Kaiser Permanente Mid-Atlantic States Region (KPMAS) Commercial/Exchange/FEHB Formulary Prior Authorization Criteria

Effective 02/03/2026

Reference:

KPMAS Regional Pharmacy and Therapeutics Committee (P&T)

P&T Approval/Revision Date: 12/05/2025, 10/03/2025, 08/01/2025, 06/06/2025, 04/04/2025, 02/07/2025, 12/06/2024, 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, 07/05/2022, 06/07/2022, 04/05/2022, 05/14/2021, 11/6/2020, 7/29/2020, 5/1/2020

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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
PEGINTERFERON BETA-1A	PLEGRIDY SOSY 125 MCG/0.5ML	41331	081976	64406001701
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

Agents to Treat Multiple Sclerosis – Modestly Effective Therapy (Cont'd)

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 ALL 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: 1/29/2025; Effective date: 4/1/2025

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
SIPONIMOD FUMARATE	MAYZENT STARTER PACK TBPK 7 x 0.25 MG	45670	083189	00078097989
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
PONESIMOD	PONVORY STARTER PACK TBPK 2-3-4-5-6-7-8-9 & 10 MG	47221	082093	50458070714
PONESIMOD	PONVORY TABS 20 MG	47221	082092	50458072030

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
    - KP-preferred rituximab biosimilar *(Refer to Notes section for guidance on the preferred rituximab option)* or Tysabri (natalizumab), AND
- Patient is not using in addition to another DMT, AND
- Patient does NOT have any of the following contraindications:
    - Myocardial infarction in the last 6 months
    - Unstable angina in the last 6 months
    - Stroke or transient ischemic attack in the last 6 months
    - Decompensated heart failure requiring hospitalization, or class III or IV HF in the last 6 months
    - Mobitz type II second- or third-degree atrioventricular block, sick sinus syndrome, or sinoatrial block, unless the patient has a functioning pacemaker
    - Additional criteria for Mayzent (siponimod):
        - CYP2C9*3/*3 Genotype
    - Additional criteria for Gilenya:
        - QTc interval of 500 milliseconds or greater
        - Concurrent use of class Ia or III antiarrhythmic
        - Concurrent use with other products containing fingolimod (e.g., Tascensco ODT)

Notes:

- Serious precautions regarding QTc:
    - Mayzent and Ponvory: Consult with a cardiologist before initiating ponesimod in patients with QTc >500 msec
- In addition to CBC criteria, review patient eligibility based on clinical parameters. Multiple drug-drug interactions and drug-disease state interactions exist for this agent
- Riabni is the KP-preferred rituximab biosimilar if rituximab has never been tried

Continuation of Therapy Criteria:

- Patient is not using in addition to another DMT, AND
- Patient is experiencing positive clinical response, AND
- Patient has been seen by a dermatologist AND ophthalmologist in the past 12 months (to rule out skin cancer and macular edema)

Agents to Treat Multiple Sclerosis – Highly Effective Therapy (cont'd)

Generic	Brand	HICL	GSN	Representative NDC
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

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
    - KP-preferred rituximab biosimilar (Refer to the Notes section for guidance on the preferred rituximab option) or Tysabri (natalizumab),
- 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

Notes:

- In addition to CBC criteria, review patient eligibility based on clinical parameters. Multiple drug-drug interactions and drug-disease state interactions exist for this agent.
- Riabni is the KP-preferred rituximab biosimilar if rituximab has never been tried

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, AND • 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: 1/31/2025; Effective date: 4/1/2025

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

Prior Authorization Criteria:

Length of Authorization:

- Initial: 3 months
- Reauthorization: 6 months

Initial Review Criteria:

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

Continuation of Therapy Criteria:

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

Nuclear Factor Erythroid 2-Rel. Factor 2 Activator

Last revised: 2/6/2024

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

Prior Authorization Criteria:

Length of Authorization:

- Initial: 3 months
- Reauthorization: 6 months

Initial Review Criteria:

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

Continuation of Therapy Criteria:

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

Anthelmintics

Generic	Brand	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

Attention Deficit-Hyperactive (ADHD)/Narcolepsy

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

Generic	Brand	HICL	GSN	Representative NDC
METHYLPHENIDATE HCL	QUILLIVANT XR SRER 25 MG/5ML	1682	070374	24478020525
METHYLPHENIDATE HCL	QUILLICHEW ER CHER 20 MG	1682	075263	24478007401
METHYLPHENIDATE HCL	QUILLICHEW ER CHER 30 MG	1682	075264	24478013001
SERDEXMETHYLPHENIDATE CHLORIDE-DEXMETHYLPHENIDATE HCL	AZSTARYS CAPS 26.1-5.2 MG	47187	082022	65038028699
SERDEXMETHYLPHENIDATE CHLORIDE-DEXMETHYLPHENIDATE HCL	AZSTARYS CAPS 39.2-7.8 MG	47187	082023	65038042999
SERDEXMETHYLPHENIDATE CHLORIDE-DEXMETHYLPHENIDATE HCL	AZSTARYS CAPS 52.3-10.4 MG	47187	082024	65038056199
METHYLPHENIDATE HCL	JORNAY PM CP24 20 MG	1682	078724	71376020103
METHYLPHENIDATE HCL	JORNAY PM CP24 40 MG	1682	078725	71376020203
METHYLPHENIDATE HCL	JORNAY PM CP24 60 MG	1682	078726	71376020303
METHYLPHENIDATE HCL	JORNAY PM CP24 80 MG	1682	078727	71376020403
METHYLPHENIDATE HCL	JORNAY PM CP24 100 MG	1682	078728	71376020503
METHYLPHENIDATE HCL	RELEXXII TBCR 18 MG	1682	045981	68025009510
METHYLPHENIDATE HCL	RELEXXII TBCR 27 MG	1682	050172	68025009610
METHYLPHENIDATE HCL	RELEXXII TBCR 36 MG	1682	045982	68025009710
METHYLPHENIDATE HCL	RELEXXII TBCR 45 MG	1682	083501	68025008830
METHYLPHENIDATE HCL	RELEXXII TBCR 54 MG	1682	047318	68025009810
METHYLPHENIDATE HCL	RELEXXII TBCR 63 MG	1682	083502	68025008930
METHYLPHENIDATE HCL	RELEXXII TBCR 72 MG	1682	078038	68025008410

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Patient is ≥ 6 years of age AND
- Has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) as confirmed by psychoeducational testing***, AND
- Patient has had an adequate trial* (1 week) and/or intolerance** or allergy to:
    - Dextroamphetamine-amphetamine (generic Adderall XR)
    - AND intermediate or long-acting methylphenidate (methylphenidate SR, methylphenidate CD, or methylphenidate ER),
    - AND dexmethylphenidate (generic Focalin XR)

NOTES:

*Adequate trial of a long-acting agent is further defined as wearing off that is not resolved by increasing the dose, AND adding a short-acting agent OR increasing frequency to twice daily OR clinically significant side effects related to the dosage form that cannot be resolved by adjusting the dose or timing

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

***Criteria only applies for 18 years of age and older

Continuation of Therapy Criteria:

- Patient meets initial review criteria and has demonstrated positive clinical response to medication

Generic	Brand	HICL	GSN	Representative NDC
METHYLPHENIDATE	DAYTRANA PTCH 10 MG/9HR	33556	060615	68968555201
METHYLPHENIDATE	DAYTRANA PTCH 15 MG/9HR	33556	060616	68968555303
METHYLPHENIDATE	DAYTRANA PTCH 20 MG/9HR	33556	060617	68968555403
METHYLPHENIDATE	DAYTRANA PTCH 30 MG/9HR	33556	060618	68968555503
METHYLPHENIDATE	COTEMPLA XR-ODT TBED 8.6 MG	33556	077494	70165010030
METHYLPHENIDATE	COTEMPLA XR-ODT TBED 17.3 MG	33556	077495	70165020030
METHYLPHENIDATE	COTEMPLA XR-ODT TBED 25.9 MG	33556	077496	70165030030

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Patient is between the ages of 6 years and 17 years AND
- Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) as confirmed by psychoeducational testing***, AND
- Patient has had an adequate trial* (1 week) and/or intolerance** or allergy to dextroamphetamine-amphetamine (generic Adderall XR), intermediate or long-acting methylphenidate (methylphenidate SR, methylphenidate CD, or methylphenidate ER), and dexmethylphenidate (generic Focalin XR)

NOTES:

*Adequate trial of a long-acting agent is further defined as wearing off that is not resolved by increasing the dose, AND adding a short-acting agent OR increasing frequency to twice daily OR clinically significant side effects related to the dosage form that cannot be resolved by adjusting the dose or timing

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

***Criteria only applies for 18 years of age and older

Continuation of Therapy Criteria:

- Patient meets initial review criteria and has demonstrated positive clinical response to medication

Generic	Brand	HICL	GSN	Representative NDC
AMPHETAMINE SULFATE	EVEKEO ODT TBDP 5 MG	2064	079479	24338003101
AMPHETAMINE SULFATE	EVEKEO ODT TBDP 10 MG	2064	079480	24338003301
AMPHETAMINE SULFATE	EVEKEO ODT TBDP 15 MG	2064	079481	24338003501
AMPHETAMINE SULFATE	EVEKEO ODT TBDP 20 MG	2064	079482	24338003715

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Patient is 6 years of age or older, AND
- Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) as confirmed by psychoeducational testing***, AND
- Patient has had an adequate trial* (1 week) and/or intolerance** or allergy to dextroamphetamine-amphetamine (generic Adderall), dextroamphetamine (generic Dexedrine) and methylphenidate (generic Ritalin, Methylin)

NOTES:

*Adequate trial is further defined as clinically significant side effects related to the dosage form that cannot be resolved by adjusting the dose or timing

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

***Criteria only applies for 18 years of age and older

Continuation of Therapy Criteria:

- Patient meets initial review criteria and has demonstrated positive clinical response to medication

Generic	Brand	HICL	GSN	Representative NDC
AMPHETAMINE-DEXTROAMPHETAMINE	MYDAYIS CP24 12.5 MG	13449	077498	54092046801
AMPHETAMINE-DEXTROAMPHETAMINE	MYDAYIS CP24 25 MG	13449	077499	54092047101
AMPHETAMINE-DEXTROAMPHETAMINE	MYDAYIS CP24 37.5 MG	13449	077500	54092047401
AMPHETAMINE-DEXTROAMPHETAMINE	MYDAYIS CP24 50 MG	13449	077501	54092047701

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Patient is 13 years of age or older, AND
- Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) as confirmed by psychoeducational testing***, AND
- Patient has had an adequate trial* (1 week) and/or intolerance** or allergy to dextroamphetamine-amphetamine (generic Adderall XR), intermediate or long-acting methylphenidate (methylphenidate SR, methylphenidate CD, or methylphenidate ER), and dexmethylphenidate (generic Focalin XR)

NOTES:

*Adequate trial of a long-acting agent is further defined as wearing off that is not resolved by increasing the dose, AND adding a short-acting agent OR increasing frequency to twice daily OR clinically significant side effects related to the dosage form that cannot be resolved by adjusting the dose or timing

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

***Criteria only applies for 18 years of age and older

Continuation of Therapy Criteria:

- Patient meets initial review criteria and has demonstrated positive clinical response to medication

Generic	Brand	HICL	GSN	Representative NDC
AMPHETAMINE	ADZENYS XR-ODT TBED 12.5 MG	43652	075547	70165002030
AMPHETAMINE	ADZENYS XR-ODT TBED 15.7 MG	43652	075548	70165002530
AMPHETAMINE	ADZENYS XR-ODT TBED 18.8 MG	43652	075549	70165003030
AMPHETAMINE	ADZENYS XR-ODT TBED 3.1 MG	43652	075544	70165000530
AMPHETAMINE	ADZENYS XR-ODT TBED 6.3 MG	43652	075545	70165001030
AMPHETAMINE	ADZENYS XR-ODT TBED 9.4 MG	43652	075546	70165001530
AMPHETAMINE	DYANAVEL XR SUER 2.5 MG/ML	43652	075025	27808010201
DEXTROAMPHETAMINE	XELSTRYM PTCH 4.5 MG/9 HR	47926	083233	68968020501
DEXTROAMPHETAMINE	XELSTRYM PTCH 9 MG/9 HR	47926	083234	68968021001
DEXTROAMPHETAMINE	XELSTRYM PTCH 13.5 MG/9 HR	47926	083227	68968021501
DEXTROAMPHETAMINE	XELSTRYM PTCH 18 MG/9 HR	47926	083232	68968022001

Adrenergics, Aromatic, Non-Catecholamine agents (cont'd)

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Patient is 6 years of age or older, AND
- Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) as confirmed by psychoeducational testing***, AND
- Patient has had an adequate trial* (1 week) and/or intolerance** or allergy to:
    - Dextroamphetamine-amphetamine (generic Adderall XR),
    - AND intermediate or long-acting methylphenidate (methylphenidate SR, methylphenidate CD, or methylphenidate ER),
    - AND dexmethylphenidate (generic Focalin XR)

NOTES:

*Adequate trial of a long-acting agent is further defined as wearing off that is not resolved by increasing the dose, AND adding a short-acting agent OR increasing frequency to twice daily OR clinically significant side effects related to the dosage form that cannot be resolved by adjusting the dose or timing

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

***Criteria only applies for 18 years of age and older

Continuation of Therapy Criteria:

- Patient meets initial review criteria and has demonstrated positive clinical response to medication

Generic	Brand	HICL	GSN	Representative NDC
LISDEXAMFETAMINE DIMESYLATE	VYVANSE CAPS 10 MG	34486	073292	59417010110
LISDEXAMFETAMINE DIMESYLATE	VYVANSE CAPS 20 MG	34486	063645	59417010210
LISDEXAMFETAMINE DIMESYLATE	VYVANSE CAPS 30 MG	34486	062283	59417010310
LISDEXAMFETAMINE DIMESYLATE	VYVANSE CAPS 40 MG	34486	063646	59417010410
LISDEXAMFETAMINE DIMESYLATE	VYVANSE CAPS 50 MG	34486	062284	59417010510
LISDEXAMFETAMINE DIMESYLATE	VYVANSE CAPS 60 MG	34486	063647	59417010610
LISDEXAMFETAMINE DIMESYLATE	VYVANSE CAPS 70 MG	34486	062285	59417010710
LISDEXAMFETAMINE DIMESYLATE	VYVANSE CHEW 10 MG	34486	077083	59417011501
LISDEXAMFETAMINE DIMESYLATE	VYVANSE CHEW 20 MG	34486	077142	59417011601
LISDEXAMFETAMINE DIMESYLATE	VYVANSE CHEW 30 MG	34486	077143	59417011701
LISDEXAMFETAMINE DIMESYLATE	VYVANSE CHEW 40 MG	34486	077144	59417011801
LISDEXAMFETAMINE DIMESYLATE	VYVANSE CHEW 50 MG	34486	077145	59417011901
LISDEXAMFETAMINE DIMESYLATE	VYVANSE CHEW 60 MG	34486	077146	59417012001

Adrenergics, Aromatic, Non-Catecholamine agents (cont'd)

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Patient has a diagnosis of Binge Eating Disorder (BED)***, AND
- Patient is 18 years of age or older, AND
- Prescribed by or in consultation with a psychiatrist, AND
- Prior adequate trial* (6 weeks) and failure of 2 formulary Selective Serotonin Reuptake Inhibitors (SSRIs) unless contraindication, intolerance, or allergy, AND
- Prior adequate trial* (1 month) and failure of topiramate or atomoxetine unless contraindication, intolerance, or allergy, AND
- Prior adequate trial* (1 week) and/or intolerance** or allergy to lisdexamfetamine (generic Vyvanse)

OR

- Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) as confirmed by psychoeducational testing****, AND
- Patient is 6 years of age or older, AND
- Prescribed by or in consultation with a psychiatrist, AND
- Patient has had an adequate trial* (1 week) and/or intolerance** or allergy to:
    - Dextroamphetamine-amphetamine (generic Adderall XR), AND
    - Intermediate or long-acting methylphenidate (methylphenidate SR, methylphenidate CD, or methylphenidate ER), AND
    - Dexmethylphenidate (generic Focalin XR), AND
    - Lisdexamfetamine (generic Vyvanse)

NOTE:

*Adequate trial of a long-acting agent is further defined as wearing off that is not resolved by increasing the dose, AND adding a short-acting agent OR increasing frequency to twice daily OR clinically significant side effects related to the dosage form that cannot be resolved by adjusting the dose or timing

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

***Criteria only applies to new start patients
****Criteria only applies for 18 years of age and older

Continuation of Therapy Criteria:

- Patient meets initial review criteria and has demonstrated positive clinical response to medication

Agents for Acute Tx of HAE Attacks

Generic	Brand	HICL	GSN	Representative NDC
ICATIBANT ACETATE	FIRAZYR SOSY 30 MG/3ML	35962	064564	54092070203
ICATIBANT ACETATE	SAJAZIR SOSY 30 MG/3ML	35962	064564	70709001301
C1 ESTERASE INHIBITOR (HUMAN)	BERINERT KIT 500 UNIT	18568	068384	63833082502
C1 ESTERASE INHIBITOR (RECOMBINANT)	RUCONEST SOLR 2100 UNIT	37766	067598	71274035001
SEBETRALSTAT	EKTERLY TABS 300 MG	50678	087936	82928030001

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is an Allergist, Immunologist, or Physician who specializes in the treatment of hereditary angioedema (HAE), AND
- Patient meets the age cutoff for the requested medication:
  - Firazyr/Sajazir*: ≥18 years
  - Berinert**: any age
  - Ruconest: ≥12 years
  - Ekterly: ≥12 years
- AND patient has diagnosis of HAE type I or type II confirmed by either:
  - Mutation known to cause HAE in either the SERPING1 or F12 gene, OR
  - A C4 level below the lower limit of normal and/or a C1 inhibitor (C1-INH) antigenic level or functional level below the lower limit of normal,
- AND requested medication is being prescribed for the acute treatment of HAE attacks, and will NOT be used in combination with other products indicated for acute treatment of HAE attacks, AND
- Documented treatment failure/inadequate response, intolerance, or contraindication to generic icatibant

Notes:
**Sajazir is only available through a limited distribution program, and cannot be dispensed from KP pharmacies*
***There is limited data for use of Berinert in ages <5 years*

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
  - Specialist follow-up occurred in the past 12 months with documented improvement while on the requested medication, AND
  - Requested medication continues to NOT be used in combination with other products indicated for treatment of acute HAE attacks

Amyloidosis Agents-Transthyretin (TTR) Suppression

Last revised: 7/29/2025; Effective date: 10/7/2025

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

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 6 months

Initial Review Criteria:

- Prescriber is a Neurologist,
- Patient is ≥18 years,
- Diagnosis of Polyneuropathy of Hereditary Transthyretin-mediated Amyloidosis (hATTR-PN),
- Documented confirmed transthyretin (TTR) mutation from genetic testing,
- Karnofsky performance score ≥50,
- Patient has signs of large fiber neuropathy and/or clinically significant autonomic findings (e.g., orthostatic hypotension, tachycardia, bradycardia, etc.),
- Patient has objective weakness in motor strength exam consistent with diagnosis and with confirmation via electrodiagnostic studies (i.e. electromyogram, nerve conduction study),
- Patient does not have eGFR < 30 mL/min/1.73m^2,
- Patient has not had a prior liver transplant,
- Patient does not have severe hepatic impairment [alanine transaminase (ALT) >2.5 times the upper limit of normal] and/or cirrhosis,
- Patient does not have active untreated infection (hepatitis C virus (HCV) infection , human immunodeficiency virus (HIV) infection), or active malignancy,
- Patient is not pregnant or of childbearing age without adequate contraception

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS and have not been reviewed previously:** confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - The following assessments have been performed within the past 6 months:
        - Medical research Council (MRC) strength testing scale (0-5)
    - Patient has a Karnofsky performance score ≥30,
    - No significant clinical decline with life expectancy of less than one year,
    - Patient does not have cardiogenic shock requiring inotropic support,
    - Patient does not have severe renal or hepatic impairment within the last 6 months,
    - Patient is not pregnant,
    - Patient is NOT in hospice care

Antidepressant – Postpartum Depression (PPD)

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

Prior Authorization Criteria:

Length of Authorization:

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

Initial Review Criteria:

- Patient is 18-45 years old, AND
- Prescribed by a psychiatrist or AFM/OB/GYN in consultation with a psychiatrist, AND
- Documented diagnosis of postpartum depression, AND
  - Onset no earlier than third trimester of pregnancy and no later than four weeks postpartum, AND
- Patient is ≤12 months postpartum, AND
- Documentation of moderately severe to severe depression correlating to Patient Health Questionnaire-9 (PHQ-9) score ≥15, within prior two weeks of treatment initiation, AND
- Documentation of negative serum pregnancy test within one day prior to start of treatment initiation, AND
- Documentation that patient agrees to use effective contraception during treatment with zuranolone and for one week after the final dose, AND
- If patient is currently on antidepressants, documentation that dose is stable for approximately two weeks and is not titrated or changed during active treatment with zuranolone (except for cases of adverse reactions), AND
- Patient is willing to delay start of benzodiazepine, anxiolytics, sleep aids and other CNS depressants during active treatment of zuranolone and five days post-treatment

Notes:

- Use of zuranolone beyond the 14-day treatment course has not been studied and is not recommended
- Zuranolone is present in low levels (<1%) in human milk. Recommend shared decision making if patient is breastfeeding
- Do not approve if patient has **at least one** of the following:
  - Pregnancy
    - Note: Pregnancy tests may show positive within 4 weeks postpartum
  - Active psychosis (consider electroconvulsive therapy (ECT) instead for these patients)
  - Diagnosis of bipolar disorder, schizophrenia or schizoaffective disorder
  - Active alcohol or drug abuse within prior 30 days
  - Significant risk of suicide as determined by the provider
  - Concomitant use of opioids, benzodiazepines, anxiolytic and sleep aids
  - Concomitant use with CYP3A4 inducers (i.e. phenobarbital, phenytoin, rifampin, St. John's wort)

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

Antihyperglycemics, Sodium/Glucose Cotransporter 2 (SGLT2) Inhibitors and SGLT-2 and DPP-4 Inhibitor Combinations

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

Generic	Brand	HICL	GSN	Representative NDC
DAPAGLIFLOZIN PROPANEDIOL	FARXIGA TABS 5 MG	40137	071740	00310620530
DAPAGLIFLOZIN PROPANEDIOL	FARXIGA TABS 10 MG	40137	070755	00310621030
DAPAGLIFLOZIN-METFORMIN HCL	XIGDUO XR TB24 2.5-1000 MG	41188	078062	00310622560
DAPAGLIFLOZIN-METFORMIN HCL	XIGDUO XR TB24 5-500 MG	41188	073029	00310625030
DAPAGLIFLOZIN-METFORMIN HCL	XIGDUO XR TB24 5-1000 MG	41188	073031	00310626060
DAPAGLIFLOZIN-METFORMIN HCL	XIGDUO XR TB24 10-500 MG	41188	073030	00310627030
DAPAGLIFLOZIN-METFORMIN HCL	XIGDUO XR TB24 10-1000 MG	41188	073032	00310628030
CANAGLIFLOZIN	INVOKANA TABS 300 MG	40171	070792	50458014190
CANAGLIFLOZIN	INVOKANA TABS 100 MG	40171	070791	50458014030
CANAGLIFLOZIN-METFORMIN HCL	INVOKAMET XR TB24 50-500 MG	41287	076620	50458094001
CANAGLIFLOZIN-METFORMIN HCL	INVOKAMET XR TB24 50-1000 MG	41287	076621	50458094101
CANAGLIFLOZIN-METFORMIN HCL	INVOKAMET XR TB24 150-500 MG	41287	076622	50458094201
CANAGLIFLOZIN-METFORMIN HCL	INVOKAMET XR TB24 150-1000 MG	41287	076623	50458094301
CANAGLIFLOZIN-METFORMIN HCL	INVOKAMET TABS 50-500 MG	41287	072678	50458054060
CANAGLIFLOZIN-METFORMIN HCL	INVOKAMET TABS 50-1000 MG	41287	072587	50458054160
CANAGLIFLOZIN-METFORMIN HCL	INVOKAMET TABS 150-500 MG	41287	072677	50458054260
CANAGLIFLOZIN-METFORMIN HCL	INVOKAMET TABS 150-1000 MG	41287	072589	50458054360

ERTUGLIFLOZIN L-PYROGLUTAMIC ACID	STEGLATRO TABS 5 MG	44709	078041	00006536307
ERTUGLIFLOZIN L-PYROGLUTAMIC ACID	STEGLATRO TABS 15 MG	44709	078042	00006536407
ERTUGLIFLOZIN-METFORMIN HCL	SEGLUROMET TABS 2.5-500 MG	44716	078051	00006536906
ERTUGLIFLOZIN-METFORMIN HCL	SEGLUROMET TABS 2.5-1000 MG	44716	078052	00006537303
ERTUGLIFLOZIN-METFORMIN HCL	SEGLUROMET TABS 7.5-500 MG	44716	078053	00006537007
ERTUGLIFLOZIN-METFORMIN HCL	SEGLUROMET TABS 7.5-1000 MG	44716	078054	00006537406
DAPAGLIFLOZIN-SAXAGLIPTIN	QTERN TABS 5-5 MG	43957	079873	00310677030
DAPAGLIFLOZIN-SAXAGLIPTIN	QTERN TABS 10-5 MG	43957	077192	00310678030
EMPAGLIFLOZIN-LINAGLIPTIN	GLYXAMBI TABS 10-5 MG	41724	073432	00597018239
EMPAGLIFLOZIN-LINAGLIPTIN	GLYXAMBI TABS 25-5 MG	41724	073433	00597016439
ERTUGLIFLOZIN-SITAGLIPTIN	STEGLUJAN TABS 5-100 MG	44706	078036	00006536706
ERTUGLIFLOZIN-SITAGLIPTIN	STEGLUJAN TABS 15-100 MG	44706	078037	00006536803

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria (For Diabetes treatment indication):

- Diagnosis of type 2 diabetes mellitus, AND
- Patient ≥ 18 years old, AND
- Most recent HbA1c was obtained within 3 months of the PA request, AND meets ONE of the following requirements:
    - HbA1c is within 2% ABOVE goal (as per ADA guidelines)
    - HbA1c is ≥2% ABOVE goal, AND patient is **optimized*** on concomitant insulin therapy (insulin glargine-yfgn preferred)
- Patient has had adequate trial (adherence/MRAR ≥80% for at least 3 months) of BOTH of the following preferred oral medications at maximum tolerated dose unless resulting in a therapeutic failure, contraindication, or intolerance:
    - Metformin

- Jardiance
- 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 (adherence/MRAR ≥80% for at least 3 months) of ALL of the following more preferred medications for diabetes, unless allergy, intolerance, or contraindication:
    - Sulfonylurea
    - Pioglitazone (if BMI <35)
    - Sitagliptin (unbranded Zituvio)
    - Liraglutide*PA (AG of Victoza)

Additional criteria for Invokana/Invokamet/Invokamet XR:

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

** Note: Patients should demonstrate adherence to insulin regimen that has been titrated to max tolerated dose; OR have documented intolerance to insulin that cannot be resolved with appropriate dose adjustments*

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

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

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

NOTES:

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

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
  - If treating DM and no qualifying conditions, must have documented A1C lowering at least 0.5% from initial or A1C now at goal
  - If treating HF (Farxiga and Xigduo XR only):
    - Specialist follow-up has occurred since last review,
    - AND patient has experienced positive clinical response to therapy

Antihyperglycemics, Dipeptidyl Peptidase-4 (DPP4) inhibitors

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

Generic	Brand	HICL	GSN	Representative NDC
SAXAGLIPTIN HCL	ONGLYZA TABS 5 MG	36471	065431	00310610590
SITAGLIPTIN PHOSPHATE	JANUVIA TABS 25 MG	34126	061612	00006022128
SITAGLIPTIN PHOSPHATE	JANUVIA TABS 50 MG	34126	061613	00006011254
SITAGLIPTIN PHOSPHATE	JANUVIA TABS 100 MG	34126	061614	00006027731
SITAGLIPTIN-METFORMIN HCL	JANUMET TABS 50-500 MG	34665	062531	00006057582
SITAGLIPTIN-METFORMIN HCL	JANUMET TABS 50-1000 MG	34665	062532	00006057782
SITAGLIPTIN-METFORMIN HCL	JANUMET XR TB24 50-500 MG	34665	068538	00006007882
SITAGLIPTIN-METFORMIN HCL	JANUMET XR TB24 50-1000 MG	34665	068539	00006008062
SITAGLIPTIN-METFORMIN HCL	JANUMET XR TB24 100-1000 MG	34665	068540	00006008131
LINAGLIPTIN	TRADJENTA TABS 5 MG	37576	067353	00597014090
LINAGLIPTIN-METFORMIN HCL	JENTADUETO TABS 2.5-500 MG	38464	068516	00597014618
LINAGLIPTIN-METFORMIN HCL	JENTADUETO TABS 2.5-850 MG	38464	068517	00597014718
LINAGLIPTIN-METFORMIN HCL	JENTADUETO TABS 2.5-1000 MG	38464	068518	00597014818
LINAGLIPTIN-METFORMIN HCL	JENTADUETO XR TB24 2.5-1000 MG	38464	076256	00597027094
LINAGLIPTIN-METFORMIN HCL	JENTADUETO XR TB24 5-1000 MG	38464	076257	00597027581

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Diagnosis of type 2 diabetes mellitus, AND
- Patient is ≥ 18 years old, AND
- Most recent HbA1c obtained within 3 months of the PA request meets ONE of the following requirements:
    - HbA1c is within 2% ABOVE goal (as per ADA guidelines)
    - HbA1c is ≥2% ABOVE goal, AND patient is **optimized*** on concomitant insulin therapy (insulin glargine-yfgn preferred)
- Patient is not on another DPP-4 inhibitor, or any agent within the GLP-1 agonist drug class, AND
- Patient has had adequate trial (adherence/MRAR ≥80% for at least 3 months) of ALL of the following medications for diabetes, unless allergy, intolerance, or contraindication:
    - Metformin
    - Sulfonylurea
    - Pioglitazone (if BMI <35)
    - Jardiance
    - Sitagliptin (unbranded Zituvio)
    - Liraglutide*PA (AG of Victoza)

** Note: Patients should demonstrate adherence to insulin regimen that has been titrated to max tolerated dose; OR have documented intolerance to insulin that cannot be resolved with appropriate dose adjustments*

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

NOTES:

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

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - Documented A1C lowering of 0.5% from initial or A1C now at goal

Antihyperglycemics, Incretin Mimetic (GLP-1 Receptor Agonist)

Last revised: 12/5/2025; Effective date: 2/3/2026

Generic	Brand	HICL	GSN	Representative NDC
LIRAGLUTIDE	LIRAGLUTIDE SOPN 18 MG/3ML	36436	065344	00480366720

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 6 months

Initial Review Criteria:

- Diagnosis of type 2 diabetes mellitus *(Note: if requesting GLP-1 RA or GIP/GLP-1 RA approval for non-DM indications, refer to corresponding criteria for Wegovy, Saxenda, or Zepbound)*, AND
- Most recent HbA1c was obtained within 3 months of the PA request, AND meets ONE of the following requirements:
    - HbA1c is within 2% ABOVE goal (as per ADA guidelines)
    - HbA1c is ≥2% ABOVE goal, AND patient is on concomitant insulin therapy (insulin glargine-yfgn preferred)
- Patient is not on another GLP-1 agonist or any agent within the DPP-4 inhibitor drug class, AND
- Patient has failed adequate trial (adherence/MRAR ≥80% for at least 3 months) of ALL of the following at maximum tolerated dose unless intolerance or contraindication:
    - Metformin
    - Jardiance

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS and have not been reviewed previously:** confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - Diagnosis of type 2 diabetes mellitus *(Note: if requesting GLP-1 RA or GIP/GLP-1 RA renewall for non-DM indications, refer to corresponding criteria for Wegovy, Saxenda, or Zepbound)*, AND
    - Patient has demonstrated good adherence/MRAR ≥80% to liraglutide, AND
    - If no diagnosis of ASCVD or indicators of high ASCVD risk, patient must meet ONE of the following A1c requirements:
        - A1c <9%,
        - 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

Antihyperglycemics, Incretin Mimetic (GLP-1 Receptor Agonist) (cont'd)

Last revised: 12/5/2025; Effective date: 2/3/2026

Generic	Brand	HICL	GSN	Representative NDC
LIRAGLUTIDE	VICTOZA	36436	065344	00169406013
SEMAGLUTIDE	OZEMPIC (0.25 OR 0.5 MG/DOSE) SOPN 2 MG/3ML	44675	084300	00169418113
SEMAGLUTIDE	OZEMPIC (1 MG/DOSE) SOPN 4 MG/3ML	44675	081168	00169413013
SEMAGLUTIDE	OZEMPIC (2 MG/DOSE) SOPN 8 MG/3 ML	44675	083225	00169477211
SEMAGLUTIDE	RYBELSUS TABS 3 MG	44675	080228	00169430313
SEMAGLUTIDE	RYBELSUS TABS 7 MG	44675	080229	00169430713
SEMAGLUTIDE	RYBELSUS TABS 14 MG	44675	080230	00169431413
DULAGLUTIDE	TRULICITY SOPN 0.75 MG/0.5ML	41421	072872	00002143301
DULAGLUTIDE	TRULICITY SOPN 1.5 MG/0.5ML	41421	072873	00002143401
DULAGLUTIDE	TRULICITY SOPN 3 MG/0.5ML	41421	081455	00002223680
DULAGLUTIDE	TRULICITY SOPN 4.5 MG/0.5ML	41421	081454	00002318280
INSULIN DEGLUDEC-LIRAGLUTIDE	XULTOPHY SOPN 100-3.6 UNIT-MG/ML	41880	073919	00169291115
INSULIN GLARGINE-LIXISENATIDE	SOLIQUA SOPN 100-33 UNT-MCG/ML	43944	076864	00024576105
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 *(Note: if requesting GLP-1 RA or GIP/GLP-1 RA approval for non-DM indications, refer to corresponding criteria for Wegovy, Saxenda, or Zepbound)*, AND
- Most recent HbA1c was obtained within 3 months of the PA request, AND meets ONE of the following requirements:
    - HbA1c is within 2% ABOVE goal (as per ADA guidelines)**
    - HbA1c is ≥2% ABOVE goal, AND patient is **optimized*** on concomitant insulin therapy (insulin glargine-yfgn preferred)
- AND
- Patient is not on another GLP-1 agonist or any agent within the DPP-4 inhibitor drug class, AND
- Patient has failed adequate trial (adherence/MRAR ≥80% for at least 3 months) of ALL of the following at maximum tolerated dose unless intolerance, or contraindication:
    - Metformin
    - Jardiance
    - Liraglutide[*PA] (AG of Victoza)

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

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

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

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

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

*Patients should demonstrate adherence to insulin regimen that has been titrated to max tolerated dose; OR have documented intolerance to insulin that cannot be resolved with appropriate dose adjustments

**If a patient is already on insulin therapy, dose titration and optimization are required before considering a non-preferred GLP-1 agonist; insulin should also be considered as add-on therapy for patients with A1c within 2% above goal, especially if ordering a non-preferred GLP-1 agonist, and insulin has not been trialed in the past

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS and have not been reviewed previously:** confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria:**
    - Diagnosis of type 2 diabetes mellitus *(Note: if requesting GLP-1 RA or GIP/GLP-1 RA renewal for non-DM indications, refer to corresponding criteria for Wegovy, Saxenda, or Zepbound)*, AND
    - Patient has failed adequate trial (adherence/MRAR ≥80% for at least 3 months), or has intolerance or contraindication to liraglutide (AG of 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

Weight Management Agents

Last revised: 12/5/2025; Effective date: 2/3/2026

Generic	Brand	HICL	GSN	Representative NDC
LIRAGLUTIDE (WEIGHT MANAGEMENT)	SAXENDA SOPN 18 MG/3ML	36436	073258	00169280015
LIRAGLUTIDE (WEIGHT MANAGEMENT)	LIRAGLUTIDE -WEIGHT MANAGEMENT SOPN 18 MG/3ML	36436	073258	00480725046
SEMAGLUTIDE (WEIGHT MANAGEMENT)	WEGOVY SOAJ 0.25 MG/0.5ML	44675	082355	00169452514
SEMAGLUTIDE (WEIGHT MANAGEMENT)	WEGOVY SOAJ 0.5 MG/0.5ML	44675	082356	00169450514
SEMAGLUTIDE (WEIGHT MANAGEMENT)	WEGOVY SOAJ 1 MG/0.5ML	44675	082357	00169450114
SEMAGLUTIDE (WEIGHT MANAGEMENT)	WEGOVY SOAJ 1.7 MG/0.75ML	44675	082358	00169451714
SEMAGLUTIDE (WEIGHT MANAGEMENT)	WEGOVY SOAJ 2.4 MG/0.75ML	44675	082359	00169452414
TIRZEPATIDE (WEIGHT MANAGEMENT)	ZEPBOUND SOAJ 2.5 MG/0.5ML	48014	085488	00002250601
TIRZEPATIDE (WEIGHT MANAGEMENT)	ZEPBOUND SOAJ 5 MG/0.5ML	48014	085489	00002249501
TIRZEPATIDE (WEIGHT MANAGEMENT)	ZEPBOUND SOAJ 7.5 MG/0.5ML	48014	085490	00002248401
TIRZEPATIDE (WEIGHT MANAGEMENT)	ZEPBOUND SOAJ 10 MG/0.5ML	48014	085491	00002247101
TIRZEPATIDE (WEIGHT MANAGEMENT)	ZEPBOUND SOAJ 12.5 MG/0.5ML	48014	085492	00002246001
TIRZEPATIDE (WEIGHT MANAGEMENT)	ZEPBOUND SOAJ 15 MG/0.5ML	48014	085493	00002245701
TIRZEPATIDE (WEIGHT MANAGEMENT)	ZEPBOUND SOLN 10 MG/0.5ML	48014	086891	00002134004
TIRZEPATIDE (WEIGHT MANAGEMENT)	ZEPBOUND SOLN 2.5 MG/0.5ML	48014	086396	00002015204

TIRZEPATIDE (WEIGHT MANAGEMENT)	ZEPBOUND SOLN 5 MG/0.5ML	48014	086393	00002024304
TIRZEPATIDE (WEIGHT MANAGEMENT)	ZEPBOUND SOLN 7.5 MG/0.5ML	48014	086895	00002121404
TIRZEPATIDE (WEIGHT MANAGEMENT)	ZEPBOUND SOLN 12.5 MG/0.5ML	48014	086892	00002142304
TIRZEPATIDE (WEIGHT MANAGEMENT)	ZEPBOUND SOLN 15 MG/0.5ML	48014	086893	00002200204

Prior Authorization Criteria:

Length of Authorization:

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

Initial Review Criteria:

<u>If using for weight management:</u>

- Patient is referred through Pharmacy Review – Injectable Weight Loss (or medication prescribed by Endocrinologist, Pediatrician, or Weight Management Specialist), AND
- Patient at least 12 years of age (Saxenda & Wegovy), or at least 18 years of age (Zepbound), AND
- Patient falls in ONE of the baseline BMI categories as follows:
  - **For baseline BMI 27 to <30 kg/m^2:**
    - Has <u>at least ONE</u> of the following weight-related comorbidities (established cardiovascular disease or stroke; hypertension; type 2 DM; CKD; CHD; polycystic ovarian syndrome; dyslipidemia; nonalcoholic fatty liver disease [e.g., MASH, MASLD]; idiopathic intracranial hypertension; osteoarthritis in weight-bearing joints), AND
    - Actively adhering to prescriber-documented lifestyle interventions* (90 days of lifestyle changes documented with nutrition and physical activity components) and will continue with lifestyle modifications while on Saxenda, Wegovy, or Zepbound, AND
    - Patient has documented intolerance, contraindication, or failure to lose and maintain >/= 5% body weight after a 3-month trial of <u>one</u> of the following <u>oral</u> medications indicated for weight management**:
      - Monotherapy: Phentermine or diethylpropion, OR
      - Combination therapy:
        - Generic phentermine and topiramate (IR preferred) (used at similar doses and prescribed simultaneously) (preferred) or brand Qsymia (phentermine IR + topiramate XR) (nonpreferred), OR
        - Generic naltrexone and bupropion (used at similar doses and prescribed simultaneously) (preferred) or brand Contrave (naltrexone + bupropion) (nonpreferred)
  - **For baseline BMI 30 to < 35 kg/m^2:**
    - Actively adhering to prescriber-documented lifestyle interventions* (90 days of lifestyle changes documented with nutrition and physical activity components) and will continue with lifestyle modifications while on Saxenda, Wegovy, or Zepbound, AND

        - Patient has documented intolerance, contraindication, or failure to lose and maintain >/= 5% body weight after a 3-month trial of <u>one</u> of the following <u>oral</u> medications indicated for weight management**:
            - Monotherapy: Phentermine or diethylpropion, OR
            - Combination therapy:
                - Generic phentermine and topiramate (IR preferred) (used at similar doses and prescribed simultaneously) (preferred) or brand Qsymia (phentermine IR + topiramate XR) (nonpreferred), OR
                - Generic naltrexone and bupropion (used at similar doses and prescribed simultaneously) (preferred) or brand Contrave (naltrexone + bupropion) (nonpreferred)
    - **For baseline BMI 35 to < 40 kg/m^2:**
        - Actively adhering to prescriber-documented lifestyle interventions* (90 days of lifestyle changes documented with nutrition and physical activity components) and will continue with lifestyle modifications while on Saxenda, Wegovy, or Zepbound
    - **For baseline BMI >/= 40 kg/m^2:**
        - Currently enrolled in and/or following a lifestyle intervention program* (lifestyle changes to begin at or before time of medication initiation) and will continue with lifestyle modifications while on Saxenda, Wegovy, or Zepbound
- Documented baseline weight within the past 30 days, AND
- Saxenda, Wegovy, and Zepbound are not being used in combination with another GIP/GLP-1 RA or GLP-1 RA, AND
- Initial prescription is limited to a maximum of 30-day supply with 2 refills, AND
- <u>If ordering Zepbound</u>:
    - Actively adhering to prescriber-documented lifestyle interventions* (patient must provide detailed diet and exercise log for past 90-180 days) and will continue with lifestyle modifications while on Zepbound, AND
    - Patient has documented intolerance, contraindication, or failure to lose and maintain >/= 5% body weight (pre-GLP-1 RA or GIP/GLP-1 RA baseline weight) after a 3-month trial (at maximum tolerated dose) of semaglutide for overweight or obesity (unless BMI ≥35 kg/m^2)
- <u>If ordering generic liraglutide (for overweight or obesity):</u>
    - Patient has documented intolerance, contraindication, or failure to lose and maintain >/= 5% body weight (pre-GLP-1 RA or GIP/GLP-1 RA baseline weight) after a 3-month trial (at maximum tolerated dose) of semaglutide for overweight or obesity (unless BMI ≥35 kg/m^2), AND
    - Patient has documented intolerance, contraindication, or failure to lose and maintain >/= 5% body weight (pre-Zepbound baseline weight) after a 3-month trial (at maximum tolerated dose) of Zepbound (tirzepatide) (unless BMI ≥35 kg/m^2)
- <u>If ordering BRAND Saxenda:</u>
    - Patient has documented intolerance, contraindication, or failure to lose and maintain >/= 5% body weight (pre-Saxenda baseline weight) after a 3-month trial (at maximum tolerated dose) of generic liraglutide (for overweight or obesity) (unless BMI >/= 35 kg/m2)

**Lifestyle: Examples include, but are not limited to, internal programs such as the KP Diabetes Prevention Program (DPP), Healthy Weight by Design, or Lifestyle Medicine; or external program(s) (e.g., Weight Watchers, Noom, Jenny Craig, etc.)*

***Oral antiobesity medication by age: Bupropion (age >/= 18 years when used in combination with naltrexone for weight loss); Contrave (brand) (not indicated for age < 18 years); diethylpropion (age > 16 years); naltrexone (age >/= 18 years); phentermine (age >/= 16 years); Qsymia (brand) (age >/= 12 years [maximum of 7.5-46 mg po once daily])*

If using for MACE risk reduction (Wegovy ONLY):

- Age 55 to < 75 years, AND
- BMI ≥ 27 kg/m^2, AND
- Does not have history of DM (defined as HgA1c < 6.5%)******, AND
- Established history of MI, AND
- Currently engaged in lifestyle modifications (e.g., dietary or caloric restriction, physical activity, behavioral support, community-based program, etc.) and plans to continue lifestyle modifications while prescribed Wegovy (semaglutide), AND
- Optimized on ALL of the below standard of care treatment for CVD (or documented trial of/intolerance to/documented rationale why treatment is inappropriate):
    - Moderate- to high-intensity statin therapy or alternative lipid-lowering medication
    - Antiplatelet medication
    - Antihypertensive medication (e.g., beta-blocker, ACEi, ARB, etc.)
- Not currently prescribed another GLP-1 RA- or GIP/GLP-1 RA-containing medication

  **For guidance regarding use of GLP-1 RAs in diabetes, refer to *KP National Adult Diabetes Guidelines*

If using for MASH (Metabolic Dysfunction-Associated Steatohepatitis) (Wegovy ONLY):

- Prescriber is a Hepatologist or Gastroenterologist, AND
- Patient is at least 18 years of age, AND
- Patient is diagnosed with metabolic dysfunction-associated steatohepatitis (MASH) with Fibrosis F2 or F3 as determined by transient elastography, ultrasound elastography, magnetic resonance imaging (MRI) elastography, and/or liver biopsy, AND
- Persistent fibrosis (F2/F3) refractory to at least three months of lifestyle changes and/or structured weight loss program (e.g., diet, exercise, medication for weight loss with a goal of ≥ 5% weight loss), AND
- Patient **does NOT** have any of the following:
    - History of significant alcohol consumption within 1 year (e.g., consume > 7 drinks [98 grams of alcohol] per week if females, and >14 drinks [196 grams of alcohol] per week for males); or
    - Regular use of drugs associated with metabolic dysfunction-associated fatty liver disease (MAFLD) due to concern for drug-induced liver (e.g. amiodarone, methotrexate, systemic glucocorticoids at greater than 5 mg/day, tamoxifen, estrogen at doses greater than those used for hormone replacement or contraception, anabolic steroids [except testosterone replacement], valproic acid, and known hepatotoxins); or
    - Active, serious medical disease with a life expectancy < 2 years; or
    - ALT/AST >5 times the upper limit of normal (ULN) that is likely due to other chronic liver disease; or
    - Currently pregnant or breastfeeding or planning to become pregnant; or
    - Personal or family history of medullary thyroid carcinoma (MTC) or Multiple endocrine neoplasia syndrome type 2 (MEN 2); or
    - Prior or current pancreatitis or gallbladder disease/gallstones; or

- Had bariatric surgery within the last six months

If using for moderate-to-severe OSA (Zepbound ONLY):

- Patient is diagnosed with moderate to severe OSA (moderate OSA diagnosed by polysomnography (within the past year) with an apnea-hypopnea index [AHI] 15 – 29; severe OSA defined by AHI >/= 30), AND
- Patient unable to use positive airway pressure (PAP) therapy (examples may include, but are not limited to, documented anxiety with use, documented nasal/oral discomfort, etc. that prevents adequate sleep), OR if able to use PAP therapy, must have used for at least 3 months (and plans to continue), AND
- Patient is referred through Pharmacy Review – Injectable Weight Loss (or medication prescribed by Pulmonologist or Weight Management Specialist), AND
- Patient at least 18 years of age, AND
- Baseline BMI >/= 35 kg/m^2, AND
- Documented baseline weight within the past 30 days, AND
- Actively adhering to prescriber-documented lifestyle interventions (90 days of lifestyle changes documented with nutrition and physical activity components) [examples include, but are not limited to, internal programs such as the KP Diabetes Prevention Program (DPP), Healthy Weight by Design, or Lifestyle Medicine; or external program(s) (e.g., Weight Watchers, Noom, Jenny Craig, etc.), and will continue with lifestyle modifications while on Zepbound, AND
- Patient has documented intolerance, contraindication, or failure to lose and maintain >/= 5% body weight after a 3-month trial at maximum tolerated dose of Wegovy (or liraglutide for overweight or obesity, followed by semaglutide for overweight or obesity), AND
- Not currently prescribed another GLP-1 RA- or GIP/GLP-1 RA-containing medication, AND
- No reason(s) for non-coverage**

**Reasons for non-coverage (tirzepatide is not recommended for moderate to severe OSA in patients with >/= 1 of the following due to lack of evidence, as these patients were excluded from the SURMOUNT-OSA trials):

- Type 1 or type 2 diabetes
- Central or mixed sleep apnea
- Prior or planned surgical or minimally invasive treatment for OSA or obesity
- Significant renal, pulmonary, or liver disease
- Other comorbidities or medications that may affect weight or daytime sleepiness
- Prior acute or chronic pancreatitis
- Personal or family history of medullary thyroid carcinoma (MTC) or multiple endocrine neoplasia type 2 (MEN2)

Note: If using liraglutide or semaglutide for OSA indication, Zepbound criteria for moderate-to-severe OSA will be applied

Continuation of Therapy Criteria:

If using for weight management:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met criteria:**

- Actively adhering to prescriber-documented lifestyle interventions* (90 days of lifestyle changes documented with nutrition and physical activity components) and will continue with lifestyle modifications while prescribed GLP-1 RA or GIP/GLP-1 RA therapy, AND
- Documented weight loss within the previous 6 months of at least 5% from baseline weight (baseline weight at the time of the most recent PA approval or extension), AND
- BMI ≥27 kg/m^2 [discontinue if BMI <27 kg/m^2 (medication is no longer clinically indicated)]

<u>If using for MACE risk reduction (Wegovy ONLY):</u>

- Patient continues to meet initial review criteria (excluding baseline BMI), AND
- Patient does NOT have any of the below reason(s) for non-coverage:
  - New York Heart Association Class IV heart failure (HF)
  - Recent MI, stroke, hospitalization for unstable angina pectoris or transient ischemic attack (TIA) within 60 days prior to initiation of Wegovy (semaglutide)
  - Planned coronary, carotid, or peripheral artery revascularization
  - Type 1 or type 2 diabetes (T1D or T2D) or hgA1c >/= 6.5% (see KP National Adult Diabetes Guidelines)
  - History or presence of chronic or acute pancreatitis
  - Personal or first-degree relative(s) history of MEN 2 or MTC
  - Pregnant, breastfeeding, or planning to become pregnant, or is of childbearing potential and not using highly effective contraception
  - End-stage renal disease (ESRD), chronic or intermittent hemodialysis (HD), or peritoneal dialysis (PD)
  - Presence or history of malignant neoplasms within the past five years prior to screening (basal and squamous cell skin cancer and any carcinoma in-situ are allowed)
  - Severe psychiatric disorder which could compromise medication adherence

<u>If using for MASH (Wegovy ONLY):</u>

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

<u>If using for OSA (Zepbound ONLY)</u>: *When assessing coverage continuation, do not consider baseline BMI over the course of treatment; baseline BMI was considered when this therapy course was initially approved. Coverage continuation decisions are based on meeting the other criteria, excluding baseline BMI.*

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial indication-specific review criteria
- **For existing members who have previously met criteria:**
  - No reason(s) for non-coverage, AND

- Actively adhering to prescriber-documented lifestyle interventions (with nutrition and physical activity components) [examples include, but are not limited to, internal programs such as the KP Diabetes Prevention Program (DPP), Healthy Weight by Design, or Lifestyle Medicine; or external program(s) (e.g., Weight Watchers, Noom, Jenny Craig, etc.)], AND
- 25% improvement in AHI from baseline, AND
- BMI >/= 27 kg/m^2

Antibacterials, Miscellaneous

Last revised: 12/5/2025; Effective date: 2/3/2026

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 or *C. difficile* 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

- 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 (if ≥65 years old, trial of ONE of the following therapies is adequate):
  - 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
  - At least one tricyclic antidepressant* - at least 6 weeks, AND
- 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)

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

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):

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met criteria:**
    - Patient has documented a clinically significant benefit from medication

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

Anti-Obesity – Melanocortin 4 Receptor Agonists

Last revised: 2/6/2024

Generic	Brand	HICL	GSN	Representative NDC
SETMELANOTIDE ACETATE	IMCIVREE SOLN 10 MG/ML	46743	081724	72829001001

Prior Authorization Criteria:

Length of Authorization:

- Initial: 4 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is an endocrinologist, or a pediatric endocrinologist AND
- Age ≥ 6 years AND
- Diagnosed with obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency confirmed by genetic testing demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic or likely pathogenic* AND
- Documentation of the following:
  - Patient's obesity is ≥30 kg/m2 (adults) or ≥95th percentile (pediatric patients) AND
  - Alternative weight management options have failed to provide at least a 10% weight reduction, such as diet, exercise, bariatric surgery AND
  - Baseline body weight and BMI

*Note: If VUS (variant of uncertain significance), test results are deemed to be highly suspicious by a medical geneticist

Continuation of Therapy Criteria:

- Documentation of body weight and BMI for initial renewal AND
- Reassess to determine need for continued therapy; therapy should be discontinued if the patient meets any of the following criteria:
  - Failure to reduce at least 5% of baseline body weight, or 5% of baseline BMI for patients with continued growth potential
  - Diagnosed with melanoma
  - Patient is breastfeeding
  - Intolerance to medication
  - Non-adherence to medication, recommended diet and lifestyle measures, or follow-up labs and assessments
  - Documentation of suicidal thoughts or behaviors
  - Pregnancy (unless benefit of treatment outweighs risk)

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

Anticonvulsant - Benzodiazepine Type

Generic	Brand	HICL	GSN	Representative NDC
CLOBAZAM	ONFI SUSP 2.5 MG/ML	6536	071282	67386031321
CLOBAZAM	ONFI TABS 10 MG	6536	017026	67386031401
CLOBAZAM	ONFI TABS 20 MG	6536	020647	67386031501
CLOBAZAM	SYMPAZAN FILM 10 MG	6536	078862	10094021001
CLOBAZAM	SYMPAZAN FILM 20 MG	6536	078863	10094022060
CLOBAZAM	SYMPAZAN FILM 5 MG	6536	078861	10094020560

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Neurologist, AND
- Patient has history of ≥8-week trial of at least 2 of the following (any release formulation qualifies): carbamazepine, divalproex, gabapentin, lamotrigine, levetiracetam, oxcarbazepine, phenytoin, pregabalin, topiramate, valproic acid, zonisamide, AND
- One of the following:
    - Documented history of persisting seizures after titration to the highest tolerated dose with each medication trial AND lack of adherence as a reason for treatment failure has been ruled out, OR
    - Documentation of failure due to intolerable side effects AND reasonable efforts were made to minimize the side effect (e.g., change timing of dosing, divide dose out for more frequent but smaller doses, etc.), OR
    - For continuation of prior therapy for a seizure disorder

Continuation of Therapy Criteria:

- Documentation of positive clinical response to therapy, AND
- Office visit or telephone visit with neurologist within the past 12 months

Anticonvulsant – Cannabinoid Type

Generic	Brand	HICL	GSN	Representative NDC
CANNABIDIOL	EPIDIOLEX SOLN 100 MG/ML	45006	078778	70127010001

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Neurologist, AND
- Patient is ≥1 year, AND
- Prescribed for Dravet Syndrome or Lennox-Gastaut Syndrome, AND
- Patient has failed an adequate trial (≥2 months), or patient has intolerance to, at least 2 other antiepileptic medications that are appropriate for diagnosis:
    - Lennox Gastaut: felbamate, valproate, topiramate, rufinamide, clobazam, clonazepam, zonisamide
    - Dravet Syndrome: valproate, clobazam, levetiracetam, topiramate, zonisamide, clonazepam

Continuation of Therapy Criteria:

- Continued to be prescribed by neurologist for Dravet Syndrome or Lennox-Gastaut Syndrome, AND
- Sustained improvement in seizure control (frequency and/or severity) since starting Epidiolex as assessed and documented by neurologist, AND
- No significant hepatic impairment, AND
- Patient is not using cannabis or other cannabis derivatives, AND
- Office visit or telephone visit with neurologist within the past 12 months

Other Anticonvulsants

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

Generic	Brand	HICL	GSN	Representative NDC
RUFINAMIDE	BANZEL SUSP 40 MG/ML	34982	067131	62856058446
RUFINAMIDE	BANZEL TABS 200 MG	34982	063076	62856058252
RUFINAMIDE	BANZEL TABS 400 MG	34982	063077	62856058352
ESLICARBAZEPINE ACETATE	APTIOM TABS 200 MG	36675	072030	63402020230
ESLICARBAZEPINE ACETATE	APTIOM TABS 400 MG	36675	072031	63402020430
ESLICARBAZEPINE ACETATE	APTIOM TABS 600 MG	36675	072032	63402020660
ESLICARBAZEPINE ACETATE	APTIOM TABS 800 MG	36675	065694	63402020830
BRIVARACETAM	BRIVIACT SOLN 10 MG/ML	43088	075593	50474087015
BRIVARACETAM	BRIVIACT TABS 10 MG	43088	075598	50474037066
BRIVARACETAM	BRIVIACT TABS 100 MG	43088	075602	50474077009
BRIVARACETAM	BRIVIACT TABS 25 MG	43088	075599	50474047009
BRIVARACETAM	BRIVIACT TABS 50 MG	43088	075600	50474057066
BRIVARACETAM	BRIVIACT TABS 75 MG	43088	075601	50474067066
STIRIPENTOL	DIACOMIT CAPS 250 MG	35461	063790	68418793906
STIRIPENTOL	DIACOMIT CAPS 500 MG	35461	063791	68418794006
STIRIPENTOL	DIACOMIT PACK 250 MG	35461	063792	68418794106
STIRIPENTOL	DIACOMIT PACK 500 MG	35461	063793	68418794206
FELBAMATE	FELBATOL TABS 400 MG	8186	020041	00037043001
FELBAMATE	FELBATOL TABS 600 MG	8186	020042	00037043101
PERAMPANEL	FYCOMPA SUSP 0.5 MG/ML	39628	076056	62856029038
PERAMPANEL	FYCOMPA TABS 10 MG	39628	069992	62856028030
PERAMPANEL	FYCOMPA TABS 12 MG	39628	069993	62856028230
PERAMPANEL	FYCOMPA TABS 2 MG	39628	069988	62856027230
PERAMPANEL	FYCOMPA TABS 4 MG	39628	069989	62856027430
PERAMPANEL	FYCOMPA TABS 6 MG	39628	069990	62856027630
PERAMPANEL	FYCOMPA TABS 8 MG	39628	069991	62856027830
VIGABATRIN	SABRIL PACK 500 MG	7377	017869	67386021165
VIGABATRIN	SABRIL TABS 500 MG	7377	017870	67386011101

Prior Authorization Criteria:
Length of Authorization: • Initial: 12 months • Reauthorization: 12 months
Initial Review Criteria: • Prescriber must be a neurologist • Patient has history of ≥8-week trial of, or intolerance to, at least 2 of the following (any release formulation qualifies): carbamazepine, divalproex, gabapentin, lamotrigine, levetiracetam, oxcarbazepine, phenytoin, pregabalin, topiramate, valproic acid, zonisamide
Continuation of Therapy Criteria: • Documentation of positive clinical response to therapy, AND • Office visit or telephone visit with neurologist within the past 12 months

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

Antihyperlipidemic – Apolipoprotein Inhibitor

Generic	Brand	HICL	GSN	Representative NDC
OLEZARSEN SODIUM	TRYNGOLZA SOAJ 80 MG/0.8ML	50111	086954	71860010101

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescribed by, or in consultation with a Cardiologist, Endocrinologist, or Geneticist, AND
- Patient is ≥18 years of age, AND
- Diagnosis of familial chylomicronemia syndrome with molecular genetic test results demonstrating biallelic pathogenic variants in at least ONE of the below genes, AND:
    - Lipoprotein lipase (LPL)
    - Glycosylphosphatidylinositol-anchored high-density lipoprotein-binding protein 1 (GPIHBP1)
    - Apolipoprotein A-V (APOA5)
    - Apolipoprotein C-II (APOC2)
    - Lipase mutation factor 1 (LMF1)
- Patient has fasting triglyceride level ≥ 880 mg/Dl, AND
- The medication will be prescribed with a fat-restricted diet (<15-20 grams per day)

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - Documentation of positive clinical response (e.g., reduction in triglycerides from baseline), AND
    - Office visit or telephone visit with a specialist within the past 12 months

Antihypertensives, Endothelin Receptor Antagonists

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

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

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

Continuation of Therapy Criteria:

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

Anti-Inflammatory – Interleukin-1 Receptor Antagonist

Last revised: 12/8/2025; Effective date: 2/3/2026

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 ALLof 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)]

If using for other indications:

- Diagnosis of familial Mediterranean fever and failed colchicine, OR
- Diagnosis of cryopyrin-associated periodic syndromes (CAPS) and failed prednisone, OR
- Diagnosis of adult-onset Still's disease (AOSD)

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

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS and have not been reviewed previously:** Confirm that the patient meets all above initial review criteria
- **For existing members who have previously met the criteria:**
    - If using for recurrent pericarditis:
        - 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
    - If using for all other indications:
        - Patient has documented a clinically significant benefit from medication, AND
        - Specialist follow-up in the last 12 months, AND
        - Patient is not receiving Kineret in combination with any of the following: biologic DMARD, Janus kinase inhibitor, phosphodiesterase 4 (PDE4) inhibitor

Anti-Inflammatory – Interleukin-1 Receptor Antagonist (cont'd)

Generic	Brand	HICL	GSN	Representative NDC
RILONACEPT	ARCALYST SOLR 220 MG	35438	063759	73604091401

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 6 months

Initial Review Criteria:

- Prescriber is a Cardiologist or Rheumatologist,
- Patient is 12 years of age or older,
- History of recurrent pericarditis with at least 2 episodes of acute pericarditis,
- 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
- CRP level of at least 1 mg/dL,
- Patient has had a trial, failure, or contraindication to at least TWO of the following:
  - NSAIDs
  - Colchicine
  - Corticosteroids
- Patient has had a trial, failure, or contraindication to at least TWO of the following:
  - Methotrexate
  - Mycophenolate
  - Azathioprine
  - Tacrolimus
- Patient has had a trial, failure, or contraindication to Kineret (anakinra),
- Arcalyst will NOT be used concurrently with other IL-1 inhibitors (e.g. Ilaris, Kineret)

Continuation of Therapy Criteria:

- Patient has experienced clinical improvement in pericarditis symptoms,
- Specialist follow-up has occurred since last review

Anti-inflammatory – Tumor Necrosis Factor Inhibitor

Last revised: 12/5/2025; Effective date: 2/3/2026

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:

- Prescriber must be a Rheumatologist or Dermatologist, AND

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)^
    - Ustekinumab (Yesintek preferred)^
    - Infliximab (Inflectra preferred)
    - Adalimumab (Amjevita preferred)
    - Cosentyx (secukinumab)

^Note: conventional DMARD and IL-12/23 are not required for patients with axial disease or severe (rapidly progressive, erosive) psoriatic arthritis

If treating spondyloarthropathy/spondyloarthritis:
- Diagnosis of spondyloarthritis/spondyloarthropathy, AND
- 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), AND
- Patient has inadequate response, intolerance, or contraindication to secukinumab (Cosentyx)*PA, AND
- Inadequate response, intolerance or contraindication to the following, where applicable:
    - If treating axial spondyloarthritis (ankylosing-spondylitis or non-radiographic axial spondylarthritis): Full anti-inflammatory dose of NSAID
    - If treating peripheral spondyloarthritis WITHOUT enthesitis/tendonitis (i.e. reactive arthritis, spondyloarthritis related to inflammatory bowel disease or other peripheral spondyloarthritis rather than axial): At least one conventional DMARD (e.g., 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 ALL of the following:
    - At least one anti-TNF agent [(e.g. infliximab-dyyb product (Inflectra) IV preferred or adalimumab product (Amjevita preferred)]
    - Tocilizumab (Tyenne preferred)*PA

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 ALL of the following:
    - Adalimumab product (Amjevita preferred), AND
    - Tocilizumab (Tyenne preferred)*PA

Dermatology
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 ALL of the following unless clinically significant adverse effects, contraindication or clinical reason to avoid treatment:
    - Methotrexate or acitretin – *if ≥18 years of age*
    - Ustekinumab product [Ustekinumab-kfce (Yesintek) preferred] – *if ≥6 years of age*
    - At least 1 preferred anti-TNF product [i.e., adalimumab-atto (Amjevita), adalimumab-bwwd (Hadlima), infliximab-dyyb (Inflectra) IV]
    - Cosentyx (secukinumab) – *if ≥6 years of age*

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:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met 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
ADALIMUMAB-BWWD	HADLIMA PUSHTOUCH SOAJ 40 MG/0.4ML	45894	084519	78206018701
ADALIMUMAB-BWWD	HADLIMA PUSHTOUCH SOAJ 40 MG/0.8ML	45894	080049	78206018401
ADALIMUMAB-BWWD	HADLIMA SOSY 40 MG/0.4ML	45894	084517	78206018601
ADALIMUMAB-BWWD	HADLIMA SOSY 40 MG/0.8ML	45894	080050	78206018301

ADALIMUMAB-AFZB	ABRILADA (1 PEN) AJKT 40 MG/0.8ML	46230	080511	00069032501
ADALIMUMAB-AFZB	ABRILADA (2 PEN) AJKT 40 MG/0.8ML	46230	080511	00069032502
ADALIMUMAB-AFZB	ABRILADA (2 SYRINGE) PSKT 20 MG/0.4ML	46230	080513	00069033302
ADALIMUMAB-AFZB	ABRILADA (2 SYRINGE) PSKT 40 MG/0.8ML	46230	080512	00069032802
ADALIMUMAB-RYVK	SIMLANDI (1 PEN) AJKT 40 MG/0.4ML	49415	085776	51759040217
ADALIMUMAB-RYVK	SIMLANDI (2 PEN) AJKT 40 MG/0.4ML	49415	085776	51759040202
ADALIMUMAB-RYVK	SIMLANDI (2 SYRINGE) PSKT 20 MG/0.2ML	49415	086345	51759038622
ADALIMUMAB-RYVK	SIMLANDI (1 SYRINGE) PSKT 80 MG/0.8ML	49415	086346	51759052321
ADALIMUMAB-RYVK	SIMLANDI (1 PEN) AJKT 80 MG/0.8ML	49415	087448	51759027417
ADALIMUMAB-RYVK	ADALIMUMAB-RYVK (2 PEN) AJKT 40 MG/0.4ML	49415	085776	82009015622
ADALIMUMAB-RYVK	ADALIMUMAB-RYVK (2 SYRINGE) PSKT 40 MG/0.4ML	49415	086320	82009015822
ADALIMUMAB-AATY	YUFLYMA (1 PEN) AJKT 40 MG/0.4ML	48955	084832	72606003009
ADALIMUMAB-AATY	YUFLYMA (1 PEN) AJKT 80 MG/0.8ML	48955	085430	72606002304
ADALIMUMAB-AATY	YUFLYMA (2 PEN) AJKT 40 MG/0.4ML	48955	084832	72606003010
ADALIMUMAB-AATY	YUFLYMA (2 SYRINGE) PSKT 20 MG/0.2ML	48955	085429	72606002401
ADALIMUMAB-AATY	YUFLYMA (2 SYRINGE) PSKT 40 MG/0.4ML	48955	084831	72606003006
ADALIMUMAB-AATY	YUFLYMA-CD/UC/HS STARTER AJKT 80 MG/0.8ML	48955	085430	72606002307
ADALIMUMAB-AATY	ADALIMUMAB-AATY (1 PEN) AJKT 40 MG/0.4ML	48955	084832	72606002209
ADALIMUMAB-AATY	ADALIMUMAB-AATY (1 PEN) AJKT 80 MG/0.8ML	48955	085430	72606004004
ADALIMUMAB-AATY	ADALIMUMAB-AATY (2 PEN) AJKT 40 MG/0.4ML	48955	084832	72606002210
ADALIMUMAB-AATY	ADALIMUMAB-AATY (2 SYRINGE) PSKT 20 MG/0.2ML	48955	085429	72606004101
ADALIMUMAB-AATY	ADALIMUMAB-AATY (2 SYRINGE) PSKT 40 MG/0.4ML	48955	084831	72606002206
ADALIMUMAB-ADBM	CYLTEZO (2 PEN) AJKT 40 MG/0.4ML	44481	086039	00597049550
ADALIMUMAB-ADBM	CYLTEZO (2 PEN) AJKT 40 MG/0.8ML	44481	084819	00597037597

ADALIMUMAB-ADBM	CYLTEZO (2 SYRINGE) PSKT 10 MG/0.2ML	44481	084512	00597040089
ADALIMUMAB-ADBM	CYLTEZO (2 SYRINGE) PSKT 20 MG/0.4ML	44481	084513	00597040580
ADALIMUMAB-ADBM	CYLTEZO (2 SYRINGE) PSKT 40 MG/0.4ML	44481	086037	00597048520
ADALIMUMAB-ADBM	CYLTEZO (2 SYRINGE) PSKT 40 MG/0.8ML	44481	077687	00597037082
ADALIMUMAB-ADBM	CYLTEZO-CD/UC/HS STARTER AJKT 40 MG/0.4ML	44481	086039	00597049560
ADALIMUMAB-ADBM	CYLTEZO-CD/UC/HS STARTER AJKT 40 MG/0.8ML	44481	084819	00597037516
ADALIMUMAB-ADBM	CYLTEZO-PSORIASIS/UV STARTER AJKT 40 MG/0.4ML	44481	086039	00597049540
ADALIMUMAB-ADBM	CYLTEZO-PSORIASIS/UV STARTER AJKT 40 MG/0.8ML	44481	084819	00597037523
ADALIMUMAB-ADBM	ADALIMUMAB-ADBM (2 PEN) AJKT 40 MG/0.4ML	44481	086039	00597057550
ADALIMUMAB-ADBM	ADALIMUMAB-ADBM (2 PEN) AJKT 40 MG/0.8ML	44481	084819	00597054522
ADALIMUMAB-ADBM	ADALIMUMAB-ADBM (2 SYRINGE) PSKT 10 MG/0.2ML	44481	084512	00597058589
ADALIMUMAB-ADBM	ADALIMUMAB-ADBM (2 SYRINGE) PSKT 20 MG/0.4ML	44481	084513	00597055580
ADALIMUMAB-ADBM	ADALIMUMAB-ADBM (2 SYRINGE) PSKT 40 MG/0.4ML	44481	086037	00597056520
ADALIMUMAB-ADBM	ADALIMUMAB-ADBM (2 SYRINGE) PSKT 40 MG/0.8ML	44481	077687	00597059520
ADALIMUMAB-ADBM	ADALIMUMAB-ADBM(CD/UC/HS STRT) AJKT 40 MG/0.4ML	44481	086039	00597057560
ADALIMUMAB-ADBM	ADALIMUMAB-ADBM(CD/UC/HS STRT) AJKT 40 MG/0.8ML	44481	084819	00597054566
ADALIMUMAB-ADBM	ADALIMUMAB-ADBM(PS/UV STARTER) AJKT 40 MG/0.4ML	44481	086039	00597057540
ADALIMUMAB-ADBM	ADALIMUMAB-ADBM(PS/UV STARTER) AJKT 40 MG/0.8ML	44481	084819	00597054544
ADALIMUMAB-FKJP	HULIO (2 PEN) AJKT 40 MG/0.8ML	46685	081262	83257001932
ADALIMUMAB-FKJP	HULIO (2 SYRINGE) PSKT 20 MG/0.4ML	46685	081263	83257001642

ADALIMUMAB-FKJP	HULIO (2 SYRINGE) PSKT 40 MG/0.8ML	46685	081279	83257001742
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP (2 PEN) AJKT 40 MG/0.8ML	46685	081262	83257002232
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP (2 SYRINGE) PSKT 20 MG/0.4ML	46685	081263	83257002042
ADALIMUMAB-FKJP	ADALIMUMAB-FKJP (2 SYRINGE) PSKT 40 MG/0.8ML	46685	081279	83257002142
ADALIMUMAB-ADAZ	HYRIMOZ SOAJ 40 MG/0.4ML	45444	084543	83457010001
ADALIMUMAB-ADAZ	HYRIMOZ SOAJ 40 MG/0.8ML	45444	079220	83457010201
ADALIMUMAB-ADAZ	HYRIMOZ SOAJ 80 MG/0.8ML	45444	084553	83457010701
ADALIMUMAB-ADAZ	HYRIMOZ SOSY 10 MG/0.1ML	45444	084551	61314050964
ADALIMUMAB-ADAZ	HYRIMOZ SOSY 20 MG/0.2ML	45444	084549	83457010801
ADALIMUMAB-ADAZ	HYRIMOZ SOSY 40 MG/0.4ML	45444	084550	83457010101
ADALIMUMAB-ADAZ	HYRIMOZ SOSY 40 MG/0.8ML	45444	079219	83457010301
ADALIMUMAB-ADAZ	HYRIMOZ-CROHNS/UC STARTER SOAJ 80 MG/0.8ML	45444	084553	83457011301
ADALIMUMAB-ADAZ	HYRIMOZ-PED<40KG CROHN STARTER SOSY 80 MG/0.8ML & 40 MG/0.4ML	45444	084555	61314053164
ADALIMUMAB-ADAZ	HYRIMOZ-PED>/=40KG CROHN START SOSY 80 MG/0.8ML	45444	084563	61314045468
ADALIMUMAB-ADAZ	HYRIMOZ-PLAQ PSOR/UVEIT START SOAJ 80 MG/0.8ML & 40 MG/0.4ML	45444	084546	61314051736
ADALIMUMAB-ADAZ	HYRIMOZ-PLAQUE PSORIASIS START SOAJ 80 MG/0.8ML & 40 MG/0.4ML	45444	084546	83457011201
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOAJ 40 MG/0.4ML	45444	084543	61314032720
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ SOSY 40 MG/0.4ML	45444	084550	61314032764
ADALIMUMAB-AACF	IDACIO (2 PEN) AJKT 40 MG/0.8ML	48528	084193	65219055408
ADALIMUMAB-AACF	IDACIO (2 SYRINGE) PSKT 40 MG/0.8ML	48528	084192	65219055618

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

Prior Authorization Criteria:

Length of Authorization:

- Initial: 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-atto (Amjevita), AND

Rheumatology

If treating psoriatic arthritis:

- Diagnosis of psoriatic arthritis, AND
- Inadequate response (after at least an 3-month trial), intolerance, or contraindication to all the following:
    - At least one conventional DMARD (e.g., methotrexate or leflunomide)
    - Infliximab product (Inflectra preferred)

If treating spondyloarthropathy/spondyloarthritis:

- Diagnosis of spondyloarthritis/spondyloarthropathy, AND
- Patient has inadequate response, contraindication or intolerance to infliximab product (Inflectra IV preferred), AND
- Inadequate response, intolerance or contraindication to the following, where applicable:
    - If treating axial spondyloarthritis (ankylosing-spondylitis or non-radiographic axial spondylarthritis): Full anti-inflammatory dose of NSAID
    - If treating peripheral spondyloarthritis WITHOUT enthesitis/tendonitis (i.e. reactive arthritis, spondyloarthritis related to inflammatory bowel disease or other peripheral spondyloarthritis rather than axial): At least one conventional DMARD (e.g., sulfasalazine, methotrexate, or leflunomide)

If treating rheumatoid arthritis:

- Diagnosis of rheumatoid arthritis AND
- Documented advanced disease or high disease activity, AND
- Inadequate response (after at least a 3-month trial), intolerance or contraindication to the all the following:
    - At least one conventional DMARD (e.g. methotrexate, hydroxychloroquine, leflunomide, sulfasalazine)
    - Infliximab product [infliximab-dyyb (Inflectra) IV preferred]

If treating pediatrics with juvenile idiopathic arthritis:

- Patient is ≥2 years with moderate to severe polyarticular juvenile idiopathic arthritis, OR
- Patient is ≥2 years with diagnosis of oligoarticular juvenile idiopathic arthritis that is persistent despite trial of at least one of the conventional disease-modifying antirheumatic drugs (DMARDs) such as methotrexate, leflunomide, or sulfasalazine

Dermatology

If treating plaque psoriasis:

- 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), intolerance or contraindication to all of the following:
    - Phototherapy unless involvement in sensitive areas (e.g., face, body folds, etc.)

- Methotrexate or acitretin - *if ≥ 18 years of age*
- Ustekinumab product (Yesintek preferred) - *if ≥6 years of age*
- Secukinumab (Cosentyx)*PA - *if ≥6 years of age*

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:
  - Infliximab product (Inflectra IV preferred)
  - Ustekinumab product (Yesintek preferred)
  - 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:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met the criteria:**
  - Document clinically significant benefit from the medication, AND
  - Specialist follow-up in the last 12 months, AND
  - History of treatment failure, intolerance, or contraindication to adalimumab-atto (Amjevita)

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
CERTOLIZUMAB PEGOL	CIMZIA (1 SYRINGE) PSKT 200 MG/ML	35554	086521	50474075010

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Rheumatologist, Dermatologist, or Gastroenterologist

If using for rheumatoid arthritis*:

- Patient has diagnosis of rheumatoid arthritis, AND
- Patient has treatment failure (after at least a 3-month trial), intolerance, or contraindication to all the following:
  - At least one of the preferred anti-TNF agents [i.e. adalimumab-atto (Amjevita) or infliximab-dyyb (Inflectra)]
  - Tocilizumab product (Tyenne preferred)*PA
  - Tofacitinib (Xeljanz)*PA

If using for psoriatic arthritis*:

- Patient has a diagnosis of psoriatic arthritis, AND
- Patient has treatment failure (after at least a 3-month trial, intolerance, or contraindication to all the following:
  - Ustekinumab product (Yesintek preferred)
  - At least one of the preferred anti-TNF agents [i.e. adalimumab-atto (Amjevita) or infliximab-dyyb (Inflectra)]
  - Secukinumab (Cosentyx)*PA

If using for spondyloarthropathy/spondyloarthritis*:

- Patient has a diagnosis of spondyloarthropathy/spondyloarthritis, AND
- Patient has treatment failure (after at least a 3-month trial, intolerance, or contraindication to all the following:
  - At least one of the preferred anti-TNF agents [i.e. adalimumab-atto (Amjevita) or infliximab-dyyb (Inflectra)]
  - Tofacitinib (Xeljanz)*PA
  - Secukinumab (Cosentyx)*PA

If using for plaque psoriasis*:

- Patient has a diagnosis of moderate-to-severe plaque psoriasis (>3% body surface area unless palmar-plantar involvement is severe), AND
- Patient has treatment failure (after at least a 3-month trial, intolerance, or contraindication to all the following:
  - Ustekinumab product (Yesintek preferred)

- At least one preferred anti-TNF agents [i.e. adalimumab-atto (Amjevita), adalimumab-bwwd (Hadlima) or infliximab-dyyb (Inflectra)]
- Secukinumab (Cosentyx)*PA
- Guselkumab (Tremfya) *PA or Risankizumab-rzaa (Skyrizi) *PA
- Ixekizumab (Taltz) *PA

If using for Crohn's Disease*:

- Patient has diagnosis of Crohn's disease, AND
- Patient is intolerant to or experienced treatment failure with all of the following:
  - Ustekinumab product (Yesintek preferred)
  - At least one anti-TNF agent [i.e. adalimumab-atto (Amjevita) or infliximab-dyyb (Inflectra) preferred]
  - Vedolizumab (Entyvio)*PA
  - Upadacitinib (Rinvoq)*PA

*****Note: for ALL treatment indications, if a patient is in 3rd trimester of pregnancy, the prerequisite drug trials are NOT required.

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met 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

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

Last revised: 12/5/2025; Effective date: 2/3/2026

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

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Gastroenterologist, AND
- Patient has diagnosis of Crohn's disease or ulcerative colitis with moderate-to-severe activity or high risk of progression, AND
- Patient is currently stable on intravenous infliximab-dyyb (Inflectra) and has a documented barrier to attending infusion appointments, AND
- Patient has treatment failure, intolerance, or contraindication to ustekinumab product (Yesintek preferred)

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met the criteria**:
  - Positive clinical response to medication, AND
  - Specialist follow-up occurred 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 a diagnosis of ankylosing spondylitis or nonradiographic axial spondyloarthritis,
- AND has a history of treatment failure, intolerance, or contraindication to ALL the following:
  - At least 2 preferred anti-TNF agents (e.g. adalimumab, infliximab, etanercept)
  - Cosentyx (secukinumab) *PA
  - Xeljanz (tofacitinib) PA or Rinvoq (upadacitinib) *PA

If using for rheumatoid arthritis:

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

If using for psoriatic arthritis:

- Diagnosis of psoriatic arthritis, AND
- Patient has intolerance, contraindication to, or failed treatment with ALL of the following:
  - At least 2 anti-TNFs [e.g., adalimumab product (Amjevita preferred), infliximab product (Inflectra preferred)]
  - Ustekinumab [Yesintek (ustekinumab-kfce) preferred]*
  - Xeljanz (tofacitinib)*PA
  - Cosentyx (secukinumab)*PA
  - Orencia (abatacept)*PA

Gastroenterology

- Patient has a diagnosis of moderate to severe ulcerative colitis, AND
- Patient has intolerance, contraindication, or inadequate response to ALL of the following:
    - Ustekinumab product [Yesintek (ustekinumab-kfce) preferred]*
    - At least 1 anti-TNF agent [infliximab product (Inflectra preferred) or adalimumab product (Amjevita preferred)]
    - Tofacitinib (Xeljanz)*PA or upadacitinib (Rinvoq)*PA
    - Vedolizumab (Entyvio)*PA

**Brand Stelara/non-preferred ustekinumab biosimilars are subject to PA review*
**PA This medication is also subject to PA review*

Continuation of Therapy Criteria:

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

Anti-inflammatory – Interleukin-1 Beta Blockers

Last revised: 5/29/2025; Effective date: 8/12/2025

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: 2 months (if for acute gout); 12 months (all other indications)
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Rheumatologist

If using for systemic juvenile idiopathic arthritis (SJIA) [including adult-onset Still's disease (AOSD)]:

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

If using for gout:

- Patient is experiencing an acute flare of gout, AND
- Documented inadequate response or inability to tolerate all of the following preferred alternatives:
  - At least one NSAID
  - Prednisone or other corticosteroids
  - Colchicine

If using for familial Mediterranean fever:

- Documented diagnosis of familial Mediterranean fever, AND
- Patient has tried and failed/is intolerant to all the following:
  - Colchicine
  - Kineret (anakinra)*PA

If using for cryopyrin-associated periodic syndromes (CAPS):

- Documented diagnosis of cryopyrin-associated periodic syndromes (CAPS), AND
- Documented inadequate response or inability to tolerate either of the following:
  - Prednisone
  - Kineret (anakinra)*PA injection

If using for other indications: Approve if the patient has one of the following diagnoses:

- Tumor necrosis factor receptor-associated periodic syndrome (TRAPS)
- Hyperimmunoglobulin D syndrome (HIDS)/mevalonate kinase deficiency (MKD)

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

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS and have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria

- **For existing members who have previously met the criteria**:
    - Documented clinically significant benefits from the medication, AND
    - Specialist follow-up in the last 12 months

Anti-Inflammatory – Phosphodiesterase-4 (PDE4) Inhibitor

Last revised: 12/8/2025; Effective date: 2/3/2026

Generic	Brand	HICL	GSN	Representative NDC
APREMILAST	OTEZLA TABS 30 MG	40967	072075	59572063106
APREMILAST	OTEZLA TBPK 10 & 20 & 30 MG	40967	073370	59572063255
APREMILAST	OTEZLA TABS 20 MG	40967	086376	55513049760
APREMILAST	OTEZLA TBPK 4 X 10 & 51 X 20 MG	40967	086377	55513050855
APREMILAST	OTEZLA XR TB24 75 MG	40967	088212	55513051930
APREMILAST	OTEZLA/OTEZLA XR INITIATION PK TBPK 10&20&30&(ER)75 MG	40967	088209	55513051641

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 at least ONE of the non-biologic DMARDs (e.g., methotrexate, leflunomide, sulfasalazine)^, AND
- Documented inadequate response, intolerance, or contraindication to ALL of the following:
    - Ustekinumab (e.g., Yesintek preferred)^
    - At least ONE preferred anti-TNF agent [i.e. adalimumab-atto (Amjevita) or infliximab-dyyb (Inflectra)]
    - Secukinumab (Cosentyx)*PA

^*Note:*

- *Non-biologic DMARD and IL-12/23 (e.g. ustekinumab) are not required for patients with axial disease or severe (rapidly progressive, erosive) psoriatic arthritis disease*
- *Otezla can be combined with preferred biologics for PsA in severe cases, but not approved as a monotherapy before trying the preferred drugs.*

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
- Inadequate response to at least a 3-month trial or contraindication to phototherapy unless involvement in sensitive areas (e.g., face, body folds, etc.), AND
- Inadequate response (after at least a 3-month trial), intolerance, or contraindication to all the following:
    - Methotrexate or acitretin
    - Ustekinumab product (Yesintek preferred)
    - At least one anti-TNF agent [e.g. Amjevita or Inflectra IV preferred)

- Secukinumab (Cosentyx)*PA

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:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met criteria:**
  - 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
    - Note: Otezla can be combined with preferred biologics for PsA in severe cases, but it is not approved as a monotherapy before trying the preferred drugs.
  - Patient is NOT using Otezla starter pack for maintenance therapy, AND
  - Specialist follow-up occurred since last review

Antimigraine Preparations

Last revised: 8/1/2023

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:

<u>Migraine treatment:</u>

- 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:
    - Tricyclic antidepressants (e.g., amitriptyline, nortriptyline)
    - Beta-blocker (e.g., metoprolol, propranolol)
    - SNRIs (e.g. venlafaxine, duloxetine)
    - Candesartan
    - Lisinopril
    - Topiramate
    - Valproate, AND
- 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

<u>Cluster Headache (Emgality ONLY):</u>

- 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: 8/1/2023

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:
  - Tricyclic antidepressants (e.g., amitriptyline, nortriptyline)
  - Beta-blocker (e.g., metoprolol, propranolol)
  - SNRIs (e.g., venlafaxine, duloxetine)
  - Candesartan
  - Lisinopril
  - Topiramate
  - Valproate
- AND trial of 2 injectable CGRP antagonists (Ajovy preferred, then Emgality, then Aimovig),
- AND trial of Qulipta (atogepant)

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

- 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:

- 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: 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: • 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)

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:
    - Tricyclic antidepressant (e.g. amitriptyline, nortriptyline)
    - Beta-blocker (e.g. metoprolol, propranolol)
    - SNRIs (e.g., venlafaxine, duloxetine)
    - Candesartan
    - Lisinopril
    - Topiramate
    - Valproate
- 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 (cont'd)

Last revised: 7/31/2024; 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

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

Last revised: 12/8/2025; Effective date: 2/3/2026

Generic	Brand	HICL	GSN	Representative NDC
SODIUM OXYBATE	SODIUM OXYBATE SOLN 500 MG/ML	12346	050813	00054962857

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 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

- **Diagnosis of excessive daytime sleepiness in narcolepsy:**
  - Adequate trial (≥2 months) of a preferred stimulant (methylphenidate, amphetamine salt combination, dextroamphetamine) AND modafinil/armodafinil, unless contraindicated, AND
  - Adequate trial (≥2 months) of Sunosi[*PA], unless contraindicated

- **Diagnosis of cataplexy due to narcolepsy:**
  - Adequate trial (≥2 months) of at least 2 of the following, unless contraindicated: TCAs, SSRI, or SNRI

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

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met 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: 12/8/2025; Effective date: 2/3/2026

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

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 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

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

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

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

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met 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: 12/8/2025; Effective date: 2/3/2026

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: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

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

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

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

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

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

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

- Patient is at least 18 years of age

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

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met criteria:**
  - Patient continues to be under the care of a specialist,
  - Documentation of positive clinical response

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

Last revised: 12/8/2025; Effective date: 2/3/2026

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

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

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

Diagnosis of excessive daytime sleepiness in narcolepsy:

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

Diagnosis of cataplexy due to narcolepsy:

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

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met criteria:**
    - Patient continues to be under the care of a specialist,
    - Documentation of positive clinical response

Anti-inflammatory – Selective Co-stimulation Modulator

Last revised: 12/8/2025; Effective date: 2/3/2026

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

If using for rheumatoid arthritis:

- 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:
    - One of the following: oral/subcutaneous methotrexate, hydroxychloroquine, leflunomide, or sulfasalazine, AND
    - At least 1 TNF inhibitor (e.g., Humira, Enbrel, Inflectra), AND
    - Tocilizumab product (Tyenne preferred), AND
    - Xeljanz (tofacitinib)

If using for juvenile idiopathic arthritis:

- Diagnosis of juvenile idiopathic arthritis, AND
- Intolerance, contraindication to, or failed treatment with at least a 3-month trial of ALL of the following:
    - At least ONE TNF inhibitor (e.g., adalimumab, etanercept, golimumab, certolizumab pegol), AND
    - Tocilizumab product (Tyenne preferred)*PA

If using for psoriatic arthritis:

- Patient is ≥18 years, AND
- Diagnosis of psoriatic arthritis, AND
- Intolerance, contraindication to, or failed treatment with ALL of the following:
    - Ustekinumab (Yesintek preferred)^
    - At least a 3-month trial of a TNF inhibitor (e.g., adalimumab, etanercept, golimumab, certolizumab pegol)

^*Note: non-biologic DMARD and IL-12/23 (e.g. ustekinumab) are not required for patients with axial disease or severe (rapidly progressive, erosive) psoriatic arthritis disease*

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met 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: 12/8/2025; Effective date: 2/3/2026

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
SECUKINUMAB	COSENTYX SOSY 75 MG/0.5ML	41715	082340	00078105697
SECUKINUMAB	COSENTYX UNOREADY SOAJ 300 MG/2ML	41715	082151	00078107068

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 ALL of the following:
  - At least ONE of the conventional DMARDs (e.g., methotrexate or leflunomide)^,
  - AND ustekinumab (Yesintek preferred)^
  - AND at least ONE preferred anti-TNF [i.e. Amjevita (adalimumab-atto), Hadlima (adalimumab-bwwd), Inflectra (infliximab-dyyb)]

^*Note: Conventional DMARD and IL-12/23 (e.g. ustekinumab) are not required for patients with axial disease or severe (rapidly progressive, erosive) psoriatic arthritis disease*

If treating spondyloarthritis:

- Patient has a diagnosis of ankylosing spondylitis or nonradiographic axial spondyloarthritis, AND
- Patient has an inadequate response, contraindication or intolerance to at least 1 preferred anti-TNF agent [e.g. Amjevita (adalimumab-atto), Inflectra (infliximab-dyyb)]

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
- Patient has an inadequate response (after at least a 3-month trial), intolerance, or contraindication to ALL the following:
    - Phototherapy (unless involvement in sensitive areas such as face and/or body folds)
    - Methotrexate or acitretin if ≥ 18 years of age
    - Ustekinumab [Yesintek (ustekinumab-kfce) preferred; Stelara*PA and other nonpreferred ustekinumab biosimilars are subject to PA review]
    - At least one of the preferred anti-TNF agents [i.e. adalimumab-atto (Amjevita) or infliximab-dyyb (Inflectra)] if ≥ 18 years of age

Continuation of Therapy Criteria:

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

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: 12/8/2025; Effective date: 2/3/2026

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
- Inadequate response (after at least a 3-month trial), intolerance, or contraindication to ALL of the following:
    - Methotrexate or acitretin
    - Ustekinumab product (Yesintek preferred)*
    - 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

**Brand Stelara/nonpreferred ustekinumab biosimilars are subject to PA review*
**PAThis medication is also subject to PA review*

Continuation of Therapy Criteria:

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

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
RISANKIZUMAB-RZAA (CROHN'S)	SKYRIZI SOCT 360 MG/2.4ML	45699	083492	00074106901
RISANKIZUMAB-RZAA (CROHN'S)	SKYRIZI SOCT 180 MG/1.2ML	45699	084203	00074106501

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 ALL of the following:
  - At least 1 anti-TNF agent [e.g. adalimumab product (Amjevita preferred) or Infliximab product (Inflectra preferred)]
  - Ustekinumab [Yesintek (ustekinumab-kfce) preferred]*
  - 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 preferred TNF inhibitor (i.e. adalimumab product [Amjevita preferred] or infliximab product [Inflectra preferred])
  - Ustekinumab [Yesintek (ustekinumab-kfce) preferred]*
  - Secukinumab (Cosentyx)*PA

Gastroenterology

Crohn's disease:

- Diagnosis of active Crohn's disease with moderate-to-severe activity or high risk of progression,
- AND inadequate response (after at least a 3-month trial), intolerance, or contraindication to ALL of the following therapies:
    - Ustekinumab product (Yesintek preferred)*
    - At least 1 anti-TNF (Amjevita or Inflectra IV preferred)
    - Upadacitinib (Rinvoq)*PA

Ulcerative colitis:

- Diagnosis of active ulcerative colitis with moderate-to-severe activity or high risk of progression, AND
- Inadequate response (of at least a 3-month trial), intolerance, or contraindication to ALL the following:
    - Ustekinumab product (Yesintek preferred)*
    - At least ONE anti-TNF (Amjevita or Inflectra IV preferred)
    - Tofacitinib (Xeljanz)*PA or Upadacitinib (Rinvoq)*PA

**Brand Stelara/non-preferred ustekinumab biosimilars are subject to PA review*
**PA This medication is also subject to PA review*

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - Positive clinical response to medication, AND
    - Specialist follow-up in the last 12 month

Generic	Brand	HICL	GSN	Representative NDC
IXEKIZUMAB	TALTZ SOAJ 80 MG/ML	43193	075731	00002144509
IXEKIZUMAB	TALTZ SOSY 80 MG/ML	43193	075732	00002772411
IXEKIZUMAB	TALTZ SOSY 40 MG/0.5ML	43193	085786	00002890511
IXEKIZUMAB	TALTZ SOSY 20 MG/0.25ML	43193	085785	00002890011

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 ALL of the following:
  - At least ONE tumor necrosis factor (TNF-alpha) inhibitors [i.e. adalimumab (Amjevita preferred), infliximab (Inflectra preferred), etanercept*PA, golimumab*PA, or certolizumab*PA]
  - 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 ALL of the following:
  - At least ONE tumor necrosis factor (TNF alpha) inhibitors [i.e. infliximab (Inflectra preferred), adalimumab (Amjevita preferred), etanercept*PA, golimumab*PA, or certolizumab*PA]
  - Ustekinumab [Yesintek (ustekinumab-kfce) preferred]*
  - Cosentyx*PA (secukinumab)
  - Guselkumab (Tremfya) *PA OR risankizumab (Skyrizi) *PA

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])
  - Ustekinumab [Yesintek (ustekinumab-kfce) preferred]*
  - Secukinumab (Cosentyx)*PA
  - Guselkumab (Tremfya)*PA (preferred IL-23) OR risankizumab-rzaa (Skyrizi)*PA

**Brand Stelara/nonpreferred ustekinumab biosimilars are subject to PA review*
**PA This medication is also subject to PA review*

Continuation of Therapy Criteria:

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

Generic	Brand	HICL	GSN	Representative NDC
GUSELKUMAB	TREMFYA PEN SOAJ 100 MG/ML	44418	087492	57894064003
GUSELKUMAB	TREMFYA SOPN 100 MG/ML	44418	079520	57894064011
GUSELKUMAB	TREMFYA SOSY 100 MG/ML	44418	077565	57894064001
GUSELKUMAB	TREMFYA SOAJ 200 MG/2ML	44418	086508	57894065101
GULSEKUMAB	TREMFYA SOSY 200 MG/2ML	44418	086507	57894065122

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
- Documentation of inadequate response (of at least a 3 month trial), intolerance, or contraindication to ALL of the following:
  - At least ONE tumor necrosis factor (TNF alpha) inhibitors [i.e. adalimumab product (Amjevita preferred) or infliximab product (Inflectra preferred)]
  - Ustekinumab [Yesintek (ustekinumab-kfce) preferred]*
  - 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])
  - Ustekinumab [Yesintek (ustekinumab-kfce) preferred]*
  - Secukinumab (Cosentyx)*PA

Gastroenterology

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

- Diagnosis of active ulcerative colitis with moderate-to-severe activity or high risk of progression, AND
- Inadequate response (of at least a 3-month trial), intolerance, or contraindication to ALL the following:
    - Ustekinumab product (Yesintek preferred)*
    - At least 1 anti-TNF [i.e., adalimumab (Amjevita preferred) or infliximab (Inflectra IV preferred)]
    - Tofacitinib (Xeljanz)*PA or upadacitinib (Rinvoq)*PA

<u>If using for Crohn's Disease:</u>

- Diagnosis of active Crohn's disease with moderate-to-severe activity or high risk of progression, AND
- Inadequate response (of at least a 3-month trial), intolerance, or contraindication to **all** the following:
    - Ustekinumab product (Yesintek preferred)*
    - At least 1 anti-TNF (Amjevita or Inflectra IV preferred)
    - Upadacitinib (Rinvoq)*PA

**Brand Stelara/non-preferred ustekinumab biosimilars are subject to PA review*
**PAThis medication is also subject to PA review*

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - Positive clinical response to medication, AND
    - Specialist follow-up in the last 12 months

Antipsoriatic Agents (Cont'd)

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

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 to at least 3-month trial or contraindication to phototherapy unless involvement in sensitive areas (e.g. face, body folds, etc.),
- AND patient has failed an adequate trial (of at least a 4-week duration), allergy, intolerance or contraindication to ALL of the following:
    - o High or super-high potency topical corticosteroid (e.g., betamethasone propionate, augmented 0.05% cream, triamcinolone 0.5% cream or ointment, clobetasol propionate 0.05% ointment, lotion, or gel)
    - o Topical calcineurin inhibitor (e.g. tacrolimus 0.1% ointment)
    - o Topical vitamin D analog (e.g. calcipotriene 0.005% cream or ointment)
    - o Topical retinoid (e.g. tazarotene 0.1% cream)

Continuation of Therapy Criteria:

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

Antipsoriatics Agents (cont'd)

Generic	Brand	HICL	GSN	Representative NDC
ROFLUMILAST (TOPICAL)	ZORYVE CREA 0.3%	37123	083653	80610013060

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Diagnosis of plaque psoriasis,
- Patient is ≥6 years of age,
- Patient has failed an adequate trial (for at least 2 months), or patient has an allergy or intolerance to ALL of the following:
    - High or super-high potency topical corticosteroid (e.g., betamethasone dipropionate, augmented 0.05% cream, clobetasol propionate 0.05% ointment/lotion/gel)
    - Topical calcineurin inhibitor (e.g. tacrolimus 0.1% ointment)
    - Topical vitamin D analog (e.g. calcipotriene 0.005% cream/ointment)
    - Topical retinoid (e.g. tazarotene 0.1% cream)
    - Phototherapy (unless documented by prescriber phototherapy not appropriate)

Continuation of Therapy Criteria:

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

Antipsoriatic Agents, Systemic

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

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
BIMEKIZUMAB-BKZX	BIMZELX SOAJ 320 MG/2ML	47629	086849	50474078284
BIMEKIZUMAB-BKZX	BIMZELX SOSY 320 MG/2ML	47629	086850	50474078378

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Dermatologist or Rheumatologist, AND

<u>If treating plaque psoriasis:</u>

- 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])
  - Ustekinumab [Yesintek (ustekinumab-kfce) preferred]*
  - Secukinumab (Cosentyx)*PA
  - Guselkumab (Tremfya)*PA OR risankizumab-rzaa (Skyrizi)*PA

<u>If treating hidradenitis suppurativa:</u>

- Patient has a diagnosis of moderate-to-severe hidradenitis suppurativa,
- AND has an inadequate response, contraindication, or intolerance to ALL following therapies:
  - Topical clindamycin 1% solution/lotion/gel for a minimum of 12 weeks
  - Oral antibiotic (e.g., doxycycline, tetracycline, clindamycin +/1 rifampin, erythromycin) for a minimum of 10 weeks
  - At least 1 anti-TNF agent [e.g. adalimumab (Amjevita preferred) or infliximab (Inflectra preferred)]
  - Cosentyx (secukinumab)*PA for a minimum of 12 weeks

<u>If treating psoriatic arthritis:</u>

- Patient has a diagnosis of active psoriatic arthritis,

- AND inadequate response (after a least a 3-month trial), intolerance, or contraindication to all following therapies:
    - At least 1 anti-TNF agent (e.g., biosimilar adalimumab-atto or infliximab-dyyb preferred)
    - Ustekinumab [Yesintek (ustekinumab-kfce) preferred]*
    - Cosentyx (secukinumab)*PA
    - Xeljanz (tofacitinib)*PA or Rinvoq (upadacitinib)*PA
    - Tremfya (guselkumab) *PA or Skyrizi (risankizumab) *PA

If treating spondyloarthritis:

- Patient has a diagnosis of ankylosing spondylitis or nonradiographic axial spondyloarthritis,
- AND has a history of treatment failure, intolerance, or contraindication to ALL the following:
    - At least 1 anti-TNF agent (e.g. adalimumab, infliximab, golimumab)
    - Cosentyx (secukinumab) *PA
    - Xeljanz (tofacitinib) *PA or Rinvoq (upadacitinib) *PA

Continuation of Therapy Criteria:

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

Notes:

- Limited to 60-DS per dispensing

Brand Stelara and non-preferred ustekinumab biosimilars are subject to PA review

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

Antipsoriatic Agents, Systemic (cont'd)

Last revised: 7/29/2025; Effective date: 10/7/2025

Generic	Brand	HICL	GSN	Representative NDC
DEUCRAVACITINIB	SOTYKTU TABS 6 MG	48292	083817	00003089511

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a dermatologist,
- Patient is ≥18 years of age,
- Documented moderate-to-severe plaque psoriasis (>20% Body Surface Area Affected, unless involving scalp),
- Inadequate response (of at least a 3-month trial), intolerance or contraindication to phototherapy,
- Documented failure or clinically significant adverse effects to at least one of the following (of at least a 3-month trial), unless contraindicated or clinical reason to avoid treatment:
  - Methotrexate
  - Acitretin
- Inadequate response (of at least a 3-month trial), intolerance and/or contraindication to ALL of the following:
  - Adalimumab product [Amjevita (adalimumab-atto) preferred]
  - Cosentyx (secukinumab)*[PA]
  - Ustekinumab [Yesintek (ustekinumab-kfce) preferred]*
  - Tremfya (guselkumab)*[PA]
  - Skyrizi (risankizumab)*[PA]

**Brand Stelara/nonpreferred ustekinumab biosimilars are subject to PA review*
**[PA] This medication is also subject to PA review*

Continuation of Therapy Criteria:

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

Antipsoriatic Agents, Systemic (cont'd)

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

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a dermatologist,
- Patient is at least 12 years of age,
- Patient weighs at least 40 kilograms,
- Diagnosis of generalized pustular psoriasis (GPP),
- Patient has experienced ≥2 GPP flares previously,
- Patient has a Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of 0 or 1,
- Patient has treatment failure (after at least 2-month trial), allergy, intolerance to at least one or contraindication to all of the following:
  - Methotrexate
  - Acitretin
- Patient has treatment failure (after at least a 3-months trial), allergy, intolerance or contraindication to all of the following:
  - Infliximab product [Inflectra (infliximab-dyyb) preferred] or adalimumab product [Amjevita (adalimumab-atto) preferred],
  - Cosentyx (secukinumab)*PA

PA This medication is also subject to PA review

Continuation of Therapy Criteria:

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

Antipsychotic-Atypical, D3/D2 Partial Ag-5HT Mixed

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

Generic	Brand	HICL	GSN	Representative NDC
CARIPRAZINE HCL	VRAYLAR CAPS 1.5 MG	42552	074807	61874011511
CARIPRAZINE HCL	VRAYLAR CAPS 3 MG	42552	074808	61874013020
CARIPRAZINE HCL	VRAYLAR CAPS 4.5 MG	42552	074809	61874014530
CARIPRAZINE HCL	VRAYLAR CAPS 6 MG	42552	074810	61874016030
CARIPRAZINE HCL	VRAYLAR CPPK 1.5 & 3 MG	42552	075566	61874017008

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Psychiatrist,
- Patient is 18 years and older, AND

If using for Schizophrenia:

- Diagnosis of schizophrenia,
- Documented inadequate response, intolerance, or contraindication to at least THREE formulary antipsychotic agents (e.g., quetiapine, risperidone, olanzapine, aripiprazole, ziprasidone, clozapine or first-generation antipsychotic)

If using for Bipolar disorder:

- Diagnosis of bipolar disorder,
- Documented inadequate response, intolerance, or contraindication to THREE formulary regimens consisting of an antipsychotic, a mood stabilizer (lithium or antiepileptic used for mood disorder such as divalproex) or a combination* of these agents

If using for Major Depressive Disorder:

- Diagnosis of major depressive disorder,
- Documented inadequate response, intolerance, or contraindication to at least TWO formulary antidepressant agents,
- Documented inadequate response, intolerance, or contraindication to at least ONE formulary antipsychotic (e.g., quetiapine, risperidone, olanzapine, aripiprazole, ziprasidone, clozapine or first-generation antipsychotic) or augmenting agent (e.g., lithium, triiodothyronine)

Continuation of Therapy Criteria:

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

***Note:** Avoid carbamazepine with an antipsychotic due to hepatic enzyme induction and 3A4 induction of cariprazine

Antipsychotic, Atypical, Dopamine, Serotonin Antagonist

Generic	Brand	HICL	GSN	Representative NDC
OLANZAPINE-SAMIDORPHAN L-MALATE	LYBALVI TABS 5-10 MG	47406	082334	65757065142
OLANZAPINE-SAMIDORPHAN L-MALATE	LYBALVI TABS 20-10 MG	47406	082347	65757065442
OLANZAPINE-SAMIDORPHAN L-MALATE	LYBALVI TABS 10-10 MG	47406	082336	65757065242
OLANZAPINE-SAMIDORPHAN L-MALATE	LYBALVI TABS 15-10 MG	47406	082337	65757065342

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a psychiatrist,
- Patient is 18 years or older,
- Patient has diagnosis of one of the following:
  - Schizophrenia, OR
  - Bipolar I disorder
- Patient must not be using an opioid or going through an opioid withdrawal,
- Patient has documented inadequate response or intolerance to:
  - For schizophrenia: olanzapine AND 1 other antipsychotic agent (e.g., aripiprazole, lurasidone, ziprasidone, first-generation antipsychotic, etc.) OR
  - For bipolar I disorder: olanzapine AND 1 other antipsychotic agent (e.g., aripiprazole, lurasidone, ziprasidone, first-generation antipsychotic, etc.) OR mood stabilizers (lithium, valproate, lamotrigine, carbamazepine, etc.)

Continuation of Therapy Criteria:

- Documentation of positive clinical response

Antipsychotics, Muscarinic Agonist/Antagonist Comb

Generic	Brand	HICL	GSN	Representative NDC
XANOMELINE TARTRATE-TROSPIUM CHLORIDE	COBENFY CAPS 100-20 MG	49888	086552	00003110060
XANOMELINE TARTRATE-TROSPIUM CHLORIDE	COBENFY CAPS 125-30 MG	49888	086550	00003012560
XANOMELINE TARTRATE-TROSPIUM CHLORIDE	COBENFY CAPS 50-20 MG	49888	086554	00003005060
XANOMELINE TARTRATE-TROSPIUM CHLORIDE	COBENFY STARTER PACK CPPK 50-20 & 100-20 MG	49888	086553	00003520056

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Patient is aged 18 to 65 years old, AND
- Patient has documented diagnosis of schizophrenia, AND
- Prescribed by Psychiatry, AND
- Intolerance, contraindication, or documented treatment failure to 4 or more antipsychotics (e.g., aripiprazole, quetiapine, olanzapine, risperidone, lurasidone, ziprasidone, clozapine, etc.), AND
- Documented baseline liver enzymes and bilirubin within the past 1 month of initiating treatment, AND
- Documented baseline Positive and Negative Syndrome Scale (PANSS) score between 80 and 120, AND
- Patient does not have any of the following reasons for non-coverage:
    - Urinary retention (e.g., benign prostatic hyperplasia, diabetic cytopathy, acute urinary retention, etc.)
    - Moderate (Child-Pugh Class B) or severe (Child-Pugh Class C) liver impairment
    - Gastric retention (e.g., irritable bowel syndrome, intestinal atony, etc.)
    - Untreated narrow-angle glaucoma
    - Pregnancy or breastfeeding
    - Concurrent use with any other antipsychotic medication

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met the criteria:**
    - Documentation of improvement in signs and symptoms of schizophrenia AND
    - Documented decrease in PANSS total score AND
    - Patient does not have any of the reasons for non-coverage as listed in the initial criteria

Antiviral Agent, Topical

Last revised: 7/29/2025; Effective date: 10/7/2025

Generic	Brand	HICL	GSN	Representative NDC
BERDAZIMER SODIUM	ZELSUVMI GEL 10.3%	49364	085650	83787010331

Prior Authorization Criteria:

Length of Authorization:

- Initial: 3 months
- Reauthorization: 12 months

Initial Review Criteria:

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

Continuation of Therapy Criteria:

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

Arginine Vasopressin (AVP) Receptor Antagonists

Last revised: 7/29/2025; Effective date: 10/7/2025

Generic	Brand	HICL	GSN	Representative NDC
TOLVAPTAN	JYNARQUE TABS 15 MG	36348	081525	59148008213
TOLVAPTAN	JYNARQUE TABS 30 MG	36348	081526	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
TOLVAPTAN	JYNARQUE TBPK 30 & 15 MG	36348	081052	59148008028
TOLVAPTAN	JYNARQUE TBPK 15 MG	36348	081054	59148007907
TOLVAPTAN	JYNARQUE TBPK 15 MG	36348	081054	59148007928
TOLVAPTAN	JYNARQUE TBPK 30 & 15 MG	36348	081052	59148008007
TOLVAPTAN	TOLVAPTAN TABS 15 MG	36348	081525	70748023806
TOLVAPTAN	TOLVAPTAN TABS 30 MG	36348	081526	70748023906
TOLVAPTAN	TOLVAPTAN TBPK 15 MG	36348	081054	70748024013
TOLVAPTAN	TOLVAPTAN TBPK 30 & 15 MG	36348	081052	70748024113
TOLVAPTAN	TOLVAPTAN TBPK 45 & 15 MG	36348	075048	70748024213
TOLVAPTAN	TOLVAPTAN TBPK 60 & 30 MG	36348	075049	70748024313
TOLVAPTAN	TOLVAPTAN TBPK 90 & 30 MG	36348	075047	70748024413

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

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

OR

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

-AND -

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

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met criteria:**
    - Positive clinical response to tolvaptan, AND
    - eGFR >25 mL/min/1.73 m^2, AND
    - Patient has followed-up with a Nephrologist within the past 12 months

Artificial Tears

Generic	Brand	HICL	GSN	Representative NDC
PERFLUOROHEXYLOCTANE	MIEBO SOLN 1.338 GM/ML	45391	079188	24208037705

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is an Ophthalmologist, or Optometrist
- Patient is ≥ 18 years of age with a diagnosis of dry eye disease
- Patient has tried and failed at least one month of one OTC ocular lubricant (e.g., artificial tears, lubricating gels/ointments)
- Patient has had an adequate trial* and failure to cyclosporine ophthalmic solution (generic Restasis) AND Xiidra
- Patient is not concomitantly using an ophthalmic cyclosporine product (Cequa, Restasis, Vevye), Tyrvaya (varenicline nasal solution), or Xiidra (lifitegrast ophthalmic solution)

**Adequate trial is defined as 3 months treatment duration*

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met the criteria:**
    - Documentation of positive clinical response to therapy (e.g., increased tear production or improvement in dry eye symptoms)

Azole Antifungals

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

Generic	Brand	HICL	GSN	Representative NDC
ISAVUCONAZONIUM SULFATE	CRESEMBA CAPS 186 MG	41817	073654	00469032014
ISAVUCONAZONIUM SULFATE	CRESEMBA CAPS 74.5 MG	41817	085265	00469286001

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

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

C1 Esterase Inhibitors

Last revised: 9/30/2025; Effective date: 12/2/2025

Generic	Brand	HICL	GSN	Representative NDC
C1 ESTERASE INHIBITOR (HUMAN)	HAEGARDA SOLR 3000 UNIT	18568	077524	63833082902
C1 ESTERASE INHIBITOR (HUMAN)	HAEGARDA SOLR 2000 UNIT	18568	077523	63833082802

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is an Allergist, Immunologist, or Physician who specializes in the treatment of hereditary angioedema (HAE),
- Patient is at least 6 years of age,
- Patient has diagnosis of HAE type I or type II confirmed by either:
  - Mutation known to cause HAE in either the SERPING1 or F12 gene, OR
  - A C4 level below the lower limit of normal and/or a C1 inhibitor (C1-INH) antigenic level or functional level below the lower limit of normal,
- Documented treatment failure**/inadequate response, intolerance, or contraindication to Takhzyro (lanadelumab-flyo),
- Haegarda is not being used in combination with other products indicated for prophylaxis against HAE attacks

Notes:
**Please ensure that silicone-free syringes are ordered along with Haegarda*
***Failure is defined as no significant decrease in number of HAE acute attack frequency, decrease in HAE attack severity, or decrease in duration of HAE attacks after an adequate trial (≥3 months)*

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS and have not been reviewed previously:** confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
  - Specialist follow-up occurred in the past 12 months with documented improvement while on Haegarda,
  - Haegarda continues not to be used in combination with other products indicated for prophylaxis against HAE attacks

Cardiac Drugs, Miscellaneous

Last revised: 5/29/2025; Effective date: 8/12/2025

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) AND either:
        - Echocardiogram with end-diastolic interventricular septal wall thickness >12 mm, OR
        - Cardiac MRI consistent with, or suggestive of, amyloidosis
    - Pyrophosphate (PYP) scintigraphy cardiac uptake visual score of either:
        - Grade 2 or 3 using Perugini Grade 1-3 scoring system, OR
        - 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 recommend NOT to initiate if any of the following apply:
    - NYHA Class IV or ACC/AHA Stage D heart failure
    - Glomerular filtration rate (GFR) <25 mL/min
    - Currently receiving inotersen (Tegsedi), patisiran (Onpattro), acoramidis (Attruby), or vutrisiran (Amvuttra)
    - Severe hepatic impairment and/or cirrhosis
    - Prior heart or liver transplantation,
    - Implanted cardiac mechanical assist device
    - Patient is in hospice care
    - Patient has life expectancy of less than one year

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met the criteria:**
    - Documentation of positive clinical response AND
    - Office visit or telephone visit with a specialist within the past 12 months

Cardiac Myosin Inhibitor

Last revised: 3/18/2025; Effective date: 6/3/2025

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

Prior Authorization Criteria:

Length of Authorization:

- Initial: 3 months
- Reauthorization: 6 months

Initial Review Criteria:

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

Continuation of Therapy Criteria:

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

- AND patient continues to be managed by Cardiologist with expertise in hypertrophic cardiomyopathy

Complement Inhibitors

Last revised: 5/29/2025; Effective date: 8/12/2025

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

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 6 months

Initial Review Criteria:

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

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

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

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

- Patient has documented non-responsiveness to IVIG as bridge therapy, AND
- Patient has documented non-responsiveness to efgartigimod (Vyvgart) as bridge therapy AND

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

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

Continuation of Therapy Criteria:

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

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

Complement Inhibitors (cont'd)

Generic	Brand	HICL	GSN	Representative NDC
AVACOPAN	TAVNEOS CAPS 10 MG	47626	082745	73556016801

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescribed by, or in consultation with a Rheumatologist, Nephrologist, or Pulmonologist, AND
- Patient is ≥18 years of age, AND
- Diagnosis of anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis [granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA)], AND
- Positive test for anti-PR3 (proteinase 3) or anti-MPO (myeloperoxidase) antibodies OR positive tissue biopsy, AND
- History of significant intolerance to steroid or relative contraindication to steroid per prescriber judgement (factoring in comorbidities and other clinical considerations) OR requires a decrease in cumulative steroid dose due to steroid-induced complications, AND
- Patient does not have any of the following conditions:
    - Eosinophilic granulomatosis with polyangiitis (EGPA)
    - Active, untreated and/or uncontrolled chronic liver disease and cirrhosis [especially those with hepatic impairment (Child-Pugh C) and including hepatitis B and hepatitis C]
    - Active serious infection, including localized infections
    - Pregnant or breast-feeding

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - Documentation of positive clinical response, AND
    - Patient does not have any of the conditions as noted in the initial review criteria, AND
    - Office visit or telephone visit with a specialist within the past 12 months

Complement Inhibitors (cont'd)

Last revised: 12/5/2025; Effective date: 2/3/2026

Generic	Brand	HICL	GSN	Representative NDC
IPTACOPAN HCL	FABHALTA CAPS 200 MG	49336	085581	00078118920

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is certified through Fabhalta REMS program, AND

<u>If using for IgA nephropathy (IgAN):</u>

- Prescriber is a Nephrologist, AND
- Patient is ≥18 years of age, AND
- Documented diagnosis of IgAN verified by renal biopsy, AND
- Patient is at high risk of disease progression, as defined by urine protein-to-creatinine ratio (UPCR) >1.5, AND
- Baseline eGFR ≥30 mL/min, AND
- Currently prescribed maximum tolerated dose of ONE of the following for at least 3 months, or has documented intolerance or contraindication to therapy:
  - ACEI (e.g., lisinopril, benazepril)
  - ARB (e.g., losartan, valsartan)
- AND currently prescribed an SGLT2 inhibitor (e.g., Jardiance) for at least 3 months, or has documented intolerance or contraindication to therapy, AND
- Documented adequate therapeutic trial, intolerance, or contraindication to ALL of the following:
  - At least ONE generic systemic corticosteroid therapy (e.g., oral prednisone, methylprednisolone),
  - Tarpeyo (budesonide)
  - Filspari (sparsentan)
- AND patient does NOT have any of the following reasons for non-coverage:
  - Hx of kidney transplant, or currently undergoing dialysis
  - Concurrent treatment with Tarpeyo or Filspari
  - Severe hepatic impairment (e.g., Child-Pugh Class C)
  - Unresolved serious infection caused by encapsulated bacteria, including Streptococcus pneumoniae, Neisseria meningitidis, or Haemophilus influenza type B
  - Lack of vaccination against certain encapsulated bacteria, including Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenza type B (HiB) at least TWO weeks prior to first dose of Fabhalta

<u>If using for paroxysmal nocturnal hemoglobinuria (PNH):</u>

- Prescribed by a Geneticist or Hematologist/Oncologist, AND
- Patient is ≥18 years of age, AND
- Documented diagnosis of PNH, AND

- Patient is transfusion-dependent OR has documented history of major adverse vascular events (i.e., thromboembolism), AND
- Documented treatment failure to both of the following therapies, with persistent anemia (Hgb <10 g/dL):
    - Ultomiris (ravulizumab)
    - Epysqli (eculizumab-aagh)
- AND patient will NOT be using concurrent C5 complement inhibitor therapy (e.g., Ultomiris, Epysqli), AND
- Patient does NOT have any of the following reasons for non-coverage:
    - Severe hepatic impairment (e.g., Child-Pugh Class C)
    - Unresolved serious infection caused by encapsulated bacteria, including Streptococcus pneumoniae, Neisseria meningitidis, or Haemophilus influenza type B
    - Lack of vaccination against certain encapsulated bacteria, including Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenza type B (HiB) at least TWO weeks prior to first dose of Fabhalta

<u>If using for complement 3 glomerulopathy (C3G):</u>

- Prescribed by Nephrologist who is certified through Fabhalta REMS program,
- AND patient is ≥ 18 years of age,
- AND documented diagnosis of C3G confirmed by kidney biopsy,
- AND the following lab requirements have been obtained within 4 weeks of request:
    - Serum C3 level < 77 mg/dL,
    - AND urine protein-to-creatinine ratio (UPCR) ≥1 g/g (or 24-hour proteinuria ≥1 g/day),
    - AND eGFR ≥ 30 mL/min/1.73 m^2
- AND ruled out secondary causes of C3 deposits on biopsy and low serum complement level (e.g., active/subclinical infection, paraproteinemia, systemic autoimmune disorder[s]),
- AND received vaccinations against *Streptococcus pneumoniae, Neisseria meningitidis (types AC, C, W, Y, and B),* and *Haemophilus influenzae (type B)*,
- AND ≥ 6-month trial of mycophenolate mofetil (MMF) in combination with corticosteroid therapy, or documented intolerance or contraindication to therapy,
- AND currently prescribed the maximum tolerated dose of ONE of the following for at least 3 months, or documented intolerance or contraindication to therapy:
    - Angiotensin converting enzyme inhibitor (ACEi)
    - Angiotensin II receptor blocker (ARB)
- AND currently prescribed an SGLT2i (e.g., dapagliflozin, empagliflozin, etc.) for at least 3 months, or documented intolerance or contraindication to therapy,
- AND patient does NOT have any of the following reasons for non-coverage:
    - Unresolved serious infection caused by encapsulated bacteria
    - Severe infection(s) within 14 days
    - > 50% global glomerulosclerosis, crescentic glomerulonephritis, or interstitial fibrosis
    - Solid organ or cell transplant
    - History of recurrent invasive infections caused by encapsulated organisms
    - Fever within 7 days
    - Post-infectious glomerulonephritis
    - Monoclonal gammopathy
    - Use of immunosuppressant therapy (MMF permitted), cyclophosphamide, or systemic corticosteroids equivalent to prednisolone > 7.5 mg/day within 90 days

- AND documented trial of, contraindication, or reason to avoid use of preferred therapy to treat C3G (i.e., Empaveli [pegcetacoplan])

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - If continuation is being requested for treatment of IgAN:
        - Documentation of positive clinical response to Fabhalta (i.e., 30-40% reduction in proteinuria from baseline),
        - Specialist follow-up within the past 12 months
    - If continuation is being requested for treatment of PNH:
        - Documentation of positive clinical response to Fabhalta (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase, increased or stabilized hemoglobin levels, reduced fatigue),
        - Specialist follow-up within the past 12 months
    - If continuation is being requested for treatment of C3G:
        - Documentation of positive clinical response compared to baseline (i.e., 30-40% reduction in proteinuria from baseline),
        - AND specialist (Nephrology) follow-up within the past 12 months

Cystic Fibrosis (CFTR) Correctors

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

Generic	Brand	HICL	GSN	Representative NDC
ELEXACAFTOR-TEZACAFTOR-IVACAFTOR	TRIKAFTA TBPK 100-50-75 & 150 MG	46112	080343	51167033101
ELEXACAFTOR-TEZACAFTOR-IVACAFTOR	TRIKAFTA TBPK 50-25-37.5 & 75 MG	46112	082377	51167010602
ELEXACAFTOR-TEZACAFTOR-IVACAFTOR	TRIKAFTA THPK 80-40-60 & 59.5 MG	46112	084695	51167044501
ELEXACAFTOR-TEZACAFTOR-IVACAFTOR	TRIKAFTA THPK 100-50-75 & 75 MG	46112	084694	51167044601

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

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

Continuation of Therapy Criteria:

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

Cystic Fibrosis (CFTR) Correctors (cont'd)

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

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:

- Prescriber is a Pulmonologist or specialist in the management of cystic fibrosis (CF), AND
- Age ≥6 years, AND
- Diagnosis of CF confirmed by a clinician with expertise in proving CF care, AND
- At least two copies of the F508del mutation in the CFTR gene detected using either an FDA-cleared CF mutation test or testing was completed by a CLIA certified laboratory, OR At least one responsive mutation in the CFTR gene (consult Symdeko website to check for eligible mutations: https://www.symdeko.com/)

Continuation of Therapy Criteria:

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

Cystic Fibrosis (CFTR) Correctors (cont'd)

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

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
LUMACAFTOR-IVACAFTOR	ORKAMBI PACK 75-94 MG	42235	083804	51167012201

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Pulmonologist or specialist in the management of Cystic Fibrosis (CF), AND
- Age ≥1 year, AND
- Diagnosis of CF confirmed by a clinician in expertise in proving CF care, AND
- At least two copies of the F508del mutation in the CFTR gene detected using either an FDA-cleared CF mutation test or testing was completed by a CLIA certified laboratory, AND
- If ≥6 years, baseline percent predicted FEV1 is ≥30%

Continuation of Therapy Criteria:

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

Cystic Fibrosis-CFTR Potentiator-Corrector Combin.

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

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

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

Continuation of Therapy Criteria:

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

Cystic Fibrosis (CFTR) Potentiators

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

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
IVACAFTOR	KALYDECO PACK 5.8 MG	38461	084765	51167078501
IVACAFTOR	KALYDECO PACK 13.4 MG	38461	084755	51167077001

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Pulmonologist or specialist in the management of cystic fibrosis (CF), AND
- Age ≥1 month, AND
- Patient is NOT homozygous for the F508del mutation in the CFTR gene, AND
- At least one responsive mutation in the CFTR gene (consult Kalydeco website to check for eligible mutations: https://www.kalydeco.com/who-kalydeco#table) detected using either an FDA-cleared CF mutation test OR with testing completed by a CLIA certified laboratory

Continuation of Therapy Criteria:

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

Dipeptidyl Peptidase 1 (DPP1) Inhibitor

Generic	Brand	HICL	GSN	Representative NDC
BRENSOCATIB	BRINSUPRI TABS 10 MG	50812	088125	71558000130
BRENSOCATIB	BRINSUPRI TABS 25 MG	50812	088126	71558000230

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Pulmonologist,
- AND patient is ≥12 years of age,
- AND diagnosis of non-cystic fibrosis bronchiectasis (NCFB) as confirmed by chest computed tomography,
- AND patient meets ONE of the following requirements:
  - If ≥12 years and <18 years of age: Patient has had at least ONE pulmonary exacerbation* in the last 12 months that resulted in prescription of an antibiotic agent
  - If ≥18 years of age: Patient has had at least TWO pulmonary exacerbations* in the last 12 months that resulted in prescription of an antibiotic agent
- AND provider attests that patient's respiratory symptoms are NOT driven primarily by COPD or asthma,
- AND patient is a non-smoker

**Pulmonary exacerbation defined as worsening of 3 or more of the following major symptoms over 48 hours: increased cough, increased sputum volume or change in sputum consistency, increased sputum purulence, increased breathlessness, decreased exercise tolerance, fatigue and/or malaise, hemoptysis*

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
  - Documentation of positive clinical response to therapy (e.g., reduction in number of exacerbations, preservation of lung function, reduced cough/sputum production, less shortness of breath)
  - AND specialist follow-up within the past 12 months

Endothelin-Angiotensin Receptor Antagonist

Last revised: 7/31/2024; 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

Drugs to Treat Movement Disorders

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

Generic	Brand	HICL	GSN	Representative NDC
VALBENAZINE TOSYLATE	INGREZZA CAPS 40 MG	44202	077294	70370204001
VALBENAZINE TOSYLATE	INGREZZA CAPS 60 MG	44202	082227	70370106001
VALBENAZINE TOSYLATE	INGREZZA CAPS 80 MG	44202	077791	70370108001
VALBENAZINE TOSYLATE	INGREZZA CPPK 40 & 80 MG	44202	079676	70370204803
VALBENAZINE TOSYLATE	INGREZZA CPSP 40 MG	44202	086040	70370404001
VALBENAZINE TOSYLATE	INGREZZA CPSP 60 MG	44202	086041	70370406001
VALBENAZINE TOSYLATE	INGREZZA CPSP 80 MG	44202	086042	70370408001

Prior Authorization Criteria:

Length of Authorization:

- Initial: 3 months
- Reauthorization: 12 months

Initial Review Criteria:

- 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:
    - Switching offending antipsychotic to quetiapine or clozapine
    - Dopamine agonist (amantadine)
    - Tetrabenazine (Xenazine)
- Valbenazine 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 valbenazine therapy

Drugs to Treat Movement Disorders (cont'd)

Last revised: 7/31/2024; 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:
    - Switching offending antipsychotic to quetiapine or clozapine
    - 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 Receptor Antagonists

Generic	Brand	HICL	GSN	Representative NDC
ATRASENTAN HCL	VANRAFIA TABS 0.75 MG	50412	087539	00078142015

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescribed by a Nephrologist,
- AND 18 years of age or older,
- AND documented diagnosis of primary IgA nephropathy (IgAN) verified by renal biopsy,
- AND high-risk disease progression as defined by urine protein-to-creatinine ratio (UPCR) >/= 1.5 gm/gm or 24-hour protein >/= 1 gm/day,
- AND BP </= 150/100 mmHg,
- AND eGFR >/= 30 mL/minute/1.73 m^2,
- AND documented trial of at least 3 months at the maximum tolerated dose (and plan to continue) of <u>one</u> of the following or documented intolerance or contraindication to therapy:
  - Angiotensin-converting enzyme inhibitor (ACEi) OR
  - Angiotensin II receptor blocker (ARB)
- AND documented trial of at least 3 months at the maximum tolerated dose of SGLT2i (e.g., dapagliflozin, empagliflozin, etc.) or documented intolerance or contraindication to therapy,
- AND documented trial of at least 3 months at the maximum tolerated dose of an HMG-CoA reductase inhibitor (e.g., atorvastatin, etc.) or documented intolerance or contraindication to therapy,
- AND <u>for female patients</u>: Confirmation of negative pregnancy test prior to therapy initiation, and patient is not breastfeeding,
- AND patient does <u>not</u> have a history of any of the following:
  - Renal impairment requiring dialysis
  - eGFR < 30 mL/minute/1.73 m^2
  - IgAN secondary to another medical condition
  - History of organ transplant
  - Severe hepatic impairment (Child-Pugh Class C)
  - Rapidly progressive glomerulonephritis or IgA vasculitis
  - History of heart failure (HF), hospitalization for HF, or B type natriuretic peptide (BNP) > 200 pg/mL
  - History of fluid overload (e.g., pulmonary edema, pleural effusion, ascites, etc.)
  - Hemoglobin < 9 gm/dL or history of blood transfusion within 3 months
  - Platelet count < 80,000/mcL
  - History of malignancy (unless cancer-free >/= 5 years)
  - Pregnancy or planning to become pregnant

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
  - Specialist (Nephrology) follow-up has occurred since last review

- o AND documented improvement in proteinuria (e.g., UPCR < 1.5 gm/gm or 24-hour protein < 1 gm/day) or stable renal function compared to baseline (prior to therapy initiation)

Electrolyte Depleters

Generic	Brand	HICL	GSN	Representative NDC
TENAPANOR HCL (CKD)	XPHOZAH TABS 20 MG	46009	085414	73154012060
TENAPANOR HCL (CKD)	XPHOZAH TABS 30 MG	46009	085415	73154013060

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Nephrologist,
- Patient is 18 years of age or older,
- Documentation of chronic kidney disease on dialysis with hyperphosphatemia (phosphate level >5.5 mg/dL),
- Documented adequate therapeutic trial (>3 months) with inadequate response, contraindication and/or intolerance to ALL phosphate lowering agents listed below:
    - Sevelamer carbonate
    - Lanthanum carbonate
    - Calcium acetate
    - Ferric citrate (Auryxia)
    - Sucroferric oxyhydroxide (Velphoro)
- Patient has does not have any known or suspected mechanical gastrointestinal obstruction,
- Patient is not concurrently using stool softeners or laxatives

Continuation of Therapy Criteria:

- Phosphate levels within range (3.5 mg/dL to 5.5 mg/dL) and improvement from baseline,
- Documentation of positive clinical response during Nephrology follow up in the last 12 months

Enzyme Replacement Therapy – ADA-SCID

Generic	Brand	HICL	GSN	Representative NDC
ELAPEGADEMASE-LVLR	REVCOVI SOLN 2.4 MG/1.5ML	45340	079092	10122050201

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescribed by a Geneticist or Hematologist/Oncologist, AND
- Documented diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID), AND
- Patient has failed or is not a candidate for hematopoietic cell transplantation (HCT), AND
- Baseline levels for plasma ADA activity, trough deoxyadenosine nucleotide (dAXP) levels, and/or total lymphocyte counts have been obtained, AND
- Patient is on appropriate dosing based on weight

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - Documentation of positive clinical response to therapy, as evidenced by stabilization of disease or absence of disease progression, AND
    - Patient is on the appropriate maintenance dose based on target lab values (e.g., ADA >30 mmol/hour/L, trough dAXP <0.02 mmol/L) and/or to maintain immune reconstitution based on clinical assessment, AND
    - Specialist follow-up within the past 12 months

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

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

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

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
EPOETIN ALFA-EPBX	RETACRIT SOLN 10000 UNIT/ML	44931	081692	00069131801
EPOETIN ALFA-EPBX	RETACRIT SOLN 20000 UNIT/ML	44931	081714	00069131101

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

Factor XII Inhibitors

Generic	Brand	HICL	GSN	Representative NDC
GARADACIMAB-GXII	ANDEMBRY SOAJ 200 MG/1.2ML	50645	087872	63833092501

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is an Allergist, Immunologist, or Physician who specializes in the treatment of hereditary angioedema (HAE), AND
- Patient is at least 12 years of age, AND
- Patient has diagnosis of HAE type I or type II confirmed by either:
  - Mutation known to cause HAE in either the SERPING1 or F12 gene, OR
  - A C4 level below the lower limit of normal and/or a C1 inhibitor (C1-INH) antigenic level or functional level below the lower limit of normal,
- AND documented treatment failure*/inadequate response, intolerance, or contraindication to Takhyzro (lanadelumab-flyo), AND
- If patient weighs <90 kg: documented treatment failure/inadequate response, intolerance, or contraindication to Haegarda (C1 esterase inhibitor – human), AND
- Andembry is not being used in combination with other products indicated for prophylaxis against HAE attacks

Notes:
**Failure is defined as no significant decrease in number of HAE acute attack frequency, decrease in HAE attack severity, or decrease in duration of HAE attacks after an adequate trial (≥3 months)*

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
  - Specialist follow-up occurred in the past 12 months with documented improvement while on Andembry, AND
  - Andembry continues to NOT be used in combination with other products indicated for prophylaxis against HAE attacks

Fecal Microbiota Transplantation (FMT)

Last revised: 5/29/2025; Effective date: 8/12/2025

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

Prior Authorization Criteria:

Length of Authorization:

- Initial: 1 treatment course
- Reauthorization: 1 additional treatment course (max 2 treatment courses)

Initial Review Criteria:

- Patient age ≥18 years,
- Prescribed by Gastroenterologist or Infectious Disease Specialist,
- Prescribed for prevention of recurrent Clostridioides difficile infection (CDI),
- Documentation of at least 2 recurrent episodes of severe CDI (≥3 total CDI episodes) within the past 12 months,
- If patient has not previously received Vowst: Documented completion of antibiotic (e.g., vancomycin, fidaxomicin) treatment for recurrent CDI (defined as ≥ 3 CDI episodes),
- Documentation that fecal microbiota transplantation (FMT) from a reputable source is unavailable (if available, documentation that FMT is contraindicated),
- Documentation of trial and failure, or contraindication to Rebyota (fecal microbiota, live-jslm)

Continuation of Therapy Criteria:

- Patient must meet ALL initial criteria above,
- Documented treatment failure to initial course of Vowst (defined as the presence of CDI diarrhea within 8 weeks of the first dose of Vowst) AND positive stool test for C.difficile,
- Patient has not previously received more than one treatment course of Vowst AND the start of that treatment course was at least 12 days (and not more than 8 weeks) prior to the new request

Genetic Disorder Therapy – HDAC Inhibitor

Generic	Brand	HICL	GSN	Representative NDC
GIVINOSTAT HCL	DUVYZAT SUSP 8.86 MG/ML	49667	086182	11797011001

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescribed by a Neurologist, Pediatric Neurologist, Neuromuscular Specialist or Medical Geneticist, AND
- Patient is male and ≥6 years, AND
- Patient is ambulatory, AND
- Diagnosis of Duchenne Muscular Dystrophy (DMD) confirmed by genetic testing, AND
- Documentation of DMD characteristic clinical signs or symptoms present (e.g., proximal muscle weakness, Gowers' maneuver, elevated serum creatinine kinase level)
- Patient is stable on systemic steroid regimen (e.g., glucocorticoid, deflazacort, or vamorolone) before treatment initiation with Duvyzat (givinostat) AND
- Patient does not have any of the reasons for not initiating therapy noted below:
    - Current use of any DMD therapies (exon-skipping therapies) excluding systemic steroid regimen (e.g., glucocorticoid, deflazacort, or vamorolone). Discontinue other therapies (excluding steroid regimen) prior to initiating givinostat; or
    - Prior receipt of gene therapy for DMD as there is no evidence to support treatment using givinostat after receiving gene therapy; or
    - Platelet count $<150 \times 10^9$/L; or
    - Platelet or white blood cell count, or hemoglobin level below the lower limit of normal as givinostat can cause thrombocytopenia, hemoglobin, and neutropenia; or
    - Have a current or history of liver disease or impairment, including but not limited to a total bilirubin >1.5 x ULN, unless secondary to Gilbert disease or pattern consistent with Gilbert's; or
    - Inadequate renal function; or
    - Triglycerides >300 mg/dL in fasting condition; or
    - Positive test for hepatitis B surface antigen, hepatitis C antibody, or HIV; or
    - Have a baseline corrected QT interval, Friderica's correction >450 msec (as the mean of 3 consecutive readings 5 mins apart) or history of additional risk factors for torsardes de pointes (e.g., heart failure, hypokalemia, or family history of long QT syndrome); or
    - Have a sorbitol intolerance or sorbitol malabsorption, or have the hereditary form of fructose intolerance; or
    - Have exposure to another investigational drug within the past three months

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - Document clinically significant benefit from the medication, AND
    - Specialist follow-up since the last review AND
    - Patient does not have any of the following criteria for discontinuation:
        - Loss of ambulation

	▪ Intolerance to medication, including significant GI adverse events despite dosage modification ▪ QTc interval is >500 ms or the change from baseline is >60ms ▪ Hematologic abnormalities that worsen despite dose modification ▪ Elevated triglycerides despite adequate dietary intervention and dosage adjustment (i.e., fasting blood triglycerides >300 mg/dL) ▪ Non-adherence to medication or follow-up labs and assessments ▪ Other treatment for DMD therapy is initiated (excluding systemic steroid regimen)

Glucocorticoids

Last revised: 12/5/2025; Effective date: 2/3/2026

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
DEFLAZACORT	JAYTHARI TABS 18 MG	11668	077113	70710175003
DEFLAZACORT	JAYTHARI TABS 30 MG	11668	027605	70710175103
DEFLAZACORT	JAYTHARI TABS 36 MG	11668	077116	70710175203
DEFLAZACORT	JAYTHARI TABS 6 MG	11668	027604	70710174901
DEFLAZACORT	KYMBEE TABS 18 MG	11668	077113	00245081530
DEFLAZACORT	KYMBEE TABS 30 MG	11668	027605	00245081630
DEFLAZACORT	KYMBEE TABS 36 MG	11668	077116	00245081730
DEFLAZACORT	KYMBEE TABS 6 MG	11668	027604	00245081411
DEFLAZACORT	PYQUVI SUSP 22.75 MG/ML	11668	077117	73289008901

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 must meet the following age cutoffs, AND:
  - For Emflaza: Patient is ≥2 years,
  - For Pyquvi, Kymbee, and Jaythari: Patient is ≥5 years
- Patient has used prednisone for at least 12 months, AND
- <u>If ordering Emflaza and ≥5 years:</u> Patient must have tried and failed, or is intolerant to the equivalent formulations of generic deflazacort (Pyquvi, Kymbee, or Jaythari)

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met the criteria:**
  - 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: 7/31/2024; 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

Glucocorticoids (cont'd)

Generic	Brand	HICL	GSN	Representative NDC
BUDESONIDE	EOHILIA SUSP 2 MG/10ML	6545	085727	64764010510

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 weeks
- Reauthorization: N/A – therapy limited to 12 weeks

Initial Review Criteria:

- Prescriber is an allergy specialist, gastroenterologist, or otolaryngologist,
- Patient is 11 years of age or older,
- Confirmed diagnosis of eosinophilic esophagitis (EoE) by upper endoscopy and biopsy with an eosinophil count of at least 15 eosinophils per high-power microscopy field,
- Documented inadequate response (after at least an 8-week trial), intolerance, or contraindication to **all** following therapies:
    - Proton pump inhibitor (dose has been titrated up to twice daily)
    - Topical glucocorticoid (i.e. swallowed fluticasone 220 mcg/spray eight sprays daily swallowed [not inhaled] in 2 to 4 divided doses or budesonide oral suspension for inhalation swallowed up to 2 mg twice daily)

Continuation of Therapy Criteria: N/A – therapy limited to 12 weeks

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

Growth Hormones

Last revised: 12/5/2025; Effective date: 2/3/2026

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
LONAPEGSOMATROPIN-TCGD	SKYTROFA CART 0.7 MG	47565	088237	73362001201
LONAPEGSOMATROPIN-TCGD	SKYTROFA CART 1.4 MG	47565	088239	73362001301
LONAPEGSOMATROPIN-TCGD	SKYTROFA CART 1.8 MG	47565	088240	73362001401
LONAPEGSOMATROPIN-TCGD	SKYTROFA CART 2.1 MG	47565	088241	73362001501
LONAPEGSOMATROPIN-TCGD	SKYTROFA CART 2.5 MG	47565	088242	73362001601

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),
- If ≥3 years of age: documented inadequate response (of at least a 4-month trial), contraindication, or intolerance to Ngenla (somatrogon-ghla)

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS and have not been reviewed previously:** confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - Documented 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),
    - 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: 9/30/2025; Effective date: 12/2/2025

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),
- If ≥3 years of age: documented inadequate response (of at least a 4-month trial), contraindication, or intolerance to Ngenla (somatrogon-ghla)

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:

- **For new members who were initiated outside of KPMAS and have not been reviewed previously:** confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - Documented 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

Growth Hormones (cont'd)

Generic	Brand	HICL	GSN	Representative NDC
SOMATROGON-GHLA	NGENLA SOPN 24 MG/1.2ML	47896	083177	00069050502
SOMATROGON-GHLA	NGENLA SOPN 60 MG/1.2ML	47896	083178	00069052002

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is an Endocrinology or Pediatric Endocrinologist, AND
- Patient is ≥3 years and <18 years of age, AND
- 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
- AND documentation of open epiphyses (defined as bone age ≤16 years for males and ≤14 years for females), AND
- Documented inadequate response (of at least a 4-month trial), contraindication, or intolerance to Omnitrope (somatropin)

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - Documented 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), AND
    - Epiphyses are open (defined as bone age ≤16 years for males and ≤14 years for females)

Growth Hormone Releasing Hormone (GHRH) and Analogs

Generic	Brand	HICL	GSN	Representative NDC
TESAMORELIN ACETATE	EGRIFTA SV SOLR 2 MG	37268	080524	62064024130
TESAMORELIN ACETATE	EGRIFTA WR KIT 11.6 MG	37268	087937	62064038104

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 6 months

Initial Review Criteria:

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

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

Continuation of Therapy Criteria:

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

Hemophilia Treatment Agents, Non-Factor Replacement

Generic	Brand	HICL	GSN	Representative NDC
CONCIZUMAB-MTCI	ALHEMO SOPN 150 MG/1.5ML	50125	086973	00169208015
CONCIZUMAB-MTCI	ALHEMO SOPN 300 MG/3ML	50125	086974	00169208103
CONCIZUMAB-MTCI	ALHEMO SOPN 60 MG/1.5ML	50125	086972	00169208415

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescribed by a Hematologist, AND
- Patient is ≥ 12 y/o, AND
- Documentation of <u>one</u> of the following, AND
    - Diagnosis of hemophilia A (congenital factor VIII deficiency) with or without Factor VIII inhibitors
    - Diagnosis of hemophilia B (congenital factor IX deficiency) with or without FIX inhibitors
- Alhemo will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes, AND
- Patient is not currently being treated with non-factor prophylaxis therapy (e.g. Hemlibra, Hympavzi or Qfitlia), AND
- Patient is not pregnant, AND
- **If diagnosed with hemophilia A**: Patient has tried and failed, unable to tolerate, or has contraindication to the following:
    - Kovaltry AND Altuviiio AND Hemlibra, AND any one of the following: Advate, Afstyla, Kogenate FS, Novoeight, Xyntha, Elocate, Jivi, Esperoct
- **If diagnosed with hemophilia B**: Patient has tried and failed, unable to tolerate or has contraindication to the following:
    - Benefix AND Idelvion, AND any one of the following: Ixinity, Rixubis, Alprolix, Rebinyn

<u>Notes:</u>

- *Initial dose is 1mg/kg SubQ on day 1 (loading dose) then 0.2 mg/kg once daily starting on day 2; continue for 4 to 8 weeks*
- *Maintenance Dose:*
    - *Measure plasma concentration at least 4 weeks after initiation; adjust dose no later than 8 weeks after initiation using the following:*
        - *If concizumab plasma concentration is <200 ng/mL; increase dose to 0.25 mg/kg once daily*
        - *If concizumab plasma concentration is 200 to 4,000 ng/mL; continue 0.2 mg/kg once daily*
        - *If concizumab plasma concentration is >4,000 ng/mL; decrease dose to 0.15 mg/kg once daily*

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - Prescriber follow up in the past 12 months AND
    - Patient has documented clinical benefit compared to baseline, with documentation of improvement in bleeding rates

Hemophilia Treatment Agents, Non-Factor Replacement (cont'd)

Generic	Brand	HICL	GSN	Representative NDC
FITUSIRAN SODIUM	QFITLIA SOLN 20 MG/0.2ML	50406	087521	58468034701
FITUSIRAN SODIUM	QFITLIA SOAJ 50 MG/0.5ML	50406	087522	58468034801

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescribed by a Hematologist, AND
- Patient is ≥ 12 y/o, AND
- Documentation of <u>one</u> of the following:
    - Diagnosis of hemophilia A (congenital factor VIII deficiency) with or without Factor VIII inhibitors
    - Diagnosis of hemophilia B (congenital factor IX deficiency) with or without FIX inhibitors
- AND documentation of antithrombin (AT) activity >60% **prior** to treatment initiation and documentation of planned follow-up and monitoring with AT activity to adjust dose, AND
- Qfitlia will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes, AND
- Patient is not currently being treated with non-factor prophylaxis therapy (e.g. Hemlibra, Hympavzi, or Alhemo), AND
- Patient is not pregnant, AND
- **If diagnosed with hemophilia A**: Patient has tried and failed, unable to tolerate, or has contraindication to the following:
    - Kovaltry AND Altuviiio AND Hemlibra, AND any one of the following: Advate, Afstyla, Kogenate FS, Novoeight, Xyntha, Elocate, Jivi, Esperoct
- **If diagnosed with hemophilia B**: Patient has tried and failed, unable to tolerate or has contraindication to the following:
    - Benefix AND Idelvion, AND any one of the following: Ixinity, Rixubis, Alprolix, Rebinyn

<u>Notes:</u>

- *Initial dose is 50 mg once every 2 months*
- *Maintenance dose adjustment:*
    - *Measure plasma AT activity at weeks 4, 12, 29, and 24 following initial dose and after any dose modification.*
    - *Dose adjustments and/or interval should maintain AT activity between 15% to 35%*
    - *If AT activity <15%, reduce dose*
    - *If AT activity >35% after 6 months or if satisfactory bleed control has not been achieved, dose escalation should be considered.*
    - *Once patient's target dose is identified based on AT activity 15% to 35T, measure AT activity annually*

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - Prescriber follow up in the past 12 months AND
    - Patient has documented clinical benefit compared to baseline, with documentation of improvement in bleeding rates

Hemophilia Treatment Agents, Non-Factor Replacement (cont'd)

Generic	Brand	HICL	GSN	Representative NDC
MARSTACIMAB-HNCQ	HYMPAVZI SOAJ 150 MG/ML	49937	086640	00069215101

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescribed by a Hematologist, AND
- Patient is ≥ 12 y/o, AND
- Documentation of <u>one</u> of the following:
    - Diagnosis of severe hemophilia A (congenital factor VIII deficiency) without Factor VIII inhibitors
        - **Note**: Severe hemophilia A is defined as factor VIII activity ≤ 1; OR
    - Diagnosis of moderately severe to severe hemophilia B (congenital factor IX deficiency) without FIX inhibitors
        - **Note:** Defined as FIX activity ≤2) OR
    - Diagnosis of congenital FVIII deficiency (hemophilia A) or congenital IX deficiency (hemophilia B) with medical necessity for prophylactic treatment (e.g. ≥2 documented episodes of spontaneous bleeding into joints)
- AND, Hympavzi will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes, AND
- Patient does not have inhibitors, AND
- Patient is not currently being treated with non-factor prophylaxis therapy (e.g. Hemlibra, Qfitlia or Alhemo), AND
- Patient is not pregnant, AND
- **If diagnosed with hemophilia A**: Patient has tried and failed, unable to tolerate, or has contraindication to the following:
    - Kovaltry AND Altuviiio AND Hemlibra, AND any one of the following: Advate, Afstyla, Kogenate FS, Novoeight, Xyntha, Elocate, Jivi, Esperoct
- **If diagnosed with hemophilia B**: Patient has tried and failed, unable to tolerate or has contraindication to the following:
    - Benefix AND Idelvion, AND any one of the following: Ixinity, Rixubis, Alprolix, Rebinyn

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - Prescriber follow up in the past 12 months AND
    - Patient has documented clinical benefit compared to baseline, with documentation of improvement in bleeding rates

Hemostatics

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

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
EMICIZUMAB-KXWH	HEMLIBRA SOLN 12 MG/0.4ML	44640	085784	50242092701
EMICIZUMAB-KXWH	HEMLIBRA SOLN 300 MG/2ML	44640	085644	50242093001

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 VIII replacement products

-OR-

Hemophilia A WITH inhibitors:

- Prescribed by a hematologist with specialty in benign hematology, AND
- Patients has developed high-titer factor VIII 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

Hepatitis C Antivirals

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

Generic	Brand	HICL	GSN	Representative NDC
SOFOSBUVIR-VELPATASVIR-VOXILAPREVIR	VOSEVI TABS 400-100-100 MG	44428	077584	61958240101
SOFOSBUVIR	SOVALDI TABS 200 MG	40795	080163	61958150301
SOFOSBUVIR	SOVALDI TABS 400 MG	40795	071748	61958150101
SOFOSBUVIR	SOVALDI PACK 200 MG	40795	080165	61958150501
SOFOSBUVIR	SOVALDI PACK 150 MG	40795	080164	61958150401
SOFOSBUVIR-VELPATASVIR	EPCLUSA TABS 400-100 MG	43561	076305	61958220101
SOFOSBUVIR-VELPATASVIR	EPCLUSA TABS 200-50 MG	43561	081610	61958220301
SOFOSBUVIR-VELPATASVIR	EPCLUSA PACK 200-50 MG	43561	082396	61958220401
SOFOSBUVIR-VELPATASVIR	EPCLUSA PACK 150-37.5 MG	43561	082395	61958220501
LEDIPASVIR-SOFOSBUVIR	HARVONI TABS 90-400 MG	41457	072926	61958180101
LEDIPASVIR-SOFOSBUVIR	HARVONI TABS 45-200 MG	41457	080162	61958180301
LEDIPASVIR-SOFOSBUVIR	HARVONI PACK 33.75-150 MG	41457	080180	61958180501
LEDIPASVIR-SOFOSBUVIR	HARVONI PACK 45-200 MG	41457	080179	61958180401
LEDIPASVIR-SOFOSBUVIR	LEDIPASVIR-SOFOSBUVIR TABS 90-400 MG	41457	072926	72626260101
SOFOSBUVIR-VELPATASVIR	SOFOSBUVIR-VELPATASVIR TABS 400-100 MG	43561	076305	72626270101
GLECAPREVIR-PIBRENTASVIR	MAVYRET TABS 100-40 MG	44453	077637	00074262580
GLECAPREVIR-PIBRENTASVIR	MAVYRET PACK 50-20 MG	44453	082438	00074260028
ELBASVIR-GRAZOPREVIR	ZEPATIER TABS 50-100 MG	43030	075514	00006307401

Prior Authorization Criteria:
Length of Authorization: • Initial: based on standard length of treatment course • Reauthorization: N/A
Initial Review Criteria: • Prescriber is a Gastroenterologist, Hepatologist, or Infectious Disease Specialist, AND • Patient is ≥3 years (*for patients <18 years, prescribing is restricted to pediatric GI providers*), AND • Patient has a detectable HCV RNA level (if patient has evidence of prescriptions for past HCV treatment, the detectable HCV RNA level must be from at least 12 weeks after completion of the previous treatment or at the discretion of the reviewing Hepatitis C Clinical Pharmacist), AND • Patient does not have a limited life expectancy (i.e., <12 months) due to non-liver related comorbid conditions, AND • Confirmation of test for HBV infection by measuring HBsAg and anti-HBc within 6 months of treatment or at the discretion of Hepatitis C Clinical Pharmacist review, AND • The requested drug correlates to current KP HCV preferred therapies, based on genotype, therapy history, AND • Fibrosis status per Hepatitis C Clinical Pharmacist review
Continuation of Therapy Criteria: • None

IBS Agents, Mixed Opioid Receptor Agonists/Antagonists

Last revised: 10/3/2023

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
    - Tricyclic antidepressants* (e.g., amitriptyline, desipramine, imipramine) – at least 6 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 Agents, Sodium-Hydrogen Exchanger 3 (NHE3) Inhib

Generic	Brand	HICL	GSN	Representative NDC
TENAPANOR HCL	IBSRELA TABS 50 MG	46009	080204	73154005060

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Gastroenterologist,
- Patient is ≥18 years of age,
- Patient has a diagnosis of irritable bowel syndrome with constipation,
- History of failure (after at least a 4-week trial), intolerance or contraindication to **ALL** the following for the treatment of constipation:
    - Fiber supplement: psyllium fiber or methylcellulose
    - Osmotic laxative: Polyethylene glycol or lactulose
    - Lubiprostone*PA - if patient is female
    - Trulance (plecanatide)*PA
    - Motegrity (prucalopride) *PA
    - Linzess (linaclotide) *PA

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met the criteria:**
    - Positive clinical response to medication, AND
    - Specialist follow-up in the last 12 months

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

Last revised: 12/5/2025; Effective date: 2/3/2026

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

<u>If using for irritable bowel syndrome with constipation (IBS-constipation predominant):</u>

- 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 (i.e., psyllium fiber or methylcellulose) OR polyethylene glycol
    - Lubiprostone if patient is female
    - Trulance (plecanatide)

<u>If using for chronic idiopathic constipation (CIC):</u>

- 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 (i.e., psyllium fiber or methylcellulose) OR osmotic laxative (i.e., polyethylene glycol or lactulose)
    - Prucalopride
    - Lubiprostone
    - Trulance (plecanatide)

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria:**
    - Positive clinical response to linaclotide

IBS-C/CIC Agents, Guanylate Cyclase-C Agonist (Cont'd)

Last revised: 12/5/2025; Effective date: 2/3/2026

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

If using for irritable bowel syndrome with constipation (IBS-constipation predominant):

- 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 (e.g., psyllium fiber or methylcellulose) OR polyethylene glycol
    - Lubiprostone if patient is female

If using for chronic idiopathic constipation (CIC):

- 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 (e.g., psyllium fiber or methylcellulose) OR osmotic laxative (e.g., polyethylene glycol or lactulose)
    - Prucalopride
    - Lubiprostone

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria:**
    - Positive clinical response to plecanatide

IL-23 Receptor Antagonist, Monoclonal Antibody

Last revised: 12/8/2025; Effective date: 2/3/2026

Generic	Brand	HICL	GSN	Representative NDC
MIRIKIZUMAB-MRKZ	OMVOH SOAJ 100 MG/ML	49282	085439	00002801127
MIRIKIZUMAB-MRKZ	OMVOH (300 MG DOSE) SOAJ 100 MG/ML & 200 MG/2ML	49282	087255	00002771711
MIRIKIZUMAB-MRKZ	OMVOH (300 MG DOSE) SOSY 100 MG/ML & 200 MG/2ML	49282	087254	00002772211
MIRIKIZUMAB-MRKZ	OMVOH SOSY 100 MG/ML	49282	085527	00002887001
MIRIKIZUMAB-MRKZ	OMVOH SOAJ 100 MG/ML	49282	087865	00002801127
MIRIKIZUMAB-MRKZ	OMVOH SOSY 100 MG/ML	49282	087863	00002887027

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Gastroenterologist, AND

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

- Diagnosis of active ulcerative colitis with moderate-to-severe activity or high risk of progression,
- AND inadequate response (of at least a 3-month trial), intolerance, or contraindication to ALL the following:
    - Ustekinumab product (Yesintek preferred)*
    - At least 1 anti-TNF (Amjevita or Inflectra IV preferred)
    - Tofacitinib (Xeljanz)*PA or upadacitinib (Rinvoq)*PA
    - Guselkumab (Tremfya)*PA or risankizumab-rzaa (Skyrizi)*PA

<u>If using for Crohn's Disease:</u>

- Diagnosis of active Crohn's disease with moderate-to-severe activity or high risk of progression, AND
- Documentation of inadequate response (after at least a 3-month trial), intolerance, or contraindication to ALL of the following therapies:
    - Ustekinumab product (Yesintek preferred)*
    - At least 1 anti-TNF (Amjevita or Inflectra IV preferred)
    - Upadacitinib (Rinvoq)*PA
    - Guselkumab (Tremfya)*PA or Risankizumab-rzaa (Skyrizi)*PA

**Brand Stelara/nonpreferred ustekinumab biosimilars are subject to PA review*
**PA This medication is also subject to PA review*

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** confirm patient meets all above initial review criteria
- **For existing members who have previously met the criteria**:
    - Positive clinical response to medication, AND
    - Specialist follow-up in the last 12 month

Notes: Limited to 30-DS per dispensing

Ileal Bile Acid Transporter (IBAT) Inhibitor

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

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a hepatologist or gastroenterologist, AND

If using for moderate-to-severe cholestatic pruritus associated with Alagille syndrome (ALGS):

- Patient is ≥3 months at initiation of therapy,
- Diagnosis of Alagille syndrome (ALGS) confirmed with genetic testing with JAG1 gene mutation or Notch2 gene mutation,
- Patient does NOT have decompensated cirrhosis, or decompensated hepatic events (e.g. variceal hemorrhage, ascites, and hepatic encephalopathy),
- Documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to ursodiol (ursodeoxycholic acid),
- Documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to **two** of the following therapies (indicated for symptomatic relief only of pruritus):
    - Cholestyramine
    - Rifampin (if patient is ≥4 months of age)
    - Naltrexone (if patient is ≥18 years of age)

If using for moderate-to-severe cholestatic pruritus associated with progressive familial intrahepatic cholestasis (PFIC):

- Patient is ≥12 months of age,
- Diagnosis of progressive familial intrahepatic cholestasis (PFIC) type 1 or type 2 confirmed by genetic testing,
- Patient does NOT have decompensated cirrhosis, or decompensated hepatic events (e.g. variceal hemorrhage, ascites, and hepatic encephalopathy),
- Documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to ursodiol (ursodeoxycholic acid),
- Documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to **two** of the following therapies (indicated for symptomatic relief only of pruritus):
    - Cholestyramine
    - Rifampin (if patient is ≥4 months of age)
    - Naltrexone (if patient is ≥18 years of age)
- Documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to Bylvay (odevixibat) at 40-120 mcg/kg/dose once daily

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met the criteria:**
    - Document clinically significant benefits from the medication (e.g. a decrease in pruritus from baseline or a reduction in serum bile acid concentration),
    - Specialist follow-up in the last 12 months

Ileal Bile Acid Transporter (IBAT) Inhibitor (cont'd)

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

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a hepatologist or gastroenterologist, AND

If using for moderate-to-severe cholestatic pruritus associated with Alagille syndrome (ALGS):

- Patient is ≥12 months of age,
- Diagnosis of Alagille syndrome (ALGS) confirmed with genetic testing with JAG1 gene mutation or Notch2 gene mutation,
- Patient does NOT have decompensated cirrhosis, or decompensated hepatic events (e.g. variceal hemorrhage, ascites, and hepatic encephalopathy),
- Documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to ursodiol (ursodeoxycholic acid),
- Documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to **two** of the following therapies (indicated for symptomatic relief only of pruritus):
    - Cholestyramine
    - Rifampin (if patient is ≥4 months of age)
    - Naltrexone (if patient is ≥18 years of age)
- Documented inadequate response, intolerance, or contraindication to Livmarli (maralixibat)

If using for moderate-to-severe cholestatic pruritus associated with progressive familial intrahepatic cholestasis (PFIC):

- Patient is ≥3 months of age,
- Diagnosis of progressive familial intrahepatic cholestasis (PFIC) type 1 or type 2 confirmed by genetic testing,
- Patient does NOT have decompensated cirrhosis, or decompensated hepatic events (e.g. variceal hemorrhage, ascites, and hepatic encephalopathy),
- Documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to ursodiol (ursodeoxycholic acid),
- Documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to **two** of the following therapies (indicated for symptomatic relief only of pruritus):
    - Cholestyramine
    - Rifampin (if patient is ≥4 months of age)
    - Naltrexone (if patient is ≥18 years of age)

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met the criteria:**
    - Document clinically significant benefits from the medication (e.g. a decrease in pruritic from baseline or a reduction in serum bile acid concentration to ≤70 mcmole/L),
    - Specialist follow-up in the last 12 months

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

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

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 KP-preferred rituximab biosimilar (Refer to Notes section for guidance on the preferred rituximab option), 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

Notes:

Riabni is the KP-preferred rituximab biosimilar if rituximab has never been tried

Continuation of Therapy Criteria:

- Patient continues to meet criteria above, AND
- Patient is experiencing positive clinical response, AND
- Patient has completed the following laboratory monitoring within the last 6 months:
    - Quantitative serum immunoglobulins
    - Complete blood count with differential
    - Liver function

Immunosuppressives

Last revised: 7/31/2024; 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 eGRF >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

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

Last revised: 12/8/2025; Effective date: 2/3/2026

Generic	Brand	HICL	GSN	Representative NDC
DUPILUMAB	DUPIXENT SOSY 200 MG/1.14ML	44180	079179	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 (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 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: requires documented treatment failure, contraindication, or inadequate response to Fasenra

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 3 months 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 1 year old,
- AND patient weighs at least 15 kg,
- AND patient has contraindication, intolerance, or did not respond clinically to treatment with at least an 8-week trial of ALL of the following:
    - At least 1 swallowed inhaled glucocorticosteroid [i.e. fluticasone 220 mcg/spray 8 sprays daily swallowed (not inhaled) in 2 to 4 divided doses or budesonide oral suspension for inhalation swallowed up to 2 mg twice daily], AND
    - Eohilia (budesonide) oral suspension
- AND patient has contraindication, intolerance, or did not respond clinically to treatment with at least an 8-week trial of a proton pump inhibitor

Chronic Obstructive Pulmonary Disease (COPD):

- Prescriber is a Pulmonologist or Allergist,
- AND patient is ≥18 years,
- AND diagnosis of moderate to severe COPD with an eosinophilic phenotype, as evidenced by ALL of the following:
    - Blood eosinophil count of ≥300 cells/microliter in the past 12 months
    - Exacerbation history in the past 12 months of ONE of the following:
        - ≥2 moderate exacerbations requiring oral glucocorticoids

        - ≥1 severe exacerbation requiring hospitalization, ER visit, or IV glucocorticoids
- AND an adequate trial (≥75% adherence for at least 1 year), contraindication, or failure to high-dose dual (LAMA/LABA) therapy OR high-dose triple (LAMA/LABA/ICS) therapy in combination with ONE of the following:
    - Azithromycin 250-500 mg 3 times a week, OR
    - Roflumilast
- AND patient will continue to use dual or triple maintenance therapy for COPD,
- AND Dupixent will NOT be used with another monoclonal antibody for the treatment of asthma (e.g., Xolair, Nucala, Fasenra, Cinqair, Tezspire)

Chronic Spontaneous Urticaria:

- Prescriber is an Allergist or Dermatologist,
- Diagnosis of chronic spontaneous urticaria,
- Patient is ≥12 years of age,
- Patient has tried and failed therapy for a 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),
    - Montelukast in combination with a high-dose second-generation H1-antihistamine,
    - H2-antihistamines (e.g. famotidine, ranitidine) in combination with a high-dose second-generation H1-antihistamine
- Inadequate response after 6 months' trial, intolerance, or contraindication to Xolair (omalizumab)

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - 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: 9/30/2025; Effective date: 12/2/2025

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
BENRALIZUMAB	FASENRA SOSY 10 MG/0.5ML	44635	085947	00310174501

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is Pulmonologist, Allergist, Immunologist, or Rheumatologist,
- 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 ≥6 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
    - OR eosinophilic granulomatosis with polyangiitis (EGPA) in patients ≥18 years
- AND Fasenra will NOT be used with Dupixent (dupilumab), Cinqair (resilizumab), Nucala (mepolizumab), Xolair (omalizumab), or Tezspire (tezepelumab-ekko)

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS and have not been reviewed previously:** confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - Patient continues to be under the care of a specialist for their condition,
    - AND documentation of positive clinical response to Fasenra therapy

Interleukin-6 (IL-6) Receptor Inhibitors

Last revised: 12/8/2025; Effective date: 2/3/2026

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
TOCILIZUMAB-AAZG	TYENNE SOAJ 162 MG/0.9ML	49425	085809	65219058401
TOCILIZUMAB-AAZG	TYENNE SOSY 162 MG/0.9ML	49425	085810	65219058604

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Rheumatologist or Pulmonologist, AND
- If ordering Actemra: Patient must have documented treatment failure, intolerance, or contraindication to tocilizumab-aazg (Tyenne), 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 ALLof 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]

If using for giant cell arteritis:

- Diagnosis of giant cell arteritis

If using for polymyalgia rheumatica:

- Diagnosis of polymyalgia rheumatica (PMR)

If using for active polyarticular or systemic juvenile idiopathic arthritis:

- 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]

If using for systemic sclerosis-associated interstitial lung disease (SSc-ILD):

- Prescribed by a Pulmonologist,
- AND 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),

- AND patient is at least 18 years of age,
- AND treatment failure, intolerance, or contraindication to mycophenolate mofetil (MMF) prescribed for SSc-ILD

If using for adult-onset Still's disease (AOSD):

- Diagnosis of adult-onset Still's disease (AOSD)

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

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met criteria:**
  - Patient has documented a clinically significant benefit from the medication, AND
  - Specialist follow-up occurred in the past 12 months since last review, AND
  - If ordering Actemra: patient must have documented treatment failure, intolerance, or contraindication to tocilizumab-aazg (Tyenne)

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

Last revised: 12/8/2025; Effective date: 2/3/2026

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, AND
- Treatment failure, intolerance, or contraindication to tocilizumab (Tyenne preferred)*PA

If using for polymyalgia rheumatica:

- Diagnosis of polymyalgia rheumatica (PMR)

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

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met 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

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

Generic	Brand	HICL	GSN	Representative NDC
TRALOKINUMAB-LDRM	ADBRY SOSY 150 MG/ML	47741	082945	50222034602
TRALOKINUMAB-LDRM	ADBRY SOAJ 300 MG/2ML	47741	086237	50222035001

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 > 12 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 medication (e.g., omalizumab, rituximab, dupilumab, mepolizumab, reslizumab, benralizumab, tezepelumab-ekko, etc.) and/or janus kinase inhibitor

Note: If patient weighs <100 kg and achieved clear or almost clear skin, recommend decreasing tralokinumab dose to 300 mg every 4 weeks after 16 weeks of therapy.

Continuation of Therapy Criteria:

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

Interleukin-13 (IL-13) Inhibitors, MAB (cont'd)

Generic	Brand	HICL	GSN	Representative NDC
LEBRIKIZUMAB-LBKZ	EBGLYSS SOAJ 250 MG/2ML	49658	086171	00002777211
LEBRIKIZUMAB-LBKZ	EBGLYSS SOSY 250 MG/2ML	49658	086421	00002779701

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a dermatologist, immunologist, or allergist,
- Diagnosis of moderate-to-severe atopic dermatitis,
- Documented history of inadequate response, contraindication, or intolerance to all following therapies:
    - At least one topical therapy (e.g. medium to very-high potency topical steroids or topical calcineurin inhibitor)
    - Phototherapy unless involvement of sensitive areas (e.g. hand, feet, face, body folds or genitals)
    - Methotrexate if patient is ≥18 years of age
    - Adbry (tralokinumab-ldrm)
    - Dupixent (dupilumab)

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met the criteria:**
    - Document clinically significant benefits from the medication, AND
    - Specialist follow-up in the last 12 months, AND
    - If using for atopic dermatitis and the patient has achieved clinical response, the maintenance dose has been decreased to 250 mg every 4 weeks

Interleukin-31 (IL-31) Receptor Alpha Antagonist, MAB

Generic	Brand	HICL	GSN	Representative NDC
NEMOLIZUMAB-ILTO	NEMLUVIO AUIJ 30 MG	49814	086424	00299622015

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a dermatologist, immunologist, or allergist, AND

<u>If using for diagnosis of prurigo nodularis:</u>

- Age ≥18 years of age,
- Diagnosis of prurigo nodularis with the presence of multiple localized general pruriginous lesions,
- Documented history of inadequate response, contraindication, or intolerance to ALL following therapies:
    - Phototherapy (of a least a 3-month trial) unless involvement of sensitive areas (e.g. hand, feet, face, body folds or genitals)
    - High or super-high potency topical corticosteroid (e.g., betamethasone dipropionate, augmented 0.05% cream, clobetasol propionate 0.05% ointment, lotion, gel)
    - Topical vitamin D analog (e.g., calcipotriene 0.005% solution, calcitriol 3 mcg/g ointment)
    - Topical calcineurin inhibitor (e.g. tacrolimus 0.1% ointment)
    - Methotrexate or cyclosporine
    - Dupixent (dupilumab)

Note: *Dose check for prurigo nodularis*.

- *Weight < 90kg: 60 mg followed by 30 mg every 4 weeks*
- *Weight ≥ 90 kg: 60 mg followed by 60 mg every 4 weeks*

<u>If using for atopic dermatitis:</u>

- Diagnosis of moderate-to-severe atopic dermatitis,
- Documented history of inadequate response, contraindication, or intolerance to all the following therapies:
    - At least one topical therapy (e.g. medium to very-high potency topical steroids or topical calcineurin inhibitor)
    - Phototherapy unless involvement of sensitive areas (e.g. hand, feet, face, body folds or genitals
    - Methotrexate if patient is ≥18 years of age

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met the criteria:**
    - Document clinically significant benefits from the medication,
    - Specialist follow-up in the last 12 months,
    - Patient met one of the following for maintenance dose:
        - If using for prurigo nodularis and the patient is weighing <90 kg, the maintenance dose is 30 mg every 4 weeks unless there is documented medical necessity for continuing higher dose
        - If using for atopic dermatitis and the patient has achieved clear or almost clear skin after 16 weeks of initiating therapy, the maintenance dose is 30 mg every 8 weeks unless there is documented medical necessity reason for continuing higher dose

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

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 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

Generic	Brand	HICL	GSN	Representative NDC
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

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 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, AND
- Documented A1C lowering of 0.5% from initial or A1C now at goal

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

Generic	Brand	HICL	GSN	Representative NDC
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 ASPART (WITH NIACINAMIDE)	FIASP PUMPCART SOCT 100 UNIT/ML	49168	085163	00169320611
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

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

Insulins

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

Generic	Brand	HICL	GSN	Representative NDC
INSULIN GLARGINE	BASAGLAR KWIKPEN SOPN 100 UNIT/ML	22025	062867	00002771501
INSULIN GLARGINE	BASAGLAR TEMPO PEN SOPN 100 UNIT/ML	22025	085479	00002821401

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 prescribed for gestational diabetes, pregnant patients (these patients will be moved to NPH after birth or termination of pregnancy)
    - OR prescribed for patients with documented intolerance/allergy to Humulin N or Humulin 70/30
    - OR prescribed for 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 prescribed for 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:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - Confirm that patient continues to fall into one of the approved patient populations above, AND
    - Documentation of positive clinical response

Integrin Receptor Antagonist, Monoclonal Antibody

Last revised: 12/8/2025; Effective date: 2/3/2026

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, AND
- Diagnosis of moderate ulcerative colitis or Crohn's disease (disease limited to the colon and no extraintestinal manifestations such as arthritis, uveitis, axial spondyloarthritis, or erythema nodosum), AND
- Intolerance or contraindication to all the following:
    - Ustekinumab product [Ustekinumab-kfce (Yesintek) preferred]
    - At least 1 anti-TNF [infliximab-dyyb (Inflectra) or adalimumab-atto (Amjevita) preferred]

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met criteria:**
    - Patient has positive clinical response to medication,
    - Specialist follow-up has occurred since the last review

Notes: Limited to 30-DS per dispensing

Intestinal Motility Stimulants

Last revised: 12/5/2025; Effective date: 2/3/2026

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 (applies to brand Motegrity only):

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
- Documented side effect or adverse reaction to generic prucalopride, AND
- Patient has had an inadequate response after a 4-week trial or intolerance/contraindication to optimal dose of fiber supplement (e.g., psyllium fiber or methylcellulose) OR osmotic laxative (e.g., polyethylene glycol or lactulose)

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria:**
  - Documented side effect or adverse reaction to generic prucalopride, AND
  - Positive clinical response to Motegrity

Janus Kinase (JAK) Inhibitor

Last revised: 12/8/2025; Effective date: 2/3/2026

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
TOFACITINIB CITRATE	XELJANZ SOLN 1 MG/ML	39768	081537	00069102901

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Gastroenterologist, Rheumatologist, or Dermatologist, AND

If using for ulcerative colitis:

- Patient has diagnosis of ulcerative colitis, AND
- Inadequate response, intolerance, or contraindication to all the following:
  - Ustekinumab product (Yesintek preferred)
  - At least one anti-TNF agent (Inflectra IV or Amjevita preferred]

If using for rheumatoid arthritis:

- Diagnosis of moderate-to-severe rheumatoid arthritis,
- AND patient has a 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 the following:
  - At least one anti-TNF agent [e.g. infliximab, adalimumab biosimilars (Amjevita preferred)], AND
  - Tocilizumab product (Tyenne preferred)*PA

If using for psoriatic arthritis:

- 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 ALL of the following:
    - One nonbiologic DMARD (methotrexate, sulfasalazine, hydroxychloroquine, leflunomide)^,
    - Ustekinumab product (Yesintek preferred)^
    - At least ONE preferred anti-TNF agent [i.e. adalimumab-atto (Amjevita) or infliximab-dyyb (Inflectra)]

^*Note: nonbiologic DMARD and interleukin inhibitors 12/23 is not required for patients with axial disease or severe (rapidly progressive, erosive) psoriatic arthritis disease*

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, intolerance, or contraindication to the following:
    - At least one of the preferred anti-TNF agents [i.e. adalimumab-atto (Amjevita) or infliximab-dyyb (Inflectra)], AND
    - Tocilizumab product (Tyenne preferred)*PA

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: • **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria • **For existing members who have previously met criteria:** o Positive clinical response to tofacitinib, AND o Specialist follow-up occurred since the last review

Janus Kinase (JAK) Inhibitor (Cont'd)

Last revised: 12/8/2025; Effective date: 2/3/2026

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 is a Rheumatologist or Dermatologist, AND

If using for Rheumatoid Arthritis:

- Prescriber must be a Rheumatologist,
- AND 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 ALL of the following categories:
    - At least 1 non-biologic disease-modifying antirheumatic drug (DMARD) such as methotrexate, leflunomide, sulfasalazine or hydroxychloroquine,
    - At least 1 anti-TNF [e.g., adalimumab (Amjevita preferred), etanercept*PA, golimumab*PA, certolizumab*PA]
    - Tocilizumab product (Tyenne preferred)*PA
    - Xeljanz (tofacitinib)*PA

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 therapies 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,
- AND patient has failed (at least a 3-month trial), intolerant, or contraindication to Litfulo (ritlecitinib)*PA

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,
- AND patient has failed (at least a 3-month trial), intolerant, or contraindication to Litfulo (ritlecitinib)*PA

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

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - Positive clinical response AND
    - Specialist follow-up in the last 12 months

Janus Kinase (JAK) Inhibitor (Cont'd)

Last revised: 12/8/2025; Effective date: 2/3/2026

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
UPADACITINIB	RINVOQ LQ SOLN 1 MG/ML	45955	086026	00074232001

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Rheumatologist, Dermatologist, or Gastroenterologist

If using for Rheumatoid Arthritis:

- Patient has a diagnosis of moderate-to-severe rheumatoid arthritis,
- AND has 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., adalimumab, infliximab)
    - AND tocilizumab product (Tyenne preferred)*PA
    - AND Xeljanz (tofacitinib)

If using for psoriatic arthritis:

- Patient has a diagnosis of psoriatic arthritis,
- AND has history of treatment failure after at least a 3-month trial, intolerance, or contraindication to the following:
    - At least 1 conventional disease-modifying antirheumatic drug (e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine)^
    - AND ustekinumab (Yesintek preferred)^
    - AND at least 1 anti-TNF agent (e.g. adalimumab, infliximab, golimumab)
    - AND Cosentyx (secukinumab)
    - AND Xeljanz (tofacitinib)

^*Note: non-biologic DMARD and IL-12/23 (e.g. ustekinumab) is not required for patients with axial disease or severe (rapidly progressive, erosive) psoriatic arthritis disease*

If using for spondyloarthritis

- Prescriber is a Rheumatologist,
- AND patient has a diagnosis of ankylosing spondylitis or nonradiographic axial spondyloarthritis,
- AND has history of treatment failure, intolerance, or contraindication to ALL of the following:
    - At least 1 anti-TNF agent (e.g. adalimumab, infliximab)

- AND Cosentyx (secukinumab)*PA
- AND Xeljanz (tofacitinib)*PA

If treating pediatric patients with juvenile idiopathic arthritis:

- Patient is ≥2 years with juvenile idiopathic arthritis,
- AND has history of inadequate response, intolerance, or contraindication to the following:
  - At least 1 anti-TNF agent (e.g. adalimumab product, golimumab, etanercept)
  - AND tocilizumab product (Tyenne preferred)*PA
  - 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:
  - 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 (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 systemic immunomodulators (i.e., methotrexate, azathioprine, cyclosporine, or mycophenolate mofetil)
- AND 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:

- Diagnosis of moderately to severely active ulcerative colitis,
- AND inadequate response, intolerance, or contraindication to all the following:
  - Ustekinumab product (Yesintek preferred)
  - At least one anti-TNF agent (Inflectra IV or Amjevita preferred)
  - Tofacitinib (Xeljanz)*PA

If using for Crohn's disease:

- Diagnosis of moderately to severely active Crohn's disease,
- AND inadequate response (of at least a 3-month trial), intolerance, or contraindication to ALL of the following:
  - Ustekinumab product (Yesintek preferred)
  - At least ONE anti-TNF agent (Inflectra IV or Amjevita preferred)

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

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met the criteria**:
  - Documented clinically significant benefit from the medication, AND
  - Specialist follow-up occurred 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 is a Dermatologist,
- AND 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:
    - 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 (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 systemic immunomodulators (i.e., methotrexate, azathioprine, cyclosporine, or mycophenolate mofetil)
- AND 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) Inhibitor (Cont'd)

Last revised: 10/6/2025; Effective date: 12/2/2025

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 the patient met at least one of the following diagnoses:
    - Diagnosis of alopecia areata with >50% scalp involvement, disfiguring facial involvement, rapidly progressive, or alopecia totalis/universalis; or
    - Diagnosis of alopecia areata with <50% scalp involvement, mild facial involvement, not rapidly progressive, or not alopecia totalis/universalis, and had treatment failure to at least a 2-month trial unless clinically significant adverse effects, contraindication, or intolerance to all the following:
        - Topical corticosteroid
        - AND topical calcineurin inhibitor
        - AND topical minoxidil
        - AND intralesional Kenalog
        - AND topical JAK inhibitor
- AND if the patient is ≥18 years of age, the 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:

- **For new members who were initiated outside of KPMAS, who have not been reviewed previously**: confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria:**
    - Positive clinical response to medication,
    - AND specialist follow-up in the last 12 months

Janus Kinase (JAK) Inhibitors (cont'd)

Generic	Brand	HICL	GSN	Representative NDC
DEURUXOLITINIB PHOSPHATE	LEQSELVI TABS 8 MG	49773	086365	47335010886

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
- Patient met at least one of the following diagnoses:
    - Diagnosis of alopecia areata with >50% scalp involvement, disfiguring facial involvement, rapidly progressive, or alopecia totalis/universalis; OR
    - Diagnosis of alopecia areata with <50% scalp involvement, mild facial involvement, not rapidly progressive, or not alopecia totalis/universalis, and had treatment failure to at least a 2-month trial unless clinically significant adverse effects, contraindication, or intolerance to all the following:
        - Topical corticosteroid AND
        - Topical calcineurin inhibitor AND
        - Topical minoxidil, AND
        - Intralesional Kenalog, AND
        - Topical JAK inhibitor
- AND if the patient is ≥18 years of age, the 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, AND
- Patient has failed (at least a 3-month trial), has intolerance, or contraindication to Litfulo (ritlecitinib)

Continuation of Therapy Criteria:

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

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

Laxatives and Cathartics

Last revised: 12/5/2025; Effective date: 2/3/2026

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
- Documented side effect or adverse reaction to generic lubiprostone, AND

<u>If using for irritable bowel syndrome with constipation (IBS-constipation predominant):</u>

- 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/contraindication to an optimal dose of fiber supplement (e.g., psyllium fiber or methylcellulose) OR polyethylene glycol

<u>If using for chronic idiopathic constipation (CIC):</u>

- Diagnosis of chronic idiopathic constipation (CIC), AND
- Patient has had an inadequate response to an adequate trial of at least 4 weeks or intolerance/contraindication to an optimal dose of fiber supplement (e.g., psyllium fiber or methylcellulose) OR osmotic laxative (i.e., polyethylene glycol or lactulose)

<u>If using for opioid-induced constipation (OIC):</u>

- 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/contraindication to at least ONE of the following:
    - Polyethylene glycol
    - Lactulose or sorbitol
    - Senna
    - Bisacodyl

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria:**
    - Documented side effect or adverse reaction to generic lubiprostone, AND
    - 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: 7/29/2025; Effective date: 10/7/2025

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 (e.g., h/o breast cancer, h/o stroke, h/o cardiovascular disease, etc.),
- AND documented inadequate response, intolerance, or contraindication to **2 or more** of the following non-hormonal therapies:
  - SNRI (e.g., desvenlafaxine, duloxetine, venlafaxine XR)
  - SSRI (e.g., citalopram, escitalopram, paroxetine)
  - Gabapentin
  - Oxybutynin
- AND initial prescription is limited to a maximum of 30-day supply with 2 refills

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met 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

Metabolic Function Diagnostics

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

Prior Authorization Criteria:

Length of Authorization:

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

Initial Review Criteria:

Diagnostic agent (90-day approval):

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

Cushing's Disease (12-month approval):

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

Continuation of Therapy Criteria:

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

Monoamine Oxidase (MAO) Inhibitor Antidepressants

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

Generic	Brand	HICL	GSN	Representative NDC
SELEGILINE	EMSAM PT24 12 MG/24HR	33510	060455	49502090230
SELEGILINE	EMSAM PT24 6 MG/24HR	33510	060453	49502090001
SELEGILINE	EMSAM PT24 9 MG/24HR	33510	060454	49502090130

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Psychiatrist,
- Diagnosis of major depressive disorder,
- Patient is 12 years and older,
- Documented inadequate response, intolerance, or contraindication to at least THREE formulary antidepressant agents, OR
- Patient is unable to swallow oral formulations due to oral or motor difficulties, dysphagia, etc.

Continuation of Therapy Criteria:

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

Monoclonal Antibodies to Immunoglobulin E (IGE)

Last revised: 5/29/2025; Effective date: 8/12/2025

Generic	Brand	HICL	GSN	Representative NDC
OMALIZUMAB	XOLAIR SOAJ 300 MG/2ML	25399	085686	50242022755
OMALIZUMAB	XOLAIR SOSY 300 MG/2ML	25399	085686	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:

- **For new members who were initiated outside of KPMAS and have not been reviewed previously:** Confirm that the patient meets all above initial review criteria
- **For existing members who have previously met the criteria:**
    - Patient continues to be under the care of a specialist,
    - AND documentation of positive clinical response to Xolair therapy since last review
    - AND <u>if using for chronic spontaneous urticaria and on a **dose higher than 300 mg q4wks:**</u> Documentation that conversion to Dupixent (dupilumab) has been considered or trialed with inadequate response

Monoclonal Antibody Human Interleukin 12/23 Inhibitor

Last revised: 12/8/2025; Effective date: 2/3/2026

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
USTEKINUMAB-AEKN	SELARSDI SOSY 45 MG/0.5ML	49526	085968	51759050532
USTEKINUMAB-AEKN	SELARSDI SOSY 90 MG/ML	49526	085969	51759060732
USTEKINUMAB-AUUB	WEZLANA SOLN 45 MG/0.5ML	49290	085466	84612005501
USTEKINUMAB-AUUB	WEZLANA SOSY 45 MG/0.5ML	49290	085463	84612007601
USTEKINUMAB-AUUB	WEZLANA SOSY 90 MG/ML	49290	085465	84612008901
USTEKINUMAB-TTWE	PYZCHIVA SOSY 90 MG/ML	49730	086269	61314065201
USTEKINUMAB-TTWE	PYZCHIVA SOSY 45 MG/0.5ML	49730	086268	61314065101
USTEKINUMAB-TTWE	PYZCHIVA SOAJ 45 MG/0.5ML	49730	088081	83457065196
USTEKINUMAB-TTWE	PYZCHIVA SOAJ 90 MG/ML	49730	088082	83457065296
USTEKINUMAB-AAUZ	OTULFI SOSY 45 MG/0.5ML	49894	086561	65219082401
USTEKINUMAB-AAUZ	OTULFI SOSY 90 MG/ML	49894	086562	65219082626
USTEKINUMAB-SRLF	IMULDOSA SOSY 45 MG/0.5ML	49929	086631	69448001763
USTEKINUMAB-SRLF	IMULDOSA SOSY 90 MG/ML	49929	086630	69448001863
USTEKINUMAB-STBA	STEQEYMA SOSY 45 MG/0.5ML	50109	086948	72606002701
USTEKINUMAB-STBA	STEQEYMA SOSY 90 MG/ML	50109	086949	72606002801

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Rheumatologist, Dermatologist, or Gastroenterologist,
- Patient has had treatment failure, intolerance, or contraindication to Yesintek (ustekinumab-kfce), AND

If using for Psoriatic Arthritis:

- Diagnosis of active psoriatic arthritis,
- Documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to BOTH of the following:
    - At least 1 anti-TNF agent [adalimumab-atto (Amjevita) or infliximab-dyyb (Inflectra) preferred]
    - Cosentyx (secukinumab)*PA

If using for Plaque Psoriasis:

- Diagnosis of moderate-to-severe plaque psoriasis,
- Inadequate response after at least a 3-month trial, intolerance, or contraindication to **all** following therapies:
    - Phototherapy unless involvement of sensitive areas (e.g. hand, feet, face, body folds or genitals)
    - Methotrexate or acitretin
    - At least 1 anti-TNF agent [adalimumab-atto (Amjevita) or infliximab-dyyb (Inflectra) preferred]
    - Secukinumab (Cosentyx)*PA
    - Guselkumab (Tremfya)*PA OR risankizumab-rzaa (Skyrizi)*PA

If using for Crohn's Disease:

- Diagnosis of active Crohn's disease with moderate-to-severe activity or high risk of progression, AND
- Inadequate response (of at least a 3-month trial), intolerance, or contraindication to **all** the following:
    - At least ONE anti-TNF (Inflectra IV or Amjevita preferred)
    - Entyvio (vedolizumab)*PA
    - Rinvoq (upadacitinib)*PA

If using for Ulcerative Colitis:

- Diagnosis of active ulcerative colitis with moderate-to-severe activity or high risk of progression, AND
- Inadequate response (of at least a 3-month trial), intolerance, or contraindication to ALL the following:
    - At least ONE anti-TNF (Inflectra IV or Amjevita preferred)
    - Entyvio (vedolizumab)*PA
    - Tofacitinib (Xeljanz)*PA or upadacitinib (Rinvoq)*PA

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

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - Patient has had treatment failure, intolerance, or contraindication to Yesintek (ustekinumab-kfce), AND
    - Positive clinical response to medication, AND
    - Specialist follow-up occurred in the past 12 months

Monoclonal Antibody- Interleukin-5 Antagonist

Last revised: 8/5/2025; Effective date: 10/7/2025

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:

<u>If using for Pulmonary indications (Asthma, EGPA):</u>

- 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, AND documented treatment failure, contraindication, or inadequate response to Fasenra AND Dupixent
    - OR eosinophilic asthma (OCS-dependent) with serum eosinophil count ≥150 cells/microliter in the past 12 months, AND documented treatment failure, contraindication, or inadequate response to Fasenra AND Dupixent
    - OR eosinophilic granulomatosis with polyangiitis (EGPA) in patients ≥18 years, AND documented treatment failure, contraindication, or inadequate response to Fasenra

If using for Chronic Obstructive Pulmonary Disease (COPD):

- Prescriber is a Pulmonologist or Allergist,
- AND patient is ≥18 years,
- AND diagnosis of moderate to severe COPD with an eosinophilic phenotype, as evidenced by ALL of the following:
    - Blood eosinophil count of ≥300 cells/microliter in the past 12 months
    - Exacerbation history in the past 12 months of ONE of the following:
        - ≥2 moderate exacerbations requiring oral glucocorticoids
        - ≥1 severe exacerbation requiring hospitalization, ER visit, or IV glucocorticoids

- AND an adequate trial (≥75% adherence for at least 1 year), contraindication, or failure to high-dose dual (LAMA/LABA) therapy OR high-dose triple (LAMA/LABA/ICS) therapy in combination with ONE of the following:
    - Azithromycin 250-500 mg 3 times a week, OR
    - Roflumilast
- AND history of treatment failure/inadequate response, intolerance, or contraindication to Dupixent (dupilumab)
- AND patient will continue to use dual or triple maintenance therapy for COPD,
- AND Nucala will NOT be used with another monoclonal antibody for the treatment of COPD (e.g., 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:

- **For new members who were initiated outside of KPMAS and have not been reviewed previously:** confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - Patient continues to be under the care of a specialist, AND
    - Documentation of positive clinical response to Nucala

Mu-Opioid Receptor Antagonist, Peripherally-Acting

Last revised: 7/5/2022

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-tablet 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)

Natriuretic Peptides

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

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a geneticist or a pediatric endocrinologist,
- Age ≥ 5 years,
- Diagnosis of achondroplasia documented and genetic testing confirming FGFR3 mutation associated with achondroplasia,
- Documentation of open epiphyses,
- Patient is ambulatory and able to stand without assistance

Continuation of Therapy Criteria:

- Documentation of an increase in annualized growth velocity (AGV),
- Recent documentation showing that the member has open epiphyses

NDMA Receptor Antagonist and NDRI Comb

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

Generic	Brand	HICL	GSN	Representative NDC
DEXTROMETHORPHAN HYDROBROMIDE-BUPROPION HYDROCHLORIDE	AUVELITY TBCR 45-105 MG	48220	083732	81968004530

Prior Authorization Criteria:

Length of Authorization:

- Initial: 8 weeks
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Psychiatrist,
- AND patient is ≥ 18 years of age,
- AND diagnosed with moderate to severe major depressive disorder (MDD),
- AND inadequate treatment response after documented adequate therapeutic trial (defined as minimum 6 weeks) to at least 4 agents from various drug classes including the following unless contraindicated:
    - One to two selective serotonin reuptake inhibitors (SSRIs) (e.g. sertraline, escitalopram)
    - One to two serotonin and norepinephrine reuptake inhibitors (SNRIs) (e.g. venlafaxine, duloxetine)
    - One to two atypical antidepressants (e.g. bupropion, mirtazapine)
    - One to two serotonin modulators (e.g. vilazodone, Trintellix)
- AND patient does not have any of the following:
    - Documented seizure disorder
    - Current or prior diagnosis of bulimia or anorexia nervosa
    - Severe renal impairment (e.g. eGFR 15 to 29 mL/minute/1.73 m^2) or dialysis
    - Severe hepatic impairment (e.g. Child-Pugh C)
    - Concomitant use of monoamine oxidase inhibitors (MAOIs) (e.g . phenelzine, selegiline, including MAOIs such as linezolid or intravenous methylene blue) or if MAOIs taken within the preceding 14 days
    - Concomitant use with strong inducers of CYP2B6 (e.g. carbamazepine)
    - Concurrently prescribed bupropion
    - Pregnancy or breastfeeding

Continuation of Therapy Criteria:

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

Neonatal Fc Receptor (FcRn) Inhibitors

Last revised: 12/5/2025; Effective date: 2/3/2026

Generic	Brand	HICL	GSN	Representative NDC
EFGARTIGIMOD ALFA AND HYALURONIDASE-QVFC	VYVGART HYTRULO SOSY 1000-10000 MG-UNT/5ML	49016	087572	73475122101

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 6 months (if using for myasthenia gravis), 12 months (if using for CIDP)

Initial Review Criteria:

<u>If using for Myasthenia Gravis:</u>

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

  AND

- <u>If using for CHRONIC therapy:</u>
  - Trial of **at least 2 oral non-steroidal immunosuppressive therapy** for the duration indicated unless intolerant/contraindicated:
    - First-line
      - Azathioprine for at least 12 months
      - Mycophenolate for at least 12 months
    - Alternative agents
      - Cyclosporine for at least 6 months
      - Tacrolimus for at least 12 months
  - AND trial of preferred biologics:
    - KP-Preferred Rituximab biosimilar for at least 6 months AND
  - Trial and failure of Vyvgart IV* AND
  - Trial and failure of Ultomiris AND
  - Trial and failure of Epysqli

  **For patients weighing >81 kg or who would require 3 or more vials of Vyvgart IV vials, Vyvgart Hytrulo syringe is preferred, and prior trial of Vyvgart IV is NOT required*

- <u>If using for BRIDGE therapy:</u>

- Patient has documented non-responsiveness to IVIG as bridge therapy, AND
- Patient has documented non-responsiveness to Vyvgart as bridge therapy, AND
  - *Note: Vyvgart may be used for 12-24 months when used as a bridge to slower-acting immunotherapies (e.g., azathioprine, mycophenolate) if desirable to avoid steroid or minimize glucocorticoid use (e.g., poorly controlled diabetic patients)*
- Patient has documented non-responsiveness to Ultomiris as bridge therapy, AND
- Patient has documented non-responsiveness to Epysqli as bridge therapy, AND
- Patient must be started on a non-steroidal immunosuppressive therapy (e.g., Azathioprine, mycophenolate, rituximab, cyclosporine, tacrolimus, methotrexate)

If using for Chronic Inflammatory Demyelinating Polyneuropathy (CIDP):

- Request is for efgartigimod and hyaluronidase (Vyvgart Hytrulo), AND
- Prescribed by a Neurologist, AND
- Diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP), AND
- Patient is 18 years or older, AND
- Patient has an inadequate response to corticosteroids for at least 3 months, AND
- Patient has had an inadequate response, intolerance or has a contraindication to immune globulin (IVIG) for at least 3 months, AND
- Patient is dependent on chronic IVIG or chronic oral prednisone equivalent (if no contraindication), and has tried and failed at least one of the following for 6 months or more:
  - KP-Preferred Rituximab biosimilar
  - Azathioprine
  - Mycophenolate

Notes:

- Riabni is the KP-preferred rituximab biosimilar
- Vyvgart Hytrulo comes in two dosage forms:
  - A syringe, which can be self-administered by patients and/or caregivers, and
  - A single dose vial, which is administered a winged infusion set as a subcutaneous injection over 30 to 90 seconds by a healthcare professional
- These criteria apply to the syringe (self/caregiver-administered) dosage form
- Vyvgart Hytrulo (efgartigimod and hyaluronidase) has an additional indication for CIDP, whereas Vyvgart (efgartigimod) does NOT have the CIDP indication

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
  - If using for Myasthenia Gravis, **CHRONIC** therapy:
    - First renewal: Documented improvement of at least 2 points on the MG-ADL
    - Subsequent renewals (after first renewal): Documented maintenance of stable MG-ADL score or documented beneficial effect from therapy during neurology follow-up in the last 12 months
  - If using for Myasthenia Gravis, **BRIDGE** therapy:
    - First renewal: Documented improvement of at least 2 points on the MG-ADL
    - Subsequent renewals (after first renewal): Confirm with provider if therapy can be discontinued after 12 months of therapy (Note: it takes 12-24 months for slower acting immunotherapies (e.g., azathioprine, mycophenolate) to take effect
  - If using for CIDP:

	▪ Patient has experienced a positive clinical response to treatment, as documented by neurologist, AND ▪ Confirm patient has completed follow-up appointment with neurologist in the last 12 months

Nicotinic Recept.Partial Agonist, Alpha4Beta2 Spec

Generic	Brand	HICL	GSN	Representative NDC
VARENICLINE TARTRATE (CHOLINERGIC AGONIST)	TYRVAYA SOLN 0.03 MG/ACT	33766	082768	73521003002

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is an Ophthalmologist, or Optometrist
- Patient is ≥18 years of age with a diagnosis of dry eye disease
- Patient has tried and failed at least one month of one OTC ocular lubricant (e.g., artificial tears, lubricating gels/ointments)
- Patient has had an adequate trial (3 months treatment duration) and failure to cyclosporine 0.05% ophthalmic solution (generic Restasis) AND Cequa 0.09% AND Xiidra 5%
- Patient is not concomitantly using an ophthalmic cyclosporine product (Cequa, Restasis, Vevye), or Xiidra (lifitegrast ophthalmic solution)

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
  - Documentation of positive clinical response to therapy (e.g., increased tear production or improvement in dry eye symptoms)

Ophthalmic Anti-Inflammatory Immunomodulator-Type

Generic	Brand	HICL	GSN	Representative NDC
LIFITEGRAST	XIIDRA SOLN 5%	43610	076360	00078091112

Prior Authorization Criteria:
Length of Authorization: • Initial: 12 months • Reauthorization: 12 months
Initial Review Criteria: • Prescriber is an Ophthalmologist, or Optometrist • Patient is ≥18 years of age with a diagnosis of dry eye disease • Patient has tried and failed at least one month of one OTC ocular lubricant (e.g., artificial tears, lubricating gels/ointments) • Patient has had an adequate trial (3 months treatment duration) and failure to cyclosporine 0.05% ophthalmic solution (generic Restasis) AND Cequa 0.09% • Patient is not concomitantly using an ophthalmic cyclosporine product (Cequa, Restasis, Vevye)
Continuation of Therapy Criteria: • **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria • **For existing members who have previously met the criteria**: o Documentation of positive clinical response to therapy (e.g., increased tear production or improvement in dry eye symptoms)

Ophthalmic Anti-Inflammatory Immunomodulator-Type (cont'd)

Generic	Brand	HICL	GSN	Representative NDC
CYCLOSPORINE (OPHTH)	RESTASIS EMUL 0.05%	4524	051820	00023916330
CYCLOSPORINE (OPHTH)	RESTASIS MULTIDOSE EMUL 0.05%	4524	076793	00023530105
CYCLOSPORINE (OPHTH)	VEVYE SOLN 0.1%	4524	084847	82667090002

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is an Ophthalmologist, or Optometrist
- Patient is ≥18 years of age with a diagnosis of dry eye disease
- Patient has tried and failed at least one month of one OTC ocular lubricant (e.g., artificial tears, lubricating gels/ointments)
- Patient has had an adequate trial (3 months treatment duration) and failure to cyclosporine 0.05% ophthalmic solution (generic Restasis) AND Cequa 0.09%
- Patient is not concomitantly using another ophthalmic cyclosporine product (Cequa, Vevye, Restasis)
- If order is for Vevye: Patient has had an adequate trial (3 months' treatment duration) and failure to Xiidra 5% AND is not using Xiidra concomitantly with Vevye

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
  - Documentation of positive clinical response to therapy (e.g., increased tear production or improvement in dry eye symptoms)

Ophthalmic (Eye) Antiparasitics

Last revised: 7/31/2024; 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

Ophthalmic Human Nerve Growth Factor (hNGF)

Generic	Brand	HICL	GSN	Representative NDC
CENEGERMIN-BKBJ	OXERVATE SOLN 0.002%	45258	079287	71981002007

Prior Authorization Criteria:

Length of Authorization:

- Initial: 8 weeks per eye
- Reauthorization: N/A – therapy limited to 8 weeks per eye per lifetime

Initial Review Criteria:

- Prescriber is an Ophthalmologist, AND
- Patient is 2 years of age or older, AND
- Documented diagnosis of moderate to severe neurotrophic keratitis, AND
- Documented history of failure of ALL the following non-surgical options:
    - OTC artificial tear products, gels or lubricant ointments
    - Therapeutic Contact Lenses
    - Autologous Serum eye drops (unless contraindicated)
- Not a candidate for surgical therapies

Continuation of Therapy Criteria: N/A – therapy limited to 8 weeks per eye per lifetime

Oral Lipid Supplements

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

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

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

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

Continuation of Therapy Criteria:

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

Norepinephrine and Dopamine Reuptake Inhib (NDRIs)

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

Generic	Brand	HICL	GSN	Representative NDC
BUPROPION HYDROBROMIDE	APLENZIN TB24 174 MG	36156	065345	00187581030
BUPROPION HYDROBROMIDE	APLENZIN TB24 348 MG	36156	064896	00187581130
BUPROPION HYDROBROMIDE	APLENZIN TB24 522 MG	36156	064899	00187581230

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Psychiatrist,
- Diagnosis of Seasonal Affective Disorder (SAD),
- Patient is 18 years and older,
- Documented inadequate response, intolerance, or contraindication to at least 3 formulary antidepressant agents (one of which must be a generic bupropion)

Continuation of Therapy Criteria:

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

Overactive Bladder Agents, Beta-3 Adrenergic receptor

Last revised: 1/30/2025; Effective date: 4/1/2025

Generic	Brand	HICL	GSN	Representative NDC
MIRABEGRON	MYRBETRIQ TB24 25 MG	39357	069630	00469260130
MIRABEGRON	MYRBETRIQ TB24 50 MG	39357	069631	00469260290
MIRABEGRON	MYRBETRIQ SRER 8 MG/ML	39357	082137	00469502099
MIRABEGRON	MIRABEGRON ER TB24 25 MG	39357	069630	68180015109
MIRABEGRON	MIRABEGRON ER TB24 50 MG	39357	069631	70710116003
VIBEGRON	GEMTESA TABS 75 MG	47040	081787	73336007530

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 a contraindication to antimuscarinic therapy (e.g., history of uncontrolled tachyarrhythmias, myasthenia gravis, gastric retention, and/or narrow angle-closure glaucoma), an inadequate response*, intolerance**, 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
- AND if ordering brand Myrbetriq tablets: history of contraindication, intolerance*, or inadequate response** to generic mirabegron ER tablets
- AND if ordering Gemtesa: 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
- When antimuscarinic therapy is selected, trospium or darifenacin is preferred to potentially minimize risk of cognitive impact [other antimuscarinic therapies, such as oxybutynin products, are suitable for short-term use (i.e. postsurgical stent or spasm management)]
- 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:

- Patient has had good clinical response to the medication,
- AND patient has contraindication to antimuscarinic therapy (e.g., history of uncontrolled tachyarrhythmias, myasthenia gravis, gastric retention, and/or narrow angle-closure glaucoma), inadequate response, intolerance, 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
- AND if ordering brand Myrbetriq tablets: history of contraindication, intolerance*, or inadequate response** to generic mirabegron ER tablets
- AND if ordering Gemtesa: Patient has an inadequate response*, intolerance**, contraindication, or history of trial and failure to Myrbetriq (mirabegron)

Parathyroid Hormones

Generic	Brand	HICL	GSN	Representative NDC
PALOPEGTERIPARATIDE	YORVIPATH SOPN 168 MCG/0.56ML	49810	086417	73362010001
PALOPEGTERIPARATIDE	YORVIPATH SOPN 294 MCG/0.98ML	49810	086416	73362010101
PALOPEGTERIPARATIDE	YORVIPATH SOPN 420 MCG/1.4ML	49810	086415	73362010201

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescribed by an Endocrinologist,
- Patient is ≥18 years of age,
- Diagnosis of chronic hypoparathyroidism of postsurgical, autoimmune, genetic, or idiopathic origins based on hypocalcemia in the setting of inappropriately low serum PTH levels,
- Documented adequate trial (≥3 months) of max tolerated doses of conventional therapies: calcium and vitamin D supplements (e.g., calcitriol, ergocalciferol, cholecalciferol),
- Provider attestation that patient's condition cannot be adequately controlled on conventional therapy (i.e. symptomatic hypocalcemia, hyperphosphatemia, renal insufficiency, hypercalciuria, or poor quality of life),
- Baseline documentation within the last 4 weeks of BOTH of the following:
    - Serum 25(OH)D or 25-hydroxyvitamin D level within normal range
    - Albumin-adjusted serum calcium >7.8 mg/dL

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - Patient has experienced positive clinical response to therapy, as indicated by documentation of normocalcemia (recent albumin-adjusted serum calcium 8.3-10.6 mg/dL), AND ONE of the following:
        - Patient no longer requires active vitamin D or therapeutic doses of calcium
        - Patient has had a significant reduction in required dosages of conventional therapies and is still actively titrating doses of Yorvipath

Pharmacological Chaperone-Alpha-Galactosid.A Stabz

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

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a geneticist,
- Patient must have a diagnosis of Fabry disease,
- Patient is ≥18 years,
- Patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data,
- Galafold is not prescribed concurrently with Fabrazyme,
- Patient does not have eGFR <30 mL/min or ESRD requiring dialysis,
- Patient weighs ≥68 kg*

**Note: Fabrazyme is more cost-effective than Galafold when weight is <68 kg*

Continuation of Therapy Criteria:

- Patient continues to be under the care of a geneticist,
- Patient does not have eGFR <30 mL/min or ESRD requiring dialysis

Phosphodiesterase (PDE) Inhibitors

Generic	Brand	HICL	GSN	Representative NDC
ENSIFENTRINE	OHTUVAYRE SUSP 3 MG/2.5ML	49726	086255	83034000301

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Pulmonologist,
- Patient is ≥18 years,
- Diagnosis of chronic obstructive pulmonary disease (COPD), with ALL of the following:
    - FEV1/FVC ratio of <0.7 post-bronchodilation
    - Exacerbation history in the past 12 months of ONE of the following:
        - ≥2 moderate exacerbations requiring oral glucocorticoids
        - ≥1 severe exacerbation requiring hospitalization, ER visit, or IV glucocorticoids
- Patient has had an adequate trial (adherence/MRAR ≥75% for at least 1 year), contraindication, or intolerance to high-dose dual (LAMA/LABA) therapy OR high-dose triple (LAMA/LABA/ICS) therapy in combination with:
    - Azithromycin 250-500 mg 3 times a week, OR
    - Roflumilast
- Patient will continue to use dual or triple maintenance therapy for COPD,
- Prescriber attestation that Ohtuvayre is NOT being used to treat acute symptoms of bronchospasm, and will NOT be used in combination with roflumilast

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met the criteria:**
    - Patient continues to be under the care of a Pulmonologist and has had follow-up since last review,
    - Documentation of positive clinical response (e.g., reduction in symptoms and/or exacerbations),
    - Patient continues to be on dual or triple maintenance inhaler therapy for COPD unless contraindication or intolerance

Pituitary Suppressive Agents

Generic	Brand	HICL	GSN	Representative NDC
CRINECERFONT	CRENESSITY CAPS 100 MG	50097	086905	70370510001
CRINECERFONT	CRENESSITY CAPS 25 MG	50097	086904	70370502501
CRINECERFONT	CRENESSITY CAPS 50 MG	50097	086903	70370505001
CRINECERFONT	CRENESSITY SOLN 50 MG/ML	50097	086906	70370525001

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescribed by Endocrinology or Pediatric Endocrinology,
- Patient is ≥4 years of age,
- Diagnosis of 21-hydroxylase deficiency CAH (classic congenital adrenal hyperplasia) confirmed by at least ONE of the following:
    - Elevated 17-hydroxyprogesterone level
    - Confirmed *CYP21A2* gene mutation
    - Positive newborn screening with confirmatory second-tier testing (e.g., serum testing for 17-hydroxyprogesterone and cortisol levels; serum electrolytes)
    - Cosyntropin (ACTH) stimulation test
- Patient is currently taking a systemic glucocorticoid (e.g., hydrocortisone, prednisone, prednisolone, dexamethasone), and will continue glucocorticoid therapy in combination with Crenessity

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - Patient continues to be under the care of an Endocrinologist or Pediatric Endocrinologist, and has had follow-up since last review,
    - Documentation of clinical benefit from therapy, as evidenced by disease stability or improvement (e.g., decreased androstenedione or 17-hydroxyprogesterone levels; reduction in required glucocorticoid dose from baseline; decrease in body mass index standard deviation scores; improved insulin resistance; reduction in hirsutism; improvement in androstenedione-to-testosterone ratio)

PKU Tx Agent – Cofactor of Phenylalanine Hydroxylase

Generic	Brand	HICL	GSN	Representative NDC
SAPROPTERIN DIHYDROCHLORIDE	JAVYGTOR PACK 100 MG	35266	071802	43598009730
SAPROPTERIN DIHYDROCHLORIDE	JAVYGTOR PACK 500 MG	35266	074256	43598016230
SAPROPTERIN DIHYDROCHLORIDE	JAVYGTOR TABS 100 MG	35266	063484	43598009604
SAPROPTERIN DIHYDROCHLORIDE	KUVAN PACK 100 MG	35266	071802	68135030111
SAPROPTERIN DIHYDROCHLORIDE	KUVAN PACK 500 MG	35266	074256	68135048211
SAPROPTERIN DIHYDROCHLORIDE	KUVAN TABS 100 MG	35266	063484	68135030002

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescribed by Geneticist or Endocrinologist,
- Diagnosis of phenylketonuria with documentation of baseline blood phenylalanine levels prior to treatment initiation,
- Absence of the following medications:
  - Medications known to inhibit folate metabolism (e.g., methotrexate)
  - Nitric oxide-mediated vasorelaxation medication (e.g., sildenafil, vardenafil, tadalafil)
  - Levodopa
- Patient is compliant with a phenylalanine restricted diet,
- Patient has had inadequate response after ≥3 months' trial, or has intolerance or contraindication to generic sapropterin

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
  - Patient has experienced positive response to therapy, as defined by reduction in phenylalanine levels by ≥30% from baseline,
  - Patient has had specialist follow-up in the last 12 months

PKU Tx Agent – Cofactor of Phenylalanine Hydroxylase (cont'd)

Generic	Brand	HICL	GSN	Representative NDC
SEPIAPTERIN	SEPHIENCE PACK 250 MG	50760	088049	52856020101
SEPIAPTERIN	SEPHIENCE PACK 1000 MG	50760	088050	52856030101

Prior Authorization Criteria:

Length of Authorization:

- Initial: 3 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Geneticist, AND
- Patient is 1 month or older, AND
- Documented diagnosis of hyperphenylalaninemia (HPA) with phenylketonuria (PKU), AND
- Pre-treatment baseline phenylalanine (Phe) level >600 micromol/L, AND
- Used in conjunction with a phenylalanine (Phe)-restricted diet, AND
- Patient has had inadequate response*, or has intolerance or contraindication to sapropterin OR patient has diagnosis of classical PKU (baseline Phe level >1200 micromol/L), AND
- Patient does not have pathogenic variants in GCH1, PTS, QDPR, SPR, PCBD1 (consistent with primary BH4 deficiency), AND
- Sepiapterin will not be used in combination with sapropterin or pegvaliase, AND
- Patient has absence of the following medications:
    - Medications known to inhibit folate metabolism (e.g., methotrexate)
    - Nitric oxide-mediated vasorelaxation medication (e.g., sildenafil, vardenafil, tadalafil)
    - Levodopa
    - Sepiapterin Reductase (SR) Inhibitors (e.g. sulfasalazine or sulfamethoxazole).

**Inadequate response defined as blood Phe ≥ 360 micromol/L, despite consistent use for ≥3 months in combination with dietary Phe restriction*

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - Documented positive response to therapy (i.e. Phe percentage of ≥30% reduction from baseline)

Plasma Kallikrein Inhibitors

Last revised: 3/18/2025; Effective date: 6/3/2025

Generic	Brand	HICL	GSN	Representative NDC
BEROTRALSTAT HCL	ORLADEYO CAPS 110 MG	47016	081747	72769010201
BEROTRALSTAT HCL	ORLADEYO CAPS 150 MG	47016	081746	72769010101

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is an Allergist, Immunologist, or Physician who specializes in the treatment of hereditary angioedema (HAE),
- Patient is at least 12 years of age,
- Patient has diagnosis of HAE type I or type II confirmed by either:
    - Mutation known to cause HAE in either the SERPING1 or F12 gene, OR
    - A C4 level below the lower limit of normal and/or a C1 inhibitor (C1-INH) antigenic level or functional level below the lower limit of normal, AND
- Orladeyo is not being used in combination with other products indicated for prophylaxis against HAE attacks,
- Patient is not exceeding doses greater than 150 mg/day

Continuation of Therapy Criteria:

- Specialist follow-up occurred in the past 12 months with documented improvement while on Orladeyo,
- Orladeyo continues not to be used in combination with other products indicated for prophylaxis against HAE attacks

Plasma Kallikrein Inhibitors (cont'd)

Last revised: 7/29/2025; Effective date: 10/7/2025

Generic	Brand	HICL	GSN	Representative NDC
LANADELUMAB-FLYO	TAKHZYRO SOSY 150 MG/ML	45177	084405	47783064501
LANADELUMAB-FLYO	TAKHZYRO SOLN 300 MG/2ML	45177	078791	47783064401
LANADELUMAB-FLYO	TAKHZYRO SOSY 300 MG/2ML	45177	081825	47783064601

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is an Allergist, Immunologist, or Physician who specializes in the treatment of hereditary angioedema (HAE),
- Patient is at least 2 years of age,
- Patient has diagnosis of HAE type I or type II confirmed by either:
    - Mutation known to cause HAE in either the SERPING1 or F12 gene, OR
    - A C4 level below the lower limit of normal and/or a C1 inhibitor (C1-INH) antigenic level or functional level below the lower limit of normal, AND
- Takhzyro is not being used in combination with other products indicated for prophylaxis against HAE attacks

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS and have not been reviewed previously:** confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - Specialist follow-up occurred in the past 12 months with documented improvement while on Takhzyro,
    - Takhzyro continues not to be used in combination with other products indicated for prophylaxis against HAE attacks,
    - If patient has been stable (i.e. attack free) for >6 months, there is documentation that extending the dosing interval to 300 mg every 4 weeks has been considered, or patient's current dosing is 300 mg every 4 weeks

Plasma Kallikrein Inhibitors (cont'd)

Generic	Brand	HICL	GSN	Representative NDC
DONIDALORSEN SODIUM	DAWNZERA SOAJ 80 MG/0.8ML	50832	088166	71860010301

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is an Allergist, Immunologist, or Physician who specializes in the treatment of hereditary angioedema (HAE), AND
- Patient is at least 12 years of age, AND
- Patient has diagnosis of HAE type I or type II confirmed by either:
  - Mutation known to cause HAE in either the SERPING1 or F12 gene, OR
  - A C4 level below the lower limit of normal and/or a C1 inhibitor (C1-INH) antigenic level or functional level below the lower limit of normal,
- AND documented treatment failure*/inadequate response, intolerance, or contraindication to Takhyzro (lanadelumab-flyo), AND
- If patient weighs <90 kg: documented treatment failure/inadequate response, intolerance, or contraindication to Haegarda (C1 esterase inhibitor – human), AND
- Dawnzera is not being used in combination with other products indicated for prophylaxis against HAE attacks

Notes:
**Failure is defined as no significant decrease in number of HAE acute attack frequency, decrease in HAE attack severity, or decrease in duration of HAE attacks after an adequate trial (≥3 months)*

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
  - Specialist follow-up occurred in the past 12 months with documented improvement while on Dawnzera, AND
  - Dawnzera continues to NOT be used in combination with other products indicated for prophylaxis against HAE attacks, AND
  - If patient has been stable (i.e. attack-free) for >6 months, there is documentation that extending the dosing interval to 80 mg every 8 weeks has been considered, OR patient's current dosing is 80 mg every 8 weeks

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

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

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 (GERD, erosive esophagitis)
- Reauthorization: 1 month (*H. pylori);* 12 months (GERD, erosive esophagitis)

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:
    - Bismuth quadruple regimen (1st line) – examples include:
        - PPI + bismuth + tetracycline + metronidazole or clarithromycin
        - PPI + bismuth + amoxicillin + metronidazole or clarithromycin
        - PPI + bismuth + levofloxacin + tetracycline or metronidazole
    - Levofloxacin triple regimen (e.g. PPI + levofloxacin + amoxicillin or metronidazole)
    - High-dose dual therapy (PPI + amoxicillin 1 gm)
    - Rifabutin triple regimen (PPI + amoxicillin + rifabutin)

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 GERD or erosive esophagitis (6 months approval):

- Patient has a diagnosis of gastroesophageal reflux disease (GERD) OR 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 new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met the criteria**:
    - Documented clinically significant benefit from the medication, and continues to require treatment for maintenance, AND
    - Specialist follow-up occurred within the last 12 months

Potassium Sparing Diuretics

Last revised: 12/5/2025; Effective date: 2/3/2026

Generic	Brand	HICL	GSN	Representative NDC
FINERENONE	KERENDIA TABS 10 MG	47487	082499	50419054001
FINERENONE	KERENDIA TABS 20 MG	47487	082500	50419054101
FINERENONE	KERENDIA TABS 40 MG	47487	087976	50419054201

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Nephrologist, Endocrinologist, or Cardiologist,
- AND patient is 18 years of age or older,
- AND documented baseline eGFR and serum potassium ≤5 mEq/L within past 3 months,

<u>If using for CKD associated with type 2 diabetes:</u>

- Documented diagnosis of type 2 diabetes mellitus in patients,
- AND documented diagnosis of CKD [defined as eGFR 25-74 mL/min/1.73 m^2 and/or urinary albumin-to-creatinine ratio (UACR) of >300 mg/g],
- AND currently prescribed ACEI or ARB therapy for at least 3 months, or if not prescribed, provider has documented rationale (e.g., documented failure, intolerance, or contraindication to therapy),
- AND documented adequate therapeutic trial (≥3 months) and failure (i.e. persistent UACR >300 mg/g), contraindication, or intolerance to SGLT2i* [e.g., Jardiance (empagliflozin), dapagliflozin, etc.)

**At this time, no evidence exists for additive effect of combination therapy of SGLT2i with finerenone*

<u>If using for heart failure with preserved ejection fraction:</u>

- Documented left ventricular ejection fraction of >40%,
- AND patient is on a Renin-Angiotensin System (RAS) inhibitor (ACE, ARB, or ARNI) AND SGLT2i therapy (e.g., Jardiance [empagliflozin], dapagliflozin, etc.), or if not prescribed, provider has documented rationale,
- AND documented adequate therapeutic trial (≥3 months) and failure, contraindication, or intolerance to at least 1 steroidal anti-mineralocorticoid (i.e., spironolactone/eplerenone)

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS and have not been reviewed previously**: Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
  - Documented beneficial response to therapy (i.e. no documentation of initiation of dialysis, kidney transplant, or decrease in eGFR of 40% or greater; decrease in hospitalizations for heart failure; improved quality of life)
  - AND patient continues to be under the care of a specialist

PPAR Agonist

Last revised: 10/6/2025; Effective date: 12/2/2025

Generic	Brand	HICL	GSN	Representative NDC
ELAFIBRANOR	IQIRVO TABS 80 MG	49672	086187	15054008001
SELADELPAR LYSINE	LIVDELZI CAPS 10 MG	49816	086431	61958330101

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Gastroenterologist/Hepatologist,
- Patient is 18 years of age or older,
- Diagnosis with primary biliary cholangitis (PBC),
- Documented inadequate response (of a trial at least ≥1 year), intolerance, or contraindication to ursodiol (ursodeoxycholic acid),
- Patient is taking an optimal regimen of cholesterol treatment (fenofibrate or statin) if most recent LDL>190 mg/dL,
- If ordering Iqirvo: Documented inadequate response (of a trial at least ≥ 1 year), intolerance, or contraindication to Livdelzi (seladelpar)
- Chart review and/or prescriber confirms that patient does NOT have any of the following:
    - Presence or history of decompensated cirrhosis (i.e. Child-Pugh score B or C)
    - History of a hepatic decompensation event (i.e. ascites, gastroesophageal variceal bleeding, hepatic encephalopathy, and coagulopathy)
    - Presence of compensated cirrhosis
    - Active compensated cirrhosis with evidence of portal hypertension
    - Used concurrently with any other second-line PBC treatment [e.g., Ocaliva (obeticholic acid)]
    - Complete biliary obstruction
    - Pregnancy and/or lactation

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets ALL the above initial review criteria
- **For existing members who have previously met the criteria:**
    - Specialist follow-up in the past 12 months,
    - Patient has an alkaline phosphatase (ALP) level that is less than 1.67-times the upper limit of normal AND has decreased by at least 15 percent from baseline on treatment,
    - Chart review and/or prescriber confirms that patient does NOT have any of the following:
        - Presence or history of decompensated cirrhosis (i.e. Child-Pugh score B or C)
        - History of a hepatic decompensation event (i.e. ascites, gastroesophageal variceal bleeding, hepatic encephalopathy, and coagulopathy)
        - Presence of compensated cirrhosis
        - Active compensated cirrhosis with evidence of portal hypertension
        - Used concurrently with any other second-line PBC treatment [e.g., Ocaliva (obeticholic acid)]
        - Complete biliary obstruction
        - Pregnancy and/or lactation

Protein Stabilizers

Generic	Brand	HICL	GSN	Representative NDC
ACORAMIDIS HCL	ATTRUBY TBPK 356 MG	50022	086787	82228071228

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Cardiologist, AND
- Patient is ≥18 years of age, 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) AND either:
        - Echocardiogram with end-diastolic interventricular septal wall thickness >12 mm OR
        - Cardiac MRI consistent with, or suggestive of, amyloidosis
    - Pyrophosphate (PYP) scintigraphy cardiac uptake visual score of either
        - Grade 2 or 3 using Perugini Grade 1-3 scoring system OR
        - Calculated heart-to-contralateral (H/CL) ratio ≥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 has failed an adequate trial (≥3 months) of Vyndamax/Vyndaqel (tafamidis), or patient has intolerance to, contraindication, or clinical reason to avoid treatment, AND
- Recommend not to initiate if any of the following apply:
    - NYHA Class IV or ACC/AHA Stage D heart failure
    - Glomerular filtration rate (GFR) < 30 mL/min
    - Currently receiving inotersen (Tegsedi), patisiran (Onpattro), tafamadis (Vyndamax/Vyndaqel), or vutrisiran (Amvuttra)
    - Severe hepatic impairment and/or cirrhosis
    - Prior heart or liver transplantation
    - Implanted cardiac mechanical assist device
    - Patient is in hospice care
    - Patient has life expectancy of less than one year

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - Documentation of positive clinical response, AND
    - Office visit or telephone visit with a specialist within the past 12 months

Pulmonary Antihyper Agent, ActRIIA-Fc

Generic	Brand	HICL	GSN	Representative NDC
SOTATERCEPT-CSRK	WINREVAIR KIT 2 X 45 MG	49475	085892	00006508701
SOTATERCEPT-CSRK	WINREVAIR KIT 45 MG	49475	085892	00006509001
SOTATERCEPT-CSRK	WINREVAIR KIT 60 MG	49475	085894	00006509101
SOTATERCEPT-CSRK	WINREVAIR KIT 2 X 60 MG	49475	085894	00006508801

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Pulmonologist or Cardiologist,
- Diagnosis of pulmonary arterial hypertension (PAH) [World Health Organization (WHO) Group I],
- Patient is in WHO Functional Class (WHO-FC) II or III,
- Patient is ≥18 years of age,
- Documentation of baseline hemoglobin (Hgb) and platelets, and provider attestation that patient will be monitored for increase in Hgb and decrease in platelets prior to EACH of the first 5 doses,
- Patient is currently taking, or has documented treatment failure, intolerance, or contraindication to at least THREE of the following:
    - A phosphodiesterase type (PDE-5) inhibitor [e.g. sildenafil, tadalafil]
    - An endothelin receptor antagonist (ERA) [e.g. ambrisentan, bosentan, macitentan (Opsumit)]
    - A soluble guanylate cyclase stimulator [e.g., riociguat (Adempas)]
    - A prostacyclin [e.g., epoprostenol, treprostinil, selexipag (Uptravi)]
- If of childbearing potential: Negative pregnancy test, and patient has been counseled on use of effective contraception during therapy and for at least 4 months after the last dose

Continuation of Therapy Criteria:

- Documentation of positive clinical response, as evidenced by disease stability or improvement,
- Specialist follow-up has occurred since last review,
- Hgb and platelet values have been checked within the last 6 months and remain stable,
- If of childbearing potential: patient remains on effective contraception and is not pregnant

Pulmonary Fibrosis- Systemic Enzyme Inhibitors

Last revised: 3/18/2025; Effective date: 6/3/2025

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):
        - Greater than or equal to 10% fibrosis on a chest HRCT scan (conducted within last 12 months)
        - AND treatment failure, intolerance, or contraindication to mycophenolate mofetil (MMF) and tocilizumab product (Tyenne preferred)

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

Pulmonary HTN – Endothelin Receptor Antagonist-PDE5 Inhibitor

Generic	Brand	HICL	GSN	Representative NDC
MACITENTAN-TADALAFIL	OPSYNVI TABS 10-20 MG	47644	085879	66215081230
MACITENTAN-TADALAFIL	OPSYNVI TABS 10-40 MG	47644	082894	66215081430

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Pulmonologist or Cardiologist, AND
- Diagnosis of pulmonary arterial hypertension (PAH) [World Health Organization (WHO) Group I], AND
- Patient currently has WHO Functional Class II, III or IV symptoms, AND
- Patient is not pregnant, AND
- Documented treatment failure, intolerance or contraindication to bosentan (generic Tracleer) AND ambrisentan (generic Letairis)

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
  - Documented positive clinical response to therapy, as evidenced by disease stability or improvement, AND
  - Specialist follow-up in the past 12 months

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

Last revised: 10/6/2025; Effective date: 12/2/2025

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 ASCVD* or with 2 or more 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

- Documentation of the appropriate LDL-C (within the last 90 days) for the treatment indication:
    - HeFH/HoFH: LDL-C > 100 mg/dL
    - Suspected familial hypercholesterolemia: LDL-C >130 mg/dL
    - Very high-risk ASCVD: LDL-C ≥55 mg/dL
        - Very high-risk ASCVD is defined as history of multiple major ASCVD events*** or 1 major ASCVD event and multiple high-risk conditions**
    - Patient with high-risk conditions or ASCVD: LDL-C ≥70 mg/dL

- 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 ordering Repatha:
    - 140 mg dose will only be approved for patients with high-risk conditions, very high-risk ASCVD, suspected familial hypercholesterolemia, or HeFH
    - 420 mg dose will only be approved for HoFH
- If ordering Praluent:
    - Documented failure or adverse reaction to Repatha
    - 150 mg dose will only be approved if there has been a trial of Praluent 75 mg for a minimum of 8 weeks with an LDL-C change of <30% (requires documentation of LDL-C pre and post therapy)

Notes:
**ASCVD includes those with one or more of the following conditions: coronary artery disease, cerebrovascular disease, or peripheral vascular disease*
***High-risk conditions include:*

- *Age ≥65 years*
- *Heterozygous familial hypercholesterolemia*
- *Diabetes mellitus*
- *Hypertension*
- *CKD (eGFR 15-59 ml/min/1.73 m2*
- *Current smoking*
- *Persistently elevated LDL-C (LDL-C ≥100 mg/dL despite maximally tolerated statin therapy and ezetimibe)*
- *History of congestive HF*

****Major ASCVD events include:*

- *Recent ACS (within 12 months)*
- *History of MI*
- *History of ischemic stroke*
- *Symptomatic PAD (history of claudication with ABI <0.85, or previous revascularization or amputation)*

*****Statin intolerance defined by the following:*

- *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 (e.g., pravastatin, rosuvastatin)

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS and have not been reviewed previously:** confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - Patient continues to be under the care of a specialist for their condition, AND
    - Documentation of positive clinical response to therapy defined by LDL-C reduction >30% from baseline

Dopamine and Norepinephrine Reuptake Inhibitor (DNRI)– Solriamfetol (Sunosi)

Last revised: 12/5/2023

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Covered Indications:

- Excessive Daytime Sleepiness in Narcolepsy
- Hypersomnia associated with Sleep Apnea

Initial Review Criteria:

- Prescriber is a Pulmonologist (Sleep Specialist) or Neurologist, AND
- Diagnosis of excessive daytime sleepiness in narcolepsy, AND
- Adequate trial (≥2 months) of a preferred stimulant (methylphenidate, amphetamine salt combination, dextroamphetamine) AND modafinil/armodafinil, unless contraindicated, AND
- Patient is 18-75 years of age.

OR

- Diagnosis of hypersomnia associated with Obstructive Sleep Apnea, AND
- Adequate trial (≥2 months) of modafinil/armodafinil, unless contraindicated

Notes: For the 75 mg dose, half-tablet Sunosi 150 mg tablets should be used/approved.

Continuation of Therapy Criteria:

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

Narcolepsy Tx – H3-Receptor Antagonist/Inverse Agonist

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

Generic	Brand	HICL	GSN	Representative NDC
PITOLISANT HCL	WAKIX TABS 4.45 MG	45575	079457	72028004503
PITOLISANT HCL	WAKIX TABS 17.8 MG	45575	079458	72028017803

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is Pulmonologist (Sleep Specialist) or Neurologist,
- AND if for diagnosis of excessive daytime sleepiness in narcolepsy:
  - Patient is ≥6 years of age,
  - AND adequate trial (≥2 months) of a preferred stimulant (methylphenidate, amphetamine salt combination, dextroamphetamine) AND modafinil/armodafinil, unless contraindicated,
  - AND if ≥18 years of age, adequate trial (≥2 months) of Sunosi, unless contraindicated,
- OR if for diagnosis of cataplexy due to narcolepsy:
  - Patient is ≥18 years of age,
  - AND adequate trial (≥2 months) of at least 2 of the following, or intolerance or contraindication to use: TCAs, SSRI, or SNRI

Continuation of Therapy Criteria:

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

Retinoic Acid Receptor (RAR) Agonists

Generic	Brand	HICL	GSN	Representative NDC
PALOVAROTENE	SOHONOS CAPS 1 MG	49043	085014	15054001001
PALOVAROTENE	SOHONOS CAPS 1.5 MG	49043	085015	15054001501
PALOVAROTENE	SOHONOS CAPS 10 MG	49043	085018	15054010001
PALOVAROTENE	SOHONOS CAPS 2.5 MG	49043	085016	15054002501
PALOVAROTENE	SOHONOS CAPS 5 MG	49043	085017	15054005001

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescribed by or in consultation with a Geneticist,
- AND patient meets one of the following age requirements:
  - If female: ≥8 years of age
  - If male: ≥10 years of age
- AND patient has a diagnosis of fibrodysplasia ossificans progressiva (FOP) with *ACVR1* R206H mutation confirmed by genetic testing,
- AND documented negative pregnancy test in patients of reproductive potential,
- AND attestation that patient will use appropriate contraception methods at least 1 month before treatment, during treatment, and for at least 1 month after the last dose

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
  - Documentation of positive clinical response to therapy (e.g., reduction in annualized volume of new heterotopic ossification)
  - Specialist follow-up within the past 12 months

Sedative-Hypnotics, Non-Barbiturate

Last revised: 10/3/2023

Generic	Brand	HICL	GSN	Representative NDC
SUVOREXANT	BELSOMRA TABS 5 MG	41333	072690	00006000530
SUVOREXANT	BELSOMRA TABS 10 MG	41333	072691	00006003330
SUVOREXANT	BELSOMRA TABS 15 MG	41333	072692	00006032530
SUVOREXANT	BELSOMRA TABS 20 MG	41333	072693	00006033530
LEMBOREXANT	DAYVIGO TABS 5 MG	46275	080590	62856040530
LEMBOREXANT	DAYVIGO TABS 10 MG	46275	080591	62856041030
DARIDOREXANT HCL	QUVIVIQ TABS 25 MG	47751	082964	80491782503
DARIDOREXANT HCL	QUVIVIQ TABS 50 MG	47751	082965	80491785003

Prior Authorization Criteria:

Length of Authorization:

- Initial: 4 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Psychiatrist, Pulmonologist (Sleep Specialist) or Neurologist,
- AND patient has a diagnosis of insomnia characterized by difficulty with sleep onset and/or staying asleep, AND

If the patient is ≥ 65 years of age:

- Documented trial (≥ 2 weeks) with treatment failure, contraindication, or intolerance to OTC melatonin or ramelteon and trazodone

If the patient is 18 years to 64 years of age:

- Documented trial (≥ 2 weeks) with treatment failure, inadequate response, or contraindication to using at least 3 agents for insomnia:
  - OTC melatonin
  - Trazodone
  - Ramelteon
  - Zaleplon
  - Doxepin (max 6 mg/day)
  - Zolpidem

Additional criteria for Belsomra and Quviviq:

- Trial of preferred dual orexin receptor antagonist, Dayvigo, for a minimum of 2 weeks

Continuation of Therapy Criteria:

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

Selective Serotonin 5-HT2A Inverse Agonists (SSIA)

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

Generic	Brand	HICL	GSN	Representative NDC
PIMAVANSERIN TARTRATE	NUPLAZID TABS 10 MG	43373	078604	63090010030
PIMAVANSERIN TARTRATE	NUPLAZID CAPS 34 MG	43373	078605	63090034030

Prior Authorization Criteria:

Length of Authorization:

- Initial: 3 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a Neurologist or Psychiatrist,
- Diagnosis of Parkinson's psychosis, hallucinations, or delusions,
- Patient is 18 years and older,
- Patient meets ONE of the following:
    - Documented trial of a dose reduction, tapering or discontinuation of the medications that may cause or contribute to hallucinations (e.g. anticholinergic medications, monoamine oxidase inhibitors, or dopamine agonists), OR
    - Documentation of the clinical rationale for why 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 clozapine OR quetiapine

Continuation of Therapy Criteria:

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

Other Miscellaneous Therapeutic Agents

Last revised: 7/29/2025; Effective date: 10/7/2025

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 ≥6 months, 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), with at least one of the following:
        - Radiographic evidence of active bone disease (rickets in wrists and/or knees and/or femoral/tibial bowing), OR
        - Documented abnormal growth velocity, OR
        - <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
    - Adults and adolescents at final adult height (epiphyseal growth plates are closed) with one of the following:
        - Presence of non-healing fractures (e.g., visible fracture lines), OR
        - May consider treatment if persistent symptoms (e.g., limited mobility, musculoskeletal pain) of XLH and inadequate response, contraindication, or intolerance to standard treatment with oral phosphate and active vitamin D analogs. Consider deprescribing if no improvement in symptoms after 12 months of treatment,
- Patient does NOT have:
    - Chronic kidney disease (CKD) stage 2 or greater, OR
    - Evidence of tertiary hyperparathyroidism

Tumor-Induced Osteomalacia (TIO)

- Prescribed by an Endocrinologist or Nephrologist – consultation with an Oncologist may be warranted if receiving or planning to receive chemotherapy for TIO or other malignant tumors, AND
- Patient is ≥2 years, AND
- Patient has a diagnosis of TIO not amenable to surgical excision of the offending tumor/lesion, AND
- Fasting serum phosphorus is <2.5 mg/dL* OR below the normal reference range for age**, AND
- Corrected serum calcium is <10.8 mg/dL* OR below the normal reference range for age**, AND
- Patient has elevated serum FGF23 (assay specific), AND
- Ratio of renal tubular maximum phosphate reabsorption rate to glomerular filtration rate (TmP/GFR) is <2.5 mg/dL* OR below the normal reference range for age**, AND
- Patient does not have:
    - Chronic kidney disease (CKD) stage 2 or greater, OR
    - Evidence of tertiary hyperparathyroidism

**Reference range for adults*
***For pediatric patients, use age-adjusted value for below normal reference range*

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria
- **For existing members who have previously met the criteria:**
    - Documentation of positive clinical response (defined as an improvement in growth velocity, deformities, fractures, or bone pain), AND
    - Patient does NOT have CKD stage 2 or greater and/or evidence of tertiary hyperparathyroidism, 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

Generic	Brand	HICL	GSN	Representative NDC
GLUTAMINE (SICKLE CELL)	ENDARI PACK 5 GM	856	078050	42457042001
GLUTAMINE (SICKLE CELL)	L-GLUTAMINE PACK 5 GM	856	078050	70954041710

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:
    - ≥2 sickle cell pain crises within prior 12 months requiring intervention (e.g., home-managed, hospitalizations, emergency department, or urgent care visits), OR
    - 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

SMN Protein Deficiency Treatment

Generic	Brand	HICL	GSN	Representative NDC
RISDIPLAM	EVRYSDI SOLR 0.75 MG/ML	46765	081371	50242017507
RISDIPLAM	EVRYSDI TABS 5 MG	46765	087229	50242020201

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescribed by a Neurologist, AND
- Patient age is ≤25 y/o at initiation of therapy, AND
    - *Note: For patients <6 months old, based on current evidence and KP consensus, onasemnogene abeparvovec-xioi (Zolgensma) is recommended as the preferred therapy*
- Confirmed diagnosis of 5q-autosomal recessive spinal muscular atrophy (SMA) with biallelic deletions or mutations in the SMN1 gene, AND
- Patient has 2- 4 SMN2 gene copies, AND
- Patient has not had prior treatment and is not planning treatment with onasemnogene abeparvovec (Zolgensma) or other gene therapy for SMA, AND
- Patient is not currently receiving concurrent treatment with nusinersen (Spinraza), AND
- Baseline pregnancy test completed for females of childbearing potential, AND
- Patient does not require permanent invasive ventilation or tracheostomy, AND
- Patient is not dependent on invasive or noninvasive ventilatory support during waking hours each day to control hypercarbia, or development of hypercarbia without ventilatory support

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - Patient has completed recommended follow-up labs and assessments as part of the medical treatment plan (e.g., annual nutrition and pulmonary evaluations, motor function assessments every 6 months while on therapy, and physical therapy as appropriate), AND
    - Patient has not experienced loss of function or progressive weakness (physical and/or pulmonary), AND
    - Patient is NOT pregnant

Notes:

- This drug is part of the Interregional Emerging Therapeutics Strategy Program (ETSP)
- Ordering Information: Evrysdi is **OUTSOURCED** to Accredo Specialty Pharmacy at 1-866-759-1557 or www.accredo.com.
    - Obtain the Evrysdi Therapy Referral Form from the Accredo Specialty Pharmacy website.
    - Fax page 4 and 5 directly to Accredo at 1-888-302-1028 instead of the number on the form
- Recommended follow up labs and assessments while on treatment includes

- Motor function assessments (every 6 months)
  - Infants: HINE-2 or CHOP INTEND
  - Children, Adolescents, Adults: HFMSE and RULM
- Pulmonary Assessment annually
  - Age ≥ 6 years: PFTs; If PFTs are unsuccessful, obtain pulse oximetry and End Tidal CO2 (ETCO2) measurements
  - Age < 6 years: Pulse oximetry and ETCO2 measurements

Sphingosine 1-Phosphate (S1P) Receptor Modulator

Last revised: 12/8/2025; Effective date: 2/3/2026

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:
    - Ustekinumab product (Yesintek preferred)*
    - At least 1 anti-TNF (Amjevita or Inflectra IV preferred)
    - Xeljanz (tofacitinib)*PA or Rinvoq (upadacitinib)*PA

**Brand Stelara/nonpreferred ustekinumab biosimilars are subject to PA review*
**PAThis medication is also subject to PA review*

Continuation of Therapy Criteria:

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

Notes: Velsipity is preferred over Zeposia for UC indication

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

Last revised: 12/8/2025; Effective date: 2/3/2026

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:
    - Ustekinumab product [Yesintek (ustekinumab-kfce) preferred]*
    - At least 1 anti-TNF (Amjevita or Inflectra IV preferred)
    - Xeljanz (tofacitinib)*PA or Rinvoq (upadacitinib)*PA
    - Guselkumab (Tremfya)*PA OR risankizumab-rzaa (Skyrizi)*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:
    - Fingolimod (generic Gilenya), AND
    - KP-preferred rituximab biosimilar (Refer to the Notes section for guidance on the preferred rituximab option) OR Tysabri (natalizumab),
- Patient is not using in addition to another DMT,
- Patient does NOT have any of the following contraindications:
    - Myocardial infarction in the last 6 months
    - Unstable angina in the last 6 months
    - Stroke or transient ischemic attack in the last 6 months
    - Decompensated heart failure requiring hospitalization, or class III or IV HF in the last 6 months
    - Mobitz type II second- or third-degree atrioventricular block, sick sinus syndrome, or sinoatrial block, unless the patient has a functioning pacemaker
    - Severe untreated sleep apnea
    - Concomitant use of a monoamine oxidase (MAO) inhibitor

**Brand Stelara/nonpreferred ustekinumab biosimilars are subject to PA review*
**PA This medication is also subject to PA review*

Continuation of Therapy Criteria:

<u>If using for Ulcerative Colitis:</u>

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

<u>If using for Multiple Sclerosis:</u>

- 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 (to rule out skin cancer and macular edema)

Notes:

- **Serious precautions regarding QTc:**
    - **Zeposia (ozanimod):** Consult with a cardiologist before initiating ozanimod in individuals with significant QTc prolongation (QTcF >450 msec in males and >470 msec in females)
- 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.
- Riabni is the KP-preferred rituximab biosimilar if rituximab has never been tried

Spleen/Bruton's Tyrosine Kinase Inhibitors

Generic	Brand	HICL	GSN	Representative NDC
REMIBRUTINIB	RHAPSIDO TABS 25 MG	50918	088306	00078148320

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is an Allergist or Dermatologist,
- AND diagnosis of chronic spontaneous urticaria,
- AND patient is ≥18 years of age,
- AND tried and failed therapy after 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
- AND trial and failure after minimum of 3 months, intolerance, or contraindication to Xolair AND Dupixent

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - Patient continues to be under the care of a specialist,
    - AND documentation of positive clinical response to Rhapsido since last review

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

Thymic Stromal Lymphopoietin (TSLP) Inhibitors

Generic	Brand	HICL	GSN	Representative NDC
TEZEPELUMAB-EKKO	TEZSPIRE SOAJ 210 MG/1.91ML	47740	084017	55513012301

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Pulmonologist or Allergist,
- Diagnosis/documentation of uncontrolled 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)
- 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,
- Patient is ≥12 years,
- Tezspire is being used for ONE of the following indications*:
  - Add-on maintenance therapy for patients with severe asthma that is non-eosinophilic and non-allergic who are not dependent on OCS
  - Add-on maintenance therapy for patients with severe asthma that is non-eosinophilic and non-allergic who are OCS-dependent and with inadequate response or contraindication/intolerance to dupilumab (Dupixent)
  - Add-on maintenance therapy for patients with severe eosinophilic asthma and with inadequate response or contraindication/intolerance to benralizumab (Fasenra) AND dupilumab (Dupixent)
  - Add-on maintenance therapy for patients with severe allergic asthma and with inadequate response or contraindication/intolerance to omalizumab (Xolair) AND dupilumab (Dupixent)
- Tezspire will not be used with any other monoclonal antibody therapies for asthma (i.e. Fasenra, Dupixent, Cinqair, Nucala, Xolair)

**Note: Non-eosinophilic phenotype is defined as blood eosinophils <150 cells/mcL and non-allergic is a type of asthma that is not related to an allergy trigger like pollen or dust*

Continuation of Therapy Criteria:

- Patient continues to be under the care of a Pulmonologist or Allergist,
- Documentation or provider attestation of positive clinical response to Tezspire therapy

Thyroid Hormone Receptor (THR) Agonist

Last revised: 10/6/2025; Effective date: 12/2/2025

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

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber must be a hepatologist or gastroenterologist,
- AND patient is 18 years of age or older,
- AND Emerging Therapeutic Strategy Program (ETSP) Interregional Consultative Physician panel review completed,
- AND diagnosis of metabolic dysfunction-associated steatohepatitis (MASH) with F2 or F3 as determined by transient elastography, ultrasound elastography, magnetic resonance imaging (MRI) elastography, and/or liver biopsy,
- AND persistent fibrosis (F2/F3) refractory to at least three months of lifestyle changes and/or structured weight loss program (e.g., diet, exercise, medication for weight loss with a goal of ≥ 5% weight loss)
- AND the patient must also have one of the following:
    - Lean MASH, defined as MASH with body mass index (BMI) <27; or
    - Treatment failure (after at least a 52-week trial), intolerance, or contraindication to semaglutide
- AND patient does NOT have any of the following:
    - Thyroid disease (e.g., active hyperthyroidism, untreated clinical hypothyroidism defined by TSH >7 IU/L with symptoms of hypothyroidism or >10 IU/L without symptoms). *Note: Patients who have had a thyroidectomy and are on replacement thyroxine doses >75 µg per day are eligible.; or*
    - History of significant alcohol consumption within 1 year [e.g., consume >7 drinks (98 grams of alcohol) per week if female, and >14 drinks (196 grams of alcohol) per week if male]; or
    - Regular use of drugs historically associated with metabolic dysfunction-associated fatty liver disease (MAFLD) due to concern for drug-induced liver (e.g. amiodarone, methotrexate, systemic glucocorticoids at greater than 5 mg/day, tamoxifen, estrogen at doses greater than those used for hormone replacement or contraception, anabolic steroids (except testosterone replacement), valproic acid and know hepatotoxins); or
    - Uncontrolled or co-existing liver disease other than NAFLD/MASLD; or
    - Hemoglobin A1c (HbA1c) ≥ 9%; or
    - Diagnosis of hepatocellular carcinoma (HCC); or
    - Hepatic decompensation (i.e. one or more complications of liver cirrhosis); or
    - Uncontrolled autoimmune disease; or
    - Moderate to severe hepatic impairment (Child-Pugh Class B or C); or
    - Active, serious medical disease with likely life expectancy <2 years; or

o ALT/AST >5 times the upper limit of normal (ULN) lab range that is likely due to other chronic liver disease; or o Currently pregnant or breastfeeding or planning to become pregnant
Continuation of Therapy Criteria: • **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm patient meets all above initial review criteria • **For existing members who have previously met the criteria**: o Document clinically significant benefit from the medication defined as follows: ▪ NAFLD Activity Score (NAS) has decrease by at least 2 points from baseline ▪ Reduction in fibrosis state o Specialist follow-up in the last 12 months

Top. Anti-Inflam., Phosphodiesterase-4 (PDE4) Inhib

Generic	Brand	HICL	GSN	Representative NDC
ROFLUMILAST (ANTISEBORRHEIC)	ZORYVE FOAM 0.3%	37123	085605	80610043060
ROFLUMILAST (DERMATOLOGIC)	ZORYVE CREA 0.15%	37123	086288	80610011560

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

<u>If use for seborrheic dermatitis (Zoryve 0.3% foam ONLY):</u>

- Diagnosis of seborrheic dermatitis covering >10% of BSA,
- Patient is ≥9 years of age,
- Patient has failed an adequate trial (for at least 2 months), allergy, intolerance, or contraindication to ALL the following:
    - Topical steroid (e.g., betamethasone dipropionate, augmented 0.05% cream, clobetasol propionate 0.05% ointment, lotion, gel)
    - Topical calcineurin inhibitor (e.g. tacrolimus 0.1% ointment
    - Topical antifungal (e.g. ketoconazole, ciclopirox) for at least 3 months
    - Selenium sulfide

<u>If use for atopic dermatitis (Zoryve 0.15% cream ONLY):</u>

- Diagnosis of atopic dermatitis covering >5% of BSA,
- Patient is ≥6 years of age,
- Patient has failed an adequate trial (for at least 2 months), allergy, intolerance, or contraindication to ALL the following:
    - Medium to very high topical corticosteroid (e.g. topical triamcinolone, betamethasone dipropionate, fluocinonide, or clobetasol)
    - Topical calcineurin inhibitor (e.g. pimecrolimus 1% cream or tacrolimus 0.1% ointment)

Continuation of Therapy Criteria:

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

Topical Anticholinergic Hyperhidrosis Tx Agents

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

Prior Authorization Criteria:

Length of Authorization:

- Initial: 3 months
- Reauthorization: 6 months

Initial Review Criteria:

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

Continuation of Therapy Criteria:

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

Topical Anticholinergic Hyperhidrosis Tx Agents (cont'd)

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

Prior Authorization Criteria:

Length of Authorization:

- Initial: 3 months
- Reauthorization: 12 months

Initial Review Criteria:

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

Continuation of Therapy Criteria:

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

Topical Antineoplastic Premalignant Lesion Agents

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

Prior Authorization Criteria:
Length of Authorization: • Initial: 12 months • Reauthorization: 12 months
Initial Review Criteria: • Patient is ≥18 years, • Documented diagnosis of Cutaneous T-cell Lymphoma (mycosis fungoides type, Stage IA/IB), • Patient has had an inadequate response, intolerance, or contraindication to at least one of the following skin-directed therapy: o Topical corticosteroids o Topical retinoids o Phototherapy o Topical imiquimod o Total skin electron beam therapy o Local radiation
Continuation of Therapy Criteria: • Patient does not show evidence of progressive disease while on therapy, • Specialist follow-up occurred in the past 12 months

Topical Immunosuppressive Agents

Last revised: 7/31/2024; 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

Treatment of Hyperphagia in Prader-Willi Syndrome

Generic	Brand	HICL	GSN	Representative NDC
DIAZOXIDE CHOLINE	VYKAT XR TB24 150 MG	50391	087498	83860015001
DIAZOXIDE CHOLINE	VYKAT XR TB24 25 MG	50391	087496	83860002501
DIAZOXIDE CHOLINE	VYKAT XR TB24 75 MG	50391	087497	83860007501

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is an Endocrinologist or Geneticist
- AND patient is ≥4 years of age,
- AND documentation of the following:
    - Diagnosis of Prader-Willi syndrome (PWS) confirmed by genetic testing
    - Patient has hyperphagia (i.e., persistent sensation of hunger, food preoccupations, extreme drive to consume food, food-related behavior problems, decreased satiety)

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS who have not been reviewed previously:** Confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - Specialist follow-up occurred in the past 12 months AND
    - Positive clinical response to therapy (e.g., decreased or stable BMI in pediatrics, decreased or stable weight/BMI in adults, decreased eating, hunger or thoughts about food)

Tx for Attention Deficit-Hyperact.(ADHD), NRI-Type

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

Generic	Brand	HICL	GSN	Representative NDC
VILOXAZINE HCL (ADHD)	QELBREE CP24 100 MG	7345	082132	17772013130
VILOXAZINE HCL (ADHD)	QELBREE CP24 150 MG	7345	082134	17772013230
VILOXAZINE HCL (ADHD)	QELBREE CP24 200 MG	7345	082135	17772013330

Prior Authorization Criteria:

Length of Authorization:

- Initial: 12 months
- Reauthorization: 12 months

Initial Review Criteria:

- Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) as confirmed by psychoeducational testing***,
- AND patient is ≥ 6 years of age,
- AND patient has had an adequate trial* (1 week) and/or intolerance** or allergy to:
    - Atomoxetine
- OR patient is unable to swallow a solid dosage form (i.e. an oral tablet or capsule) due to age, oral/motor difficulties, or dysphagia

Notes:

*Atomoxetine should be titrated to effect. Use the 10, 18 or 25 mg strengths for titration.
**Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment and do not require medication discontinuation
***Criteria only applies for 18 years of age and older

Continuation of Therapy Criteria:

- Patient meets initial review criteria,
- AND has demonstrated positive clinical response to medication

410-328-0202

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.

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: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Pulmonologist or Cardiologist, AND
- Diagnosis of pulmonary arterial hypertension (PAH) [World Health Organization (WHO) Group I], AND
- Patient currently has WHO Functional Class II, III or IV symptoms, AND
- Patient is not pregnant, AND
- Documented treatment failure, intolerance or contraindication to ambrisentan (generic Letairis), AND
- If ordering Letairis: Patient is NOT diagnosed with idiopathic pulmonary fibrosis
- If ordering Tracleer or Opsumit: Documented treatment failure, intolerance or contraindication to bosentan (generic Tracleer)

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS and have not been reviewed previously:** confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
  - Documented positive clinical response to therapy, as evidenced by disease stability or improvement, AND
  - Specialist follow-up in the past 12 months

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

Generic	Brand	HICL	GSN	Representative NDC
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 (PAH) [World Health Organization (WHO) Group I], AND
- Patient currently has WHO Functional Class II, III or IV symptoms, AND
- Patient is currently taking, or has documented treatment failure, intolerance, or contraindication to at least two of the following:
    - A phosphodiesterase type (PDE-5) inhibitor (e.g. sildenafil, tadalafil),
    - An endothelin receptor antagonist (ERA) [e.g. ambrisentan, bosentan, macitentan (Opsumit)] OR
    - A soluble guanylate cyclase stimulator (e.g., riociguat (Adempas)]
- Provider attestation that patient will NOT be using with another prostanoid/prostacyclin analogue (e.g., IV epoprostenol, IV/subcut/inhaled/PO treprostinil, PO selexipag)

Continuation of Therapy Criteria:

- Patient continues to be under the care of a Pulmonologist or Cardiologist and has had follow-up since last review,
- AND documentation the patient is experiencing clinical benefit from therapy as evidenced by disease stability or disease improvement

Notes:

- *Orenitram is contraindicated in severe hepatic impairment (Child-Pugh class C)*
- *Orenitram (treprostinil ER oral) is more cost-effective than Tyvaso (treprostinil inhalation) and Uptravi (selexipag) at doses **less than** 6.5 mg TID*

Generic	Brand	HICL	GSN	Representative NDC
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	TYVASO DPI MAINTENANCE KIT POWD 16 MCG	36541	083419	66302061603
TREPROSTINIL	TYVASO DPI MAINTENANCE KIT POWD 32 MCG	36541	083420	66302063203
TREPROSTINIL	TYVASO DPI MAINTENANCE KIT POWD 48 MCG	36541	083421	66302064803
TREPROSTINIL	TYVASO DPI MAINTENANCE KIT POWD 64 MCG	36541	083422	66302066403
TREPROSTINIL	TYVASO DPI TITRATION KIT POWD 16 & 32 & 48 MCG	36541	083425	66302061002
TREPROSTINIL SODIUM	YUTREPIA CAPS 106 MCG	23650	087769	72964001401
TREPROSTINIL SODIUM	YUTREPIA CAPS 26.5 MCG	23650	087766	72964001101
TREPROSTINIL SODIUM	YUTREPIA CAPS 53 MCG	23650	087767	72964001201
TREPROSTINIL SODIUM	YUTREPIA CAPS 79.5 MCG	23650	087768	72964001301

Prior Authorization Criteria:

Length of Authorization:

- Initial: 6 months
- Reauthorization: 12 months

Initial Review Criteria:

- Prescriber is a Pulmonologist or Cardiologist, AND
- If order is for Tyvaso: History of treatment failure/inadequate response, intolerance, or contraindication to Yutrepia (treprositinil), AND

If using for pulmonary arterial hypertension:

- Diagnosis of pulmonary arterial hypertension (PAH) [World Health Organization (WHO) Group I], AND
- Patient currently has WHO Functional Class II, III or IV symptoms, AND
- Patient is currently taking, or has documented treatment failure, intolerance, or contraindication to at least two of the following:
    - A phosphodiesterase type (PDE-5) inhibitor (e.g. sildenafil, tadalafil),
    - An endothelin receptor antagonist (ERA) [e.g. ambrisentan, bosentan, macitentan (Opsumit)] OR
    - A soluble guanylate cyclase stimulator (e.g., riociguat (Adempas)]
- Provider attestation that patient will NOT be using this medication with another prostanoid/prostacyclin analogue (e.g., IV epoprostenol, IV/subcut/inhaled/PO treprostinil, PO selexipag)

If using for pulmonary hypertension associated with interstitial lung disease:

- Patient has a diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD) (WHO Group 3) verified by right heart catheterization

Continuation of Therapy Criteria:

- **For new members who were initiated outside of KPMAS and have not been reviewed previously:** confirm that the patient meets all the above initial review criteria
- **For existing members who have previously met the criteria**:
    - Patient continues to be under the care of a Pulmonologist or Cardiologist and has had follow-up since last review,
    - AND documentation the patient is experiencing clinical benefit from therapy as evidenced by disease stability or disease improvement

Notes:

- *Orenitram (treprostinil ER oral) is more cost-effective than Tyvaso (treprostinil inhalation) and Uptravi (selexipag) at doses **less than** 6.5 mg TID*

Vasodilating Agents - Respiratory Tract (cont'd)

Last revised: 3/18/2025; Effective date: 6/3/2025

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

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 (PAH) [World Health Organization (WHO) Group I], AND
- Patient currently has WHO Functional Class II, III or IV symptoms, AND
- Patient is currently taking, or has documented treatment failure, intolerance, or contraindication to at least two of the following:
    - A phosphodiesterase type (PDE-5) inhibitor (e.g. sildenafil, tadalafil),
    - An endothelin receptor antagonist (ERA) [e.g. ambrisentan, bosentan, macitentan (Opsumit)] OR
    - A soluble guanylate cyclase stimulator (e.g., riociguat (Adempas)]
- Provider attestation that patient will NOT be using with another prostanoid/prostacyclin analogue (e.g., IV epoprostenol, IV/subcut/inhaled/PO treprostinil)

Continuation of Therapy Criteria:

- Patient continues to be under the care of a Pulmonologist or Cardiologist and has had follow-up since last review,
- AND documentation the patient is experiencing clinical benefit from therapy as evidenced by disease stability or disease improvement

Notes:

- *Uptravi is contraindicated with concomitant use with strong CYP2C8 inhibitors (e.g. gemfibrozil)*
- *Orenitram (treprostinil ER oral) is more cost-effective than Tyvaso (treprostinil inhalation) and Uptravi (selexipag) at doses **less than** 6.5 mg TID*

Wound Healing Agents, Local

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

Prior Authorization Criteria:

Length of Authorization:

- Initial: 3 months
- Reauthorization: 3 months

Initial Review Criteria:

- Prescriber is a dermatologist or pediatric dermatologist,
- Emerging Therapeutic Strategy Program (ETSP) Interregional Consultative Physician panel review completed,
- Patient is 6 months of age and older,
- Confirmed diagnosis of recessive dystrophic epidermolysis bullosa (RDEB),
- Presence of partial thickness wound of 10-50 cm^2 in surface area,
- Presence of wounds that have not healed despite three months of standard wound care. If wound pain is causing significant functional impairment, a two-month trial of standard wound care is adequate,
- If applicable, negative pregnancy test at start of treatment,
- If applicable, male or female of childbearing potential should use a reliable birth control method during treatment and for three months after treatment with birch triterpenes,
- Confirmed that patient does NOT have any of the following condition/diagnosis:
    - Current or history of squamous cell carcinoma in the area that will undergo treatment,
    - Actively receiving immunosuppressive therapy or cytotoxic chemotherapy within 60 days prior to treatment initiation

Continuation of Therapy Criteria:

- **For new members who were initiated outside of Kaiser who have not been reviewed previously:** Confirm that patient meets all above initial review criteria
- **For existing members who have previously met criteria:**
    - Document clinically significant benefit from the medication,
    - Confirmed that patient does NOT have any of the following condition/diagnosis:
        - Current or history of squamous cell carcinoma in the area that will undergo treatment,
        - Actively receiving immunosuppressive therapy or cytotoxic chemotherapy within 60 days prior to treatment initiation,
        - Pregnancy or lactation, if applicable