue of affected organ(s) (can be heart or non-heart related organs) to confirm amyloid (type of protein) presence **AND** chemical typing to confirm presence of transthyretin (TTR) protein

B. You are 18 years of age or older

C. Therapy is prescribed by or given in consultation with a cardiologist (heart doctor), transthyretin amyloidosis (ATTR) specialist, or medical geneticist

D. You have New York Heart Association (NYHA) class I, II or III heart failure (classification of heart failure symptoms)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cardiomyopathy associated with wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) **AND** meet the following criterion?
   - The patient has not progressed to New York Heart Association (NYHA) Class IV heart failure

   If yes, **approve for 12 months for both of the following drugs:**
   - **Vyndaqel (tafamidis meglumine): Approve by HICL or GPI-10 with a quantity limit of #4 per day.**
   - **Vyndamax (tafamidis): Approve by HICL or GPI-10 with a quantity limit of #1 per day.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TAFAMIDIS

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TAFAMIDIS (Vyndaqel, Vyndamax)** requires the following rule(s) be met for renewal:

A. You have cardiomyopathy associated with wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM: heart disease caused by a build-up of a type of protein)
B. You have not progressed to (gotten worse to) New York Heart Association (NYHA) Class IV heart failure (classification of heart failure symptoms)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vyndaqel and Vyndamax.

REFERENCES

- Vyndaqel [Prescribing Information]. New York, NY: Pfizer Inc.; August 2019.
- Vyndamax [Prescribing Information]. New York, NY: Pfizer Inc.; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 05/19
Client Approval: 04/20
P&T Approval: 04/19

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TALAZOPARIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutation (*gBRCAm*) as confirmed by a FDA-approved test
   - The patient has been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting

   If yes, continue to #2**.**
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient does NOT have hormone receptor (HR)-positive breast cancer
   - The patient has hormone receptor (HR)-positive breast cancer AND has received prior treatment with endocrine therapy or be considered inappropriate for endocrine therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Talzenna will be used in combination with Xtandi (enzalutamide)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUE ON NEXT PAGE

TALAZOPARIB

GUIDELINES FOR USE (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   - The patient had a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., less than 50 ng/dL)
   - Talzenna will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron-Depot [leuprolide], Zoladex [goserelin], Supprelin [histrelin], Firmagon [degarelix])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TALAZOPARIB (TALZENNA)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer (cancer that does not have a type of protein and has spread from where it started to nearby tissue or lymph nodes or has spread to other parts of the body)
      2. HRR gene-mutated (abnormal change in the homologous recombination repair gene) metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)
   B. You are 18 years of age or older
   C. **If you have breast cancer, approval also requires:**
      1. You have a deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutation (*gBRCAm*: a type of gene mutation [abnormal change]) as confirmed by a Food and Drug Administration-approved test
      2. You have been treated with chemotherapy in the neoadjuvant (drugs used to treat cancer given before main treatment), adjuvant (add-on to main treatment), or metastatic setting (treating disease that has spread)
      3. If you have hormone receptor (HR)-positive breast cancer, you had additional treatment with endocrine (hormone) therapy or are considered inappropriate for endocrine therapy

   (Denial text continued on next page)

CONTINUE ON NEXT PAGE

TALAZOPARIB

GUIDELINES FOR USE (CONTINUED)

D. **If you have prostate cancer, approval also requires:**
   1. Talzenna will be used in combination with Xtandi (enzalutamide)
   2. You meet ONE of the following:
      a. You had a bilateral orchiectomy (both testicles have been surgically removed)
      b. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
      c. Talzenna will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron-Depot [leuprolide], Zoladex [goserelin], Supprelin [histrelin], Firmagon [degarelix])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Talzenna.

REFERENCES

- Talzenna [Prescribing Information]. New York, NY: Pfizer Labs; June 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/23
Created: 02/19
Client Approval: 06/23
P&T Approval: 07/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TAPINAROF

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of plaque psoriasis and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has psoriasis covering 3% to 20% of body surface area (BSA) (excluding scalp, palms, fingernails, toenails, and soles)
   - The patient is NOT concurrently using other systemic immunomodulating agents (e.g., Stelara, Otezla), topical corticosteroids (e.g., betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (e.g., calcitriol, tazarotene)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See initial denial text at the end of the guideline.

2. Has the patient had a trial of or contraindication to **TWO** of the following (from different categories)?
   - High or super-high potency topical corticosteroid (e.g., triamcinolone acetonide, fluocinonide, clobetasol propionate, halobetasol propionate)
   - Topical vitamin D analog (e.g., calcipotriene cream, calcitriol ointment)
   - Topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus)
   - Topical retinoid (e.g., tazarotene cream/gel)
   - Anthralin

   If yes, **approve for 3 months by HICL or GPI-10.**
   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **TAPINAROF (Vtama)** requires the following rule(s) be met for approval:
   A. You have plaque psoriasis (a type of skin condition)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   D. You have psoriasis covering 3% to 20% of body surface area (BSA) (excluding scalp, palms, fingernails, toenails, and soles)
   (Initial denial text continued on next page)

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TAPINAROF

INITIAL CRITERIA (CONTINUED)

E. You are NOT concurrently (at the same time) using other systemic immunomodulating agents (such as Stelara, Otezla), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (such as calcitriol, tazarotene)
F. You had a trial of or contraindication (harmful for) to TWO of the following (from different categories):
   1. High or super-high potency topical corticosteroid (such as triamcinolone acetonide, fluocinonide, clobetasol propionate, halobetasol propionate)
   2. Topical vitamin D analog (such as calcipotriene cream, calcitriol ointment)
   3. Topical calcineurin inhibitor (such as tacrolimus, pimecrolimus)
   4. Topical retinoid (such as tazarotene cream/gel)
   5. Anthralin

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of plaque psoriasis and meet **ALL** of the following criteria?
   - The patient has achieved or maintained clear or minimal disease
   - The patient is NOT concurrently using other systemic immunomodulating agents (e.g., Stelara, Otezla), topical corticosteroids (e.g., betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (e.g., calcitriol, tazarotene)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TAPINAROF (Vtama)** requires the following rule(s) be met for renewal:
   A. You have plaque psoriasis (a type of skin condition)
   B. You have achieved or maintained clear or minimal disease
   C. You are NOT concurrently (at the same time) using other systemic immunomodulating agents (such as Stelara, Otezla), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (such as calcitriol, tazarotene)

   (Renewal denial text continued on next page)

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TAPINAROF

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vtama.

REFERENCES

- Vtama [Prescribing Information]. Long Beach, CA: Dermavant Sciences, Inc.; May 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/15/22
Created: 05/22
Client Approval: 05/22
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TASIMELTEON

GUIDELINES FOR USE

1. Does the patient have a diagnosis of non-24 hour sleep-wake disorder (N24HSWD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is light-insensitive or has total blindness
   - The patient had a trial and failure of maximally-tolerated melatonin therapy
   - The requested medication is for the Hetlioz (tasimelteon) capsules

   If yes, **approve the capsule for a lifetime by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of nighttime sleep disturbances in Smith-Magenis syndrome (SMS) and meet the following criterion?
   - The patient had a trial and failure of maximally-tolerated melatonin therapy

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The requested medication is for the brand Hetlioz capsules AND the patient is 16 years of age or older
   - The requested medication is for the Hetlioz LQ oral suspension AND the patient is 3 years to 15 years of age

   If yes, **approve the requested medication for a lifetime by GPID or GPI-14 with the following quantity limits:**
   - **Brand Hetlioz capsules: #1 per day.**
   - **Hetlioz LQ oral suspension: #5mL per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TASIMELTEON

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TASIMELTEON (Hetlioz, Hetlioz LQ)** requires the following rules(s) be met for approval:

A. You have one of the following:
   1. Non-24 hour sleep-wake disorder (N24HSWD) (type of sleep disorder where your sleep time increasingly gets delayed)
   2. Nighttime sleep disturbances in Smith-Magenis syndrome (SMS) (type of genetic disorder that causes sleeping problems)

B. **If you have non-24 hour sleep-wake disorder, approval also requires:**
   1. You are 18 years of age or older
   2. You are light-insensitive or have total blindness
   3. You have previously tried and failed maximally-tolerated melatonin therapy
   4. You are requesting the capsule

C. **If you have nighttime sleep disturbances in Smith-Magenis syndrome, approval also requires:**
   1. You are requesting brand Hetlioz capsules if you are 16 years of age or older
   2. You are requesting Hetlioz LQ oral suspension if you are 3 to 15 years old
   3. You have previously tried and failed maximally-tolerated melatonin therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, refer to the Prescribing Information and/or Drug Monograph for Hetlioz.

REFERENCES

- Hetlioz [Prescribing Information]. Washington, D.C.: Vanda Pharmaceuticals, Inc.; December 2020.
- Tasimelteon [Prescribing Information]. Parsippany, NJ: Teva Pharmaceuticals; May 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/01/23
Created: 03/14
Client Approval: 01/23
P&T Approval: 01/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TAVABOROLE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of onychomycosis (fungal infection) of the toenails?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a diagnosis of diabetes, peripheral vascular disease (PVD), or immunosuppression?

   If yes, continue to #4.
   If no, continue to #3.

3. Does the patient have pain surrounding the nail or soft tissue involvement?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Has the patient previously tried or have a contraindication to oral terbinafine **OR** oral itraconazole **AND** ciclopirox topical solution?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Are five or less toenails affected?

   If yes, **approve for 48 weeks by HICL or GPI-10 with a quantity limit of #10mL (1 bottle) per 60 days.**

   If no, **approve for 48 weeks by HICL or GPI-10 with a quantity limit of #10mL (1 bottle) per 30 days.**

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TAVABOROLE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TAVABOROLE (Kerydin)** requires the following rule(s) be met for approval:

A. You have onychomycosis of the toenails (toenail fungus infection)
B. You have complicating factors such as diabetes, peripheral vascular disease (narrowed blood vessels cause low blood flow), a suppressed immune system, or pain surrounding the nail or soft tissue
C. You have previously tried the following agents, unless there is a medical reason why you cannot (contraindication):
    1. Oral terbinafine OR oral itraconazole
    2. Ciclopirox topical solution

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kerydin.

REFERENCES

- Kerydin [Prescribing Information]. Palo Alto, CA: Anacor Pharmaceuticals; October 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/09/20
Created: 11/14
Client Approval: 10/20
P&T Approval: 07/18

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TAZEMETOSTAT

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic or locally advanced epithelioid sarcoma and meet **ALL** of the following criteria?
   - The patient is 16 years of age or older
   - The patient is not eligible for complete resection

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of relapsed or refractory follicular lymphoma **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ALL** of the following criteria?
   - The tumors are positive for an EZH2 mutation as detected by an FDA-approved test
   - The patient has received at least 2 prior systemic therapies

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, continue to #4.

4. Does the patient have no satisfactory alternative treatment options?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TAZEMETOSTAT

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TAZEMETOSTAT (Tazverik)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic or locally advanced (cancer that has spread to other parts of the body or has grown outside the organ it started in, but has not yet spread to distant parts of the body) epithelioid sarcoma (rare type of soft tissue cancer)
   2. Relapsed or refractory follicular lymphoma (cancer of the white blood cells that has returned or is resistant to previous treatment)

B. **If you have metastatic or locally advanced epithelioid sarcoma, approval also requires:**
   1. You are 16 years of age or older
   2. You are not eligible for complete resection (surgically removing all of a tissue/organ)

C. **If you have relapsed or refractory follicular lymphoma, approval also requires:**
   1. You are 18 years or older
   2. You meet ONE of the following:
      a. Your tumors are positive for an EZH2 (type of gene) mutation as detected by a Food and Drug Administration (FDA)-approved test AND you have received at least 2 prior systemic therapies (medication/treatment that spreads throughout your body)
      b. You have no satisfactory alternative treatment options

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tazverik.

REFERENCES

- Tazverik [Prescribing Information]. Cambridge, MA: Epizyme, Inc.; June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/13/20
Created: 05/20
Client Approval: 06/20
P&T Approval: 07/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TBO-FILGRASTIM

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a non-myeloid malignancy and meet **ALL** of the following criteria?
   - The patient is 1 month of age or older
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
   - The patient had a trial of or contraindication to the preferred agent: Nivestym

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TBO-FILGRASTIM (Granix)** requires the following rule(s) be met for approval:
   A. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   B. You are 1 month of age or older
   C. Therapy is prescribed by or in consultation with a hematologist (blood specialist) or oncologist (cancer/tumor doctor)
   D. You are receiving myelosuppressive anti-cancer drugs (drugs that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever
   E. You had a trial of or contraindication (harmful for) to the preferred medication: Nivestym

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TBO-FILGRASTIM

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Granix.

REFERENCES

- Granix [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals; April 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/01/22
Created: 10/22
Client Approval: 10/22
P&T Approval: 07/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEDUGLUTIDE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of short bowel syndrome (SBS) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient is dependent on intravenous parenteral nutrition, defined as requiring parenteral nutrition at least three times per week

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEDUGLUTIDE (Gattex)** requires the following rule(s) be met for approval:
   A. You have short bowel syndrome (SBS: the body cannot absorb fluids and nutrients due to a lack of a functional small intestine)
   B. You are 1 year of age or older
   C. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
   D. You are dependent on parenteral nutrition (administration of nutrition through a vein), defined as requiring parenteral nutrition at least three times per week

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TEDUGLUTIDE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of short bowel syndrome (SBS) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient has achieved or maintained a decreased need for parenteral support compared to baseline

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEDUGLUTIDE (Gattex)** requires the following rule(s) be met for renewal:
   A. You have short bowel syndrome (SBS: the body cannot absorb fluids and nutrients due to a lack of a functional small intestine)
   B. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
   C. You have achieved or maintained a decreased need for parenteral support (administration of nutrition through a vein) compared to baseline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gattex.

REFERENCES

- Gattex [Prescribing Information]. Lexington, MA: Shire-NPS Pharmaceutical; January 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 02/13
Client Approval: 02/22
P&T Approval: 01/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TELOTRISTAT

GUIDELINES FOR USE

1. Does the patient have a diagnosis of carcinoid syndrome diarrhea and meet **ALL** of the following criteria?
   - The medication will be used in combination with a somatostatin analog (e.g., octreotide)
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with an oncologist or gastroenterologist
   - Documentation that the patient has been receiving or has a contraindication to a stable dose of long-acting somatostatin analog therapy [e.g., Sandostatin LAR (octreotide), Somatuline Depot (lanreotide)] for a minimum of 3 months
   - The patient's diarrhea is inadequately controlled as defined by the presence of at least four bowel movements per day

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TELOTRISTAT (Xermelo)** requires the following rule(s) be met for approval:
   A. You have carcinoid syndrome diarrhea (diarrhea caused by a type of tumor affecting nerves/hormones)
   B. The medication will be used in combination with a somatostatin analog such as octreotide
   C. You are 18 years of age or older
   D. The medication is being prescribed by or given in consultation with an oncologist (cancer/tumor doctor) or gastroenterologist (digestive system doctor)
   E. There is documentation showing that you have been receiving a stable dose of long-acting somatostatin analog therapy such as Sandostatin LAR (octreotide) or Somatuline Depot (lanreotide) for a minimum of 3 months – unless there is a medical reason why you cannot (contraindication)
   F. You have diarrhea that is inadequately controlled as defined by the presence of at least four bowel movements per day

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TELOTRISTAT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xermelo.

REFERENCES

- Xermelo [Prescribing Information]. The Woodlands, Texas. Lexicon Pharmaceuticals, Inc; March 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 03/17
Client Approval: 04/20
P&T Approval: 04/17

STANDARD COMMERCIAL AND NSA DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEMOZOLOMIDE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have **ONE** of the following diagnoses?
   - Anaplastic astrocytoma
   - Glioblastoma multiforme
   - Small cell lung cancer (SCLC)

   If yes, **approve for 12 months as follows:**
   - **If the plan covers non-self-administered (NSA) agents, approve by HICL or GPI-10.**
   - **If the plan does NOT cover NSA agents, approve only Temozolomide PO for all strengths by GPID or GPI-14.**

   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic melanoma **AND** meet the following criterion?
   - Temodar will NOT be used concurrently with an immunosuppressive therapy or a medical therapy for the treatment of melanoma

   If yes, **approve for 12 months as follows:**
   - **If the plan covers non-self-administered (NSA) agents, approve by HICL or GPI-10.**
   - **If the plan does NOT cover NSA agents, approve only Temozolomide PO for all strengths by GPID or GPI-14.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEMOZOLOMIDE (Temodar)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Anaplastic astrocytoma (type of brain tumor)
      2. Glioblastoma multiforme (type of tumor affecting brain or spine)
      3. Small cell lung cancer (SCLC: a type of lung cancer)
      4. Metastatic melanoma (type of skin cancer)

   (Initial denial text continued on next page)

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TEMOZOLOMIDE

INITIAL CRITERIA (CONTINUED)

B. **If you have metastatic melanoma, approval also requires:**
   1. You are not concurrently (at the same time) using an immunosuppressive therapy (treatment that lowers the activity of the body's immune system) or a medical therapy for the treatment of melanoma

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

NOTE: For the diagnoses of Anaplastic astrocytoma, Glioblastoma multiforme, or Small cell lung cancer (SCLC), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of metastatic melanoma **AND** meet the following criterion?
   - Temodar will NOT be used concurrently with an immunosuppressive therapy or a medical therapy for the treatment of melanoma

   If yes, **approve for 12 months as follows:**
   - **If the plan covers non-self-administered (NSA) agents, approve by HICL or GPI-10.**
   - **If the plan does NOT cover NSA agents, approve only Temozolomide PO for all strengths by GPID or GPI-14.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEMOZOLOMIDE (Temodar)** requires the following rule(s) be met for renewal:
   A. You have metastatic melanoma (type of skin cancer)
   B. You are not concurrently (at the same time) using an immunosuppressive therapy (treatment that lowers the activity of the body's immune system) or a medical therapy for the treatment of melanoma

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TEMOZOLOMIDE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Temodar.

REFERENCES

- Temodar [Prescribing Information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp.; November 2019.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 02/12
Client Approval: 05/22
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TENAPANOR

GUIDELINES FOR USE

1. Does the patient have a diagnosis of irritable bowel syndrome with constipation (IBS-C) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of the preferred agents: lubiprostone AND Linzess

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TENAPANOR (Ibsrela)** requires the following rule(s) be met for approval:
   A. You have irritable bowel syndrome with constipation (IBS-C: a type of bowel disease)
   B. You are 18 years of age or older
   C. You had a trial of the preferred agents: lubiprostone AND Linzess

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ibsrela.

REFERENCES

- Ibsrela [Prescribing Information]. Waltham, MA: Ardelyx, Inc.; April 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 05/22
Client Approval: 05/22
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEPOTINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Mesenchymal-epithelial transition (MET) exon 14 skipping alterations are present

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEPOTINIB (Tepmetko)** requires the following rule(s) be met for approval:
   A. You have metastatic non-small cell lung cancer (NSCLC) (type of lung cancer that has spread to other parts of the body)
   B. You are 18 years of age or older
   C. Mesenchymal-epithelial transition (MET) exon 14 skipping alterations (abnormal change in a gene that makes MET protein) are present

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tepmetko.

REFERENCES

- Tepmetko [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; February 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/09/21
Created: 05/21
Client Approval: 08/21
P&T Approval: 04/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TERIFLUNOMIDE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TERIFLUNOMIDE (Aubagio)** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return) and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Aubagio.

REFERENCES

- Aubagio [Prescribing Information]. Cambridge, MA: Genzyme Corporation; April 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/17/23
Created: 10/12
Client Approval: 03/23
P&T Approval: 01/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TERIPARATIDE

GUIDELINES FOR USE

1. Is the medication being used for **ONE** of the following diagnoses?
   - Postmenopausal osteoporosis
   - Primary or hypogonadal osteoporosis in a male patient
   - Glucocorticoid-induced osteoporosis

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient is at high risk for fractures defined as **ONE** of the following:
     - History of osteoporotic (i.e., fragility, low trauma) fracture(s)
     - 2 or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, BMD T-score less than or equal to -2.5, corticosteroid use, or use of GnRH analogs such as Synarel [nafarelin])
     - No prior treatment for osteoporosis **AND** FRAX score ≥ 20% for any major fracture OR ≥ 3% for hip fracture
   - The patient is unable to use oral therapy (i.e., upper gastrointestinal [GI] problems - unable to tolerate oral medication, lower GI problems - unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine)
   - The patient had a trial of, intolerance to, or a contraindication to a bisphosphonate (e.g., Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate])

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Has the patient received a total of 24 months cumulative treatment with Forteo (teriparatide)?

   If yes, continue to #4.
   If no, **approve the requested agent for up to 24 months lifetime cumulative treatment duration by GPID or GPI-14 with the following quantity limits:**
   - **Forteo (teriparatide) 600mcg/2.4mL: #2.4mL per 28 days.**
   - **Teriparatide 620mcg/2.48mL: #2.48mL per 28 days.**

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TERIPARATIDE

GUIDELINES FOR USE (CONTINUED)

4. Does the patient remain at or has returned to having a high risk for fracture?

   If yes, **approve the requested agent for up to 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Forteo (teriparatide) 600mcg/2.4mL: #2.4mL per 28 days.**
   - **Teriparatide 620mcg/2.48mL: #2.48mL per 28 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TERIPARATIDE (Forteo)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Postmenopausal osteoporosis (a type of bone condition in women after menopause)
      2. Primary or hypogonadal (low level of sex hormones) osteoporosis (a type of bone condition) in a male patient
      3. Glucocorticoid (steroid)-induced osteoporosis (a type of bone condition)

   B. You meet ONE of the following:
      1. You are at high risk for fractures defined as ONE of the following:
         a. You have a history of osteoporotic (i.e., fragility, low trauma) fracture(s)
         b. You have two or more risk factors for a fracture (such as a history of multiple recent low trauma fractures, bone marrow density [BMD: a type of lab test] T-score less than or equal to -2.5, corticosteroid [such as prednisone] use, or use of GnRH analogs [such as Synarel (nafarelin)])
         c. You have had no prior treatment for osteoporosis AND you have a FRAX (test for your risk of fractures) score of at least 20 percent for any major fracture OR at least 3 percent for a hip fracture
      2. 2. You are unable to use oral therapy due to reasons such as upper gastrointestinal (GI) problems (such as unable to tolerate oral medications), lower GI problems (such as unable to absorb oral medications), trouble remembering to take oral medications or coordinating an oral bisphosphonate (such as Fosamax [alendronate]) with other oral medications or your daily routine
      3. You had a trial of, intolerance (side effect), or contraindication to (harmful for you to use) a bisphosphonate (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate])

   (Denial text continued on next page)

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TERIPARATIDE

GUIDELINES FOR USE (CONTINUED)

C. You meet ONE of the following:
   1. You have received a total of 24 months of cumulative treatment with Forteo (teriparatide) AND remain at or have returned to having a high risk for fracture
   2. You have received less than 24 months of cumulative treatment with Forteo (teriparatide)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Forteo and teriparatide.

REFERENCE

- Forteo [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC; September 2021.
- Teriparatide [Prescribing Information]. Morristown, NJ: Alvogen, Inc; November 2019.
- Teriparatide [Prescribing Information]. Weston, FL: Apotex Corp.; January 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 05/03
Client Approval: 11/23
P&T Approval: 01/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TESAMORELIN

GUIDELINES FOR USE

1. Does the patient have a diagnosis of HIV with lipodystrophy and meets **ALL** the following criteria?
   - The patient is 18 years of age or older
   - The requested medication is being used for the reduction of excess abdominal fat
   - The patient is currently receiving treatment with a protease inhibitor (PI), PI combination (i.e., saquinavir, ritonavir, indinavir, nelfinavir, lopinavir/ritonavir, atazanavir, fosamprenavir, or tipranavir), a nucleoside reverse transcriptase inhibitor (NRTI), OR an NRTI combination (i.e., zidovudine, didanosine, stavudine, lamivudine, abacavir, tenofovir, emtricitabine, lamivudine/zidovudine, or abacavir/lamivudine/zidovudine, efavirenz/emtricitabine/tenofovir, emtricitabine/tenofovir)

   If yes, **approve for 3 months by HICL or GPI-10 with a quantity limit of #60 vials per month.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TESAMORELIN (Egrifta, Egrifta SV)** requires the following rule(s) be met for approval:
   A. You have human immunodeficiency virus (HIV: a type of immune disorder) with lipodystrophy (abnormal distribution of fat in the body)
   B. You are 18 years of age or older
   C. The requested medication is being used for the reduction of excess abdominal fat
   D. You are currently receiving treatment with a protease inhibitor (PI: a type of drug), PI combination (saquinavir, ritonavir, indinavir, nelfinavir, lopinavir/ritonavir, atazanavir, fosamprenavir, or tipranavir), a nucleoside reverse transcriptase inhibitor (NRTI: a type of drug), OR an NRTI combination (zidovudine, didanosine, stavudine, lamivudine, abacavir, tenofovir, emtricitabine, lamivudine/zidovudine, or abacavir/lamivudine/zidovudine, efavirenz/emtricitabine/tenofovir, emtricitabine/tenofovir)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TESAMORELIN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Egrifta.

REFERENCES

- Egrifta SV [Prescribing Information]. Montreal, Québec, Canada: Theratechnologies Inc.; July 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 02/11
Client Approval: 03/22
P&T Approval: 02/11

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TESTOSTERONE CYPIONATE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) who meets **ONE** of the following criteria?
   - The patient has a previously approved prior authorization for testosterone or has been receiving any form of testosterone replacement therapy
   - The patient has AT LEAST ONE of the following laboratory values confirming low testosterone levels:
     - At least two total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
     - Free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient 40 years of age or older?

   If yes, continue to #3.
   If no, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **100 mg/mL, 200 mg/mL (10 mL vial): up to #10 mL per 28 days.**
   - **200 mg/mL (1 mL vial): up to #10 mL per 30 days.**

3. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **100 mg/mL, 200 mg/mL (10 mL vial): up to #10 mL per 28 days.**
   - **200 mg/mL (1 mL vial): up to #10 mL per 30 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TESTOSTERONE CYPIONATE

INITIAL CRITERIA (CONTINUED)

4. Is the requested agent for gender dysphoria as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb) **AND** the patient meets the following criterion?
   - The patient is 16 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 and override quantity limits.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TESTOSTERONE CYPIONATE (Depo-Testosterone)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
      2. Gender dysphoria (you identify yourself as a member of the opposite sex)
   B. **If you have gender dysphoria, approval also requires:**
      1. You are 16 years of age or older
      2. Only agents supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria may be approved
   C. **If you are a male with primary or secondary hypogonadism, approval also requires:**
      1. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening
      2. You meet ONE of the following:
         a. You have a previously approved prior authorization for testosterone, or you have been receiving any form of testosterone replacement therapy
         b. You have ONE of the following lab values showing you have low testosterone levels:
            i. At least two total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
            ii. Free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TESTOSTERONE CYPIONATE

RENEWAL CRITERIA

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) who meets **ALL** of the following criteria?
   - The patient has improved symptoms compared to baseline and tolerance to treatment
   - The patient's serum testosterone level and hematocrit concentration have normalized compared to baseline
   - If the patient is 40 years of age or older, the patient's prostate specific antigen (PSA) has been evaluated for prostate cancer screening

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **100 mg/mL, 200 mg/mL (10 mL vial): up to #10 mL per 28 days.**
   - **200 mg/mL (1 mL vial): up to #10 mL per 30 days.**

   If no, continue to #2.

2. Is the requested agent for gender dysphoria as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve for 12 months by GPID or GPI-14 and override quantity limits.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TESTOSTERONE CYPIONATE (Depo-Testosterone)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
      2. Gender dysphoria (you identify yourself as a member of the opposite sex)
   B. **If you have gender dysphoria, renewal also requires:**
      1. Only agents supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria may be approved

   (Renewal denial text continued on next page)

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TESTOSTERONE CYPIONATE

RENEWAL CRITERIA (CONTINUED)

C. **If you are a male patient with primary or secondary hypogonadism, renewal also requires:**
   1. You have shown improvement in your symptoms compared to baseline and tolerance to treatment
   2. Your serum testosterone level and hematocrit concentration (types of blood tests) have normalized compared to baseline
   3. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Depo-Testosterone.

REFERENCES

- Depo-Testosterone [Prescribing Information]. New York, NY: Pharmacia & Upjohn Company; August 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/28/23
Created: 02/23
Client Approval: 08/23
P&T Approval: 07/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TESTOSTERONE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) who meets **ONE** of the following criteria?
   - The patient has a previously approved prior authorization for testosterone or has been receiving any form of testosterone replacement therapy
   - The patient has AT LEAST ONE of the following laboratory values confirming low testosterone levels:
     - At least two total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
     - Free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)

   If yes, continue to #2.
   If no, continue to #6.

2. Is the patient 40 years of age or older?

   If yes, continue to #3.
   If no, continue to #4.

3. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TESTOSTERONE

INITIAL CRITERIA (CONTINUED)

4. Is the request for AndroGel 1%, AndroGel 1.62%, Axiron, Testim, or Vogelxo?

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **AndroGel (testosterone):**
     - **25mg (1%) gel packet: #5 grams per day.**
     - **50mg (1%) gel packet: #10 grams per day.**
     - **1.25g-1.62% gel packet: #1.25 grams per day.**
     - **2.5g-1.62% gel packet: #5 grams per day.**
     - **20.25/1.25 gel pump: #5 grams per day.**
   - **Axiron (testosterone):**
     - **30mg/1.5mL sol pump: #6 mL per day.**
   - **Testim (testosterone):**
     - **50mg (1%) gel packet: #10 grams per day.**
   - **Vogelxo (testosterone):**
     - **12.5/1.25g gel pump: #10 grams per day.**
     - **50mg (1%) gel tube/packet: #10 grams per day.**

   If no, continue to #5.

5. Is the request for Androderm, Fortesta, Natesto, or Striant, **AND** the patient meets the following criterion?
   - The patient had a trial of or contraindication to TWO preferred agents: testosterone cypionate and intramuscular testosterone enanthate

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Androderm (2mg/24hr, 4mg/24hr): #1 patch per day.**
   - **Fortesta (testosterone):**
     - **10mg (2%): #4 grams per day.**
   - **Natesto (5.5/0.122 gel pump): #0.732 grams per day.**
   - **Striant (30mg): #2 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TESTOSTERONE

INITIAL CRITERIA (CONTINUED)

6. Is the requested agent for gender dysphoria as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb) **AND** the patient meets the following criterion?
   - The patient is 16 years of age or older

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 and override quantity limits.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TESTOSTERONE** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
      2. Gender dysphoria (you identify yourself as a member of the opposite sex)
   B. **If you are a male with primary or secondary hypogonadism, approval also requires:**
      1. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening
      2. You meet ONE of the following:
         a. You have a previously approved prior authorization for testosterone, or you have been receiving any form of testosterone replacement therapy
         b. You have ONE of the following lab values showing you have low testosterone levels:
            i. At least two total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
            ii. Free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)
   C. If the request is for Androderm, Fortesta, Natesto or Striant, you had a trial of or contraindication (harmful for) to TWO preferred agents: testosterone cypionate and intramuscular [injected into the muscle] testosterone enanthate
   D. **If you have gender dysphoria, approval also requires:**
      1. Only agents supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria may be approved
      2. You are 16 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TESTOSTERONE

RENEWAL CRITERIA

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) who meets **ALL** of the following criteria?
   - The patient has improved symptoms compared to baseline and tolerance to treatment
   - The patient's serum testosterone level and hematocrit concentration have normalized compared to baseline
   - If the patient is 40 years of age or older, the patient's prostate specific antigen (PSA) has been evaluated for prostate cancer screening

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **AndroGel (testosterone):**
     - **25mg (1%) gel packet: #5 grams per day.**
     - **50mg (1%) gel packet: #10 grams per day.**
     - **1.25g-1.62% gel packet: #1.25 grams per day.**
     - **2.5g-1.62% gel packet: #5 grams per day.**
     - **20.25/1.25 gel pump: #5 grams per day.**
   - **Axiron (testosterone):**
     - **30mg/1.5mL sol pump: #6 mL per day.**
   - **Testim (testosterone):**
     - **50mg (1%) gel packet: #10 grams per day.**
   - **Vogelxo (testosterone):**
     - **12.5/1.25g gel pump: #10 grams per day.**
     - **50mg (1%) gel tube/packet: #10 grams per day.**
   - **Androderm (2mg/24hr, 4mg/24hr): #1 patch per day.**
   - **Fortesta (testosterone):**
     - **10mg (2%): #4 grams per day.**
   - **Natesto (5.5/0.122 gel pump): #0.732 grams per day.**
   - **Striant (30mg): #2 per day.**

   If no, continue to #2.

2. Is the requested agent for gender dysphoria as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 and override quantity limits.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TESTOSTERONE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TESTOSTERONE** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   2. Gender dysphoria (you identify yourself as a member of the opposite sex)

B. **If you are a male with primary or secondary hypogonadism, renewal also requires:**
   1. You have shown improvement in your symptoms compared to baseline and tolerance to treatment
   2. Your serum testosterone level and hematocrit concentration (types of blood tests) have normalized compared to baseline
   3. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

C. **If you have gender dysphoria, renewal also requires:**
   1. Only agents supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria may be approved

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for the related testosterone formulation.

REFERENCES

- Androderm [Prescribing Information]. Madison, NJ: Allergan; May 2020.
- Androgel 1% [Prescribing Information]. North Chicago, IL: AbbVie Inc.; April 2020.
- Androgel 1.62% [Prescribing Information]. North Chicago, IL: Abbvie Inc.; November 2020.
- Axiron [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC.; July 2017.
- Fortesta [Prescribing Information]. Malvern, PA: Endo Pharmaceuticals.; January 2022.
- Natesto [Prescribing Information]. Regensburg, Germany: Haupt Pharma Amareg GmbH; December 2021.
- Striant [Prescribing Information]. Malvern, PA: Actient Pharmaceuticals LLC.; October 2016.
- Testim [Prescribing Information]. San Antonio, TX: DPT Laboratories, Ltd.; August 2021.
- Vogelxo [Prescribing Information]. Maple Grove, MN: Upsher-Smith Lab., Inc.; July 2020.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TESTOSTERONE

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/09/23
Created: 02/01
Client Approval: 09/23
P&T Approval: 07/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TESTOSTERONE ENANTHATE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) who meets **ONE** of the following criteria?
   - The patient has a previously approved prior authorization for testosterone or has been receiving any form of testosterone replacement therapy
   - The patient has AT LEAST ONE of the following laboratory values confirming low testosterone levels:
     - At least TWO total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
     - Free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)

   If yes, continue to #2.
   If no, continue to #6.

2. Is the patient 40 years of age or older?

   If yes, continue to #3.
   If no, continue to #4.

3. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Is the request for generic intramuscular testosterone enanthate 200 mg/mL?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #5 mL per 28 days**.

   If no, continue to #5.

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TESTOSTERONE ENANTHATE

INITIAL CRITERIA (CONTINUED)

5. Is the request for Xyosted and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication is being used for testosterone replacement therapy

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with a quantity limit of #2 mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Is the request for a male patient with a diagnosis of delayed puberty not secondary to a pathological disorder who meets the following criterion?
   - The request is for generic intramuscular testosterone enanthate 200 mg/mL

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #5 mL per 28 days.**
   If no, continue to #7.

7. Is the request for a female patient with a diagnosis of metastatic breast cancer who meets the following criterion?
   - The request is for generic intramuscular testosterone enanthate 200 mg/mL

   If yes, continue to #8.
   If no, continue to #9.

8. Does the patient meet **ONE** of the following criteria?
   - The patient is postmenopausal
   - The patient is premenopausal who benefitted from an oophorectomy AND is considered to have a hormone-responsive tumor

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #5 mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TESTOSTERONE ENANTHATE

INITIAL CRITERIA (CONTINUED)

9. Is the requested agent for gender dysphoria as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb) **AND** the patient meets the following criterion?
   - The patient is 16 years of age or older

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 and override quantity limits.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TESTOSTERONE ENANTHATE (Xyosted)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
      2. Delayed puberty not due to a pathological disorder (disease) in a male
      3. Metastatic breast cancer (cancer that has spread to other parts of the body) in a female
      4. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

   B. **If you are a male with primary or secondary hypogonadism, approval also requires:**
      1. You meet ONE of the following:
         a. You have a previously approved prior authorization for testosterone, or you have been receiving any form of testosterone replacement therapy
         b. You have ONE of the following lab values showing you have low testosterone levels:
            i. At least TWO total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
            ii. Free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)
      2. If you are 40 years of age or older, approval also requires that your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening
      3. If the request is for Xyosted, approval also requires:
         a. You are 18 years of age or older
         b. The requested medication is being used for testosterone replacement therapy

   C. **If you are a male with delayed puberty not secondary to a pathological disorder, approval also requires:**
      1. Your request is for generic intramuscular (injected into muscle) testosterone enanthate 200 mg/mL

   (Initial denial text continued on next page)

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TESTOSTERONE ENANTHATE

INITIAL CRITERIA (CONTINUED)

D. **If you are a female with metastatic breast cancer, approval also requires:**
   1. You meet ONE of the following:
      a. You are postmenopausal (after menopause)
      b. You are premenopausal (before menopause), you have benefited from an oophorectomy (surgical removal of the ovaries), and your tumor is hormone-responsive
   2. Your request is for generic intramuscular (injected into muscle) testosterone enanthate 200 mg/mL

E. **If you have gender dysphoria, approval also requires:**
   1. Only agents supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria may be approved
   2. You are 16 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TESTOSTERONE ENANTHATE

RENEWAL CRITERIA

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) who meets **ALL** of the following criteria?
   - The patient has improved symptoms compared to baseline and tolerance to treatment
   - The patient's serum testosterone level and hematocrit concentration have normalized compared to baseline

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient 40 years of age or older?

   If yes, continue to #3.

   If no, **approve all strengths of the requested agent for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Intramuscular testosterone enanthate: #5 mL per 28 days.**
   - **Xyosted: #2 mL per 28 days.**

3. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   If yes, **approve all strengths of the requested agent for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Intramuscular testosterone enanthate: #5 mL per 28 days.**
   - **Xyosted: #2 mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Is the request for a male patient with a diagnosis of delayed puberty not secondary to a pathological disorder who meets **ALL** of the following criteria?
   - The patient has not received more than two 6-month courses of testosterone replacement therapy
   - The request is for generic intramuscular testosterone enanthate 200 mg/mL

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #5 mL per 28 days.**
   If no, continue to #5.

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TESTOSTERONE ENANTHATE

RENEWAL CRITERIA (CONTINUED)

5. Is the request for a female patient with a diagnosis of metastatic breast cancer who meets the following criterion?
   - The request is for generic intramuscular testosterone enanthate 200 mg/mL

   If yes, continue to #6.
   If no, continue to #7.

6. Does the patient meet **ONE** of the following criteria?
   - The patient is postmenopausal
   - The patient is premenopausal who benefitted from an oophorectomy AND is considered to have a hormone-responsive tumor

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #5 mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

7. Is the requested agent for gender dysphoria as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 and override quantity limits.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TESTOSTERONE ENANTHATE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TESTOSTERONE ENANTHATE (Xyosted)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   2. Delayed puberty not due to a pathological disorder (disease) in a male
   3. Metastatic breast cancer (cancer that has spread to other parts of the body) in a female
   4. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

B. **If you are a male with primary or secondary hypogonadism, renewal also requires:**
   1. You have shown improvement in your symptoms compared to baseline and tolerance to treatment
   2. Your serum testosterone level and hematocrit concentration (types of blood tests) have normalized compared to baseline
   3. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

C. **If you are a male with delayed puberty not secondary to a pathological disorder, renewal also requires:**
   1. You have NOT received more than two 6-month courses of testosterone replacement therapy
   2. Your request is for generic intramuscular (injected into muscle) testosterone enanthate 200 mg/mL

D. **If you are a female with metastatic breast cancer, renewal also requires:**
   1. You meet ONE of the following:
      a. You are postmenopausal (after menopause)
      b. You are premenopausal (before menopause), you have benefited from an oophorectomy (surgical removal of the ovaries), and your tumor is hormone-responsive
   2. Your request is for generic intramuscular (injected into muscle) testosterone enanthate 200 mg/mL

E. **If you have gender dysphoria, renewal also requires:**
   1. Only agents supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria may be approved

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TESTOSTERONE ENANTHATE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for the related testosterone enanthate/Xyosted.

REFERENCES

- Testosterone Enanthate [Prescribing Information]. Berkeley Heights, NJ: Hikma Pharmaceuticals, Inc.; November 2021.
- Xyosted [Prescribing Information]. Ewing, NJ: Antares Pharma, Inc.; August 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 02/23
Client Approval: 02/24
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TESTOSTERONE UNDECANOATE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) **AND** the patient meets the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, continue to #7.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has a previously approved prior authorization for testosterone or has been receiving any form of testosterone replacement therapy
   - The patient has AT LEAST ONE of the following laboratory values confirming low testosterone levels:
     - At least two total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
     - Free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the patient 40 years of age or older?

   If yes, continue to #4.
   If no, continue to #5.

4. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TESTOSTERONE UNDECANOATE

INITIAL CRITERIA (CONTINUED)

5. Is the request for Kyzatrex?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **100 mg: #2 per day.**
   - **150 mg and 200 mg: #4 per day.**

   If no, continue to #6.

6. Is the request for Jatenzo or Tlando **AND** the patient meets the following criterion?
   - The patient had a trial of or contraindication to TWO preferred agents: intramuscular testosterone cypionate and intramuscular testosterone enanthate

   If yes, **approve all strengths of the requested agent for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Jatenzo 158 mg and 198 mg: #4 per day.**
   - **Jatenzo 237 mg: #2 per day.**
   - **Tlando 112.5 mg: #4 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Is the requested agent for gender dysphoria as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb) **AND** the patient meets the following criterion?
   - The patient is 16 years of age or older

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 and override quantity limits.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TESTOSTERONE UNDECANOATE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TESTOSTERONE UNDECANOATE (Jatenzo, Kyzatrex, Tlando)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   2. Gender dysphoria (you identify yourself as a member of the opposite sex)

B. **If you have gender dysphoria, approval also requires:**
   1. You are 16 years of age or older
   2. Only agents supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria may be approved

C. **If you are a male with primary or secondary hypogonadism, approval also requires:**
   1. You are 18 years of age or older
   2. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening
   3. You meet ONE of the following:
      a. You have a previously approved prior authorization for testosterone, or you have been receiving any form of testosterone replacement therapy
      b. You have ONE of the following lab values showing you have low testosterone levels:
         i. At least two total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
         ii. Free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)
   4. If the request is for Jatenzo or Tlando, you had a trial of or contraindication to (harmful for) TWO preferred agents: intramuscular testosterone cypionate and intramuscular testosterone enanthate

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TESTOSTERONE UNDECANOATE

RENEWAL CRITERIA

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) who meets **ALL** of the following criteria?
   - The patient has improved symptoms compared to baseline and tolerance to treatment
   - The patient's serum testosterone level and hematocrit concentration have normalized compared to baseline
   - If the patient is 40 years of age or older, the patient's prostate specific antigen (PSA) has been evaluated for prostate cancer screening

   If yes, **approve all strengths of the requested agent for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Kyzatrex 100 mg: #2 per day.**
   - **Kyzatrex 150 mg and 200 mg: #4 per day.**
   - **Jatenzo 158 mg and 198 mg: #4 per day.**
   - **Jatenzo 237 mg: #2 per day.**
   - **Tlando 112.5 mg: #4 per day.**

   If no, continue to #2.

2. Is the requested agent for gender dysphoria as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 and override quantity limits.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TESTOSTERONE UNDECANOATE (Jatenzo, Kyzatrex, Tlando)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
      2. Gender dysphoria (you identify yourself as a member of the opposite sex)
   B. **If you have gender dysphoria, renewal also requires:**
      1. Only agents supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria may be approved

   (Renewal denial text continued on next page)

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TESTOSTERONE UNDECANOATE

RENEWAL CRITERIA (CONTINUED)

C. **If you are a male with primary or secondary hypogonadism, renewal also requires:**
1. You have shown improvement in your symptoms compared to baseline and tolerance to treatment
2. Your serum testosterone level and hematocrit concentration (types of blood tests) have normalized compared to baseline
3. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Jatenzo, Kyzatrex, and Tlando.

REFERENCES

- Jatenzo [Prescribing Information]. Northbrook, IL: Clarus Therapeutics, Inc.; September 2019.
- Kyzatrex [Prescribing Information]. Raleigh, NC: Marius Pharmaceuticals; July 2022.
- Tlando [Prescribing Information]. Ewing, NJ: Antares Pharma, Inc.; March 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/09/23
Created: 02/23
Client Approval: 09/23
P&T Approval: 01/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TETRABENAZINE

GUIDELINES FOR USE

1. Is the request for a tetrabenazine dosage that exceeds 50mg?

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient have a diagnosis of chorea (involuntary movements) associated with Huntington's disease and meets **ALL** of the following criteria?
   - Therapy is prescribed by or given in consultation with a neurologist
   - The patient has been genotyped for CYP2D6 and is identified as an extensive metabolizer (EM) or intermediate metabolizer (IM) of CYP2D6

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Xenazine 12.5mg: #3 per day**
   - **Xenazine 25mg: #4 per day**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of chorea (involuntary movements) associated with Huntington's disease and meets **ALL** of the following criteria?
   - Therapy is prescribed by or given in consultation with a neurologist

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Xenazine 12.5mg: #3 per day**
   - **Xenazine 25mg: #2 per day**

   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **TETRABENAZINE (Xenazine)** requires the following rule(s) be met for approval:
   A. You have chorea (involuntary movements) associated with Huntington's disease (type of inherited disease that causes nerve cells in brain to break down over time)
   B. The medication has been prescribed or given in consultation with a neurologist (nerve doctor)
   C. If your request is for a tetrabenazine dosage that exceeds 50mg, approval also requires:
      1. You have been genotyped for CYP2D6 (type of enzyme) and you are identified as an extensive (EM) or intermediate metabolizer (IM) of CYP2D6.

   (Denial text continued on next page)

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TETRABENAZINE

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xenazine.

REFERENCES

- Xenazine [Prescribing Information]. Deerfield, IL: Lundbeck Pharmaceuticals, Inc.; November 2019.

Library	Commercial	NSA
Yes	Yes	No

Created: 02/09
Effective: 07/01/20 Client Approval: 04/20 P&T Approval: 11/15

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEZACAFTOR/IVACAFTOR

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cystic fibrosis (CF) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or given in consultation with a pulmonologist or cystic fibrosis (CF) expert

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - Documentation that the patient is homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene
   - Documentation that the patient has at least **ONE** of the following mutations in the CFTR gene:

546insCTA	E92K	G576A	L346P	R117G	S589N
711+3A→G	E116K	G576A; R668C	L967S	R117H	S737F
2789+5G→A	E193K	G622D	L997F	R117L	S912L
3272-26A→G	E403D	G970D	L1324P	R117P	S945L
3849+10kbC→T	E588V	G1069R	L1335P	R170H	S977F
A120T	E822K	G1244E	L1480P	R258G	S1159F
A234D	E831X	G1249R	M152V	R334L	S1159P
A349V	F191V	G1349D	M265R	R334Q	S1251N
A455E	F311del	H939R	M952I	R347H	S1255P
A554E	F311L	H1054D	M952T	R347L	T338I
A1006E	F508C	H1375P	P5L	R347P	T1036N
A1067T	F508C; S1251N	I148T	P67L	R352Q	T1053I
D110E	F508del	I175V	P205S	R352W	V201M
D110H	F575Y	I336K	Q98R	R553Q	V232D
D192G	F1016S	I601F	Q237E	R668C	V562I
D443Y	F1052V	I618T	Q237H	R751L	V754M
D443Y; G576A; R668C	F1074L	I807M	Q359R	R792G	V1153E
D579G	F1099L	I980K	Q1291R	R933G	V1240G

D614G	G126D	I1027T	R31L	R1066H	V1293G
D836Y	G178E	I1139V	R74Q	R1070Q	W1282R
D924N	G178R	I1269N	R74W	R1070W	Y109N
D979V	G194R	I1366N	R74W; D1270N	R1162L	Y161S
D1152H	G194V	K1060T	R74W; V201M	R1283M	Y1014C
D1270N	G314E	L15P	R74W; V201M; D1270N	R1283S	Y1032C
E56K	G551D	L206W	R75Q	S549N	
E60K	G551S	L320V	R117C	S549R	

If yes, **approve for 24 weeks by HICL or GPI-10 with a quantity limit of #2 per day.**
APPROVAL TEXT: Renewal requires the patient have shown improvement in clinical status compared to baseline as shown by ONE of the following: i) patient has improved, maintained, or demonstrated less than expected decline in FEV1, ii) patient has improved, maintained, or demonstrated less than expected decline in BMI, or iii) patient has experienced a reduction in rate of pulmonary exacerbations.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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TEZACAFTOR/IVACAFTOR

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **TEZACAFTOR/IVACAFTOR (Symdeko)** requires the following rule(s) be met for approval:

A. You have cystic fibrosis (inherited life-threatening disorder that damages the lungs and digestive system)
B. You are 6 years of age or older
C. Therapy is prescribed by or given in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
D. You have documentation that you are either homozygous (you have 2 copies of the same gene) for the F508del-CFTR (Cystic fibrosis transmembrane conductance regulator) gene mutation; **OR** you have documentation that you have at least one of the following mutations in the CFTR gene:

546insCTA	E92K	G576A	L346P	R117G	S589N
711+3A→G	E116K	G576A; R668C	L967S	R117H	S737F
2789+5G→A	E193K	G622D	L997F	R117L	S912L
3272-26A→G	E403D	G970D	L1324P	R117P	S945L
3849+10kbC→T	E588V	G1069R	L1335P	R170H	S977F
A120T	E822K	G1244E	L1480P	R258G	S1159F
A234D	E831X	G1249R	M152V	R334L	S1159P
A349V	F191V	G1349D	M265R	R334Q	S1251N
A455E	F311del	H939R	M952I	R347H	S1255P
A554E	F311L	H1054D	M952T	R347L	T338I
A1006E	F508C	H1375P	P5L	R347P	T1036N
A1067T	F508C; S1251N	I148T	P67L	R352Q	T1053I
D110E	F508del	I175V	P205S	R352W	V201M
D110H	F575Y	I336K	Q98R	R553Q	V232D
D192G	F1016S	I601F	Q237E	R668C	V562I
D443Y	F1052V	I618T	Q237H	R751L	V754M
D443Y; G576A; R668C	F1074L	I807M	Q359R	R792G	V1153E
D579G	F1099L	I980K	Q1291R	R933G	V1240G

D614G	G126D	I1027T	R31L	R1066H	V1293G
D836Y	G178E	I1139V	R74Q	R1070Q	W1282R
D924N	G178R	I1269N	R74W	R1070W	Y109N
D979V	G194R	I1366N	R74W; D1270N	R1162L	Y161S
D1152H	G194V	K1060T	R74W; V201M	R1283M	Y1014C
D1270N	G314E	L15P	R74W; V201M; D1270N	R1283S	Y1032C
E56K	G551D	L206W	R75Q	S549N	
E60K	G551S	L320V	R117C	S549R	

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cystic fibrosis (CF) and improvement in clinical status compared to baseline as shown by **ONE** of the following?
   - The patient has improved, maintained, or demonstrated less than expected decline in FEV1 (forced expiratory volume)
   - The patient has improved, maintained, or demonstrated less than expected decline in BMI (body mass index)
   - The patient has experienced a reduction in rate of pulmonary exacerbations

   If yes, **approve for lifetime by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TEZACAFTOR/IVACAFTOR

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TEZACAFTOR/IVACAFTOR (Symdeko)** requires the following rule(s) be met for renewal:

A. You have cystic fibrosis (CF: inherited life-threatening disorder that damages the lungs and digestive system)
B. You have shown improvement in clinical (medical) status compared to baseline as shown by ONE of the following:
    1. You have improved, maintained, or demonstrated less than expected decline in FEV1 (forced expiratory volume: amount of air you can exhale in 1 second)
    2. You have improved, maintained, or demonstrated less than expected decline in BMI (body mass index)
    3. You have experienced a reduction in rate of pulmonary exacerbations (you have less attacks of breathing problems)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Symdeko.

REFERENCES

- Symdeko [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Inc.; December 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/01/21
Created: 02/18
Client Approval: 01/21
P&T Approval: 01/21

STANDARD COMMERCIAL AND NSA DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEZEPELUMAB-EKKO

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of severe asthma and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with a physician specializing in allergy or pulmonary medicine
   - The patient is concurrently treated with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., salmeterol, formoterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast, zileuton], theophylline)
   - Tezspire will NOT be used concurrently with Xolair (omalizumab), Dupixent (dupilumab), or an anti-IL5 biologic (e.g., Nucala [mepolizumab], Cinqair [reslizumab], Fasenra [benralizumab]) when these are used for the treatment of asthma

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced at least ONE asthma exacerbation requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months
   - The patient has experienced at least ONE serious asthma exacerbation requiring a hospitalization or emergency room visit within the past 12 months

   If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #1.91mL per 28 days.**
   If no, continue to #3.

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TEZEPELUMAB-EKKO

INITIAL CRITERIA (CONTINUED)

3. Does the patient have poor symptom control despite current therapy as evidenced by at least **THREE** of the following within the past 4 weeks?
   - Daytime asthma symptoms more than twice per week
   - Any night waking due to asthma
   - Use of a short-acting inhaled beta2-agonist (SABA) (e.g., albuterol) reliever for symptoms more than twice per week
   - Any activity limitation due to asthma

   If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #1.91mL per 28 days.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEZEPELUMAB-EKKO (Tezspire)** requires the following rule(s) be met for approval:
   A. You have severe asthma (a type of lung condition)
   B. You are 12 years of age or older
   C. Therapy is prescribed by or in consultation with a doctor specializing in allergy or pulmonary (lung/breathing) medicine
   D. You are being treated at the same time with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as salmeterol, formoterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast, zileuton), or theophylline
   E. You meet ONE of the following:
      1. You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months OR at least ONE serious asthma exacerbation requiring a hospitalization or emergency room visit within the past 12 months
      2. You have poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks:
         a. Daytime asthma symptoms more than twice per week
         b. Any night waking due to asthma
         c. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
         d. Any activity limitation due to asthma

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TEZEPELUMAB-EKKO

INITIAL CRITERIA (CONTINUED)

F. You will NOT use Tezspire concurrently (at the same time) with Xolair (omalizumab), Dupixent (dupilumab), or an anti-IL5 (anti-interleukin-5) biologic (such as Nucala [mepolizumab], Cinqair [reslizumab], Fasenra [benralizumab]) when these are used for the treatment of asthma

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TEZEPELUMAB-EKKO

RENEWAL CRITERIA

1. Has the patient shown a clinical response as evidenced by **ONE** of the following?
   - Reduction in asthma exacerbation from baseline
   - Decreased utilization of rescue medications (e.g., albuterol)
   - Increase in percent predicted FEV1 from pretreatment baseline
   - Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient will continue to use an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., salmeterol, formoterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline)
   - Tezspire will NOT be used concurrently with Xolair (omalizumab), Dupixent (dupilumab), or an anti-IL5 biologic (e.g., Nucala [mepolizumab], Cinqair [reslizumab], Fasenra [benralizumab]) when these are used for the treatment of asthma

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1.91mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TEZEPELUMAB-EKKO

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TEZEPELUMAB-EKKO (Tezspire)** requires the following rule(s) be met for renewal:

A. You have shown a clinical response as evidenced by ONE of the following:
   1. Reduction in asthma exacerbation (worsening of symptoms) from baseline
   2. Decreased use of rescue medications (such as albuterol)
   3. Increase in percent predicted FEV1 (amount of air exhaled in one second) from pretreatment baseline
   4. Reduction in severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

B. You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), or theophylline

C. You will NOT use Tezspire concurrently (at the same time) with Xolair (omalizumab), Dupixent (dupilumab), or an anti-IL5 (anti-interleukin-5) biologic (such as Nucala [mepolizumab], Cinqair [reslizumab], Fasenra [benralizumab]) when used for the treatment of asthma

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tezspire.

REFERENCES

- Tezspire [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; May 2023.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 01/22
Client Approval: 11/23
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

THALIDOMIDE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma **AND** meet the following criterion?
   - Thalomid will be used in combination with dexamethasone

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of erythema nodosum leprosum (ENL)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of anemia due to myelodysplastic syndrome **AND** meet the following criterion?
   - The patient has been previously treated for anemia due to myelodysplastic syndrome

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #4.

4. Does the patient have a diagnosis of Waldenström's macroglobulinemia?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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THALIDOMIDE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **THALIDOMIDE (Thalomid)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Multiple myeloma (a type of blood cancer)
   2. Erythema nodosum leprosum (ENL: a type of immune condition)
   3. Anemia due to myelodysplastic syndrome (a type of blood condition due to blood cancer)
   4. Waldenström's macroglobulinemia (a type of blood cancer)

B. **If you have multiple myeloma, approval also requires:**
   1. Thalomid will be used in combination with dexamethasone

C. **If you have anemia due to myelodysplastic syndrome, approval also requires:**
   1. You have been previously treated for anemia due to myelodysplastic syndrome

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Thalomid.

REFERENCES

- Thalomid [Prescribing Information]. Summit, NJ: Celgene Corporation; February 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 08/12
Client Approval: 03/22
P&T Approval: 08/12

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TIVOZANIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory advanced renal cell carcinoma (RCC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient received two or more prior systemic therapies (e.g., Cabometyx, Keytruda, Opdivo)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #21 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TIVOZANIB (Fotivda)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory advanced renal cell carcinoma (type of kidney cancer that returned or no longer responds to treatment)
   B. You are 18 years of age or older
   C. You previously received two or more systemic therapies (such as Cabometyx, Keytruda, Opdivo)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fotivda.

REFERENCES

- Fotivda [Prescribing Information]. Boston, MA: AVEO Pharmaceuticals, Inc.; March 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/21
Created: 05/21
Client Approval: 05/21
P&T Approval: 04/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOBRAMYCIN INHALED

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cystic fibrosis and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - The patient has a lung infection with a gram-negative species (such as *Pseudomonas aeruginosa*; *Staphylococcus aureus* is not a gram-negative species)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the request for Bethkis (tobramycin), Tobi (tobramycin) inhalation solution, or Kitabis Pak (tobramycin)?

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 as follows:**
   - **Tobi inhalation solution: #280mL (#56 of 5mL ampules) per 28 days (fill count = 6).**
   - **Bethkis: #224mL (#56 of 4mL ampules) per 28 days (fill count = 6).**
   - **Kitabis Pak: #280mL per 28 days (fill count = 6).**

   If no, continue to #3.

3. Is the request for Tobi Podhaler and the patient meets **ONE** of the following criteria?
   - The patient had a trial and failure of or contraindication to ONE generic inhaled tobramycin product
   - The patient is not able to tolerate the prolonged administration of nebulizers

   If yes, **Tobi Podhaler for 12 months by GPID or GPI-14 with a quantity limit of #224 capsules per 28 days (fill count = 6).**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TOBRAMYCIN INHALED

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.
Our guideline named **TOBRAMYCIN INHALED (Bethkis, Tobi, Tobi Podhaler, Kitabis Pak)** requires the following rule(s) be met for approval:

A. You have cystic fibrosis (inherited life-threatening disorder that damages the lungs and digestive system)
B. You are 6 years of age or older
C. You have a lung infection with a gram-negative species (type of bacteria that does not stain a purple color)
D. **If the request is for Tobi Podhaler, approval also requires ONE of the following:**
   1. You had a trial and failure of or contraindication (harmful for) to ONE generic inhaled tobramycin product
   2. You are not able to tolerate the prolonged administration of nebulizers

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tobi, Tobi Podhaler, Bethkis or Kitabis.

REFERENCES

- Tobi [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2018.
- Tobi Podhaler [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2020.
- Bethkis [Prescribing Information]. Woodstock, IL: Chiesi USA, Inc.; December 2019.
- Kitabis Pak [Prescribing Information]. Midothian, VA: PARI Respiratory Equipment, Inc.; September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 05/12
Client Approval: 11/21
P&T Approval: 10/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOCILIZUMAB - SQ

PAC NOTE: For requests for the IV dosage form of Actemra, please see the TOCILIZUMAB - IV PA guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Humira (adalimumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 6 months by GPID or GPI-14 for all subcutaneous formulations (syringe and pen injector) with a quantity limit of #3.6mL per 28 days.**

     If no, continue to #2.

2. Does the patient have a diagnosis of giant cell arteritis (GCA) **AND** meet the following criterion?
   - The patient is 18 years of age or older

     If yes, **approve for 6 months by GPID or GPI-14 for all subcutaneous formulations (syringe and pen injector) with a quantity limit of #3.6mL per 28 days.**

     If no, continue to #3.

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INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a diagnosis of systemic sclerosis (SSc) according to American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
   - Therapy is prescribed by or in consultation with a pulmonologist or rheumatologist
   - The patient does NOT have other etiologies of interstitial lung disease (ILD) [e.g., heart failure/fluid overload, drug-induced lung toxicity (cyclophosphamide, methotrexate, ACE-inhibitors), recurrent aspiration (such as from GERD), pulmonary vascular disease, pulmonary edema, pneumonia, chronic pulmonary thromboembolism, alveolar hemorrhage or ILD caused by another rheumatic disease, such as mixed connective tissue disease (MCTD)]

   If yes, **approve for 6 months by GPID or GPI-14 for all subcutaneous formulations (syringe and pen injector) with a quantity limit of #3.6mL per 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Humira (adalimumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14 for all subcutaneous formulations (syringe and pen injector) with a quantity limit of #1.8mL per 28 days.**

   If no, continue to #5.

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INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist, dermatologist, or immunologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by GPID or GPI-14 for all subcutaneous formulations (syringe and pen injector) with a quantity limit of #3.6mL per 28 days.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOCILIZUMAB - SQ (Actemra - subcutaneous)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Giant cell arteritis (GCA: a type of inflammatory condition)
      3. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
      4. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
      5. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

   B. If **you have moderate to severe rheumatoid arthritis, approval also requires:**
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
      3. You have tried or have a contraindication to (harmful for you to use) 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
      4. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Humira (adalimumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

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INITIAL CRITERIA (CONTINUED)

C. **If you have giant cell arteritis, approval also requires:**
   1. You are 18 years of age or older
D. **If you have systemic sclerosis-associated interstitial lung disease, approval also requires:**
   1. You are 18 years of age or older
   2. Your diagnosis of systemic sclerosis (SSc) is according to the American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
   3. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a type of immune system doctor)
   4. Other causes of interstitial lung disease have been ruled out. Other causes may include heart failure or fluid overload, drug-induced lung toxicity [cyclophosphamide, methotrexate, ACE-inhibitors (class of blood pressure medications)], recurrent aspiration (inhaling) such as from GERD (acid reflux), pulmonary vascular disease (affecting blood vessels in lungs), pulmonary edema (excess fluid in the lungs), pneumonia (type of lung infection), chronic pulmonary thromboembolism (blood clot in lungs), alveolar hemorrhage (bleeding of a part of the lungs) or interstitial lung disease caused by another rheumatic (inflammatory) disease, such as mixed connective tissue disease
E. **If you have polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Humira (adalimumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
F. **If you have systemic juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

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TOCILIZUMAB - SQ

INITIAL CRITERIA (CONTINUED)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TOCILIZUMAB - SQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Humira (adalimumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by GPID or GPI-14 for all subcutaneous formulations (syringe and pen injector) with a quantity limit of #3.6mL per 28 days.**

     If no, continue to #2.

2. Does the patient have a diagnosis of giant cell arteritis (GCA)?

   If yes, **approve for 12 months by GPID or GPI-14 for all subcutaneous formulations (syringe and pen injector) with a quantity limit of #3.6mL per 28 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) **AND** meet the following criterion?
   - The patient has experienced a clinical meaningful improvement or maintenance in annual rate of decline

   If yes, **approve for 12 months by GPID or GPI-14 for all subcutaneous formulations (syringe and pen injector) with a quantity limit of #3.6mL per 28 days.**

   If no, continue to #4.

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TOCILIZUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Humira (adalimumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by GPID or GPI-14 for all subcutaneous formulations (syringe and pen injector) with a quantity limit of #1.8mL per 28 days.**

     If no, continue to #5.

5. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) and meet **ONE** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient has maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis)

     If yes, **approve for 12 months by GPID or GPI-14 for all subcutaneous formulations (syringe and pen injector) with a quantity limit of #3.6mL per 28 days.**

     If no, do not approve.

     RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

     Our guideline named **TOCILIZUMAB - SQ (Actemra - subcutaneous)** requires the following rule(s) be met for renewal:
     A. You have ONE of the following diagnoses:
        1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
        2. Giant cell arteritis (GCA: a type of inflammatory condition)
        3. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
        4. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
        5. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

     (Renewal denial text continued on next page)

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TOCILIZUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Humira (adalimumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

C. **If you have polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Humira (adalimumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

D. **If you have systemic sclerosis-associated interstitial lung disease, renewal also requires:**
   1. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline

E. **If you have systemic juvenile idiopathic arthritis, renewal also requires ONE of the following:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You have maintained or improved systemic inflammatory disease (such as fevers, pain, rash, arthritis)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TOCILIZUMAB – SQ

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Actemra.

REFERENCE

- Actemra [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; December 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 11/13
Client Approval: 03/24
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOFACITINIB

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., Humira [adalimumab], Enbrel [etanercept], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Hyrimoz [adalimumab-adaz])

   If yes, **approve for 6 months for the requested strength by GPID or GPI-14 as follows:**
   - **5mg: #2 per day.**
   - **11mg: #1 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., Humira [adalimumab], Enbrel [etanercept], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Hyrimoz [adalimumab-adaz])

   If yes, **approve for 6 months for the requested strength by GPID or GPI-14 as follows:**
   - **5mg: #2 per day.**
   - **11mg: #1 per day.**

   If no, continue to #3.

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TOFACITINIB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam, diclofenac)
   - The patient had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., Humira [adalimumab], Enbrel [etanercept], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Hyrimoz [adalimumab-adaz])

   If yes, **approve for 6 months for the requested strength by GPID or GPI-14 as follows:**
   - **5mg: #2 per day.**
   - **11mg: #1 per day.**

   If no, continue to #4.

4. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to ONE conventional therapy (e.g., corticosteroids [e.g., budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)
   - The patient had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., Humira [adalimumab], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Hyrimoz [adalimumab-adaz])

   If yes, **approve for 6 months for ALL strengths by GPID or GPI-14 as follows:**
   - **5mg and 10mg: #2 per day.**
   - **11mg and 22mg: #1 per day.**

   If no, continue to #5.

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TOFACITINIB

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of polyarticular course juvenile idiopathic arthritis (pcJIA) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., Humira [adalimumab], Enbrel [etanercept], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Hyrimoz [adalimumab-adaz])

   If yes, **approve for 6 months for the requested strength by GPID or GPI-14 as follows:**
   - **5mg: #2 per day.**
   - **1mg/mL: #10mL per day.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOFACITINIB (Xeljanz, Xeljanz XR)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Ankylosing spondylitis (AS: a type of joint condition)
      4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
      5. Polyarticular course juvenile idiopathic arthritis (pcJIA: a type of joint condition)
   B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
      3. You have tried or have a contraindication to (harmful for you to use) at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
      4. You had an inadequate response (drug did not work) or intolerance (side effect) to one or more tumor necrosis factor (TNF) blockers (such as Humira [adalimumab], Enbrel [etanercept], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Hyrimoz [adalimumab-adaz])

   (Initial denial text continued on next page)

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INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You had an inadequate response (drug did not work) or intolerance (side effect) to one or more tumor necrosis factor (TNF) blockers (such as Humira [adalimumab], Enbrel [etanercept], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Hyrimoz [adalimumab-adaz])

D. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) an NSAID (nonsteroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam, diclofenac)
   4. You had an inadequate response (drug did not work) or intolerance (side effect) to one or more tumor necrosis factor (TNF) blockers (such as Humira [adalimumab], Enbrel [etanercept], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Hyrimoz [adalimumab-adaz])

E. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
   3. You have tried or have a contraindication to (harmful for you to use) ONE standard therapy, such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. You had an inadequate response (drug did not work) or intolerance (side effect) to one or more tumor necrosis factor (TNF) blockers (such as Humira [adalimumab], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Hyrimoz [adalimumab-adaz])

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TOFACITINIB

INITIAL CRITERIA (CONTINUED)

F. **If you have polyarticular course juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You had an inadequate response (drug did not work) or intolerance (side effect) to one or more tumor necrosis factor (TNF) blockers (such as Humira [adalimumab], Enbrel [etanercept], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Hyrimoz [adalimumab-adaz])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TOFACITINIB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) or psoriatic arthritis (PsA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months for the requested strength by GPID or GPI-14 as follows:**
   - **5mg: #2 per day.**
   - **11mg: #1 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of ankylosing spondylitis (AS) **AND** meet the following criterion?
   - The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy

   If yes, **approve for 12 months for the requested strength by GPID or GPI-14 as follows:**
   - **5mg: #2 per day.**
   - **11mg: #1 per day.**

   If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC)?

   If yes, **approve for 12 months for ALL strengths by GPID or GPI-14 as follows:**
   - **5mg and 10mg: #2 per day.**
   - **11mg and 22mg: #1 per day.**

   If no, continue to #4.

4. Does the patient have a diagnosis of polyarticular course juvenile idiopathic arthritis (pcJIA) and meet the following criterion?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months for the requested strength by GPID or GPI-14 as follows:**
   - **5mg: #2 per day.**
   - **1mg/mL: #10mL per day.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TOFACITINIB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOFACITINIB (Xeljanz, Xeljanz XR)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   5. Polyarticular course juvenile idiopathic arthritis (pcJIA: a type of joint condition)

B. **If you have moderate to severe rheumatoid arthritis, psoriatic arthritis, or polyarticular course juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

C. **If you have ankylosing spondylitis, renewal also requires**:
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xeljanz/Xeljanz XR.

REFERENCES

- Xeljanz, Xeljanz XR [Prescribing Information]. New York, NY: Pfizer Laboratories Div Pfizer Inc.; January 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 11/12
Client Approval: 11/23
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOLVAPTAN

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of autosomal dominant polycystic kidney disease (ADPKD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a nephrologist
   - The patient does not have end-stage renal disease (ESRD; including no renal transplantation or dialysis)

   If yes, **approve for 6 months for all strengths as follows:**
   - **90mg-30mg (GPID or GPI-14): #56 per 28 days.**
   - **45mg-15mg (GPID or GPI-14): #56 per 28 days.**
   - **60mg-30mg (GPID or GPI-14): #56 per 28 days.**
   - **30-15mg (GPID or GPI-14): #56 per 28 days.**
   - **15-15mg (GPID or GPI-14): #56 per 28 days.**
   - **15mg (NDC 59148-0082-13) [FDB & Medi-Span]: #60 per 30 days.**
   - **30 mg (NDC 59148-0083-13) [FDB & Medi-Span]: #30 per 30 days.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOLVAPTAN (Jynarque)** requires the following rule(s) be met for approval:
   A. You have autosomal dominant polycystic kidney disease (ADPKD: inherited disorder in which clusters of cysts develop in the kidneys)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a nephrologist (kidney specialist)
   D. You do not have end-stage renal disease (ESRD: advanced kidney disease) including no renal transplantation (kidney transplant) or dialysis

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TOLVAPTAN

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of autosomal dominant polycystic kidney disease (ADPKD) **AND** meet the following criterion?
   - The patient has not progressed to end-stage renal d isease (ESRD)

   If yes, **approve for 12 months for all strengths as follows:**
   - **90mg-30mg (GPID or GPI-14): #56 per 28 days.**
   - **45mg-15mg (GPID or GPI-14): #56 per 28 days.**
   - **60mg-30mg (GPID or GPI-14): #56 per 28 days.**
   - **30-15mg (GPID or GPI-14): #56 per 28 days.**
   - **15-15mg (GPID or GPI-14): #56 per 28 days.**
   - **15mg (NDC 59148-0082-13) [FDB & Medi-Span]: #60 per 30 days.**
   - **30 mg (NDC 59148-0083-13) [FDB & Medi-Span]: #30 per 30 days.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOLVAPTAN (Jynarque)** requires the following rule(s) be met for renewal:
   A. You have autosomal dominant polycystic kidney disease (ADPKD: inherited disorder in which clusters of cysts develop in the kidneys)
   B. You have NOT progressed to end stage renal (kidney) disease (ESRD)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TOLVAPTAN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Jynarque.

REFERENCES

- Jynarque [Prescribing Information]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; October 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/23
Created: 08/18
Client Approval: 02/23
P&T Approval: 01/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOPIRAMATE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of partial-onset or primary generalized tonic-clonic seizures and meet **ALL** of the following criteria?
   - Eprontia will be used as initial monotherapy OR adjunctive therapy
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient is unable to take oral tablets or capsules
   - The patient meets ONE of the following:
     - The patient is 2 to 5 years of age AND had a trial of or contraindication to ONE preferred agent: generic topiramate tablet/sprinkle, topiramate ER sprinkle
     - The patient is 6 years of age or older AND had a trial of or contraindication to ONE preferred agent: Trokendi XR, generic topiramate tablet/sprinkle, topiramate ER sprinkle

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #16mL per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of seizures associated with Lennox-Gastaut syndrome and meet **ALL** of the following criteria?
   - Eprontia will be used as adjunctive therapy
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient is unable to take oral tablets or capsules
   - The patient meets ONE of the following:
     - The patient is 2 to 5 years of age AND had a trial of or contraindication to ONE preferred agent: generic topiramate tablet/sprinkle, topiramate ER sprinkle
     - The patient is 6 years of age or older AND had a trial of or contraindication to ONE preferred agent: Trokendi XR, generic topiramate tablet/sprinkle, topiramate ER sprinkle

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #16mL per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of migraine and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Eprontia will be used as preventative treatment of migraines
   - The patient is unable to take oral tablets or capsules
   - The patient had a trial of or contraindication to ONE preferred agent: Trokendi XR, generic topiramate tablet/sprinkle, topiramate ER sprinkle

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #4mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TOPIRAMATE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOPIRAMATE (Eprontia)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Partial-onset seizures (a type of seizure)
   2. Primary generalized tonic-clonic seizures (a type of seizure)
   3. Seizures associated with Lennox-Gastaut syndrome (a type of seizure disorder in young children)
   4. Migraine

B. You are unable to take oral tablets or capsules

C. **If you have partial-onset seizures or primary generalized tonic-clonic seizures, approval also requires:**
   1. Eprontia will be used as initial monotherapy OR adjunctive therapy (drugs taken together with)
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
   3. You meet ONE of the following:
      a. You are 2 to 5 years of age AND had a trial of or contraindication (harmful for) to ONE preferred agent: generic topiramate tablet/sprinkle, topiramate ER sprinkle
      b. You are 6 years of age or older AND had a trial of or contraindication (harmful for) to ONE preferred agent: Trokendi XR, generic topiramate tablet/sprinkle, topiramate ER sprinkle

D. **If you have seizures associated with Lennox-Gastaut syndrome, approval also requires:**
   1. Eprontia will be used as adjunctive therapy (drugs taken together with)
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
   3. You meet ONE of the following:
      a. You are 2 to 5 years of age AND had a trial of or contraindication (harmful for) to ONE preferred agent: generic topiramate tablet/sprinkle, topiramate ER sprinkle
      b. You are 6 years of age or older AND had a trial of or contraindication (harmful for) to ONE preferred agent: Trokendi XR, generic topiramate tablet/sprinkle, or topiramate ER sprinkle

E. **If you have migraines, approval also requires:**
   1. You are 12 years of age or older
   2. Eprontia will be used as preventative treatment of migraines
   3. You had a trial of or contraindication (harmful for) to ONE preferred agent: Trokendi XR, generic topiramate tablet/sprinkle, topiramate ER sprinkle

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TOPIRAMATE

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Eprontia.

REFERENCES

- Eprontia [Prescribing Information]. Wilmington, MA: Azurity Pharmaceuticals, Inc.; November 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 02/22
Client Approval: 05/22
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOREMIFENE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient is a postmenopausal female
   - The patient has an estrogen-receptor positive or unknown tumor

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #30 per 30 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOREMIFENE (Fareston)** requires the following rule(s) be met for approval:
   A. You have metastatic breast cancer (cancer has spread to other parts of body)
   B. You are a postmenopausal female (already gone through menopause)
   C. You have an estrogen-receptor positive or unknown tumor

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fareston.

REFERENCES

- Fareston [Prescribing Information] Bedminster, NJ: Kyowa Kirin Inc. May 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 08/13
Client Approval: 04/20
P&T Approval: 08/13

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TORSEMIDE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of edema associated with heart failure or renal disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to TWO generic loop diuretics (e.g., furosemide, bumetanide)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **40mg: #5 per day.**
   - **60mg: #3 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TORSEMIDE (Soaanz)** requires the following rule(s) be met for approval:
   A. You have edema (swelling caused by fluid build-up in the body) associated with heart failure (a type of heart condition) or renal (kidney) disease
   B. You are 18 years of age or older
   C. You had a trial of or contraindication (harmful for) to TWO generic loop diuretics (such as furosemide, bumetanide)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Soaanz.

REFERENCES

- Soaanz [Prescribing Information]. Vienna, VA: Sarfez Pharmaceuticals, Inc.; December 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 05/22
Client Approval: 05/22
P&T Approval: 05/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOVORAFENIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory pediatric low-grade glioma (LGG) (ICD-10 D33.2) and meet **ALL** of the following criteria?
   - The patient is 6 months of age or older
   - The patient's cancer has a BRAF fusion, BRAF rearrangement, or BRAF V600 mutation

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **100mg: #24 per 28 days.**
   - **25mg/mL: #96mL per 28 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOVORAFENIB (Ojemda)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory pediatric low-grade glioma (LGG) (a type of children's brain cancer that has returned or did not respond to treatment)
   B. You are 6 months of age or older
   C. Your cancer has a BRAF fusion, BRAF rearrangement, or BRAF V600 mutation (types of abnormal changes in genes)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ojemda.

REFERENCES

- Ojemda [Prescribing Information]. Brisbane, CA: Day One Biopharmaceuticals, Inc.; April 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/13/24
Created: 05/24
Client Approval: 05/24
P&T Approval: 07/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRALOKINUMAB-LDRM

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist, allergist, or immunologist
   - The patient has atopic dermatitis involving at least 10 percent of body surface area (BSA) OR atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas
   - The patient has TWO of the following: intractable pruritus, cracking and oozing/bleeding of affected skin, impaired activities of daily living
   - The patient had a trial of or contraindication to ONE preferred agent: Dupixent (dupilumab), Rinvoq (upadacitinib)
   - Adbry will NOT be used concurrently with other systemic biologics (e.g., Dupixent [dupilumab]) or any JAK inhibitors (e.g., Cibinqo [abrocitinib], topical Opzelura [ruxolitinib], Rinvoq [upadacitinib]) for the treatment of atopic dermatitis

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have a trial of or contraindication to **TWO** of the following?
   - High potency topical corticosteroid (e.g., halobetasol propionate 0.01% lotion, triamcinolone acetonide 0.5% cream or ointment) or a super high potency topical corticosteroid (e.g., fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
   - Topical calcineurin inhibitor (e.g., tacrolimus, Elidel [pimecrolimus])
   - Topical PDE-4 inhibitor (e.g., Eucrisa [crisaborole])
   - Topical JAK inhibitor (e.g., Opzelura [ruxolitinib])
   - Phototherapy

   If yes, **enter two approvals by HICL or GPI-10 for a total of 6 months as follows:**
   - **<u>FIRST APPROVAL</u>: Approve with an end date of 30 days with a quantity limit of #6mL per 28 days.**
   - **<u>SECOND APPROVAL</u>: Approve for 5 months (enter a start date of 2 days before the end of the first approval) with a quantity limit of #4mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TRALOKINUMAB-LDRM

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TRALOKINUMAB-LDRM (Adbry)** requires the following rule(s) be met for approval:

A. You have moderate to severe atopic dermatitis (a type of skin condition)
B. You are 12 years of age or older
C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
D. You have atopic dermatitis involving at least 10 percent of body surface area (BSA) OR atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas (areas between skin folds)
E. You have TWO of the following: intractable pruritus (uncontrollable itching), cracking and oozing/bleeding of affected skin, impaired activities of daily living
F. You have tried or have a contraindication to (harmful for you to use) TWO of the following:
    1. High potency topical corticosteroid (such as halobetasol propionate 0.01% lotion, triamcinolone acetonide 0.5% cream or ointment) or a super high potency topical corticosteroid (such as fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
    2. Topical calcineurin inhibitor (such as tacrolimus, Elidel [pimecrolimus])
    3. Topical PDE-4 inhibitor (such as Eucrisa [crisaborole])
    4. Topical JAK inhibitor (such as Opzelura [ruxolitinib])
    5. Phototherapy (light therapy)
G. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Dupixent (dupilumab), Rinvoq (upadacitinib)
H. You will NOT use Adbry concurrently (at the same time) with other systemic biologics (such as Dupixent [dupilumab]) or any JAK inhibitors (such as Cibinqo [abrocitinib], topical Opzelura [ruxolitinib], Rinvoq [upadacitinib]) for the treatment of atopic dermatitis

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRALOKINUMAB-LDRM

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis and meet **ALL** of the following criteria?
   - The patient has shown improvement while on Adbry
   - The patient had a trial of or contraindication to ONE preferred agent: Dupixent (dupilumab), Rinvoq (upadacitinib)
   - Adbry will NOT be used concurrently with other systemic biologics (e.g., Dupixent [dupilumab]) or any JAK inhibitors (e.g., Cibinqo [abrocitinib], topical Opzelura [ruxolitinib], Rinvoq [upadacitinib]) for the treatment of atopic dermatitis

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4mL per 28 days.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRALOKINUMAB-LDRM (Adbry)** requires the following rule(s) be met for renewal:
   A. You have moderate to severe atopic dermatitis (a type of skin condition)
   B. You have shown improvement while on Adbry
   C. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Dupixent (dupilumab), Rinvoq (upadacitinib)
   D. You will NOT use Adbry concurrently (at the same time) with other systemic biologics (such as Dupixent [dupilumab]) or any JAK inhibitors (such as Cibinqo [abrocitinib], topical Opzelura [ruxolitinib], Rinvoq [upadacitinib]) for the treatment of atopic dermatitis

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Adbry.

REFERENCES

- Adbry [Prescribing Information]. Ballerup, Denmark: LEO Pharma A/X; December 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/15/24
Created: 01/22
Client Approval: 12/23
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRAMADOL

GUIDELINES FOR USE

1. Is the request for the management of pain and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's pain is severe enough to require an opioid analgesic and alternative treatments are inadequate
   - The patient had a trial of or contraindication to generic tramadol IR tablet or a generic tramadol with acetaminophen product
   - The patient is unable to take oral solid formulations of tramadol or tramadol with acetaminophen (e.g., difficulty swallowing)

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #80mL per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRAMADOL (Qdolo)** requires the following rule(s) be met for approval:
   A. The request is for the management of pain
   B. You are 18 years of age or older
   C. Your pain is severe enough to require an opioid analgesic (type of pain medication) and alternative treatments are inadequate
   D. You had a trial of or contraindication (harmful for) to generic tramadol immediate-release (IR) tablet or a generic tramadol with acetaminophen product
   E. You are unable to take oral solid formulations of tramadol or tramadol with acetaminophen (such as with difficulty swallowing)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRAMADOL

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Qdolo.

REFERENCES

- Qdolo [Prescribing Information]. Athens, GA: Athena Bioscience, LLC; September 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 03/14/22
Created: 02/21
Client Approval: 02/22
P&T Approval: 01/21

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRAMETINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E or V600K mutation as detected by an FDA-approved test
   - The requested medication will be used as a single agent in a BRAF-inhibitor treatment-naive patient OR in combination with Tafinlar (dabrafenib)

   If yes, continue to #7.
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E mutation as detected by an FDA-approved test
   - The requested medication will be used in combination with Tafinlar (dabrafenib)

   If yes, continue to #7.
   If no, continue to #3.

3. Does the patient have a diagnosis of melanoma and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E or V600K mutation as detected by an FDA-approved test
   - The requested medication will be used as an adjuvant therapy in combination with Tafinlar (dabrafenib)
   - There is involvement of lymph node(s), following complete resection

   If yes, continue to #7.
   If no, continue to #4.

4. Does the patient have a diagnosis of locally advanced or metastatic anaplastic thyroid cancer (ATC) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E mutation
   - The requested medication will be used in combination with Tafinlar (dabrafenib)
   - The patient has no satisfactory locoregional treatment options available

   If yes, continue to #7.
   If no, continue to #5.

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TRAMETINIB

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of unresectable or metastatic solid tumor and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient has a BRAF V600E mutation
   - The requested medication will be used in combination with Tafinlar (dabrafenib)
   - The patient's disease has progressed following prior treatment and has no satisfactory alternative treatment options

   If yes, continue to #7.
   If no, continue to #6.

6. Does the patient have a diagnosis of low-grade glioma (LGG) and meet **ALL** of the following criteria?
   - The patient is 1 to 17 years of age
   - The patient has a BRAF V600E mutation
   - The requested medication will be used in combination with Tafinlar (dabrafenib)
   - The patient requires systemic therapy

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Is the request for the tablet formulation?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **2mg: #1 per day.**
   - **0.5mg: #3 per day.**

   If no, continue to #8.

8. Is the request for the oral solution **AND** the patient meets the following criterion?
   - The patient is unable to swallow Mekinist (trametinib) tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #42mL per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TRAMETINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TRAMETINIB (Mekinist)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Unresectable or metastatic melanoma (a type of skin cancer that cannot be removed by surgery or has spread to other parts of the body)
   2. Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
   3. Melanoma (a type of skin cancer)
   4. Locally advanced or metastatic anaplastic thyroid cancer (ATC: a type of thyroid cancer that has spread from where it started to nearby tissue or lymph nodes or has spread to other parts of the body)
   5. Unresectable or metastatic solid tumor (tumor that cannot be removed by surgery or has spread to other parts of the body)
   6. Low-grade glioma (LGG: a type of brain cancer)

B. **If you have unresectable or metastatic melanoma, approval also requires:**
   1. You have a BRAF V600E or V600K mutation (abnormal change in gene) as detected by a Food and Drug Administration (FDA)-approved test
   2. The requested medication will be used as a single agent in a BRAF-inhibitor treatment-naïve patient (you have not been previously treated for this cancer) OR in combination with Tafinlar (dabrafenib)

C. **If you have metastatic non-small cell lung cancer, approval also requires:**
   1. You have a BRAF V600E mutation (abnormal change in gene) as detected by a Food and Drug Administration (FDA)-approved test
   2. The requested medication will be used in combination with Tafinlar (dabrafenib)

D. **If you have melanoma, approval also requires:**
   1. You have a BRAF V600E or V600K mutation (abnormal change in gene) as detected by a Food and Drug Administration (FDA)-approved test
   2. The requested medication will be used in combination with Tafinlar (dabrafenib)
   3. There is involvement of lymph node(s), following complete resection (surgical removal)

E. **If you have locally advanced or metastatic anaplastic thyroid cancer, approval also requires:**
   1. You have a BRAF V600E mutation (abnormal change in gene)
   2. The requested medication will be used in combination with Tafinlar (dabrafenib)
   3. You do not have any satisfactory locoregional treatment options available (treatments that are focused on the affected area)

(Denial text continued on next page)

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TRAMETINIB

GUIDELINES FOR USE (CONTINUED)

F. **If you have an unresectable or metastatic solid tumor, approval also requires:**
   1. You are 1 year of age or older
   2. You have a BRAF V600E mutation (abnormal change in gene)
   3. The requested medication will be used in combination with Tafinlar (dabrafenib)
   4. Your disease has progressed following prior treatment and have no satisfactory alternative treatment options

G. **If you have low-grade glioma, approval also requires:**
   1. You are 1 to 17 years of age
   2. You have a BRAF V600E mutation (abnormal change in gene)
   3. The requested medication will be used in combination with Tafinlar (dabrafenib)
   4. You require systemic therapy (treatment that targets the entire body)

H. **If the request is for the oral solution, approval also requires:**
   1. You are unable to swallow Mekinist (trametinib) tablets

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mekinist.

REFERENCES

- Mekinist [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/23
Created: 07/13
Client Approval: 09/23
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TREPROSTINIL DPI

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient have documentation (e.g., chart note, lab result, diagnostic test result, etc.) confirming a PAH diagnosis based on right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

3. Has the patient had a trial of or contraindication to **TWO** of the following agents from different drug classes?
   - Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
   - Oral phosphodiesterase-5 inhibitor (e.g., Revatio [sildenafil], Adcirca [tadalafil])
   - Oral cGMP stimulator (e.g., Adempas [riociguat])
   - IV/SQ prostacyclin (e.g., Flolan [epoprostenol], Remodulin [treprostinil])

   If yes, **approve for a total of 12 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve the requested strength for 1 month for 1 fill as follows:**
     - **16-32mcg Titration Kit**
     - **16-32-48mcg Titration Kit**
   - **SECOND APPROVAL: Approve the requested strength for 11 months as follows (enter start date of 3 days before the end date of the first approval.):**
     - **16mcg**
     - **32mcg**
     - **48mcg**
     - **64mcg**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD) (WHO Group 3) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TREPROSTINIL DPI

INITIAL CRITERIA (CONTINUED)

5. Does the patient have documentation (e.g., chart note, lab result, diagnostic test result, etc.) confirming a PAH diagnosis based on right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve the requested strength for 1 month for 1 fill as follows:**
     - **16-32mcg Titration Kit**
     - **16-32-48mcg Titration Kit**
   - **SECOND APPROVAL: Approve the requested strength for 5 months as follows (enter start date of 3 days before the end date of the first approval.):**
     - **16mcg**
     - **32mcg**
     - **48mcg**
     - **64mcg**

   If not, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL DPI (Tyvaso DPI)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
      2. Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) (World Health Organization [WHO] Group 3)

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TREPROSTINIL DPI

INITIAL CRITERIA (CONTINUED)

B. **If you have PAH (WHO Group 1), approval also requires:**
   1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   2. There is documentation (such as, chart note, lab result, diagnostic test result) showing you have pulmonary arterial hypertension based on ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR) greater than 2 Wood units
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following medications from different drug classes:
      a. Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
      b. Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
      c. Oral cGMP stimulator (such as Adempas [riociguat])
      d. Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil])

C. **If you have PH-ILD (WHO Group 3), approval also requires:**
   1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   2. There is documentation (such as, chart note, lab result, diagnostic test result) showing you have pulmonary arterial hypertension based on ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR) greater than 2 Wood units

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TREPROSTINIL DPI

RENEWAL CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
   - Pulmonary arterial hypertension (PAH) (WHO Group 1)
   - Pulmonary hypertension associated with interstitial lung disease (PH-ILD) (WHO Group 3)

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 as follows:**
   - **16mcg**
   - **32mcg**
   - **48mcg**
   - **64mcg**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL DPI (Tyvaso DPI)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
      2. Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) (World Health Organization [WHO] Group 3)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tyvaso DPI.

REFERENCES

- Tyvaso DPI [Prescribing Information]. Research Triangle Park, NC: United Therapeutics Corp.; June 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 03/24
Client Approval: 03/24
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TREPROSTINIL INHALED

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient have documentation (e.g., chart note, lab result, diagnostic test result, etc.) confirming a PAH diagnosis based on right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TREPROSTINIL INHALED

INITIAL CRITERIA (CONTINUED)

3. Has the patient had a trial of or contraindication to **TWO** of the following agents from different drug classes?
   - Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
   - Oral phosphodiesterase-5 inhibitor (e.g., Revatio [sildenafil], Adcirca [tadalafil])
   - Oral cGMP stimulator (e.g., Adempas [riociguat])
   - IV/SQ prostacyclin (e.g., Flolan [epoprostenol], Remodulin [treprostinil])

   If yes, **approve for a total of 12 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve Tyvaso Starter Kit for 1 month for 1 fill.**
   - **SECOND APPROVAL: Approve Tyvaso or Tyvaso Refill Kit for 11 months (enter start date of 3 days before the end date of the first approval).**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD) (WHO Group 3) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Does the patient have documentation (e.g., chart note, lab result, diagnostic test result, etc.) confirming a PAH diagnosis based on right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve Tyvaso Starter Kit for 1 month for 1 fill.**
   - **SECOND APPROVAL: Approve Tyvaso or Tyvaso Refill Kit for 5 months (enter start date of 3 days before the end date of the first approval).**

   If not, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TREPROSTINIL INHALED

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TREPROSTINIL INHALED (Tyvaso)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   2. Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) (World Health Organization [WHO] Group 3)

B. **If you have PAH (WHO Group 1), approval also requires:**
   1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   2. There is documentation (such as, chart note, lab result, diagnostic test result) showing you have pulmonary arterial hypertension based on ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR) greater than 2 Wood units
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following medications from different drug classes:
      a. Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
      b. Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
      c. Oral cGMP stimulator (such as Adempas [riociguat])
      d. Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil])

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TREPROSTINIL INHALED

INITIAL CRITERIA (CONTINUED)

C. **If you have PH-ILD (WHO Group 3), approval also requires:**
   1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   2. There is documentation (such as, chart note, lab result, diagnostic test result) showing you have pulmonary arterial hypertension based on ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart
      a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR) greater than 2 Wood units

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TREPROSTINIL INHALED

RENEWAL CRITERIA

1. Does the patient have ONE of the following diagnoses?
   - Pulmonary arterial hypertension (PAH) (WHO Group 1)
   - Pulmonary hypertension associated with interstitial lung disease (PH-ILD) (WHO Group 3)

   If yes, **approve Tyvaso or Tyvaso Refill Kit for 12 months by GPID or GPI-14.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL INHALED (Tyvaso)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
      2. Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) (World Health Organization [WHO] Group 3)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tyvaso.

REFERENCES

- Tyvaso [Prescribing Information]. Research Triangle Park, NC: United Therapeutics Corp.; May 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 03/23
Client Approval: 03/24
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TREPROSTINIL INJECTABLE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have documentation (e.g., chart note, lab result, diagnostic test result, etc.) confirming a PAH diagnosis based on right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the request for continuation of Remodulin (treprostinil) therapy from a hospital discharge?

   If yes, **approve for 12 months by HICL or GPI-14.**
   If no, continue to #4.

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INITIAL CRITERIA (CONTINUED)

4. Is the request for a new start of Remodulin (treprostinil) therapy and the patient meets **ONE** of the following criteria?
   - The patient is intermediate or high risk
   - The patient had a trial of or contraindication to TWO of the following agents from different drug classes:
     - Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
     - Oral phosphodiesterase-5 inhibitor (e.g., Revatio [sildenafil], Adcirca [tadalafil])
     - Oral cGMP stimulator (e.g., Adempas [riociguat])

   If yes, **approve for 12 months by HICL or GPI-14.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL INJECTABLE (Remodulin)** requires the following rule(s) be met for approval:

   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   C. There is documentation (such as, chart note, lab result, diagnostic test result) showing you have pulmonary arterial hypertension based on ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      3. Pulmonary vascular resistance (PVR) greater than 2 Wood units
   D. **For new start requests of Remodulin (treprostinil), approval also requires ONE of the following:**
      1. You are intermediate or high risk
      2. You have tried or have a contraindication to (harmful for you to use) TWO of the following medications from different drug classes:
         a. Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
         b. Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
         c. Oral cGMP stimulator (such as Adempas [riociguat])

   (Initial denial text continued on next page)

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TREPROSTINIL INJECTABLE

INITIAL CRITERIA (CONTINUED)

E. **If you are continuing current Remodulin (treprostinil) therapy from a hospital discharge, there is no additional requirement for approval.**

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TREPROSTINIL INJECTABLE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1)?

   If yes, **approve for 12 months by HICL or GPI-14.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL INJECTABLE (Remodulin)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Remodulin.

REFERENCES

- Remodulin [Prescribing Information]. Research Triangle Park, NC; United Therapeutics Corp.; October 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 03/23
Client Approval: 02/24
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TREPROSTINIL ORAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The patient does NOT have severe hepatic impairment

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have documentation (e.g., chart note, lab result, diagnostic test result, etc.) confirming a PAH diagnosis based on right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the request for continuation of Orenitram therapy from a hospital discharge?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

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TREPROSTINIL ORAL

INITIAL CRITERIA (CONTINUED)

4. Is the request for a new start of Orenitram therapy and the patient meets **ALL** of the following criteria?
   - The patient had a trial of or contraindication to the preferred oral prostanoid: Uptravi (selexipag)
   - The patient had a trial of or contraindication to TWO of the following agents from different drug classes:
     - Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
     - Oral phosphodiesterase-5 inhibitor (e.g., Revatio [sildenafil], Adcirca [tadalafil])
     - Oral cGMP stimulator (e.g., Adempas [riociguat])
     - IV/SQ prostacyclin (e.g., Flolan [epoprostenol], Remodulin [treprostinil])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL ORAL (Orenitram)** requires the following rule(s) be met for approval:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   C. There is documentation (such as, chart note, lab result, diagnostic test result) showing you have pulmonary arterial hypertension based on ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      3. Pulmonary vascular resistance (PVR) greater than 2 Wood units
   D. You do NOT have severe hepatic (liver) impairment
   (Initial denial text continued on next page)

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TREPROSTINIL ORAL

INITIAL CRITERIA (CONTINUED)

E. **For new start requests of Orenitram, approval also requires:**
   1. You have tried or have a contraindication to (harmful for you to use) the preferred oral prostanoid: Uptravi (selexipag)
   2. You have tried or have a contraindication to (harmful for you to use) TWO of the following medications from different drug classes:
      a. Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
      b. Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
      c. Oral cGMP stimulator (such as Adempas [riociguat])
      d. Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil])

F. **If you are continuing current Orenitram therapy from a hospital discharge, there is no additional requirement for approval.**

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TREPROSTINIL ORAL

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL ORAL (Orenitram)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orenitram.

REFERENCES

- Orenitram [Prescribing Information]. Research Triangle Park, NC: United Therapeutics Corp.; August 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 09/05
Client Approval: 02/24
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIENTINE CAPSULE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Wilson's disease and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hepatologist or gastroenterologist
   - The patient has a Leipzig score of 4 or greater
   - The patient is willing to follow a diet avoiding high copper foods (e.g., shellfish, nuts, chocolate, mushrooms, organ meat)
   - The patient has had a trial of or contraindication to penicillamine (Depen, Cuprimine)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with a quantity limit as follows:**
   - **250 mg: #8 per day.**
   - **500 mg: #4 per day.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRIENTINE CAPSULE (Syprine, Clovique)** requires the following rule(s) be met for approval:
   A. You have Wilson's disease (a type of genetic disorder)
   B. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor) or gastroenterologist (a type of digestive system doctor)
   C. You have a Leipzig score (a type of diagnostic score) of 4 or higher
   D. You are willing to follow a diet avoiding high copper foods (such as shellfish, nuts, chocolate, mushrooms, organ meat)
   E. You had a trial of or contraindication (harmful for) to penicillamine (Depen, Cuprimine)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIENTINE CAPSULE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Wilson's disease **AND** meet the following criterion?
   - The patient has achieved a free serum copper of less than 10 mcg/dL

   If yes, **approve for lifetime by GPID or GPI-14 for all strengths with a quantity limit as follows:**
   - **250 mg: #8 per day.**
   - **500 mg: #4 per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRIENTINE CAPSULE (Syprine, Clovique)** requires the following rules be met for renewal:
   A. You have Wilson's disease (a type of genetic disorder)
   B. You have achieved a free serum copper level (amount of copper in your blood) of less than 10 mcg/dL

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Syprine, Clovique, or trientine hydrochloride.

REFERENCES

- Syprine [Prescribing Information]. Bridgewater, NJ: Bausch Health US, LLC; September 2020.
- Clovique [Prescribing Information]. Warrendale, PA: Kadmon Pharmaceuticals, LLC; September 2019.
- Trientine hydrochloride capsules [Prescribing Information]. East Brunswick, NJ: Rising Pharma Holdings, Inc.; May 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/23/23
Created: 08/16
Client Approval: 10/23
P&T Approval: 10/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIENTINE TABLET

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Wilson's disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a prior or current Leipzig score of 4 or greater
   - The patient has a non-ceruloplasmin copper (NCC) level between 50 to 150 mcg/L or a 24-hour urinary copper excretion (UCE) of between 100 to 500 mcg/24 hours
   - Therapy is prescribed by or in consultation with a hepatologist or gastroenterologist
   - The patient is willing to maintain a diet that avoids high copper foods (e.g., shellfish, nuts, chocolate, mushrooms, organ meat)
   - The patient had a trial of penicillamine (Depen, Cuprimine) for at least one year prior to starting Cuvrior
   - The patient had a trial of trientine hydrochloride (Syprine)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #10 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRIENTINE TABLET (Cuvrior)** requires the following rule(s) be met for approval:
   A. You have Wilson's disease (a type of genetic disorder)
   B. You are 18 years of age or older
   C. You have a prior or current Leipzig score (a type of diagnostic score) of 4 or higher
   D. You have a non-ceruloplasmin copper (NCC: a type of test to check copper levels) level between 50 to 150 mcg/L or a 24-hour urinary copper excretion (UCE: a type of test to check copper levels) between 100 to 500 mcg per 24 hours
   E. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor) or gastroenterologist (a type of digestive system doctor)
   F. You are willing to maintain a diet that avoids high copper foods (such as shellfish, nuts, chocolate, mushrooms, organ meat)
   G. You have tried penicillamine (Depen, Cuprimine) for at least one year prior to starting Cuvrior
   H. You have tried trientine hydrochloride (Syprine)
   (Initial denial text continued on the next page)

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TRIENTINE TABLET

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIENTINE TABLET

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Wilson's disease **AND** meet the following criterion?
   - The patient's copper levels are monitored via non-ceruloplasmin copper (NCC) or 24-hour urinary copper excretion (UCE) laboratory test

   If yes, **approve for lifetime by HICL or GPI-10 with a quantity limit of #10 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRIENTINE TABLET (Cuvrior)** requires the following rules be met for renewal:
   A. You have Wilson's disease (a type of genetic disorder)
   B. Your body's copper levels are monitored by a non-ceruloplasmin copper (NCC: a type of test to check copper levels) test or 24-hour urinary copper excretion (UCE: a type of test to check copper levels) test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cuvrior.

REFERENCES

- Cuvrior [Prescribing Information]. Chicago, IL: Orphalan SA; April 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/30/23
Created: 04/23
Client Approval: 10/23
P&T Approval: 10/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIFLURIDINE/TIPIRACIL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic colorectal cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy in combination with an anti-VEGF biological therapy [e.g., Zaltrap (ziv-aflibercept), Cyramza (ramucirumab)]
   - Lonsurf will be used as a single agent OR in combination with bevacizumab

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient's metastatic colorectal cancer RAS wild-type?

   If yes, continue to #3.
   If no, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **15/6.14mg: #100 per 28 days.**
   - **20/8.19mg: #80 per 28 days.**

3. Has the patient had previous treatment with an anti-EGFR agent [e.g., Erbitux (cetuximab), Vectibix (panitumumab)]?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **15/6.14mg: #100 per 28 days.**
   - **20/8.19mg: #80 per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TRIFLURIDINE/TIPIRACIL

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received previous treatment with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **15/6.14mg: #100 per 28 days.**
   - **20/8.19mg: #80 per 28 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRIFLURIDINE/TIPIRACIL (Lonsurf)** requires the following rule(s) be met for approval:

   A. You have ONE of the following diagnoses:
      1. Metastatic colorectal cancer (a type of digestive system cancer that has spread to other parts of the body)
      2. Metastatic gastric or gastroesophageal junction adenocarcinoma (a type of digestive system cancer that has spread to other parts of the body)

   B. **If you have metastatic colorectal cancer, approval also requires:**
      1. You are 18 years of age or older
      2. Lonsurf will be used as a single agent OR in combination with bevacizumab
      3. You had previous treatment with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy (drugs used to treat cancer) in combination with an anti-VEGF biological therapy such as Zaltrap (ziv-aflibercept) or Cyramza (ramucirumab)
      4. If your metastatic colorectal cancer is RAS wild-type (a type of gene), you also had a previous treatment with an anti-EGFR agent such as Erbitux (cetuximab), Vectibix (panitumumab)

   C. **If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:**
      1. You are 18 years of age or older
      2. You had previous treatment with at least two prior lines of chemotherapy (drugs used to treat cancer) that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2 (type of gene)/neu-targeted therapy

   (Denial text continued on next page)

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TRIFLURIDINE/TIPIRACIL

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lonsurf.

REFERENCES

- Lonsurf [Prescribing Information]; Princeton, NJ: Taiho Oncology, Inc; August 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/01/23
Created: 10/15
Client Approval: 08/23
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIHEPTANOIN

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a long-chain fatty acid oxidation disorder (LC-FAOD) and meet **ALL** of the following criteria?
   - The patient's diagnosis is confirmed by documentation of at least **TWO** of the following:
     - Disease-specific elevations of acylcarnitines on a newborn blood spot or in plasma
     - Low enzyme activity in cultured fibroblasts
     - One or more known pathogenic mutations in *CPT2, ACADVL, HADHA, or HADHB*
   - The patient is symptomatic (e.g. rhabdomyolysis, cardiomyopathy) for LC-FAOD
   - Therapy is prescribed by or given in consultation with a gastroenterologist or physician specialist in medical genetics/inherited metabolic disorders
   - The patient had a trial of or contraindication to commercial MCT oil (medical food product)

   If yes, **approve for 4 months by HICL or GPI-10.**
   APPROVAL TEXT: Renewal requires the patient had a positive clinical response (e.g., improved exercise tolerance) or stabilization of clinical status compared to baseline.

   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **TRIHEPTANOIN (Dojolvi)** requires the following rule(s) be met for approval:
   A. You have a long-chain fatty acid oxidation disorder (LC-FAOD: rare, genetic disorder that affects how the body breaks down fat)
   B. Your diagnosis is confirmed by documentation of at least TWO of the following:
      1. Disease-specific elevations of acylcarnitines on a newborn blood spot or in plasma
      2. Low enzyme activity in cultured fibroblasts
      3. One or more known pathogenic mutations in *CPT2, ACADVL, HADHA, or HADHB*
   C. You are symptomatic for LC-FAOD (for example you have rhabdomyolysis [break down of muscle tissue] or cardiomyopathy [disease of the heart muscle])
   D. Therapy is prescribed by or given in consultation with a gastroenterologist (digestive tract doctor) or physician specialist in medical genetics/inherited metabolic disorders
   E. You have previously tried commercial MCT oil (a medical food product) unless there is a medical reason you are unable to (contraindication)

   (Initial denial text continued on next page)

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIHEPTANOIN

INITIAL CRITERIA (CONTINUED ON NEXT)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of a long-chain fatty acid oxidation disorder (LC-FAOD) **AND** meet the following criterion?
   - The patient had a positive clinical response (e.g. improved exercise tolerance) or stabilization of clinical status compared to baseline

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRIHEPTANOIN (Dojolvi)** requires the following rule(s) be met for renewal:
   A. You have a long-chain fatty acid oxidation disorder (LC-FAOD: rare, genetic disorder that affects how the body breaks down fat)
   B. You had a positive clinical response (such as improved exercise tolerance) or stabilization of clinical status compared to baseline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Dojolvi.

REFERENCES

- Dojolvi [Prescribing Information]. Novato, CA: Ultragenyx Pharmaceutical Inc.; June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21
Created: 10/20
Client Approval: 11/20
P&T Approval: 10/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TROFINETIDE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Rett syndrome **AND** meet the following criterion?
   - The patient is 2 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #120mL per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TROFINETIDE (Daybue)** requires the following rule(s) be met for approval:
   A. You have Rett syndrome (a type of nervous system disorder)
   B. You are 2 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Daybue.

REFERENCES

- Daybue [Prescribing Information]. San Diego, CA, Acadia Pharmaceuticals Inc.; March 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 04/23
Client Approval: 05/23
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TUCATINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced unresectable or metastatic HER2-positive breast cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received one or more prior anti-HER2-based regimens (i.e., trastuzumab or trastuzumab with pertuzumab) in the metastatic setting
   - The requested medication will be used in combination with trastuzumab and capecitabine

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **50mg: #10 per day.**
   - **150mg: #4 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of RAS wild-type, HER2-positive unresectable or metastatic colorectal cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy
   - The requested medication will be used in combination with trastuzumab

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **50mg: #10 per day.**
   - **150mg: #4 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TUCATINIB (Tukysa)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Advanced unresectable (cannot be removed with surgery) or metastatic (disease that has spread to other parts of the body) human epidermal growth factor receptor 2 (HER2: type of protein)-positive breast cancer
      2. RAS wild-type (a type of gene), HER2-positive unresectable or metastatic colorectal cancer (a type of digestive cancer)

   (Denial text continued on next page)

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TUCATINIB

GUIDELINES FOR USE (CONTINUED)

B. **If you have advanced unresectable or metastatic HER2-positive breast cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have received one or more prior anti-HER2-based treatment (specifically either trastuzumab or trastuzumab with pertuzumab) for metastatic disease
   3. The requested medication will be used in combination with trastuzumab and capecitabine

C. **If you have RAS wild-type, HER2-positive unresectable or metastatic colorectal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (drugs used to treat cancer)
   3. The requested medication will be used in combination with trastuzumab

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tukysa.

REFERENCES

- Tukysa [Prescribing Information]. Bothell, WA: Seattle Genetics, Inc.; January 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/06/23
Created: 08/20
Client Approval: 01/23
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

UBROGEPANT

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the acute treatment of migraines and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Ubrelvy will NOT be used concurrently with other cGRP inhibitors (e.g., Zavzpret [zavegepant]) for the acute treatment of migraines
   - The patient had a trial of or contraindication to ONE triptan (e.g., Imitrex [sumatriptan], Maxalt [rizatriptan])

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #16 per 30 days.** If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **UBROGEPANT (Ubrelvy)** requires the following rule(s) be met for approval:
   A. The request is for the acute (quick onset) treatment of migraines (a type of headache)
   B. You are 18 years of age or older
   C. You will NOT use Ubrelvy concurrently (at the same time) with other calcitonin gene-related peptide (cGRP) inhibitors (such as Zavzpret [zavegepant]) for the acute treatment of migraines
   D. You have tried or have a contraindication (harmful for) to ONE triptan (such as Imitrex [sumatriptan], Maxalt [rizatriptan])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

UBROGEPANT

RENEWAL CRITERIA

1. Is the request for the acute treatment of migraines **AND** the patient meets the following criterion?
   - Ubrelvy will NOT be used concurrently with other cGRP inhibitors (e.g., Zavzpret [zavegepant]) for the acute treatment of migraines

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (e.g., Migraine Assessment of Current Therapy [Migraine-ACT])?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #16 per 30 days.**
   If no, continue to #3.

3. Has the patient experienced clinical improvement as defined by **ONE** of the following criteria?
   - Ability to function normally within 2 hours of dose
   - Headache pain disappears within 2 hours of dose
   - Therapy works consistently in majority of migraine attacks

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #16 per 30 days.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **UBROGEPANT (Ubrelvy)** requires the following rule(s) be met for renewal:
   A. The request is for the acute (quick onset) treatment of migraines
   B. You will NOT use Ubrelvy concurrently (at the same time) with other calcitonin gene-related peptide (cGRP) inhibitors (such as Zavzpret [zavegepant]) for the acute treatment of migraines
   C. You meet ONE of the following:
      1. You have experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (assessment tool used to help guide treatment such as migraine assessment of current therapy [MIGRAINE-ACT])
      2. You have experienced clinical improvement as defined by ONE of the following:
         a. Ability to function normally within 2 hours of dose
         b. Headache pain disappears within 2 hours of dose
         c. Treatment works consistently in majority of migraine attacks

   (Renewal denial text continued on the next page)

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UBROGEPANT

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ubrelvy.

REFERENCES

- Ubrelvy [Prescribing Information]. North Chicago, IL: AbbVie Inc.; June 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 01/20
Client Approval: 11/23
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

UPADACITINIB

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., Humira [adalimumab], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Enbrel [etanercept], Hyrimoz [adalimumab-adaz])

   If yes, **approve 15mg for 6 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., Humira [adalimumab], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Enbrel [etanercept], Hyrimoz [adalimumab-adaz])

   If yes, **approve 15mg for 6 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, continue to #3.

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UPADACITINIB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of moderate to severe atopic dermatitis and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist, allergist, or immunologist
   - The patient has at least TWO of the following: intractable pruritus, cracking and oozing/bleeding of affected skin, impaired activities of daily living
   - Rinvoq will NOT be used concurrently with other systemic biologics (e.g., Adbry [tralokinumab-ldrm], Dupixent [dupilumab]) for atopic dermatitis or other JAK inhibitors (e.g., topical Opzelura [ruxolitinib], Xeljanz [tofacitinib]) for any indication

   If yes, continue to #4.
   If no, continue to #6.

4. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic (e.g., Adbry [tralokinumab-ldrm], Dupixent [dupilumab]) and is switching to the requested drug
   - The patient has atopic dermatitis involving at least 10 percent of body surface area (BSA)
   - The patient has atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See initial denial text at the end of the guideline.

5. Did the patient have a trial of or contraindication to **ONE** of the following?
   - Topical corticosteroid (e.g., hydrocortisone, clobetasol, halobetasol propionate)
   - Topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]
   - Topical PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]
   - Topical JAK inhibitor [e.g., Opzelura (ruxolitinib)]
   - Phototherapy

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths as follows:**
   - **15mg: #1 per day.**
   - **30mg: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: See initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed or in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to ONE conventional therapy (e.g., corticosteroids [e.g., budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)
   - The patient had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., Humira [adalimumab], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Hyrimoz [adalimumab-adaz])

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve 45mg for 8 weeks with a quantity limit of #1 per day.**
   - **SECOND APPROVAL: Approve 15mg and 30mg for 4 months with a quantity limit of #1 per day. (Please enter start date of 2 days before the end date of the first approval).**

   If no, continue to #7.

7. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to ONE conventional agent (e.g., corticosteroids [e.g., budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)
   - The patient had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., Humira [adalimumab], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Hyrimoz [adalimumab-adaz])

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve 45mg for 12 weeks with a quantity limit of #1 per day.**
   - **SECOND APPROVAL: Approve 15mg and 30mg for 3 months with a quantity limit of #1 per day. (Please enter start date of 2 days before the end date of the first approval).**

   If no, continue to #8.

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UPADACITINIB

INITIAL CRITERIA (CONTINUED)

8. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)
   - The patient had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., Humira [adalimumab], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Enbrel [etanercept], Hyrimoz [adalimumab-adaz])

   If yes, **approve 15mg for 6 months by GPID or GPI-14 with a quantity limit of #1 per day.**

   If no, continue to #9.

9. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., Cimzia [certolizumab])
   - The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)

   If yes, continue to #10.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

10. Does the patient meet **ONE** of the following criteria?
    - The patient was previously stable on another biologic (e.g., Cimzia [certolizumab], Cosentyx [secukinumab]) and is switching to the requested drug
    - The patient has C-reactive protein (CRP) levels above the upper limit of normal
    - The patient has sacroiliitis on magnetic resonance imaging (MRI)

    If yes, **approve 15mg for 6 months by GPID or GPI-14 with a quantity limit of #1 per day.**

    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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UPADACITINIB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **UPADACITINIB (Rinvoq)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: type of joint condition)
   2. Psoriatic arthritis (PsA: type of skin and joint condition)
   3. Moderate to severe atopic dermatitis (a type of skin condition)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   6. Ankylosing spondylitis (AS: a type of joint condition)
   7. Non-radiographic axial spondyloarthritis (NR-axSpA: a type of joint condition)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You had an inadequate response (drug did not work) or intolerance (side effect) to one or more tumor necrosis factor (TNF) blockers (such as Humira [adalimumab], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Enbrel [etanercept], Hyrimoz [adalimumab-adaz])

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (skin doctor)
   3. You have tried or have a contraindication to (harmful for you to use) ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You had an inadequate response (drug did not work) or intolerance (side effect) to one or more tumor necrosis factor (TNF) blockers (such as Humira [adalimumab], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Enbrel [etanercept], Hyrimoz [adalimumab-adaz])

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INITIAL CRITERIA (CONTINUED)

D. **If you have moderate to severe atopic dermatitis, approval also requires:**
   1. You are 12 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
   3. You have at least TWO of the following: intractable pruritus (severe itching), cracking and oozing/bleeding of affected skin, impaired activities of daily living
   4. You have tried or have a contraindication to (harmful for you to use) ONE of the following: topical corticosteroid (such as hydrocortisone, clobetasol, halobetasol propionate), topical calcineurin inhibitor (such as Elidel [pimecrolimus], Protopic [tacrolimus]), topical PDE-4 inhibitor (such as Eucrisa [crisaborole]), topical JAK inhibitor (such as Opzelura [ruxolitinib]), phototherapy (light therapy)
   5. You will NOT use Rinvoq concurrently (at the same time) with other systemic biologics (such as Adbry [tralokinumab-ldrm], Dupixent [dupilumab) for atopic dermatitis or other Janus kinase (JAK) inhibitors (such as topical Opzelura [ruxolitinib], Xeljanz [tofacitinib]) for any indication
   6. You meet ONE of the following:
      a. You were previously on another biologic (such as Adbry [tralokinumab-ldrm], Dupixent [dupilumab]) and are switching to the requested drug
      b. You have atopic dermatitis involving at least 10 percent of body surface area (BSA)
      c. You have atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas (between skin folds)

E. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You have tried or have a contraindication to (harmful for you to use) ONE standard therapy, such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. You had an inadequate response (drug did not work) or intolerance (side effect) to one or more tumor necrosis factor (TNF) blockers (such as Humira [adalimumab], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Hyrimoz [adalimumab-adaz])

F. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
   3. You have tried or have a contraindication to (harmful for you to use) ONE standard therapy, such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. You had an inadequate response (drug did not work) or intolerance (side effect) to one or more tumor necrosis factor (TNF) blockers (such as Humira [adalimumab], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Hyrimoz [adalimumab-adaz])

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UPADACITINIB

INITIAL CRITERIA (CONTINUED)

G. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) an NSAID (nonsteroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
   4. You had an inadequate response (drug did not work) or intolerance (side effect) to one or more tumor necrosis factor (TNF) blockers (such as Humira [adalimumab], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Enbrel [etanercept], Hyrimoz [adalimumab-adaz])

H. **If you have non-radiographic axial spondyloarthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You had an inadequate response (drug did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blockers (such as Cimzia [certolizumab])
   4. You have tried or have a contraindication (harmful for) to an NSAID (non-steroidal anti-inflammatory drug: such as ibuprofen, naproxen, meloxicam)
   5. You meet ONE of the following:
      a. You were previously on another biologic (such as Cimzia [certolizumab], Cosentyx [secukinumab]) and are switching to the requested drug
      b. You have C-reactive protein (CRP: a measure of how much inflammation is in the body) levels above the upper limit of normal
      b. You have sacroiliitis (type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI: type of imaging lab)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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UPADACITINIB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) OR psoriatic arthritis (PsA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve 15mg for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe atopic dermatitis and meet **ALL** of the following criteria?
   - The patient has shown improvement while on therapy
   - Rinvoq will NOT be used concurrently with other systemic biologics (e.g., Adbry [tralokinumab-ldrm], Dupixent [dupilumab]) for atopic dermatitis or other JAK inhibitors (e.g., topical Opzelura [ruxolitinib], Xeljanz [tofacitinib]) for any indication

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **15mg: #1 per day.**
   - **30mg: #1 per day.**

   If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC)?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **15mg: #1 per day.**
   - **30mg: #1 per day.**

   If no, continue to #4.

4. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD)?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **15mg: #1 per day.**
   - **30mg: #1 per day.**

   If no, continue to #5.

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UPADACITINIB

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of ankylosing spondylitis (AS) or non-radiographic axial spondyloarthritis (nr-axSpA) **AND** meet the following criterion?
   - The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy

   If yes, **approve 15mg for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **UPADACITINIB (Rinvoq)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following diagnoses:
      1. Moderate to severe rheumatoid arthritis (RA: type of joint condition)
      3. Psoriatic arthritis (PsA: a type of skin and joint condition)
      4. Moderate to severe atopic dermatitis (a type of skin condition)
      5. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
      6. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
      7. Ankylosing spondylitis (AS: a type of joint condition)
      8. Non-radiographic axial spondyloarthritis (NR-axSpA: a type of joint condition)

   B. **If you have moderate to severe rheumatoid arthritis or psoriatic arthritis, renewal also requires:**
      1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

   C. **If you have moderate to severe atopic dermatitis, renewal also requires:**
      1. You have shown improvement while on therapy
      2. You will NOT use Rinvoq concurrently (at the same time) with other systemic biologics (such as Adbry [tralokinumab-ldrm], Dupixent [dupilumab]) for atopic dermatitis or other Janus kinase (JAK) inhibitors (such as topical Opzelura [ruxolitinib], Xeljanz [tofacitinib]) for any indication

   D. **If you have ankylosing spondylitis or non-radiographic axial spondyloarthritis, renewal also requires:**
      1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy

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RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rinvoq.

REFERENCES

- Rinvoq [Prescribing Information]. North Chicago, IL: AbbVie Inc.; June 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 08/19
Client Approval: 11/23
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

URIDINE TRIACETATE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a documented diagnosis of hereditary orotic aciduria as confirmed by **ALL** of the following criteria?
   - Presence of a mutation in the uridine monophosphate synthase (UMPS) gene
   - Patient has an elevated urinary orotic acid level according to an age-specific reference range

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at end of the guideline.

2. Is the medication prescribed by or given in consultation with a prescriber specializing in inherited metabolic diseases?

   If yes, **approve for 6 months by GPID or GPI-10 up to #4 packets per day.**
   APPROVAL TEXT: Renewal requires that the patient's age dependent hematologic parameters (e.g., neutrophil count, neutrophil percent, white blood cell count, mean corpuscular volume) have stabilized or improved from baseline while on treatment with uridine triacetate.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **URIDINE TRIACETATE (Xuriden)** requires the following rule(s) be met for approval:
   A. You have hereditary orotic aciduria (HOA: genetic disease where you do not have a type of protein to make a chemical)
   B. Your diagnosis is confirmed by ALL of the following:
      1. Presence of a mutation in the uridine monophosphate synthase (UMPS) gene
      2. Elevated urinary orotic acid levels according to your age-specific reference range
   C. Therapy is prescribed by or given in consultation with a doctor specializing in inherited metabolic diseases (genetic diseases that result in metabolism problems)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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URIDINE TRIACETATE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Has the patient's age dependent hematologic parameters (e.g., neutrophil count, neutrophil percent, white blood cell count, mean corpuscular volume) stabilized or improved from baseline while on treatment with uridine triacetate?

   If yes, **approve for 12 months by GPID or GPI-10 up to #4 packets per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **URIDINE TRIACETATE (Xuriden)** requires the following rule(s) to be met for renewal:
   A. Your age dependent hematologic parameters (blood lab tests) have stabilized or improved from baseline while on treatment with Xuriden (uridine triacetate).

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xuriden.

REFERENCES

- Xuriden [Prescribing Information]. Gaithersburg, MD: Wellstat Therapeutics Corporation. December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/07/20
Created: 02/16
Client Approval: 08/20
P&T Approval: 05/16

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

URSODIOL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of radiolucent, noncalcified gallbladder stones and meet **ALL** of the following criteria?
   - The patient's gallbladder stones are less than 20 mm in greatest diameter
   - Elective cholecystectomy is planned unless the patient is at increased surgical risk due to systemic disease, advanced age, or idiosyncratic reaction to general anesthesia, OR the patient refuses surgery
   - The patient had a trial of generic ursodiol (300mg capsule, 250mg tablet, or 500mg tablet)
   - The patient is unable to take generic ursodiol formulations (300mg capsule, 250mg tablet, or 500mg tablet)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength.**
   If no, do not approve.
   CLINICIAL SPECIALIST NOTE: Use for prevention of gallstone formation in obese patients with rapid weight loss is not covered for this medication.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **URSODIOL (Reltone)** requires the following rule(s) be met for approval:
   A. You have radiolucent, noncalcified gallbladder stones (hardened deposits of bile, that is barely visible on x-ray, in your gallbladder that do not contain calcium)
   B. Your gallbladder stones are less than 20 mm in diameter
   C. You plan to have elective cholecystectomy (surgery to remove gallbladder) unless you are at increased surgical risk due to systemic (entire body) disease, advanced age, or idiosyncratic reaction (an unexpected adverse reaction) to general anesthesia, OR you refuse surgery
   D. You have tried generic ursodiol (300mg capsule, 250mg tablet, or 500mg tablet)
   E. You are unable to take generic ursodiol (300mg capsule, 250mg tablet, or 500mg tablet) formulations

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

URSODIOL

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Reltone.

REFERENCES

- Ursodiol 200 mg & 400 mg Capsules [Prescribing Information]. Las Vegas, NV: Intra-Sana Laboratories LLC; February 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 02/21
Client Approval: 03/22
P&T Approval: 01/21

STANDARD COMMERCIAL AND NSA DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

USTEKINUMAB

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient had a trial of or contraindication to ONE or more forms of conventional therapies, (e.g., PUVA [psoralen and ultraviolet light A], UVB [ultraviolet light B], topical corticosteroids [e.g., betamethasone dipropionate, clobetasol propionate], calcipotriene, acitretin, methotrexate, or cyclosporine)

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic and is switching to Stelara
   - The patient has psoriasis covering 3% or more of body surface area (BSA)
   - The patient has psoriatic lesions affecting the hands, feet, face, or genital area

   If yes, **enter two approvals for a total of 6 months by GPID or GPI-14 as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of 1mL per 28 days for 1 fill.**
   - **SECOND APPROVAL: Approve for 5 months with a quantity limit of 1mL per 84 days for 2 fills (Start date is 3 weeks AFTER the start date of the first approval).**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guidelines.

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #4.
   If no, continue to #5.

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

4. Does the patient have coexistent moderate to severe plaque psoriasis (PsO)?

   If yes, **enter two approvals for a total of 6 months by GPID or GPI-14 as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of 1mL per 28 days for 1 fill.**
   - **SECOND APPROVAL: Approve for 5 months with a quantity limit of 1mL per 84 days for 2 fills (Start date is 3 weeks AFTER the start date of the first approval).**

   If no, **enter two approvals for a total of 6 months by GPID or GPI-14 as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of 0.5mL per 28 days for 1 fill.**
   - **SECOND APPROVAL: Approve for 5 months with a quantity limit of 0.5mL per 84 days for 2 fills (Start date is 3 weeks AFTER the start date of the first approval).**

5. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to ONE conventional agent, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

   If yes, continue to #7.
   If no, continue to #6.

6. Does the patient have a diagnosis of moderate to severe active ulcerative colitis (UC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to ONE conventional agent, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

7. Is the prescriber requesting an intravenous infusion induction dose of **Stelara 130mg/26mL**?

   If yes, **enter two approvals for a total of 6 months by GPID or GPI-14 as follows:**
   - **FIRST APPROVAL: Approve for 2 months by GPID or GPI-14 with a quantity limit of 104mL (130mg/26mL) per 56 days for 1 fill.**
   - **SECOND APPROVAL: Approve for 4 months by GPID or GPI-14 with a quantity limit of 1mL (45mg/0.5mL or 90mg/mL) per 56 days for 2 fills (Start date is 7 weeks AFTER the start date of the first approval).**

   If no, **approve for 6 months by GPID or GPI-14 with a quantity limit of 1mL per 56 days for 3 fills.**

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **USTEKINUMAB (Stelara)** requires the following rules be met for approval:

   A. You have ONE of the following diagnoses:
      1. Psoriatic arthritis (PsA: a type of skin and joint condition)
      2. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
      3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
      4. Moderate to severe active ulcerative colitis (UC: a type of digestive disorder)

   B. **If you have moderate to severe plaque psoriasis, approval also requires:**
      1. You are 6 years of age or older
      2. Therapy is prescribed by or in consultation with a dermatologist (type of skin doctor)
      3. You have tried or have a contraindication (harmful for) to ONE or more forms of standard therapies, such as PUVA (psoralen and ultraviolet light A: a type of light therapy), UVB (ultraviolet light B: a type of light therapy), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), calcipotriene, acitretin, methotrexate, or cyclosporine
      4. You meet ONE of the following:
         a. You were previously stable on another biologic and are switching to Stelara
         b. You have psoriasis covering 3 percent or more of body surface area (BSA)
         c. You have psoriatic lesions (rashes) affecting the hands, feet, genital area, or face

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (type of immune system doctor) OR dermatologist (type of skin doctor)
   3. You have tried or have a contraindication (harmful for) to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
   3. You have tried or have a contraindication (harmful for) to ONE standard therapy, such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

E. **If you have moderate to severe active ulcerative colitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
   3. You have tried or have a contraindication (harmful for) to ONE standard therapy, such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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USTEKINUMAB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of psoriatic arthritis (PsA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient have coexistent moderate to severe plaque psoriasis (PsO)?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of 1mL per 84 days.**
   If no, **approve for 12 months by GPID or GPI-14 with a quantity limit of 0.5mL per 84 days.**

3. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?
   - The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of 1mL per 84 days.**
   If no, continue to #4.

4. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD)?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of 1mL per 56 days.**
   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC)?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of 1mL per 56 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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USTEKINUMAB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **USTEKINUMAB (Stelara)** requires the following rules be met for renewal:

A. You have ONE of the following diagnoses:
   1. Psoriatic arthritis (PsA: a type of skin and joint condition)
   2. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

C. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Stelara.

REFERENCES

- Stelara [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. July 2022.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 10/09
Client Approval: 03/24
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VALBENAZINE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of tardive dyskinesia (TD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, movement disorder specialist, or psychiatrist
   - The patient's TD has been present for at least 3 months
   - The patient has a history of using antipsychotic medications (e.g., aripiprazole, haloperidol, ziprasidone) or metoclopramide for at least 3 months (or at least 1 month if the patient is 60 years of age or older) as documented in the prescription claims history
   - The patient had a trial of or contraindication to the preferred agent: Austedo (deutetrabenazine)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **40mg, 60mg, 80mg: #1 per day.**
   - **Initiation pack (40mg-80mg): 1 pack (#28) per fill.**

   If no, continue to #2.

2. Does the patient have a diagnosis of chorea associated with Huntington's disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist or movement disorder specialist
   - The patient had a trial of or contraindication to the preferred agent: Austedo (deutetrabenazine)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VALBENAZINE (Ingrezza)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Tardive dyskinesia (TD: uncontrolled body movements)
      2. Chorea (involuntary muscle movements) associated with Huntington's disease (a type of brain disorder)

(Denial text continued on the next page)

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VALBENAZINE

GUIDELINES FOR USE (CONTINUED)

B. **If you have tardive dyskinesia, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor), movement disorder specialist, or psychiatrist (a type of mental health doctor)
   3. Your tardive dyskinesia has been present for at least 3 months
   4. You have a history of using antipsychotic medications (such as aripiprazole, haloperidol, ziprasidone) or metoclopramide for at least 3 months (or at least 1 month if you are 60 years of age or older) as documented in your prescription claims history
   5. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Austedo (deutetrabenazine)

C. **If you have chorea associated with Huntington's disease, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor) or movement disorder specialist
   3. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Austedo (deutetrabenazine)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ingrezza.

REFERENCES

- Ingrezza [Prescribing Information]. San Diego, CA: Neurocrine Biosciences, Inc; August 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 04/17
Client Approval: 02/24
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VAMOROLONE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) and meet **ALL** of the following criteria?
   - The patient is 2 years of age and older
   - Therapy is prescribed by or in consultation with a neurologist specializing in the treatment of Duchenne muscular dystrophy (DMD) at a DMD treatment center
   - The patient's diagnosis of DMD is confirmed by genetic testing

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the patient tried prednisone or prednisolone for at least 6 months?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Did the patient experience lack of efficacy with prednisone or prednisolone and meet **ALL** of the following criteria?
   - The patient is not in Stage 1 of the disease (the pre-symptomatic phase)
   - Steroid myopathy has been ruled out
   - The patient has experienced deterioration in ambulation, functional status, or pulmonary function while on prednisone or prednisolone that is consistent with advancing disease (stage 2 or higher) and assessed using standard measures over time (e.g., 6-minute walking distance [6MWD], ascending or descending 4 stairs, rise from floor time, 10-meter run/walk time, North Star Ambulatory Assessment [NSAA])

   If yes, **approve for 6 months by HICL with a quantity limit of #7.69mL per day.**
   If no, continue to #4.

4. Did the patient experience a significant adverse effect (e.g., weight gain) on prednisone or prednisolone that is negatively impacting a comorbid condition (e.g., diabetes)?

   If yes, **approve for 6 months by HICL with a quantity limit of #7.69mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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VAMOROLONE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VAMOROLONE (Agamree)** requires the following rules be met for approval:

A. You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
B. You are 2 years of age and older
C. Therapy is prescribed by or in consultation with a neurologist (nerve system doctor) specializing in the treatment of Duchenne muscular dystrophy (DMD) at a DMD treatment center
D. Your diagnosis of DMD is confirmed by genetic testing
E. You have tried prednisone or prednisolone for at least 6 months
F. You meet ONE of the following:
    1. Prednisone or prednisolone did not work for you, and you meet ALL of the following:
        a. You are not in Stage 1 of the disease (the pre-symptomatic phase)
        b. There is no steroid myopathy (muscle disease due to steroid use)
        c. You have experienced a decrease in ambulation (walking), functional status, or pulmonary (lung) function, while treated with prednisone or prednisolone, that is consistent with advancing disease (stage 2 or higher) and that is assessed by standard measures over time (such as, the 6-minute walking distance [6MWD], going up or down 4 stairs, time to rise from the floor, 10-meter run/walk time, North Star Ambulatory Assessment [NSAA: a tool for evaluating Duchenne muscular dystrophy])
    2. You have experienced a significant adverse effect (such as, weight gain) on prednisone or prednisolone that is negatively impacting a co-existing comorbid condition (such as, diabetes [a disorder with high blood sugar])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VAMOROLONE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient currently ambulatory **AND** meets the following criterion?
   - The patient has shown improvement while on Agamree, as assessed by a standard set of ambulatory or functional status measures (e.g., 6-minute walking distance [6MWD], ascending or descending 4 stairs, rise from floor time [Gower's maneuver], 10-meter (30 feet) run/walk time, North Star Ambulatory Assessment [NSAA])

   If yes, **approve for 12 months by HICL with a quantity limit of #7.69mL per day.**
   If no, continue to #3.

3. Is the patient currently non-ambulatory **AND** meets the following criterion?
   - The patient has maintained or demonstrated a less than expected decline in pulmonary function or upper limb strength while on Agamree, as assessed by standard measures (e.g., pulmonary function [FVC, PFTs], upper limb strength)

   If yes, **approve for 12 months by HICL with a quantity limit of #7.69mL per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VAMOROLONE (Agamree)** requires the following rules be met for renewal:
   A. You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
   B. **If you are currently ambulatory (can walk), approval also requires:**
      1. You have shown improvement while on Agamree as measured by a standard set of ambulatory or functional status measures (such as, the 6-minute walking distance [6MWD], going up or down 4 stairs, time to rise from the floor [Gower's maneuver], 10-meter (30 feet) run/walk time, North Star Ambulatory Assessment [NSAA: a tool for evaluating Duchenne muscular dystrophy])
   C. **If you are currently non-ambulatory (cannot walk), approval also requires:**
      1. You have maintained or had a less than expected decrease in pulmonary (lung) function or upper limb strength while on Agamree as assessed by standard measures (such as pulmonary function [forced vital capacity, pulmonary function tests], upper limb strength)

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VAMOROLONE

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Agamree.

REFERENCES

- Agamree [Prescribing Information]. Burlington, MA: Santhera Pharmaceuticals, Inc.; October 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/22/24
Created: 01/24
Client Approval: 01/24
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VANDETANIB

GUIDELINES FOR USE

1. Is the patient currently stable on the requested medication?

   If yes, **approve for 12 months by GPID or GPI-14 as follows:**
   - **Caprelsa 100mg: #2 per day.**
   - **Caprelsa 300mg: #1 per day.**

   If no, continue to #2.

2. Does the patient have diagnosis of symptomatic or progressive medullary thyroid cancer with unresectable locally advanced or metastatic disease?

   If yes, **approve for 12 months by GPID or GPI-14 as follows:**
   - **Caprelsa 100mg: #2 per day.**
   - **Caprelsa 300mg: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline for **VANDETANIB (Caprelsa)** requires **ONE** of the following rule(s) be met for approval:
   A. You are currently stable on the requested medication
   B. You have symptomatic or progressive medullary thyroid cancer with unresectable locally advanced or metastatic disease (advanced thyroid cancer that cannot be removed with surgery or has spread in body)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VANDETANIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Caprelsa.

REFERENCS

- Caprelsa [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP. October 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 05/11
Client Approval: 03/21
P&T Approval: 11/13

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VARENICLINE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of dry eye disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an ophthalmologist or optometrist
   - The patient has at least one positive diagnostic test (e.g., tear breakup time, tear film osmolarity, ocular surfacing staining, Schirmer test, etc.)
   - The patient had a trial of or contraindication to ONE ocular lubricant (e.g., carboxymethylcellulose [Refresh, Celluvisc, Thera Tears, Genteal, etc.], polyvinyl alcohol [Liquitears, Refresh Classic, etc.], or wetting agents [Systane, Lacrilube, etc.])
   - The patient had a trial of or contraindication to BOTH of the following preferred agents: Restasis (cyclosporine) AND Xiidra (lifitegrast)

   If yes, **approve for 3 months by GPID or GPI-10 with a quantity limit of #8.4 mL per 30 days.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VARENICLINE (Tyrvaya)** requires the following rule(s) be met for approval:
   A. You have dry eye disease
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with an ophthalmologist or optometrist (types of eye doctor)
   D. You have at least one positive diagnostic test (such as tear breakup time, tear film osmolarity, ocular surfacing staining, Schirmer test)
   E. You had a trial of or contraindication to (harmful for) to ONE ocular lubricant (such as carboxymethylcellulose [Refresh, Celluvisc, Thera Tears, Genteal, etc.], polyvinyl alcohol [Liquitears, Refresh Classic], or wetting agents [Systane, Lacrilube])
   F. You had a trial of or contraindication to (harmful for) BOTH of the following preferred agents: Restasis (cyclosporine) AND Xiidra (lifitegrast)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VARENICLINE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of dry eye disease **AND** meet the following criterion?
   - The patient has demonstrated improvement of dry eye disease

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #8.4 mL per 30 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VARENICLINE (Tyrvaya)** requires the following rule(s) be met for renewal:
   A. You have dry eye disease
   B. You have demonstrated improvement of dry eye disease

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tyrvaya.

REFERENCES

- Tyrvaya [Prescribing Information]. Princeton, NJ: Oyster Point Pharma, Inc., October 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 10/21
Client Approval: 05/23
P&T Approval: 04/23

STANDARD COMMERCIAL AND NSA DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VEDOLIZUMAB

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Entyvio will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication
   - The patient had a trial of or contraindication to ONE conventional therapy (e.g., corticosteroids [e.g., budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz) [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
     - **<u>FIRST APPROVAL:</u> Approve the 300 mg vial for 1 month with a quantity limit of #2.**
     - **<u>SECOND APPROVAL:</u> Approve for 5 months for the requested strength as follows (Enter a start date of ONE WEEK after the last date of the first approval):**
       - **300 mg vial: #1 per 56 days.**
       - **108 mg/0.68 mL pen: #1.36 mL per 28 days.**

     If no, continue to #2.

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VEDOLIZUMAB

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Entyvio will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication
   - The patient had a trial of or contraindication to ONE conventional therapy (e.g., corticosteroids [e.g., budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz) [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **<u>FIRST APPROVAL:</u> Approve the 300 mg vial for 1 month with a quantity limit of #2.**
   - **<u>SECOND APPROVAL:</u> Approve for 5 months for the requested strength as follows (Enter a start date of ONE WEEK after the last date of the first approval):**
     - **300 mg vial: #1 per 56 days.**
     - **108 mg/0.68 mL pen: #1.36 mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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VEDOLIZUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VEDOLIZUMAB (Entyvio)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   2. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Entyvio concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE standard therapy (such as corticosteroids [such as budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)
   5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

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VEDOLIZUMAB

INITIAL CRITERIA (CONTINUED)

C. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Entyvio concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   4. You have tried or have a contraindication to (harmful for you to use) ONE standard therapy (such as corticosteroids [such as budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)
   5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VEDOLIZUMAB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meet **ALL** of the following criteria?
   - Entyvio will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz) [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **300 mg vial: #1 per 56 days.**
   - **108 mg/0.68 mL pen: #1.36 mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?
   - Entyvio will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz) [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **300 mg vial: #1 per 56 days.**
   - **108 mg/0.68 mL pen: #1.36 mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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VEDOLIZUMAB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VEDOLIZUMAB (Entyvio)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   2. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have moderate to severe Crohn's disease, renewal also requires:**
   1. You will NOT use Entyvio concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   2. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

C. **If you have moderate to severe ulcerative colitis, renewal also requires:**
   1. You will NOT use Entyvio concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for an autoimmune indication (condition where your immune system attacks your own body)
   2. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate-release or extended-release), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VEDOLIZUMAB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Entyvio.

REFERENCES

- Entyvio [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; April 2024.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 05/01/24
Created: 05/14
Client Approval: 04/24
P&T Approval: 04/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VEMURAFENIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma and meet **ALL** of the following criteria?
   - The patient has a genetic mutation called BRAF V600E as detected by an FDA-approved test
   - Zelboraf will be used alone or in combination with Cotellic (cobimetinib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of Erdheim-Chester Disease **AND** meet the following criterion?
   - The patient has a genetic mutation called BRAF V600

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VEMURAFENIB (Zelboraf)** requires the following rules be met for approval:
   A. You have ONE of the following diagnoses:
      1. Unresectable or metastatic melanoma (a type of skin cancer that cannot be removed with surgery or has spread to other parts of the body)
      2. Erdheim-Chester Disease (a type of multisystem mutation)
   B. **If you have unresectable or metastatic melanoma, approval also requires:**
      1. You have a BRAF V600E mutation (a type of gene mutation) as detected by a Food and Drug Administration (FDA)-approved test
      2. Zelboraf will be used alone or in combination with Cotellic (cobimetinib)
   C. **If you have Erdheim-Chester Disease, approval also requires:**
      1. You have a BRAF V600 mutation (a type of gene mutation)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VEMURAFENIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zelboraf.

REFERENCES

- Zelboraf [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 08/11
Client Approval: 05/22
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VENETOCLAX

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) OR small lymphocytic lymphoma (SLL) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months for all strengths by GPID or GPI-14 with the following quantity limits:**
   - **Starting Pack: #42 (1 pack) per 28 days.**
   - **10mg: #2 per day.**
   - **50mg: #1 per day.**
   - **100mg: #4 per day.**

   If no, continue to #2.

2. Does the patient have a newly-diagnosed acute myeloid leukemia (AML) and meet **ONE** of the following criteria?
   - The patient is 75 years of age or older
   - The patient is 18 years of age or older with comorbidities that preclude the use of intensive induction chemotherapy

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Will Venclexta be used in combination with azacitidine or decitabine?

   If yes, **approve for 12 months for all strengths by GPID or GPI-14 with the following quantity limits:**
   - **10mg: #2 per day.**
   - **50mg: #1 per day.**
   - **100mg: #4 per day.**

   If no, continue to #4.

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VENETOCLAX

GUIDELINES FOR USE (CONTINUED)

4. Will Venclexta be used in combination with low-dose cytarabine?

   If yes, **approve for 12 months for all strengths by GPID or GPI-14 with the following quantity limits:**
   - **10mg: #2 per day.**
   - **50mg: #1 per day.**
   - **100mg: #6 per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VENETOCLAX (Venclexta)** requires that the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
      2. Small lymphocytic lymphoma (SLL: a type of blood cancer)
      3. Newly-diagnosed acute myeloid leukemia (AML: a type of blood and bone marrow cancer)

   B. **If you have chronic lymphocytic leukemia or small lymphocytic lymphoma, approval also requires:**
      1. You are 18 years of age or older

   C. **If you have newly-diagnosed acute myeloid leukemia, approval also requires:**
      1. You are 75 years of age or older, OR you are 18 years of age or older with comorbidities (additional diseases) that preclude (prevent) the use of intensive induction chemotherapy (a type of therapy to treat cancer)
      2. Venclexta will be used in combination with azacitidine or decitabine or low-dose cytarabine

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VENETOCLAX

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Venclexta.

REFERENCES

- Venclexta [Prescribing Information]. South San Francisco, CA: Genentech USA, Inc.; June 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/26/24
Created: 11/16
Client Approval: 02/24
P&T Approval: 07/19

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VERICIGUAT

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic heart failure and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has an ejection fraction of less than 45%
   - The patient is **NOT** concurrently taking long-acting nitrates or nitric oxide donors (e.g. isosorbide dinitrate, isosorbide mononitrate, transdermal nitroglycerin), riociguat, or PDE-5 inhibitors (e.g. vardenafil, tadalafil)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient had a trial of or contraindication to **ONE** of the following preferred SGLT-2 inhibitors: Farxiga, Xigduo XR, Jardiance, Synjardy
   - The patient had a trial of or contraindication to **ONE** agent from **EACH** of the following classes:
     - ACE inhibitor (e.g., enalapril, lisinopril), ARB (e.g., valsartan, candesartan), or angiotensin receptor-neprilysin inhibitor [ARNI] (e.g., sacubitril/valsartan)
     - Beta-blocker (bisoprolol, carvedilol, metoprolol succinate)
     - Aldosterone antagonists (spironolactone or eplerenone)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **VERICIGUAT (Verquvo)** requires the following rule(s) be met for approval:
   A. You have chronic heart failure
   B. You have an ejection fraction (measurement of how well your heart pumps out blood with each heartbeat) of less than 45%
   C. You are 18 years of age or older
   (Initial denial text continued on next page)

CONTINUED ON NEXT PAGE

VERICIGUAT

INITIAL CRITERIA (CONTINUED)

D. You will not be taking Verquvo together with long-acting nitrates or nitric oxide donors (such as isosorbide dinitrate, isosorbide mononitrate, transdermal nitroglycerin), riociguat, or PDE-5 inhibitors (such as vardenafil, tadalafil)
E. You have previously tried ONE of the following sodium-glucose transporter-2 inhibitors (SGLT-2 inhibitors: class of drugs) unless there is a medical reason why you cannot (contraindication): Farxiga, Xigduo XR, Jardiance, Synjardy
F. You have previously tried ONE agent from EACH of the following classes unless there is a medical reason why you cannot (contraindication):
    1. Angiotensin converting enzyme (ACE) inhibitors (such as enalapril, lisinopril), angiotensin II receptor blockers (ARB: such as valsartan, candesartan), or angiotensin receptor-neprilysin inhibitor (ARNI: such as sacubitril/valsartan)
    2. Beta-blocker (bisoprolol, carvedilol, metoprolol succinate)
    3. Aldosterone antagonists (spironolactone or eplerenone)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic heart failure and meet **ALL** of the following criteria?
    - The patient has an ejection fraction of less than 45%
    - The patient is **NOT** concurrently taking long-acting nitrates or nitric oxide donors (e.g. isosorbide dinitrate, isosorbide mononitrate, transdermal nitroglycerin), riociguat, or PDE-5 inhibitors (e.g. vardenafil, tadalafil)

    If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
    If no, do not approve.
    RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **VERICIGUAT (Verquvo)** requires the following rule(s) be met for renewal:
    A. You have chronic heart failure
    B. You have an ejection fraction (measurement of how well your heart pumps out blood with each heartbeat) of less than 45%
    (Renewal denial text continued on next page)

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VERICIGUAT

RENEWAL CRITERIA (CONTINUED)

C. You will not be taking Verquvo together with long-acting nitrates or nitric oxide donors (such as isosorbide dinitrate, isosorbide mononitrate, transdermal nitroglycerin), riociguat, or PDE-5 inhibitors (such as vardenafil, tadalafil)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Verquvo.

REFERENCES

- Verquvo [Prescribing Information]. Whitehouse Station, NJ: Merck & Co., Inc.; January 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/15/21
Created: 02/21
Client Approval: 02/21
P&T Approval: 10/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VIGABATRIN

GUIDELINES FOR USE

1. Does the patient have a diagnosis of refractory complex partial seizures (CPS) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The requested medication will be used as adjunctive therapy
   - The potential benefits outweigh the risk of vision loss
   - The patient had a trial of or contraindication to THREE antiepileptic medications, at least two of which must be generic (e.g., carbamazepine, divalproex/valproic acid, oxcarbazepine, levetiracetam IR/ER, gabapentin, zonisamide, topiramate, lamotrigine)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of infantile spasms and meet **ALL** of the following criteria?
   - The patient is 1 month to 2 years of age
   - Therapy is prescribed by or in consultation with a neurologist
   - The requested medication will be used as monotherapy
   - The potential benefits outweigh the risk of vision loss

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VIGABATRIN (Sabril, Vigadrone)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Refractory complex partial seizures (a type of seizure)
      2. Infantile spasms (a type of seizure disorder in infancy and childhood)

   (Denial text continued on the next page)

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VIGABATRIN

GUIDELINES FOR USE (CONTINUED)

B. **If you have refractory complex partial seizures, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
   3. The requested medication will be used as adjunctive (add-on) therapy
   4. The potential benefits outweigh the risk of vision loss
   5. You had a trial of or contraindication (harmful for) to THREE antiepileptic medications, at least two of which must be generic (seizure drugs such as carbamazepine, divalproex/valproic acid, oxcarbazepine, levetiracetam immediate-release/extended-release, gabapentin, zonisamide, topiramate, lamotrigine)

C. **If you have infantile spasms, approval also requires:**
   1. You are 1 month to 2 years of age
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
   3. The requested medication will be used as monotherapy (one drug for treatment)
   4. The potential benefits outweigh the risk of vision loss

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sabril.

REFERENCES

- Sabril [Prescribing Information]. Deerfield, IL: Lundbeck, October 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/22/23
Created: 05/22
Client Approval: 05/23
P&T Approval: 04/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VISMODEGIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic basal cell carcinoma **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of locally advanced basal cell carcinoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has recurred following surgery or the patient is not a candidate for surgery or radiation

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VISMODEGIB (Erivedge)** requires the following rule(s) be met for approval:
   A. You have metastatic basal cell carcinoma or locally advanced basal cell carcinoma (type of skin cancer that has spread in the body or is advanced but has not spread)
   B. You are 18 years of age or older
   C. **If you have locally advanced basal cell carcinoma, approval also requires:**
      1. Your cancer has returned after surgery OR you are not a candidate for surgery or radiation

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VISMODEGIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Erivedge.

REFERENCES

- Erivedge [Prescribing Information]. South San Francisco, CA: Genentech, Inc., July 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 02/12
Client Approval: 12/21
P&T Approval: 01/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VOCLOSPORIN

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of active lupus nephritis (LN) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist or nephrologist
   - The requested medication will be used in combination with a background immunosuppressive therapy regimen (e.g., mycophenolate mofetil, corticosteroids)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   APPROVAL TEXT: Renewal requires improvement in renal response from baseline laboratory values (eGFR or proteinuria) and/or clinical parameters (e.g., fluid retention, use of rescue drugs, glucocorticoid use).

   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **VOCLOSPORIN (Lupkynis)** requires the following rule(s) be met for approval:
   A. You have active lupus nephritis (LN: inflammation of the kidneys caused by lupus when the immune system attacks its own tissues)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints) or nephrologist (doctor who specializes in the kidney)
   D. The requested medication will be used in combination with a background immunosuppressive therapy regimen (such as mycophenolate mofetil, corticosteroids)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VOCLOSPORIN

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of active lupus nephritis (LN) **AND** meet the following criterion?
   - The patient has improvement in renal response from baseline laboratory values (i.e., eGFR or proteinuria) and/or clinical parameters (e.g., fluid retention, use of rescue drugs, glucocorticoid use)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VOCLOSPORIN (Lupkynis)** requires the following rule(s) be met for renewal:
   A. You have active lupus nephritis (LN: inflammation of the kidneys caused by lupus when the immune system attacks its own tissues)
   B. You have improvement in renal response from baseline laboratory values (eGFR [measurement of kidney function] or proteinuria [level of protein in urine]) and/or clinical parameters (such as fluid retention, use of rescue drugs, glucocorticoid use)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lupkynis.

REFERENCES

- Lupkynis [Prescribing Information]. Victoria, BC: Aurinia Pharmaceuticals Inc.; January 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/15/21
Created: 02/21
Client Approval: 02/21
P&T Approval: 10/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VONOPRAZAN

GUIDELINES FOR USE

INITIAL CRITERIA

1. Does the patient have a diagnosis of *Helicobacter pylori (H. pylori)* infection and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to a bismuth-based quadruple regimen (i.e., bismuth/tetracycline/metronidazole plus PPI [e.g., omeprazole, lansoprazole])

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The request is for Voquezna 20mg and will be used in combination with amoxicillin
   - The request is for Voquezna 20mg and will be used in combination with amoxicillin and clarithromycin
   - The request is for Voquezna Dual Pak
   - The request is for Voquezna Triple Pak

   If yes, **approve for 30 days by HICL or GPI-10 for the requested agent as follows:**
   - **Voquezna 20mg: #28 per 14 days for 1 fill.**
   - **Voquezna Dual Pak: #112 per 14 days for 1 fill.**
   - **Voquezna Triple Pak: #112 per 14 days for 1 fill.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

VONOPRAZAN

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of erosive esophagitis and meet **ALL** of the following criteria?
   - The request is for Voquezna
   - The patient is 18 years of age or older
   - The patient's diagnosis is confirmed by endoscopy (e.g., Los Angeles Classification of Reflux Esophagitis Grade A-D)
   - The patient had an 8-week trial of or contraindication to ONE generic proton pump inhibitor (e.g., omeprazole, lansoprazole)

   If yes, **approve for 8 weeks by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VONOPRAZAN (Voquezna Dual Pak, Voquezna Triple Pak, Voquezna)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. *Helicobacter pylori (H. pylori*: a type of bacteria*)* infection
      2. Erosive esophagitis (a type of digestive disorder)

   B. **If you have a *Helicobacter pylori* infection, approval also requires:**
      1. You are 18 years of age or older
      2. You have tried or have a contraindication to (harmful for you to use) a bismuth-based quadruple regimen (bismuth/tetracycline/metronidazole plus proton pump inhibitor [PPI: such as omeprazole, lansoprazole])
      3. You meet ONE of the following:
         a. Your request is for Voquezna 20mg in combination with amoxicillin
         b. Your request is for Voquezna 20mg in combination with amoxicillin and clarithromycin
         c. Your request is for Voquezna Dual Pak
         d. Your request is for Voquezna Triple Pak

   C. **If you have erosive esophagitis, approval also requires:**
      1. Your request is for Voquezna
      2. You are 18 years of age or older
      3. Your diagnosis is confirmed by endoscopy (a procedure to look inside your body) (such as Los Angeles Classification of Reflux Esophagitis Grade A-D: a tool that your doctor can use to rate the severity of the disease)
      4. You had an 8-week trial of or contraindication to (harmful for you to use) ONE generic proton pump inhibitor (such as omeprazole, lansoprazole)

   (Initial denial text continued on the next page)

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VONOPRAZAN

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE

VONOPRAZAN

RENEWAL CRITERIA

NOTE: For the diagnosis of *Helicobacter pylori* (*H. pylori*) infection, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of erosive esophagitis **AND** the request is for Voquezna?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the request for a continuation of treatment (i.e., the patient recently received an initial prior authorization approval for 8 weeks)?

   If yes, continue to #3.
   If no, refer to initial criteria.

3. Has the patient maintained a clinical response while on Voquezna?

   If yes, **approve for 24 weeks by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VONOPRAZAN (Voquezna Dual Pak, Voquezna Triple Pak, Voquezna)** requires the following rule(s) be met for renewal:
   A. You have erosive esophagitis (a type of digestive disorder)
   B. Your request is for Voquezna
   C. You have maintained a clinical response on Voquezna (the treatment is working)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VONOPRAZAN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Voquezna TRIPLE PAK, Voquezna DUAL PAK, and Voquezna.

REFERENCES

- Voquezna TRIPLE PAK, Voquezna DUAL PAK [Prescribing Information]. Buffalo Grove, IL: Phathom Pharmaceuticals, Inc.; October 2023.
- Voquezna [Prescribing Information]. Buffalo Grove, IL: Phathom Pharmaceuticals, Inc.; November 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/13/24
Created: 06/22
Client Approval: 03/24
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VOSORITIDE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of achondroplasia **AND** meet the following criterion?
   - The patient has open epiphyses

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 vial per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VOSORITIDE (Voxzogo)** requires the following rule(s) be met for approval:
   A. You have achondroplasia (a type of bone condition)
   B. You have open epiphyses (the end part of a long bone)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Voxzogo.

REFERENCES

- Voxzogo [Prescribing Information]. Novato, CA: BioMarin Pharmaceutical, Inc.; October 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/13/23
Created: 01/22
Client Approval: 10/23
P&T Approval: 01/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VOXELOTOR

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of sickle cell disease and meet **ALL** of the following criteria?
   - The patient is 4 years of age or older
   - The patient has a hemoglobin of less than 10.5 g/dL
   - Therapy is prescribed by or in consultation with a hematologist
   - The patient is having symptoms of anemia which are interfering with activities of daily living
   - The patient had a trial of or contraindication to hydroxyurea

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the request for the 300 mg tablet for oral suspension **AND** the patient weighs less than 40 kg?

   If yes, **approve 300mg tablets for oral suspension for 6 months by GPID or GPI-14 with a quantity limit of #5 per day.**
   If no, continue to #3.

3. Is the request for the 300 mg tablet for oral suspension and the patient meets **ALL** of the following criteria?
   - The patient weighs 40 kg or more
   - The patient has tried or has a contraindication to Oxbryta 500mg tablets
   - The patient is unable to swallow Oxbryta 500mg tablets

   If yes, **approve 300mg tablets for oral suspension for 6 months by GPID or GPI-14 with a quantity limit of #5 per day.**

   If no, **approve for 6 months by GPID or GPI-14 as follow:**
   - **500mg tablets: #3 per day.**
   - **300mg tablets: #3 per day.**

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VOXELOTOR

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VOXELOTOR (Oxbryta)** requires the following rule(s) be met for approval:

A. You have sickle cell disease (a type of blood disorder)
B. You are 4 years of age or older
C. Your hemoglobin (a type of blood cell) is less than 10.5 g/dL
D. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
E. You are having symptoms of anemia (a type of blood condition) which are interfering with activities of daily living
F. You had a trial of or contraindication (harmful for) to hydroxyurea
G. **If the request is for the 300 mg tablets for oral suspension, approval also requires ONE of the following:**
    1. You weigh less than 40 kilograms
    2. You weigh 40 kilograms or more and meet ALL of the following:
        a. You have tried or have a contraindication (harmful for) to Oxbryta 500mg tablets
        b. You are unable to swallow Oxbryta 500mg tablets

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of sickle cell disease **AND** meet the following criterion?
    - The patient has maintained an improvement in symptoms associated with anemia

    If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
    - **500mg tablets: #3 per day.**
    - **300mg tablets: #3 per day.**
    - **300mg tablets for oral suspension: #5 per day.**

    If no, do not approve.
    DENIAL TEXT: See the renewal denial text at the end of the guideline.

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VOXELOTOR

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VOXELOTOR (Oxbryta)** requires the following rule(s) be met for renewal:
A. You have sickle cell disease (a type of blood disorder)
B. You have maintained an improvement in symptoms associated with anemia (a type of blood condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Oxbryta.

REFERENCES

- Oxbryta [Prescribing Information]. South San Francisco, CA: Global Blood Therapeutics, Inc., October 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/16/23
Created: 02/20
Client Approval: 01/23
P&T Approval: 01/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZANUBRUTINIB

GUIDELINES FOR USE

1. Does the patient have a diagnosis of mantle cell lymphoma (MCL) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least ONE prior therapy (e.g., R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone])
   - The patient had a trial of or contraindication to the following preferred agent: Calquence (acalabrutinib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of Waldenstrom's macroglobulinemia (WM) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to the following preferred agent: Imbruvica (ibrutinib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of relapsed or refractory marginal zone lymphoma (MZL) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least ONE anti-CD20-based regimen (e.g., rituximab)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #4.

4. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Imbruvica (ibrutinib), Calquence (acalabrutinib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #5.

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ZANUBRUTINIB

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of relapsed or refractory follicular lymphoma (FL) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Brukinsa will be used in combination with Gazyva (obinutuzumab)
   - Brukinsa will be used after at least TWO lines of systemic therapy (e.g., lenalidomide with rituximab)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZANUBRUTINIB (Brukinsa)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Mantle cell lymphoma (MCL: a type of blood cancer)
      2. Waldenstrom's macroglobulinemia (WM: a type of blood cancer)
      3. Relapsed or refractory marginal zone lymphoma (MZL: a type of blood cancer that has returned or did not respond to treatment)
      4. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
      5. Small lymphocytic lymphoma (SLL: a type of blood cancer)
      6. Relapsed or refractory follicular lymphoma (FL: a type of blood cancer that has returned or did not respond to treatment)

   B. **If you have mantel cell lymphoma, approval also requires:**
      1. You are 18 years of age or older
      2. You have received at least ONE prior therapy (such as R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone])
      3. You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Calquence (acalabrutinib)

   C. **If you have Waldenstrom's macroglobulinemia, approval also requires:**
      1. You are 18 years of age or older
      2. You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Imbruvica (ibrutinib)

   D. **If you have relapsed or refractory marginal zone lymphoma, approval also requires:**
      1. You are 18 years of age or older
      2. You have received at least ONE anti-CD20-based regimen (a type of blood cancer treatment plan, such as rituximab)

   (Denial text continued on the next page)

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ZANUBRUTINIB

GUIDELINES FOR USE (CONTINUED)

E. **If you have chronic lymphocytic leukemia or small lymphocytic lymphoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Imbruvica (ibrutinib), Calquence (acalabrutinib)

F. **If you have relapsed or refractory follicular lymphoma, approval also requires:**
   1. You are 18 years of age or older
   2. Brukinsa will be used in combination with Gazyva (obinutuzumab)
   3. Brukinsa will be used after at least TWO lines of systemic therapy (such as lenalidomide with rituximab)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Brukinsa.

REFERENCES

- Brukinsa [Prescribing Information]. San Mateo, CA: BeiGene USA, Inc.; March 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/15/24
Created: 02/20
Client Approval: 03/24
P&T Approval: 04/24

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZAVEGEPANT

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the acute treatment of migraines and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Zavzpret will NOT be used concurrently with other cGRP inhibitors (e.g., Ubrelvy [ubrogepant]) for the acute treatment of migraines
   - The patient had a trial of or contraindication to ONE triptan (e.g., Imitrex [sumatriptan], Maxalt [rizatriptan])
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Reyvow (lasmiditan), Nurtec ODT (rimegepant), Ubrelvy (ubrogepant)
   - The patient is unable to tolerate oral medications

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #8 per 30 days.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZAVEGEPANT (Zavzpret)** requires the following rule(s) be met for approval:
   A. The request is for the acute (quick onset) treatment of migraines (a type of headache)
   B. You are 18 years of age or older
   C. You will NOT use Zavzpret concurrently (at the same time) with other calcitonin gene-related peptide (cGRP) inhibitors (such as Ubrelvy [ubrogepant]) for the acute treatment of migraines
   D. You have tried or have a contraindication (harmful for) to ONE triptan (such as Imitrex [sumatriptan], Maxalt [rizatriptan])
   E. You have tried or have a contraindication (harmful for) to TWO of the following medications: Reyvow (lasmiditan), Nurtec ODT (rimegepant), Ubrelvy (ubrogepant)
   F. You are NOT able to tolerate oral medications

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZAVEGEPANT

RENEWAL CRITERIA

1. Is the request for the acute treatment of migraines **AND** the patient meets the following criterion?
   - Zavzpret will NOT be used concurrently with other cGRP inhibitors (e.g., Ubrelvy [ubrogepant]) for the acute treatment of migraines

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (e.g., Migraine Assessment of Current Therapy [Migraine-ACT])?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per 30 days.**
   If no, continue to #3.

3. Has the patient experienced clinical improvement as defined by **ONE** of the following criteria?
   - Ability to function normally within 2 hours of dose
   - Headache pain disappears within 2 hours of dose
   - Therapy works consistently in majority of migraine attacks

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per 30 days.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZAVEGEPANT (Zavzpret)** requires the following rule(s) be met for approval:
   A. The request is for the acute (quick onset) treatment of migraines (a type of headache)
   B. You will NOT use Zavzpret concurrently (at the same time) with other calcitonin gene-related peptide (cGRP) inhibitors (such as Ubrelvy [ubrogepant]) for the acute treatment of migraines
   C. You meet ONE of the following:
      1. You have experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (assessment tool used to help guide treatment such as migraine assessment of current therapy [MIGRAINE-ACT])
      2. You have experienced clinical improvement as defined by ONE of the following:
         a. Ability to function normally within 2 hours of dose
         b. Headache pain disappears within 2 hours of dose
         c. Treatment works consistently in a majority of migraine attacks

   (Renewal denial text continued on the next page)

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ZAVEGEPANT

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zavzpret.

REFERENCES

- Zavzpret [Prescribing Information]. New York, NY: Pfizer, Inc.; March 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 06/23
Client Approval: 11/23
P&T Approval: 10/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZILUCOPLAN

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) and meet **ALL** of the following criteria?
   - The patient is 18 years of age and older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient's diagnosis is confirmed by a positive serologic test for anti-acetylcholine receptor (AChR) antibody
   - The patient is Myasthenia Gravis Foundation of America class II, III, or IV
   - The patient had a trial of or contraindication to ONE corticosteroid (e.g., prednisone)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO non-steroidal immunosuppressive therapies (e.g., azathioprine, cyclophosphamide, methotrexate)
   - The patient had a trial of or contraindication to ONE non-steroidal immunosuppressive therapy if on chronic plasmapheresis or plasma exchange

   If yes, **approve the requested strength for 6 months by GPID or GPI-14 with the following quantity limits:**
   - **16.6mg syringe: #0.416mL per day.**
   - **23mg syringe: #0.574mL per day.**
   - **32.4mg syringe: #0.81mL per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ZILUCOPLAN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ZILUCOPLAN (Zilbrysq)** requires the following rule(s) be met for approval:

A. You have generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
B. You are 18 years of age and older
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
D. Your diagnosis is confirmed by a positive serologic test for anti-acetylcholine receptor (AChR) antibody (a type of blood test that shows you have myasthenia gravis)
E. You have Myasthenia Gravis Foundation of America class II, III, or IV (types of severity of disease)
F. You had a trial of or contraindication to (harmful for you to use) ONE corticosteroid (such as, prednisone)
G. You meet ONE of the following:
    1. You had a trial of or contraindication to (harmful for you to use) TWO non-steroidal immunosuppressive therapies (such as, azathioprine, cyclophosphamide, methotrexate)
    2. You had a trial of or contraindication to (harmful for you to use) ONE non-steroidal immunosuppressive therapy if you are on chronic plasmapheresis or plasma exchange (types of blood therapy)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ZILUCOPLAN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) **AND** meet the following criterion?
   - The patient has had clinical benefit compared to baseline according to validated gMG instruments (e.g., Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **16.6mg syringe: #0.416mL per day.**
   - **23mg syringe: #0.574mL per day.**
   - **32.4mg syringe: #0.81mL per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZILUCOPLAN (Zilbrysq)** requires the following rule(s) be met for renewal:
   A. You have generalized myasthenia gravis (gMG: chronic autoimmune disorder)
   B. You have had clinical benefit compared to baseline according to validated gMG instruments (such as, the Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zilbrysq.

REFERENCES

- Zilbrysq [Prescribing Information]. Smyrna, GA: UCB, Inc.; October 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/22/24
Created: 01/24
Client Approval: 01/24
P&T Approval: 04/23

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZONISAMIDE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of partial-onset seizures and meet **ALL** of the following criteria?
   - The patient is 16 years of age or older
   - Zonisade will be used as adjunctive treatment
   - The patient is unable to swallow zonisamide capsules

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #30 mL per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZONISAMIDE (Zonisade)** requires the following rule(s) be met for approval:
   A. You have partial-onset seizures (a type of seizure)
   B. You are 16 years of age or older
   C. Zonisade will be used as adjunctive (add-on) treatment
   D. You are unable to swallow to zonisamide capsules

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zonisade.

REFERENCES

- Zonisade [Prescribing Information]. Wilmington, MA: Azurity Pharmaceuticals, Inc., July 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/23
Created: 11/22
Client Approval: 11/22
P&T Approval: 10/22

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZURANOLONE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of postpartum depression (PPD)?

   If yes, **approve for 30 days by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **20mg: #28 per 14 days for 1 fill.**
   - **25mg: #28 per 14 days for 1 fill.**
   - **30mg: #14 per 14 days for 1 fill.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZURANOLONE (Zurzuvae)** requires the following rule(s) be met for approval:
   A. You have postpartum depression (PPD: a type of depression that occurs after giving birth)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zurzuvae.

REFERENCES

- Zurzuvae [Prescribing Information]. Cambridge, MA: Biogen Inc.; November 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/22/24
Created: 11/23
Client Approval: 01/24
P&T Approval: 07/23