Kaiser Permanente Mid-Atlantic States Region (KPMAS)

Maryland Medicaid

Prior Authorization Criteria

Effective 12/3/2024

Reference:
KPMAS Regional Pharmacy and Therapeutics (P&T) Committee
P&T Approval/Revision Date: 10/04/2024, 08/02/2024, 06/07/2024, 04/05/2024, 02/02/2024, 12/01/2023, 10/06/2023, 08/04/2023, 06/02/2023, 04/07/2023, 02/03/2023, 12/06/2022, 10/04/2022, 08/15/2022, 07/05/2022, 06/07/2022, 04/05/2022, 5/14/2021, 11/6/2020, 7/29/2020, 5/1/2020, 10/4/2019

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Agents to Treat Multiple Sclerosis – Modestly Effective Therapy

Last revised: 10/1/2024; Effective date: 12/3/2024

Generic	Brand	HICL	GSN	Representative NDC
INTERFERON BETA-1A	AVONEX PEN AJKT 30 MCG/0.5 ML	11253	067628	59627033304
INTERFERON BETA-1A	AVONEX PREFILLED PSKT 30 MCG/0.5 ML	11253	052882	59627022205
INTERFERON BETA-1A	REBIF REBIDOSE SOAJ 22 MCG/0.5ML	23353	070587	44087332201
INTERFERON BETA-1A	REBIF REBIDOSE SOAJ 44 MCG/0.5ML	23353	070588	44087334409
INTERFERON BETA-1A	REBIF REBIDOSE TITRATION PACK SOAJ 6X8.8 & 6X22 MCG	23353	070586	44087018801
INTERFERON BETA-1A	REBIF SOSY 22 MCG/0.5ML	23353	050035	44087002203
INTERFERON BETA-1A	REBIF SOSY 44 MCG/0.5ML	23353	050039	44087004409
INTERFERON BETA-1A	REBIF TITRATION PACK SOSY 6X8.8 & 6X22 MCG	23353	058776	44087882201
INTERFERON BETA-1A	REBIF REBIDOSE SOAJ 22 MCG/0.5ML	23353	070587	44087332201
INTERFERON BETA-1A	REBIF REBIDOSE SOAJ 44 MCG/0.5ML	23353	070588	44087334409
PEGINTERFERON BETA-1A	PLEGRIDY SOPN 125 MCG/0.5ML	41331	072682	64406001101
PEGINTERFERON BETA-1A	PLEGRIDY SOSY 125 MCG/0.5ML	41331	072675	64406001502
PEGINTERFERON BETA-1A	PLEGRIDY STARTER PACK SOPN 63 & 94 MCG/0.5ML	41331	072680	64406001201
PEGINTERFERON BETA-1A	PLEGRIDY STARTER PACK SOSY 63 & 94 MCG/0.5ML	41331	072674	64406001601
TEFLUNOMIDE	AUBAGIO 7 MG	39624	069979	58468021101
TEFLUNOMIDE	AUBAGIO 14 MG	39624	069980	58468021002
DIMETHYL FUMARATE	TECFIDERA CPDR 120 MG	40168	070786	64406000501
DIMETHYL FUMARATE	TECFIDERA CPDR 240 MG	40168	070787	64406000602
DIMETHYL FUMARATE	TECFIDERA MISC 120 & 240 MG	40168	070785	64406000703
DIROXIMEL FUMARATE	VUMERITY CPDR 231 MG	46164	080393	64406002003

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Neurologist, AND
- Patient has diagnosis of relapsing form of multiple sclerosis (including non-progressive relapsing, progressive relapsing, relapsing remitting), AND
- Patient has failed an adequate trial (≥3 months) of, or has a documented allergy or intolerance to, or is not a candidate for any of the following:
    - Glatiramer acetate, AND
    - Interferon-beta 1b (Betaseron) AND
    - Dimethyl fumarate (generic Tecfidera), AND
    - If for Aubagio, documented allergy to, or is not a candidate for teriflunomide (generic Aubagio)
- Patient does not previously or currently have high risk features for early progression to non-relapsing progressive MS. <u>High risk features defined as meeting at least 1 of the following criteria</u>:
    - Incomplete recovery defined as an attack that lasts ≥ 30 days and has significant functional limitations with the exception of ongoing sensory symptom
    - Relapse w sphincter dysfunction, including urinary urgency or hesitancy
    - Motor relapse
    - Cerebellar relapse
    - 3 or more relapses in the first 2 years after diagnosis
    - After at least 6 months of therapy, a relapse in the next 6 months
    - Annualized relapse rate of ≥1
    - After 1yr of therapy, ≥ 3 new or enlarging T2, gadolinium-enhancing lesions, or
    - Diffusion-weighted imaging lesions
    - ≥ 1 cord lesion on imaging, AND
- Patient has CBC, TSH (for interferon therapy only), LFTs (for Interferon and Aubagio) checked within the last 6 months, AND
- Patient is not using in addition to another DMT, AND
- Patient is not pregnant and will not be pregnant soon

<u>Additional criteria for Aubagio only</u>:

- Patient is a female and between 12-50 years old with a negative pregnancy test AND on highly effective contraception (highly effective contraception = oral birth control, medroxyprogesterone, IUD, implant, surgical intervention, same sex partner, partner with vasectomy) AND
- Patient does not have a documented history of neuropathy, diabetes (type 1 or 2), or other medical condition that would suggest patient is at an increased risk of developing neuropathy

Continuation of Therapy Criteria:

- Patient has completed the following laboratory monitoring within the last 6 months:
    - Complete blood count with differential
    - Liver function, AND
- Patient is not using in addition to another disease-modifying therapy and is not pregnant
- Patients using teriflunomide continue to meet initial review criteria

Agents to Treat Multiple Sclerosis – Highly Effective Therapy

Last revised: 8/1/2023

Generic	Brand	HICL	GSN	Representative NDC
FINGOLIMOD HCL	GILENYA CAPS 0.25 MG	37180	078464	00078096589
FINGOLIMOD HCL	GILENYA CAPS 0.5 MG	37180	066709	00078060789
CLADRIBINE	MAVENCLAD (10 TABS) TBPK 10 MG	7840	078079	44087400000
CLADRIBINE	MAVENCLAD (4 TABS) TBPK 10 MG	7840	078079	44087400004
CLADRIBINE	MAVENCLAD (5 TABS) TBPK 10 MG	7840	078079	44087400005
CLADRIBINE	MAVENCLAD (6 TABS) TBPK 10 MG	7840	078079	44087400006
CLADRIBINE	MAVENCLAD (7 TABS) TBPK 10 MG	7840	078079	44087400007
CLADRIBINE	MAVENCLAD (8 TABS) TBPK 10 MG	7840	078079	44087400008
CLADRIBINE	MAVENCLAD (9 TABS) TBPK 10 MG	7840	078079	44087400009
SIPONIMOD FUMARATE	MAYZENT STARTER PACK TBPK 0.25 MG	45670	079603	00078097912
SIPONIMOD FUMARATE	MAYZENT TABS 0.25 MG	45670	079602	00078097950
SIPONIMOD FUMARATE	MAYZENT TABS 1 MG	45670	083188	00078101415
SIPONIMOD FUMARATE	MAYZENT TABS 2 MG	45670	079601	00078098615

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Neurologist, AND
- Patient has diagnosis of relapsing form of multiple sclerosis (including non-progressive relapsing, progressive relapsing, relapsing remitting), AND
- Patient has failed an adequate trial (≥3 months) of, or has a documented allergy or intolerance to, or is not a candidate for:
    - Fingolimod (generic Gilenya), AND
    - Truxima (rituximab-abbs) or Tysabri (natalizumab), AND
- Patient is not using in addition to another DMT

Continuation of Therapy Criteria:

- Patient is not using in addition to another DMT, AND
- Patient is experiencing positive clinical response, AND
- <u>For Gilenya and Mayzent only:</u> Patient has been seen by a dermatologist and ophthalmologist in the past 12 months

Neuromuscular Transmission – Potassium Channel Blocker

Last revised: 2/6/2024

Generic	Brand	HICL	GSN	Representative NDC
DALFAMPRIDINE	AMPYRA TB12 10 MG	13907	066066	10144042760

Prior Authorization Criteria:

Length of Authorization:

- Initial: 3 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Neurologist, AND
- Documented diagnosis of multiple sclerosis (MS), AND
- Prescribed for walking problems specifically related to MS, AND
- Patient can walk (not restricted to wheelchair or bed), AND
- Patient's renal function estimated (using glomerular filtration rate (eGFR) or creatinine clearance (CrCl)) to be >50 mL/min, AND
- Patient does not have history of seizures, AND
- Patient has failed an adequate trial (≥ 3 months) of, or has a documented allergy or intolerance to, or is not a candidate for dalfampridine (generic Ampyra)

Continuation of Therapy Criteria:

- Patient has demonstrated improvement in walking speed or demonstrates improvement in core activities of daily living (e.g., meal preparation or household chores), AND
- Dose does not exceed 20 mg per day

Notes:

- Daily doses >20 mg will not be approved.

Neuromuscular Transmission – Potassium Channel Blocker (Cont'd)

Last revised: 2/6/2024

Generic	Brand	HICL	GSN	Representative NDC
AMIFAMPRIDINE PHOSPHATE	FIRDAPSE TABS 10 MG	36930	066227	69616021106

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

Amyotrophic Lateral Sclerosis Agents

Last revised: 2/6/2024

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) ≥ 80% within past 2 months,
- AND patient has had a trial of riluzole

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 ≤ 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

Amyotrophic Lateral Sclerosis Agents (Cont'd)

Last revised: 2/6/2024

Generic	Brand	HICL	GSN	Representative NDC
SODIUM PHENYLBUTYRATE-TAURURSODIOL	RELYVRIO PACK 3-1 GM	48081	083686	73063003503

Prior Authorization Criteria:

Length of Authorization:

- Initial: 3 months
- Reauthorization: 6 months

Initial Review Criteria:

- Prescriber is a Neurologist,
- AND clinical ALS diagnosed by a neurologist with duration of 18 months or less from onset for first symptom,
- AND forced vital capacity (%FVC) > 60%,
- AND patient has had a trial of riluzole
- AND patient does not have a tracheostomy

Continuation of Therapy Criteria:

- Documentation of positive clinical response,
- AND Neurologist follow-up occurred since last review,
- AND patient does not have any of the following:
    - %FVC ≤ 50% and blood gas PaCO2 >45 mmHg
    - Patient is requiring a tracheotomy or non-invasive ventilation all day
    - 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

Amyloidosis Agents – Transthyretin (TTR) Suppression

Last revised: 2/6/2024

Generic	Brand	HICL	GSN	Representative NDC
INOTERSEN SODIUM	TEGSEDI SOSY 284 MG/1.5ML	45353	079122	72126000701

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 6 months

Initial Review Criteria:

- Prescriber is a Neurologist, AND
- Patient is ≥18 years, AND
- Diagnosis of Neuropathic Heredofamilial Amyloidosis, AND
- Documented confirmed transthyretin (TTR) mutation from genetic testing, AND
- Patient does not have end stage renal disease (chronic kidney disease Stage 5), AND
- Patient has not had a prior liver transplant AND
- Patient does not have severe hepatic impairment [alanine transaminase (ALT) >2.5 times the upper limit of normal] and/or cirrhosis, AND
- Patient does not have hepatitis B or C infection, human immunodeficiency virus (HIV) infection, or active malignancy, AND
- Patient must have documented intolerance or contraindication to Onpattro before being approved for Tegsedi

Continuation of Therapy Criteria:

- The following assessments have been performed within the past 6 months: Medical research Council (MRC) strength testing scale (0-5), hand grip strength (with or without dynamometer), and 10-meter walk test (10MWT) and Timed Up and Go (TUG) test, if applicable, AND
- Karnofsky performance score ≥30, AND
- No significant clinical decline, AND
- No development of cardiogenic shock requiring inotropic support, AND
- Patient is NOT in hospice care

Anthelmintics

Generic	Brand	HICL	GSN	Representative NDC
MEBENDAZOLE	EMVERM CHEW 100 MG	4167	009607	64896066930

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

Last revised: 10/1/2024; Effective date: 12/3/2024

Generic	Brand	HICL	GSN	Representative NDC
METHOTREXATE	OTREXUP SOAJ 10 MG/0.4ML	40683	071561	54436001002
METHOTREXATE	OTREXUP SOAJ 12.5 MG/0.4ML	40683	076329	54436001202
METHOTREXATE	OTREXUP SOAJ 15 MG/0.4ML	40683	071562	54436001502
METHOTREXATE	OTREXUP SOAJ 17.5 MG/0.4ML	40683	075849	54436001704
METHOTREXATE	OTREXUP SOAJ 20 MG/0.4ML	40683	071563	54436002002
METHOTREXATE	OTREXUP SOAJ 22.5 MG/0.4ML	40683	075850	54436002204
METHOTREXATE	OTREXUP SOAJ 25 MG/0.4ML	40683	071564	54436002502
METHOTREXATE	RASUVO SOAJ 10 MG/0.2ML	40683	072578	59137051004
METHOTREXATE	RASUVO SOAJ 12.5 MG/0.25ML	40683	072579	59137051504
METHOTREXATE	RASUVO SOAJ 15 MG/0.3ML	40683	072580	59137052004
METHOTREXATE	RASUVO SOAJ 17.5 MG/0.35ML	40683	072581	59137052504
METHOTREXATE	RASUVO SOAJ 20 MG/0.4ML	40683	071563	59137053001
METHOTREXATE	RASUVO SOAJ 22.5 MG/0.45ML	40683	072582	59137053504
METHOTREXATE	RASUVO SOAJ 25 MG/0.5ML	40683	072583	59137054004
METHOTREXATE	RASUVO SOAJ 30 MG/0.6ML	40683	072585	59137055000
METHOTREXATE	RASUVO SOAJ 7.5 MG/0.15ML	40683	072577	59137050500

Anti-Arthritic – Folate Antagonist Agents (Cont'd)

Prior Authorization Criteria:
Length of Authorization: • Initial: 12 months • Reauthorization: 12 months
Initial Review Criteria: • Prescriber is a Rheumatologist or Dermatologist, AND • Diagnosis of adult with severe, active rheumatoid arthritis, AND • Patient has tried and had an inadequate response or intolerance to generic oral methotrexate, AND • Patient is unable to prepare and administer generic injectable methotrexate OR • Diagnosis of child with active polyarticular juvenile idiopathic arthritis, AND • Patient has tried and had an inadequate response or intolerance to generic oral methotrexate, AND • Patient is unable to prepare and administer generic injectable methotrexate
Continuation of Therapy Criteria: • Documentation of a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition, AND • Patient continues to be unable to prepare and administer generic injectable methotrexate

Antifibrotic Therapy- Pyridone Analogs

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

Generic	Brand	HICL	GSN	Representative NDC
PIRFENIDONE	ESBRIET CAPS 267 MG	40237	070889	64116012101
PIRFENIDONE	ESBRIET TABS 267 MG	40237	077032	50242012206
PIRFENIDONE	ESBRIET TABS 801 MG	40237	077034	50242012301

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 nintedanib or any CYP1A2 inhibitors (e.g., fluvoxamine, ciprofloxacin),
- AND using for one of the following diagnoses:
    - Idiopathic pulmonary fibrosis (IPF):
        - NO known cause of interstitial lung disease
    - 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

Antihyperglycemics, Biguanide Type

Generic	Brand	HICL	GSN	Representative NDC
METFORMIN HCL	FORTAMET TB24 1000 MG	4763	054018	59630057560
METFORMIN HCL	FORTAMET TB24 500 MG	4763	054019	59630057460
METFORMIN HCL	GLUMETZA TB24 1000 MG	4763	061273	68012000316
METFORMIN HCL	GLUMETZA TB24 500 MG	4763	061267	68012000213
METFORMIN HCL	METFORMIN HCL ER (MOD) TB24 1000 MG	4763	061273	68682001890
METFORMIN HCL	METFORMIN HCL ER (MOD) TB24 500 MG	4763	061267	68682001710
METFORMIN HCL	METFORMIN HCL ER (OSM) TB24 1000 MG	4763	054018	00378600191
METFORMIN HCL	METFORMIN HCL ER (OSM) TB24 500 MG	4763	054019	00591271960

Prior Authorization Criteria:

Length of Authorization:

- Initial: 3 months
- Reauthorization: 12 months

Initial Review Criteria:

- Diagnosis of type 2 diabetes mellitus, AND
- Documented failure/intolerance to Metformin IR and generic Metformin 500 mg ER after adequate trial (3 months) AND after documentation of all three of the following strategies to mitigate GI intolerance:
    - Slow dose titration of Metformin IR or generic 500 mg ER tabs (dose increase every two weeks) to maximally tolerated dose (up to 2000 mg daily), AND
    - Patient has been instructed to take with food (as seen on SIG), AND
    - Patient has been switched from Metformin IR to generic Metformin 500 mg ER tabs; with adequate trial of 3 months

Continuation of Therapy Criteria:

- Adherence (>80%) to diabetic regimen, AND
- Must continue to meet inclusion criteria, AND
  Documented A1C lowering of 1% from initial or A1C now at goal

Notes:

- Criteria only applies to new start patients

Antihyperglycemic – Incretin Mimetics Combination

Last revised: 10/10/2024; Effective date: 12/3/2024

Generic	Brand	HICL	GSN	Representative NDC
TIRZEPATIDE	MOUNJARO SOPN 2.5 MG/0.5ML	48014	083391	00002150601
TIRZEPATIDE	MOUNJARO SOPN 5 MG/0.5ML	48014	083392	00002149501
TIRZEPATIDE	MOUNJARO SOPN 7.5 MG/0.5ML	48014	083393	00002148401
TIRZEPATIDE	MOUNJARO SOPN 10 MG/0.5ML	48014	083388	00002147101
TIRZEPATIDE	MOUNJARO SOPN 12.5 MG/0.5ML	48014	083389	00002146001
TIRZEPATIDE	MOUNJARO SOPN 15 MG/0.5ML	48014	083390	00002145701

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 6 months

Initial Review Criteria:

- Diagnosis of type 2 diabetes mellitus,
- AND patient is not using for chronic weight management (CWM),
- AND patient is not on any agent in any of the following drug classes: GLP-1 agonists or DPP-4 inhibitors,
- AND most recent A1c within 2% above goal (as per ADA guidelines) within 3 months of the PA request (*Note: if A1c is >2% above goal, insulin therapy is required)*,
- AND patient is currently taking, or previously failed adequate trial (adherence/MRAR ≥80% for at least 3 months), experienced intolerance or contraindication to ALL of the following agents or associated combination products:
    - Metformin
    - Sulfonylurea
    - Pioglitazone (if BMI <35)
    - Sitagliptin (unbranded Zituvio)
    - Jardiance
    - At least TWO of the following preferred GLP-1 agonists: Victoza, Ozempic, OR Rybelsus

Continuation of Therapy Criteria:

- Patient has failed adequate trial (adherence/MRAR ≥80% for at least 3 months), or has intolerance or contraindication to at least TWO of the following GLP-1 agonists: Victoza, Ozempic, OR Rybelsus,
- AND patient is not using for CWM,
- AND patient has demonstrated good adherence/MRAR ≥80% to diabetic regimen,
- AND patient must meet ONE of the following A1c requirements:
    - Achieved A1c goal, OR
    - Documented A1c lowering of 1% from initial (baseline A1c prior to starting Mounjaro), OR
    - Documented A1c lowering of 0.5% from time of last review

Anti-Inflammatory – Interleukin-1 Receptor Antagonist

Last revised: 10/1/2024; Effective date: 12/3/2024

Generic	Brand	HICL	GSN	Representative NDC
ANAKINRA	KINERET SOSY 100 MG/0.67ML	22953	048899	66658023428

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 6 months (recurrent pericarditis); 12 months (all other indications)

Initial Review Criteria:

- Prescriber must be a Rheumatologist, Dermatologist, or Cardiologist

Rheumatology

If using for rheumatoid arthritis:

- Diagnosis of moderate to severe rheumatoid arthritis, AND
- Inadequate response or no response to at least 3- month trial of 1 non-biologic DMARD AND 1 biologic DMARD, AND
- Documented inadequate response, contraindication, or inability to tolerate ALL of the following:
  - Adalimumab product (Amjevita preferred)
  - Enbrel (etanercept)*PA
  - Xeljanz (tofacitinib)*PA
- AND documented inadequate response, contraindication, or inability to tolerate at least ONE of the following:
  - Tocilizumab product (Tyenne preferred)
  - Orencia (abatacept)*PA

If using for juvenile idiopathic arthritis (JIA):

- Prescribed for patients ≥2 years for treatment of systemic-onset juvenile idiopathic arthritis (JIA) who have failure, intolerance or contraindications to NSAIDs and glucocorticoids; NOT covered for other subtypes of JIA

If using for neonatal-onset multisystem inflammatory disease (NOMID):

- Prescribed for Neonatal-onset multisystem inflammatory disease (NOMID), AND
- Patient is not receiving Kineret in combination with any of the following: biologic DMARD, Janus kinase inhibitor, phosphodiesterase 4 (PDE4) inhibitor

If using for recurrent pericarditis:

- Patient is 12 years of age or older,
- AND history of recurrent pericarditis with at least 2 episodes of acute pericarditis,
- AND patient has TWO of the following pericarditis-related symptoms:
  - Chest pain
  - Friction rub
  - ECG showing diffuse ST-segment elevation or PR-segment depression
  - New or worsening effusion
- AND CRP level of at least 1 mg/dL,
- AND patient has had a trial, failure, or contraindication to at least TWO of the following:
  - NSAIDs
  - Colchicine
  - Corticosteroids

- AND patient has had a trial, failure, or contraindication to at least TWO of the following:
    - Methotrexate
    - Mycophenolate
    - Azathioprine
    - Tacrolimus
- AND Kineret will NOT be used concurrently with other IL-1 inhibitors [e.g. Ilaris (canakinumab)[*PA], Arcalyst (rilonacept)]

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

Continuation of Therapy Criteria:

<u>If using for recurrent pericarditis:</u>

- Patient has experienced clinical improvement in pericarditis symptoms and requires continuation of therapy beyond initial 6-month treatment course
- AND specialist follow-up has occurred since last review

<u>If using for all other indications:</u>

- Patient has documented a clinically significant benefit from medication, AND
- Specialist follow-up occurred in past 12 months since last review, AND
- Patient is not receiving Kineret in combination with any of the following: biologic DMARD, Janus kinase inhibitor, phosphodiesterase 4 (PDE4) inhibitor

Anti-inflammatory – Tumor Necrosis Factor Inhibitor

Last revised: 10/1/2024; Effective date: 12/3/2024

Generic	Brand	HICL	GSN	Representative NDC
ETANERCEPT	ENBREL SOSY 25 MG/0.5ML	18830	062624	58406045504
ETANERCEPT	ENBREL SOSY 50 MG/ML	18830	058214	58406043504
ETANERCEPT	ENBREL SURECLICK SOAJ 50 MG/ML	18830	061938	58406044504
ETANERCEPT	ENBREL MINI SOCT 50 MG/ML	18830	077783	58406045601

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

Rheumatology:

If treating psoriatic arthritis:

- Diagnosis of psoriatic arthritis, AND
- History of inadequate response after a 3-month trial, intolerance or contraindication to ALL of the following:
  - At least one of the conventional DMARDs (e.g., methotrexate or leflunomide)
  - Infliximab product (Inflectra preferred)
  - Adalimumab product (Amjevita preferred)
  - Cosentyx (secukinumab)

If treating spondyloarthropathy/spondyloarthritis:

- Patient has had inadequate response after at least a 3-month trial, contraindication or intolerance to TWO of the following: infliximab product (Inflectra preferred), adalimumab product (Amjevita preferred), Xeljanz (tofacitinib)
- Patient also has at least ONE of the following:
  - Diagnosis of active ankylosing spondylitis or nonradiographic axial spondyloarthritis, AND has inadequate response, contraindication, or intolerance to full anti-inflammatory dose of an NSAID taken on a regular continuing basis for at least 4 weeks
  - Presence of enthesitis/tendinitis as part of manifestation of peripheral spondyloarthritis such as Achilles tendinopathy or plantar fasciitis
  - Diagnosis of peripheral spondyloarthritis (i.e. reactive arthritis, spondyloarthritis related to inflammatory bowel disease or other peripheral spondyloarthritis rather than axial), does NOT have enthesitis, AND has had inadequate response after a 3-month trial, contraindication, or intolerance to at least one nonbiologic DMARD such as sulfasalazine, methotrexate, or leflunomide

If treating rheumatoid arthritis:

- Diagnosis of rheumatoid arthritis AND
- Inadequate response after at least a 3-month trial, intolerance, or contraindication to one of the following: oral/subcutaneous methotrexate, hydroxychloroquine, leflunomide or sulfasalazine, AND

- Patient has history of inadequate response after at least a 3-month trial, contraindication, or intolerance to infliximab product [Inflectra (preferred)] and adalimumab product [Amjevita (preferred)]

If treating juvenile idiopathic arthritis:

- Pediatric patients ≥2 years with juvenile idiopathic arthritis who have failed methotrexate, AND
- History of inadequate response, contraindication, or intolerance to adalimumab product [Amjevita (preferred)]

Dermatology

If treating plaque psoriasis in adults ≥18 years of age:

- Diagnosis of moderate to severe plaque psoriasis (>3% body surface area, unless palmar-plantar involvement is severe), AND
- Inadequate response or contraindication to at least a 3-month trial of phototherapy unless involvement in sensitive areas (e.g., face, body folds, etc.), AND
- Failed at least a 1-month trial of high or ultra-high potency topical corticosteroids, unless clinically significant adverse effects, contraindication or clinical reason to avoid treatment, AND
- Failed at least a 3-month trial of ALL of the following unless clinically significant adverse effects, contraindication or clinical reason to avoid treatment:
    - Methotrexate or acitretin
    - Adalimumab product (Amjevita preferred)
    - Cosentyx (secukinumab)

If treating plaque psoriasis in pediatrics <18 years of age:

- Diagnosis of moderate to severe plaque psoriasis in pediatric patients <18 years who have contraindication, intolerance or inadequate response to topical psoriasis treatment, AND
- Inadequate response, intolerance, or contraindication to methotrexate or at least a 12-week trial of phototherapy

If treating other indications:

- Approve for treatment of Mediterranean fever, familial (FMF) if intolerance to colchicine AND prescribed by a specialist, OR
- Approve for adjunct treatment of Kawasaki disease if prescribed by a specialist

Continuation of Therapy Criteria:

- Positive clinical response to medication (i.e., asymptomatic or in clinical remission), AND
- Specialist follow-up occurred since the last review

Generic	Brand	HICL	GSN	Representative NDC
ADALIMUMAB	HUMIRA PEN PNKT 40 MG/0.8ML	24800	061205	00074433902
ADALIMUMAB	HUMIRA PSKT 40 MG/0.8ML	24800	051599	00074379902
ADALIMUMAB	HUMIRA PEDIATRIC CROHNS START PSKT 40 MG/0.8ML	24800	051599	00074379903
ADALIMUMAB	HUMIRA PEDIATRIC CROHNS START PSKT 40 MG/0.8ML	24800	051599	00074379906
ADALIMUMAB	HUMIRA PEDIATRIC CROHNS START PSKT 80 MG/0.8ML	24800	077767	00074254003
ADALIMUMAB	HUMIRA PEDIATRIC CROHNS START PSKT 80 MG/0.8ML & 40MG/0.4ML	24800	078360	00074006702
ADALIMUMAB	HUMIRA PEN PNKT 40 MG/0.4ML	24800	077470	00074055471
ADALIMUMAB	HUMIRA PEN-CD/UC/HS STARTER PNKT 40 MG/0.8ML	24800	061205	00074433906
ADALIMUMAB	HUMIRA PEN-CD/UC/HS STARTER PNKT 80 MG/0.8ML	24800	077870	00074012403
ADALIMUMAB	HUMIRA PEN-CD/UC/HS STARTER PNKT 80 MG/0.8ML	24800	077870	00074012474
ADALIMUMAB	HUMIRA PEN-PS/UV/ADOL HS START PNKT 40 MG/0.8ML	24800	061205	00074433907
ADALIMUMAB	HUMIRA PEN-PS/UV/ADOL HS START PNKT 80 MG/0.8ML & 40MG/0.4ML	24800	078672	00074153903
ADALIMUMAB	HUMIRA PSKT 10 MG/0.1ML	24800	078347	00074081702
ADALIMUMAB	HUMIRA PSKT 20 MG/0.2ML	24800	078348	00074061602
ADALIMUMAB	HUMIRA PSKT 40 MG/0.4ML	24800	077469	00074024302

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Rheumatologist, Dermatologist, or Gastroenterologist,
- AND history of treatment failure, intolerance, or contraindication to adalimumab biosimilars (Amjevita preferred), AND
- Negative test for tuberculosis within the past 12 months (prefer within the last 3 months), AND
- Negative test for hepatitis B within the past 24 months, AND

Rheumatology

If treating psoriatic arthritis:

- Diagnosis of psoriatic arthritis, AND
- History of inadequate response after at least a 3-month trial, contraindication or intolerance to one or more medications to treat psoriatic arthritis such as conventional DMARDs (e.g., methotrexate or leflunomide), AND
- Inadequate response after at least a 3-month trial, contraindication, or intolerance to an infliximab product OR Cosentyx (secukinumab)

If treating spondyloarthropathy/spondyloarthritis:

- Patient has inadequate response, contraindication or intolerance to infliximab product (Inflectra preferred), AND
- Patient meets at least ONE of the following conditions:
    - Diagnosis of active ankylosing spondylitis or nonradiographic axial spondyloarthritis AND has inadequate response after at least 4 weeks, contraindication, or intolerance to full anti-inflammatory dose of an NSAID taken on a regular continuing basis,
    - Presence of enthesitis/tendinitis as part of manifestation of peripheral spondyloarthritis such as Achilles tendinopathy or plantar fasciitis
    - Diagnosis of peripheral spondyloarthritis (i.e. reactive arthritis, spondyloarthritis related to inflammatory bowel disease or other peripheral spondyloarthritis rather than axial), does NOT have enthesitis, AND has had inadequate response after 3-month trial, contraindication, or intolerance to at least one nonbiologic DMARD such as sulfasalazine, methotrexate or leflunomide

If treating rheumatoid arthritis:

- Diagnosis of rheumatoid arthritis AND
- Documented advanced disease or high disease activity, AND
- Inadequate response (after a 3-month minimum trial), contraindication or intolerance to at least ONE of the following:
    - Methotrexate (oral or injectable),
    - Hydroxychloroquine,
    - Leflunomide,
    - Sulfasalazine,
- Patient has history of inadequate response after at least a 3-month trial, contraindication, or intolerance to infliximab

If treating pediatrics with juvenile idiopathic arthritis:

- Patient is ≥2 years with juvenile idiopathic arthritis,
- Inadequate response, contraindication, or intolerance to methotrexate

Dermatology

If treating plaque psoriasis in adults ≥ 18 years of age:

- Diagnosis of moderate to severe plaque psoriasis (>3% body surface area, unless palmar-plantar involvement is severe), AND
- Inadequate response after at least a 3-month trial or contraindication to phototherapy unless involvement in sensitive areas (e.g., face, body folds, etc.), AND
- Failed at least a 1-month trial of high or ultra-high potency topical corticosteroids, unless clinically significant adverse effects, contraindication or clinical reason to avoid treatment, AND
- Failed at least a 3-month trial of 1 of the following unless clinically significant adverse effects, contraindication or clinical reason to avoid treatment (i.e. pregnancy/breastfeeding, history of alcoholism or alcoholic liver disease, chronic liver disease, immunodeficiency syndrome, pre-existing blood dyscrasia, hemodialysis, or end-stage renal disease)
    - Methotrexate
    - Acitretin
- AND has inadequate response, intolerance or contraindication to Cosentyx (secukinumab)

If treating plaque psoriasis in pediatrics < 18 years of age:

- Diagnosis of moderate to severe plaque psoriasis,
- AND patient is <18 years of age,
- AND patient has inadequate response, contraindication or intolerance to topical psoriasis treatments,
- AND patient has inadequate response, contraindication or intolerance to methotrexate OR at least a 12-week trial of phototherapy

Gastroenterology

If using for Crohn's disease or ulcerative colitis:

- Prescribed for treatment of moderate to severe Crohn's disease or ulcerative colitis (UC), AND
- Patient has inadequate response, intolerance to, or contraindication to ALL of the following:
    - One conventional therapy [Mesalamine (UC only), azathioprine, 6-mercaptopurine, OR methotrexate],
    - Corticosteroids,
    - Infliximab
    - Xeljanz (tofacitinib) – for ulcerative colitis only, not applicable to Crohn's disease

If using for other indications: approve if patient is being treated for any of the following labeled indications AND prescribed by a specialist:

- Hidradenitis suppurativa if <18 years of age or history of treatment failure to Amjevita
- Uveitis and related conditions if <18 years of age or history of treatment failure to Amjevita

Continuation of Therapy Criteria:

- History of treatment failure, intolerance, or contraindication to adalimumab biosimilars (Amjevita preferred), AND
- Positive clinical response to medication (i.e., asymptomatic or in clinical remission), AND
- Specialist follow-up occurred in the past 12 months since last review

Generic	Brand	HICL	GSN	Representative NDC
CERTOLIZUMAB PEGOL	CIMZIA KIT 2 X 200 MG	35554	063903	50474070062
CERTOLIZUMAB PEGOL	CIMZIA PREFILLED KIT 2 X 200 MG/ML	35554	065189	50474071079

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Rheumatologist, Dermatologist, or Gastroenterologist

Rheumatology

- Patient has diagnosis of rheumatoid arthritis, psoriatic arthritis, or spondyloarthropathy, AND
- If of childbearing potential, patient is pregnant, attempting to conceive, and/or breastfeeding, AND
- Patient is intolerant to or experienced treatment failure with at least one of the preferred anti-TNF agents [i.e. adalimumab-atto (Amjevita) or infliximab-dyyb (Inflectra)]

Gastroenterology

- Patient has diagnosis of Crohn's disease, AND
- If of childbearing potential, patient is pregnant, attempting to conceive, and/or breastfeeding, AND
- Patient is intolerant to or experienced treatment failure with at least one of the preferred anti-TNF agents [i.e. adalimumab-atto (Amjevita) or infliximab-dyyb (Inflectra)]

Continuation of Therapy Criteria:

- If of childbearing potential, patient is pregnant, attempting to conceive, and/or breastfeeding, AND
- Patient has a clinically significant benefit from medication (i.e. asymptomatic or in clinical remission), AND
- Specialist follow-up occurred in the past 12 months since last review

Generic	Brand	HICL	GSN	Representative NDC
GOLIMUMAB	SIMPONI SOAJ 100 MG/ML	36278	071262	57894007102
GOLIMUMAB	SIMPONI SOAJ 50 MG/0.5ML	36278	065113	57894007002
GOLIMUMAB	SIMPONI SOSY 100 MG/ML	36278	071017	57894007101
GOLIMUMAB	SIMPONI SOSY 50 MG/0.5ML	36278	065114	57894007001

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Rheumatologist, Dermatologist, or Gastroenterologist

Rheumatology

If using for spondyloarthropathy/spondyloarthritis:

- Patient has inadequate response, contraindication or intolerance to at least 2 anti-tumor necrosis factors inhibitors (i.e. adalimumab product [AMJEVITA preferred], infliximab product [INFLECTRA preferred]), AND
- Patient meets at least ONE of the following conditions:
    - Diagnosis of active ankylosing spondylitis (ankylosing spondylitis or non-radiographic axial spondyloarthritis) AND has inadequate response, contraindication, or intolerance to a full anti-inflammatory dose of an NSAID taken on a regular continuing basis for at least 4 weeks.
    - Presence of enthesitis/tendinitis as part of manifestation of peripheral spondyloarthritis such as Achilles tendinopathy or plantar fasciitis.
    - Diagnosis of peripheral spondylarthritis (i.e. reactive arthritis, spondylarthritis related to inflammatory bowel disease or other peripheral spondyloarthritis rather than axial), does not have enthesitis AND had inadequate response after a 3-month trial, intolerance, or contraindication to a least one nonbiologic DMARDs such as sulfasalazine, methotrexate, or leflunomide.

If using for rheumatoid arthritis:

- Diagnosis of rheumatoid arthritis, AND
- Patient has intolerance, contraindication to, or failed treatment with ALL of the following:
    - Xeljanz (tofacitinib)[*PA], tocilizumab product (Tyenne preferred), and Orencia (abatacept)[*PA],
    - At least 2 anti-TNFs [adalimumab product (Amjevita preferred), Enbrel (etanercept)[*PA], infliximab product (Inflectra preferred)]

If using for psoriatic arthritis:

- Diagnosis of psoriatic arthritis, AND
- Patient has intolerance, contraindication to, or failed treatment with ALL of the following:
    - Xeljanz (tofacitinib)[*PA], Cosentyx (secukinumab)[*PA], and Orencia (abatacept)[*PA],

o At least 2 anti-TNFs [adalimumab product (Amjevita preferred), Enbrel (etanercept)*PA, infliximab product (Inflectra preferred)]
Gastroenterology • Patient has diagnosis of moderate to severe ulcerative colitis, AND • Patient has intolerance, contraindication to, or inadequate response to: o Preferred anti-TNF agent [i.e. infliximab product (Inflectra preferred) or adalimumab product (Amjevita preferred)], AND o At least one of the following: ▪ Entyvio (vedolizumab) ▪ Xeljanz (tofacitinib)*PA *PA*This medication is also subject to PA review*
Continuation of Therapy Criteria: • Patient has documented a clinically significant benefit from medication, AND • Specialist follow-up occurred in past 12 months since last review

Anti-inflammatory – Interleukin-1 Beta Blockers

Last revised: 10/1/2024; Effective date: 12/3/2024

Generic	Brand	HICL	GSN	Representative NDC
CANAKINUMAB	ILARIS SOLN 150 MG/ML	36497	077202	00078073461
CANAKINUMAB	ILARIS SOLR 150 MG	36497	065997	00078058261

Prior Authorization Criteria:

Length of Authorization:

- Initial: 1 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Rheumatologist

Rheumatology

- Patient is ≥2 years old and has a diagnosis of systemic juvenile idiopathic arthritis, AND
- Documented inadequate response, contraindication, or inability to tolerate BOTH of the following:
    - o Tocilizumab product (Tyenne preferred)
    - o Kineret (anakinra)*PA

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

Continuation of Therapy Criteria:

- Physician documentation of disease stability and improvement

Anti-Inflammatory – Phosphodiesterase-4 (PDE4) Inhibitor

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

Generic	Brand	HICL	GSN	Representative NDC
APREMILAST	OTEZLA TABS 30 MG	40967	072075	59572063106
APREMILAST	OTEZLA TBPK 10 & 20 & 30 MG	40967	073370	59572063255

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Rheumatologist or Dermatologist

Rheumatology

- Diagnosis of psoriatic arthritis, AND
- Documented inadequate response after a 3-month trial or intolerance to TWO non-biologic DMARDs (e.g., methotrexate, leflunomide, sulfasalazine), AND
- Documented inadequate response, intolerance, or contraindication to preferred anti-TNF agents [i.e. adalimumab-atto (Amjevita) or infliximab-dyyb (Inflectra)]

Dermatology

- Diagnosis of moderate to severe plaque psoriasis (>3% body surface area unless palmar-plantar involvement is severe), AND
- Failed at least a 1-month trial of high or ultra-high potency topical corticosteroids, unless clinically significant adverse effects, contraindication or clinical reason to avoid treatment, AND
- Failed at least a 3-month trial of 1 of the following unless clinically significant adverse effects, contraindication or clinical reason to avoid treatment (i.e. pregnancy/breastfeeding, history of alcoholism or alcoholic liver disease, chronic liver disease, immunodeficiency syndrome, pre-existing blood dyscrasia, hemodialysis, or end-stage renal disease):
  - Methotrexate
  - Acitretin

AND

- Inadequate response to at least a 3-month trial or contraindication to phototherapy unless involvement in sensitive areas (e.g., face, body folds, etc.)

Behcet's Disease

- Diagnosis of Behcet's Disease with mucocutaneous (oral or genital ulcers), AND
- Failed at least a 1-month trial of topical corticosteroids, unless clinically significant adverse effects, contraindication or clinical reason to avoid treatment, AND
- Failed at least a 1-month trial of colchicine, unless clinically significant adverse effects, contraindication or clinical reason to avoid treatment, AND
- Failed at least a 1-month trial of azathioprine, unless clinically significant adverse effects, contraindication or clinical reason to avoid treatment

Note:

If patient has any additional signs of active Behcet's (uveitis, etc.), recommend infliximab prior to Otezla
Continuation of Therapy Criteria:
Rheumatology • Documentation of positive clinical response to Otezla therapy, AND • Patient is not receiving Otezla in combination with either biologic DMARD OR janus kinase inhibitor, AND • Patient is NOT using Otezla starter pack for maintenance therapy, AND • Specialist follow-up occurred since last review
Dermatology • Documentation of positive clinical response to Otezla therapy, AND • Patient is NOT using Otezla starter pack for maintenance therapy, AND • Specialist follow-up occurred since last review

Antimigraine Preparations

Last revised: 8/2/2024; Effective date: 9/1/2024

Generic	Brand	HICL	GSN	Representative NDC
ERENUMAB-AOOE	AIMOVIG (140 MG DOSE) SOAJ 70 MG/ML	44923	078424	55513084102
ERENUMAB-AOOE	AIMOVIG SOAJ 140 MG/ML	44923	079588	55513084301
ERENUMAB-AOOE	AIMOVIG SOAJ 70 MG/ML	44923	078424	55513084101
GALCANEZUMAB-GNLM	EMGALITY SOAJ 120 MG/ML	45281	078996	00002143611
GALCANEZUMAB-GNLM	EMGALITY SOSY 120 MG/ML	45281	078997	00002237701
GALCANEZUMAB-GNLM	EMGALITY (300 MG DOSE) SOSY 100 MG/ML	45281	079818	00002311501

Prior Authorization Criteria:

Length of Authorization:

- Initial: 4 months
- Reauthorization: 12 months

Initial Review Criteria:

Migraine treatment:

- Prescriber is a Neurologist and/or pain management specialist with expertise in diagnosis/treating headache, AND
- Patient's age is ≥18 years or ≤75 years, AND
- Prescribed for treatment of chronic migraine (defined as ≥ 15 headache days [migraine-like or tension-like] per month for the past 3 months)or episodic migraine (≥ 8 days/month or ≥ 2 disabling migraines/month lasting at least 72 hours for the past 3 months), AND
- Documented trial (≥2 months) with treatment failure, inadequate response, or contraindication to use to at least 3 preventative agents for migraine, 2 of which must include:
    - Beta-blocker (e.g., metoprolol, propranolol)
    - Candesartan
    - Lisinopril
- If for Emgality, patients must have documented treatment failure or inadequate response to a ≥2-month trial of Ajovy (preferred)
- If for Aimovig, patients must have documented treatment failure or inadequate response to a ≥2-month trial of Ajovy (preferred) and Emgality

Cluster Headache (Emgality ONLY):

- Prescriber is a Neurologist and/or pain management specialist with expertise in diagnosis/treating headache, AND
- Patient's age is ≥18 years or ≤75 years, AND
- Prescribed for the treatment of episodic cluster headache (≥ 2 cluster periods lasting from 7 days to 1 year, separated with pain-free remission periods between attacks ≥ 1 months), currently with frequency of attacks ≥1 attack every other day, AND

• History of cluster headache period lasting ≥6 weeks.
Continuation of Therapy Criteria: • Patient meets all the initial criteria for coverage, AND • After 3 months of treatment, the patient has positive clinical response.

Antimigraine Preparations (Cont'd)

Last revised: 2/7/2023

Generic	Brand	HICL	GSN	Representative NDC
UBROGEPANT	UBRELVY TABS 100 MG	46273	080589	00023650110
UBROGEPANT	UBRELVY TABS 50 MG	46273	080588	00023649810

Prior Authorization Criteria:

Length of Authorization:

- Initial: 4 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a neurologist and/or pain management specialist with expertise in diagnosing/treating headaches,
- AND patient's age is ≥18 years or ≤75 years,
- AND use is for treatment of migraine,
- AND documented trial (≥2 months) with treatment failure, or inadequate response, to at least 3 generic oral triptan agents at maximally tolerated doses

Continuation of Therapy Criteria:

- If patient meets all the initial criteria for coverage, AND
- After 3 months of treatment patient has evidence of positive clinical response

Antimigraine Preparations (Cont'd)

Last revised: 8/2/2024; Effective date: 9/1/2024

Generic	Brand	HICL	GSN	Representative NDC
RIMEGEPANT SULFATE	NURTEC TBDP 75 MG	46383	080787	72618300002

Prior Authorization Criteria:

Length of Authorization:

- Initial: 4 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a neurologist and/or pain management specialist with expertise in diagnosing/treating headaches,
- AND prescribed for the treatment of acute migraine* or prevention of episodic migraine

<u>If using for treatment of acute migraine:</u>

- Documented trial (≥ 2 months) with treatment failure, or inadequate response, to at least 3 generic oral triptan agents at maximally tolerated doses,
- AND patient has failed or has contraindications to Ubrelvy (ubrogepant)

<u>If using for prevention of episodic migraine:</u>

- Patient has ≥4 and <15 migraine headache days per month (prior to initiating a migraine-preventative medication),
- AND documented trial (≥2 months) with treatment failure, inadequate response, or contraindication to use to at least 3 preventative agents for migraine, 2 of which must include:
  - Beta-blocker (e.g., metoprolol, propranolol)
  - Candesartan
  - Lisinopril
- AND trial of 2 injectable CGRP antagonists (Ajovy preferred, then Emgality, then Aimovig),
- AND trial of Qulipta (atogepant)

<u>Additional Criteria for Nurtec:</u>

- If patient is on opioids or barbiturates, use is ≤ 4 days in the month prior to initiation AND,
- Patient does not have BMI <18 or >40

<u>Notes:</u>

*Limit quantity of Nurtec to 8 tablets per 30 days when used for the treatment of acute migraine

**For either indication, patient should not use in combination with another CGRP antagonist Ajovy (fremanezumab-vfrm), Emgality (galcanezumab-gnlm), Aimovig (ernumab-aooe) or Vyepti (eptinezumab). CGRP inhibitors for migraine prevention have not been studied for use in combination with another agent in the same class. The clinical trial of Nurtec ODT for the preventive treatment of episodic migraine did not permit the use of a concomitant medication that acts on the CGRP pathway.

Continuation of Therapy Criteria:

- Patient meets all the initial criteria for coverage, AND
- After 3 months of treatment patient has evidence of positive clinical response

Antimigraine Preparations (Cont'd)

Last revised: 12/6/2022

Generic	Brand	HICL	GSN	Representative NDC
LASMIDITAN SUCCINATE	REYVOW TABS 50 MG	46082	080308	00002431208
LASMIDITAN SUCCINATE	REYVOW TABS 100 MG	46082	080309	00002449108

Prior Authorization Criteria:
Length of Authorization: • Initial: 4 months • Reauthorization: 12 months
Initial Review Criteria: • Prescriber is a neurologist and/or pain management specialist with expertise in diagnosing/treating headaches, • AND prescribed for the treatment of acute migraine, • AND documented trial (≥ 2 months) with treatment failure, or inadequate response, to at least 3 generic oral triptan agents at maximally tolerated doses, • AND patient has failed or has contraindications to Ubrelvy (ubrogepant)
Continuation of Therapy Criteria: • Patient meets all the initial criteria for coverage, AND • After 3 months of treatment patient has evidence of positive clinical response

Antimigraine Preparations (cont'd)

Last revised: 8/2/2024; Effective date: 9/1/2024

Generic	Brand	HICL	GSN	Representative NDC
ATOGEPANT	QULIPTA TABS 10 MG	47599	082700	00074709530
ATOGEPANT	QULIPTA TABS 30 MG	47599	082701	00074709630
ATOGEPANT	QULIPTA TABS 60 MG	47599	082702	00074709430

Prior Authorization Criteria:

Length of Authorization:

- Initial: 4 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Neurologist and/or Pain Management Specialist with expertise in diagnosis/treating headaches,
- AND patient has ≥4 and <15 migraine headache days per month (prior to initiating a migraine-preventative medication),
- AND documented trial (≥2 months) with treatment failure, inadequate response, or contraindication to use at least 3 preventative agents for migraine, 2 of which must include:
    - Beta-blocker (e.g. metoprolol, propranolol)
    - Candesartan
    - Lisinopril
- AND trial of at least 2 injectable CGRP antagonists (Ajovy preferred, then Emgality, then Aimovig) for a minimum of 8 weeks,
- AND limit quantity of Qulipta to 30 tablets per 30 days

Continuation of Therapy Criteria:

- Patient meets all the initial criteria for coverage,
- AND after 3 months of treatment, the patient has positive clinical response

Antimigraine Preparations

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

Generic	Brand	HICL	GSN	Representative NDC
ZAVEGEPANT HCL	ZAVZPRET SOLN 10 MG/ACT	48771	084508	00069350002

Prior Authorization Criteria:

Length of Authorization:

- Initial: 4 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Neurologist and/or Pain Management Specialist with expertise in diagnosing/treating headaches,
- Prescribed for the treatment of acute migraine,
- Documented trial (≥ 2 months) with treatment failure, or inadequate response to at least 3 generic triptan agents at maximally tolerated doses,
- Patient has failed or has contraindication to Ubrelvy (ubrogepant)*PA AND Nurtec (rimegepant)*PA

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

Continuation of Therapy Criteria:

- Patient meets all the initial criteria for coverage,
- After 3 months of treatment, the patient has positive clinical response

Notes: Limited to 6 nasal sprays per 30-day supply

Antibacterials, Miscellaneous

Last revised: 8/2/2024; Effective date: 9/1/2024

Generic	Brand	HICL	GSN	Representative NDC
RIFAXIMIN	XIFAXAN TABS 200 MG	20401	041880	65649030103
RIFAXIMIN	XIFAXAN TABS 550 MG	20401	066295	65649030302

Length of Authorization:

- Initial: 12 months for Hepatic Encephalopathy
- Reauthorization: 6 months Hepatic Encephalopathy
- 14 days for Irritable Bowel Syndrome with diarrhea (IBS-D), one-time
- 1 month for *C. difficile* associated diarrhea, one-time
- 3 days for Traveler's diarrhea, one-time
- 14 days for Small Intestinal Bacterial Overgrowth (SIBO), 2 treatment courses per year

Initial Review Criteria:

- Prescribed by an Infectious Disease Specialist or Gastroenterologist, except for treatment for hepatic encephalopathy may be prescribed in consultation (i.e. KP consult, chart review) with Gastroenterology, AND

Hepatic Encephalopathy – 12 months

- Diagnosis of hepatic encephalopathy AND
- Patient is ≥18 years of age AND
- Xifaxan (rifaximin) is being used as add-on therapy to lactulose AND
- Patient is unable to achieve an optimal response with lactulose monotherapy after receiving an adequate trial OR
- Patient is intolerant or has contraindications to lactulose

Irritable Bowel Syndrome with diarrhea – 14 days

- Diagnosis of irritable bowel syndrome diarrhea predominant (IBS-D) AND
- Patient has inadequate response (must try for the minimum duration listed before considered treatment failure), contraindication or intolerance to at least TWO of the following medications:
    - Loperamide - at least 2 weeks
    - Diphenoxylate-atropine (Lomotil) - at least 2 weeks
    - A bile acid sequestrant (e.g., cholestyramine, colestipol) - at least 2 weeks
    - Dicyclomine (generic Bentyl) - at least 2 weeks
- Patient received no greater than 3 total treatments with rifaximin for IBS-D within the past 12 months (maximum 3 treatments with rifaximin for IBS-D per patient per year)

C. *difficile* – 1 month

- Diagnosis of third recurrence of *C. difficile* associated diarrhea AND
- Patient has failed treatment with metronidazole and vancomycin for previous episodes

Traveler's Diarrhea – 3 days

- Diagnosis of Traveler's Diarrhea AND
- Patients intolerant or unable to take a fluoroquinolone AND
- Patient intolerant or allergic to azithromycin

Small Intestinal Bacterial Overgrowth (SIBO) – 14 days

- Diagnosis of small intestinal bacterial overgrowth (SIBO), AND
- Patient has documented failure of treatment with at least ONE of the following:
  - Amoxicillin-clavulanate
  - Ciprofloxacin
  - Trimethoprim-sulfamethoxazole
  - Metronidazole
  - Doxycycline
  - Tetracycline
- Limited to a 14-day course of treatment, and 2 treatment courses per year

Continuation of Therapy Criteria (for hepatic encephalopathy only):

- Diagnosis of hepatic encephalopathy,
- AND patient has documented a clinically significant benefit from medication

Note: Continuation of therapy criteria is not applicable for IBD-S, C. difficile, Traveler's diarrhea, and small intestinal bacterial overgrowth

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

Last revised: 8/2/2024; Effective date: 9/1/2024

Generic	Brand	HICL	GSN	Representative NDC
SODIUM OXYBATE	XYREM SOLN 500 MG/ML	12346	050813	68727010001

Prior Authorization Criteria:
Length of Authorization: • Initial: 12 months • Reauthorization: 12 months
Initial Review Criteria: • Prescriber is Pulmonologist (Sleep Specialist) or 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 • Patient has had adequate trial (≥2 months) of Xywav
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: 8/5/2024; Effective date: 10/1/2024

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 idiopathic hypersomnia:</u> • Patient is at least 18 years of age
Continuation of Therapy Criteria: • Patient continues to be under the care of a specialist, • Documentation of positive clinical response

Anti-inflammatory – Selective Costimulation Modulator

Generic	Brand	HICL	GSN	Representative NDC
ABATACEPT	ORENCIA CLICKJECT SOAJ 125 MG/ML	37825	076265	00003218851
ABATACEPT	ORENCIA SOSY 125 MG/ML	37825	067681	00003218811
ABATACEPT	ORENCIA SOSY 50 MG/0.4ML	37825	077399	00003281411
ABATACEPT	ORENCIA SOSY 87.5 MG/0.7ML	37825	077400	00003281811

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Rheumatologist
- Diagnosis of rheumatoid arthritis, AND
- Intolerance, contraindication to, or failed treatment with at least a 3-month trial of the following, unless other documented clinical rationale:
    - o One of the following: oral/subcutaneous methotrexate, hydroxychloroquine, leflunomide, or sulfasalazine, AND
    - o Xeljanz (tofacitinib), AND
    - o At least 1 TNF inhibitor (e.g., Humira, Enbrel, Inflectra)

  OR
- Diagnosis of juvenile idiopathic arthritis, AND
- Intolerance, contraindication to, or failed treatment with at least a 3-month trial of a TNF inhibitor

  OR
- Patient is ≥18 years, AND
- Diagnosis of psoriatic arthritis, AND
- Intolerance, contraindication to, or failed treatment with at least a 3-month trial of a TNF inhibitor

  AND
- Patient must not be receiving Orencia in combination with any of the following:
    - o Biologic DMARD (e.g., Enbrel, Humira, Cimzia, Simponi)
    - o Janus kinase inhibitor (e.g., Xeljanz, Olumiant)

Continuation of Therapy Criteria:

- Patient has documented a clinically significant benefit from medication, AND
- Specialist follow-up occurred in past 12 months since last review

Anti-psoriatic Agents

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

Generic	Brand	HICL	GSN	Representative NDC
SECUKINUMAB	COSENTYX (300 MG DOSE) SOSY 150 MG/ML	41715	073394	00078063998
SECUKINUMAB	COSENTYX SENSOREADY (300 MG) SOAJ 150 MG/ML	41715	073395	00078063941
SECUKINUMAB	COSENTYX SENSOREADY PEN SOAJ 150 MG/ML	41715	073395	00078063968

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Rheumatologist, or Dermatologist, AND

If treating psoriatic arthritis:

- Diagnosis of psoriatic arthritis, AND
- History of inadequate response after at least a 3-month trial, contraindication, or intolerance to at least ONE of the conventional DMARDs (e.g., methotrexate or leflunomide),
- AND inadequate response, intolerance, or contraindication to adalimumab product [Amjevita (preferred), Humira]

If treating spondylarthritis:

- Patient has inadequate response, contraindication or intolerance to infliximab product (Inflectra preferred) or adalimumab product (Amjevita preferred), AND
- Patient meets at least ONE of the following conditions:
    - Diagnosis of active ankylosing spondylitis or nonradiographic axial spondyloarthritis, AND has inadequate response, contraindication, to intolerance to full anti-inflammatory dose of an NSAID taken on a regular continuing basis for at least 4 weeks
    - Presence of enthesitis/tendinitis as part of manifestation of peripheral spondyloarthritis such as Achilles tendinopathy or plantar fasciitis
    - Diagnosis of peripheral spondyloarthritis (i.e. reactive arthritis, spondyloarthritis related to inflammatory bowel disease or other peripheral spondyloarthritis rather than axial), does NOT have enthesitis, AND has had inadequate response after a 3-month trial, contraindication, or intolerance to at least one nonbiologic DMARD such as sulfasalazine, methotrexate, or leflunomide

If treating hidradenitis suppurativa:

- Patient has a diagnosis of moderate-to-severe hidradenitis suppurativa, AND
- Patient has inadequate response, contraindication, or intolerance to ALL of the following therapies:
    - Topical clindamycin 1% solution/lotion/gel (minimum of 12 weeks)
    - Oral antibiotics (e.g., doxycycline, tetracycline, clindamycin +/- rifampin, erythromycin) (minimum of 10 weeks)
    - Adalimumab product (Amjevita preferred) or infliximab product (Inflectra preferred) (minimum of 12 weeks)

Note: Significantly severe hidradenitis suppurativa may proceed with preferred TNF without trial of topical/oral antibiotics or intralesional corticosteroids.

If treating Plaque Psoriasis:

- Diagnosis of moderate to severe plaque psoriasis (>3% body surface area unless palmar-plantar involvement is severe),
- AND inadequate response or contraindication to at least a 3-month trial of phototherapy unless involvement in sensitive areas (e.g., face, body folds, etc.),
- AND failed at least a 3-month trial of 1 of the following unless clinically significant adverse effects, contraindication or clinical reason to avoid treatment(i.e. pregnancy/breastfeeding, history of alcoholism or alcoholic liver disease, chronic liver disease, immunodeficiency syndrome, pre-existing blood dyscrasia, hemodialysis, or end-stage renal disease), :
    - Methotrexate
    - Acitretin
- AND inadequate response (at least 3-month trial), intolerance, or contraindication to at least one of the preferred anti-TNF agents [i.e. adalimumab-atto (Amjevita) or infliximab-dyyb (Inflectra)]

Continuation of Therapy Criteria:

- Patient has documented a clinically significant benefit from medication, AND
- Specialist follow-up occurred in past 12 months since last review

Notes

- Approve Cosentyx 150 mg maintenance dose for patients weighing <100 kg; 300 mg maintenance dose for patients weighing ≥100 kg, or with documentation of severe disease
- Do NOT approve a loading dose for psoriatic arthritis and ankylosing spondylitis

Anti-psoriatic Agents (Cont'd)

Last revised: 4/8/2024; Effective date: 6/4/2024

Generic	Brand	HICL	GSN	Representative NDC
TILDRAKIZUMAB-ASMN	ILUMYA SOSY 100 MG/ML	44823	078258	47335017795
BRODALUMAB	SILIQ SOSY 210 MG/1.5ML	44102	077139	00187000402

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Dermatologist

Dermatology

Plaque Psoriasis:

- Diagnosis of moderate-to-severe plaque psoriasis (>3% body surface area unless palmar-plantar involvement is severe), AND
- Inadequate response or contraindication to at least a 3-month trial of phototherapy unless involvement in sensitive areas (e.g., face, body folds, etc.), AND
- Failed at least a 3-month trial of one of the following unless clinically significant adverse effects, contraindication or clinical reason to avoid treatment (i.e. pregnancy/breastfeeding, history of alcoholism or alcoholic liver disease, chronic liver disease, immunodeficiency syndrome, pre-existing blood dyscrasia, hemodialysis, or end-stage renal disease):
  - Methotrexate
  - Acitretin
- Documentation of inadequate response, intolerance, or contraindication to ALL of the following:
  - At least one TNF inhibitor (i.e. adalimumab product [Amjevita preferred] or infliximab product [Inflectra preferred])
  - Secukinumab (Cosentyx)*PA
  - Guselkumab (Tremfya)*PA OR risankizumab-rzaa (Skyrizi)*PA
  - Ustekinumab (Stelara)*PA

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

Continuation of Therapy Criteria:

- Positive clinical response to medication, AND
- Specialist follow-up occurred in the past 12 months since last review

Generic	Brand	HICL	GSN	Representative NDC
RISANKIZUMAB-RZAA	SKYRIZI SOSY 150 MG/ML	45699	082262	00074105001
RISANKIZUMAB-RZAA	SKYRIZI PEN SOAJ 150 MG/ML	45699	082261	00074210001

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Rheumatologist, Dermatologist, or Gastroenterologist

Rheumatology

Psoriatic Arthritis:

- Diagnosis of active psoriatic arthritis, AND
- Documented inadequate response (of at least a 3 month trial), intolerance, or contraindication to BOTH of the following:
  - ONE or more tumor necrosis factor (TNF alpha) inhibitors: Inflectra or Remicade (infliximab), Enbrel*PA (etanercept), adalimumab biosimilars (Amjevita preferred) or Humira
  - Cosentyx*PA (secukinumab)

Dermatology

Plaque Psoriasis:

- Diagnosis of moderate-to-severe plaque psoriasis (>3% body surface area unless palmar-plantar involvement is severe), AND
- Inadequate response or contraindication to at least a 3-month trial of phototherapy unless involvement in sensitive areas (e.g., face, body folds, etc.), AND
- Failed at least a 3-month trial of one of the following unless clinically significant adverse effects, contraindication or clinical reason to avoid treatment (i.e. pregnancy/breastfeeding, history of alcoholism or alcoholic liver disease, chronic liver disease, immunodeficiency syndrome, pre-existing blood dyscrasia, hemodialysis, or end-stage renal disease):
  - Methotrexate
  - Acitretin
- Documentation of inadequate response (at least 3-month trial), intolerance, or contraindication to ALL of the following:
  - At least one TNF inhibitor (i.e. adalimumab product [Amjevita preferred] or infliximab product [Inflectra preferred])
  - Secukinumab (Cosentyx)*PA

Gastroenterology

Crohn's Disease:

- Prescriber is a Gastroenterologist,
- AND diagnosis of moderately to severely active Crohn's disease,
- AND inadequate response, contraindication, or inability to tolerate ONE conventional therapy (e.g. azathioprine or 6-mercaptopurine),
- AND inadequate response, contraindication or an inability to tolerate corticosteroids (e.g. prednisone, methylprednisolone, budesonide),
- AND documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to the following:
  - Inflectra (infliximab), AND
  - adalimumab biosimilars (Amjevita preferred) or Humira OR Entyvio (vedolizumab), AND
  - Stelara*PA (ustekinumab)
- AND patient has documented negative test for tuberculosis within the past 12 months

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

Continuation of Therapy Criteria:

- Positive clinical response to medication, AND
- Specialist follow-up occurred in the past 12 months since last review

Anti-psoriatic Agents (Cont'd)

Last revised: 4/8/2024; Effective date: 6/4/2024

Generic	Brand	HICL	GSN	Representative NDC
IXEKIZUMAB	TALTZ SOAJ 80 MG/ML	43193	075731	00002144509
IXEKIZUMAB	TALTZ SOSY 80 MG/ML	43193	075732	00002772411

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Rheumatologist, or Dermatologist

Rheumatology

Ankylosing Spondylitis:

- Diagnosis of ankylosing spondylitis, AND
- Documented inadequate response (of at least 3 month trial), intolerance, or contraindication to BOTH of the following:
  - ONE or more tumor necrosis factor (TNF-alpha) inhibitors: Infliximab (Inflectra, Remicade, Enbrel*PA (etanercept), adalimumab biosimilars (Amjevita preferred) or Humira
  - Cosentyx*PA (secukinumab)

Psoriatic Arthritis:

- Diagnosis of active psoriatic arthritis, AND
- Documented inadequate response (of at least a 3 month trial), intolerance, or contraindication to BOTH of the following:
  - ONE or more tumor necrosis factor (TNF alpha) inhibitors: Inflectra or Remicade (infliximab), Enbrel*PA (etanercept), adalimumab biosimilars (Amjevita preferred) or Humira
  - Cosentyx*PA (secukinumab)

Dermatology

Plaque Psoriasis:

- Diagnosis of moderate-to-severe plaque psoriasis (>3% body surface area unless palmar-plantar involvement is severe), AND
- Inadequate response or contraindication to at least a 3-month trial of phototherapy unless involvement in sensitive areas (e.g., face, body folds, etc.), AND
- Failed at least a 3-month trial of one of the following unless clinically significant adverse effects, contraindication or clinical reason to avoid treatment (i.e. pregnancy/breastfeeding, history of alcoholism or alcoholic liver disease, chronic liver disease, immunodeficiency syndrome, pre-existing blood dyscrasia, hemodialysis, or end-stage renal disease):
  - Methotrexate
  - Acitretin
- Documentation of inadequate response, intolerance, or contraindication to ALL of the following:
  - At least one TNF inhibitor (i.e. adalimumab product [Amjevita preferred] or infliximab product [Inflectra preferred])
  - Secukinumab (Cosentyx)*PA
  - Guselkumab (Tremfya)*PA OR risankizumab-rzaa (Skyrizi)*PA
  - Ustekinumab (Stelara)*PA

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

Continuation of Therapy Criteria:

- Positive clinical response to medication, AND
- Specialist follow-up occurred in the past 12 months since last review

Anti-psoriatic Agents (Cont'd)

Last revised: 4/8/2024; Effective date: 6/4/2024

Generic	Brand	HICL	GSN	Representative NDC
GUSELKUMAB	TREMFYA SOPN 100 MG/ML	44418	079520	57894064011
GUSELKUMAB	TREMFYA SOSY 100 MG/ML	44418	077565	57894064001

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Rheumatologist, or Dermatologist

Rheumatology

Psoriatic Arthritis:

- Diagnosis of active psoriatic arthritis, AND
- Documented inadequate response (of at least a 3 month trial), intolerance, or contraindication to BOTH of the following:
  - ONE or more tumor necrosis factor (TNF alpha) inhibitors: Inflectra or Remicade (infliximab), Enbrel (etanercept), adalimumab biosimilars (Amjevita preferred) or Humira
  - Cosentyx (secukinumab)

Dermatology

Plaque Psoriasis:

- Diagnosis of moderate-to-severe plaque psoriasis (>3% body surface area unless palmar-plantar involvement is severe), AND
- Inadequate response or contraindication to at least a 3-month trial of phototherapy unless involvement in sensitive areas (e.g., face, body folds, etc.), AND
- Failed at least a 3-month trial of one of the following unless clinically significant adverse effects, contraindication or clinical reason to avoid treatment (i.e. pregnancy/breastfeeding, history of alcoholism or alcoholic liver disease, chronic liver disease, immunodeficiency syndrome, pre-existing blood dyscrasia, hemodialysis, or end-stage renal disease):
  - Methotrexate
  - Acitretin
- Documentation of inadequate response (at least 3-month trial), intolerance, or contraindication to ALL of the following:
  - At least one TNF inhibitor (i.e. adalimumab product [Amjevita preferred] or infliximab product [Inflectra preferred])
  - Secukinumab (Cosentyx)*PA

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

Continuation of Therapy Criteria:

- Positive clinical response to medication, AND
- Specialist follow-up occurred in the past 12 months since last review

Anti-psoriatic Agents (Cont'd)

Generic	Brand	HICL	GSN	Representative NDC
TAPINAROF	VTAMA CREAM 1%	48031	083417	81672505101

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Dermatologist,
- AND patient is ≥18 years of age,
- AND diagnosis of moderate to severe plaque psoriasis (BSA involvement >3% and <20%),
- AND inadequate response or contraindication to at least 3-month trial of phototherapy unless involvement in sensitive areas (e.g. face, body folds, etc.),
- AND documented history of inadequate response (≥4-weeks trial), contraindication, or intolerance to high- to super high-potency topical corticosteroids (e.g., betamethasone dipropionate 0.05% cream or ointment, triamcinolone 0.5% cream or ointment, clobetasol propionate 0.05% ointment, lotion, solution),
- AND documented history of inadequate response (≥ 4 weeks trial), contraindication, or intolerance to at least 1 of the following topical combination regimen:
    - High- or ultra high-potency topical corticosteroids used with topical calcitriol or calcipotriene
    - High- or ultra high-potency topical corticosteroids used with topical tazarotene

Continuation of Therapy Criteria:

- Patient meets all the initial criteria for coverage,
- AND documentation of positive clinical response

Antipsoriatic Agents, Systemic

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

Generic	Brand	HICL	GSN	Representative NDC
BIMEKIZUMAB-BKZX	BIMZELX SOSY 160 MG/ML	47629	082752	50474078079
BIMEKIZUMAB-BKZX	BIMZELX SOAJ 160 MG/ML	47629	085412	50474078185

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Dermatologist,
- Diagnosis of moderate to severe plaque psoriasis (>3% body surface area unless palmar-plantar involvement is severe),
- Inadequate response or contraindication to at least a 3-month trial of phototherapy unless involvement in sensitive areas (e.g., face, body folds, etc.),
- Failed at least a 3-month trial of one of the following unless clinically significant adverse effects, contraindication or clinical reason to avoid treatment (i.e. pregnancy/breastfeeding, history of alcoholism or alcoholic liver disease, chronic liver disease, immunodeficiency syndrome, pre-existing blood dyscrasia, hemodialysis, or end-stage renal disease):
  - Methotrexate
  - Acitretin
- Documentation of inadequate response (at least 3-month trial), intolerance, or contraindication to ALL of the following:
  - At least one TNF inhibitor (i.e. adalimumab product [Amjevita preferred] or infliximab product [Inflectra preferred])
  - Secukinumab (Cosentyx)*PA
  - Guselkumab (Tremfya)*PA OR risankizumab-rzaa (Skyrizi)*PA
  - Ustekinumab (Stelara)*PA

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

Continuation of Therapy Criteria:

- Patient has positive clinical response to medication,
- Specialist follow-up occurred since last review

Arginine Vasopressin (AVP) Receptor Antagonists

Last revised: 10/3/2023

Generic	Brand	HICL	GSN	Representative NDC
TOLVAPTAN	JYNARQUE TABS 15 MG	36348	065227	59148008213
TOLVAPTAN	JYNARQUE TABS 30 MG	36348	065228	59148008313
TOLVAPTAN	JYNARQUE TBPK 30 & 15MG	36348	081052	59148008007
TOLVAPTAN	JYNARQUE TBPK 45 & 15 MG	36348	075048	59148008707
TOLVAPTAN	JYNARQUE TBPK 60 & 30 MG	36348	075049	59148008828
TOLVAPTAN	JYNARQUE TBPK 90 & 30 MG	36348	075047	59148008907

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)
- 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

Azole Antifungals

Generic	Brand	HICL	GSN	Representative NDC
ISAVUCONAZONIUM SULFATE	CRESEMBA CAPS 186 MG	41817	073654	00469032014

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 6 months

Initial Review Criteria:

- Provider is an infectious disease specialist, hematologist/oncologist, or transplant specialist, AND
- Individual is 18 years of age or older

-AND-

- Individual has a diagnosis of invasive aspergillosis **AND**
- Has treatment failure/intolerance of voriconazole **OR**
- Voriconazole has a drug-drug interaction with the individual's current therapy which requires therapy modification

-OR-

- Individual has diagnosis of invasive mucormycosis **AND**
- Has treatment failure/intolerance of posaconazole **OR**
- Posaconazole has a drug-drug interaction with the individual's current therapy which requires therapy modification

-OR-

- The prescriber has documentation supporting use of the requested agent for primary or secondary prophylaxis of invasive fungal infections in patients who have documented intolerance and/or drug-drug interactions which require therapy modification to posaconazole and voriconazole

Continuation of Therapy Criteria:

- Patient continues to be followed by an infectious disease specialist, hematologist/oncologist, or transplant specialist; follow-up has occurred in the past 6 months
- Patient has demonstrated positive clinical and/or laboratory response to therapy

Beta-Lactams

Generic	Brand	HICL	GSN	Representative NDC
AZTREONAM LYSINE	CAYSTON SOLR 75 MG	36792	065913	61958090101

Prior Authorization Criteria:
Length of Authorization: • Initial: 6 months • Reauthorization: 12 months
Initial Review Criteria: • Prescriber is a Pulmonologist or Infectious Disease Specialist, AND • Diagnosis of Cystic Fibrosis (CF) AND Pseudomonas aeruginosa is present in at least one airway culture, AND • Patient is 7 years to 65 years, AND • Patient does NOT have forced expiratory volume (FEV1) < 25 % or > 75%, AND • Patient has tried and failed an adequate trial of inhaled tobramycin OR inhaled tobramycin is contraindicated, AND • Dose does not exceed 225 mg/day (75 mg three times daily) on a 28 days on/28 days off cycle • Patients have NOT been colonized with Burkholderia cepacia
Continuation of Therapy Criteria: • Patient continues to be under the care of a pulmonologist, AND • Member is responding positively to therapy based on reduction in frequency of pulmonary exacerbations and hospitalization

Blood formation, Coagulation, Thrombosis Agents

Last revised: 4/8/2024; Effective date: 6/4/2024

Generic	Brand	HICL	GSN	Representative NDC
VOXELOTOR	OXBRYTA TBSO 300 MG	46225	082925	72786011102
VOXELOTOR	OXBRYTA TABS 500 MG	46225	080506	72786010101

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a hematology-oncology specialist, AND
- Age ≥4 years, AND
- Diagnosed with sickle cell anemia or hemoglobin S (HbS) beta thalassemia (documented by hemoglobin electrophoresis), AND
- Hemoglobin level ≤10.5 g/dL prior to treatment, AND
- Documentation of one of the following:
    - Transfusion-dependent anemia with alloantibodies
    - Symptomatic anemia without transfusion dependence
    - Pulmonary hypertension and hypoxia

Continuation of Therapy Criteria:

- Reassess to determine need for continued therapy; therapy should be discontinued if the patient meets any of the following criteria:
    - Lack of efficacy (e.g., no increase in Hb that leads to a decrease in transfusion requirement and/or symptoms)
    - Non-adherence to the medication

Cardiac Drugs, Miscellaneous

Last revised: 12/6/2022

Generic	Brand	HICL	GSN	Representative NDC
TAFAMIDIS MEGLUMINE	VYNDAQEL CAPS 20 MG	41631	073210	00069197512
TAFAMIDIS	VYNDAMAX CAPS 61 MG	45729	079710	00069873001

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,
- AND 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: 2/6/2024

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 before 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

Cystic Fibrosis (CFTR) Correctors

Generic	Brand	HICL	GSN	Representative NDC
ELEXACAFTOR-TEZACAFTOR-IVACAFTOR	TRIKAFTA TBPK 100-50-75 & 150 MG	46112	080343	51167033101

Prior Authorization Criteria:
Length of Authorization: • Initial: 12 months • Reauthorization: 12 months
Initial Review Criteria: • Age ≥12 years, AND • Diagnosis of CF confirmed by a clinician with expertise in proving CF care, AND • At least one 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 • Patient does not have either of the following: o Severe liver impairment (Child-Pugh Class C), OR o 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 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 (cont'd)

Generic	Brand	HICL	GSN	Representative NDC
TEZACAFTOR-IVACAFTOR	SYMDEKO TBPK 50-75 & 75 MG	44771	079924	51167011301
TEZACAFTOR-IVACAFTOR	SYMDEKO TBPK 100-150 & 150 MG	44771	078161	51167066101

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- 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
- One of the following mutations known to be responsive to tezacaftor-ivacaftor, invacaftor in the CFTR gene

A1067T	D1270N	E56K	K1060T	R117C	S945L	2789+5G→A
A455E	D110E	E831X	L206W	R347H	S977F	3272-26A→G
D110H	D579G	F1052V	P67L	R352Q		3849+10kbC→T
D1152H	E193K	F1074L	R1070W	R74W		711+3A→G

Continuation of Therapy Criteria:

- Documentation of positive clinical response 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 (cont'd)

Generic	Brand	HICL	GSN	Representative NDC
LUMACAFTOR-IVACAFTOR	ORKAMBI PACK 150-188 MG	42235	078705	51167050002
LUMACAFTOR-IVACAFTOR	ORKAMBI TABS 100-125 MG	42235	076661	51167070002
LUMACAFTOR-IVACAFTOR	ORKAMBI TABS 200-125 MG	42235	074379	51167080901
LUMACAFTOR-IVACAFTOR	ORKAMBI PACK 100-125 MG	42235	078704	51167090001

Prior Authorization Criteria:
Length of Authorization: • Initial: 12 months • Reauthorization: 12 months
Initial Review Criteria: • Prescriber is a specialist in the management of Cystic Fibrosis (CF), AND • Age ≥2 years, 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 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) Potentiators

Generic	Brand	HICL	GSN	Representative NDC
IVACAFTOR	KALYDECO TABS 150 MG	38461	068512	51167020001
IVACAFTOR	KALYDECO PACK 50 MG	38461	073697	51167030001
IVACAFTOR	KALYDECO PACK 75 MG	38461	073698	51167040001
IVACAFTOR	KALYDECO PACK 25 MG	38461	079693	51167060001

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Age ≥6 months, AND
- Patient is NOT homozygous for the F508del mutation in the CFTR gene, AND
- At least one of the following mutations in the CFTR gene:

P67L	R117C	R347H	E831X	K1060T	R1070W	S1251N	2789+5G→A
R74W	G178R	R352Q	S945L	A1067T	F1074L	S1255P	3272-26A→G
D110E	E193K	A455E	S977F	G1069R	D1152H	D1270N	3849+10kbC→T
D110H	L206W	S549N	F1052V	R1070Q	G1244E	G1349D	711+3A→G
						E56K	

-OR-

- Patients with a R117H mutation in the CFTR gene who have clinically significant disease (patients with RII7H and the 5T form of the poly-T tract, but not 7T or 9T)

Continuation of Therapy Criteria:

- Documentation of positive clinical response 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

Drugs to Treat Movement Disorders

Last revised: 8/5/2024; Effective date: 10/1/2024

Generic	Brand	HICL	GSN	Representative NDC
DEUTETRABENAZINE	AUSTEDO TABS 12 MG	44192	077271	68546017260
DEUTETRABENAZINE	AUSTEDO TABS 6 MG	44192	077269	68546017060
DEUTETRABENAZINE	AUSTEDO TABS 9 MG	44192	077270	68546017160
DEUTETRABENAZINE	AUSTEDO XR PATIENT TITRATION TEPK 6 & 12 & 24 MG	44192	084436	68546049052
DEUTETRABENAZINE	AUSTEDO XR TB24 12 MG	44192	084433	68546047156
DEUTETRABENAZINE	AUSTEDO XR TB24 24 MG	44192	084434	68546047256
DEUTETRABENAZINE	AUSTEDO XR TB24 30 MG	44192	086152	68546047356
DEUTETRABENAZINE	AUSTEDO XR TB24 36 MG	44192	086155	68546047456
DEUTETRABENAZINE	AUSTEDO XR TB24 42 MG	44192	086154	68546047556
DEUTETRABENAZINE	AUSTEDO XR TB24 48 MG	44192	086153	68546047656
DEUTETRABENAZINE	AUSTEDO XR TB24 6 MG	44192	084432	68546047056

Prior Authorization Criteria:

Length of Authorization:

- Initial: 3 months
- Reauthorization: 12 months

Initial Review Criteria:

<u>If using for Tardive dyskinesia:</u>

- Prescriber must be a Neurologist or Psychiatrist,
- Diagnosis of moderate to severe tardive dyskinesia,
- Patient is 18 years and older,
- Tardive dyskinesia (TD) has been present for at least 3 months,
- Patient meets ONE of the following:
    - Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering or discontinuation of the offending medication, OR
    - Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication,
- Documented inadequate response, intolerance or contraindication to ALL of the agents or regimens listed below:
    - Dopamine agonist (amantadine)
    - Tetrabenazine (Xenazine)
- Deutetrabenazine is NOT being used concurrently with another vesicular monoamine transporter 2 (VMAT2) inhibitor, a monoamine oxidase inhibitor (MAOI), or reserpine

<u>If using for Chorea associated with Huntington's disease:</u>

- Prescriber must be a Neurologist,
- Patient has documented choreiform movements secondary to Huntington's disease,
- Patient is 18 years and older,
- Documented inadequate response, intolerance or contraindication to tetrabenazine (Xenazine),
- Deutetrabenazine is NOT being used concurrently with another vesicular monoamine transporter 2 (VMAT2) inhibitor, a monoamine oxidase inhibitor (MAOI), or reserpine

Continuation of Therapy Criteria:

- Patient meets all above coverage criteria,
- Documentation of positive clinical response to deutetrabenazine therapy

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, 30-day supply per dispensing

Generic	Brand	HICL	GSN	Representative NDC
DARBEPOETIN ALFA	ARANESP (ALBUMIN FREE) SOLN 100 MCG/ML	22890	048586	55513000501
DARBEPOETIN ALFA	ARANESP (ALBUMIN FREE) SOLN 200 MCG/ML	22890	048587	55513000601
DARBEPOETIN ALFA	ARANESP (ALBUMIN FREE) SOLN 25 MCG/ML	22890	048583	55513000204
DARBEPOETIN ALFA	ARANESP (ALBUMIN FREE) SOLN 40 MCG/ML	22890	048584	55513000301
DARBEPOETIN ALFA	ARANESP (ALBUMIN FREE) SOLN 60 MCG/ML	22890	048585	55513000404
DARBEPOETIN ALFA	ARANESP (ALBUMIN FREE) SOSY 10 MCG/0.4ML	22890	048908	55513009804
DARBEPOETIN ALFA	ARANESP (ALBUMIN FREE) SOSY 100 MCG/0.5ML	22890	048914	55513002504
DARBEPOETIN ALFA	ARANESP (ALBUMIN FREE) SOSY 150 MCG/0.3ML	22890	049630	55513002701
DARBEPOETIN ALFA	ARANESP (ALBUMIN FREE) SOSY 200 MCG/0.4ML	22890	061269	55513002801
DARBEPOETIN ALFA	ARANESP (ALBUMIN FREE) SOSY 25 MCG/0.42ML	22890	061270	55513005701
DARBEPOETIN ALFA	ARANESP (ALBUMIN FREE) SOSY 300 MCG/0.6ML	22890	061271	55513011101
DARBEPOETIN ALFA	ARANESP (ALBUMIN FREE) SOSY 40 MCG/0.4ML	22890	048911	55513002104
DARBEPOETIN ALFA	ARANESP (ALBUMIN FREE) SOSY 500 MCG/ML	22890	061006	55513003201
DARBEPOETIN ALFA	ARANESP (ALBUMIN FREE) SOSY 60 MCG/0.3ML	22890	048913	55513002301

Erythropoiesis-Stimulating Agents (Cont'd)

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 weeks
- Reauthorization: 12 weeks

Initial Review Criteria:

- Patient has contraindication, intolerance or failure to preferred epoetin alfa product (i.e., Procrit), AND
- Diagnosis of one of the following:
  - ESRD or chronic kidney disease of at least stage 3 (eGFR <60mL/min/1.73 m2)
  - Chemotherapy-induced anemia in non-myeloid malignancies
  - Cancer patients who are undergoing palliative treatment
  - Myelodysplastic syndrome (MDS)
  - Chronic hepatitis C
  - Anemia in patients whose religious beliefs forbid blood transfusions
  - Patient taking chemotherapeutic medications when medically necessary for non-cancer diagnosis or following stem cell transplantation and associated immunosuppression

  AND

- Hemoglobin <10 g/dL within 7 days (unless medical documentation showing need – e.g., severe angina, severe pulmonary distress, severe hypertension), AND
- TSAT ≥20% unless ferritin >500, then may be approved with TSAT <20%, AND
- B12 and folate NOT deficient, AND
- Does NOT have uncontrolled hypertension, AND
- NOT used in combination with another erythropoiesis stimulating agent

Continuation of Therapy Criteria:

- Target hemoglobin <12 g/dL within 7 days, AND
- Clinical response to ESA therapy – increase in HGB of at least 1g/dL after at least 12 weeks of therapy

Erythropoiesis-Stimulating Agents (Cont'd)

Generic	Brand	HICL	GSN	Representative NDC
EPOETIN ALFA-EPBX	RETACRIT SOLN 10000 UNIT/ML	44931	078435	59353001001
EPOETIN ALFA-EPBX	RETACRIT SOLN 2000 UNIT/ML	44931	078432	59353000201
EPOETIN ALFA-EPBX	RETACRIT SOLN 3000 UNIT/ML	44931	078433	00069130601
EPOETIN ALFA-EPBX	RETACRIT SOLN 4000 UNIT/ML	44931	078434	00069130701
EPOETIN ALFA-EPBX	RETACRIT SOLN 40000 UNIT/ML	44931	078436	00069130904

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 weeks
- Reauthorization: 12 weeks

Initial Review Criteria:

- Patient has contraindication, intolerance or failure to preferred epoetin alfa product (i.e., Procrit), AND
- Diagnosis of one of the following:
  - ESRD or chronic kidney disease of at least stage 3 (eGFR <60mL/min/1.73 m2)
  - Chemotherapy-induced anemia in non-myeloid malignancies
  - Cancer patients who are undergoing palliative treatment
  - Myelodysplastic syndrome (MDS)
  - Anemia in patients whose religious beliefs forbid blood transfusions
  - Reduction of allogenic red blood cell transfusion in patients undergoing elective, noncardiac, nonvascular surgery
  - Chronic Hepatitis C
  - Anemia Due to Zidovudine in HIV-infected patients
  - Patient taking chemotherapeutic medications when medically necessary for non-cancer diagnosis or following stem cell transplantation and associated immunosuppression

  AND

- Hemoglobin <10 g/dL within 7 days (unless medical documentation showing need – e.g., severe angina, severe pulmonary distress, severe hypertension), AND
- TSAT ≥20% unless ferritin >500, then may be approved with TSAT <20%,AND
- B12 and folate NOT deficient, AND
- Does NOT have uncontrolled hypertension
- NOT used in combination with another erythropoiesis stimulating agent

Continuation of Therapy Criteria:

- Target hemoglobin <12 g/dL within 7 days, AND
- Clinical response to ESA therapy – increase in HGB of at least 1g/dL after at least 12 weeks of therapy

Generic	Brand	HICL	GSN	Representative NDC
METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA	MIRCERA SOSY 100 MCG/0.3ML	35005	063132	00004040309
METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA	MIRCERA SOSY 120 MCG/0.3ML	35005	064737	59353040709
METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA	MIRCERA SOSY 150 MCG/0.3ML	35005	063133	59353040409
METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA	MIRCERA SOSY 200 MCG/0.3ML	35005	063134	59353040509
METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA	MIRCERA SOSY 30 MCG/0.3ML	35005	064736	59353040009
METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA	MIRCERA SOSY 50 MCG/0.3ML	35005	063115	00004040109
METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA	MIRCERA SOSY 75 MCG/0.3ML	35005	063131	00004040209

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 6 months

Initial Review Criteria:

- Patient has contraindication, intolerance or failure to preferred epoetin alfa product (i.e., Procrit), AND
- Diagnosis of anemia associated with chronic kidney disease, AND
- Serum ferritin ≥100 ng/mL, AND
- NOT used in combination with another erythropoiesis stimulating agent AND
- NOT used for anemia due to cancer chemotherapy, AND
- B12 and folate NOT deficient, AND
- Does NOT have uncontrolled hypertension
- One of the following:
    - If patient is NOT on dialysis, hemoglobin <10 g/dL (initial treatment); hemoglobin ≤10 g/dL*(continuing treatment)
    - If patient is on dialysis, hemoglobin <10 g/dL (initial treatment); hemoglobin ≤11 g/dL* (continuing treatment)
    - **If the hemoglobin level exceeds this level then the prescribing physician must confirm that the dose will be held or reduced until the hemoglobin level returns to the required level.*

Continuation of Therapy Criteria:

- Continues to meet initial coverage criteria, AND
- Clinical response to ESA therapy – increase in HGB of at least 1g/dL after at least 12 weeks of therapy

Enzymes

Generic	Brand	HICL	GSN	Representative NDC
PEGVALIASE-PQPZ	PALYNZIQ SOSY 2.5 MG/0.5ML	44944	078457	68135005890
PEGVALIASE-PQPZ	PALYNZIQ SOSY 20 MG/ML	44944	078459	68135067340
PEGVALIASE-PQPZ	PALYNZIQ SOSY 10 MG/0.5ML	44944	078458	68135075620

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

Farnesoid X Receptor (FXR) Agonist, Bile AC Analog

Generic	Brand	HICL	GSN	Representative NDC
OBETICHOLIC ACID	OCALIVA 10MG TABS	43438	076157	69516001030
OBETICHOLIC ACID	OCALIVA 5MG TABS	43438	076156	69516000530

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Gastroenterologist or Hepatologist, AND
- Diagnosis of primary biliary cholangitis (PBC) AND
- Member has had an inadequate response to an adequate trial of ursodeoxycholic acid (UDCA) unless contraindication, AND
- Member is taking an optimal regimen of cholesterol treatment (fenofibrate or statin) if most recent LDL >190 mg/dL, AND
- Member has no history of severe pruritis, AND
- There is absence of complete biliary obstruction, AND
- Member is not listed/scheduled for liver transplant

Continuation of Therapy Criteria:

- Documentation of laboratory values showing a reduction in ALP level from pre-treatment baseline while on Ocaliva therapy

Glucocorticoids

Generic	Brand	HICL	GSN	Representative NDC
DEFLAZACORT	EMFLAZA SUSP 22.75 MG/ML	11668	077117	42998050521
DEFLAZACORT	EMFLAZA TABS 18 MG	11668	077113	52856050203
DEFLAZACORT	EMFLAZA TABS 30 MG	11668	027605	52856050303
DEFLAZACORT	EMFLAZA TABS 36 MG	11668	077116	42998050403
DEFLAZACORT	EMFLAZA TABS 6 MG	11668	027604	52856050101

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Neurologist and is experienced in the treatment of muscular dystrophy, AND
- Patient has diagnosis of Duchenne Muscular Dystrophy (DMD) with confirmatory genetic testing, AND
- Patient is ≥ 5 years, AND
- Onset of muscle weakness before the age of 5 years, AND
- Patient has used prednisone for at least 12 months, AND
- Patient experienced clinically significant weight gain, defined as crossing at least 2 stanines on the weight growth chart, during the first 2 years of prednisone use, AND
- Patient has documented baseline Hgb A1C, blood pressure, and BMI

Continuation of Therapy Criteria:

- Patient has Hgb A1C, blood pressure, and BMI monitored over the last 12 months, AND
- Patient is not experiencing persistent or worsening abnormal weight gain

Glucocorticoids (cont'd)

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

Generic	Brand	HICL	GSN	Representative NDC
BUDESONIDE	TARPEYO CPDR 4 MG	6545	082942	81749000401

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 3 months *(cumulative treatment period should not exceed 38 weeks)*

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 ≥35 ml/min,
- Currently prescribed maximum tolerated dose of ONE of the following for at least 12 weeks, or documented intolerance, contraindication: Angiotensin-converting enzyme inhibitors (ACEI) OR Angiotensin II receptor blockers (ARB),
- Documented trial of at least 12 weeks at the maximum tolerated dose of the following or documented intolerance or contraindication: Filspari (sparsentan)*PA
- Adequate therapeutic trial or contraindication to one generic systemic corticosteroid therapy (e.g., oral prednisone, methylprednisolone),
- Patient does **not** have history of each of the following:
    - Currently undergoing dialysis
    - Kidney transplant
    - Active TB infection
    - Severe hepatic impairment (Child-Pugh Class C)
    - Concurrently taking Filspari (sparsentan)

**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:
    - Cumulative treatment period should not exceed 38 weeks
    - Documented proteinuria reduction of at least 50% by time of review

Notes: Limited to 4 capsules per day, 30-day supply per dispensing

Glypromate (GPE) Analogs

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

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

Prior Authorization Criteria:

Length of Authorization:

- Initial: 3 months
- Reauthorization: 6 months

Initial Review Criteria:

- Prescriber is a Neurologist,
- Patient with classic/typical Rett syndrome,
- Documented disease-causing mutation in the MECP2 gene,
- Female aged 5 to 10 years old,
- Patient has failed behavioral, rehabilitative and/or pharmacological therapies targeting Rett syndrome related characteristics (e.g., physical therapy, occupational therapy, applied behavioral analysis [ABA], behavioral health treatment [BHT], and/or anxiolytics),
- Body weight ≥12 kg, stable weight gain, and does not have progressive weight loss prior to therapy initiation,
- At least six months “post regression” at treatment initiation (i.e., no loss or degradation in ambulation, hand function, speech, nonverbal communicative or social skills within six months of treatment initiation),
- Clinical Global Impression Scale-Severity (CGI-S) score of ≥4,
- Patient has stable pattern of seizures or has had no seizures within eight weeks of treatment initiation

Continuation of Therapy Criteria:

- Patient continues to be under the care of a specialist,
- Patient experiences clinically meaningful benefit, defined as improvement of at least one point on at least one of the clinical domains in the CGI-S. If patient achieved improvement, but there has been a lack of measurable progress over one year, a gradual temporary withdrawal trial of trofinetide is recommended to determine if trofinetide is providing any benefit,
- CGI-S has not worsened

Hemostatics

Generic	Brand	HICL	GSN	Representative NDC
EMICIZUMAB-KXWH	HEMLIBRA SOLN 30 MG/ML	44640	077934	50242092001
EMICIZUMAB-KXWH	HEMLIBRA SOLN 60 MG/0.4ML	44640	077935	50242092101
EMICIZUMAB-KXWH	HEMLIBRA SOLN 105 MG/0.7ML	44640	077936	50242092201
EMICIZUMAB-KXWH	HEMLIBRA SOLN 150 MG/ML	44640	077937	50242092301

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

Hemophilia A WITHOUT inhibitors:

- Prescribed by hematologist with specialty in benign hematology, AND
- Diagnosis of Hemophilia A, AND
- Prescribed for routine prophylaxis, AND
- Documented failure to meet clinical goals (e.g., continuation of spontaneous bleeds, inability to achieve appropriate trough level, previous history of inhibitors) after a trial of formulary prophylactic factor VII replacement products

-OR-

Hemophilia A WITH inhibitors:

- Prescribed by a hematologist with specialty in benign hematology, AND
- Patients has developed high-titer factor VII inhibitors [≥5 Bethesda units (BU)], AND
- Prescribed for routine prophylaxis

Continuation of Therapy Criteria:

- Documentation of positive clinical response to Hemlibra therapy, AND
- Office or telephone visit with a specialist in the past 12 months

IBS Agents, Mixed Opioid Receptor Agonists/Antagonists

Last revised: 8/2/2024; Effective date: 9/1/2024

Generic	Brand	HICL	GSN	Representative NDC
ELUXADOLINE	VIBERZI TABS 100 MG	42445	074655	61874010060
ELUXADOLINE	VIBERZI TABS 75 MG	42445	074654	61874007560

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Gastroenterologist, AND
- Diagnosis of irritable bowel syndrome (IBS- diarrhea predominant), AND
- Patient has had an inadequate response (must try for the minimum duration listed before considered treatment failure); intolerance or contraindication to two of the following medications/medication classes. If ≥65 years old, trial of one of the following therapies is adequate:
  - Antidiarrheal agents (e.g., loperamide, diphenoxylate/atropine*) – 2 weeks' trial
  - Bile acid sequestrants (e.g., cholestyramine, colestipol, colesevelam) – at least 2 weeks' trial
  - Antispasmodics* (e.g., dicyclomine, diphenoxylate/atropine, chlordiazepoxide/clidinium, or hyoscyamine) – at least 2 weeks' trial
- AND patient has had an inadequate response (at least 4 weeks' trial), intolerance, or contraindication to Xifaxan (rifaximin) – also criteria-based

*****Beer's Criteria; NOT recommended if ≥65 years old.

Continuation of Therapy Criteria:

- Positive clinical response to Viberzi

IBS-C/CIC Agents, Guanylate Cyclase-C Agonist

Last revised: 10/3/2023

Generic	Brand	HICL	GSN	Representative NDC
LINACLOTIDE	LINZESS CAPS 145 MCG	39583	069922	00456120130
LINACLOTIDE	LINZESS CAPS 290 MCG	39583	069923	00456120230
LINACLOTIDE	LINZESS CAPS 72 MCG	39583	077085	00456120330

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescribed by a Gastroenterologist or in consultation with a Gastroenterologist, AND
- Diagnosis of irritable bowel syndrome with constipation (IBS-constipation predominant), AND
- Patient has had an inadequate response to an adequate trial of at least 4 weeks or intolerance or contraindication to scheduled doses of the following medications:
    - Fiber supplement: psyllium fiber or methylcellulose
    - Polyethylene glycol
    - Amitiza (lubiprostone) – also criteria based, if patient is female
    - Trulance (plecanatide) – also criteria based

-OR-

- Prescribed by a Gastroenterologist or in consultation with a Gastroenterologist, AND
- Diagnosis of chronic idiopathic constipation, AND
- Patient has had an inadequate response to an adequate trial of at least 4 weeks or intolerance or contraindication to scheduled doses of the following medications:
    - Fiber supplement: psyllium fiber or methylcellulose
    - Osmotic laxative: polyethylene glycol or lactulose
    - Stimulant laxative: senna or bisacodyl
    - Amitiza (lubiprostone) – also criteria based
    - Trulance (plecanatide) – also criteria based

Continuation of Therapy Criteria:

- Positive clinical response to Linzess

Generic	Brand	HICL	GSN	Representative NDC
PLECANATIDE	TRULANCE TABS 3 MG	44054	77047	70194000330

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescribed by a Gastroenterologist or in consultation with a Gastroenterologist, AND
- Diagnosis of irritable bowel syndrome with constipation (IBS-constipation predominant), AND
- Patient has had an inadequate response to an adequate trial of at least 4 weeks or intolerance or contraindication to scheduled doses of the following medications:
    - Fiber supplement: psyllium fiber or methylcellulose
    - Polyethylene glycol
    - Amitiza (lubiprostone) – also criteria based; if patient is female

-OR-

- Prescribed by a Gastroenterologist or in consultation with a Gastroenterologist, AND
- Diagnosis of chronic idiopathic constipation, AND
- Patient has had an inadequate response to an adequate trial of at least 4 weeks or intolerance or contraindication to scheduled doses of the following medications:
    - Fiber supplement: psyllium fiber or methylcellulose
    - Osmotic laxative: polyethylene glycol or lactulose
    - Stimulant laxative: senna or bisacodyl
    - Amitiza (lubiprostone) – also criteria based

Continuation of Therapy Criteria:

- Positive clinical response to Trulance

IL-23 Receptor Antagonist, Monoclonal Antibody

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

Generic	Brand	HICL	GSN	Representative NDC
MIRIKIZUMAB-MRKZ	OMVOH SOAJ 100 MG/ML	49282	085439	00002801127

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Gastroenterologist,
- Documented moderate-to-severe active ulcerative colitis,
- Inadequate response, contraindication, or inability to tolerate one conventional therapy (e.g., mesalamine, azathioprine, or 6-mercaptopurine),
- Inadequate response, contraindication, or inability to tolerate corticosteroids,
- Documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to ALL of the following:
    - Infliximab product (Inflectra preferred) OR adalimumab product (Amjevita preferred)
    - Entyvio (vedolizumab)*PA
    - Xeljanz (tofacitinib)*PA or Rinvoq (upadacitinib)*PA

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

Continuation of Therapy Criteria:

- Positive clinical response to medication,
- Specialist follow-up has occurred since last review

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

Immunomodulatory Agents

Generic	Brand	HICL	GSN	Representative NDC
Ofatumumab	Kesimpta Soaj 20mg/0.4mL	36708	081415	00078100768

Prior Authorization Criteria:
Length of Authorization: • Initial: 6 months • Reauthorization: 12 months
Initial Review Criteria: • Prescribed by a neurologist AND • Patient has a diagnosis of relapsing form of multiple sclerosis (including clinically isolated syndrome, relapsing-remitting, active secondary progressive disease), AND • Patient is not on another DMT, AND • Patient has failed an adequate trial (≥3 months) of, or has a documented allergy or intolerance to, or is not a candidate for Truxima (rituximab-abbs), AND • Patient has failed an adequate trial (≥3 months) of, or has a documented allergy or intolerance to, or is not a candidate for Ocrevus
Continuation of Therapy Criteria: • Patient continues to meet criteria above, AND • Patient has completed the following laboratory monitoring within the last 6 months: o Quantitative serum immunoglobulins o Complete blood count with differential o Liver function

Immunosuppressives

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

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: 12 months

Initial Review Criteria:

- Prescribed by a Nephrologist or Rheumatologist,
- Age 18 years or older,
- Kidney biopsy confirmed lupus nephritis of class III (focal lupus nephritis) or class IV (diffuse lupus nephritis) or class V (membranous lupus nephritis) within past 12 months,
- Baseline urine protein-to-creatine ratio (UPCR) ≥1.5 g/g and eGFR >45 ml/min,
- Documented inadequate response, intolerance or contraindication to ALL of the following:
    - At least one immunomodulator (e.g. mycophenolate mofetil, cyclophosphamide) ± glucocorticoid
    - Tacrolimus
    - Benlysta (belimumab)*PA (if class III or IV)
- Patient does **not** have history of each of the following:
    - Concurrently taking cyclophosphamide
    - Concurrently taking Benlysta (belimumab)
    - Concurrently taking strong CYP3A4 inhibitors (e.g., Ketoconazole, itraconazole, clarithromycin)
    - Blood pressure ≥165/105 mmHg or with hypertensive emergency
    - History of Kidney transplant
    - Severe hepatic impairment (Child-Pugh Class C)
    - Pregnancy or breastfeeding
    - Pure Red Cell Aplasia (PRCA) diagnosis

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

Continuation of Therapy Criteria:

- Labs within last 2 months show improvement in UPCR (i.e. ≤0.5 mg/mg) and eGFR (i.e. ≥60 ml/min), or no decrease of baseline eGFR by ≥20%

Notes: Limited to 6 capsules per day, 30-day supply per dispensing

Insulins

Last revised: 12/5/2023

Generic	Brand	HICL	GSN	Representative NDC
INSULIN ASPART PROTAMINE & ASPART (HUMAN)	INSULIN ASPART PROT & ASPART SUSP (70-30) 100 UNIT/ML	23400	051718	73070020011
INSULIN ASPART PROTAMINE & ASPART (HUMAN)	NOVOLOG MIX 70/30 SUSP (70-30) 100 UNIT/ML	23400	051718	00169368512
INSULIN ASPART PROTAMINE & ASPART (HUMAN)	INSULIN ASP PROT & ASP FLEXPEN SUPN (70-30) 100 UNIT/ML	23400	050134	73070020310
INSULIN ASPART PROTAMINE & ASPART (HUMAN)	NOVOLOG MIX 70/30 FLEXPEN SUPN (70-30) 100 UNIT/ML	23400	050134	00169369619
INSULIN NPH ISOPHANE & REG (HUMAN)	NOVOLIN 70/30 RELION SUSP (70-30) 100 UNIT/ML	6215	016311	00169183702
INSULIN NPH ISOPHANE & REG (HUMAN)	NOVOLIN 70/30 FLEXPEN RELION SUPN (70-30) 100 UNIT/ML	6215	058952	00169300725

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Failed adequate trial or documented intolerance with preferred insulin isophane/insulin regular (Humulin 70/30; Humulin N; Humulin R)
- Pens reserved for the following situations:
- Patients unable to self-inject insulin due to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection
- Pediatric patients who are required to use such a device by their school, OR
- Patients requiring small doses of insulin (<5 units per dose)

Continuation of Therapy Criteria:

- Adherence (>80%) to diabetic regimen, AND
- Must continue to meet inclusion criteria

Notes:

- Criteria only applies to new start patients

Generic	Brand	HICL	GSN	Representative NDC
INSULIN DETEMIR	LEVEMIR SOLN 100 UNIT/ML	26407	059586	00169368712
INSULIN DETEMIR	LEVEMIR FLEXTOUCH SOPN 100 UNIT/ML	26407	057439	00169643810
INSULIN DEGLUDEC	TRESIBA SOLN 100 UNIT/ML	40844	079385	00169266211
INSULIN DEGLUDEC	TRESIBA FLEXTOUCH SOPN 100 UNIT/ML	40844	071842	00169266015
INSULIN DEGLUDEC	TRESIBA FLEXTOUCH SOPN 200 UNIT/ML	40844	071843	00169255013
INSULIN GLARGINE	TOUJEO SOLOSTAR SOPN 300 UNIT/ML	22025	073567	00024586903
INSULIN GLARGINE	TOUJEO MAX SOLOSTAR SOPN 300 UNIT/ML	22025	078265	00024587102

Insulins (cont'd)

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Patients who are intolerant or failed an adequate trial of NPH AND insulin glargine-yfgn (unbranded Semglee), AND
- Prescribed for Type 1 Diabetes as basal insulin, OR
- Prescribed for patients with Type 2 Diabetes who experience recurrent nocturnal hypoglycemia (low blood sugar at night) with bedtime NPH insulin dosing defined as: ≥3 episodes of nocturnal capillary blood glucose (CBG) at night <70 mg/dL over the preceding 30 days, OR
- Prescribed for patients with Type 2 Diabetes on NPH insulin that experience any episode of severe hypoglycemia defined as: hypoglycemia resulting in seizures, loss of consciousness, episode necessitating assistance from someone else, and/or use of glucagon, OR
- Prescribed for patients with Type 2 Diabetes that requires ultra-long-acting insulin due to work (i.e., night shift work where hours of sleep are significantly and repeatedly varied over time, frequent time-zone traveler)

Solo-Star/Pen Criteria (must meet above criteria) PLUS:

- Unable to draw up insulin accurately from a vial with a syringe due to young age, visual impairment, physical disabilities (i.e., amputation, tremors/Parkinson's disease, rheumatoid arthritis), OR
- Requires small doses of insulin (<5 units per dose), OR
- Pediatric patient who is requires using such a device by their school

Continuation of Therapy Criteria:

- Adherence (>80%) to diabetic regimen, AND
- Must continue to meet inclusion criteria, AND
- Documented A1C lowering of 0.5% from initial or A1C now at goal

Notes:

- Criteria only applies to new start patients

Insulins (cont'd)

Last revised: 10/1/2024; Effective date: 12/3/2024

Generic	Brand	HICL	GSN	Representative NDC
INSULIN REGULAR (HUMAN)	AFREZZA POWD 4 UNIT	768	073242	47918087490
INSULIN REGULAR (HUMAN)	AFREZZA POWD 8 UNIT	768	073243	47918087890
INSULIN REGULAR (HUMAN)	AFREZZA POWD 12 UNIT	768	074308	47918089190
INSULIN REGULAR (HUMAN)	AFREZZA POWD 90 x 4 UNIT & 90X8 UNIT	768	073246	47918088018
INSULIN REGULAR (HUMAN)	AFREZZA POWD 90 x 8 UNIT & 90X12 UNIT	768	079460	47918089818
INSULIN REGULAR (HUMAN)	AFREZZA POWD 4 & 8 & 12 UNIT	768	076973	47918090218

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Diagnosis of type 1 diabetes mellitus, AND
- Used in combination with a basal insulin or continuous insulin pump, OR
- Diagnosis of type 2 diabetes mellitus, AND
- Patient is unable to self-inject due to physical impairment OR visual impairment OR lipohypertrophy, AND
- FEV1 within the last 60 days is greater than or equal to 70% of expected, AND
- Patient is not a smoker OR has quit smoking in the last 6 months, AND
- Patient without chronic lung disease (asthma, COPD)

Continuation of Therapy Criteria:

- Repeat pulmonary function test confirms that patient has NOT experienced a decline of 20% or more in FEV1, AND
- Patient continues to be unable to self-inject due to physical impairment OR visual impairment OR lipohypertrophy

Notes:

- Criteria only applies to new start patients

Generic	Brand	HICL	GSN	Representative NDC
INSULIN REGULAR (HUMAN)	NOVOLIN R RELION SOLN 100 UNIT/ML	768	001723	00169183302
INSULIN REGULAR (HUMAN)	NOVOLIN R FLEXPEN RELION SOPN 100 UNIT/ML	768	049833	00169300325
INSULIN ASPART	INSULIN ASPART SOLN 100 UNIT/ML	20769	044340	73070010011
INSULIN ASPART	NOVOLOG SOLN 100 UNIT/ML	20769	044340	00169750111
INSULIN ASPART	INSULIN ASPART FLEXPEN SOPN 100 UNIT/ML	20769	044341	73070010315
INSULIN ASPART	NOVOLOG FLEXPEN SOPN 100 UNIT/ML	20769	044341	00169633910
INSULIN ASPART	INSULIN ASPART PENFILL SOCT 100 UNIT/ML	20769	044093	73070010215
INSULIN ASPART	NOVOLOG PENFILL SOCT 100 UNIT/ML	20769	044093	00169330312
INSULIN ASPART (WITH NIACINAMIDE)	FIASP SOLN 100 UNIT/ML	44099	077138	00169320111
INSULIN ASPART (WITH NIACINAMIDE)	FIASP FLEXTOUCH SOPN 100 UNIT/ML	44099	077137	00169320415
INSULIN ASPART (WITH NIACINAMIDE)	FIASP PENFILL SOCT 100 UNIT/ML	44099	077136	00169320511
INSULIN GLULISINE	APIDRA SOLN 100 UNIT/ML	33152	059985	00088250033
INSULIN GLULISINE	APIDRA SOLOSTAR SOPN 100 UNIT/ML	33152	060371	00088250205
INSULIN LISPRO	ADMELOG SOLN 100 UNIT/ML	11528	027413	00024592605
INSULIN LISPRO	ADMELOG SOLOSTAR SOPN 100 UNIT/ML	11528	034731	00024592501

Insulins (cont'd)

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Failed adequate trial or documented intolerance with preferred insulin product (Humulin 70/30; Humulin N; Humulin R), AND
- Failed adequate trial or documented intolerance with Humalog
- Pens reserved for the following situations:
  - Patients unable to self-inject insulin due to cognitive function, difficulties with manual dexterity, visual disturbances, visual impairment, uncorrectable poor injection, OR
  - Pediatric patients who are required to use such a device by their school, OR
  - Patients requiring small doses of insulin (<5 units per dose)

Continuation of Therapy Criteria:

- Adherence (>80%) to diabetic regimen, AND
- Must continue to meet inclusion criteria

Insulins (cont'd)

Last revised: 12/5/2023

Generic	Brand	HICL	GSN	Representative NDC
INSULIN LISPRO	HUMALOG KWIKPEN SOPN 200 UNIT/ML	11528	073403	00002771227

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- One of the following situations applies:
  - Patients with Type 1 Diabetes, OR
  - On insulin pump therapy, OR
  - Pregnant patients, OR
  - Patients with Type 2 Diabetes who require intensive glycemic control (≥4 injections per day) AND not controlled or recurrent hypoglycemia (low blood sugar) with regular insulin defined as ≥3 episodes of low blood sugar (<70 mg/dL) over the preceding 30 days that persists despite regular insulin dose adjustments, OR
  - Failed adequate trial or documented intolerance with preferred insulin products (Humulin 70/30; Humulin N; Humulin R)
- AND Humalog PENS/CARTRIDGES reserved for the following patients:
  - Unable to draw up insulin accurately from a vial with a syringe due to young age, visual impairment, physical disabilities (i.e., amputation, tremors/Parkinson's disease, rheumatoid arthritis), OR
  - Requires small doses of insulin (<5 units per dose), OR
  - Pediatric patient who is required to use such a device by their school

Continuation of Therapy Criteria:

- Adherence (>80%) to diabetic regimen, AND
- Must continue to meet inclusion criteria

Notes:

- Criteria only applies to new start patients

Generic	Brand	HICL	GSN	Representative NDC
INSULIN GLARGINE	BASAGLAR KWIKPEN SOPN 100 UNIT/ML	22025	062867	00002771501

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Patient has tried and failed prior therapy with insulin glargine-yfgn (unbranded Semglee),
- AND prescribed for one of the following patient populations:
    - Type 1 Diabetes as basal insulin
    - OR pediatric patients
    - OR gestational diabetes, pregnant patients (these patients will be moved to NPH after birth or termination of pregnancy)
    - OR patients with documented intolerance/allergy to Humulin N or Humulin 70/30
    - OR patients with Type 2 Diabetes who experienced significant hypoglycemia, defined as, 2 to 3 episodes of blood glucose < 70 mg/dL on separate days in 1 week despite NPH insulin dose reduction or hypoglycemia resulting in coma/seizure, or any episode necessitating assistance from someone else or use of glucagon/emergency services
    - OR patient with Type 2 Diabetes that requires ultra-long acting insulin due to work (i.e., night shift work where hours of sleep are significantly and repeatedly varied over time, frequent time-zone travelers)

<u>Pen Criteria (must meet above criteria) PLUS:</u>

- Unable to draw up insulin accurately from a vial with a syringe due to young age, visual impairment, physical disabilities (e.g., amputation, tremors/ Parkinson's disease, rheumatoid arthritis),
- OR requires small doses of insulin (<5 units per dose),
- OR pediatric patient who is required to use such a device by their school

Continuation of Therapy Criteria:

- Currently on therapy, not a new start

Notes:

- Criteria only applies to new start patients

Integrin Receptor Antagonist, Monoclonal Antibody

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

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

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Gastroenterologist
- Diagnosis of moderately to severely active Crohn's disease or ulcerative colitis
- Inadequate response, contraindication, or inability to tolerate at least one conventional therapy (e.g. azathioprine or 6-mercaptopurine)
- Inadequate response, contraindication or an inability to tolerate corticosteroids (e.g. prednisone, methylprednisolone, budesonide)
- Documented inadequate response (after at least a 3-month trial), intolerance, or contraindication to infliximab product (Inflectra preferred) OR adalimumab product (Amjevita preferred)

Continuation of Therapy Criteria:

- Patient has positive clinical response to medication,
- Specialist follow-up has occurred since last review

Interleukin-4 (IL-4) Receptor Alpha Antagonist, MAB

Last revised: 10/1/2024; Effective date: 12/3/2024

Generic	Brand	HICL	GSN	Representative NDC
DUPILUMAB	DUPIXENT SOSY 200 MG/1.14ML	44180	79179	00024591801
DUPILUMAB	DUPIXENT SOPN 200 MG/1.14 ML	44180	081615	00024591902
DUPILUMAB	DUPIXENT SOSY 300 MG/2ML	44180	077263	00024591401
DUPILUMAB	DUPIXENT SOPN 300 MG/2ML	44180	081231	00024591502

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Pulmonologist, ENT Specialist, Allergist, Gastroenterologist, or Dermatologist

Asthma:

- Diagnosis of uncontrolled moderate to severe asthma defined as any of the following:
  - ≥2 exacerbations in the past 12 months requiring systemic corticosteroids for more than 3 days
  - ≥1 asthma exacerbation(s) leading to hospitalization in the past 12 months
  - Dependence on daily oral corticosteroids for asthma control
  - Poor symptom control (ACT score less than 20)
- AND patient has uncontrolled asthma despite good adherence (at least 75% over the past 3 months) to a regimen containing: a high dose inhaled corticosteroid, long-acting beta 2 agonist, AND long-acting muscarinic antagonist, and consideration given to use of a leukotriene receptor antagonist
- AND patient is ≥ 6 years,
- AND Dupixent will NOT be used with Fasenra (benralizumab), Cinqair (resilizumab), Xolair (omalizumab), Nucala (mepolizumab), or Tezspire (tezepelumab-ekko)
- AND Dupixent is being used for one of the following indications:
  - Eosinophilic asthma (non-OCS dependent) with eosinophil count ≥150 cells/microliter in the past 12 months,
  - OR OCS-dependent asthma (no minimum serum eosinophil requirement)
  - OR clinical diagnosis of allergic asthma AND requiring high-dose Xolair (i.e. q2week dosing frequency)
- AND if using for eosinophilic asthma and aged ≥12 years: requires documented treatment failure, contraindication, or inadequate response to Fasenra

Interleukin-4 (IL-4) Receptor Alpha Antagonist, MAB (cont'd)

Atopic Dermatitis/Eczema:

- Diagnosis of moderate to severe atopic dermatitis,
- AND history of failure, contraindication, or intolerance to at least one of the following topical therapies:
    - Medium to very-high potency topical steroids
    - Topical calcineurin inhibitor
- AND history of failure, inadequate response, contraindication or intolerance to narrow-band short wave ultraviolet B light (NB-UV light); *history of worsening eczema with sunlight/heat is considered contraindication*
- AND if patient is ≥18 years, history of inadequate response (after at least 1 month of treatment), intolerance, or contraindication (i.e. pregnancy/breastfeeding, history of alcoholism or alcoholic liver disease, chronic liver disease, immunodeficiency syndrome, pre-existing blood dyscrasia, hemodialysis, or end-stage renal disease) to methotrexate

Prurigo Nodularis:

- Prescriber is a Dermatologist,
- AND patient is at least 18 years old,
- AND diagnosis of prurigo nodularis (PN) for at least 3 months with widespread distribution (BSA involvement ≥ 20%) and severe itch,
- AND inadequate response or contraindication to at least 3-month trial of phototherapy unless involvement in sensitive areas (e.g. face, body folds, etc.),
- AND failed at least 3-month trial of one of the following unless clinically significant adverse effects or contraindications (i.e. pregnancy/breastfeeding, history of alcoholism or alcoholic liver disease, chronic liver disease, immunodeficiency syndrome, pre-existing blood dyscrasia, hemodialysis, or end-stage renal disease):
    - Methotrexate
    - Cyclosporine

Chronic Rhinosinusitis with Polyps:

- Diagnosis of rhinosinusitis (chronic) with polyps

Eosinophilic Esophagitis:

- Prescriber is an Allergist or Gastroenterologist,
- AND patient is at least 12 years old,
- AND patient weighs at least 40 kg,
- AND patient has contraindication, intolerance, or did not respond clinically to treatment with at least a 8-week trial of a topical glucocorticosteroid (i.e. swallowed fluticasone, budesonide),
- AND patient has contraindication, intolerance, or did not respond clinically to treatment with at least a 8-week trial of a proton pump inhibitor

Continuation of Therapy Criteria:

- Documentation of positive clinical response to Dupixent therapy,
- AND specialist follow-up occurred in the past 12 months since last review

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

Last revised: 2/6/2024

Generic	Brand	HICL	GSN	Representative NDC
BENRALIZUMAB	FASENRA PEN SOAJ 30 MG/ML	44635	080268	00310183030
BENRALIZUMAB	FASENRA SOSY 30 MG/ML	44635	077921	00310173030

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is Pulmonologist, Allergist, or Immunologist
- AND diagnosis/documentation of uncontrolled moderate to severe asthma defined as any of the following:
  - ≥2 exacerbations in the past 12 months requiring systemic corticosteroids for more than 3 days
  - ≥1 asthma exacerbation(s) leading to hospitalization in the past 12 months
  - Dependence on daily oral corticosteroids (OCS) for asthma control
  - Poor symptom control (ACT score less than 20)
- AND patient has uncontrolled asthma despite good adherence (at least 75% over the past 3 months) to a regimen containing: a high dose inhaled corticosteroid, long-acting beta 2 agonist, AND long-acting muscarinic antagonist, and consideration given to use of a leukotriene receptor antagonist
- AND patient is ≥12 years
- AND Fasenra is being used for one of the following indications:
  - Eosinophilic asthma (non-OCS dependent) with serum eosinophil count ≥300 cells/microliter in the past 12 months
  - OR eosinophilic asthma (OCS-dependent) with serum eosinophil count ≥150 cells/microliter in the past 12 months
- AND Fasenra will NOT be used with Dupixent (dupilumab), Cinqair (resilizumab), Nucala (mepolizumab), Xolair (omalizumab), or Tezspire (tezepelumab-ekko)

Continuation of Therapy Criteria:

- Patient continues to be under the care of a pulmonologist/allergist,
- AND documentation of positive clinical response to Fasenra therapy

Interleukin-6 (IL-6) Receptor Inhibitors

Last revised: 10/1/2024; Effective date: 12/3/2024

Generic	Brand	HICL	GSN	Representative NDC
TOCILIZUMAB	ACTEMRA ACTPEN SOAJ 162 MG/0.9ML	36466	078707	50242014301
TOCILIZUMAB	ACTEMRA SOSY 162 MG/0.9ML	36466	071590	50242013801

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Rheumatologist, AND
- Patient must have documented treatment failure, intolerance, or contraindication to tocilizumab-aazg (Tyenne), AND

<u>If using for rheumatoid arthritis:</u>

- Diagnosis of moderate-to-severe rheumatoid arthritis, AND
- Documented treatment failure (with at least a 3-month trial), intolerance, or contraindication to ALL of the following, unless other documented clinical rationale:
  - At least ONE of the following: oral/subcutaneous methotrexate, hydroxychloroquine, leflunomide, or sulfasalazine
  - At least 1 TNF inhibitor [e.g., adalimumab product (Amjevita preferred), infliximab product (Inflectra preferred), Enbrel (etanercept)*PA]

<u>If using for giant cell arteritis:</u>

- Diagnosis of giant cell arteritis

<u>If using for active polyarticular or systemic juvenile idiopathic arthritis:</u>

- Diagnosis of active polyarticular or systemic juvenile idiopathic arthritis, AND
- Patient must not be receiving tocilizumab product in combination with ANY of the following:
  - Biologic DMARD [e.g., adalimumab, Enbrel (etanercept)*PA, Cimzia (certolizumab pegol)*PA, Simponi (golimumab)*PA]
  - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)*PA, Olumiant (baricitinib)*PA]

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

Continuation of Therapy Criteria:

- Positive clinical response to medication, AND
- Specialist follow-up occurred in the past 12 months since last review

Interleukin-6 (IL-6) Receptor Inhibitors (cont'd)

Last revised: 10/1/2024; Effective date: 12/3/2024

Generic	Brand	HICL	GSN	Representative NDC
SARILUMAB	KEVZARA SOAJ 150 MG/1.14ML	44183	078046	00024592001
SARILUMAB	KEVZARA SOAJ 200 MG/1.14ML	44183	078047	00024592201
SARILUMAB	KEVZARA SOSY 150 MG/1.14ML	44183	077264	00024590801
SARILUMAB	KEVZARA SOSY 200 MG/1.14ML	44183	077265	00024591001

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Rheumatologist, AND

If using for rheumatoid arthritis:

- Diagnosis of moderate-to-severe rheumatoid arthritis, AND
- Documented treatment failure (with at least a 3-month trial), intolerance, or contraindication to ALL of the following, unless other documented clinical rationale:
  - At least ONE of the following: oral/subcutaneous methotrexate, hydroxychloroquine, leflunomide, or sulfasalazine
  - Xeljanz (tofacitinib)*PA
  - At least 1 TNF inhibitor [e.g., adalimumab product (Amjevita preferred), Enbrel (etanercept)*PA, Cimzia (certolizumab pegol)*PA, Simponi (golimumab)*PA]
  - Tocilizumab product (Tyenne preferred) or abatacept (reserve for last line therapy)

If using for active polyarticular or systemic juvenile idiopathic arthritis:

- Diagnosis of active polyarticular or systemic juvenile idiopathic arthritis

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

Continuation of Therapy Criteria:

- Positive clinical response to medication, AND
- Specialist follow-up occurred in the past 12 months since last review

Interleukin-6 (IL-6) Receptor Inhibitors (cont'd)

Generic	Brand	HICL	GSN	Representative NDC
SATRALIZUMAB-MWGE	ENSPRYNG SOSY 120 MG/ML	46781	081389	50242000701

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Neurologist,
- AND documented neuromyelitis optica spectrum disorder (NMOSD) in patients at least 18 years of age,
- AND AQP4 antibody seropositive,
- AND at least one of the following:
    - Severe breakthrough relapse while on rituximab for at least 6 months not attributed to rapid steroid. Examples of severe breakthrough relapse include, but are not limited to:
        - Hospitalization for neurological deficits from NMOSD relapse (e.g., quadriparesis or paraparesis)
        - Optic neuritis severity (hand motion only or worse) confirmed by an ophthalmologist
    - Recurrent moderate breakthrough relapses after 6 month trial of rituximab in combination with maximum tolerated doses of either mycophenolate mofetil or azathioprine:
        - Mycophenolate mofetil: 1,000 to2,000 mg/day to target an absolute lymphocyte count of 1,000 to 1,500 cells/µL
        - Azathioprine: 3 mg/kg/day
    - Patient has a severe intolerance or contraindication to rituximab
- AND if previously on tocilizumab, patient did not experience relapse

Continuation of Therapy Criteria:

- Documented beneficial response to therapy (i.e. no documentation of recurrent relapses or MRI changes 3-6 months after initiation of therapy)

Interleukin-13 (IL-13) Inhibitors, MAB

Generic	Brand	HICL	GSN	Representative NDC
TRALOKINUMAB-LDRM	ADBRY SOSY 150 MG/ML	47741	082945	50222034602

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescribed by a dermatologist or an allergist,
- AND patient's age > 18 years,
- AND documented diagnosis of moderate-to-severe atopic dermatitis (BSA > 10%),
- AND documented inadequate response, intolerance or contraindication to BOTH of the following topical therapies for a minimum of 2 weeks each:
    - Medium or very high potency topical corticosteroid
    - Topical calcineurin inhibitors
- AND documented treatment failure, contraindication or intolerance to narrow-band short wave ultraviolet B light (NB-UV light); history of worsening eczema with sunlight/heat is considered contraindication,
- AND documented inadequate response (after at least 1 month of treatment), intolerance, or contraindication (i.e. pregnancy/breastfeeding, history of alcoholism or alcoholic liver disease, chronic liver disease, immunodeficiency syndrome, pre-existing blood dyscrasia, hemodialysis, or end-stage renal disease) to systemic immunomodulator (i.e., methotrexate, azathioprine, mycophenolate mofetil, or cyclosporine),
- AND Adbry is NOT being used in combination with another biologic medications (omalizumab, rituximab, etc.)

Continuation of Therapy Criteria:

- Documentation of positive clinical response to Adbry therapy
- AND specialist follow-up occurred since last review

Intestinal Motility Stimulants

Last revised: 10/3/2023

Generic	Brand	HICL	GSN	Representative NDC
PRUCALOPRIDE SUCCINATE	MOTEGRITY TABS 1 MG	36920	066216	54092054601
PRUCALOPRIDE SUCCINATE	MOTEGRITY TABS 2 MG	36920	066215	54092054701

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescribed by a Gastroenterologist or in consultation with a Gastroenterologist,, AND
- Diagnosis of chronic idiopathic constipation, AND
- Patient has had an inadequate response, contraindication, or intolerance to an adequate trial of at least 4 weeks or intolerance to scheduled doses of the following medications:
    - Fiber supplement: psyllium fiber or methylcellulose
    - Osmotic laxative: polyethylene glycol or lactulose
    - Stimulant laxative: senna or bisacodyl
    - Amitiza (lubiprostone) – also criteria based
    - Trulance (plecanatide) – also criteria based

Continuation of Therapy Criteria:

- Positive clinical response to Motegrity

Irritable Bowel Syndrome Agents, 5-HT3 Antagonist

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

Generic	Brand	HICL	GSN	Representative NDC
ALOSETRON HCL	LOTRONEX TABS 0.5 MG	20953	053708	54766089403
ALOSETRON HCL	LOTRONEX TABS 1 MG	20953	044634	54766089503

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Gastroenterologist,
- Diagnosis of irritable bowel syndrome (IBS- diarrhea predominant),
- Patient has had an inadequate response (must try for the minimum duration listed before considered treatment failure), intolerance or contraindication to two of the following medications/medication classes (if ≥65 years old, trial of one of the following therapies is adequate):
    - Antidiarrheal agents (e.g., loperamide, diphenoxylate/atropine*) – at least 2 weeks' trial
    - Bile acid sequestrants (e.g., cholestyramine, colestipol, colesevelam) – at least 2 weeks' trial
    - Antispasmodics* (e.g., dicyclomine, diphenoxylate/atropine, chlordiazepoxide/clidinium, or hyoscyamine) – at least 2 weeks' trial
- Patient has had an inadequate response (at least 4 weeks' trial), intolerance, or contraindication to Xifaxan (rifaximin)*PA

*Beer's Criteria; NOT recommended if ≥65 years old
*PA *This medication is also subject to PA review*

Continuation of Therapy Criteria:

- Patient has positive clinical response to medication

Janus Kinase (JAK) Inhibitor

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

Generic	Brand	HICL	GSN	Representative NDC
TOFACITINIB CITRATE	XELJANZ TABS 10 MG	39768	078538	00069100201
TOFACITINIB CITRATE	XELJANZ TABS 5 MG	39768	070233	00069100101
TOFACITINIB CITRATE	XELJANZ XR TB24 11 MG	39768	075641	00069050130
TOFACITINIB CITRATE	XELJANZ XR TB24 22 MG	39768	080628	00069050230

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Gastroenterologist, Rheumatologist, or Dermatologist

<u>If using for ulcerative colitis</u>:

- Patient has diagnosis of ulcerative colitis,
- AND patient has had an inadequate response to at least one anti-TNF agent (e.g., infliximab, adalimumab)

<u>If using for rheumatoid arthritis or psoriatic arthritis</u>:

- Diagnosis of moderate-to-severe rheumatoid arthritis,
- AND patient has contraindication, intolerance or inadequate response after a 3-month minimum trial of one of the following:
  - Methotrexate
  - Hydroxychloroquine
  - Leflunomide
  - Sulfasalazine
- AND patient has had an inadequate response after a 3-month minimum trial to at least one anti-TNF agent (e.g. infliximab, adalimumab biosimilars (Amjevita preferred) or Humira)

OR

- Prescriber must be a Rheumatologist,
- AND diagnosis of psoriatic arthritis,
- AND patient has had an inadequate response or intolerance after a 3 month trial to:
  - One nonbiologic DMARD (methotrexate, sulfasalazine, hydroxychloroquine, leflunomide),
  - OR a biologic medication (e.g., adalimumab biosimilars (Amjevita preferred) or Humira, certolizumab, etanercept, golimumab, infliximab, secukinumab, ustekinumab) or apremilast

If using for ankylosing spondylitis:

- Prescriber is a Rheumatologist,
- AND diagnosis of ankylosing spondylitis,
- AND patient has had an inadequate response after a 3-month minimum trial to at least one of the preferred anti-TNF agents [i.e. adalimumab-atto (Amjevita) or infliximab-dyyb (Inflectra)]

If using for polyarticular juvenile idiopathic arthritis:

- Prescriber is a Rheumatologist,
- AND diagnosis of polyarticular juvenile idiopathic arthritis,
- AND intolerance or inadequate response after a 3-month minimum trial of **one** of the following:
    - Methotrexate
    - Leflunomide
    - Sulfasalazine
- AND patient has had an inadequate response after a 3-month minimum trial to at least one of the preferred anti-TNF agents [i.e. adalimumab-atto (Amjevita) or infliximab-dyyb (Inflectra)]

If using for Alopecia Areata:

- Prescriber is a Dermatologist,
- AND diagnosis of alopecia areata (with <50% scalp involvement, mild facial involvement, not rapidly progressive, not alopecia totalis/universalis),
- AND patient has tried a 2-month trial of all of the following unless clinically significant adverse effects, contraindication, or clinical reason to avoid treatment:
    - Topical corticosteroid,
    - AND topical calcineurin inhibitor,
    - AND topical minoxidil,
    - AND intralesional Kenalog,
    - AND topical JAK inhibitor
- AND patient has tried a 3-month trial of at least one of the systemic immunosuppressants such as methotrexate or cyclosporine unless clinically significant adverse effects, contraindication, or clinical reason to avoid treatment

OR

- Diagnosis of alopecia areata (with >50% scalp involvement, disfiguring facial involvement, rapidly progressive, alopecia totalis/universalis),
- AND patient has tried a 3-month trial of at least one of the systemic immunosuppressants such as methotrexate or cyclosporine unless clinically significant adverse effects, contraindication, or clinical reason to avoid treatment

Continuation of Therapy Criteria:

- Positive clinical response to Xeljanz, AND
- Specialist follow-up occurred in the past 12 months since last review

Janus Kinase (JAK) Inhibitor (Cont'd)

Last revised: 4/8/2024; Effective date: 6/4/2024

Generic	Brand	HICL	GSN	Representative NDC
BARICITINIB	OLUMIANT TABS 1 MG	44296	080389	00002473230
BARICITINIB	OLUMIANT TABS 2 MG	44296	077445	00002418230
BARICITINIB	OLUMIANT TABS 4 MG	44296	077446	00002447930

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Rheumatologist or Dermatologist

If using for Rheumatoid Arthritis:

- Patient is ≥18 years old and has a diagnosis of moderate-to-severe rheumatoid arthritis,
- AND patient had a history of treatment failure after an adequate trial (≥3 months), intolerance or contraindication to at least one agent in each of the following categories:
    - At least 1 non-biologic disease-modifying antirheumatic drug (DMARD) such as methotrexate, leflunomide, sulfasalazine or hydroxychloroquine,
    - AND at least 1 TNF-alpha biologic DMARD: e.g., Enbrel (etanercept), adalimumab biosimilars (Amjevita preferred) or Humira,
    - AND Xeljanz (tofacitinib)

If using for Alopecia Areata:

- Patient is ≥ 18 years,
- AND diagnosis of alopecia areata (with <50% scalp involvement, mild facial involvement, not rapidly progressive, not alopecia totalis/universalis),
- AND patient has tried a 2-month trial of all of the following unless clinically significant adverse effects, contraindication, or clinical reason to avoid treatment:
    - Topical corticosteroid,
    - AND topical calcineurin inhibitor,
    - AND topical minoxidil,
    - AND intralesional Kenalog,
    - AND topical JAK inhibitor
- AND patient has tried a 3-month trial of at least one of the systemic immunosuppressants such as methotrexate or cyclosporine unless clinically significant adverse effects, contraindication, or clinical reason to avoid treatment

OR

- Patient is ≥ 18 years,
- AND diagnosis of alopecia areata (with >50% scalp involvement, disfiguring facial involvement, rapidly progressive, alopecia totalis/universalis),
- AND patient has tried a 3-month trial of at least one of the systemic immunosuppressants such as methotrexate or cyclosporine unless clinically significant adverse effects, contraindication, or clinical reason to avoid treatment

Continuation of Therapy Criteria:

- Positive clinical response, AND
- Specialist follow-up occurred in the past 12 months since last review

Generic	Brand	HICL	GSN	Representative NDC
UPADACITINIB	RINVOQ TB24 15 MG	45955	080125	00074230630
UPADACITINIB	RINVOQ TB24 30 MG	45955	082927	00074231030
UPADACITINIB	RINVOQ TB24 45 MG	45955	083196	00074104328

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Rheumatologist, Dermatologist, or Gastroenterologist

If using for Rheumatoid Arthritis:

- Patient is ≥18 years old and has a diagnosis of moderate-to-severe rheumatoid arthritis,
- AND patient had a history of treatment failure after an adequate trial (≥3 months), intolerance or contraindication to at least one agent in each of the following categories:
    - At least 1 non-biologic disease-modifying antirheumatic drug (DMARD) such as methotrexate, leflunomide, sulfasalazine or hydroxychloroquine,
    - AND at least 1 TNF-alpha biologic DMARD: e.g., Enbrel (etanercept), adalimumab biosimilars (Amjevita preferred) or Humira,
    - AND Xeljanz (tofacitinib)

If using for atopic dermatitis:

- Patient is ≥12 years, AND
- Diagnosis of moderate to severe atopic dermatitis, AND
- History of failure, contraindication, or intolerance to BOTH of the following topical therapies, AND:
    - Medium to very-high potency topical steroids
    - Topical calcineurin inhibitor
- History of failure, inadequate response, contraindication or intolerance to narrow-band short wave ultraviolet B (NB-UV light); *history of worsening eczema with sunlight/heat is considered contraindication*, AND
- AND if patient is ≥18 years, history of inadequate response (after at least 1 month of treatment), intolerance, or contraindication (i.e. pregnancy/breastfeeding, history of alcoholism or alcoholic liver disease, chronic liver disease, immunodeficiency syndrome, pre-existing blood dyscrasia, hemodialysis, or end-stage renal disease) to systemic immunomodulators (i.e., methotrexate, azathioprine, cyclosporine, or mycophenolate mofetil)
- Documented inadequate response (of at least a 4-month trial), intolerance, or contraindication to tralokinumab (Adbry) or dupilumab (Dupixent), AND
- Initial approval limited to only the 15-mg dose for patients new to therapy

If using for ulcerative colitis:

- Prescriber is a Gastroenterologist,

- AND diagnosis of moderately to severely active ulcerative colitis,
- AND inadequate response, contraindication or intolerance to corticosteroids (e.g., prednisone),
- AND inadequate response (of at least a 3-month trial), intolerance, or contraindication to:
    - ONE of the preferred anti-TNF agents [i.e. adalimumab-atto (Amjevita) or infliximab-dyyb (Inflectra)]
    - AND Entyvio (vedolizumab) OR Xeljanz (tofacitinib)

If using for Crohn's disease:

- Prescriber is a Gastroenterologist,
- AND diagnosis of moderately to severely active Crohn's disease,
- AND inadequate response, contraindication or intolerance to corticosteroids (e.g., prednisone),
- AND inadequate response (of at least a 3-month trial), intolerance, or contraindication to:
    - ONE of the preferred anti-TNF agents [i.e. adalimumab-atto (Amjevita) or infliximab-dyyb (Inflectra)]
    - AND Entyvio (vedolizumab)

Continuation of Therapy Criteria:

- Positive clinical response, AND
- Specialist follow-up occurred in the past 12 months since last review

Janus Kinase (JAK) Inhibitor (Cont'd)

Last revised: 4/8/2024; Effective date: 6/4/2024

Generic	Brand	HICL	GSN	Representative NDC
ABROCITINIB	CIBINQO TABS 50 MG	47767	082989	00069023530
ABROCITINIB	CIBINQO TABS 100 MG	47767	082990	00069033530
ABROCITINIB	CIBINQO TABS 200 MG	47767	082991	00069043530

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Rheumatologist or Dermatologist

If using for atopic dermatitis:

- Patient is ≥12 years, AND
- Diagnosis of moderate to severe atopic dermatitis, AND
- History of failure, contraindication, or intolerance to BOTH of the following topical therapies, AND:
  - Medium to very-high potency topical steroids
  - Topical calcineurin inhibitor
- History of failure, inadequate response, contraindication or intolerance to narrow-band short wave ultraviolet B (NB-UV light); *history of worsening eczema with sunlight/heat is considered contraindication*, AND
- AND if patient is ≥18 years, history of inadequate response (after at least 1 month of treatment), intolerance, or contraindication (i.e. pregnancy/breastfeeding, history of alcoholism or alcoholic liver disease, chronic liver disease, immunodeficiency syndrome, pre-existing blood dyscrasia, hemodialysis, or end-stage renal disease) to systemic immunomodulators (i.e., methotrexate, azathioprine, cyclosporine, or mycophenolate mofetil)
- Documented inadequate response (of at least a 4-month trial), intolerance, or contraindication to tralokinumab (Adbry) or dupilumab (Dupixent)

***Note: Initial approval of Cibinqo limited to only the 100-mg dose for patients new to therapy, and quantity limit of 30 tablets every 30 days*

Continuation of Therapy Criteria:

- Positive clinical response, AND
- Specialist follow-up occurred in the past 12 months since last review

Janus Kinase (JAK) Inhibitors (cont'd)

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

Generic	Brand	HICL	GSN	Representative NDC
RITLECITINIB TOSYLATE	LITFULO CAPS 50 MG	49026	084997	00069033428

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Dermatologist,
- AND patient is ≥ 12 years of age,
- AND diagnosis of alopecia areata (with <50% scalp involvement, mild facial involvement, not rapidly progressive, not alopecia totalis/universalis),
- AND patient has tried a 2-month trial of all of the following unless clinically significant adverse effects, contraindication, or clinical reason to avoid treatment:
  - Topical corticosteroid
  - AND topical calcineurin inhibitor
  - AND topical minoxidil
  - AND intralesional Kenalog
  - AND topical JAK inhibitor
- AND if patient is ≥18 years of age, patient has tried a 3-month trial of at least one of the systemic immunosuppressants such as methotrexate or cyclosporine unless clinically significant adverse effects, contraindication, or clinical reason to avoid treatment.

OR

- Prescriber is a Dermatologist,
- AND patient is ≥ 12 years of age,
- AND diagnosis of alopecia areata (with >50% scalp involvement, disfiguring facial involvement, rapidly progressive, alopecia totalis/universalis),
- AND if patient is ≥18 years of age, patient has tried a 3-month trial of at least one of the systemic immunosuppressants such as methotrexate or cyclosporine unless clinically significant adverse effects, contraindication, or clinical reason to avoid treatment.

Continuation of Therapy Criteria:

- Positive clinical response,
- AND specialist follow-up occurred since last review

Topical Janus Kinase (JAK) Inhibitors

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

Generic	Brand	HICL	GSN	Representative NDC
RUXOLITINIB PHOSPHATE (TOPICAL)	OPZELURA CREAM 1.5%	38202	082689	50881000705

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Dermatologist, AND

If treating atopic dermatitis:

- Patient has diagnosis of mild to moderate atopic dermatitis,
- AND patient is non-immunocompromised,
- AND patient has inadequate response, contraindication, or intolerance to ALL of the following:
    - At least one moderate- to very high-potency topical corticosteroid (2-weeks trial)
    - At least one topical calcineurin inhibitor (6-weeks trial)

If treating vitiligo:

- Patient has diagnosis of vitiligo,
- AND patient has had an inadequate response or contraindication to at least a 3-month trial of phototherapy unless involvement in sensitive areas (e.g. face, body folds, etc.),
- AND patient has inadequate response, contraindication or intolerance to ALL of the following:
    - At least one moderate- to very high-potency corticosteroid (2-week trial)
    - At least one topical calcineurin inhibitor (2 month trial)

Continuation of Therapy Criteria:

- Patient has had positive clinical response,
- AND specialist follow-up occurred since last review

Notes:

- Quantity limit of one 60 gm tube per week

Topical Immunosuppressive Agents

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

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

Prior Authorization Criteria:
Length of Authorization: • Initial: 3 months • Reauthorization: 12 months
Initial Review Criteria: • Prescribed by or in consultation with a dermatologist or a physician who specialized in the management of patients with tuberous sclerosis complex, • Patient is 6 years of age or older, • Patient has definitive diagnosis of facial angiofibroma associated with tuberous sclerosis with 3 or more facial angiofibromas (≥ 2 mm in diameter with redness in each) • Patient has been determined to be a non-candidate for laser therapy or surgery
Continuation of Therapy Criteria: • Patient has positive clinical response to therapy (e.g., improvement in skin lesions), • Specialist follow-up has occurred since last review
Note: Quantity limit of 30 grams (3 x 10 g tubes) per 30-day supply

Laxatives and Cathartics

Last revised: 10/3/2023

Generic	Brand	HICL	GSN	Representative NDC
LUBIPROSTONE	AMITIZA CAPS 24 MCG	33451	060341	64764024060
LUBIPROSTONE	AMITIZA CAPS 8 MCG	33451	063946	64764008060

Prior Authorization Criteria (applies to brand Amitiza only):

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescribed by an Oncologist, Pain Specialist, Gastroenterologist or in consultation with a Gastroenterologist, AND
- Diagnosis of irritable bowel syndrome with constipation (IBS-constipation predominant) in women ≥18 years of age, AND
- Patient has had an inadequate response to an adequate trial of at least 4 weeks or intolerance or contraindication to scheduled doses of the following medications:
    - Fiber supplement: psyllium fiber or methylcellulose
    - Polyethylene glycol

-OR-

- Prescribed by an Oncologist, Pain Specialist, Gastroenterologist or in consultation with a Gastroenterologist, AND
- Diagnosis of chronic idiopathic constipation, AND
- Patient has had an inadequate response to an adequate trial of at least 4 weeks or intolerance or contraindication to scheduled doses of the following medications:
    - Fiber supplement: psyllium fiber or methylcellulose
    - Osmotic laxative: polyethylene glycol or lactulose
    - Stimulant laxative: senna or bisacodyl

-OR-

- Prescribed by an Oncologist, Pain Specialist, Gastroenterologist or in consultation with a Gastroenterologist, AND
- Diagnosis of opioid induced constipation in an adult with an active opioid prescription, AND
- Opioid medication is being prescribed by an oncologist or a hospice/palliative care clinician for a patient currently enrolled in hospice or palliative care program, or after consultation with a pain management specialist, AND
- Patient has failed a trial of at least 2 weeks or has an intolerance or contraindication to scheduled dosing of the following medications, used in combination with other agent(s) with different mechanism of action (i.e., osmotic with a stimulant) and route of administration:
    - Polyethylene glycol
    - Lactulose or sorbitol
    - Senna
    - Bisacodyl

Continuation of Therapy Criteria:

- Positive clinical response to Amitiza

Leptins

Generic	Brand	HICL	GSN	Representative NDC
METRELEPTIN	MYALEPT SOLR 11.3 MG	41078	072265	76431021001
METRELEPTIN	MYALEPT INJ 11.3MG			66780031001

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: 8/2/2024; Effective date: 9/1/2024

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

Prior Authorization Criteria:

Length of Authorization:

- Initial: 3 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescribed by an OB/gyn or Gynecologic Oncology specialist,
- AND patient's age < 65 years,
- AND documented diagnosis of moderate to severe menopausal vasomotor symptoms (VMS),
- AND patient does NOT have any of the following at baseline:
  - Cirrhosis,
  - ALT, AST, or bilirubin ≥ 2x ULN
  - Severe renal impairment (eGFR < 30 mL/min/1.73 m^2) or end-stage renal disease
  - Uncontrolled HTN (or ≥ 2 blood pressure readings >130/80 mmHg in past 1 month)
  - Concomitant use with CYP1A2 inhibitor(s) (e.g., acyclovir, ciprofloxacin, estradiol, propranolol, verapamil, etc.),
- AND documentation that patient is unable to use OR contraindication to hormonal therapy,
- AND documented inadequate response, intolerance, or contraindication to **3 or more** non-hormonal therapies (i.e. clonidine, oxybutynin, etc.)

Continuation of Therapy Criteria:

- Documentation that patient has a continued need for VMS treatment,
- AND documentation that patient has a 50% reduction in frequency OR severity of VMS after initiating fezolinetant

Generic	Brand	HICL	GSN	Representative NDC
BUROSUMAB-TWZA	CRYSVITA SOLN 20 MG/ML	44867	078330	69794020301
BUROSUMAB-TWZA	CRYSVITA SOLN 10 MG/ML	44867	2043864	69794010201
BUROSUMAB-TWZA	CRYSVITA SOLN 30 MG/ML	44867	2043878	69794030401

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

Monoclonal Antibodies to Immunoglobulin E (IGE)

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

Generic	Brand	HICL	GSN	Representative NDC
OMALIZUMAB	XOLAIR SOAJ 300 MG/2ML	25399	085686	50242022755
OMALIZUMAB	XOLAIR SOSY 300 MG/2ML	25399	085685	50242022701
OMALIZUMAB	XOLAIR SOLR 150 MG	25399	052758	50242004062
OMALIZUMAB	XOLAIR SOAJ 150 MG/ML	25399	085684	50242021555
OMALIZUMAB	XOLAIR SOSY 150 MG/ML	25399	067908	50242021501
OMALIZUMAB	XOLAIR SOAJ 75 MG/0.5ML	25399	085683	50242021455
OMALIZUMAB	XOLAIR SOSY 75 MG/0.5ML	25399	067907	50242021401

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

If using for asthma:

- Prescriber is a Pulmonologist or Allergist,
- AND diagnosis of uncontrolled moderate to severe asthma defined as any of the following:
  - ≥2 exacerbations in the past 12 months requiring systemic corticosteroids for more than 3 days
  - ≥1 asthma exacerbation(s) leading to hospitalization in the past 12 months
  - Dependence on daily oral corticosteroids (OCS) for asthma control
  - Poor symptom control (ACT score less than 20)
- AND patient has uncontrolled asthma despite good adherence (at least 75% over the past 3 months) to a regimen containing: a high dose inhaled corticosteroid, long-acting beta 2 agonist, AND long-acting muscarinic antagonist, and consideration given to use of a leukotriene receptor antagonist,
- AND patient is ≥6 years,
- AND clinical diagnosis of allergic asthma,
- AND if requiring Xolair q2week dosing, patient has documented treatment failure, contraindication, or inadequate response to Dupixent,
- AND Xolair will NOT be used with Fasenra (benralizumab), Cinqair (resilizumab), Dupixent (dupilumab), Nucala (mepolizumab), or Tezspire (tezepelumab-ekko)

If using for nasal polyps:

- Prescriber is an Allergist or ENT Specialist,
- AND diagnosis of rhinosinusitis with nasal polyps,
- AND history of failure, inadequate response, contraindication, or intolerance to Dupixent (dupilumab)

If using for chronic spontaneous urticaria:

- Prescriber is an Allergist or Dermatologist,
- AND diagnosis of chronic spontaneous urticaria,
- AND patient is 12 years of age or older,
- AND tried and failed therapy for minimum of 4 weeks on ALL of the following, unless contraindicated:

- At least two different high-dose second generation H1-antihistamines (e.g. loratadine, cetirizine) 2-4 times normal dose daily OR two second-generation H1-antihistamines in combination (e.g. fexofenadine 180 mg daily in the morning plus cetirizine 10-20 mg daily at bedtime),
- AND montelukast in combination with a high-dose second generation H1-antihistamine,
- AND H2-antihistamines (e.g. famotidine, ranitidine) in combination with a high-dose second generation H1-antihistamine

If using for IgE-mediated food allergies:

- Prescriber is an Allergist,
- AND patient meets the age, weight, and baseline IgE cutoffs below:
  - Prefilled syringe: ≥1 year of age
  - Auto-injector: ≥12 years of age
  - Weight ≥10 kg
  - IgE level ≥30 IU/mL
- AND patient has a documented IgE-mediated food allergy and meets BOTH of the following criteria:
  - Positive skin prick test OR positive food-specific IgE test OR experiences dose-limiting symptoms during food challenge conducted by Allergy
  - AND documented history of repeated anaphylaxis (2 or more episodes), defined using World Allergy Organization criteria:
    - Acute onset of illness (minutes to several hours) with simultaneous involvement of skin, mucosal tissue, or both, and at least ONE of the following: respiratory compromise, circulatory compromise, or severe gastrointestinal symptoms
    - OR acute onset of hypotension, bronchospasm, or laryngeal involvement after exposure to a known or highly probable allergen for the patient in the absence of typical skin involvement
- AND patient will be using Xolair in conjunction with food allergy avoidance and has an active prescription for an epinephrine product

Continuation of Therapy Criteria:

- Patient continues to be under the care of a specialist,
- AND documentation of positive clinical response to Xolair therapy since last review

Monoclonal Antibody Human Interleukin 12/23 Inhibitor

Last revised: 5/2/2023

Generic	Brand	HICL	GSN	Representative NDC
USTEKINUMAB	STELARA SOLN 45 MG/0.5ML	36187	064967	57894006002
USTEKINUMAB	STELARA SOSY 45 MG/0.5ML	36187	065993	57894006003
USTEKINUMAB	STELARA SOSY 90 MG/ML	36187	065994	57894006103

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Rheumatologist, Dermatologist, or Gastroenterologist

Rheumatology

- Diagnosis of active psoriatic arthritis, AND
- Documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to BOTH of the following:
    - ONE or more tumor necrosis factor (TNF alpha) inhibitors: Inflectra or Remicade (infliximab), Enbrel (etanercept), adalimumab biosimilars (Amjevita preferred) or Humira, AND
    - Cosentyx (secukinumab)

Dermatology

- Diagnosis of moderate-to-severe plaque psoriasis, AND
- Meets criteria for Cosentyx, AND
- Documented inadequate response (of at least 3 mo trial), intolerance, or contraindication to Cosentyx (secukinumab) AND at least 1 TNF inhibitor (e.g. adalimumab biosimilars (Amjevita preferred) or Humira, Enbrel, Inflectra),
- AND documentation of inadequate response, intolerance, or contraindication to Tremfya OR Skyrizi

Gastroenterology

- Documented moderately to severely active Crohn's disease, AND
- Inadequate response, contraindication or inability to tolerate ONE conventional therapy (i.e., azathioprine or 6-mercaptopurine), AND
- Inadequate response, contraindication or an inability to tolerate corticosteroids (i.e., prednisone, methylprednisolone, budesonide), AND
- Documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to the following:
    - Inflectra or Remicade (infliximab), AND
    - adalimumab biosimilars (Amjevita preferred) or Humira OR Entyvio (vedolizumab), AND
- Patient has documented negative test for tuberculosis within the past 12 months

OR

- Documented moderately to severely active Ulcerative Colitis, AND
- Inadequate response, contraindication or inability to tolerate ONE conventional therapy (i.e., mesalamine, azathioprine or 6-mercaptopurine), AND
- Inadequate response, contraindication or an inability to tolerate corticosteroids (i.e., prednisone), AND
- Documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to the following:
    - Inflectra or Remicade (infliximab), AND
    - adalimumab biosimilars (Amjevita preferred) or Humira OR Entyvio (vedolizumab) OR Xeljanz (tofacitinib), AND
- Patient has documented negative test for tuberculosis within the past 12 months

Continuation of Therapy Criteria:

- Positive clinical response to medication, AND
- Specialist follow-up occurred in the past 12 months since last review

Monoclonal Antibody- Interleukin-5 Antagonist

Last revised: 10/1/2024; Effective date: 12/3/2024

Generic	Brand	HICL	GSN	Representative NDC
MEPOLIZUMAB	NUCALA SOSY 40 MG/0.4ML	42775	083454	00173090442
MEPOLIZUMAB	NUCALA SOAJ 100 MG/ML	42775	079829	00173089201
MEPOLIZUMAB	NUCALA SOLR 100 MG	42775	075111	00173088101
MEPOLIZUMAB	NUCALA SOSY 100 MG/ML	42775	079828	00173089242

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

If using for Pulmonary indications:

- Prescriber is Pulmonologist, Allergist, or Rheumatologist,
- AND diagnosis of uncontrolled moderate to severe asthma defined as any of the following:
    - ≥2 exacerbations in the past 12 months requiring systemic corticosteroids for more than 3 days
    - ≥1 asthma exacerbation(s) leading to hospitalization in the past 12 months
    - Dependence on daily oral corticosteroids (OCS) for asthma control
    - Poor symptom control (ACT score less than 20)
- AND patient has uncontrolled asthma despite good adherence (at least 75% over the past 3 months) to a regimen containing: a high dose inhaled corticosteroid, long-acting beta 2 agonist, AND long-acting muscarinic antagonist, and consideration given to use of a leukotriene receptor antagonist,
- 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 for one of the following indications:
    - Eosinophilic asthma (non-OCS dependent) with serum eosinophil count ≥300 cells/microliter in the past 12 months,
    - OR eosinophilic asthma (OCS-dependent) with serum eosinophil count ≥150 cells/microliter in the past 12 months,
    - OR eosinophilic granulomatosis with polyangiitis in patients ≥18 years
- AND if using for eosinophilic asthma and aged 6-12 years, documented treatment failure, contraindication or inadequate response to Dupixent,
- AND if using for eosinophilic asthma and aged ≥12 years, documented treatment failure, contraindication or inadequate response to Fasenra AND Dupixent

If using for Chronic Rhinosinusitis with Nasal Polyps (CRSwNP):

- Prescriber is an Allergist or ENT Specialist,
- AND diagnosis of rhinosinusitis with nasal polyps,
- AND history of failure, inadequate response, contraindication, or intolerance to Dupixent (dupilumab) and Xolair (omalizumab)

If using for Hypereosinophilic Syndrome (HES):

- Medication is being prescribed by an Oncologist or in consultation with an Oncologist,
- AND patient is 12 years of age or older,
- AND documented diagnosis of HES

Continuation of Therapy Criteria:

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

Generic	Brand	HICL	GSN	Representative NDC
GLUTAMINE (SICKLE CELL)	ENDARI PACK 5 GM	856	078050	42457042001

Prior Authorization Criteria:
Length of Authorization: • Initial: 12 months • Reauthorization: 12 months
Initial Review Criteria: • Patient has documented diagnosis of sickle cell anemia or sickle beta-thalassemia, AND • Patient is ≥5 years, AND • Prescribed by a hematology-oncology specialist, AND • Patient is currently taking hydroxyurea, unless contraindication or intolerance, AND one of the following: o ≥2 sickle cell pain crises within prior 12 months requiring intervention (e.g., home-managed, hospitalizations, emergency department, or urgent care visits), OR o History of acute chest syndrome (documented by pulmonary infiltrate on chest x-ray films)
Continuation of Therapy Criteria: • Discontinue therapy if patient is nonadherent to follow-up assessment or medication itself, AND • No reduction in frequency of sickle cell pain crises and/or acute chest syndrome events

Mu-Opioid Receptor Antagonist, Peripherally-Acting

Generic	Brand	HICL	GSN	Representative NDC
NALDEMEDINE TOSYLATE	SYMPROIC TABS 0.2 MG	44176	077258	59011052330

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Gastroenterologist, Oncology, or Pain Specialist, AND
- Diagnosis of opioid induced constipation in an adult with an active opioid prescription, AND
- Opioid medication is being prescribed by an oncologist or a hospice/palliative care clinician for a patient currently enrolled in hospice or palliative care program, or after consultation with a pain management specialist, AND
- Patient has failed a trial of at least 2 weeks or has an intolerance or contraindication to scheduled dosing of the following medications, used in combination with other agent(s) with different mechanism of action (i.e., osmotic with a stimulant) and route of administration, AND:
    - Polyethylene glycol
    - Lactulose or sorbitol
    - Senna
    - Bisacodyl
- Inadequate response, contraindication or intolerance to both of the following:
    - Generic Amitiza (lubiprostone) – 1st line
    - Movantik – 2nd line

Continuation of Therapy Criteria:

- Positive clinical response to Symproic

Mu-Opioid Receptor Antagonist, Peripherally-Acting (Cont.)

Last revised: 7/5/2022

Generic	Brand	HICL	GSN	Representative NDC
NALOXEGOL OXALATE	MOVANTIK TABS 12.5 MG	41686	073335	00310196930
NALOXEGOL OXALATE	MOVANTIK TABS 25 MG	41686	073336	00310197030

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Gastroenterologist, Oncology, or Pain Specialist, AND
- Diagnosis of opioid induced constipation in an adult with an active opioid prescription, AND
- Opioid medication is being prescribed by an oncologist or a hospice/palliative care clinician for a patient currently enrolled in hospice or palliative care program, or after consultation with a pain management specialist, AND
- Patient has failed a trial of at least 2 weeks or has an intolerance or contraindication to scheduled dosing of the following medications, used in combination with other agent(s) with different mechanism of action (i.e., osmotic with a stimulant) and route of administration, AND:
    - Polyethylene glycol
    - Lactulose or sorbitol
    - Senna
    - Bisacodyl
- Inadequate response, contraindication or intolerance to generic Amitiza (lubiprostone)

Continuation of Therapy Criteria:

- Positive clinical response to Movantik

Notes:

Half-tab Movantik 25 mg is preferred

Generic	Brand	HICL	GSN	Representative NDC
METHYLNALTREXONE BROMIDE	RELISTOR SOLN 12 MG/0.6ML	35611	064011	65649055102
METHYLNALTREXONE BROMIDE	RELISTOR SOLN 12 MG/0.6ML	35611	068482	65649055103
METHYLNALTREXONE BROMIDE	RELISTOR SOLN 8 MG/0.4ML	35611	068483	65649055204
METHYLNALTREXONE BROMIDE	RELISTOR TABS 150 MG	35611	076398	65649015090

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

Oral tablets:

- Prescriber is a Gastroenterologist, Oncology, or Pain Specialist, AND
- Diagnosis of opioid induced constipation in an adult with an active opioid prescription, AND
- Opioid medication is being prescribed by an oncologist or a hospice/palliative care clinician for a patient currently enrolled in hospice or palliative care program, or after consultation with a pain management specialist, AND
- Patient has failed a trial of at least 2 weeks or has an intolerance or contraindication to scheduled dosing of ALL of the following medications, used in combination with other agent(s) with different mechanism of action (i.e., osmotic with a stimulant) and route of administration:
  - Polyethylene glycol
  - Lactulose or sorbitol
  - Senna
  - Bisacodyl
- AND inadequate response, contraindication or intolerance to the following:
  - Symproic (naldemidine)*PA
  - Movantik (naloxegol)*PA
  - Amitiza (lubiprostone)*PA

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

Injectable:

- Prescriber is a Gastroenterologist, Oncology, or Pain Specialist, AND
- Diagnosis of opioid induced constipation in an adult with an active opioid prescription, AND
- Opioid medication is being prescribed by an oncologist or a hospice/palliative care clinician for a patient currently enrolled in hospice or palliative care program, or after consultation with a pain management specialist, AND
- Patient is unable to take ANY oral medications (or unable to use any oral laxatives through feeding tube)

Continuation of Therapy Criteria:

- Positive clinical response to Relistor (oral tablets or injectable)

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

Overactive Bladder Agents, Beta-3 Adrenergic receptor

Generic	Brand	HICL	GSN	Representative NDC
MIRABEGRON	MYRBETRIQ TB24 25 MG	39357	069630	00469260130
MIRABEGRON	MYRBETRIQ TB24 50 MG	39357	069631	00469260290
VIBEGRON	GEMTESA			

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Patient has a diagnosis of overactive bladder, urge incontinence, urgency, urinary frequency or bladder spasm, AND
- Patient has an inadequate response*, intolerance**, contraindication to antimuscarinics or history of trial and failure of ≥ 2 of the following***
    - Oxybutynin OTC patch, oxybutynin IR/ER, solifenacin, darifenacin, tolterodine IR/ER, trospium IR/XR

Additional Questions for Gemesa only:

- Patient has an inadequate response*, intolerance**, contraindication, or history of trial and failure to Myrbetriq (mirabegron)

NOTES:

*An inadequate response is defined as no reduction of episodes of frequency or incontinence per day from baseline after an adequate trial period of 4-6 weeks.

** Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment and do not require medication discontinuation

*** Alternative antimuscarinics:

- Promote use of OTC products when possible
- When available, ER formulations are preferred over IR formulations
- KPMAS prescription antimuscarinic treatment algorithm for overactive bladder is as follows:

Age	1st Line	2nd Line
	Agents listed in order of preference	
Age < 65 years	• Oxybutynin ER • Solifenacin	• Darifenacin • Tolterodine ER
Age ≥ 65 years	• Solifenacin	• Darifenacin • Tolterodine ER

Continuation of Therapy Criteria:

- Patients previously taking mirabegron with good clinical response and history of trial and failure, inadequate response, intolerance, or contraindication to ≥ 2 of the following***:
    - Oxybutynin OTC patch, oxybutynin IR/ER, solifenacin, darifenacin, tolterodine IR/ER, trospium IR/XR

Additional Questions for Gemesa only:

- Patient has an inadequate response*, intolerance**, contraindication, or history of trial and failure to Myrbetriq (mirabegron)

Notes:

- Criteria only applies to new start patients

Potassium-Competitive Acid Blockers (PCABs), Anti-Ulcer H. pylori Agents

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

Generic	Brand	HICL	GSN	Representative NDC
VONOPRAZAN FUMARATE	VOQUEZNA TABS 10 MG	48007	084066	81520010030
VONOPRAZAN FUMARATE	VOQUEZNA TABS 20 MG	48007	083371	81520020030
AMOXICILLIN (TRIHYDRATE)-VONOPRAZAN FUMARATE	VOQUEZNA DUAL PAK THPK 500-20 MG	47981	083354	81520025001
AMOXICILLIN (TRIHYDRATE)-CLARITHROMYCIN-VONOPRAZAN FUMARATE	VOQUEZNA TRIPLE PAK THPK 500-500-20 MG	47983	083353	81520025501

Prior Authorization Criteria:

Length of Authorization:

- Initial: 1 month (*H. pylori*); 6 months (erosive esophagitis)
- Reauthorization: 6 months (for erosive esophagitis only)

Initial Review Criteria:

- Prescriber must be a Gastroenterologist, AND

If treating *Helicobacter pylori (H. pylori)* infection (1 month approval):

- Patient has a diagnosis of H. pylori infection,
- Patient is 18 years of age or older,
- Patient has had inadequate response, contraindication or intolerance to at least TWO of the following preferred therapies for H. pylori:
    - Clarithromycin-based quadruple therapy (i.e., amoxicillin + metronidazole + clarithromycin + pantoprazole) - *1st line*
    - Bismuth-based quadruple regimen (i.e. amoxicillin + clarithromycin + bismuth pantoprazole) - *1st line*
    - Bismuth-based quadruple regimen (i.e. metronidazole + doxycycline + bismuth + pantoprazole) - *1st line if patient has penicillin allergy*
    - Bismuth quadruple regimen (levofloxacin + bismuth + doxycycline + pantoprazole) - *2nd line*
    - Bismuth + metronidazole + doxycycline + pantoprazole OR bismuth + doxycycline + clarithromycin + pantoprazole) - *2nd line if suspected Levaquin resistance*
    - Rifabutin triple regimen (amoxicillin + rifabutin + pantoprazole) - *3rd line*
    - High dose dual regimen (amoxicillin 1gm + pantoprazole 40 mg BID) - *3rd line*
    - Levaquin quadruple (levofloxacin + bismuth + doxycycline or metronidazole + pantoprazole - *3rd line*

Note: If yes to all of the above, approve for 30 days with quantity limit of #112 per 14 days for 1 fill.

If treating erosive esophagitis (6 months approval):

- Patient has a diagnosis of erosive esophagitis (EE),
- Patient is 18 years of age or older,
- Patient has inadequate response (after an 8-week trial), contraindication or intolerance to at least FOUR of the following generic or over-the counter (OTC) PPIs:
    - Omeprazole (Prilosec)
    - Esomeprazole (Nexium)
    - Pantoprazole (Protonix)
    - Lansoprazole (Prevacid/Prevacid Solutab)
    - Rabeprazole (Aciphex), dexlansoprazole (Dexilant)

Continuation of Therapy Criteria (for EE indication ONLY):

- Patient has positive clinical response,
- Specialist follow-up occurred within the last 12 months

Potassium Sparing Diuretics

Last revised: 10/1/2024; Effective date: 12/3/2024

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 ≤5 mEq/L within past 3 months,
- AND documented adequate therapeutic trial (≥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

Pulmonary Fibrosis- Systemic Enzyme Inhibitors

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

Generic	Brand	HICL	GSN	Representative NDC
NINTEDANIB ESYLATE	OFEV CAPS 100 MG	41489	072961	00597014360
NINTEDANIB ESYLATE	OFEV CAPS 150 MG	41489	072962	00597014560

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Pulmonologist
- AND patient is a non-smoker,
- AND patient is not receiving concomitant treatment with pirfenidone or any CYP3A4 inducers,
- AND pregnancy has been excluded in patients of reproductive potential prior to starting treatment, and patient has been provided with contraceptive counseling on the risks of taking nintedanib if the patient were to become pregnant,
- AND using for one of the following diagnoses:
    - Idiopathic pulmonary fibrosis (IPF):
        - NO known cause of interstitial lung disease
        - AND patient has tried and failed prior use of pirfenidone (generic Esbriet)
    - OR diagnosis of progressive pulmonary fibrosis
    - 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

Dipeptidyl Peptidase-IV (DPP-IV) Inhibitors & Combinations

Last revised: 10/1/2024; Effective date: 12/3/2024

Generic	Brand	HICL
SAXAGLIPTIN HCL	ONGLYZA	36471
SITAGLIPTIN PHOSPHATE	JANUVIA	34126
SITAGLIPTIN PHOS/METFORMIN HCL	JANUMET JANUMET XR	34665

*representative list

Prior Authorization Criteria:

Length of Authorization:

- Initial: 1 year
- Reauthorization: 1 year

Initial Review Criteria:

- Diagnosis of diabetes mellitus type 2
- Patient ≥18 years old
- HbA1c within 2% above goal (as per ADA guidelines) within 90 days of the PA request *(Note: if A1c is >2% above goal, insulin therapy is recommended)*
- Patient is not on another DPP-4 inhibitor, or any agent within the GLP-1 agonist drug class,
- Patient has had adequate trial (90-days) of ALL of the following medications for diabetes, unless allergy or intolerance:
    - Metformin
    - Sulfonylurea
    - Pioglitazone (if BMI <35)
    - Jardiance
    - Sitagliptin (unbranded Zituvio)
    - Victoza[*PA]

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

Continuation of Therapy Criteria:

- Documented A1c lowering of 0.5% from initial, or A1c now at goal

Glucagon-Like Peptide-1 (GLP-1) Receptor Agonist

Last revised: 10/10/2024; Effective date: 12/3/2024

Generic	Brand	HICL
EXENATIDE MICROSPHERES	BYDUREON	38451
LIRAGLUTIDE	VICTOZA 2-PAK, VICTOZA 3-PAK	36436
DULAGLUTIDE	TRULICITY	41421
INSULIN DEGLUDEC-LIRAGLUTIDE	XULTOPHY	41880
INSULIN GLARGINE-LIXISENATIDE	SOLIQUA	43944
SEMAGLUTIDE	OZEMPIC	44675
SEMAGLUTIDE	RYBELSUS	44675

*representative list

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 6 months

Initial Review Criteria:

- Patient is not using for chronic weight loss management (CWM), unless patient is enrolled in and managed by KPMAS Pharmacy Weight Management Service *(if prescribed for CWM, refer to weight loss GLP-1 criteria for review)*,* AND
- Diagnosis of type 2 diabetes mellitus, AND
- Most recent HbA1c within 2% above goal (as per ADA guidelines) within 3 months of the PA request (*Note: if A1c is >2% above goal, insulin therapy is required),* AND
- Patient is not on another GLP-1 agonist or any agent within the DPP-4 inhibitor drug class, AND

If patient <u>has</u> diagnosis of ASCVD or indicators of high ASCVD risk [conditions include: acute coronary syndromes (ACS), history of myocardial infarction (MI), stable or unstable angina, coronary or other arterial revascularization, ischemic stroke, transient ischemic attack (TIA), carotid stenosis ≥50%, or symptomatic peripheral arterial disease (PAD) presumed to be of atherosclerotic origin]:

- Patient has failed adequate trial (adherence/MRAR ≥80% for at least 3 months) of metformin and Jardiance at maximum tolerated dose unless intolerance or contraindication

If patient <u>does not have</u> diagnosis of ASCVD or indicators of high ASCVD risk:

- Patient is currently taking, or has failed adequate trial (adherence/MRAR ≥80% for at least 3 months) of ALL of the following medications for diabetes, unless contraindication or intolerance:
    - Metformin
    - Sulfonylurea
    - Pioglitazone (if BMI <35)
    - Jardiance
    - Sitagliptin (unbranded Zituvio)

<u>Additional criteria for Ozempic:</u>

- Patient has documented trial, intolerance, or contraindication to Victoza[*PA]

<u>Additional criteria for Trulicity, Bydureon, or Rybelsus:</u>

- Patient has documented trial, intolerance, or contraindication to Victoza[*PA] and Ozempic[*PA]

<u>Additional criteria for Soliqua or Xultophy:</u>

- Patient has documented trial, intolerance, or contraindication to Victoza[*PA] and Ozempic[*PA]
- Patient has clinical need for use of the combination product over separate agents

*[*PA]This medication is also subject to PA review*
**Notes:*

- *Applies to Ozempic only*
- *MD Medicaid covers weight loss medications ONLY for MACE risk reduction*

Continuation of Therapy Criteria:

- Patient is not using for CWM, unless patient is enrolled in and managed by KPMAS Pharmacy Weight Management Service *(if prescribed for CWM, refer to weight loss GLP-1 criteria for review),* AND
- Diagnosis of type 2 diabetes mellitus, AND
- <u>If order is for Ozempic, Rybelsus, Trulicity, Bydureon, Xultophy, or Soliqua:</u> Patient has failed adequate trial (adherence/MRAR ≥80% for at least 3 months), or has intolerance or contraindication to Victoza, AND
- Patient has demonstrated good adherence/MRAR ≥80% to diabetic regimen, AND
- <u>If no diagnosis of ASCVD or indicators of high ASCVD risk</u>, patient must meet ONE of the following A1c requirements:
    - Achieved goal A1c, OR
    - Documented A1c lowering of 1% from initial (baseline A1c prior to starting GLP-1 agonist treatment), OR
    - Documented A1c lowering of 0.5% from time of last review

Anti-Obesity Glucagon-Like Peptide-1 Recep Agonist

Last revised: 9/3/2024; Effective date: 9/15/2024

Generic	Brand	HICL
SEMAGLUTIDE	WEGOVY	44675

*representative list

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 6 months

Initial Review Criteria:

- Patient is 18 years of age or older,
- Patient has established and documented atherosclerotic cardiovascular disease (ASCVD) and is either obese or overweight, defined as the following:
    - Obesity/overweight defined as:
        - For patient ≥27 kg/m^2
            - Documentation of BMI ≥27 kg/m^2 within the last 90 days (current height and weight)
    - ASCVD defined as one or more of the following:
        - Prior myocardial infarction
        - Prior stroke (ischemic or hemorrhagic stroke)
        - Symptomatic peripheral arterial disease (PAD) as evidenced by:
            - Intermittent claudication with ankle-brachial index (ABI) less than 0.85 (at rest); OR
            - Peripheral arterial revascularization procedure; OR
            - Amputation due to atherosclerotic disease
- Patient does NOT have type 1 or type 2 diabetes,
- Prescriber attests that medication is prescribed in accordance with prescribing information, including screening for any black box warnings and all contraindications,
- Co-administration with other semaglutide-containing products or with any other GLP-1 receptor agonist is not recommended and excluded from coverage

Continuation of Therapy Criteria:

- Patient continues to meet all initial criteria above

Growth Hormones

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

Generic	Brand	HICL	GSN	Representative NDC
LONAPEGSOMATROPIN-TCGD	SKYTROFA CART 11 MG	47565	082614	73362001001
LONAPEGSOMATROPIN-TCGD	SKYTROFA CART 13.3 MG	47565	082615	73362001101
LONAPEGSOMATROPIN-TCGD	SKYTROFA CART 3 MG	47565	082607	73362000301
LONAPEGSOMATROPIN-TCGD	SKYTROFA CART 3.6 MG	47565	082608	73362000401
LONAPEGSOMATROPIN-TCGD	SKYTROFA CART 4.3 MG	47565	082609	73362000501
LONAPEGSOMATROPIN-TCGD	SKYTROFA CART 5.2 MG	47565	082610	73362000601
LONAPEGSOMATROPIN-TCGD	SKYTROFA CART 6.3 MG	47565	082611	73362000701
LONAPEGSOMATROPIN-TCGD	SKYTROFA CART 7.6 MG	47565	082612	73362000801
LONAPEGSOMATROPIN-TCGD	SKYTROFA CART 9.1 MG	47565	082613	73362000901

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescribed by Pediatric Endocrinologist or Endocrinologist,
- Patient is ≥1 and <18 years of age, AND weighs ≥11.5 kg,
- Documented diagnosis of growth hormone deficiency (GHD) as indicated by BOTH of the following:
    - The patient's height is at least 2 Standard Deviations (SD) below the mean height for normal children of the same age and gender, or the patient has a height velocity that is less than 25th percentile for age,
    - The patient has a low peak growth hormone (less than 10 ng/ml) on two growth hormone stimulation tests, or has an Insulin-like growth factor 1 (IGF-1) that is at least 2 SD below the mean for same age and gender
- Documentation of open epiphyses (defined as bone age ≤16 years for males and ≤14 years for females),
- Documented inadequate response (of at least a 4-month trial), contraindication, or intolerance to Omnitrope (somatropin)

Continuation of Therapy Criteria:

- Patient has an annual growth velocity of at least 2 cm compared with what was observed from the previous year AND epiphyses are open (defined as bone age ≤16 years for males and ≤14 years for females)

Note: Quantity limit of 8 cartridges per 28-day supply

Growth Hormones (cont'd)

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

Generic	Brand	HICL	GSN	Representative NDC
SOMAPACITAN-BECO	SOGROYA SOPN 10MG/1.5ML	46831	081477	00169203011
SOMAPACITAN-BECO	SOGROYA SOPN 15MG/1.5ML	46831	084749	00169203711
SOMAPACITAN-BECO	SOGROYA SOPN 5MG/1.5ML	46831	083876	00169203511

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

Criteria for Pediatrics (<18 years of age):

- Prescribed by Pediatric Endocrinologist or Endocrinologist,
- Patient is ≥ 2.5 and <18 years of age,
- Documented diagnosis of growth hormone deficiency (GHD) as indicated by BOTH of the following:
    - The patient's height is at least 2 Standard Deviations (SD) below the mean height for normal children of the same age and gender, or the patient has a height velocity that is less than 25th percentile for age
    - The patient has a low peak growth hormone (less than 10 ng/ml) on two growth hormone stimulation tests, or has an Insulin-like growth factor 1 (IGF-1) that is at least 2 SD below the mean for same age and gender
- Documentation of open epiphyses (defined as bone age ≤16 years for males and ≤14 years for females),
- Documented inadequate response (of at least a 4-month trial), contraindication, or intolerance to Omnitrope (somatropin)

Criteria for Adults (≥18 years of age):

- Prescribed by endocrinologist,
- Patient is ≥18 years of age,
- Documented diagnosis of adult- OR childhood onset of growth hormone deficiency (GHD), with biochemical diagnosis of GHD confirmed via two GH stimulation tests (see note below)
- Documented inadequate response (of at least a 4-month trial), contraindication, or intolerance to Omnitrope or other somatropin product

Continuation of Therapy Criteria:

- Documented positive response to therapy (i.e., the patient has an annual growth velocity of at least 2 cm compared with what was observed from the previous year),
- If patient is <18 years of age, epiphyses are open (defined as bone age ≤16 years for males and ≤14 years for females)

Notes:

- Quantity limit of 4 pens per 28-day supply
- No retesting required for those with known mutations, congenital defects, irreversible hypothalamic-pituitary structural lesions, or evidence of panhypopituitarism (at least 3 pituitary hormone deficiencies), with serum IGF-1 levels below the age- and sex-appropriate reference range off GH therapy

Hepatitis C Agents

Last revised: 6/13/2024; Effective date: 8/13/2024

Generic	Brand	HICL	GCN
LEDIPASVIR/SOFOSBUVIR	HARVONI	41457	
SOFOSBUVIR	SOVALDI		35708
OMBITASVIR/PARITAPREV/RITONAV	TECHNIVIE	41734	
ELBASVIR/GRAZOPREVIR	ZEPATIER	43030	
SOFOSBUVIR/VELPATASVIR	EPCLUSA	43561	
SOFOSBUVIR-VELPATASVIR-VOXILAPREVIR	VOSEVI	44428	
GLECAPREVIR-PIBRENTASVIR	MAVYRET	44453	

*representative list

Prior Authorization Criteria:

Length of Authorization:

- Initial: Standard course of treatment
- Reauthorization: N/A

Pediatric use:

- Patients ≥ 3 years old
  - Epclusa
  - Harvoni
  - Mavyret

Initial Review Criteria:

- Patient must be ≥ 18 years old
- Documentation of diagnosis of Acute Hepatitis C, Chronic Hepatitis C, Hepatocellular Carcinoma, Decompensated Cirrhosis (Child Pugh Score Class B or C), and/or Compensated cirrhosis
- Documentation of HCV RNA within 180 days of application for therapy, unless the patient is cirrhotic then the baseline lab values must be within 90 days of prior authorization request
- For Chronic Hep C documented evidence that Hep C is present for ≥ 6 months established by one of the following:
  - Lab testing such as an HCV antibody or HCV RNA test completed 6 months apart
  - HCV diagnosis documented in prescribers note from the past office visit(s)
  - Exposure risk history documented in prescribers notes from the past office visit(s)
- Documentation of HCV genotype test result, liver biopsy results, and fibrosis test results
- Selected therapy should be FDA-approved based on indication and specific genotype
- Documentation of prescriber assessment of patient's adherence with medical and pharmacological treatment and review of Hepatitis C treatment plan with patient
- Documentation of any past treatment for Hepatitis C with dates, agents, and outcomes
  - Genotype pre-DAA therapy and date
  - Genotype post-DAA therapy and date

    - Patient outcome, i.e., relapsed, partial responder, non-responder, failed therapy due to toxicities, reinfection
- Documentation of baseline hepatic panel, CBC, GFR/Scr, Child-pugh Score, negative Q80K Polymorphism (Sovaldi), NS5A Polymorphisms (Zepatier) laboratory results including type of test used:
    - Baseline HCV RNA Level
    - HCV RNA Week 4 of Treatment:
    - HCV RNA Week 6 of Treatment (recommended only when detectable at week 4)
    - HCV RNA Other or End of Treatment:
- History of HIV infection including viral load and date drawn, and current antiretroviral regimen
- History of HBV infection inducing status, viral load, date drawn, and current antiretroviral regimen
- History of solid organ transplant, specify type of transplant and date
- If the patient's Medicaid eligibility changes during therapy and the patient is no longer eligible for Medicaid prescription drug assistance, physician to enroll the patient in other patient assistant drug programs to complete therapy and provide

Retreatment Criteria:

- Previous exposure to an HCV treatment direct acting antiviral (DAA) regimen, which does NOT result in achievement of SVR and current need for an additional course of therapy to treat chronic HCV infection.
  Conditions required:
    - Detectable HCV RNA at 12 weeks post treatment.
    - HCV genotype is the SAME before and after the INITIAL HCV treatment regimen.

Reinfection:

Exposure to an HCV treatment regimen, which results in achievement of SVR.
Conditions required:

- Detectable HCV RNA > 12 weeks post treatment
- HCV genotype is DIFFERENT after the INITIAL HCV treatment regimen.
- Current infection has been present ≥ 6 months.

Opioid Agents

Short-Acting Opioids
Long-Acting Opioids, including Fentanyl products
Methadone

Prior Authorization Criteria:

Length of Authorization:

- Initial: 1 month for acute/post-op pain; up to 6 months for chronic pain
- Reauthorization: Up to 6 months for chronic pain

Initial Review Criteria:

- Authorization required for:
  - All Long Acting Opioids
  - Any Fentanyl products
  - Methadone
  - Any opioid (short- and long-acting) exceeding Morphine Milligram Equivalents (MME) dose of 90 mg/day
  - Opioids Exceeding quantity limits set by MDH
- Authorization Exclusion Criteria:
  - Active cancer treatment
  - Sickle Cell disease
  - Hospice or Palliative Care
  - Long Term Care
- Documentation of type of pain being treated
- Documentation of non-opioid treatments trial and outcome
- Prescriber attests to checking the PDMP (CRISP) and documents the last fill date of the patient's most recent opioid prescription
- Documentation of clinical rationale if patient's total MME exceeds 90 mg/day when including the requested opioid(s)
- For inpatient hospital based, ambulatory surgery and emergency room prescribers, attestation required of the following:
  - The risks associated with opioid use discussed with patient/patient's household
  - Naloxone prescription provided or offered to patient/patient's household
  - The patient is exempt from need for patient-provider agreement and random urine drug screen because they are being discharged from hospital/ambulatory surgery/emergency department and opioid treatment is for less than 30 days
- For outpatient prescribers providing on-going care, attestation required of the following:
  - Documentation of a treatment plan and signed agreement with the patient
  - Documentation of random urine drug screen
  - Naloxone prescription provided or offered to patient/patient's household

Proprotein Convertase Subtilisin Kexin Type-9 (PCSK-9) Inhibitors

Generic	Brand	HICL
ALIROCUMAB	PRALUENT	42347
EVOLOCUMAB	REPATHA	42378

*representative list

Prior Authorization Criteria:

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 includes:
                - ❑ 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 a 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%

Sphingosine 1-Phosphate (S1P) Receptor Modulator

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

Generic	Brand	HICL	GSN	Representative NDC
ETRASIMOD ARGININE	VELSIPITY TABS 2 MG	49267	085399	00069027430

Prior Authorization Criteria:

Length of Authorization:

- Initial: 3 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Gastroenterologist,
- Documented moderate-to-severe active ulcerative colitis,
- Inadequate response, contraindication, or inability to tolerate ONE conventional therapy (e.g., mesalamine, azathioprine, or 6-mercaptopurine),
- Inadequate response, contraindication, or inability to tolerate corticosteroids
- Documented inadequate response (after at least a 3-month trial), intolerance, or contraindication to ALL of the following:
    - Infliximab product (Inflectra preferred) OR adalimumab product (Amjevita preferred)
    - Entyvio (vedolizumab)*PA
    - Xeljanz (tofacitinib)*PA or Rinvoq (upadacitinib)*PA

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

Continuation of Therapy Criteria:

- Positive clinical response to medication,
- Specialist follow-up has occurred since last review

Notes: Velsipity is preferred over Zeposia for UC indication

Sphingosine 1-Phosphate (S1P) Receptor Modulator (cont'd)

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

Generic	Brand	HICL	GSN	Representative NDC
OZANIMOD HCL	ZEPOSIA 7-DAY STARTER PACK CPPK 4 X 0.23MG & 3 X 0.46MG	46431	080878	59572081007
OZANIMOD HCL	ZEPOSIA CAPS 0.92 MG	46431	080877	59572082030
OZANIMOD HCL	ZEPOSIA STARTER KIT CPPK 0.23MG & 0.46MG & 0.92MG (21)	46431	084883	59572089091

Prior Authorization Criteria:

Length of Authorization:

- Initial: 3 months
- Reauthorization: 12 months

Initial Review Criteria:

If using for Ulcerative Colitis (UC):

- Prescriber is a Gastroenterologist,
- Documented moderate-to-severe active Ulcerative Colitis,
- Inadequate response, contraindication, or inability to tolerate ONE conventional therapy (e.g., mesalamine, azathioprine, or 6-mercaptopurine),
- Inadequate response, contraindication, or inability to tolerate corticosteroids,
- Documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to ALL of the following:
    - Infliximab product (Inflectra preferred) OR adalimumab product (Amjevita preferred),
    - Entyvio*PA (vedolizumab),
    - Xeljanz (tofacitinib)*PA or Rinvoq (upadacitinib)*PA

If using for Multiple Sclerosis (MS):

- Prescriber is a Neurologist,
- Patient has diagnosis of relapsing form of multiple sclerosis (including non-progressive relapsing, progressive relapsing, relapsing remitting),
- Patient has failed an adequate trial (≥3 months) of, or has a documented allergy or intolerance to, or is not a candidate for Truxima (rituximab-abbs) (first-line preferred) or Tysabri (natalizumab),
- Patient has a documented trial and intolerance to fingolimod (Gilenya) that is expected to be reduced with ozanimod (Zeposia),
- Patient is not using in addition to another DMT

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

Continuation of Therapy Criteria:

If using for Ulcerative Colitis:

- Positive clinical response to medication,
- Specialist follow-up occurred in the past 12 months

If using for Multiple Sclerosis:

- Patient is not using in addition to another DMT,
- Patient is experiencing positive clinical response,
- Patient has been seen by a Dermatologist AND Ophthalmologist in the past 12 months

Notes:

- Velsipity preferred over Zeposia for **UC** indication
- Fingolimod (Gilenya) is the preferred alternative to ozanimod for **MS** as they have highly similar modes of action
- In addition to above criteria, review patient eligibility based on clinical parameters. Multiple drug-drug interactions and drug-disease state interactions exist for this agent.

Sodium Glucose Cotransporter-2 (SGLT-2) Inhibitors

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

Generic	Brand	HICL
DAPAGLIFLOZIN	FARXIGA	40137
CANAGLIFLOZIN	INVOKANA	40171
DAPAGLIFLOZIN-METFORMIN HCL	XIGDUO XR	41188
CANAGLIFLOZIN-METFORMIN HCL	INVOKAMET	41287
EMPAGLIFLOZIN-LINAGLIPTIN	GLYXAMBI	41724
DAPAGLIFLOZIN/SAXAGLIPTIN HCL	QTERN	43957
ERTUGLIFLOZIN L-PYROGLUTAMIC ACID	STEGLATRO	44709
ERTUGLIFLOZIN-SITAGLIPTIN	STEGLUJAN	44706
ERTUGLIFLOZIN-METFORMIN	SEGLUROMET	44716

*representative list

Prior Authorization Criteria:

Length of Authorization:

- Initial: 1 year
- Reauthorization: 1 year

Initial Review Criteria (For Diabetes treatment indication):

- Diagnosis of diabetes mellitus type 2
- Patient > 18 years old
- HbA1c within 2% above goal (as per ADA guidelines) within 90 days of the PA request *(Note: if A1c is >2% above goal, insulin therapy is recommended)*
- Patient has had adequate trial (90 days) of BOTH of the following preferred oral medications: metformin and Jardiance at maximum tolerated dose unless resulting in a therapeutic failure, contraindication, or intolerance
- Patient must meet ONE of the following:
    - Patient has at least one of the following 3 qualifying conditions:
        - Atherosclerotic Cardiovascular Disease (ASCVD) [conditions include acute coronary syndromes (ACS), history of myocardial infarction (MI), stable or unstable angina, coronary or other arterial revascularization, ischemic stroke, transient ischemic attack (TIA), or symptomatic peripheral arterial disease (PAD)]
        - Chronic Kidney Disease (must have GFR between 30 and 59 mL/min or urine albumin/creatinine ratio over 300 mg/g, and on maximally tolerated dose of ACEI/ARB unless allergy or intolerance
        - Heart Failure
    - OR patient has had adequate trial (90 days) of ALL of the following more preferred medications for diabetes, unless allergy or intolerance:
        - Sulfonylurea
        - Pioglitazone (if BMI <35)
        - Sitagliptin (unbranded Zituvio)
        - Victoza[*PA]

Additional criteria for Invokana/Invokamet/Invokamet XR:

- Patient should NOT have a history of diabetes-related lower limb amputation or diabetic foot ulceration

Initial Review Criteria (For Heart Failure treatment indication – Farxiga and Xigduo XR ONLY):

- Diagnosis of heart failure with ejection fraction of 40% or less,
- Prescribed by or in consultation with Cardiology,
- Patient is on maximally tolerated dose, or patient has an allergy or intolerance* to ACE/ARB and beta blocker,
- Patient has eGFR of at least 20 mL/min,
- Failed adequate trial (≥3 months), had intolerance to, or contraindication to Jardiance

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

Continuation of Therapy Criteria:

- If treating DM and no qualifying conditions, must have documented A1c lowering at least 0.5% from initial or A1c now at goal

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:

Length of Authorization:

- Initial: 3 months
- Reauthorization: 6 months

Initial Review Criteria:

- Prescribed by immunologist or allergist,
- AND patient is 12 years of age or older,
- AND patient weighs ≥45 kg,
- AND documented diagnosis of activated PI3Kδ syndrome (APDS; also known as PASLI disease),
- AND documented nodal and/or extranodal lymphoproliferation, clinical findings/manifestations compatible with APDS (e.g., history of repeated oto-sino-pulmonary infections, and/or organ dysfunction), and presence of ≥1 measurable nodal lesion on a CT or MRI scan
- AND for females of childbearing age (12 to 50 years of age):
    - Documented baseline negative pregnancy test within the past month
    - AND must be on at least one form of a highly effective method of contraception during treatment and 1 week after the last dose

Continuation of Therapy Criteria:

- Patient meets all initial criteria,
- AND no documented disease progression,
- AND documented reduction in the size of nodal lesions on CT or MRI scan

Vasodilating Agents - Respiratory Tract

Generic	Brand	HICL	GSN	Representative NDC
RIOCIGUAT	ADEMPAS TABS 0.5 MG	40644	071525	50419025001
RIOCIGUAT	ADEMPAS TABS 1 MG	40644	071526	50419025101
RIOCIGUAT	ADEMPAS TABS 1.5 MG	40644	071527	50419025301
RIOCIGUAT	ADEMPAS TABS 2 MG	40644	071528	50419025301
RIOCIGUAT	ADEMPAS TABS 2.5 MG	40644	071529	50419025401

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Pulmonologist or Cardiologist

Pulmonary Arterial Hypertension

- Diagnosis of pulmonary arterial hypertension World Health Organization [WHO] Group I Patient diagnosed with WHO/New York Heart Association Functional Class II, III or IV symptoms, AND
- Patient is NOT pregnant, AND
- Patients does NOT have pulmonary hypertension associated with idiopathic interstitial pneumonias (PH-IIP), AND
- Documented treatment failure, intolerance or contraindication to sildenafil or tadalafil (phosphodiesterase-5 inhibitors), AND
- Documented treatment failure, intolerance or contraindication to ambrisentan (generic Letairis®) or bosentan (generic Tracleer) or macitentan (Opsumit®), AND
- Patient is not currently receiving intravenous prostanoid analogues (e.g. treprostinil (Remodulin®) or epoprostenol (Flolan®)) orphosphodiesterase type (PDE-5) inhibitor (e.g. sildenafil (Revatio®), tadalafil (Adcirca®))

Chronic Thromboembolic Pulmonary Hypertension (CTEPH)

- Diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH)
- Patient is NOT pregnant AND
- Patient is not a candidate for pulmonary endarterectomy OR
- Persistent recurrent CTEPH after pulmonary endarterectomy based on pulmonology/cardiology recommendations

Continuation of Therapy Criteria:

- Documentation the patient is experiencing clinical benefit from therapy as evidenced by disease stability or disease improvement, AND
- Patient continues to meet initial review criteria

Notes:

- Prescribers, female patients, and pharmacies must enroll in the restricted distribution program as part of a REMS
- Adempas is not recommended in patients with pulmonary veno-occlusive (PVOD) disease or in patients with creatinine clearance <15mL/minute or on dialysis.

Vasodilating Agents - Respiratory Tract (cont'd)

Generic	Brand	HICL	GSN	Representative NDC
AMBRISENTAN	LETAIRIS	34849	062792	61958-0801-05
AMBRISENTAN	LETAIRIS	34849	062793	61958-0802-01
BOSENTAN	TRACLEER	22990	048987	66215-0102-06
BOSENTAN	TRACLEER	22990	048988	66215-0101-06
BOSENTAN	TRACLEER	22990	077706	66215-0103-56
MACITENTAN	OPSUMIT TABS 10 MG	40677	071567	66215050115

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Pulmonologist or Cardiologist, AND
- Diagnosis of pulmonary arterial hypertension World Health Organization [WHO] Group I OR
- Patient diagnosed with WHO/New York Heart Association Functional Class II, III or IV symptoms, AND
- Patient is not pregnant, AND
- Documented treatment failure, intolerance or contraindication to bosentan (generic Tracleer), ambrisentan (generic Letairis)
- For Letairis (ambrisentan) only: Patient is NOT diagnosed with idiopathic pulmonary fibrosis
- For Opsumit (macitentan) only: Documented treatment failure, intolerance or contraindication to bosentan (generic Tracleer), ambrisentan (generic Letairis)

Continuation of Therapy Criteria:

- Documentation the patient is experiencing clinical benefit from therapy as evidenced by disease stability or disease improvement, AND
- Patient continues to meet initial review criteria

Notes:

- ERAs are generally not recommended in moderate (Child-Pugh Class B) to severe hepatic impairment (Child-Pugh Class C), or in patients with AST/ALT levels greater than 3 times the upper limit of normal (ULN) or bilirubin greater than 2 ULN. Dose of bosentan may be adjusted if AST/ALT>3 times ULN but ≤ 8 times ULN.
- Ambrisentan and bosentan are available through restricted risk evaluation and mitigation strategy (REMS)
- Bosentan is contraindicated in patients currently receiving cyclosporine A or glyburide

Vasodilating Agents - Respiratory Tract (cont'd)

Last revised: 10/3/2023

Generic	Brand	HICL	GSN	Representative NDC
SELEXIPAG	UPTRAVI TABS 200 MCG	42922	075312	66215060214
SELEXIPAG	UPTRAVI TABS 400 MCG	42922	075313	66215060406
SELEXIPAG	UPTRAVI TABS 600 MCG	42922	075314	66215060606
SELEXIPAG	UPTRAVI TABS 800 MCG	42922	075315	66215060806
SELEXIPAG	UPTRAVI TABS 1000 MCG	42922	075316	66215061006
SELEXIPAG	UPTRAVI TABS 1200 MCG	42922	075317	66215061206
SELEXIPAG	UPTRAVI TABS 1400 MCG	42922	075318	66215061406
SELEXIPAG	UPTRAVI TABS 1600 MCG	42922	075319	66215061606
SELEXIPAG	UPTRAVI TBPK 200 & 800 MCG	42922	075321	66215062820
TREPROSTINIL	TYVASO STARTER SOLN 0.6 MG/ML	36537	065500	66302020601
TREPROSTINIL	TYVASO REFILL SOLN 0.6 MG/ML	36539	065501	66302020602
TREPROSTINIL	TYVASO SOLN 0.6 MG/ML	36541	065502	66302020603
TREPROSTINIL DIOLAMINE	ORENITRAM TBCR 0.125 MG	40827	071808	66302030001
TREPROSTINIL DIOLAMINE	ORENITRAM TBCR 0.25 MG	40827	071807	66302030201
TREPROSTINIL DIOLAMINE	ORENITRAM TBCR 1 MG	40827	071809	66302031001
TREPROSTINIL DIOLAMINE	ORENITRAM TBCR 2.5 MG	40827	071810	66302032501
TREPROSTINIL DIOLAMINE	ORENITRAM TBCR 5 MG	40827	077482	66302035001
TREPROSTINIL DIOLAMINE	ORENITRAM MONTH 1 TEPK 0.125 & 0.25 MG	40827	084443	66302036128
TREPROSTINIL DIOLAMINE	ORENITRAM MONTH 2 TEPK 0.125 & 0.25 MG	40827	084441	66302036256
TREPROSTINIL DIOLAMINE	ORENITRAM MONTH 3 TEPK 0.125 & 0.25 & 1 MG	40827	084442	66302036384

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Pulmonologist or Cardiologist, AND
- Diagnosis of pulmonary arterial hypertension World Health Organization [WHO] Group I OR
- Patient diagnosed with WHO/New York Heart Association Functional Class II, III or IV symptoms, AND
- Patient is not currently receiving a prostanoid/prostacyclin analogue (e.g. treprostinil (Orenitram®, Tyvaso®, Remodulin®)), AND
- Documented treatment failure, intolerance, or contraindication to at least two of the following:
    - One phosphodiesterase type (PDE-5) inhibitor (e.g. sildenafil (Revatio®), tadalafil (Adcirca®) OR
    - One endothelin receptor antagonist (ERA) (e.g. ambrisentan (Letairis®), or bosentan (Tracleer®) or macitentan (Opsumit) OR
    - A soluble guanylate cyclase stimulator Riociguat (Adempas®)

Continuation of Therapy Criteria:

- Documentation the patient is experiencing clinical benefit from therapy as evidenced by disease stability or disease improvement, AND
- Patient continues to meet initial review criteria

Notes:

- Uptravi is contraindicated with concomitant use with strong CYP2C8 inhibitors (e.g. gemfibrozil)
- Orenitram is contraindicated in severe hepatic impairment (Child-Pugh class C)