Kaiser Permanente Mid-Atlantic States Region (KPMAS)

Virginia Medicaid

Prior Authorization and Step Therapy Criteria

Effective 07/19/2025

Reference:

1. KPMAS Regional Pharmacy and Therapeutics (P&T) Committee
   P&T Approval/Revision Date: 04/04/2025; 02/07/2025, 12/06/2024, 10/04/2024, 08/02/2024, 06/07/2024, 12/01/2023, 10/06/2023, 08/04/2023, 06/02/2023, 04/07/2023, 02/03/2023, 12/06/2022, 10/04/2022, 07/05/2022, 06/07/2022, 04/05/2022; 02/04/2022; 12/3/2021, 05/07/2021, 04/05/2021, 02/05/21, 11/06/20, 9/3/2020; 6/5/2020; 12/6/2019; 10/5/2018

2. DMAS Virginia Medicaid's Preferred Drug List/Common Core Formulary
   https://www.virginiamedicaidpharmacyservices.com/provider/preferred-drug-list/

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Agents to Treat Multiple Sclerosis – Modestly Effective Therapy

Last revised 06/09/2023 (Effective 07/01/2023)

Generic	Brand
PEGINTERFERON BETA-1A	PLEGRIDY SOPN
DIROXIMEL FUMARATE	VUMERITY

Prior Authorization Criteria follows the state's criteria (DMAS)

Length of Authorization: 12 months

Initial Therapy:

- Member cannot be changed to a preferred drug. (e.g. Avonex, Betaseron, Copaxone, Tecfidera, Kesimpta) Acceptable reasons include: **AND**
  - Allergy to preferred drug.
  - Contraindication to or drug-to-drug interaction with preferred drug.
  - History of unacceptable/toxic side effects to preferred drug.
  - Member's condition is clinically stable; changing to a preferred drug might cause deterioration of the member's condition.
- Member has therapeutic failure of at least two preferred drugs within the same class as appropriate for diagnosis

Additional criteria for Vumerity only:

- Member tried and failed at least one preferred injectable (see above) and Tecfidera
- Member is using for Vumerity's approved indication - treatment of relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and/or active secondary progressive disease?

Agents to Treat Multiple Sclerosis – Highly Effective Therapy

Generic	Brand
CLADRIBINE	MAVENCLAD
SIPONIMOD FUMARATE	MAYZENT
OZANIMOD	ZEPOSIA
PONESIMOD	PONVORY

Prior Authorization Criteria follows the state's criteria (DMAS)

Length of Authorization: 12 months

Initial Review Criteria for Mavenclad, Mayzent, Zeposia, and Ponvory:

- Member is ≥18 years old AND
- Has had a baseline MRI before initiating the first treatment course, within 3 months prior, AND
- Has at least one of the following diagnoses, AND:
  - Relapsing-remitting Disease (RRMS)
  - Secondary Progressive Disease (SPMS) with relapses
  - Clinically Isolated Syndrome (CIS)
  - Member has had ≥ 1 relapse within the previous two years
  - Member has new and unequivocally enlarging T2 contrast enhancing lesions as evidenced by MRI and has had ≥ 1 relapse in the previous 12 months
- Failed an adequate trial (≥3 months) of, or has a documented allergy or intolerance to, or is not a candidate for other preferred MS agents (e.g., Avonex, Betaseron, Copaxone), AND
- Member is NOT using requested drug therapy in addition to another DMT, AND
- Member has been screened for the presence of tuberculosis according to local guidelines, AND
- Member has been tested for antibodies to the varicella zoster virus (VZV) or received immunization for VZV four weeks prior to beginning therapy, AND
- Member has been evaluated and screened for the presence of hepatitis B and hepatitis C virus (HBV/HCV) prior to initiating treatment, AND

If the authorization is for Mavenclad:

- Lymphocyte count ≥ 800 cells/mL prior to start of therapy, AND
- Women of childbearing age are not pregnant AND that members of reproductive potential use effective contraception during treatment with therapy and for at least six months after the last dose, AND
- Member does not have human immunodeficiency virus (HIV) infection

If the authorization is for Mayzent:

- Member has been tested for CYP2C9 variant status to determine genotyping (required for dosing)
- Attest that member does not have CYP2C9*3/*3 Genotype

If the authorization is for Mayzent, Zeposia, or Ponvory:

- Provider attestation that members of childbearing age are NOT pregnant, and members of reproductive potential must use effective contraception during treatment,
- Member obtained a baseline electrocardiogram (ECG), AND

- Member had a baseline ophthalmic evaluation of the fundus, including the macula, before starting treatment, AND
- Attest that the member does NOT have any of the following: AND
    - Recent Myocardial Infarction
    - Unstable Angina
    - Stroke
    - Transient Ischemic Attack
    - Decompensated Heart Failure with Hospitalization
    - Class III/IV Heart Failure within the Previous 6 Months
    - Prolonged QTc Interval at Baseline (> 500 msec)
    - History of Mobitz Type II second or third-degree atrioventricular block or sick sinus syndrome (unless treated with a functioning pacemaker)

Mayzent™ will NOT be used in combination with the following:

- Moderate or strong CYP3A4 inducers (e.g., modafinil, efavirenz, etc.) in members with a CYP2C9*1/*3 and CYP2C9*2/*3 genotype
- Drug regimens that contain CYP2C9/CY3A4 dual inhibitors (e.g., fluconazole)
- Moderate CYP2C9 inhibitor plus a moderate-to-strong CYP3A4 inhibitor
- Other antineoplastic, immunosuppressive or immunomodulating drugs

Updated Criteria: Zeposia

- Confirmation that Zeposia will not be used in the following circumstances:
- Initiating therapy after previous treatment with alemtuzumab; OR
- In combination with:
- Monoamine oxidase inhibitor (MAOI) (e.g., selegiline, phenelzine, linezolid); OR
- Drugs known to prolong the QT-interval (e.g., fluoroquinolone or macrolide antibiotics, venlafaxine, fluoxetine, quetiapine, ziprasidone, sumatriptan, zolmitriptan), OR
- Strong cytochrome p450 2C8 (CYP2C8) inhibitors (e.g., gemfibrozil) or inducers (e.g., rifampin); OR
- BCRP inhibitors (e.g., cyclosporine, eltrombopag); OR Adrenergic or serotonergic drugs which can increase norepinephrine or serotonin (e.g., opioids, selective serotonin reuptake inhibitors [SSRIs], selective norepinephrine reuptake inhibitors [SNRIs], tricyclics, tyramine); OR
- Foods with large amounts of tyramine (e.g., > 150 mg), such as aged cheeses, cured meats, craft/unfiltered beers, beans); OR
- Other antineoplastic, immunosuppressive or immunomodulating drugs (Note: if there is a history of prior use of these drugs, consider possible unintended additive immunosuppressive effects); AND
- Patient will not receive live vaccines during and at least 4 weeks prior to and 12 weeks after treatment; AND
- Patient does not have an active infection, including clinically important localized infections

Neuromuscular Transmission – Potassium Channel Blocker

Adapted from DMAS Preferred Drug List

Last revised 10/02/2023 (Effective 12/05/2023)

Generic	Brand
DALFAMPRIDINE	AMPYRA

Prior Authorization Criteria follows the state's criteria (DMAS)
Length of Authorization: 12 months
Initial Review Criteria: • Member has a documented diagnosis of multiple sclerosis (MS), **AND** • Member has a gait disorder or difficulty walking, **AND** • Member has documentation of baseline timed 25-foot walk test, **AND** • Member's renal function estimated (using glomerular filtration rate (eGFR) or creatinine clearance (CrCl) to be >50 mL/min, **AND** • Member does not have history of seizures • Member has tried other preferred agents (e.g., Avonex, Betaseron, Copaxone) **Continuation of Therapy:** • Member has current documentation of timed 25-foot walk test

Neuromuscular Transmission – Potassium Channel Blocker (Cont'd)

Last revised: 2/6/2024

Generic	Brand
AMIFAMPRIDINE PHOSPHATE	FIRDAPSE

Prior Authorization Criteria:
Length of Authorization: • Initial: 6 months • Reauthorization: 12 months
Initial Review Criteria: • Prescriber is a Neurologist, AND • Documented confirmed diagnosis of Lambert-Eaton metabolic syndrome (LEMS) based on clinical, serologic, and electrodiagnostic exam AND • Patient is ≥18 years for Firdapse, AND • Patient is ambulatory, AND • Patient does NOT have a history of seizures or active brain metastases • Forced vital capacity (%FVC) ≥60%
Continuation of Therapy Criteria: • ECG, renal function, and liver function testing completed annually AND • Patient is still ambulatory AND • Patient has NOT developed epileptic seizures AND • Patient is adherent to therapy AND • Patient has documented improvement from baseline

Amyloidosis Agents-Transthyretin (TTR) Suppression

Prior Authorization Criteria follows the state's criteria (DMAS)

Generic	Brand	HICL	GSN	Representative NDC
EPLONTERSEN SODIUM	WAINUA SOAJ 45 MG/0.8ML	49355	085619	00310940001

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a specialist in the area of the member's diagnosis, or the prescriber has consulted with a specialist in the area of the member's diagnosis,
- Patient is ≥18 years,
- Diagnosis of Polyneuropathy of Hereditary Transthyretin-mediated Amyloidosis (hATTR-PN) confirmed by testing (e.g., genetic testing, biopsy),
- Patient has clinical manifestations of polyneuropathy (e.g., neuropathic pain, altered sensation, numbness, tingling, impaired balance, motor disability),
- Patient will avoid using this medication in combination with inotersen (Tegsedi), tafamidis (Vyndamax), tafamidis meglumine (Vyndaqel), patisiran (Onpattro), or vutrisiran (Amvuttra),
- Prescriber will supplement vitamin A at the recommended daily allowance as appropriate and refer to an ophthalmologist if ocular symptoms suggestive of vitamin A deficiency (e.g., night blindness, dry eyes) occur,
- Patient has NOT received a liver transplant

Continuation of Therapy Criteria:

- Patient continues to meet initial criteria above,
- Patient continues to experience clinical benefit from the requested treatment,
- Patient is free from unacceptable toxicity

Amyotrophic Lateral Sclerosis Agents

Last Revised: 1/31/2025; Effective date: 4/1/2025

Generic	Brand	HICL	GSN	Representative NDC
EDARAVONE	RADICAVA ORS STARTER KIT SUSP 105 MG/5 ML	44252	083378	70510232101
EDARAVONE	RADICAVA ORS SUSP 105 MG/5 ML	44252	083378	70510232201

Prior Authorization Criteria:

Length of Authorization:

- Initial: 3 months
- Reauthorization: 6 months

Initial Review Criteria:

- Prescriber is a Neurologist,
- AND ALS Functional Rating Scale –Revised (ALSFRS-R) score of 2 points or better on each of the 12 items within past 2 months,
- AND clinical ALS diagnosed by a neurologist with duration of 2 years or less from onset for first symptom,
- AND forced vital capacity (%FVC) $\geqslant$ 80% within past 2 months,
- AND patient is currently taking riluzole or has previously tried riluzole, unless contraindicated

Continuation of Therapy Criteria:

- Documentation of positive clinical response,
- AND specialist follow-up occurred since last review,
- AND patient does not have any of the following:
    - %FVC $\leqslant$ 50% and blood gas PaCO2 >45 mmHg
    - Significant clinical decline based on ALSFRS-R and/or %FVC status
    - Non-adherence to follow-up assessments
    - Patient is requiring hospice care

Nuclear Factor Erythroid 2-Rel. Factor 2 Activator

Last Revised 2/6/2024

Generic	Brand	HICL	GSN	Representative NDC
OMAVELOXOLONE	SKYCLARYS CAPS 50 MG	48741	084475	73179025090

Prior Authorization Criteria:

Length of Authorization:

- Initial: 3 months
- Reauthorization: 6 months

Initial Review Criteria:

- Prescriber is a Neurologist, Pediatric Neurologist, or Medical Geneticist,
- AND patient is ≥16 years and ≤40 years of age,
- AND patient has diagnosis of Friedreich's ataxia with confirmatory genetic testing,
- AND patient has a modified Friedreich's Ataxia Rating Scale (mFARS) score ≥20 and ≤80,
- AND patient has a left ventricular ejection fraction (LVEF) ≥40%,
- AND patient is using effective contraception, if patient is of childbearing potential

Continuation of Therapy Criteria:

- Documentation of positive clinical response,
- AND specialist follow-up occurred since last review,
- AND documentation of completing the following labs:
  - SCr, if patient has clinically significant renal disease
  - Liver function tests (ALT, AST, bilirubin), BNP, and lipids
- AND patient does not have any of the following:
  - Increase in transaminase levels >5X ULN or >3X ULN with evidence of liver dysfunction
  - Becomes wheelchair bound or non-ambulatory
  - Intolerance to medication
  - Documented non-adherence to medication
  - Pregnancy or breastfeeding

Anthelmintics

Generic	Brand
MEBENDAZOLE	EMVERM

Prior Authorization Criteria:

Length of Authorization:

- Initial: 1 month
- Reauthorization: N/A; treatment may be repeated in 3 weeks if necessary

Initial Review Criteria:

- Prescriber is an Infectious Disease Specialist, AND
- Diagnosis of *enterobius vermicularis* (pinworm), AND
- Patient has had a trial or contraindication to both pyrantel pamoate and albendazole
    - o Approve treatment as: 100 mg x 1; may repeat in 3 weeks if necessary

-OR-

- Prescriber is an Infectious Disease Specialist, AND
- Confirmed diagnosis of *ascaris lumbricoides* (common roundworm), AND
- Patient has had a trial or contraindication to both pyrantel pamoate and albendazole
    - o Approve treatment as: 100 mg BID x 3 days; may repeat in 3 weeks if necessary

-OR-

- Prescriber is an Infectious Disease Specialist, AND
- Confirmed diagnosis of *trichuris trichiura* (whipworm), AND
- Patient has had a trial or contraindication to albendazole
    - o Approve treatment as: 100 mg BID x 3 days; may repeat in 3 weeks if necessary

-OR-

- Prescriber is an Infectious Disease Specialist, AND
- Confirmed diagnosis of *ancylostoma duodenale* (common hookworm), AND
- Patient has had a trial or contraindication to albendazole
    - o Approve treatment as: 100 mg BID x 3 days; may repeat in 3 weeks if necessary

-OR-

- Prescriber is an Infectious Disease Specialist, AND
- Confirmed diagnosis of *necator americanus* (American hookworm), AND
- Patient has had a trial or contraindication to albendazole
    - o Approve treatment as: 100 mg BID x 3 days; may repeat in 3 weeks if necessary

-OR-

- Prescriber is an Infectious Disease Specialist, AND
- Cystic hydatid disease, AND
- Patient has had treatment failure or contraindication to albendazole
    - o Approve treatment as: 100 mg BID x 3 days; may repeat in 3 weeks if necessary

Notes

- Please approve brand formulation, this is KP-preferred and adjudicates as generic

Anti-Arthritic – Folate Antagonist Agents

Generic	Brand
METHOTREXATE	OTREXUP; RASUVO

Prior Authorization Criteria follows the state's criteria (DMAS)

- **Length of Authorization:**
  6 months initial; 12 months continuation (6 months if using for PsO)

Initial Review Criteria:

- Member has a diagnosis of at least one of the following
  - Rheumatoid Arthritis (RA)
  - Plaque Psoriasis (PsO)
  - Polyarticular juvenile idiopathic arthritis (pJIA)

- Member has an allergy or contraindication to benzoyl alcohol or other preservative contained in generic injectable, AND
- If this is being used for Rheumatoid Arthritis (RA): member had had therapeutic failure to two preferred DMARD agents
- If this is being used for Polyarticular juvenile idiopathic arthritis (pJIA): member has had therapeutic failure to two preferred NSAIDS agents
- If this is being used for Psoriasis: member has had therapeutic failure on a topical psoriasis agent (emollients and/or topical corticosteroids, topical retinoids, topical vitamin D analogs, and topical tacrolimus AND pimecrolimus)

Continuation criteria: member is followed by a physician for monitoring of renal and hepatic function and complete blood counts with differential and platelet count

Anticonvulsant – Cannabinoid Type

Last revised 07.15.2022

Generic	Brand
CANNABIDIOL	EPIDIOLEX SOLN 100 MG/ML

Prior Authorization Criteria follows the state's criteria (DMAS)
Length of Authorization: 12 months
Initial Review Criteria: • Member is ≥1 years? AND • Diagnosed with Epilepsy and recurrent seizures including o Dravet Syndrome, or o Lennox-Gastaut Syndrome, or o Tuberous Sclerosi

Antidepressant – Postpartum Depression (PPD)

Adapted from DMAS Preferred Drug List

Generic	Brand	HICL	GSN	Representative NDC
ZURANOLONE	ZURZUVAE CAPS 20 MG	49127	085130	64406002901
ZURANOLONE	ZURZUVAE CAPS 25 MG	49127	085131	64406003002
ZURANOLONE	ZURZUVAE CAPS 30 MG	49127	085132	64406003101

Prior Authorization Criteria:

Length of Authorization:

- Initial: 14 days
- Reauthorization: N/A – one time authorization only

Initial Review Criteria:

- Patient is ≥18 years of age, AND
- Patient has a diagnosis of postpartum depression (PPD) based on Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria for a major depressive episode (DSM-5), AND
- Patient is not currently pregnant, and is using effective contraception

Continuation of Therapy Criteria: N/A – one time authorization only

Antifibrotic Therapy- Pyridone Analogs

Last revised: 1/29/2024; Effective date: 4/2/2024

Generic	Brand
PIRFENIDONE	ESBRIET

Prior Authorization Criteria:
Length of Authorization: • Initial: 12 months • Reauthorization: 12 months
Initial Review Criteria: • Prescriber is a Pulmonologist, • AND if ordering brand Esbriet, patient has tried and failed prior use of pirfenidone (generic Esbriet), • AND patient is a non-smoker, • AND patient is not receiving concomitant treatment with pirfenidone or any CYP1A2 inhibitors (e.g., fluvoxamine, ciprofloxacin), • AND using for one of the following diagnoses: o Idiopathic pulmonary fibrosis (IPF): ▪ NO known cause of interstitial lung disease o OR diagnosis of systemic sclerosis associated with interstitial lung disease (SSc-ILD) with greater than or equal to 10% fibrosis on a chest HRCT scan (conducted within last 12 months)
Continuation of Therapy Criteria: • Patient continues to be under the care of a pulmonologist, • AND hepatic function and spirometry are monitored at least annually, • AND patient continues to meet initial criteria with positive clinical response

Antihyperglycemic-Incretin Mimetics

Prior Authorization Criteria follows the state's criteria (DMAS)

Last revised: 1/27/2025; Effective date: 4/1/2025

Generic	Brand
DULAGLUTIDE	TRULICITY
EXENATIDE	BYETTA BYDUREON BCISE
LIRAGLUTIDE	VICTOZA
SEMAGLUTIDE	RYBELSUS OZEMPIC
TIRZEPATIDE	MOUNJARO
INSULIN GLARGINE-LIXISENATIDE	SOLIQUA
INSULIN DEGLUDEC-LIRAGLUTIDE	XULTOPHY

Length of Authorization: 12 months

Initial Review Criteria:

Preferred Products:

- Byetta
- Victoza
- Trulicity

- Diagnosis of type 2 diabetes mellitus

Non-Preferred Products:

- Bydureon
- Mounjaro
- Ozempic
- Rybelsus
- Soliqua
- Xultophy

- Diagnosis of type 2 diabetes mellitus
- HGA1c of greater than or equal to 6.5 is required for first starts in the last 12 months
- Tried and failed an adequate trial of 2 different preferred Incretin Mimetic agents

Antihypertensives, Endothelin Receptor Antagonists

Generic	Brand	HICL	GSN	Representative NDC
APROCITENTAN	TRYVIO TABS 12.5 MG	49465	085865	80491801203

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Cardiologist or Nephrologist, AND
- Age ≥18 years, AND
- Diagnosis of resistant hypertension, AND
- Patient is on a stabilized dose and receiving concomitant therapy with all of the following (unless documented contraindication or intolerance):
  - Angiotensin converting enzyme (ACE) inhibitor or Angiotensin II receptor blocker (ARB)
  - Calcium channel blocker
  - Thiazide/thiazide-like diuretic
  - Mineralocorticoid receptor antagonist
- AND treatment with one additional antihypertensive agent of a different mechanism of action (unless documented contraindication or intolerance):
  - Beta-blocker
  - Central alpha-adrenergic agonist
  - Direct vasodilator
  - Alpha-adrenergic blockers
  - Direct renin inhibitor

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria:**
  - Documented clinical benefit from the medication (e.g., lowering of systolic and/or diastolic blood pressure), AND
  - Patient remains on concomitant therapies as indicated in the initial review criteria

Anti-Inflammatory – Interleukin-1 Receptor Antagonist

Generic	Brand
ANAKINRA	KINERET SOSY

Prior Authorization Criteria follows the state's criteria (DMAS)

Length of Authorization: 12 months

Initial Review Criteria:

- Medication is being used for Cryopyrin-Associated Periodic Syndromes (CAPS) or treatment of Neonatal-Onset Multisystem Inflammatory Disease, or Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

OR

- Member has diagnosis of one of the following AND
    - Rheumatoid Arthritis (RA)
    - Juvenile Idiopathic Arthritis (JIA)
- Member had therapeutic failure on oral methotrexate AND
- Member had therapeutic failure to one of the preferred agents (e.g. Enbrel, Humira) AND
    - If this is being used for Rheumatoid arthritis (RA): member tried and failed or had a contraindication, or adverse reaction to methotrexate and at least one other DMARD (sulfasalazine, hydroxychloroquine, minocycline)

Anti-Inflammatory – Interleukin-1 Receptor Antagonist

Generic	Brand
RILONACEPT	ARCALYST SOLR

Prior Authorization Criteria follows the state's criteria (DMAS)
Length of Authorization: 12 months
Initial Review Criteria: • Medication is being used for: • Cryopyrin-Associated Periodic Syndromes (CAPS) • Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children ≥ 12 years old • Maintenance of remission of deficiency of interleukin-1 receptor antagonist (DIRA) in adults and pediatric patients weighing ≥ 10 kg • Member had therapeutic failure on oral methotrexate • Member had therapeutic failure to one of the preferred agents

Generic	Brand
CERTOLIZUMAB PEGOL	CIMZIA

Prior Authorization Criteria follows the state's criteria (DMAS)

Length of Authorization: 12 months

Initial Review Criteria:

- Member has diagnosis of one of the following AND
  - Rheumatoid Arthritis (RA)
  - Adult Crohn's disease (CD)
  - Psoriatic Arthritis (PsA)
  - Ankylosing Spondylitis (AS)
  - Active Non-radiographic Axial Spondylarthritis (nr-axSpA)
  - Moderate to severe Plaque Psoriasis
    Treatment of active polyarticular juvenile idiopathic arthritis (pJIA) for patients ≥ 2 years of age.
- <u>If this is being used for Rheumatoid Arthritis (RA):</u>
  - Member tried and failed or have a contraindication, or adverse reaction to methotrexate alone and at least one other DMARD (azathioprine, hydroxychloroquine, leflunomide, sulfasalazine, etc.), AND
  - Member had therapeutic failure to one of the preferred agents (e.g. Enbrel, Humira)
- <u>If this is being used for Crohn's disease (CD):</u>
  - Member had therapeutic failure to one of the preferred agents (e.g. Enbrel, Humira) AND
  - Member tried and failed a compliant regimen of oral corticosteroids (for moderate to severe CD) unless contraindicated, or intravenous corticosteroids (for severe and fulminant CD or failure to respond to oral corticosteroids) AND
  - Member tried and failed a compliant regimen of azathioprine or mercaptopurine for three consecutive months, AND
  - Member tried and failed a compliant regimen of parental methotrexate for 3 consecutive months, AND
- <u>If this is being used for Psoriatic Arthritis (PsA):</u>
  - Trial and failure of methotrexate OR requested medication will be used with methotrexate OR contraindication to methotrexate (e.g., alcohol abuse, cirrhosis, chronic liver disease, etc.), AND
  - Member had therapeutic failure to one of the preferred agents (e.g. Enbrel, Humira)
- <u>If this is being used for Ankylosing Spondylitis (AS):</u>
  - Member tried and failed or have a contraindication, or adverse reaction to at least 2 NSAIDs, AND
  - Member had therapeutic failure to one of the preferred agents (e.g. Enbrel, Humira)
- <u>If this is being used for Plaque Psoriasis:</u>
  - Member had previous failure on a topical psoriasis agent, AND
  - Member had therapeutic failure to one of the preferred agents (e.g. Enbrel, Humira)
- <u>Treatment of active polyarticular juvenile idiopathic arthritis (pJIA) for patients ⩾ 2 years of age</u>
  - Trial and failure of methotrexate; OR requested medication will be used in conjunction with methotrexate; OR member has a contraindication to methotrexate
  - Member had therapeutic failure to one of the preferred agents (e.g. Enbrel, Humira)
- <u>Active Non-radiographic Axial Spondylarthritis (nr-axSpA)</u>
  - Member has inadequate response, intolerance, or contraindication to at least TWO non-steroidal anti-inflammatory drugs (NSAIDs)

Anti-Inflammatory – Tumor Necrosis Factor Inhibitor (Cont'd)

Generic	Brand
GOLIMUMAB	SIMPONI

Prior Authorization Criteria follows the state's criteria (DMAS)

Length of Authorization: 12 months

Initial Review Criteria:

- Member has diagnosis of one of the following AND
  - Rheumatoid Arthritis (RA)
  - Psoriatic Arthritis (PsA)
  - Ankylosing Spondylitis (AS)
  - Ulcerative Colitis (UC)
- Member had therapeutic failure on oral methotrexate AND
- Member had therapeutic failure to one of the preferred agents (e.g. Enbrel, Humira) AND

- If this is being used for Rheumatoid Arthritis (RA):
  - Member tried and failed or have a contraindication, or adverse reaction to methotrexate alone and at least one other DMARD (sulfasalazine, hydroxychloroquine, minocycline)? AND
  - Simponi must be used in combination therapy with methotrexate
- If this is being used for Ulcerative Colitis (UC):
  - Member tried and failed a compliant regimen of oral or rectal aminosalicylates (i.e., sulfasalazine or mesalamine) for two consecutive months AND
  - Member tried and failed a compliant regimen of oral corticosteroids (for moderate to severe CD) unless contraindicated, or intravenous corticosteroids (for severe and fulminant CD or failure to respond to oral corticosteroids) AND
  - Member tried and failed a compliant regimen of azathioprine or mercaptopurine for three consecutive months

Anti-Inflammatory – Tumor Necrosis Factor Inhibitor (cont'd)

Prior Authorization Criteria follows the state's criteria (DMAS) – routine PDL edits

Generic	Brand	HICL	GSN	Representative NDC
ADALIMUMAB-BWWD	HADLIMA PUSHTOUCH SOAJ 40 MG/0.4ML	45894	084519	78206018701
ADALIMUMAB-BWWD	HADLIMA PUSHTOUCH SOAJ 40 MG/0.8ML	45894	080049	78206018401
ADALIMUMAB-BWWD	HADLIMA SOSY 40 MG/0.4ML	45894	084517	78206018601
ADALIMUMAB-BWWD	HADLIMA SOSY 40 MG/0.8ML	45894	080050	78206018301
ADALIMUMAB-AFZB	ABRILADA (1 PEN) AJKT 40 MG/0.8ML	46230	080511	00069032501
ADALIMUMAB-AFZB	ABRILADA (2 PEN) AJKT 40 MG/0.8ML	46230	080511	00069032502
ADALIMUMAB-AFZB	ABRILADA (2 SYRINGE) PSKT 20 MG/0.4ML	46230	080513	00069033302
ADALIMUMAB-AFZB	ABRILADA (2 SYRINGE) PSKT 40 MG/0.8ML	46230	080512	00069032802
ADALIMUMAB-RYVK	SIMLANDI (1 PEN) AJKT 40 MG/0.4ML	49415	085776	51759040217
ADALIMUMAB-RYVK	SIMLANDI (2 PEN) AJKT 40 MG/0.4ML	49415	085776	51759040202
ADALIMUMAB-RYVK	SIMLANDI (2 SYRINGE) PSKT 20 MG/0.2ML	49415	086345	51759038622
ADALIMUMAB-RYVK	SIMLANDI (1 SYRINGE) PSKT 80 MG/0.8ML	49415	086346	51759052321
ADALIMUMAB-RYVK	ADALIMUMAB-RYVK (2 PEN) AJKT 40 MG/0.4ML	49415	085776	82009015622
ADALIMUMAB-RYVK	ADALIMUMAB-RYVK (2 SYRINGE) PSKT 40 MG/0.4ML	49415	086320	82009015822
ADALIMUMAB-AATY	YUFLYMA (1 PEN) AJKT 40 MG/0.4ML	48955	084832	72606003009
ADALIMUMAB-AATY	YUFLYMA (1 PEN) AJKT 80 MG/0.8ML	48955	085430	72606002304
ADALIMUMAB-AATY	YUFLYMA (2 PEN) AJKT 40 MG/0.4ML	48955	084832	72606003010
ADALIMUMAB-AATY	YUFLYMA (2 SYRINGE) PSKT 20 MG/0.2ML	48955	085429	72606002401
ADALIMUMAB-AATY	YUFLYMA (2 SYRINGE) PSKT 40 MG/0.4ML	48955	084831	72606003006
ADALIMUMAB-AATY	YUFLYMA-CD/UC/HS STARTER AJKT 80 MG/0.8ML	48955	085430	72606002307
ADALIMUMAB-AATY	ADALIMUMAB-AATY (1 PEN) AJKT 40 MG/0.4ML	48955	084832	72606002209

ADALIMUMAB-AATY	ADALIMUMAB-AATY (1 PEN) AJKT 80 MG/0.8ML	48955	085430	72606004004
ADALIMUMAB-AATY	ADALIMUMAB-AATY (2 PEN) AJKT 40 MG/0.4ML	48955	084832	72606002210
ADALIMUMAB-AATY	ADALIMUMAB-AATY (2 SYRINGE) PSKT 20 MG/0.2ML	48955	085429	72606004101
ADALIMUMAB-AATY	ADALIMUMAB-AATY (2 SYRINGE) PSKT 40 MG/0.4ML	48955	084831	72606002206
ADALIMUMAB-ADBM	CYLTEZO (2 PEN) AJKT 40 MG/0.4ML	44481	086039	00597049550
ADALIMUMAB-ADBM	CYLTEZO (2 PEN) AJKT 40 MG/0.8ML	44481	084819	00597037597
ADALIMUMAB-ADBM	CYLTEZO (2 SYRINGE) PSKT 10 MG/0.2ML	44481	084512	00597040089
ADALIMUMAB-ADBM	CYLTEZO (2 SYRINGE) PSKT 20 MG/0.4ML	44481	084513	00597040580
ADALIMUMAB-ADBM	CYLTEZO (2 SYRINGE) PSKT 40 MG/0.4ML	44481	086037	00597048520
ADALIMUMAB-ADBM	CYLTEZO (2 SYRINGE) PSKT 40 MG/0.8ML	44481	077687	00597037082
ADALIMUMAB-ADBM	CYLTEZO-CD/UC/HS STARTER AJKT 40 MG/0.4ML	44481	086039	00597049560
ADALIMUMAB-ADBM	CYLTEZO-CD/UC/HS STARTER AJKT 40 MG/0.8ML	44481	084819	00597037516
ADALIMUMAB-ADBM	CYLTEZO-PSORIASIS/UV STARTER AJKT 40 MG/0.4ML	44481	086039	00597049540
ADALIMUMAB-ADBM	CYLTEZO-PSORIASIS/UV STARTER AJKT 40 MG/0.8ML	44481	084819	00597037523
ADALIMUMAB-ADBM	ADALIMUMAB-ADBM (2 PEN) AJKT 40 MG/0.4ML	44481	086039	00597057550
ADALIMUMAB-ADBM	ADALIMUMAB-ADBM (2 PEN) AJKT 40 MG/0.8ML	44481	084819	00597054522
ADALIMUMAB-ADBM	ADALIMUMAB-ADBM (2 SYRINGE) PSKT 10 MG/0.2ML	44481	084512	00597058589
ADALIMUMAB-ADBM	ADALIMUMAB-ADBM (2 SYRINGE) PSKT 20 MG/0.4ML	44481	084513	00597055580
ADALIMUMAB-ADBM	ADALIMUMAB-ADBM (2 SYRINGE) PSKT 40 MG/0.4ML	44481	086037	00597056520
ADALIMUMAB-ADBM	ADALIMUMAB-ADBM (2 SYRINGE) PSKT 40 MG/0.8ML	44481	077687	00597059520
ADALIMUMAB-ADBM	ADALIMUMAB-ADBM(CD/UC/HS STRT) AJKT 40 MG/0.4ML	44481	086039	00597057560

ADALIMUMAB-ADBM	ADALIMUMAB-ADBM(CD/UC/HS STRT) AJKT 40 MG/0.8ML	44481	084819	00597054566
ADALIMUMAB-ADBM	ADALIMUMAB-ADBM(PS/UV STARTER) AJKT 40 MG/0.4ML	44481	086039	00597057540
ADALIMUMAB-ADBM	ADALIMUMAB-ADBM(PS/UV STARTER) AJKT 40 MG/0.8ML	44481	084819	00597054544
ADALIMUMAB-FKJP	HULIO (2 PEN) AJKT 40 MG/0.8ML	46685	081262	83257001932
ADALIMUMAB-FKJP	HULIO (2 SYRINGE) PSKT 20 MG/0.4ML	46685	081263	83257001642
ADALIMUMAB-FKJP	HULIO (2 SYRINGE) PSKT 40 MG/0.8ML	46685	081279	83257001742
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP (2 PEN) AJKT 40 MG/0.8ML	46685	081262	83257002232
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP (2 SYRINGE) PSKT 20 MG/0.4ML	46685	081263	83257002042
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP (2 SYRINGE) PSKT 40 MG/0.8ML	46685	081279	83257002142
ADALIMUMAB-ADAZ	HYRIMOZ SOAJ 40 MG/0.4ML	45444	084543	83457010001
ADALIMUMAB-ADAZ	HYRIMOZ SOAJ 40 MG/0.8ML	45444	079220	83457010201
ADALIMUMAB-ADAZ	HYRIMOZ SOAJ 80 MG/0.8ML	45444	084553	83457010701
ADALIMUMAB-ADAZ	HYRIMOZ SOSY 10 MG/0.1ML	45444	084551	61314050964
ADALIMUMAB-ADAZ	HYRIMOZ SOSY 20 MG/0.2ML	45444	084549	83457010801
ADALIMUMAB-ADAZ	HYRIMOZ SOSY 40 MG/0.4ML	45444	084550	83457010101
ADALIMUMAB-ADAZ	HYRIMOZ SOSY 40 MG/0.8ML	45444	079219	83457010301
ADALIMUMAB-ADAZ	HYRIMOZ-CROHNS/UC STARTER SOAJ 80 MG/0.8ML	45444	084553	83457011301
ADALIMUMAB-ADAZ	HYRIMOZ-PED<40KG CROHN STARTER SOSY 80 MG/0.8ML & 40 MG/0.4ML	45444	084555	61314053164
ADALIMUMAB-ADAZ	HYRIMOZ-PED>/=40KG CROHN START SOSY 80 MG/0.8ML	45444	084563	61314045468
ADALIMUMAB-ADAZ	HYRIMOZ-PLAQ PSOR/UVEIT START SOAJ 80 MG/0.8ML & 40 MG/0.4ML	45444	084546	61314051736
ADALIMUMAB-ADAZ	HYRIMOZ-PLAQUE PSORIASIS START SOAJ 80 MG/0.8ML & 40 MG/0.4ML	45444	084546	83457011201
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOAJ 40 MG/0.4ML	45444	084543	61314032720
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOSY 40 MG/0.4ML	45444	084550	61314032764

ADALIMUMAB-AACF	IDACIO (2 PEN) AJKT 40 MG/0.8ML	48528	084193	65219055408
ADALIMUMAB-AACF	IDACIO (2 SYRINGE) PSKT 40 MG/0.8ML	48528	084192	65219055618
ADALIMUMAB-AACF	IDACIO-CROHNS/UC STARTER AJKT 40 MG/0.8ML	48528	084193	65219055438
ADALIMUMAB-AACF	IDACIO-PSORIASIS STARTER AJKT 40 MG/0.8ML	48528	084193	65219055428
ADALIMUMAB-AACF	ADALIMUMAB-AACF (2 PEN) AJKT 40 MG/0.8ML	48528	084193	65219061299
ADALIMUMAB-AACF	ADALIMUMAB-AACF (2 SYRINGE) PSKT 40 MG/0.8ML	48528	084192	65219062020
ADALIMUMAB-AACF	ADALIMUMAB-AACF(CD/UC/HS STRT) AJKT 40 MG/0.8ML	48528	084193	65219061289
ADALIMUMAB-AACF	ADALIMUMAB-AACF(PS/UV STARTER) AJKT 40 MG/0.8ML	48528	084193	65219061269
ADALIMUMAB-AQVH	YUSIMRY SOAJ 40 MG/0.8ML	47742	084535	70114022002

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial & Continuation of Therapy Criteria:

- Patient has one of the following diagnoses:
  - Adult rheumatoid arthritis (RA)
  - Juvenile idiopathic arthritis (JIA)
  - Psoriatic arthritis (PsA)
  - Ankylosing spondylitis (AS)
  - Adult Crohn’s disease (CD)
  - Pediatric Crohn’s disease
  - Ulcerative colitis (UC)
  - Plaque psoriasis (Ps)
  - Hidradenitis suppurativa (HS): age ≥12 years
  - Uveitis (UV)
- Patient had therapeutic failure on oral methotrexate,
- Patient had therapeutic failure to one of the preferred agents (e.g., infliximab, Humira, Enbrel)

Anti-Inflammatory – Tumor Necrosis Factor Inhibitor (cont'd)

Prior Authorization Criteria follows the state's criteria (DMAS)

Generic	Brand	HICL	GSN	Representative NDC
INFLIXIMAB-DYYB	ZYMFENTRA (2 SYRINGE) PSKT 120 MG/ML	43249	085585	72606002510
INFLIXIMAB-DYYB	ZYMFENTRA (2 PEN) AJKT 120 MG/ML	43249	085586	72606002502
INFLIXIMAB-DYYB	ZYMFENTRA (1 PEN) AJKT 120 MG/ML	43249	085586	72606002501

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial & Continuation of Therapy Criteria:

- Patient has diagnosis of one of the following,
  - Crohn's Disease (Adult or Pediatric)
  - Ulcerative Colitis (Adult or Pediatric)
  - Rheumatoid Arthritis in combination with methotrexate
  - Ankylosing spondylitis
  - Psoriatic Arthritis
  - Plaque Psoriasis
- Patient has had treatment failure on oral methotrexate,
- Patient has had therapeutic failure to one of the preferred agents (e.g., Humira, Enbrel)
- <u>If treating Pediatric Crohn's Disease or Ulcerative Colitis:</u> patient is ≥6 years of age

Anti-inflammatory – Interleukin-1 Beta Blockers

Last revised: 06/07/2024; Effective date: 07/01/2024

Generic	Brand
CANAKINUMAB	ILARIS SOLN

Prior Authorization Criteria follows the state's criteria (DMAS)
Length of Authorization: 12 months

Initial Review Criteria:
• Member has diagnosis of one of the following:
  o Periodic Fever Syndromes [e.g., Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS), or Muckle-Wells Syndrome (MWS)]
  o Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)
  o Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)
  o Familial Mediterranean Fever (FMF)
  o Active Still's Disease [including Adult-Onset Still's Disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (SJIA)] in members 2 years of age or older
  o Gout Flares (NSAIDs and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate) in members aged 18 years or older
• AND if using for Active Still's Disease: member has failed oral methotrexate AND at least one of the preferred agents (e.g., Enbrel, Humira)

Anti-Inflammatory – Phosphodiesterase-4 (PDE4) Inhibitor

Generic	Brand
APREMILAST	OTEZLA

Last reviewed:3.3.2025 Effective date 4.1.2025

Prior Authorization Criteria follows the state's criteria (DMAS)

Length of Authorization: 12 months

Initial Review Criteria

- Member has a diagnosis of one of the following AND
  - Active Psoriatic arthritis (PsA)
  - Moderate to severe Plaque Psoriasis (PsO) – ages 6 and up, weighing 20 kg or more
- Member had therapeutic failure on oral methotrexate AND
- Member had therapeutic failure to one of the preferred agents (e.g. Enbrel, Humira) AND
- If this is being used for Plaque Psoriasis:
  - Member had therapeutic failure on a topical psoriasis agent AND
  - Member is a candidate for phototherapy or systemic therapy

OR

- If this is being used for adult members with oral ulcers associated with Behcet's Disease: approvable with diagnosis

Anti-Narcolepsy, Anti-Cataplexy, Sedative-Type Agent

Last revised: 1/31/2025; Effective date: 4/1/2025

Generic	Brand
SODIUM OXYBATE	XYREM

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is Pulmonologist (Sleep Specialist) and Neurologist, AND
- Prescriber must enroll in Xyrem Patient Success Program, AND
- Patient is 7 years to 65 years of age, AND
- Patient may NOT be on any sedative-hypnotic agents, opioids, benzodiazepines, or alcohol, AND

- **Diagnosis of excessive daytime sleepiness in narcolepsy:**
  - Adequate trial (≥2 months) of a preferred stimulant (methylphenidate, amphetamine salt combination, dextroamphetamine) AND modafinil/armodafinil, unless contraindicated, AND
  - Adequate trial (≥2 months) of ALL of the following, unless contraindicated:
    - Sunosi*PA
    - Wakix*PA
    - Sodium oxybate IR*PA (generic Xyrem)
    - Xywav*PA

- **Diagnosis of cataplexy due to narcolepsy**:
  - Adequate trial (≥2 months) of at least 2 of the following: TCAs, SSRI, or SNRI or there is a contraindication, AND
  - Adequate trial (≥2 months) of ALL of the following, unless contraindicated:
    - Wakix*PA
    - Sodium oxybate IR*PA (generic Xyrem)
    - Xywav*PA

**PA This medication is also subject to PA review*

Continuation of Therapy Criteria:

- Patient continues to be under the care of a specialist, AND
- Documentation of positive clinical response

Anti-Narcolepsy, Anti-Cataplexy, Sedative-Type Agent (cont'd)

Last revised: 1/31/2025; Effective date: 4/1/2025

Generic	Brand	HICL	GSN	Representative NDC
CALCIUM, MAGNESIUM, POTASSIUM, & SODIUM OXYBATES	XYWAV SOLN 500 MG/ML	46743	081341	68727015001

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is Pulmonologist (Sleep Specialist) or Neurologist,
- Prescriber must enroll in Xywav REMS Program,
- Patient is 7 years to 65 years of age,
- Patient may NOT be on any sedative-hypnotic agents, opioids, benzodiazepines, or alcohol, AND

<u>For diagnosis of excessive daytime sleepiness in narcolepsy:</u>

- Adequate trial (≥2 months) of a preferred stimulant (methylphenidate, amphetamine salt combination, dextroamphetamine) AND modafinil/armodafinil, unless contraindicated,
- Adequate trial (≥2 months) of ALL of the following, unless contraindicated:
  - Sunosi*PA
  - Wakix*PA
  - Sodium oxybate IR (generic Xyrem)*PA

<u>For diagnosis of cataplexy due to narcolepsy:</u>

- Adequate trial (≥2 months) of at least 2 of the following: TCAs, SSRI, or SNRI or there is a contraindication,
- Adequate trial (≥2 months) of ALL of the following, unless contraindicated:
  - Wakix*PA
  - Sodium oxybate IR (generic Xyrem)

<u>For diagnosis of idiopathic hypersomnia:</u>

- Patient is at least 18 years of age

**PA This medication is also subject to PA review*

Continuation of Therapy Criteria:

- Patient continues to be under the care of a specialist,
- Documentation of positive clinical response

Anti-Narcolepsy, Anti-Cataplexy, Sedative-Type Agent (cont'd)

Generic	Brand	HICL	GSN	Representative NDC
SODIUM OXYBATE	LUMRYZ PACK 4.5 GM	12346	084718	13551000130
SODIUM OXYBATE	LUMRYZ PACK 6 GM	12346	084719	13551000230
SODIUM OXYBATE	LUMRYZ PACK 7.5 GM	12346	084721	13551000330
SODIUM OXYBATE	LUMRYZ PACK 9 GM	12346	084722	13551000430
SODIUM OXYBATE	LUMRYZ STARTER PACK THPK 4.5 & 6 & 7.5 GM	12346	086567	13551000501

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is Pulmonologist (Sleep Specialist) or Neurologist,
- Prescriber must enroll in Lumryz REMS program,
- Patient is 7 years to 65 years of age,
- Patient may not be on any sedative-hypnotic agents, opioids, benzodiazepines, or alcohol, AND

Diagnosis of excessive daytime sleepiness in narcolepsy:

- Adequate trial (≥2 months) of a preferred stimulant (methylphenidate, amphetamine salt combination, dextroamphetamine) AND modafinil/armodafinil, unless contraindicated,
- Adequate trial (≥2 months) of ALL of the following, unless contraindicated:
    - Sunosi
    - Wakix
    - Sodium oxybate IR (generic Xyrem)

Diagnosis of cataplexy due to narcolepsy:

- Adequate trial (≥2 months) of at least 2 of the following: TCAs, SSRI, or SNRI or there is a contraindication,
- Adequate trial (≥2 months) of ALL of the following, unless contraindicated:
    - Wakix
    - Sodium oxybate IR (generic Xyrem)

Continuation of Therapy Criteria:

- Patient continues to be under the care of a specialist,
- Documentation of positive clinical response

Anti-Narcolepsy and Sleep Disorder Therapy

Last revised: 05/20/20254; Effective date: 07/19/2025

Generic	Brand
modafinil	Provigil
armodafinil	Nuvigil
solriamfetol HCl	Sunosi
pitolisant HCl	Wakix

Prior Authorization Criteria follows the state's criteria (DMAS)

Length of authorization:

Initial: 6 months

Renewal:12 months

Initial Review Criteria:

- Age ≥ 18 years old
- Diagnosis of one of the following:
  - Narcolepsy *(sleep study must be attached)*
  - Excessive daytime sleepiness (EDS) in adult members with narcolepsy
  - Obstructive sleep apnea *(sleep study must be attached)*
  - Sudden onset of weak or paralyzed muscles (cataplexy)
  - Shift work sleep disorder:
    - Documentation of the current shift schedule is required.
    - Assessment that it doesn't occur during another sleep disorder or mental disorder.
    - Assessment that it not due to the direct physiological effects of a medication or a general medical condition.

Additional Criteria for Wakix (pitolisant)

- Diagnosis of narcolepsy consistent with the International Classification of Sleep Disorder (ICSD-3) or Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5)
- Member has a baseline daytime sleepiness as measured by a validated scale? (e.g., Epworth Sleepiness Scale, Stanford Sleepiness Scale, Karolinska Sleepiness Scale, Cleveland Adolescent Sleepiness Questionnaire, or a Visual Analog Scale); AND
- A mean sleep latency of ≤ 8 minutes AND ≥ 2 sleep onset REM periods (SOREMPs) are found on a mean sleep latency test (MSLT) performed according to standard techniques (A SOREMP [within 15 minutes of sleep onset] on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT); AND
- Either cerebrospinal fluid (CSF) hypocretin-1 concentration has not been measured OR CSF hypocretin-1 concentration measured by immunoreactivity is either > 110 pg/mL OR > 1/3 of mean values obtained in normal subjects with the same standardized assay; AND
- The hypersomnolence and/or MSLT findings are not better explained by other causes such as insufficient sleep, obstructive sleep apnea, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal; AND

- Patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for ≥ 3 months; AND
- Patient is not receiving treatment with sedative-hypnotic agents (e.g., zolpidem, eszopiclone, zaleplon, benzodiazepines, barbiturates); AND
- Patient is not using drugs that prolong the QT interval (e.g., quinidine, procainamide, disopyramide, amiodarone, sotalol, ziprasidone, chlorpromazine, thioridazine, moxifloxacin) concomitantly; AND
- Patient is not using histamine-1 (H1) receptor antagonists (e.g., pheniramine maleate, diphenhydramine, promethazine, imipramine, clomipramine, mirtazapine) concomitantly; AND
- Patient does not have a history of prolonged QTc interval (e.g., QTc interval > 450 milliseconds); AND
- Therapy is not being used in patients with severe hepatic impairment (Child-Pugh C); AND
- Patient does not have end-stage renal disease (ESRD) (e.g., eGFR < 15 mL/minute/1.73 m2

For brand Nuvigil or Provigil:

- Member tried and failed the preferred generics for the requested products.

For Sunosi:

- Member tried and failed or there is contraindication to preferred modafinil or armodafinil

Continuation Criteria:

- Member continues to meet initial criteria, AND
- Member reports a reduction in excessive daytime sleepiness from pre-treatment baseline.
- Member does not report any adverse effects related to treatment.

Anti-inflammatory – Selective Costimulation Modulator

Generic	Brand
ABATACEPT	ORENCIA

Prior Authorization Criteria follows the state's criteria (DMAS)
Length of Authorization: 12 months

Initial Review Criteria:
• Member has diagnosis of one of the following AND
  o Rheumatoid Arthritis (RA) – adult members
  o Juvenile Idiopathic Arthritis (JIA) – age ≥2 years
  o Psoriatic Arthritis (PsA) – age ≥2 years
• Member had therapeutic failure on oral methotrexate AND
• Member had therapeutic failure to one of the preferred agents (e.g. Enbrel, Humira) AND
• <u>If using for RA:</u> Member tried and failed another DMARD (other than Methotrexate), such as minocycline, hydroxychloroquine, sulfasalazine

Anti-psoriatic Agents

Last revised 12.1.2023; Effective 1.1.2024

Generic	Brand
SECUKINUMAB	COSENTYX

Prior Authorization Criteria follows the state's criteria (DMAS)

Length of Authorization: 12 months

Initial Review Criteria:

- Member has diagnosis of at least one of the following, AND
    - Psoriatic arthritis (PsA)
    - Ankylosing Spondylitis (AS)
    - Plaque Psoriasis (PsO)
    - Active Non-Radiographic Spondyloarthritis
    - Active Enthesitis-related arthritis (ERA) in patients 4 years of age and older

- Member had therapeutic failure on oral methotrexate AND
- Member had therapeutic failure to one of the preferred agents (e.g. Enbrel, Humira), AND
- If this is being used for Plaque Psoriasis: member must have therapeutic failure on a topical psoriasis agent

Generic	Brand
TILDRAKIZUMAB-ASMN	ILUMYA

Prior Authorization Criteria follows the state's criteria (DMAS)

Length of Authorization: 12 months

Review Criteria:

- Member has diagnosis of
  - Adult Moderate-to severe plaque psoriasis (PSO) who are candidates for systemic therapy or phototherapy.
  - Member has had moderate-to-severe plaque psoriasis for at least 6 months AND
  - There is involvement of at least 10% of body surface area (BSA) OR
  - Psoriasis Area and Severity Index (PASI) score 10 or greater OR
  - Incapacitation due to plaque location (e.g., head and neck, palms, soles or genitalia) AND
  - Member has not responded adequately (or is not a candidate) to a 3-month minimum trial of topical agents (e.g., anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, retinoic acid derivatives, and/or Vitamin D analogues) AND
  - Member has not responded adequately (or is not a candidate) to a 3-month minimum trial of at least 1 systemic agent (e.g. Immunosuppressives, retinoic acid derivatives, and/or methotrexate) AND
  - Member has not responded adequately (or is not a candidate) to a 3-month minimum trial of phototherapy (e.g. Psoralens with UVA light (PUVA) OR UVB with coal tar or dithranol)

Generic	Brand
RISANKIZUMAB-RZAA	SKYRIZI

Prior Authorization Criteria follows the state's criteria (DMAS)

Length of Authorization: 12 months

Review Criteria:

- Member has diagnosis of one of the following
  - Plaque Psoriasis (PsO) (Moderate to severe)
  - Psoriatic Arthritis (PsA)
  - Crohn's disease (Moderate to severe)
  - Ulcerative colitis (UC) (Moderate to severe)
- Member is ≥ 18 years AND
- Member had therapeutic failure to one of the preferred agents (e.g. Enbrel, Humira) AND
- Member is not receiving risankizumab-rzaa in combination with another biologic agent for UC or non-biologic immunomodulator (e.g., upadacitinib)

Additional criteria for Plaque Psoriasis

- Diagnosis of moderate to severe plaque psoriasis for ≥ 6 months with ≥ 1 of the following:
  - Affected body surface area (BSA) of ≥ 10%; OR
  - Psoriasis Area and Severity Index (PASI) score ≥ 10; OR
  - Incapacitation due to plaque location (e.g., head and neck, palms, soles or genitalia)
- Member has not responded adequately (or is not a candidate) to a 3-month minimum trial of topical agents (e.g., anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, retinoic acid derivatives, and/or Vitamin D analogues) AND
- Member has not responded adequately (or is not a candidate) to a 3-month minimum trial of at least 1 systemic agent (e.g. Immunosuppressives, retinoic acid derivatives, and/or methotrexate) AND
- Member has not responded adequately (or is not a candidate) to a 3-month minimum trial of phototherapy (e.g. Psoralens with UVA light (PUVA) OR UVB with coal tar or dithranol)

Additional criteria for Psoriatic Arthritis (PsA)

- Diagnosis of moderate to severe psoriatic arthritis
- Member had therapeutic failure to one of the preferred agents (e.g. Enbrel, Humira) AND
- Member did not respond adequately (or is not a candidate) to a 3 month minimum trial of ≥ 1systemic agent (e.g. Immunosuppressives, and/or methotrexate) AND

Additional criteria for Crohn's disease

- Diagnosis of moderate to severe Crohn's Disease, AND
- Trial and failure of a compliant regimen of oral corticosteroids unless contraindicated or intravenous corticosteroids, AND

Additional criteria for Ulcerative colitis

- Member had therapeutic failure to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC after at least a 3-month duration of therapy, AND

Generic	Brand
GUSELKUMAB	TREMFYA

Prior Authorization Criteria follows the state's criteria (DMAS)

Length of Authorization: 12 months

Review Criteria:

- Member has diagnosis of one of the following
  - Adult Plaque Psoriasis (PsO) (Moderate-to-Severe), in patient candidate for systemic therapy or phototherapy
  - Adult Psoriatic Arthritis (PsA)
  - Ulcerative colitis (UC) (Moderate to severe)
  - Adults with moderate to severe Crohn's Disease (CD)
- Member is ≥ 18 years
- Member had therapeutic failure to one of the preferred agents (e.g. Enbrel, Humira) AND

Additional criteria for Plaque Psoriasis

- Diagnosis of moderate to severe plaque psoriasis for ≥ 6 months with ≥ 1 of the following:
  - Affected body surface area (BSA) of ≥ 10%; OR
  - Psoriasis Area and Severity Index (PASI) score ≥ 10; OR
  - Incapacitation due to plaque location (e.g., head and neck, palms, soles or genitalia)
- Member has not responded adequately (or is not a candidate) to a 3-month minimum trial of topical agents (e.g., anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, retinoic acid derivatives, and/or Vitamin D analogues) AND
- Member has not responded adequately (or is not a candidate) to a 3-month minimum trial of at least 1 systemic agent (e.g. Immunosuppressives, retinoic acid derivatives, and/or methotrexate) AND
- Member has not responded adequately (or is not a candidate) to a 3-month minimum trial of phototherapy (e.g. Psoralens with UVA light (PUVA) OR UVB with coal tar or dithranol)
- Member is not receiving guselkbumab in combination with another biologic agent for psoriasis or non-biologic immunomodulator (e.g., apremilast, tofacitinib, baricitinib)

Additional criteria for Ulcerative Colitis (UC)

- Diagnosis of moderate to severe UC AND
- Trial and failure to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC after at least a 3-month duration of therapy, AND
- Member is not receiving guselkbumab in combination with another biologic agent for psoriasis or non-biologic immunomodulator (e.g., upadacitinib)

Additional criteria for Crohn's Disease (CD)

- Diagnosis of moderate to severe Crohn's Disease (CD)
- Trial and failure or contraindication of oral or intravenous corticosteroids
- Member is not receiving guselkumab in combination with another biologic agent for Crohn's
- disease or non-biologic immunomodulator (e.g., upadacitinib)

Anti-psoriatic Agents (Cont'd)

Generic	Brand
BRODALUMAB	SILIQ

Prior Authorization Criteria follows the state's criteria (DMAS)

Length of Authorization: 12 months initial; 12 months continuation

Initial Review Criteria:

- Member has diagnosis of Plaque Psoriasis (PsO), AND
- Member failed oral methotrexate (at least 3 months) unless contraindication or intolerance , AND
- Member had therapeutic failure to both preferred agents (e.g. Enbrel, Humira) AND
- Member has had moderate-to-severe plaque psoriasis AND
    - There is involvement of at least 5% of body surface area (BSA) OR palmoplantar, facial, genital, or severe scalp psoriasis
- Member has not responded adequately (or is not a candidate) to a 3-month minimum trial of topical agents (e.g., anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, retinoic acid derivatives, and/or Vitamin D analogues) AND
- Member is not receiving Siliq in combination with any of the following:
    - Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
    - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
    - Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

Continuation Criteria:

- There is documentation of positive clinical response to Siliq therapy AND
- Member is not receiving Siliq in combination with any of the following:
    - Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
    - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
    - Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

Generic	Brand
IXEKIZUMAB	TALTZ

Prior Authorization Criteria follows the state's criteria (DMAS)
Length of Authorization: 12 months initial
Initial Review Criteria: • Member has diagnosis of one of the following, AND: o Plaque Psoriasis (PsO) adults and children 6 years of age or older who are candidates for systemic therapy or phototherapy o Psoriatic Arthritis (PsA) o Ankylosing Spondylitis (AS) o Non-Radiographic spondyloarthritis (nr-axSpA) • Member failed oral methotrexate (at least 3 months) unless contraindication or intolerance, AND • Member had therapeutic failure to one preferred agent (e.g. Enbrel, Humira) AND • Member has not responded adequately (or is not a candidate) to a 3-month minimum trial of at least 2 topical agents (e.g., anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, retinoic acid derivatives, and/or Vitamin D analogues)

Generic	Brand
BIMEKIZUMAB-BKZX	BIMZELX

Prior Authorization Criteria follows the state's criteria (DMAS)
Length of Authorization: 12 months
Review Criteria: • Member has diagnosis of one of the following, AND o Plaque Psoriasis (PsO), moderate to severe, adult candidates for systemic therapy or phototherapy o Adult active psoriatic arthritis o Adult active ankylosing spondylitis o Adults with non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation • Trial and failure for preferred products • Additional Criteria for Plaque Psoriasis (PsO) o Member has a prior failure on a topical agent. o Member is candidate for systemic therapy or phototherapy.

Antipsoriatic Agents, Systemic

Prior Authorization Criteria follows the state's criteria (DMAS)

Generic	Brand	HICL	GSN	Representative NDC
SPESOLIMAB-SBZO	SPEVIGO SOSY 150 MG/ML	48270	085900	00597062010

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial & Continuation of Therapy Criteria:

- Patient is at least 12 years of age,
- Patient weighs at least 40 kilograms,
- Prescribed by, or in consultation with, a dermatologist, rheumatologist, or other specialist in the treatment of psoriasis,
- Patient has a known documented history of generalized pustular psoriasis (GPP), either relapsing (greater than 1 episode) or persistent (greater than 3 months),
- Patient has had treatment failure to oral methotrexate,
- Patient has had treatment failure to one of the preferred agents (e.g., infliximab, Humira, Enbrel),
- AND if treating active flares:
    - Patient is presenting with primary, sterile, macroscopically visible pustules on non-acral skin (excluding cases where pustulation is restricted to psoriatic plaques),
    - Patient has at least ONE of the following documented:
        - IL36RN, CARD14, or AP1S3 gene mutation, OR
        - Skin biopsy confirming presence of Kogoj's spongiform pustules, OR
        - Systemic symptoms or laboratory abnormalities commonly associated with GPP flare (e.g., fever, asthenia, myalgia, elevated C-reactive protein [CRP], leukocytosis, neutrophilia [above ULN]), OR
        - GPP flare of moderate-to-severe intensity (e.g., at least 5% body surface area is covered with erythema and the presence of pustules; Generalized Pustular Psoriasis Physician Global Assessment [GPPPGA] total score of greater or equal to 3)

Antiviral Agent, Topical

Generic	Brand	HICL	GSN	Representative NDC
BERDAZIMER	ZELSUVMI TOPICAL GEL			

Prior Authorization Criteria:

Length of Authorization:

- Initial: 3 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Dermatologist, AND
- Patient is 1 year of age or older, AND
- Diagnosis of molluscum contagiosum (MC), AND
- Patient meets one of the following:
    - Experiencing itching or pain,
    - Has a concomitant bacterial infection,
    - Has concomitant AD,
    - There is concern for contagion (e.g. other siblings, daycare) and lesions cannot be reasonably covered using a bandage

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria:**
    - Document clinically significant benefits from the medication, AND
    - Specialist follow-up in the last 12 months

Arginine Vasopressin (AVP) Receptor Antagonists

Last revised: 10/3/2023

Generic	Brand
TOLVAPTAN	JYNARQUE

Prior Authorization Criteria: (Jynarque)

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Nephrologist, AND
- Patient must be 18 years to 55 years old, AND
- eGFR ≥25 mL/min/1.73 m^2, AND
- Baseline labs completed within 30 days and within normal limits: ALT, AST, bilirubin; and negative pregnancy test (if applicable), AND
- Patient has a diagnosis of typical autosomal dominant polycystic kidney disease (ADPKD) confirmed by one of the following:
    - Ultrasonography:
        - With family history: ≥ 3 cysts (unilateral or bilateral) in patients aged 15-39 years OR ≥ 2 cysts in each kidney in patients aged 40-59 years
        - Without family history: ≥ 10 cysts per kidney

OR

- Magnetic resonance imaging (MRI) or computed tomography (CT) scan:
    - With family history: ≥ 5 cysts per kidney
    - Without family history: ≥ 10 cysts per kidney

-AND -

- High risk of disease progression defined by one of the following:
    - Mayo ADPKD Classification 1C, 1D, or 1E
    - eGFR decline ≥5 mL/min/1.73m2 in one year OR eGFR decline ≥2.5 mL/min/1.73m2 per year over a period of ≥5 years
    - Truncating PKD1 mutation AND PROPKD score >6

Continuation of Therapy Criteria:

- Positive clinical response to tolvaptan, AND
- eGFR >25 mL/min/1.73 m2, AND
- Patient has followed-up with a Nephrologist within the past 12 months

Duchenne Muscular Dystrophy Oral Therapy

Prior Authorization Criteria follows DMAS's

Last revised 12/06/2024/01/2024; Effective 01/01/1/2025

Generic	Brand
deflazacort	Emflaza
vamorole	Agamree
givinostat	**Duvyzat**

Length of Authorization: 12 months

Initial Review Criteria:

Agamree and Emflaza

- Member is ≥2 years AND
- Diagnosis of Duchenne muscular dystrophy (DMD) AND
- Trial and failure or intolerance to prednisone or prednisolone

Additional criteria for Agamree (vamorole) and Duvyzat (givinostat)

- Trial and failure or intolerance to preferred formulary, product Emflaza

Additional question for Duvyzat

- Member is ≥6 years

Fecal Microbiota Transplantation (FMT)

Prior Authorization Criteria follows the state's criteria (DMAS)

Generic	Brand	HICL	GSN	Representative NDC
FECAL MICROBIOTA SPORES, LIVE-BRPK	VOWST CAPS	48888	084699	71881040012

Prior Authorization Criteria:

Length of Authorization:

- Initial: 30 days
- Reauthorization: N/A

Initial Review Criteria:

- Patient age ≥18 years,
- Confirmed diagnosis of recurrent Clostridioides difficile infection (CDI) with a total of ≥3 episodes of CDI within 12 months,
- Antibiotic treatment for recurrent CDI must be completed 2 to 4 days prior to initiation of Vowst therapy,
- Patient will take 10 oz of magnesium citrate (or 250 mL polyethylene glycol electrolyte solution for patients with impaired kidney function) the evening prior to initiation of Vowst therapy,
- Patient must not have absolute neutrophil count (ANC) <500 cells/uL, toxic megacolon, or small bowel ileus

Glypromate (GPE) Analogs

Last revised: 7/31/2024; Effective date: 10/1/2024

Prior Authorization Criteria follows the state's criteria (DMAS)

Generic	Brand	HICL	GSN	Representative NDC
TROFINETIDE	DAYBUE SOLN 200 MG/ML	48773	084510	63090066001

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Daybue is being prescribed by or in consultation with a Neurologist,
- Member is 2 years of age or older,
- Member has a diagnosis of classical/typical or variant/atypical Rett syndrome, as established by both of the following:
    - Molecular genetic testing with heterozygous methyl-CpG-binding protein-2 (MECP2) pathogenic variant gene mutations,
    - Diagnosis based on clinical presentation meeting ALL criteria to support diagnosis
- Member does not have moderate or severe renal impairment (e.g., eGFR < 45 mL/min/1.73 m^2)
- Physician attests to assessment of baseline severity of behavior and/or functionality using an objective measure or tool [e.g., Clinical Global Impression-Improvement (CGI-I) score, Motor-Behavior Assessment (MBA), Interval History Form, Clinical Severity Scale, Rett Syndrome Gross Motor Scale)

Continuation of Therapy Criteria:

- Member continues to meet the first 4 initial criteria above,
- Member has had response to therapy from pre-treatment baseline with disease stability or improvement in core symptoms as evidenced on objective measure or tool [e.g., Rett Syndrome Behavior Questionnaire (RSBQ), CGI-I, MBA, Interval History Form, Clinical Severity Scale, Rett Syndrome Gross Motor Scale]

Interleukin-5 (IL-5) Receptor Alpha Antagonist, MAB

Last revised: 05/20/2025; Effective date: 07/19/2025

Prior Authorization Criteria follows the state's criteria (DMAS)

Generic	Brand
BENRALIZUMAB	FASENRA

Prior Authorization Criteria:

Length of Authorization:
Initial: 6 months
Continuation of Therapy: 12 months

Initial Review Criteria:

Severe* asthma:

- Diagnosis/documentation of uncontrolled moderate to severe asthma defined as any of the following:
- Diagnosis of asthma with an eosinophilic phenotype defined as blood eosinophils ⩾150 cells/μL
- ≥2 exacerbations in the past 12 months requiring systemic corticosteroids
- ≥1 asthma exacerbation(s) leading to hospitalization in the past 12 months
- Requires use of systemic corticosteroids (OCS) for asthma control
- Requires use of inhaled corticosteroids
- Forced expiratory volume in 1 second (FEV1)
- AND patient is ≥12 years
- A number of hospitalizations, ER visits, or unscheduled visits to healthcare providers due to asthma
- Fasenra (benralizumab) will NOT be used with Dupixent (dupilumab), Cinqair (resilizumab), Nucala (mepolizumab), Xolair (omalizumab), or Tezspire (tezepelumab-ekko).

***Components of severity for classifying asthma as severe may include any of the following (not all-inclusive).**

- Asthma remains uncontrolled despite optimized treatment with high-dose ICS-LABA
- Asthma requires high-dose ICS-LABA to prevent it from being uncontrolled
- Symptoms throughout the day
- Nighttime awakenings, often 7 times/week
- SABA use for symptom control occurs several times per day
- Extremely limited normal activities
- Lung function (percent predicted FEV1) < 60%
- Exacerbations requiring oral systemic corticosteroids are generally more frequent and intensely relative to moderate asthma

****Eosinophilic granulomatosis with polyangiitis (EGPA)**

- Diagnosis of EGPA (aka Churg-Strauss Syndrome
- Patient is ≥ 18 years
- Blood eosinophils ⩾ 1000 cells/μL or >10% of leukocytes
- Requires maximally tolerated oral corticosteroid therapy
- Intolerance, hypersensitivity or contraindication to oral corticosteroid therapy
- Baseline disease severity is assessed by utilizing an objective measure/tool (e.g., Birmingham Vasculitis Activity Score [BVAS], history of asthma symptoms and/or exacerbations, duration of remission, rate of relapses)
- Fasenra (benralizumab) will NOT be used with Dupixent (dupilumab), Cinqair (resilizumab), Nucala (mepolizumab), Xolair (omalizumab), or Tezspire (tezepelumab-ekko).

****Eosinophilic Granulomatosis Polyangiitis (EGPA) is defined as all of the following:**

- History or presence of asthma
- Blood eosinophil level > 10% or an absolute count > 1000 cells/mm3
- Two or more of the following criteria:
    - Histopathologic evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil rich granulomatous inflammation
    - Neuropathy
    - Pulmonary infiltrates
    - Sinonasal abnormalities
    - Cardiomyopathy
    - Glomerulonephritis
    - Alveolar hemorrhage
    - Palpable purpura
    - Antineutrophil Cytoplasmic Antibody (ANCA) positivity

Continuation of Therapy Criteria
Severe *asthma:

- There is no evidence of toxicity to therapy.
- Documentation of positive clinical response to Fasenra therapy demonstrated by decrease in one or more of the following:
    - Use of systemic corticosteroids
    - Hospitalization, ER visits, unscheduled visits to health care provider
    - Improvement from baseline in forced expiratory volume in 1 second (FEV1)

****Eosinophilic granulomatosis with polyangiitis (EGPA)**

- There is no evidence of toxicity to therapy.
- Documentation of positive clinical response to Fasenra therapy demonstrated by improvement in one or more of the following compared to baseline:
    - Member is in remission [defined as a Birmingham Vasculitis Activity Score (BVAS) score=0 and a prednisone/prednisolone daily dose of ≤ 7.5 mg]
    - Decrease in maintenance dose of systemic corticosteroids
    - Improvement in BVAS score compared to baseline
    - Improvement in asthma symptoms or asthma exacerbations
    - Improvement in duration of remission or decrease in the rate of relapses

Interleukin-6 (IL-6) Receptor Inhibitors (Actemra)

Last revised: 1/29/2025; Effective 4/1/2025

Generic	Brand
TOCILIZUMAB	ACTEMRA
TOCILIZUMAB-AAZG	TYENNE

Prior Authorization Criteria follows the state's criteria (DMAS)

Length of Authorization: 12 months

Review Criteria:

- Member has diagnosis of one of the following AND
  - Rheumatoid Arthritis (RA)
  - Polyarticular juvenile idiopathic arthritis (pJIA) – 2 years of age or older
  - Systemic Juvenile Idiopathic Arthritis – 2 years of age or older
  - Systemic sclerosis (scleroderma)-associated interstitial lung disease in adults (Actemra ONLY)
  - Giant cell arteritis (GCA) in adults
- If being used for Rheumatoid Arthritis (RA), Polyarticular Juvenile Idiopathic Arthritis (PJIA) or Systemic Juvenile Idiopathic Arthritis (SJIA):
  - Member tried and failed methotrexate, OR
  - This medication be used in conjunction with methotrexate OR
  - Member has a contraindication to methotrexate (e.g., alcohol abuse, cirrhosis, chronic liver disease, or other contraindication) AND
  - Member tried and failed another DMARD (other than methotrexate), such as azathioprine, d-penicillamine, cyclophosphamide, cyclosporine, gold salts, hydroxychloroquine, leflunomide, sulfasalazine, or tacrolimus
  - Therapeutic failure to one of the preferred agents (e.g., Humira, Enbrel)

Interleukin-6 (IL-6) Receptor Inhibitors (Kevzara

Last revised: 12/06/2024; Effective 1/1/2025

Generic	Brand
SARILUMAB	KEVZARA

Prior Authorization Criteria follows the state's criteria (DMAS)

Length of Authorization: 12 months

Initial Review Criteria:

- Member has diagnosis of one of the following AND
  - Rheumatoid Arthritis (RA)
  - Polymyalgia rheumatica (PMR)
  - Polyarticular juvenile idiopathic arthritis (pJIA) in pts weighing ≥ 63 kg

- Rheumatoid arthritis (RA)
  - ≥18 years old AND
  - Diagnosis of moderately to severely active rheumatoid arthritis (RA) AND
  - Prescribed by or in consultation with a rheumatologist AND
  - History of failure, contraindication, or intolerance to one non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Rheumatrex /Trexall (methotrexate), Arava (leflunomide), Azulfidine (sulfasalazine) ANDRenew Criteria
- Polymyalgia Rheumatica (PMR):
  - ≥18 years old? AND
  - Diagnosis of Polymyalgia Rheumatica (PMR)-AND
  - Prescribed by or in consultation with a rheumatologist -AND
  - History of failure, contraindication, or intolerance to corticosteroids or who cannot tolerate a steroid taper.
- Polyarticular juvenile idiopathic arthritis (pJIA) in pts weighing ≥ 63 kg
  - Member weight ≥ 63 kg
  - Prescribed by or in consultation with a rheumatologist -AND
  - History of failure, contraindication, or intolerance to one non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Rheumatrex /Trexall (methotrexate), Arava (leflunomide), Azulfidine (sulfasalazine)]

- Renew Criteria:
  - Patient is not receiving Kevzara in combination with any of the following:
    - Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
    - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
    - Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)

Interleukin-6 (IL-6) Receptor Inhibitors-Enspryng

Generic	Brand
SATRALIZUMAB-MWGE	ENSPRYNG

Prior Authorization Criteria follows DMAS's criteria
Length of Authorization: 12 months
Initial Review Criteria: • Member has diagnosis of Neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive (NMOSD) • Patient has a confirmed diagnosis based on the following: o Patient was found to be seropositive for aquaporin-4 (AQP4) IgG antibodies; AND o Patient has ≥ 1 core clinical characteristic (e.g., 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); AND • Alternative diagnoses have been excluded (e.g., multiple sclerosis, sarcoidosis, cancer, chronic infection)

Janus Kinase (JAK) Inhibitor

Last Revised 3.3.2025, Effective date: 4.1.2025

Generic	Brand
TOFACITINIB CITRATE	XELJANZ XELJANZ XR

Prior Authorization Criteria follows the state's criteria (DMAS)
Length of Authorization: 12 months
Initial Review Criteria: • Member has diagnosis of one of the following: o Adult Rheumatoid Arthritis (RA), moderate to severe o Polyarticular Course Juvenile Idiopathic Arthritis (pcJIA) (≥2 years) o Adult Psoriatic arthritis (PsA) o Adult Ulcerative Colitis (UC), moderate to severe o Ankylosing spondylitis • Ulcerative Colitis (UC) OR Ankylosing spondylitis: o Member had therapeutic failure, or inadequate response, or intolerant to one or more, preferred TNF blockers (e.g. Enbrel, Humira) • Rheumatoid Arthritis, Polyarticular Course Juvenile Idiopathic Arthritis, and Psoriatic arthritis o Member had therapeutic failure on oral methotrexate AND o Member had therapeutic failure to one of the preferred agents (e.g. Enbrel, Humira) AND o Member had therapeutic failure on or contraindication, or adverse reaction to methotrexate and at least one other DMARD (sulfasalazine, hydroxychloroquine, minocycline) o

Janus Kinase (JAK) Inhibitor (Cont'd)

Last Revised 12/1/2023

Generic	Brand
BARICITINIB	OLUMIANT

Prior Authorization Criteria follows the state's criteria (DMAS)
Length of Authorization: 12 months
Initial Review Criteria: • Member is ≥18 years, AND • Member has diagnosis of Rheumatoid Arthritis (RA) • Member had therapeutic failure on oral methotrexate AND • Member had therapeutic failure to one of the preferred agents (e.g. Enbrel, Humira) AND • Member had therapeutic failure on, inadequate response to or intolerant to TNF blockers • Member is not using in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants such as azathioprine or cyclosporine, AND

Janus Kinase (JAK) Inhibitor (Cont'd)

Last Revised 05/20/2025; Effective date: 07/19/2025

Generic	Brand
UPADACITINIB	RINVOQ, RINVOQ LQ

Prior Authorization Criteria follows the state's criteria (DMAS)

Length of Authorization: 12 months

Initial Review Criteria:

- Member meets the age cutoffs for the diagnoses below, AND:
  - ≥2 years:
    - Active psoriatic arthritis
    - Active polyarticular JIA (pJIA)
  - ≥12 years:
    - Atopic dermatitis
  - ≥18 years:
    - Active ankylosing spondylitis
    - Moderately to severely active ulcerative colitis
    - Moderately to severely active rheumatoid arthritis
    - Non-radiographic axial spondylarthritis
    - Moderately to severely active Crohn's Disease
    - Giant Cell Arteritis
- <u>If using for atopic dermatitis:</u>
  - Member had therapeutic failure to at least TWO of the preferred agents for atopic dermatitis (e.g., tacrolimus, Elidel, Eucrisa, Dupixent, Adbry)
- <u>If using for other indications:</u>
  - Member had therapeutic failure on oral methotrexate, AND
  - Member had therapeutic failure to one of the preferred agents (e.g. Enbrel, Humira) AND
- Member is not using in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants such as azathioprine or cyclosporine

Janus Kinase (JAK) Inhibitor (Cont'd)

Last Revised 12/1/2023

Generic	Brand
ABROCITINIB	CIBINQO

Prior Authorization Criteria follows the state's criteria (DMAS)
Length of Authorization: 12 months
Initial Review Criteria: • ≥12 years, and • Diagnosis of moderate to severe atopic dermatitis, AND • Documented trial and failure (or contraindication) of 1 topical corticosteroid of medium to high potency (e.g., mometasone, fluocinolone) and 1 topical calcineurin inhibitor (tacrolimus or pimecrolimus), AND • Inadequate response to a 3-month minimum trial of at least 1 immunosuppressive systemic agent (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, etc.), AND • Inadequate response (or is not a candidate) to a 3-month minimum trial of phototherapy (e.g., psoralens with UVA light [PUVA], UVB, etc.) provided member has reasonable access to photo treatment, AND • Member had therapeutic failure on oral methotrexate, AND • Member had therapeutic failure to one of the preferred agents (e.g. Enbrel, Humira), AND • Member is not using in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants such as azathioprine or cyclosporine

Monoclonal Antibodies to Immunoglobulin E (IGE)

Last revised: 05/20/2025; Effective date: 07/19/2025

Prior Authorization Criteria follows the state's criteria (DMAS)

Generic	Brand
OMALIZUMAB	XOLAIR

Length of Authorization:
Initial: 6 months
Renewal: 12 months
Initial Review Criteria:

Severe* Asthma:

- Diagnosis of severe asthma defined as any of the following:
  - ≥2 exacerbations in the past 12 months requiring systemic corticosteroids
  - ≥1 asthma exacerbation(s) leading to hospitalization in the past 12 months
  - Dependence on daily oral corticosteroids (OCS) for asthma control
- AND patient is ≥6 years,
- AND member weigh between 20 kg (44 lbs.) and 150 kg (330 lbs.),
- AND member has a positive skin test or in vitro reactivity to a perennial aero‑allergen
- AND Member has serum total IgE level, measured before the start of treatment, of either:
  - ⩾ 30 IU/mL and ⩽ 700 IU/mL in patients age ⩾ 12 years; OR
  - ⩾ 30 IU/mL and ⩽ 1300 IU/mL in patients age 6 to 12 years
- AND Xolair will NOT be used with Fasenra (benralizumab), Cinqair (resilizumab), Dupixent (dupilumab), Nucala (mepolizumab), or Tezspire (tezepelumab-ekko)
- AND Xolair will be used for add‑on maintenance treatment in members regularly receiving both (unless otherwise contraindicated) of the following:
  - Medium‑ to high‑dose inhaled corticosteroids; AND
  - An additional controller medication (e.g., long‑acting beta agonist, leukotriene modifiers)
- Member has at least one of the following:
  - Use of systemic corticosteroids
  - Use of inhaled corticosteroids
  - A number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition
  - Forced expiratory volume in 1 second (FEV1)

***Components of severity for classifying asthma as severe may include any of the following (not all-inclusive).**

- Asthma remains uncontrolled despite optimized treatment with high-dose ICS-LABA
- Asthma requires high-dose ICS-LABA to prevent it from being uncontrolled
- Symptoms throughout the day
- Nighttime awakenings, often 7 times/week
- SABA use for symptom control occurs several times per day
- Extremely limited normal activities
- Lung function (percent predicted FEV1) < 60%
- Exacerbations requiring oral systemic corticosteroids are generally more frequent and intensely relative to moderate asthma

CHRONIC RHINOSINUSITIS WITH NASAL POLYPS (CRSwNP):

- Patient is 18 years of age or older, AND
- Tried and failed at least 8 weeks of intranasal corticosteroid therapy, AND
- Presence of at least 3 of the following indicators for biologic treatment:

[Note: members with a history of sino‑nasal surgery are only required to have at least 3 of the indicators]:

    - evidence of type 2 inflammation (e.g., tissue eosinophils ⩾10/hpf, blood eosinophils ⩾ 150 cells/μL, or total IgE ⩾ 100 IU/mL)
    - required ⩾2 courses of systemic corticosteroids per year or >3 months of low dosecorticosteroids, unless contraindicated.
    - disease significantly impairs the patient's quality of life
    - there is significant loss of smell
    - there is comorbid diagnosis of asthma; AND
- The member does not have any of the following:
    - Antrochoanal polyps
    - Nasal septal deviation that would occlude at least one nostril
    - Disease with lack of signs of type 2 inflammation
    - Cystic fibrosis
    - Mucoceles; AND
    - Other causes of nasal congestion/obstruction have been ruled out (e.g., acute sinusitis, nasal infection or upper respiratory infection, rhinitis medicamentosa, tumors, infections, granulomatosis)? AND
- Physician assessed baseline disease severity utilizing an objective measure/tool, AND
- Therapy is used in combination with intranasal corticosteroids unless patient is unable to tolerate or corticosteroid therapy is contraindicated
- Xolair will NOT be used with Fasenra (benralizumab), Cinqair (resilizumab), Dupixent (dupilumab), Nucala (mepolizumab), or Tezspire (tezepelumab-ekko)
-

Clinical Criteria for IgE‑Mediated Food Allergy:

- Patient is 1 year of age or older, AND
- Prescribing physician is an allergist or immunologist, or an allergist or immunologist has been consulted, AND
- Diagnosis of food allergy as confirmed by:
    - A positive skin prick test under a drop of allergen extract; OR
    - A positive IgE screening (⩾ kUA/L) to identified foods? AND
    - Member practices allergen avoidance

- Xolair will NOT be used with Fasenra (benralizumab), Cinqair (resilizumab), Dupixent (dupilumab), Nucala (mepolizumab), or Tezspire (tezepelumab-ekko)

Continuation of therapy for all indications:

- Member been assessed for toxicity, AND

Severe asthma renewal

- Member has improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in one or more of the following:
    - Use of systemic corticosteroids
    - Hospitalizations, ER visits, Unscheduled visits to healthcare provider
    - Improvement from baseline in forced expiratory volume in 1 second (FEV1)

CHRONIC IDIOPATHIC URTICARTIA/CHRONIC SPONTANEOUS URTICARIA renewal

- Member has a clinical improvement as documented by an objective clinical evaluation tool (e.g.,UAS7, AAS, DLQI, AE - QoL, UCT, AECT, CU - Q2oL, etc.)

CRSwNP renewal

- Improvement of the disease state as indicated by improvement in signs and symptoms compared to baseline in one or more of the following: nasal/obstruction symptoms, improvement of sinus opacifications as assessed by CT - scans and/or an improvement on a disease activity scoring tool [e.g., nasal polyposis score (NPS), nasal congestion (NC) symptom severity score, sinonasal outcome test - 22 (SNOT - 22), etc.] OR
- There is improvement in at least one of the following response criteria:
    - Reduction in nasal polyp size
    - Reduction in need for systemic corticosteroids
    - Improvement in quality of life
    - Improvement in sense of smell
    - Reduction of impact of comorbidities

IgE-Mediated Food Allergy renewal

- Member is experiencing a clinical response and improvement as attested by the prescriber

Monoclonal Antibody Human Interleukin 12/23 Inhibitor

Last revised 3/19/2025; Effective 6/3/2025

Generic	Brand
USTEKINUMAB	STELARA
USTEKINUMAB-AEKN	SELARSDI
USTEKINUMAB-AUUB	WEZLANA
USTEKINUMAB-TTWE	PYZCHIVA
USTEKINUMAB-AAUZ	OTULFI
USTEKINUMAB-SRLF	IMULDOSA
USTEKINUMAB-STBA	STEQEYMA

Prior Authorization Criteria follows the state's criteria (DMAS)

- **Length of Authorization:** 12 months

Initial Review Criteria:

- Member has diagnosis of at least one of the following, AND
  - Adult Crohn's disease (CD), moderate to severe
  - Psoriatic arthritis (PsA), adult and pediatric patient 6 years of age and older
  - Adult Ulcerative Colitis (UC), moderate to severe
  - Plaque Psoriasis (PsO), moderate to severe, adult and pediatric patient 6 years of age and older
- Member had therapeutic failure to the preferred agents (e.g. Enbrel, Humira)

Additional Criteria for Plaque Psoriasis:

- Member is a candidate for phototherapy or systemic therapy

Monoclonal Antibody- Interleukin-5 Antagonist

Last revised: 05/20/2025; Effective date: 07/19/2025

Prior Authorization Criteria follows the state's criteria (DMAS)

Generic	Brand
MEPOLIZUMAB	NUCALA

Length of Authorization:
Initial: 6 months
Renewal: 12 months

Initial Review Criteria:

Clinical Criteria for Severe* Asthma

- Diagnosis of severe asthma AND
- Asthma with an eosinophilic phenotype defined as blood eosinophils ⩾150 cells/μL, AND
  - ≥2 exacerbations in the past 12 months requiring systemic corticosteroids
  - ≥1 asthma exacerbation(s) leading to hospitalization in the past 12 months
- AND patient is ≥ 6 years,
- AND Nucala will NOT be used with Fasenra (benralizumab), Cinqair (resilizumab), Dupixent (dupilumab), Xolair (omalizumab), or Tezspire (tezepelumab-ekko)
- AND Nucala is being used as an add‐on maintenance treatment in members regularly receiving both (unless otherwise contraindicated) of the following:
  - Medium‐ to high‐dose inhaled corticosteroids; AND
  - An additional controller medication (e.g., long‐acting beta agonist, leukotriene modifiers)
- AND member has at least one of the following documented for assessment of clinical status:
  - Use of systemic corticosteroids
  - Use of inhaled corticosteroids
  - Number of hospitalizations, ER visits, or unscheduled visits to healthcare providers due to condition
  - Forced expiratory volume in 1 second (FEV1)
- AND if using for eosinophilic asthma documented treatment failure, contraindication or inadequate response to Fasenra AND Xolair

***Components of severity for classifying asthma as severe may include any of the following (not all-inclusive):**

- Asthma remains uncontrolled despite optimized treatment with high-dose ICS-LABA
- Asthma requires high-dose ICS-LABA to prevent it from being uncontrolled
- Symptoms throughout the day
- Nighttime awakenings, often 7 times/week
- SABA use for symptom control occurs several times per day
- Extremely limited normal activities
- Lung function (percent predicted FEV1) < 60%
- Exacerbations requiring oral systemic corticosteroids are generally more frequent and intensely relative to moderate asthma

Clinical Criteria for **EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS§ (EGPA)

- Patient is ⩾ 18 years, AND

- Diagnosis of EGPA (aka Churg‐Strauss Syndrome), AND
- Blood eosinophils ⩾ 1000 cells/μL or ≥ 10% eosinophils on white blood cell differential count, AND
- Patient has been on stable doses of concomitant oral corticosteroid therapy for at least 4 weeks (i.e., prednisone or prednisolone at a dose of 7.5 mg/day), AND
- Physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., Birmingham Vasculitis Activity Score [BVAS], history of asthma symptoms and/or exacerbations, duration of remission, rate of relapses)
- Documented treatment failure, contraindication or inadequate response to Fasenra
- Nucala will NOT be used with Fasenra (benralizumab), Cinqair (resilizumab), Dupixent (dupilumab), Xolair (omalizumab), or Tezspire (tezepelumab-ekko)

****Eosinophilic Granulomatosis Polyangiitis (EGPA) is defined as all of the following:**

- History or presence of asthma
- Blood eosinophil level > 10% or an absolute count > 1000 cells/mm3
- Two or more of the following criteria:
    - Histopathologic evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil rich granulomatous inflammation
    - Neuropathy
    - Pulmonary infiltrates
    - Sinonasal abnormalities
    - Cardiomyopathy
    - Glomerulonephritis
    - Alveolar hemorrhage
    - Palpable purpura
    - Antineutrophil Cytoplasmic Antibody (ANCA) positivity

Clinical Criteria for HYPEREOSINOPHILIC SYNDROME (HES):

- Patient is ≥ 12 years, AND
- Diagnosis of HES (without an identifiable non‐hematologic secondary cause (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non‐hematologic malignancy) or FIP1L1‐PDGFRα kinase‐positive HES) for at least 6 months prior to starting treatment, AND
- History of 2 or more HES flares within the previous 12 months (e.g., documented HES‐related worsening of clinical symptoms or blood eosinophil counts requiring an escalation in therapy), AND
- Nucala will be used in combination with stable doses of at least one other HES therapy, (e.g., oral corticosteroids, immunosuppressive agents, cytotoxic therapy) unless the member cannot tolerate other therapy
- Nucala will NOT be used with Fasenra (benralizumab), Cinqair (resilizumab), Dupixent (dupilumab), Xolair (omalizumab), or Tezspire (tezepelumab-ekko)

Clinical Criteria for CHRONIC RHINOSINUSITIS WITH NASAL POLYPS (CRSwNP)

- Patient is ≥ 18 years, AND
- Member has bilateral symptomatic sino‐nasal polyposis with symptoms lasting at least 8 weeks, AND

- Failure of at least 8 weeks of intranasal corticosteroid therapy AND
- Therapy will be used in combination with intranasal corticosteroids unless unable to tolerate or contraindicated, AND
- Failure of an adequate trial of the preferred product Xolair
- Nucala will NOT be used with Fasenra (benralizumab), Cinqair (resilizumab), Dupixent (dupilumab), Xolair (omalizumab), or Tezspire (tezepelumab-ekko)

Continuation of Therapy Criteria:

- Patient has been assessed for toxicity

Severe asthma

- Improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in one or more of the following:
    - Use of systemic corticosteroids,
    - Hospitalizations, ER visits, Unscheduled visits to healthcare provider
    - Improvement from baseline in forced expiratory volume in 1 second (FEV1)

EGPA

- Member has disease response as indicated by improvement in signs and symptoms compared to baseline as evidenced in one or more of the following:
    - Member is in remission [defined as a Birmingham Vasculitis Activity Score (BVAS) score=0 and a prednisone/prednisolone daily dose of $\leqslant$ 7.5 mg]
    - Decrease in maintenance dose of systemic corticosteroids.
    - Improvement in BVAS score compared to baseline.
    - Improvement in asthma symptoms or asthma exacerbations
    - Improvement in duration of remission or decrease in the rate of relapses

HES

- Member has a disease response as indicated by a decrease in HES flares from baseline (Note: An HES flare is defined as worsening of clinical signs and symptoms of HES or increasing eosinophils (on at least 2 occasions), resulting in the need to increase oral corticosteroids or increase/add cytotoxic or immunosuppressive HES therapy.)

CRSwNP

- Member has disease response as indicated by improvement in signs and symptoms compared to baseline in one or more of the following: nasal/obstruction symptoms, improvement of sinus opacifications as assessed by CT‐scans and/or an improvement on a disease activity scoring tool [e.g., nasal polyposis score (NPS), nasal congestion (NC) symptom severity score, sinonasal outcome test‐22 (SNOT‐22), etc.], **OR**
- Member has improvement in at least one of the following response criteria:
    - Reduction in nasal polyp size
    - Reduction in need for systemic corticosteroids
    - Improvement in quality of life
    - Improvement in sense of smell
    - Reduction of impact of comorbidities

Respiratory Tract Agents-(Miscellaneous)-THYMIC STROMAL LYMPHOPOIETIN (TSLP) INHIBITORS (Tezspire)

Last revised 05/20/2025; Effective date: 07/19/2025

Generic	Brand
TEZEPELUMAB-EKKO	Tezspire

Prior Authorization Criteria follows the state's criteria (DMAS)

Length of Authorization:
Initial: 6 months
Renewal: 12 months

Initial Review Criteria:

- Member is ≥ 12 years of age.
- Member has a diagnosis of severe * asthma
- Coadministration with another monoclonal antibody will be avoided (e.g., omalizumab, mepolizumab, reslizumab, benralizumab, dupilumab), **AND**
- Therapy is being used as an add-on maintenance treatment in members regularly receiving **both** (unless otherwise contraindicated) of the following:
    - Medium- to high-dose inhaled corticosteroids; **AND**
    - An additional controller medication (e.g., long-acting beta agonist, leukotriene modifiers)
- Member had two or more exacerbations in the previous year requiring oral or injectable corticosteroid treatment (in addition to the regular maintenance therapy defined above) or one exacerbation resulting in a hospitalization, AND
- Member has at least one of the following for assessment of clinical status:
    - Use of systemic corticosteroids
    - Use of inhaled corticosteroids
    - Several hospitalizations (e.g., ER visits, or unscheduled visits to healthcare provider due to condition)
    - Forced expiratory volume in 1 second (FEV_1), **AND**
- Member tried and failed an adequate trial of the 2 different preferred products (Fasenra® and Xolair®), or have an intolerance to a preferred agents, OR
- Member lacks an eosinophilic phenotype with blood eosinophils ≥150 cells/Ml, AND
- Member has a serum IgE level < 30 IU/mL
- Member has another predicted intolerance to the preferred agent

Continuation of Therapy Criteria:

- Member has been assessed for toxicity, **AND**
- **M**ember has improvement in asthma symptoms or asthma exacerbations as evidenced by a decrease in one or more of the following:

- Use of systemic corticosteroids
- Hospitalizations
- ER visits
- Unscheduled visits to healthcare provider
- Improvement from baseline in forced expiratory volume in 1 second (FEV_1)

*Components of severity for classifying asthma as severe may include any of the following (not all-inclusive).

- Asthma remains uncontrolled despite optimized treatment with high-dose ICS-LABA
- Asthma requires high-dose ICS-LABA to prevent it from being uncontrolled
- Symptoms throughout the day
- Nighttime awakenings, often 7 times/week
- SABA use for symptom control occurs several times per day
- Extremely limited normal activities
- Lung function (percent predicted FEV1) < 60%
- Exacerbations requiring oral systemic corticosteroids are generally more frequent and intensely relative to moderate asthma

Pulmonary Fibrosis- Systemic Enzyme Inhibitors

Last revised: 3/19/2025; Effective date: 6/3/2025

Prior Authorization Criteria follows the state's criteria (DMAS)

Generic	Brand
NINTEDANIB ESYLATE	OFEV

Prior Authorization Criteria:
Length of Authorization: • Initial: 12 months • Reauthorization: 12 months

Initial & Continuation of Therapy Criteria:
• Prescriber is a Pulmonologist,
• AND patient is 18 years of age or older,
• AND patient has one of the following diagnoses:
  o Systemic sclerosis-associated interstitial lung disease (SSc-ILD), and Ofev is being used to slow the rate of decline in pulmonary function,
  o Chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype
  o Idiopathic pulmonary fibrosis (IPF)
• AND baseline percent predicted forced vital capacity (FVC) ≥50%,
• AND liver function tests have been performed,
• AND patient is not a smoker,
• AND if patient is female, there is a negative pregnancy test,
• AND documentation has been provided of clinical evidence to support use of this medication

Antibiotics, Inhaled (Tobi Podhaler) – Step Therapy (ST)

Generic	Brand
TOBRAMYCIN	TOBI PODHALER

*representative list

Step Therapy Criteria:
Adapted from DMAS Preferred Drug List– Step Therapy (ST)

Length of Authorization:
- Initial: 1 year
- Reauthorization: 1 year

Initial Review Criteria:
- Patient must be ≥ 6 years old
- Must provide a clinical reason as to why one of the preferred tobramycin inhalation nebulizer solutions cannot be used

Continuation of Therapy Criteria:
- Documentation of continued medical necessity

Antiemetic Agents (Cannabinoid Derivatives)

Generic	Brand
DRONABINOL	MARINOL, SYNDROS
NABILONE	CESAMET

*representative list

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 6 months
- Reauthorization: 6 months

Initial Review Criteria:

- Patient must have diagnosis of HIV or Cancer (FDA-approved age indication)
- Non-preferred agents must have documented trial and treatment failure with dronabinol (generic) prior to approval

Continuation of Therapy Criteria:

- Documentation of continued medical necessity

Antimigraine

Last revised 05/20/2025 Effective 07/19/2025

Generic	Brand
ERENUMAB-AOOE	AIMOVIG
FREMANEZUMAB-VFRM	AJOVY
GALCANEZUMAB-GNLM	EMGALITY
LASMIDTAN	REYVOW
UBROGEPANT	UBRELVY
RIMEGEPANT SULFATE	NURTEC
ATOGEPANT	QULIPTA
ZAVEGEPANT	ZAVZEPRET

*representative list

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 6 months
- Reauthorization: 1 year

Initial Review Criteria:

- Patient must be 18 years old or older

For preventative treatment of migraine:

- Preferred agents are Aimovig, Ajovy, Emgality 120 mg, Nurtec ODT, and Qulipta
- Provider assessed baseline disease severity utilizing an objective measure/tool (e.g., International Classification of Headache Disorders (ICHD-III); Headache Impact Test [HIT-6]; monthly headache day [MHD]; Migraine Disability Assessment [MIDAS]; Migraine Physical Function Impact Diary [MPFID]) AND
- , AND
- Patient has ≥ 4 migraine days per month for at least 3 months, AND
- Tried and failed a ≥ 1-month trial of any 2 of the following oral generic medications:
    - Antidepressants (e.g., amitriptyline, venlafaxine)
    - Beta blockers (e.g., propranolol, metoprolol, timolol, atenolol)
    - Anti-epileptics (e.g., valproate, topiramate)
    - Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (e.g., lisinopril, candesartan)
-
- Additional criteria for the preferred agents- Nurtec and Qulipta
    - Trial and failure of one injectable agent
- For the non-preferred agents, Emgality 100 mg the above criteria apply and non-formulary exception is required, (trial and failure of two preferred agents)

For acute treatment of migraine:

- Preferred Nurtec ODT and Ubrelvy require trial of 2 generic triptans
- Diagnosis of migraine with or without aura,
- Non-preferred Reyvow and must meet the following criteria:
    - Diagnosis of migraine with or without aura, AND
    - Trial and failure, or has contraindications to, two preferred triptans, AND
    - Non-formulary exception is required for using the non-preferred product.

For Episodic Cluster Headache:

- Diagnosis of episodic cluster headache, AND
- Patient experienced at least two cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months, AND
- Medication requested will not be used in combination with another CGRP antagonist or inhibitor used for the preventive treatment of migraines, AND
- Trial and failure (or has contraindications to) of at least one formulary preferred therapy for cluster headache

Continuation of Therapy Criteria:

- Patient demonstrates a significant decrease in the number, frequency, and/or intensity of headache

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Weight Loss Drugs

Revised 05/20/2025 ; Effective 07/19/2025

Generic	Brand
ORLISTAT	XENICAL
BENZPHETAMINE HCL	DIDREX, REGIMEX
PHENTERMINE HCL	ADIPEX-P, OBY-CAP, LOMAIRA
DIETHYLPROPION HCL	DIETHYLPROPION HCL
PHENDIMETRAZINE TARTRATE	BONTRIL PDM, BONTRIL SLOW-RELEASE
LIRAGLUTIDE	SAXENDA
SEMAGLUTIDE	WEGOVY
SETMELANOTIDE ACETATE	IMCIVREE
TIRZEPATIDE	ZEPBOUND

*representative list

Prior Authorization Criteria:
Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial:
  - 3 months: Benzphetamine, diethylpropion, phendimetrazine, phentermine,
  - 4 months: Imcivree
  - 6 months: Wegovy, Zepbound, Saxenda, Orlistat (Xenical)

Initial Review Criteria:
Coverage for all weight loss medications is limited to the following and in the absence of the medical contraindications:

- No contraindications to use (i.e. uncontrolled hypertension, hyperthyroidism etc for stimulant based products); AND
- No malabsorption syndromes, cholestasis, pregnancy, and/or lactation (for orlistat); AND
- No history of an eating disorder (e.g., anorexia, bulimia); AND
- No acute pancreatitis, acute suicidal behavior/ideation, personal or family history of medullary thyroid cancer or multiple endocrine neoplasia 2 syndrome (if requesting a GLP-1 Receptor Agonists)
- Provider attest patient's obesity is disabling and life threatening (i.e., puts the patient at risk for high-morbidity conditions
- **For all others except Imcivree®, additional qualifying criteria are:**
- Participation in nutritional counseling
- Participation in physical activity program, unless medically contraindicated
- Commitment to continue the above weight-loss treatment plan
- Nutritional or Dietetic Assessment
- Description of current weight loss plan with diet and exercise components

Group/Drug Specific Criteria: **Anti-obesity-Anorexic and Fat Absorbing agents** (phentermine; phendimetrazine tablet; phendimetrazine ER capsule; orlistat

- Age Requirements:
  - phentermine: minimum age 17
  - phendimetrazine tablet: minimum age 18
  - phendimetrazine ER capsule: minimum age 17
  - orlistat: minimum age 12
- Body Mass Index (BMI) Requirements:
  - BMI ⩾ 30 kg/m2, if no applicable risk factors
  - BMI ⩾ 27 kg/m2, with one or more of the following risk factors:
    - Coronary heart disease
    - Dyslipidemia
    - Hypertension
    - Sleep apnea
    - Type 2 Diabetes

Group/Drug Specific Criteria: **Anti-obesity-Anorexic** (benzphentamine, diethylpropion)

- Age Requirements:

- benzphetamine: minimum age 17
- diethylpropion: minimum age 16

➢ Body Mass Index (BMI) Requirements:
- BMI ⩾ 30 kg/m2

Group/Drug Specific Criteria: **Anti-Obesity Melanocortin 4 Receptor Agonists** (Imcivree®)

- Minimum age 6
- Body Mass Index (BMI) ⩾ 30 kg/m2
- Prescribed by or in consultation with an endocrinologist or geneticist
- Member has Bardet-Biedl syndrome (BBS
- Member has proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency, as confirmed by a genetic test

Group/Drug Specific Criteria **GLP-1/Incretin mimetics FDA indicated for weight loss** (Wegovy®, Saxenda®, and Zepbound)

- Wegovy/Saxenda: minimum age 12
- Zepbound: minimum age 18
- BMI > 40 kg/m2, if no applicable risk factors; OR
- BMI > 37 kg/m2 with one or more of the following risk factors:
  - Dyslipidemia
  - Hypertension
  - Type 2 diabetes
- Member has tried and failed one of the non-GLP1 weight-loss medications(*), OR
- Member is intolerant to all non-GLP1 weight-loss medications(*)
- Member not concurrently on another GLP-1 receptor agonists
- For an FDA-indicated GLP-1 agonist, the member has tried and failed the selected (*) medication for the duration and outcome listed below:
  - benzphetamine*; diethylpropion*; phendimetrazine*; phentermine*: 3 month trial without a weight loss of 10 lbs
  - orlistat*: 6-month trial without a weight loss of 10 lbs
  - GLP-1 Receptor Agonist: 6-month trial without a body weight reduction of 5%

Additional criteria for Wegovy- FDA approved for Weight Loss and Cardiovascular Risk Reduction

➢ Initial authorizations- 6 months

Initial Review Criteria:

- Prescribed by a cardiologist or vascular specialist, and
- 45 years of age or older, AND
- Clinical history of one of the following:

    - Myocardial infarction (MI) defined as cardiac biomarkers, an electrocardiogram or cardiac imaging, OR
    - Stroke defined as neurological dysfunction because of a hemorrhage or infarction, OR
    - Peripheral artery disease as defined by intermittent claudication with ankle-brachial index less than 0.85 at rest, or peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease
- Member has not had a MI, stroke, transient ischemic attack or hospitalization for unstable angina in the last 60 days, AND
    - BMI ⩾ 27 kg/m2; AND
    - Provider attests that the member received individualized healthy lifestyle counseling; AND
    - The member does not have a previous diagnosis of diabetes; AND
    - The member does not have pancreatitis, acute suicidal behavior/ideation, personal or family history of medullary thyroid cancer or multiple endocrine neoplasia 2 syndrome

Renewal Criteria Wegovy - FDA approved for Weight Loss and Cardiovascular Risk Reduction

- Renewal authorizations- 12 months

    - The member continues to meet the initial criteria
    - The member is being treated with a maintenance dosage of the requested drug

Additional criteria for Zepbound- FDA approved for Weight Loss and Obstructive Sleep Apnea (OSA)

- Initial authorizations- 6 months

Initial Review Criteria:

- Prescribed by a sleep apnea specialist, pulmonologist, otolaryngologist (ENT), or neurologist
- 18 years of age or older
- Requesting provider is managing the member's obstructive sleep apnea
- Diagnosis of moderate to severe Obstructive Sleep Apnea (OSA), as diagnosed by polysomnography with an apnea-hypopnea index (AHI) ⩾15 events per hour
- BMI ⩾30 kg/m2
- Member is currently on, or has tried, failed, or there is documented evidence of being unable to tolerate continuous positive airway pressure therapy (CPAP) through an adequate trial of CPAP use for ⩾ 4 hours per night on ⩾ 70% of nights for two or more months.
- Member has participated in a weight loss treatment plan (e.g. nutritional counseling, an exercise regimen, and calorie restricted/fat restricted diet) in the

past 6 months and will they continue to follow this treatment plan while taking an anti-obesity medication for obstructive sleep apnea
- Member does not have craniofacial abnormalities that may affect breathing
- Member does not have a diagnosis of central or mixed sleep apnea or Cheyne-Stokes respiration
- Member does not have pancreatitis, acute suicidal behavior/ideation, or gastroparesis, is the member using prokinetic drugs (e.g., metoclopramide), or does the member have a personal or family history of medullary thyroid cancer or multiple endocrine neoplasia 2 syndrome
- Attestation and submission of polysomnography conducted within the last 12 months
- Attestation and submission of weight loss treatment plan within the past 6 months

Renewal Criteria for Zepbound- FDA approved for Weight Loss and Obstructive Sleep Apnea (OSA)

- Renewal authorizations- 12 months

  - Member meets initial criteria
  - Member is treated with a maintenance dosage of the requested drug
  - Member experienced improvement of OSA symptoms through documented evidence provided

Continuation of Therapy Criteria FOR ALL Weight Loss drugs

- Continue to meet initial review criteria
- No contraindication to the medication used
- Documentation of continued weight loss- Varies (drug specific)
  - Benzphetamine, diethylpropion, phendimetrazine, phentermine – If the member achieves at least a 10 lb. weight loss during the initial 3 months of therapy, an additional 3-month approval may be granted. Maximum length of continuous drug therapy is 6 months (waiting period of 6 months before next request).
  - Orlistat (Xenical®) – If the member achieves at least a 10 lb. weight loss, an additional 6-month approval may be granted. Maximum length of continuous drug therapy is 24 months (waiting period of 6 months before next request).
  - Imcivree™ – If the member has experienced ≥ 5% reduction in body weight (or ≥ 5% of baseline BMI in those with continued growth potential), an additional 1 year SA may be granted.
  - GLP-1 Receptor Agonists (Wegovy™, Saxenda®, Zepbound®) - If the member achieves a weight loss of at least 5% of baseline weight, an additional 6 month SA may be granted.

Antipsychotic Agents

Last revised: 05/20/2025; Effective 07/19/2025

Generic	Brand
CLOZAPINE	FAZACLO, CLOZARIL, VERSACLOZ
OLANZAPINE,	ZYPREXA
HALOPERIDOL LACTATE, HALOPERIDOL , HALOPERIDOL DECANOATE	HALDOL
FLUPHENAZINE HCL, FLUPHENAZINE DECANOATE	
THIORIDAZINE HCL	
THIOTHIXENE	
CHLORPROMAZINE HCL	
TRIFLUOPERAZINE HCL	
PERPHENAZINE	
QUETIAPINE FUMARATE	SEROQUEL
ARIPIPRAZOLE	ABILIFY, OPIPZA
PIMOZIDE	ORAP
RISPERIDONE, RISPERIDONE MICROSPHERES RISPERIDONE ODT	RISPERDAL, RISPERDAL ODT, RISPERDAL CONSTA, PERSERIS, UZEDY, RYKINDO
ZIPRASIDONE HCL, ZIPRASIDONE MESYLATE	GEODON
ARIPIPRAZOLE LAUROXIL	ARISTADA, ARISTADA INITIO
PALIPERIDONE, PALIPERIDONE PALMITATE	INVEGA ERZOFRI
LOXAPINE, LOXAPINE SUCCINATE	ADASUVE
ILOPERIDONE	FANAPT
BREXPIPRAZOLE	REXULTI
CARIPRAZINE HCL	VRAYLAR
ASENAPINE MALEATE	SAPHRIS
LURASIDONE HCL	LATUDA
MOLINDONE HCL	
PIMAVANSERIN TARTRATE	NUPLAZID
LUMATEPERONE TOSYLATE	CAPLYTA
OLANZAPINE-SAMIDORPHAN L-MALATE	LYBALVI
XANOMELINE TARTRATE-TROSPIUM CHLORIDE	COBENFY

*representative list

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 1 year
- Reauthorization: 1 year

Initial Review Criteria:

- Required for use of antipsychotics in children ≤ 17 years old
- Prescribing provider must be either a Psychiatrist, Neurologist, or a Developmental/Behavioral Pediatrician or have consulted with one of these providers before prescribing the requested medication
- Documentation of a developmentally appropriate, comprehensive psychiatric assessment with diagnoses, impairments, treatment target, and treatment plans clearly identified
- Documentation of psychosocial treatment without adequate clinical response
- Documentation of patient's current behavior health program and pharmaceutical agents attempted with outcomes
- Treatment plan includes psychosocial treatment with parental involvement for the duration of medication therapy
- Documentation of informed consent for this medication from the parent or guardian
- Documentation of a family assessment having been performed, including parental psychopathology and treatment needs
- Documentation of evaluation of family functioning and parent-child relationship

Continuation of Therapy Criteria:

- Documentation of continued medical necessity

Cardiac Drugs, Miscellaneous

Last revised: 12/6/2022

Generic	Brand
TAFAMIDIS MEGLUMINE	VYNDAQEL
TAFAMIDIS	VYNDAMAX

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Cardiologist,
- AND patient is ≥18 years,
- AND diagnosis of cardiac amyloidosis on the problem list or per cardiologist documentation,
- AND evidence of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) demonstrated by positive biopsy demonstrating transthyretin (TTR)-amyloid deposition OR meeting all 3 of the following:
    - Diagnosis of heart failure (defined as stage C heart failure plus NYHA Class I, II, or III).
    - Pyrophosphate (PYP) scintigraphy cardiac uptake visual score of either grade 2 or 3 using Perugini Grade 1-3 scoring system, calculated heart-to-contralateral (H/CL) ration ≥1.5.
    - Absence of monoclonal gammopathy after testing for serum immunofixation (IFE) and serum free light chains
- AND medical history of heart failure with at least 1 prior hospitalization for heart failure or clinical evidence of heart failure (without hospitalization) manifested by signs or symptoms of volume overload or elevated intracardiac pressures that require treatment diuretic
- AND patient is NOT receiving inotersen or patisiran
- AND patient has NOT had prior heart or liver transplantation
- Patient does NOT have an implanted cardiac mechanical assist device

Continuation of Therapy Criteria:

- Documentation of positive clinical response AND
- Office visit or telephone visit with a specialist within the past 12 months

Cardiac Myosin Inhibitor

Last revised: 3/19/2025; Effective date: 6/3/2025

Generic	Brand	HICL	GSN	Representative NDC
MAVACAMTEN	CAMZYOS CAPS 2.5 MG	47972	083317	73625011111
MAVACAMTEN	CAMZYOS CAPS 5 MG	47972	083318	73625011211
MAVACAMTEN	CAMZYOS CAPS 10 MG	47972	083319	73625011311
MAVACAMTEN	CAMZYOS CAPS 15 MG	47972	083320	73625011411

Prior Authorization Criteria:

Length of Authorization:

- Initial: 3 months
- Reauthorization: 6 months

Initial Review Criteria:

- Prescriber is a Cardiologist,
- AND patient is 18 years of age or older,
- AND diagnosed with oHCM consistent with current AHA/ACC guidelines and satisfies both of the following:
    - Left ventricular ejection fraction (LVEF) ⩾55%
    - NYHA class II or III
- AND peak Valsalva LVOT gradient ⩾50 mmHg,
- AND symptomatic oHCM despite highest tolerated dose of a non-vasodilating beta-blocker (or non-dihydropyridine calcium channel blocker if beta-blocker is not tolerated),
- AND if clinically indicated, consider other AHA/ACC Guideline Class I therapies as an alternative to mavacamten:
    - Disopyramide
    - Septal reduction therapy for NYHA class III patients
- AND using effective contraception, if patient is of childbearing potential,
- AND recommend not to initiate if any of the following situations apply:
    - Known infiltrative or storage disorder causing cardiac hypertrophy that mimics oHCM (e.g. Fabry disease, amyloidosis, or Noonan syndrome with LV hypertrophy)
    - History of syncope or sustained ventricular tachyarrhythmia with exercise within 6 months prior
    - History of resuscitated sudden cardiac arrest (at any time) or known history of appropriate implantable cardioverter defibrillator discharge for life-threatening ventricular arrhythmia within 6 months prior
    - Poorly controlled atrial fibrillation
    - Treatment with disopyramide or ranolazine within 14 days prior to initiation of mavacamten
    - Taking a beta blocker in combination with a calcium channel blocker
    - Successfully treated with invasive septal reduction therapy within 6 months prior
    - QTc interval >500 milliseconds

Continuation of Therapy Criteria:

- LVEF remains ⩾50%,
- AND patient has not developed heart failure symptoms or worsening clinical status,
- AND patient is adherent to labs and monitoring as required by the REMS program (e.g. ECHO with Valsalva LVOT gradient, NYHA classification at least every 12 weeks),
- AND patient continues to be managed by Cardiologist with expertise in hypertrophic cardiomyopathy

Complement Inhibitors

Last revised: 3/27/2025; Effective date: 6/3/2025

Generic	Brand	HICL	GSN	Representative NDC
ZILUCOPLAN SODIUM	ZILBRYSQ SOSY 16.6 MG/0.416ML	49273	085405	50474099080
ZILUCOPLAN SODIUM	ZILBRYSQ SOSY 23 MG/0.574ML	49273	085406	50474099180
ZILUCOPLAN SODIUM	ZILBRYSQ SOSY 32.4 MG/0.81ML	49273	085407	50474099280

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 6 months

Initial Review Criteria:

- Prescribed by a Neurologist,
- Patient is 18 years or older,
- Diagnosis of generalized myasthenia gravis (gMG),
- Confirmed positive serological test for anti-acetylcholine receptor (AChR) antibodies,
- No history of thymoma or thymic neoplasm OR patient has history of thymoma and has had a thymectomy that was completed over 3 months ago,
- Patient has a Myasthenia Gravis Activities of Daily Living (MG-ADL) score ≥5,
- Patient is currently taking pyridostigmine for symptomatic management unless there is a severe intolerance or contraindication,
- Patient has tried corticosteroid at maximum tolerated dose for at least 6 months or has contraindication to corticosteroid therapy AND
- Patient has tried and failed or has contraindication to chronic IV immunoglobulin (IVIG), AND

<u>If using for chronic therapy:</u>

- Trial of **at least 2 oral non-steroidal immunosuppressive therapy** for the duration indicated unless intolerant/contraindicated:
    - First-line
        - Azathioprine for at least 12 months
        - Mycophenolate for at least 12 months
    - Alternative agents
        - Cyclosporine for at least 6 months
        - Tacrolimus for at least 12 months
- AND trial of preferred biologics:
    - KP-Preferred Rituximab biosimilar* for at least 6 months
- AND patient has tried and failed or has a contraindication to efgartigmod (Vyvgart)
- AND patient has tried and failed or has a contraindication to ravulizumab (Ultomiris)

<u>If using for bridge therapy:</u>

- Patient has documented non-responsiveness to IVIG as bridge therapy, AND
- Patient has documented non-responsiveness to efgartigimod (Vyvgart) as bridge therapy AND
- Patient has documented non-responsiveness to ravulizumab (Ultomiris) as bridge therapy AND
- Patient must be started on a non-steroidal immunosuppressive therapy (e.g., azathioprine, mycophenolate, rituximab, cyclophosphamide, cyclosporine, tacrolimus, methotrexate)

**Note: Riabni is the KP-preferred rituximab biosimilar*

Continuation of Therapy Criteria:

- **If using for CHRONIC therapy:**
  - **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
  - **For existing members who have previously met the criteria:**
    - For first renewal: documented improvement of at least 2 points on the MG-ADL
    - For subsequent renewals after the first renewal: documented maintenance of stable MG-ADL score or documented beneficial effect from therapy during Neurology follow-up in the last 12 months

- **If using for BRIDGE therapy**:
  - **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
  - **For existing members who have previously met the criteria:**
    - For first renewal: Documented improvement of at least 2-points on the MG-ADL
    - For subsequent renewals for bridge therapy: Confirm with provider if it can be discontinued after 12 months of therapy
      - *Note: It takes 12-24 months for slower acting immunotherapies (e.g. azathioprine, mycophenolate) to take effect

Cystic Fibrosis (CFTR) Correctors-Trikafta

Last revised: 1/31/2025; Effective date: 4/1/2025

Generic	Brand
ELEXACAFTOR-TEZACAFTOR-IVACAFTOR	TRIKAFTA TBPK

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Pulmonologist or specialist in the management of cystic fibrosis (CF), AND
- Age ≥2 years, AND
- Diagnosis of CF confirmed by a clinician with expertise in proving CF care, AND
- Patient has at least ONE of the following mutations, detected using either an FDA-cleared CF mutation test or testing was completed by a CLIA certified laboratory:
  - At least one F508del mutation in the CFTR gene, OR
  - At least one responsive mutation in the CFTR gene (consult Trikafta website to check for eligible mutations: https://www.trikafta.com/who-trikafta-is-for)
- Patient does not have either of the following:
  - Severe liver impairment (Child-Pugh Class C), OR
  - Prior solid organ or hematological transplantation, unless use of the medication is approved by the transplant center

Continuation of Therapy Criteria:

- Documentation of positive clinical response (e.g., improvement in FEV1, sweat chloride; decrease in pulmonary exacerbations or infections; increase in weight; decrease in hospitalizations), AND
- Specialist follow-up has occurred in the past 12 months, AND
- AST, ALT, bilirubin, and ophthalmic changes (patients up to 17 years) are monitored at least annually

Cystic Fibrosis (CFTR) Correctors-Symdeko

Last revised: 1/31/2025; Effective date: 4/1/2025

Generic	Brand
TEZACAFTOR-IVACAFTOR	SYMDEKO

Prior Authorization Criteria:
Length of Authorization: • Initial: 12 months • Reauthorization: 12 months
Initial Review Criteria: • Prescriber is a Pulmonologist or specialist in the management of cystic fibrosis (CF), AND • Age ≥6 years, AND • Diagnosis of CF confirmed by a clinician with expertise in proving CF care, AND • At least two copies of the F508del mutation in the CFTR gene detected using either an FDA-cleared CF mutation test or testing was completed by a CLIA certified laboratory, OR • At least one responsive mutation in the CFTR gene (consult Symdeko website to check for eligible mutations: https://www.symdeko.com/)
Continuation of Therapy Criteria: • Documentation of positive clinical response (e.g., improvement in FEV1, sweat chloride; decrease in pulmonary exacerbations or infections; increase in weight; decrease in hospitalizations), AND • Specialist follow-up has occurred in the past 12 months, AND • AST, ALT, bilirubin, and ophthalmic changes (patients up to 17 years) are monitored at least annually

Cystic Fibrosis (CFTR) Correctors-Orkambi

Last revised: 1/31/2025; Effective date: 4/1/2025

Generic	Brand
LUMACAFTOR-IVACAFTOR	ORKAMBI PACK

Prior Authorization Criteria:
Length of Authorization: • Initial: 12 months • Reauthorization: 12 months
Initial Review Criteria: • Prescriber is a Pulmonologist or specialist in the management of Cystic Fibrosis (CF), AND • Age ≥1 year, AND • Diagnosis of CF confirmed by a clinician in expertise in proving CF care, AND • At least two copies of the F508del mutation in the CFTR gene detected using either an FDA-cleared CF mutation test or testing was completed by a CLIA certified laboratory, AND • If ≥6 years, baseline percent predicted FEV1 is ≥30%
Continuation of Therapy Criteria: • Documentation of positive clinical response (e.g., improvement in FEV1, sweat chloride; decrease in pulmonary exacerbations or infections; increase in weight; decrease in hospitalizations), AND • Specialist follow-up has occurred in the past 12 months, AND • AST, ALT, bilirubin, and ophthalmic changes (patients up to 17 years) are monitored at least annually

Cystic Fibrosis-CFTR Potentiator-Corrector Combin.

Generic	Brand	HICL	GSN	Representative NDC
VANZACAFTOR-TEZACAFTOR-DEUTIVACAFTOR	ALYFTREK TABS 10-50-125 MG	50120	086964	51167012101
VANZACAFTOR-TEZACAFTOR-DEUTIVACAFTOR	ALYFTREK TABS 4-20-50 MG	50120	086963	51167013501

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Pulmonologist or specialist in the management of cystic fibrosis (CF),
- Patient is ≥6 years,
- Diagnosis of CF confirmed by a clinician with expertise in providing CF care,
- Patient has at least ONE of the following mutations, detected using either an FDA-cleared CF mutation test, or testing was completed by a CLIA-certified laboratory:
  - At least one F508del mutation in the CFTR gene, OR
  - At least one responsive mutation in the CFTR gene [consult Alyftrek website to check for eligible mutations: uspi_vanzacaftor_tezacaftor_deutivacaftor.pdf (Table 5)]
- Patient does NOT have moderate or severe hepatic impairment (Child-Pugh Class B or C),
- Documentation of baseline LFTs (ALT, AST, alkaline phosphatase, bilirubin) and ophthalmological exam,
- Provider attestation that LFTs will be monitored every month during the first 6 months of therapy, then every 3 months during the next 12 months, then at least annually thereafter

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met the criteria:**
  - Documentation of positive clinical response (e.g., improvement in FEV1, sweat chloride; decrease in pulmonary exacerbations or infections; increase in weight; decrease in hospitalizations),
  - Specialist follow-up has occurred in the past 12 months,
  - LFTs and ophthalmic changes (patients up to 17 years) are monitored at least annually

Cystic Fibrosis (CFTR) Potentiators-Kalydeco

Last revised: 1/31/2025; Effective date: 4/1/2025

Generic	Brand
IVACAFTOR	KALYDECO

Prior Authorization Criteria:
Length of Authorization: • Initial: 12 months • Reauthorization: 12 months
Initial Review Criteria: • Prescriber is a Pulmonologist or specialist in the management of cystic fibrosis (CF), AND • Age ≥1 month, AND • Patient is NOT homozygous for the F508del mutation in the CFTR gene, AND • At least one responsive mutation in the CFTR gene (consult Kalydeco website to check for eligible mutations: https://www.kalydeco.com/who-kalydeco#table) detected using either an FDA-cleared CF mutation test OR with testing completed by a CLIA certified laboratory
Continuation of Therapy Criteria: • Documentation of positive clinical response (e.g., improvement in FEV1, sweat chloride; decrease in pulmonary exacerbations or infections; increase in weight; decrease in hospitalizations), AND • Specialist follow-up has occurred in the past 12 months, AND • AST, ALT, bilirubin, and ophthalmic changes (patients up to 17 years) are monitored at least annually

Endothelin-Angiotensin Receptor Antagonist

Last revised: 7/30/2024; Effective date: 10/1/2024

Generic	Brand	HICL	GSN	Representative NDC
SPARSENTAN	FILSPARI TABS 200 MG	48721	084437	68974020030
SPARSENTAN	FILSPARI TABS 400 MG	48721	084438	68974040030

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescribed by a nephrologist,
- 18 years of age or older,
- Documented diagnosis of IgA nephropathy (IgAM) verified by renal biopsy,
- High risk disease progression as defined urine protein-to-creatine ratio (UPCR) ≥1.5 and eGFR ≥30 ml/min,
- Proteinuria ≥1g/day,
- Prescriber and patient is enrolled in the **FILSPARI REMS** program,
- Documented trial of at least 12 weeks at the maximum tolerated dose of ONE of the following or documented intolerance or contraindication: Angiotensin-converting enzyme inhibitors (ACEI) OR Angiotensin II receptor blockers (ARB),
- Adequate therapeutic trial or contraindication to one generic systemic corticosteroid therapy (e.g., oral prednisone, methylprednisolone),
- Currently NOT taking ARB, Endothelin receptor antagonists (e.g. ambrisentan and bosentan) or aliskiren,
- For female patients: Confirmation of negative pregnancy test; and patient is not breastfeeding,
- Baseline LFTs and total bilirubin are ≤ 3x Upper Limit of Normal,
- Patient does **not** have history of each of the following:
    - Currently undergoing dialysis
    - Kidney transplant
    - Active TB infection
    - Hepatic impairment (Child-Pugh Class A-C)
    - Concurrently taking Tarpeyo*PA

**PA This medication is also subject to PA review*

Continuation of Therapy Criteria:

- Patient continues to meet initial review criteria above with BOTH of the following:
    - Documented reduction in proteinuria,
    - Documented improved or stable kidney function compared to baseline

Notes: Limited to 1 tablet per day, 34-day supply per dispensing

Enzymes

Generic	Brand
PEGVALIASE-PQPZ	PALYNZIQ

Prior Authorization Criteria:
Length of Authorization: • Initial: 6 months • Reauthorization: 12 months
Initial Review Criteria: • Patient is ≥18 years, AND • Documented diagnosis of classical phenylketonuria (PKU) confirmed by metabolic specialist, AND • Pre-treatment baseline phenylalanine (Phe) level >600 micromol//L, AND • Dose does not exceed maximum FDA-approved dosing, AND • Not using concurrent Kuvan (sapropterin); sapropterin should be discontinued prior to initiation of pegvaliase-pqpz
Continuation of Therapy Criteria: • Documentation of positive clinical response AND • Office visit or telephone visit with a specialist within the past 12 months
Notes: • Do not approve continuation of therapy if Phe level >600 micromol/L after 16 weeks on the maximum 40 mg daily dose

Gastrointestinal (GI) Motility Agents

Last Revised 05/20/2025; Effective 07/19/2025

Generic	Brand
LUBIPROSTONE	AMITIZA
LINACLOTIDE	LINZESS
NALOXEGOL OXALATE	MOVANTIK
ALOSETRON HCL	LOTRONEX
METHYLNALTREXONE BROMIDE	RELISTOR
NALDEMEDINE TOSYLATE	SYMPROIC
PLECANATIDE	TRULANCE
ELUXADOLINE	VIBERZI
PRUCALOPRIDE	MOTEGRITY
TENAPANOR	IBSRELA

*representative list

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 6 months
- Reauthorization: 1 year

Initial Review Criteria:

- Documented diagnosis of:
    - Chronic Idiopathic Constipation (CIC),
    - Constipation Predominant Irritable Bowel Syndrome (IBS-C),
    - Severe Diarrhea Predominant Irritable Bowel Syndrome (IBS-D),
    - Opioid Induced Constipation in chronic non-cancer pain (OIC)
    - Functional Constipation (FC) with provider attestation that all other causes of constipation have been ruled out.
- Criteria for Amitiza, Linzess, Trulance, Ibsrela:
    - Documentation of trial and treatment failure on at least two of the following classes:
        - Osmotic Laxatives (i.e. lactulose, polyethylene glycol, sorbitol)
        - Bulk Forming Laxatives (i.e. psyllium, fiber)
        - Stimulant Laxatives (i.e. bisacodyl, senna)
- Criteria for Amitiza, Movantik, Relistor, Symproic (Diagnosis of OIC only):
    - Documentation of trial and treatment failure or contraindication on both polyethylene glycol and lactulose
- Criteria for Linzess 72 mcg only (Functional Constipation):
    - Patient aged 6 to 17 years
    - Provider attests that other causes of constipation have been ruled out
    - Documentation of trial and treatment failure or contraindication on at least two of the following classes
        - Osmotic Laxatives (i.e. lactulose, polyethylene glycol, sorbitol)
        - Bulk Forming Laxatives (i.e. psyllium, fiber)
        - Stimulant Laxatives (i.e. bisacodyl, senna)
- Criteria for Alosetron, Lotronex, Viberzi:
    - Documentation of trial and treatment failure or contraindication on at least three of the following classes
        - Bulk Forming Laxatives (i.e. psyllium, fiber)
        - Antispasmodic Agents (i.e. dicyclomine, hyoscyamine)
        - Antidiarrheal Agents (i.e. loperamide, diphenoxylate/atropine)
- Criteria for Motegrity:
    - Documentation of trial and treatment failure or contraindication on at least:
        - two preferred traditional laxatives (i.e. lactulose, polyethylene glycol) AND
        - one preferred newer agent for CIC (linaclotide, lubiprostone)

Additional criteria for non-preferred medication:

- Documented list of pharmaceutical agents attempted and outcome
- Documented clinical evidence that preferred agents will not provide adequate benefit

Continuation of Therapy Criteria:

- Patient meets all the initial criteria for the requested medication and therapy is medically necessary

Growth Hormones

Last Revised 12/18/2023; Effective 02/06/2024

Generic	Brand
SOMATROPIN	GENOTROPIN, HUMATROPE, NORDITROPIN, NORDITROPIN FLEXPRO, NUTROPIN AQ NUSPIN, OMNITROPE, SAIZEN, SEROSTIM, ZOMACTON ZORBTIVE
MECASERMIN	INCRELEX
LONAPEGSOMATROPIN-TCGD	SKYTROFA
SOMATROGON-GHLA	NGENLA
SOMAPACITAN-BECO	SOGROYA

*representative list

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 1 year (Exception: Serostim: 3 months)
- Reauthorization: 1 year

Initial Review Criteria:

For Pediatric Patients (≤18 years old)

- Requested medication must be prescribed by or in consultation with a specialist:
  - Endocrinology, Nephrology,
- Documentation of diagnosis of one of the following conditions:
  - Turner Syndrome, Prader-Willi Syndrome, Renal Insufficiency, Pediatric Chronic Kidney Disease, Small for Gestational Age, Idiopathic Short Stature, Growth Hormone Deficiency, or Newborn with Hypoglycemia and Diagnosis of Hypopituitarism or Panhypopituitarism, Familial Short Stature, Noonan Syndrome, SHOX Deficiency
- Requirements for Growth Hormone Deficiency:
  - Growth velocity < 25th percentile for bone age in a child with no other identifiable cause and in whom hypothyroidism, chronic illness, under nutrition and genetic syndromes have been excluded AND growth hormone response of less than 10 ng/mL to at least 2 provocative stimuli of growth hormone release: insulin, levodopa, arginine, clonidine, or glucagon; priming with sex steroids prior to stimulation test should be considered
- Requirements for Pediatric Chronic Kidney Disease/Chronic Renal Insufficiencies:
  - Creatinine clearance of 75 mL/min/1.73 m2 or less
  - Serum creatinine greater than 3.0 g/dL
  - Dialysis dependency

For Adult Patients (>18 years old)

- Requested medication must be prescribed by or in consultation with Endocrinology
- Documentation of diagnosis of growth hormone deficiency confirmed by growth hormone stimulation tests and rule-out of other hormonal deficiency, as follows: growth hormone response of fewer than five nanograms per mL to at least two provocative stimuli of growth hormone release: insulin, levodopa, L-Arginine, clonidine or glucagon when measured by polyclonal antibody (RIA) or fewer than 2.5 nanograms per mL when measured by monoclonal antibody (IRMA)
- Documentation of whether the cause of growth hormone deficiency is a result of Adult Onset Growth Hormone Deficiency (AO-GHD) alone or with multiple hormone deficiencies, such as hypopituitarism, because of hypothalamic or pituitary disease, radiation therapy, surgery, or trauma
- Documentation of rule-out of other hormonal deficiencies such as thyroid, cortisol, or sex steroids
- Documentation of diagnosis of short bowel syndrome
- Documentation of diagnosis of AIDS Wasting or cachexia

Continuation of Therapy Criteria:
Requirements for Pediatrics

- Documentation of improved/normalized growth velocity of at least 2 cm per year

Requirements for Adults

- Documentation of prescriber affirmation of positive response to therapy (improved body composition, reduced body fat, and increased lean body mass)

Growth Hormone Releasing Hormone (GHRH) and Analogs

Generic	Brand	HICL	GSN	Representative NDC
TESAMORELIN ACETATE	EGRIFTA SV SOLR 2 MG	37268	080524	62064024130

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 6 months

Initial Review Criteria:

- Age ≥18 to <65 years, AND
- Prescribed by Endocrinology or Infectious Diseases Specialist and approved by respective Physician Chief and/or peer-reviewed (recommended), AND
- Prescribed indication is HIV-associated visceral lipodystrophy, AND
- Patient meets one of the following criteria:
  - Men: Waist circumference is ≥95 cm (37.4 in) and waist-to-hip ratio is ≥0.74, OR
  - Women: Waist circumference is ≥ 94 cm (37.0 in) and waist-to-hip ratio is >0.88
- Patient is stable on antiretroviral (ARV) regimen (e.g., protease inhibitor-based regimen*) for at least 8 weeks, AND
- Baseline fasting blood glucose (FBG) <150 mg/dL within the past 3 months, AND
- No reason(s) for non-coverage:
  - Active malignancy or history of malignancy
  - Pregnancy
  - BMI ≤20 kg/m^2
  - FBG >150 mg/dL or known type 1 or type 2 DM
  - Hypopituitarism

**Evidence suggests that the use of protease inhibitors (PIs) is commonly associated with the development of lipodystrophy*

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
  - Documented clinical improvement, defined as reduction and maintenance of visceral adipose tissue (VAT) as measured by waist circumference reduction of ≥2-3 cm from baseline

Hepatitis C Agents

Last revised: 12/3/2024; Effective date: 2/4/2025

Generic	Brand
LEDIPASVIR/SOFOSBUVIR	HARVONI
SOFOSBUVIR	SOVALDI
ELBASVIR/GRAZOPREVIR	ZEPATIER
SOFOSBUVIR/VELPATASVIR	EPCLUSA
SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR	VOSEVI
PEGINTERFERON ALFA-2A	PEGASYS, PEGASYS PROCLICK

*representative list

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: based on standard length of treatment course
- Reauthorization: N/A

Initial Review Criteria:

- Non-preferred medication must be prescribed by or in consultation with a specialist
  - Gastroenterology, Hepatology, Infectious Disease, Transplant
- Patient may benefit from specialty consultation if meets any of these criteria: coinfected with hepatitis B or HIV; pregnant, breastfeeding, or planning to breastfeed; taking atazanavir or rifampin; severe kidney problems or is on dialysis; severe decompensated liver cirrhosis or a Child-Pugh score class B or C
- Documentation of diagnosis of Acute or Chronic Hepatitis C, Compensated cirrhosis, Hepatocellular Carcinoma, Decompensated Cirrhosis (Child Pugh Score Class B or C), Status Post Liver Transplant, and severe renal impairment (eGFR < 30 mL/min) or end stage renal disease requiring hemodialysis
- Documentation of HCV Genotype Test Results with corresponding treatment plan
- Selected therapy should be FDA-approved based on indication and specific genotype
- Documentation of any past treatment for Hepatitis C with dates, agents, and outcomes

Hereditary Angioedema (HAE) Agents

Last revised 08/09/2023 (effective 10/03/2023)

Generic	Brand
C1 ESTERASE INHIBITOR	BERINERT; CINRYZE
C1 ESTERASE INHIBITOR	HAEGARDA
ECALLANTIDE	KALBITOR
LANADELUMAB-FLYO	TAKHZYRO 150 MG/ML; 300MG/2ML
ICATIBANT ACETATE	FIRAZYR
BEROTRALSTAT HCL	ORLADEYO

*representative list

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 1 year
- Reauthorization: 1 year

Review Criteria:

- Confirmed diagnosis of HAE by C1 inhibitor (C1-INh) deficiency or dysfunction (type I or II HAE) as documented by one of the following:
    - C1-INh antigenic level below the lower limit of normal, OR
    - C1-INh functional level below the lower limit of normal, AND
- Prescribed by, or in consultation with, a board-certified allergist, immunologist, pulmonologist, hematologist, or medical geneticist
- For prophylactic use, therapy must be with one of the following:
    - Cinryze (C1 esterase inhibitor)
    - Haegarda (C1 estarase inhibitor)
    - Orladeyo (berotralstat)
    - Takhzyro (ianadelumab-flyo)
- For the treatment of acute HAE attacks, monotherapy with one of the following must be used:
    - Berinert (C1 esterase inhibitor)
    - Firazyr (icatibant)
    - Kalbitor (ecallantide)
    - Ruconest (C1 esterase inhibitor)
    - Sajazir (icatibant)
- Documentation prior pharmaceutical agents used as well as treatment outcomes
- Documentation of medical necessity providing clinical evidence that the preferred agent(s) will not provide adequate benefit
    -

IL-23 Receptor Antagonist, Monoclonal Antibody

Last revised: 3/27/2025; Effective date: 6/3/2025

Adapted from DMAS Preferred Drug List

Generic	Brand	HICL	GSN	Representative NDC
MIRIKIZUMAB-MRKZ	OMVOH SOAJ 100 MG/ML	49282	085439	00002801127
MIRIKIZUMAB-MRKZ	OMVOH (300 MG DOSE) SOAJ 100 MG/ML & 200 MG/2ML	49282	087255	00002771711
MIRIKIZUMAB-MRKZ	OMVOH (300 MG DOSE) SOSY 100 MG/ML & 200 MG/2ML	49282	087254	00002772211
MIRIKIZUMAB-MRKZ	OMVOH SOSY 100 MG/ML	49282	085527	00002887001

Prior Authorization Criteria:

Length of Authorization:

- 12 months

Initial Review Criteria:

- Member is at least 18 years old,
- Member has diagnosis of moderate to severe Ulcerative Colitis (UC),
- Member had therapeutic failure on oral methotrexate,
- Member had therapeutic failure to one of the preferred agents (e.g. Enbrel, Humira)

Ileal Bile Acid Transporter (IBAT) Inhibitor

Adapted from DMAS Preferred Drug List

Generic	Brand	HICL	GSN	Representative NDC
MARALIXIBAT CHLORIDE	LIVMARLI SOLN 19 MG/ML	47604	086371	79378011101
MARALIXIBAT CHLORIDE	LIVMARLI SOLN 9.5 MG/ML	47604	082710	79378011001

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial & Continuation of Therapy Criteria:

- Patient has a confirmed diagnosis of cholestatic pruritus in one of the following situations:
    - 3 months of age or older, with Alagille syndrome (ALGS)
    - 12 months of age or older, with progressive familial intrahepatic cholestasis (PFIC)

Ileal Bile Acid Transporter (IBAT) Inhibitor

Adapted from DMAS Preferred Drug List

Generic	Brand	HICL	GSN	Representative NDC
ODEVIXIBAT	BYLVAY (PELLETS) CPSP 200 MCG	47501	082527	74528002001
ODEVIXIBAT	BYLVAY (PELLETS) CPSP 600 MCG	47501	082528	74528006001
ODEVIXIBAT	BYLVAY CAPS 400 MCG	47501	082529	74528004001
ODEVIXIBAT	BYLVAY CAPS 1200 MCG	47501	082530	74528012001

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial & Continuation of Therapy Criteria:

- Patient has a confirmed diagnosis of cholestatic pruritus in one of the following situations:
    - 12 months of age or older, with Alagille syndrome (ALGS)
    - 3 months of age or older, with progressive familial intrahepatic cholestasis (PFIC)

Integrin Receptor Antagonist, Monoclonal Antibody

Last revised: 7/30/2024; Effective date: 10/1/2024

Adapted from DMAS Preferred Drug List

Generic	Brand	HICL	GSN	Representative NDC
VEDOLIZUMAB	ENTYVIO SOPN 108 MG/0.68ML	41146	081509	64764010820

Prior Authorization Criteria:

Length of Authorization:

- 12 months

Initial Review Criteria:

- Therapeutic failure to at least two of the preferred agents (e.g., Enbrel, Humira, infliximab, methotrexate),
- Diagnosis of moderately to severely active Crohn's Disease (CD) or Ulcerative Colitis (UC),
- Trial and failure of a compliant regimen of oral corticosteroids (moderate to severe) unless contraindicated or intravenous corticosteroids (severe and fulminant or failure to respond to oral corticosteroids),
- Trial and failure of a compliant regimen of azathioprine or mercaptopurine for three consecutive months,
- Trial and failure of a compliant regimen of parenteral methotrexate for three consecutive months

Interleukin Inhibitors (Dupixent)

Last Revised 12/06/2024. Effective 01/01/2025

Generic	Brand
DUPILUMAB	DUPIXENT

*representative list

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 1 year
- Reauthorization: 1 year

Review Criteria:

- Atopic Dermatitis
  - ≥ 6 months of age, AND
  - Diagnosis of moderate to severe atopic dermatitis, AND
  - Prior documented trial for 30 days and failure (or contraindication) of:
    - One topical corticosteroid of medium to high potency (e.g., mometasone, fluocinolone); OR
    - One topical calcineurin inhibitor (tacrolimus or pimecrolimus)

- Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)
  - ≥ 18 years of age, AND
  - Memberhas inadequate response after 3 consistent months' use of intranasal steroids or oral corticosteroids, AND
  - Memberis concurrently treated with intranasal corticosteroids, AND
  - Physician has assessed baseline disease severity utilizing an objective measurement/tool

- Asthma
  - ≥ 6 years of age, AND
  - Diagnosis of moderate to severe asthma with either:
    - Eosinophil count ≥ 150 cells/mcL, OR
    - Oral corticosteroid-dependent asthma with at least one month of daily oral corticosteroid use within the last 3 months

- Diagnosis of eosinophilic esophagitis (EoE)
  - ≥ 1 year of age, AND
  - Patient weighs ≥ 15 kg, AND
  - Prescribed by or consultation with an allergist or gastroenterologist; AND
  - Member did not respond clinically to treatment with a topical glucocorticosteroid or proton pump inhibitor

- Prurigo nodularis (PN)
  - ≥ 18 years of age, AND
  - Diagnosis of PN, AND

- Diagnosis of inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype

- o ≥ 18 years of age, AND
- o Member has a diagnosis of COPD with moderate to severe airflow limitation (post-bronchodilator FEV1/FVC ratio < 0.7 and post-bronchodilator FEV1 of 30% to 70% predicted) and a minimum blood eosinophil count of 300 cells/mcL at screening
- o Member is receiving maintenance triple therapy consisting of a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS)
- o Member has a history of at least 2 moderate (requiring treatment with systemic corticosteroids and/or antibiotics) or 1 severe exacerbation(s) (resulting in hospitalization or observation for over 24 hours in an emergency department or urgent care facility) in the previous year
- o Member has a Medical Research Council (MRC) dyspnea score ⩾ 2 (range 0–4)

Immunomodulator,B-lymphocyte Stim(BLYS)-Spec Inhib

Last revised 4/8/2024; Effective date: 8/13/2024

Generic	Brand	HICL	GSN	Representative NDC
BELIMUMAB	BENLYSTA SOSY 200 MG/ML	37462	077606	49401008842
BELIMUMAB	BENLYSTA SOAJ 200 MG/ML	37462	077604	49401008801

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Rheumatologist or Nephrologist, AND

If prescribed for lupus nephritis (LN) class III, IV or V:

- Patient is 5 years of age or older,
- AND disease severity (with or without kidney biopsy) - lupus nephritis class III (focal lupus nephritis), class IV (diffused lupus nephritis), or class V (membranous lupus nephritis),
- AND eGFR ≥ 30 mL/min/1.73 m^2,
- AND patient is not pregnant,
- AND no previous use of dialysis in the past 12 months,
- AND no current use with Lupkynis (voclosporin),
- AND patient is currently receiving standard of care therapy with one or more of the following: cyclophosphamide, mycophenolate, azathioprine, calcineurin inhibitor or corticosteroid

If prescribed for systemic lupus erythematosus (SLE):

- Patient is 18 years or older for SC Benlysta [*note: IV Benlysta is indicated for 5 years of age or older*],
- AND patient has autoantibody-positive SLE (antinuclear antibody titers ≥ 1:80, anti-double-stranded DNA antibodies or both) OR biopsy proven SLE by kidney OR anti-double-stranded DNA positive lupus with a history of hypocomplementemia,
- AND patient does NOT have severe active central nervous system lupus,
- AND Benlysta will not be used in combination with biologics (e.g., rituximab),
- AND patient is on concomitant standard-of-care with hydroxychloroquine unless contraindicated or intolerant,
- AND history of contraindication, intolerance or inadequate clinical response to at least one of the following: corticosteroid, methotrexate, or mycophenolate

Continuation of Therapy Criteria:

- Physician documentation of disease stability and improvement within the last 12 months

Immunomodulators (Atopic Dermatitis)

Last revised: 05/20/2025; Effective date 07/19//2025

Generic	Brand
PIMECROLIMUS	ELIDEL
CRISABOROLE	EUCRISA
TACROLIMUS	PROTOPIC
RUXOLITINIB	OPZELURA
TRALOKINUMAB-LDRM	ADBRY
ROFLUMILAST	ZORYVE CREA 0.15%; ZORYVE FOAM 0.3%
LEBRIKIZUMAB-LBKZ	EBGLYSS
NEMOLIZUMAB-ILTO	NEMLUVIO

*representative list

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 1 year
- Reauthorization: 1 year

Initial Review Criteria:

- **Clinical Criteria for Elidel and pimecrolimus, Protopic, and tacrolimus**
  - Patient must have an FDA age approved diagnosis of atopic dermatitis
    - Elidel (-mild to moderate for ages ≥ 2 years old
    - Protopic 0.03%: moderate to severe for ages ≥ 2 years old
    - Protopic 0.1%: moderate to severe for ages ≥ 16 years
  - Failure of 8 weeks therapy to topical corticosteroids (i.e. desonide, fluticasone propionate, hydrocortisone butyrate, etc.)
- **Clinical Criteria for Eucrisa and Adbry**
  - Patient must have an FDA age approved diagnosis of atopic dermatitis
    - Eucrisa: mild to moderate for ages equal or > 3 months old
    - Adbry: moderate to severe for ages equal or ≥ 12 years of age
  - Documented of 30 days trial and failure (or contraindication) of one topical corticosteroid of medium to high potency (i.e., mometasone, fluocinolone)
  - Documented of 30 days trial and failure (or contraindication) of one (1) topical calcineurin inhibitors (tacrolimus or pimecrolimus)
- **Clinical Criteria for *Opzelura, Ebglyss, **Nemluvio**
  - Patient must have an FDA age approved diagnosis of atopic dermatitis
    - Opzelura: mild to moderate for ages ≥ 12 years old
    - Ebglyss: moderate to severe for ages ≥ 12 years old
    - Nemluvio: moderate to severe for ages ≥ 12 years old
  - Documented of 8 weeks trial and failure (or contraindication) to
    - one topical corticosteroid of medium to high potency (i.e., mometasone, fluocinolone
    - one topical calcineurin inhibitors (tacrolimus or pimecrolimus)
    - Dupixient

  NOTE: Topical *Opzelura is not covered for nonsegmental vitiligo in adult and pediatric patients ≥ 12 years old
- **Additional Criteria for ** Nemluvio for Prurigo Nodularis**
  - Patient must have an FDA age approved diagnosis of Prurigo Nodularis
  - Patient is ≥ 18 years old
  - Documented of 8 weeks trial and failure (or contraindication) to Dupixent
- **Clinical Criteria for Zoryve cream, 0.15%**
  - Patient must have an FDA age approved diagnosis of atopic dermatitis
    - Mild to moderate for ages ≥6 years
- **Clinical Criteria for Zoryve foam, 0.3%**
  - Patient must have a diagnosis of seborrheic dermatitis, AND
  - Patient is 9 years of age or older

Continuation of Therapy Criteria:

- Documentation that the initial review criteria are still met

Immunosuppressives

Last revised 7/30/2024; Effective date: 10/1/2024

Prior Authorization Criteria follows the state's criteria (DMAS)

Generic	Brand	HICL	GSN	Representative NDC
VOCLOSPORIN	LUPKYNIS CAPS 7.9 MG	47077	081863	75626000101

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 6 months

Initial Review Criteria:

- Prescriber is a Rheumatologist, Nephrologist, or consulting with a Rheumatologist or Nephrologist,
- Member is 18 years of age or older,
- Member has a diagnosis of lupus nephritis with International Society of Nephrology/Renal Pathology Society (ISN/RPS) biopsy-proven active Class III or IV lupus nephritis alone, or in combination with Class V lupus nephritis,
- Urine protein to creatinine ratio (UPCR) ≥ 1.5 mg/mg for Class III or IV or UPCR ≥ 2 mg/mg for Class V,
- Confirmation that the member does not have any of the following:
    - Concomitant use of strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin)
    - Severe hepatic impairment
- Member is receiving concomitant mycophenolate mofetil and corticosteroids,
- Member's baseline blood pressure is < 165/105 mmHg,
- Member's baseline estimated glomerular filtration rate (eGFR) > 45 mL/min/1.73 m^2,
- Member's renal function (eGFR) will be assessed at regular intervals thereafter

Continuation of Therapy Criteria:

- Member continues to meet the initial criteria above,
- Member has experienced disease improvement and/or stabilization or improvement in the slope of decline,
- Confirmation that member has not experienced any treatment-restricting adverse effects (e.g., neurotoxicities, irreversible hyperkalemia)

Notes: Limited to 6 capsules per day, 34-day supply per dispensing

Leptins

Generic	Brand
METRELEPTIN	MYALEPT

Prior Authorization Criteria:

Length of Authorization:

- Initial: 4 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is an Endocrinologist, AND
- Diagnosis of congenial or acquired generalized lipodystrophy associated with leptin deficiency (less than 12.0 ng/mL in females and less than 8.0 mg/mL in males), AND
- Is being used as an adjunct to diet modification, AND
- Documentation demonstrates that patient has at least ONE of the following:
    - Diabetes mellitus or insulin resistance with persistent hyperglycemia (HgbA1C >7) despite BOTH of the following:
        - Dietary intervention
        - Optimized insulin therapy at maximum tolerated doses
    - Persistent hypertriglyceridemia (TG >200) despite BOTH of the following:
        - Dietary intervention
        - Optimized therapy with at least two triglyceride-lowering agents from different classes (e.g., fibrates, statins) at maximum tolerated doses

Continuation of Therapy Criteria:

- Documentation of positive clinical response and/or stabilization of laboratory parameters provided in initial authorization (i.e. fasting triglyceride concentrations, and/or HbA1C), AND
- Is being used as an adjunct to diet modification, AND
- Continues to be prescribed by an Endocrinologist

Menopausal Symptoms Suppressant-NK3 Receptor Antag

Last revised: 4/8/2024; Effective date: 8/13/2024

Generic	Brand	HICL	GSN	Representative NDC
FEZOLINETANT	VEOZAH TABS 45 MG	48921	084780	00469266030

Prior Authorization Criteria: Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 3 months
- Reauthorization: 12 months

Initial Review Criteria:

- Member is 18 years of age or older,
- Diagnosis of menopause with moderate to severe vasomotor symptoms,
- Member has had a trial and failure, or is not a candidate for, hormone therapy,
- Member does not have cirrhosis,
- Member does not have severe renal impairment or end-stage renal disease,
- Member will avoid concomitant therapy with weak, moderate, or strong CYP1A2 inhibitor(s) (e.g., fluvoxamine, mexiletine, cimetidine),
- Prescriber attests that baseline liver function tests have been conducted and total bilirubin, alanine aminotransferase (ALT), and aspartate aminotransferase (AST) levels are not elevated ≥2 times the upper limit of normal (ULN),
- Prescriber attests that liver function testing follow-up will be conducted as outlined in prescribing information

Continuation of Therapy Criteria:

- Member continues to meet initial review criteria,
- Member has symptom improvement,
- Member has been assessed for adverse effects (e.g., ALT or AST >3 times the ULN)

Metabolic Function Diagnostics

Generic	Brand	HICL	GSN	Representative NDC
METYRAPONE	METOPIRONE CAPS 250 MG	2836	018119	76336045518

Prior Authorization Criteria:

Length of Authorization:

- Initial: 90 days (diagnostic agent); 12 months (Cushing's Disease)
- Reauthorization: 12 months

Initial Review Criteria:

Diagnostic agent (90-day approval):

- Metopirone is being utilized for adrenocorticotropic hormone (ACTH) function testing

Cushing's Disease (12-month approval):

- Medication was prescribed by an Endocrinologist,
- Patient has confirmed diagnosis of Cushing's Disease,
- Pituitary surgery is not an option or has not been curative,
- Patient has had a documented trial and failure, intolerance, or contraindication to ketoconazole,
- Patient is being prescribed an appropriate dose based on current guidelines and/or evidence

Continuation of Therapy Criteria:

- Patient continues to be under the care of an Endocrinologist,
- Patient has a positive clinical response,
- Current dosing continues to be supported by current guidelines and/or evidence

Movement Disorder Agents

Generic	Brand
TETRABENAZINE	XENAZINE
DEUTRABENAZINE	AUSTEDO
VALBENAZINE	INGREZZA and INGREZZA CPPK

*representative **list**

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 1 year
- Reauthorization: 1 year

Initial Review Criteria:

- Diagnosis of Tardive Dyskinesia or Huntington's disease
- Prescribed by or in consult with a neurologist or psychiatrist

Continuation of Therapy Criteria:

- Documentation of continued medical necessity

Multiple Sclerosis (Kesimpta) – Step Therapy (ST)

Generic	Brand
OFATUMUMAB	Kesimpta

*representative list

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 1 year
- Reauthorization: 1 year

Initial Review Criteria:

- Authorization required for:
  - Kesimpta - Step therapy – Trial and failure of preferred Tecfidera

Continuation of Therapy Criteria:

- Documentation of continued medical necessity

Natriuretic Peptides

Prior Authorization Criteria follows the state's criteria (DMAS)

Generic	Brand	HICL	GSN	Representative NDC
VOSORITIDE	VOXZOGO SOLR 1.2 MG	47677	082837	68135018193
VOSORITIDE	VOXZOGO SOLR 0.56 MG	47677	082836	68135011966
VOSORITIDE	VOXZOGO SOLR 0.4 MG	47677	082835	68135008236

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Age ≥ 5 years,
- Definitive diagnosis of achondroplasia as confirmed by one of the following:
  - Clinical (e.g., proximal shortening of arms, large head, narrow chest, short fingers) and radiographic (e.g., ilia and horizonal acetabula, narrow sacrosciatic notch, proximal radiolucency of the femurs, generalized metaphyseal abnormality, decreasing interpedicular distance caudally) features consistent with the disorder, OR
  - Identification of a heterozygous pathogenic variant in the *FGFR3* gene (e.g., 1138G>A and 1138G>C being the two most common) by molecular genetic testing
- Other causes of achondroplasia or short stature have been ruled out [e.g., malnutrition, hypothyroidism, hypocortisolism, hypochondroplasia, thanatophoric dysplasia, SADDAN syndrome, homozygous achondroplasia (excludes approved labeled indication)],
- Patient has open epiphyses,
- Patient's body weight, growth, and physical development will be measured at baseline and monitored throughout therapy,
- Vosoritide will NOT be used in combination with growth hormones (e.g., somatropin), growth hormone analogs (e.g., somapacitan), or insulin-like growth factors (IGF-1) (e.g., mecasermin),
- Patient has estimated glomerular filtration rate (eGFR) ≥60 mL/min/1.73m^2,
- Patient did NOT have limb-lengthening surgery within the previous 18 months and will not be receiving limb-lengthening surgery

Continuation of Therapy Criteria:

- Patient continues to meet initial criteria above,
- Patient has open epiphyses,
- Patient has NOT had treatment-limiting toxicity (e.g., severe hypotension),
- Patient has shown a beneficial response to treatment as evidenced by the following:
  - Improvement in height compared to pre-treatment baseline, AND
  - Improvement in growth velocity compared to pre-treatment baseline

Ophthalmic (Eye) Antiparasitics

Last revised: 7/30/2024; Effective date: 10/1/2024

Generic	Brand	HICL	GSN	Representative NDC
LOTILANER	XDEMVY SOLN 0.25%	45544	085092	81942012501

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months (limited to 1 treatment course/bottle per patient per year)

Initial Review Criteria:

- Prescribed by an Optometrist or Ophthalmologist
- Patient is ≥ 18 years old,
- Patient has a diagnosis of Demodex blepharitis evidenced by ALL of the following:
    - Presence of grade 2+ collarettes (10+ collarettes on lids/lashes) on the upper lid on slit lamp examination,
    - Presence or strong clinical suspicion of mites upon examination of eyelashes,
    - Presence of at least mild erythema on upper eyelid margin (documentation required),
- Patient's symptoms persist despite treatment with warm compress, eyelid cleansing, and/or artificial tears

Continuation of Therapy Criteria:

- Patient meets all the initial criteria for coverage,
- Documented clinical response to the previous course of treatment, and clinical need for retreatment

Notes:

- Quantity limit of one bottle/year
- The benefits of a longer treatment course beyond 6 weeks are unknown

Opioid Agents

Last reviewed 3.3.2025; Effective 4.1.2025)

Short-Acting Opioids
Long-Acting Opioids
Methadone

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Up to 1 month for severe acute pain/post-surgical pain.
- Up to 3 months for pain associated with HIV/AIDS, chronic back pain, arthritis, fibromyalgia, diabetic neuropathy, postherpetic neuralgia.
- Up to 6 months for cancer pain, sickle cell disease, palliative care, end-of life care, hospice.

Review Criteria:

- Authorization required for:
  - All Long-Acting Opioids
  - Any Short-Acting Opioid prescribed for > 7 days or two (2) 7-day supplies per 60 days
  - Any cumulative opioid prescription > 90 morphine milligram equivalents (MME)
- Authorization Exclusion Criteria:
  - Pain associated with cancer, sickle cell disease end-of-life, palliative care, hospice care
  - Remission from cancer and prescriber is safely weaning patient off opioids
- Documentation of Cumulative Total Daily MME dose calculated from PMP
  - If patient's Active Daily MME ≥ 90, the prescriber must attest that he/she will be managing the patient's opioid therapy long term, has reviewed the Virginia BOM Regulations for Opioid Prescribing, has prescribed naloxone, and acknowledges the warnings associated with high dose opioid therapy including fatal overdose, and that therapy is medically necessary for this patient
- Criteria for methadone pain management:
- Additional Authorization Exclusion Criteria:
  - an infant discharged from the hospital on a methadone taper (under 1 year of age)
- Documentation of treatment failure with at least 2 or more preferred long-acting opioids
- Documentation of signed chronic pain agreement with patient
- Documentation of type of pain being treated as well as a list of opioid and non-opioid treatments trialed with outcomes
- If the patient is female between 18 and 45 years old, documentation of discussion of risk of neonatal abstinence syndrome and counseling on contraceptive options
- Documentation that prescriber has checked the PMP and provide the last fill date of the patient's most recent opioid and benzodiazepine prescription
  - If benzodiazepine filled in past 30 days, the prescriber must attest that he/she has counseled the patient on the FDA black box warning on the dangers of prescribing Opioids and Benzodiazepines including fatal overdose, has documented that the therapy is medically necessary, and has recorded a tapering plan to achieve the lowest possible effective doses of both opioids and benzodiazepines

- Documentation that naloxone has been prescribed for patients with risk factors of substance use disorder, doses more than 50 MME/day, antihistamines, antipsychotics, benzodiazepines, gabapentin, pregabalin, tricyclic antidepressants, or the “Z” drugs (zopiclone, zolpidem, or zaleplon).
- Documentation of a treatment plan with goals that addresses benefits and harm established with patient.

Opioid-Benzodiazepine Concurrent Use

Opioids
Benzodiazepines

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 1 year
- Reauthorization: 1 year

Initial Review Criteria:

- Authorization required when a benzodiazepine is prescribed while a patient is taking an opioid medication to ensure patient safety according to CDC Guidelines and FDA Black Box Warning when these agents are concurrently used
- Documentation of the patient's diagnosis for taking a benzodiazepine:
    - Acute alcohol withdrawal
    - Adjunct for relief of skeletal muscle spasms
    - Anxiety
    - Convulsive disorders
- Documentation of the patient's diagnosis for taking an opioid:
    - Active Cancer Pain
    - Hospice care/Palliative care
    - Chronic, non-cancer pain
    - Acute Pain
- Documentation that prescriber has checked the PMP and provide the last fill date of the patient's most recent opioid and benzodiazepine prescription
- Prescriber attestation that he/she will be managing the patient's therapy long term and that they have read the FDA Black Box Warning on prescribing opioids and benzodiazepines and the dangers involved and that therapy is medically necessary for this patient

Continuation of Therapy Criteria:

- Documentation that initial review criteria are still met

Opioid Dependency Oral Agents

Buprenorphine-Naloxone SL film
Zubsolv SL tablet

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 3 months
- Reauthorization: 6 months

Review Criteria:

The following criteria applies to non-preferred products only.

- Patient must be ≥ 16 years old
- Patient must meet criteria for a diagnosis of Opioid Use Disorder (defined by DSM 5)
- If the patient is pregnant, include expected date of delivery as well as positive pregnancy test
- Buprenorphine monotherapy will only be covered during the following:
    - Pregnant women for a maximum of 10 months
    - Patients when being converted to buprenorphine/naloxone combination therapy for 7 days
- If the requested product is non-preferred, provide documentation indicating medical necessity and reasoning for why a non-preferred product is required
- Daily doses of buprenorphine greater than 24 mg will deny.

Oral Lipid Supplements

Generic	Brand	HICL	GSN	Representative NDC
TRIHEPTANOIN	DOJOLVI LIQD 100%	46676	081254	69794005050

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Geneticist,
- AND confirmed diagnosis via molecular genetic testing for one of the following deficiencies:
  - Very long-chain acylCoA dehydrogenase (VLCAD)
  - Carnitine palmitoyltransferase 2 (CPT2)
  - Mitochondrial trifunctional protein (TFP)
  - Long-chain 3-hydroxyacyl-CoA dehydrogenase (LCHAD)
  - Carnitine acylcarnitine translocase (CACT)
- AND either of the following:
  - Recurrent episodes of rhabdomyolysis requiring intervention and not improving with standard medical therapy or recommended lifestyle measures
  - Cardiomyopathy/cardiac involvement that is not improving or stabilizing to an acceptable degree with standard medical therapy*

**Note: Standard medical therapy is defined as reduced dietary intake of long-chain fats plus supplementation with MCT (medium-chain triglyceride product)*

Continuation of Therapy Criteria:

- Patient continues to be under the care of Geneticist,
- AND no episodes of rhabdomyolysis after 12 months or more of treatment,
- AND no continued progression of cardiomyopathy after 12 months or more of treatment,
- AND at least 70% adherence to medication,
- AND continued diet and lifestyle measures,
- AND the following labs and assessments completed:
  - Plasma carnitine (free and total) every 3 months
  - Creatinine kinase every 3 months
  - Lipid panel every 6-12 months (other than initial labs when triheptanoin started)
  - Essential fatty acids every 6-12 months (other than initial labs when triheptanoin started)
  - One follow-up appointment with Genetics within past 12 months (other than initial assessment when triheptanoin started)

Other Miscellaneous Therapeutic Agents

Generic	Brand
BUROSUMAB-TWZA	CRYSVITA

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

X-Linked Hypophosphatemia

- Prescribed by, or in consultation with, a specialist experienced in the treatment of metabolic bone disorders, AND
- Patient is ≥1 year, AND
- Patient has a diagnosis of X-linked hypophosphatemia (XLH) supported by at least one of the following: genetic testing (PHEX mutation) OR family member with X-linked inheritance OR serum fibroblast growth factor 23 (FGF23) level >30 pg/mL, AND
- Fasting serum phosphorus below the reference range for age, AND
- Patient meets either of the following based on age group: pediatric patients (epiphyseal growth plates are open), at least one of the following:
    - o radiographic evidence of active bone disease (rickets in wrists and/or knees and/or femoral/tibial bowing), OR
    - o documented abnormal growth velocity, OR
    - o 1 to 2 years of age without radiographic evidence or abnormal growth velocity; but with confirmed genetic testing or family history, and low fasting serum phosphorus; consider treatment per clinical judgement

  -OR-
- Adults and adolescents at final adult height (epiphyseal growth plates are closed) have presence of non-healing fractures (e.g., visible fracture lines), AND
- Patient does NOT have any of the following: chronic kidney disease (CKD) stage 2 or greater, evidence of tertiary hyperparathyroidism

Tumor-Induced Osteomalacia (TIO)

- Prescribed by, or in consultation with, a specialist experienced in the treatment of metabolic bone disorders and/or oncologist, AND
- Patient is ≥2 years, AND
- Patient has a diagnosis of TIO not amenable to surgical excision of the offending tumor/lesion, AND
- Serum phosphorus is within or above the normal range for age prior to treatment initiative, AND,
- Patient has no evidence of tertiary hyperparathyroidism

Continuation of Therapy Criteria:

- Documentation of positive clinical response (defined below), AND
- Office visit or telephone visit with a specialist within the past 12 months

Notes:

- Discontinuation only recommended if: intolerance to medication OR non-adherence to medication, lab-monitoring or follow-up assessments with a specialist OR lack of normalization of serum phosphorus OR lack of positive clinical response (a positive response is defined as an improvement in growth velocity, deformities, fractures, or bone pain) OR if initiating chemotherapy or planned surgical excision of tumor/lesion

Pancreatic Enzymes

Generic	Brand
PANCRELIPASE	CREON, ZENPEP, PANCREAZE, VIOKACE , PERTZYE

*representative list

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 1 year
- Reauthorization: 1 year

Initial Review Criteria:

- Documentation of diagnosis of pancreatic insufficiency due to one of the following conditions:
    - Cystic fibrosis
    - Chronic pancreatitis
    - Pancreatectomy

Continuation of Therapy Criteria:

- Documentation of continued medical necessity

Pharmacological Chaperone-Alpha-Galactosid.A Stabz

Prior Authorization Criteria follows the state's criteria (DMAS)

Generic	Brand	HICL	GSN	Representative NDC
MIGALASTAT HCL	GALAFOLD CAPS 123 MG	44433	077590	71904010001

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 6 months

Initial Review Criteria:

- Patient has a documented diagnosis of Fabry disease with biochemical/genetic confirmation by one of the following:
  - Males only: α-galactosidase A (α-Gal A) activity in plasma, isolated leukocytes, and/or cultural cells, OR
  - Plasma or urinary globotriaosylceramide (Gb3/GL-3) or globotriaosylsphingosine (lyso-Gb3), OR
  - Detection of pathogenic mutations in the GALA/GLA gene by molecular genetic testing
- Patient is 18 years or older,
- Patient has an amenable GLA mutation (as defined in the migalastat labeling) determined by or in consult with a clinical genetics professional as causing Fabry disease (pathogenic),
- If taking an angiotensin-converting enzyme inhibitor (ACEI) or angiotensin II receptor blocker (ARB), patient must be stable on therapy for at least 4 weeks,
- Baseline echocardiogram, estimated glomerular filtration rate (eGFR), 24-hour urine protein, urine GL-3 and/or GL-3 inclusions, and alpha-galactosidase (α-Gal, male patients only) must be performed prior to treatment initiation,
- Patient has not undergone or scheduled to undergo kidney transplantation or currently on dialysis,
- Medication will NOT be used in combination with agalsidase beta

Continuation of Therapy Criteria:

- Patient continues to meet initial criteria above,
- Disease response with treatment as defined by a reduction in urine GL-3 and/or GL-3 inclusions compared to pre-treatment baseline,
- Absence of unacceptable toxicity (e.g., kidney infections) and absence of progression into renal impairment or end-stage renal disease (e.g., eGFR <30 mL/min/1.73m^2)

Potassium Sparing Diuretics

Generic	Brand	HICL	GSN	Representative NDC
FINERENONE	KERENDIA TABS 10 MG	47487	082499	50419054001
FINERENONE	KERENDIA TABS 20 MG	47487	082500	50419054101

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Nephrologist or Endocrinologist,
- AND documented diagnosis of type 2 diabetes mellitus in patients at least 18 years of age,
- AND documented diagnosis of CKD (defined as eGFR 25-74 mL/min/1.73 m^2 and/or urinary albumin-to-creatinine ratio of >300),
- AND patient is on ACEI or ARB therapy, or if not prescribed, provider has documented rationale,
- AND documented baseline eGFR and serum potassium $\leqslant$5 mEq/L within past 3 months,
- AND documented adequate therapeutic trial ($\geqslant$3 months) and failure, contraindication, or intolerance to Jardiance AND at least 1 anti-mineralocorticoid (i.e. spironolactone/eplerenone)

Continuation of Therapy Criteria:

- Documented beneficial response to therapy (i.e. no documentation of initiation of dialysis, kidney transplant, or decrease in eGFR of 40% or greater)
- AND patient continues to be under the care of a specialist

Proprotein Convertase Subtilisin Kexin Type-9 (PCSK-9) Inhibitors and Antihyperlipidemic – Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors

Last revised 12.1.2023; Effective 1.1.2024

Adapted from DMAS Preferred Drug List

Generic	Brand
ALIROCUMAB	PRALUENT
EVOLOCUMAB	REPATHA
BEMPEDOIC ACID	NEXLETOL
BEMPEDOIC ACID-EZETIMIBE	NEXLIZET

*representative list

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 1 year
- Reauthorization: 1 year

Initial Review Criteria:

- Must be prescribed by or in consultation with either a Cardiologist or Endocrinologist
- Documentation of age group for appropriate indication:
    - 13-75 years old being considered for treatment of homozygous familial hypercholesterolemia (HoFH)
    - 18-75 years old being considered for treatment of heterozygous familial hypercholesterolemia (HeFH)
    - 18-75 years old being considered for treatment of suspected familial hypercholesterolemia (LDL ≥220 mg/dL)
    - 40-75 years old being considered for treatment of very high-risk ASCVD
        - Very high-risk ASCVD is defined as history of multiple major ASCVD events or 1 major ASCVD event and multiple high-risk conditions.
            - Major ASCVD events include:
                - ❑ Recent ACS (within 12 months)
                - ❑ History of MI
                - ❑ History of ischemic stroke
                - ❑ Symptomatic PAD (history of claudication with ABI <0.85, or previous revascularization or amputation
            - High-risk conditions include:
                - ❑ Age ≥65 years
                - ❑ Heterozygous familial hypercholesterolemia
                - ❑ History of prior CABG or PCI outside of the major ASCVD events
                - ❑ Diabetes mellitus
                - ❑ Hypertension
                - ❑ CKD (eGFR 15-59 ml/min/1.73 m^2
                - ❑ Current smoking
                - ❑ Persistently elevated LDL-C (LDL-C ≥100 mg/dL despite maximally tolerated statin therapy and ezetimibe
                - ❑ History of congestive HF

- For HeFH/HoFH: Documentation of LDL-C > 100 mg/dL in the last 90 days
- For patients with suspected familial hypercholesterolemia: Documentation of LDL-C > 130 mg/dL in the last 90 days
- For patient with very high-risk ASCVD: Documentation of LDL-C ≥ 70 mg/dL in the last 90 days
- Patient had an adequate trial (8+ weeks) of high-dose, high-potency statin (atorvastatin 40-80 mg daily or rosuvastatin 20-40 mg daily) plus ezetimibe

- If statin intolerant:
    - Inability to tolerate at least 2 statins, with at least one started at the lowest starting daily dose AND
        - Statin dose reduction attempted for resolution of muscle symptoms, abnormal biomarkers OR
        - Muscle symptoms, abnormal biomarkers recur with low intensity/lowest possible statin dose re-challenge OR
        - Muscle symptoms, abnormal biomarkers recur with an adequate trial of hydrophilic statins – Pravastatin, Rosuvastatin
- Repatha 140 mg will only be approved for very high-risk ASCVD, suspected familial hypercholesterolemia, heterozygous familial hypercholesterolemia (HeFH).
- Repatha 420 mg will only be approved for diagnosis of homozygous familial hypercholesterolemia (HoFH).
- Praluent should only be prescribed if the patient has a documented failure to or adverse drug reaction to Repatha.
    - Praluent 150 mg will only be approved if there has been a trial of Praluent 75 mg for a minimum of 8 weeks with an LDL-C change of less than 30%: including lab results demonstrating LDL-C reduction pre and post therapy

Continuation of Therapy Criteria:

- Repatha should only be continued beyond 8 weeks in presence of LDL-C decrease of greater than 30%
- Praluent should only be continued beyond 8 weeks in presence of LDL-C decrease of greater than 30%
- Leqvio should only be continued beyond 8 weeks in presence of LDL-C decrease of greater than 30%

ACL Inhibitors

Initial Approval Criteria

- Patient is ≥ 18 years of age; AND
- Patient has diagnosis of heterozygous familial hypercholesterolemia (HeFH) or established atherosclerotic cardiovascular disease (ASCVD); AND
- Patient has failed to achieve a target LDL-C despite physician attestation that the patient is adherent to maximally tolerated doses of statins prior to the lipid panel demonstrating suboptimal reduction; AND
- Patient can be classified into ONE of the following risk factor groups:
- Extremely high risk ASCVD: (defined as extensive or active burden of ASCVD, or ASCVD with extremely high burden of adverse or poorly controlled risk cardio-metabolic risk factors including HeFH or severe hypercholesterolemia [SH] LDL-C > 220 mg/dl) with an LDL-C ≥ 70 mg/dL; OR
- Very high risk ASCVD: (defined as less extensive ASCVD and poorly controlled cardiometabolic risk factors) with an LDL-C ≥ 100 mg/dL; OR
- High risk ASCVD: (defined as either less extensive ASCVD and well-controlled risk factors or primary prevention HeFH or SH >220 mg/dl with poorly controlled risk factors) with LDL-C ≥ 130 mg/dL; AND

- Therapy will be used in conjunction with the maximum tolerated doses of a statin; AND
- Therapy will not be used with concurrent doses of simvastatin > 20 mg or pravastatin > 40 mg.

Renewal Criteria

- Laboratory analyses demonstrate a reduction in LDL-C when compared to the baseline values (prior to initiating bempedoic acid or bempedoic acid/ezetimibe); AND
- Patient has shown continued adherence to maximally tolerated statin dosage

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Pulmonary Arterial Hypertension (PAH) Agents

Generic	Brand
SILDENAFIL CITRATE (PULMONARY HYPERTENSION)	REVATIO
TADALAFIL (PULMONARY HYPERTENSION)	ADCIRCA ALYQ

*representative list

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 1 year
- Reauthorization: 1 year

Initial Review Criteria:

- Patient must have diagnosis of pulmonary hypertension if ≥ 18 years old
- Prescriber must be a pulmonologist or cardiologist or in consultation with a specialty provider
- Documentation of clinical rationale for not taking sildenafil tablet to receive authorization for injectable Revatio

Continuation of Therapy Criteria:

- Documentation of continued medical necessity

Sotyktu (deucravacitinib)

Adapted from DMAS Preferred Drug List

Last reviewed 06/09/2023 (Effective 07/01/2023)

Prior Authorization Criteria:

Length of Authorization:

- Initial: 1 year
- Reauthorization: 1 year

Initial Review Criteria:

- Patient must be 18 years of age or older
- Diagnosis of moderate to severe plaque psoriasis
- Prescribed by, or in consultation with, a dermatologist, rheumatologist, or other specialist in the treatment of psoriasis
- Symptoms persistent for ≥ 6 months with at least one of the following:
  - Involvement of at least 3% of body surface area (BSA), OR
  - Psoriasis Area and Severity Index (PASI) score of 10 or greater, OR
  - Incapacitation due to plaque location (i.e., head and neck, palms, soles, or genitalia), AND
- Trial and failure (≥3 months) of at least one of the following conventional therapy:
  - DMARD (e.g., methotrexate), OR
  - Immunosuppressant (e.g., cyclosporine), OR
  - Oral retinoid (e.g., acitretin), AND
- Patient is not using Sotyktu (deucravacitinib) in combination with any other biologic agent
- Trial and failure (≥3 months) unless contraindication or intolerance to, at least one preferred cytokine or CAM antagonist indicated for the treatment of this condition

Continuation of Therapy Criteria:

- Patient has a documented response to therapy compared to baseline (e.g., redness, thickness, scaliness, amount of surface area involvement, and/or PASI score)

Stimulants (ADHD)

Last revised 08/01/2024; Effective 10/1/2024

Generic	Brand
DEXMETHYLPHENIDATE HCL	FOCALIN, FOCALIN XR
METHYLPHENIDATE HCL	QUILLICHEW ER, QUILLIVANT XR, CONCERTA, APTENSIO XR, METADATE ER, METHYLIN, RELEXXII, RITALIN, RITALIN LA, METADATE CD
METHYLPHENIDATE	DAYTRANA, COTEMPLA XR
DEXTROAMPHETAMINE/AMPHETAMINE	ADDERALL, ADDERALL XR, MYDAVIS
DEXTROAMPHETAMINE SULFATE	DEXEDRINE, DEXEDRINE SPANSULE, ZENZEDI, PROCENTRA
LISDEXAMFETAMINE DIMESYLATE	VYVANSE
METHAMPHETAMINE HCL	DESOXYN
AMPHETAMINE SULFATE	EVEKEO
AMPHETAMINE	ADZENYS ER, ADZENYS XR-ODT, DYANAVEL XR
SERDEXMETHYLPHENIDATE CHLORIDE-DEXMETHYLPHENIDATE HCL45	AZSTARYS

*representative list

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 1 year
- Reauthorization: 1 year

Initial Review Criteria:

- Required for patients ≤ 4 years old OR ≥ 18 years old
- For patients ≤ 4 years old, prescriber must be a pediatric psychiatrist, pediatric neurologist, developmental/behavioral pediatrician, or in consultation with one of these specialists.
- For patients ≥ 18 years old:
    - Documentation of diagnosis of ADHD by Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (including documentation of impairment in more than one major setting), determined by the primary care clinician
- If the requested product is non-preferred, provide documentation of the following:
    - Pharmaceutical agents attempted with outcome
    - Indicating medical necessity and reasoning for why a non-preferred product is required
- If the request is for Vyvanse chewable tablets, member must have tried and failed methylphenidate solution

Continuation of Therapy Criteria:

- Documentation that the prescriber has regularly evaluated the patient for stimulant and/or other substance use disorder, and, if present, initiated specific treatment, consulted with an appropriate healthcare provider, or referred the patient for evaluation for treatment if indicated

Systemic Enzyme Inhibitors

Last revised 4/8/2024; Effective date: 8/13/2024

Generic	Brand	HICL	GSN	Representative NDC
LENIOLISIB PHOSPHATE	JOENJA TABS 70 MG	48803	084559	71274017060

Prior Authorization Criteria: Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Member is 12 years of age or older and weighing ≥45 kg,
- Member has confirmed diagnosis of activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS), as demonstrated by the presence of an APDS-associated genetic PI3Kδ mutation with a documented variant in either *PIK3CD* or *PIK3R1,*
- Member has nodal and/or extranodal lymphoproliferation, with the presence of ≥1 measurable nodal lesion, as measured on computed tomography (CT) or magnetic resonance imaging (MRI) **OR** have clinical findings/manifestations compatible with APDS [e.g., history of repeated oto-sino-pulmonary infections, organ dysfunction (e.g., lung, liver)],
- Pregnancy status has been confirmed in individuals of reproductive potential prior to initiating therapy and highly effective methods of contraception will be used during treatment,
- Member will avoid concomitant therapy with all the following:
    - Coadministration with strong and moderate CYP3A4 inducers (e.g., rifampin, bosentan, efavirenz, etravirine, St. John's Wort),
    - Coadministration with strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, clarithromycin)
- Member will avoid concurrent immunosuppressive therapy [e.g., mammalian target of rapamycin (mTOR) inhibitors, B-cell depleters, glucocorticoids (doses >25 mg/day of prednisone equivalent), cyclophosphamide, mycophenolate]

Continuation of Therapy Criteria:

- Member continues to meet all initial criteria,
- Member has disease response with treatment as defined by stabilization of or improvement of disease signs and symptoms,
- Member has been assessed for toxicity

Thyroid Hormone Receptor (THR) Agonist

Generic	Brand	HICL	GSN	Representative NDC
RESMETIROM	REZDIFFRA TABS 100 MG	49451	085843	82576010030
RESMETIROM	REZDIFFRA TABS 60 MG	49451	085841	82576006030
RESMETIROM	REZDIFFRA TABS 80 MG	49451	085842	82576008030

Prior Authorization Criteria:
Length of Authorization: • Initial: 12 months • Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a hepatologist or gastroenterologist,
- Patient is 18 years of age or older,
- Emerging Therapeutic Strategy Program (ETSP) Interregional Consultative Physician panel review completed,
- Diagnosed with noncirrhotic nonalcoholic steatohepatitis (NASH) or metabolic dysfunction-associated steatohepatitis (MASH) consistent with stages F2 or F3 as determined by transient electrographic and/or liver biopsy and Nonalcoholic liver disease (NAFLD) Activity Score (NAS) of ≥4,
- Disease progression refractory to lifestyle changes (e.g., healthy lifestyle/weight loss programs, 3 to 6-months trial of medication for weight loss with a goal of 7% to 10% weight loss etc.),
- Documented use as an adjust to lifestyle changes (e.g., caloric restrictions, regular exercise, and/or a diet diary),
- Documented completion of the following baseline assessments and labs within 3 months, prior to initiation:
    - Assessments: History of alcohol consumption (e.g. Peth test or AUDIT score), MELD score, ultrasound, CT scan, and/or MRI (within the past 6 months)
    - Labs: HbA1c, hepatic function panel (ALT, AST, ALP, albumin, direct bilirubin, total bilirubin, serum sodium, CBC, IRN, TSH, Free T4, Score, MELD score, hepatitis serology if not completed in patient's lifetime.
- Prescriber's attestation or documentation confirming that the patient does NOT have any of the following:
    - Thyroid disease (e.g., active hyperthyroidism, untreated clinical hypothyroidism defined by TSH >7 IU/L with symptoms of hypothyroidism or >10 IU/L without symptom. *Note: Patients who have had a thyroidectomy and are on replacement thyroxine doses >75 µg per day are eligible.*
    - History of significant alcohol consumption as determined by the provider
    - Regular use of drugs historically associated with metabolic dysfunction-associated fatty liver disease (MAFLD) due to concern for drug-induced liver (e.g. amiodarone, methotrexate, systemic glucocorticoids at greater than 5 mg/day, tamoxifen, estrogen at doses greater than those used for hormone replacement or contraception, anabolic steroids (except testosterone replacement), valproic acid and know hepatotoxins)
    - Recent significant weight gain or loss
    - Hemoglobin A1c (HbA1c) ≥ 9%
    - Diagnosis of hepatocellular carcinoma (HCC)
    - Model for End-Stage Liver Disease (MELD) score ≥12 unless due to therapeutic anticoagulation
    - Hepatic decompensation (i.e. one or more complications of liver cirrhosis)
    - Uncontrolled autoimmune disease
    - Serum alanine aminotransferase (ALT) >250 U/L
    - Moderate to severe hepatic impairment (Child-Pugh Class B or C)
    - Active, serious medical disease with likely life expectancy <2 years
    - Currently pregnant or breastfeeding or planning to become pregnant

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met the criteria**:
    - Document clinically significant benefit from the medication defined as follows:
        - NAFLD Activity Score (NAS) has decrease by at least 2 points from baseline
        - Reduction in fibrosis state
    - Specialist follow-up in the last 12 months

Topical Anticholinergic Hyperhidrosis Tx Agents

Generic	Brand	HICL	GSN	Representative NDC
GLYCOPYRRONIUM TOSYLATE	QBREXZA PADS 2.4 %	45086	078624	69489041101

Prior Authorization Criteria:

Length of Authorization:

- Initial: 3 months
- Reauthorization: 6 months

Initial Review Criteria:

- Patient is ≥ 9 years of age,
- Diagnosis of axillary hyperhidrosis that is severe, intractable and disabling,
- Inadequate response, intolerance or contraindication to the following therapies:
    - For members < 18 years of age:
        - At least 3 months of topical aluminum chloride (e.g., OTC Hypercare, Rx Drysol)
    - For member ≥18 years of age:
        - At least 3 months of topical aluminum chloride (e.g., OTC Hypercare, Rx Drysol)
        - At least 6 months of Botox

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met the criteria:**
    - Document clinically significant benefits from the medication,
    - Specialist follow-up in the last 12 months

Topical Anticholinergic Hyperhidrosis Tx Agents (cont'd)

Generic	Brand	HICL	GSN	Representative NDC
SOFPIRONIUM BROMIDE	SOFDRA GEL 12.45 %	49707	086231	83723001050

Prior Authorization Criteria:

Length of Authorization:

- Initial: 3 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a dermatologist,
- Patient is ≥9 years of age,
- Diagnosed with primary axillary hyperhidrosis (aHH) and symptoms of hyperhidrosis (HH) (e.g. focal, visible, excessive sweating) for ≥6 months that is severe, intractable, and disabling,
- Documentation of at least 2 of the following criteria:
  - Symptoms occur bilaterally
  - Symptoms impair daily activities
  - At least one episode per week
- Inadequate response, intolerance, or contraindication to ALL of the following therapies:
  - For members < 18 years of age:
    - At least 3 months of topical aluminum chloride (e.g., OTC Hypercare, Rx Drysol)
  - For members ≥18 years of age:
    - At least 3 months of topical aluminum chloride (e.g., OTC Hypercare, Rx Drysol)
    - At least 6 months of Botox
    - At least 3 months of Qbrexza (glycopyrronium)

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met the criteria:**
  - Document clinically significant benefits from the medication,
  - Specialist follow-up in the last 12 months

Topical Antineoplastic Premalignant Lesion Agents

Prior Authorization Criteria follows the state's criteria (DMAS)

Generic	Brand	HICL	GSN	Representative NDC
MECHLORETHAMINE HCL (TOPICAL)	VALCHLOR GEL 0.016%	3892	071531	69639012001

Prior Authorization Criteria:
Length of Authorization: • Initial: 6 months • Reauthorization: 6 months
Initial & Continuation of Therapy Criteria: • Patient has Stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma, • Patient has tried at least ONE of the following skin-directed therapies: o Topical corticosteroids o Topical retinoids [bexarotene (Targetin), tazarotene (Tazorac)] o Local radiation o Phototherapy o Topical imiquimod (Aldara) • Medication is being prescribed by a Dermatologist or Oncologist, • Patient is 18 years of age or older, • Documentation of medical necessity has been provided with clinical evidence to support use of the requested medication

Topical Immunosuppressive Agents

Last revised: 7/30/2024; Effective date: 10/1/2024

Prior Authorization Criteria follows the state's criteria (DMAS)

Generic	Brand	HICL	GSN	Representative NDC
SIROLIMUS (TOPICAL)	HYFTOR GEL 0.2%	20519	083237	73683010110

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Member is 6 years of age or older,
- Documented diagnosis of facial angiofibroma associated with tuberous sclerosis,
- Confirmation that live vaccines will be avoided during treatment, and all age-appropriate vaccinations will be completed before starting therapy,
- If an individual of reproductive potential, counseling has been completed to use effective contraception before and during treatment, as well as for 12 weeks after the last dose,
- Prescriber confirmation that member has been counseled on possible adverse effects (e.g., hypersensitivity reactions, serious infections, lymphoma and other malignancies, interstitial lung disease/non-infectious pneumonitis), including counseling male members that Hyftor may impair fertility,
- Member will be monitored for adverse reactions if therapy is used concurrently with ANY of the following:
    - Inhibitors of CYP3A4 (e.g., clarithromycin, ketoconazole, nefazodone), due to the potential for increased sirolimus systemic exposure,
    - Drugs that are both substrates and inhibitors of CYP3A4 (e.g., aprepitant and tipranavir), due to the potential for increased systemic exposure of these concurrently administered agents

Continuation of Therapy Criteria:

- Member continues to meet the initial criteria above,
- Member has disease improvement or stabilization, OR improvement in the slope of decline of the size and redness of the facial angiofibroma,
- Member has NOT experienced any treatment-restricting adverse effects (e.g., hypersensitivity reactions, serious infections, lymphoma and other malignancies, interstitial lung disease/non-infectious pneumonitis)

Note: Quantity limit of 30 grams (3 x 10 g tubes) per 30-day supply

Topical Retinoids

Generic	Brand
TRETINOIN	RETIN-A GEL, TRETIN-X, ATRALIN, ALTRENO, AVITA
ADAPALENE	DIFFERIN, PLIXDA
AZELAIC ACID	AZELEX
ADAPALENE-BENZOYL PEROXIDE	EPIDUO
TRETINOIN MICROSPHERE	RETIN-A MICRO

Prior Authorization Criteria:

Adapted from DMAS Preferred Drug List

Length of Authorization:

- Initial: 1 year
- Reauthorization: 1 year

Initial Review Criteria:

- All patients must have a diagnosis of acne
- Patients ≥ 18 years old will require evaluation of treatment diagnosis

Continuation of Therapy Criteria:

- Documentation of continued medical necessity

Wound Healing Agents, Local

Prior Authorization Criteria follows the state's criteria (DMAS)

Generic	Brand	HICL	GSN	Representative NDC
BIRCH TRITERPENES	FILSUVEZ GEL 10%	48746	084481	10122031001

Prior Authorization Criteria:

Length of Authorization:

- Initial: 3 months
- Reauthorization: 12 months

Initial Review Criteria:

- Patient is 6 months of age and older,
- Confirmed diagnosis of dystrophic or junctional epidermolysis bullosa (EB) as confirmed by one of the following (medical records required):
  - Immunofluorescence mapping (IFM), OR
  - Transmission electron microscopy (TEM), OR
  - Genetic testing
- Patient does NOT have either of the following in the area that will undergo treatment:
  - Current evidence or a history of squamous cell carcinoma
  - Active infection

Continuation of Therapy Criteria:

- Patient continues to meet initial criteria,
- Patient continues to experience clinical benefit from the requested treatment