PERFORMRx

Next Generation Pharmacy Benefits

AHDC PRIOR AUTHORIZATION CRITERIA

Updated 12/15/2025

Field Name	Field Description
Prior Authorization Group Description	**Medications without Drug or Class Specific Criteria**
Drugs	• Medications without drug or class specific prior authorization criteria • Brand drugs and reference biologics when a therapeutic equivalent generic drug or biosimilar/interchangeable biologic is available ***The Oncology Drugs prior authorization criteria will be applied to oncology drugs without drug or class specific criteria***
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If all of the conditions are met, requests will be approved for up to 12 months (depending on the diagnosis and usual treatment duration).
Other Criteria	**Initial Authorization:** **All Requests:** • The drug is requested for an appropriate use (per the references outlined in "Covered Uses") • The dose requested is appropriate for the requested use (per the references outlined in "Covered Uses") • Patient meets one of the three following criteria: o Documented trial and failure or intolerance of two alternative formulary/preferred medications appropriate for the requested use (per the references outlined in "Covered Uses" or has a medical reason why these drug(s) cannot be used [e.g. intolerance, contraindication]). For medications where there is only one preferred agent, only that agent must have been ineffective or not tolerated. o No other preferred medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia. o All other preferred medications are contraindicated based on the patient's diagnosis, other medical conditions, or other medication therapy.

Revision/Review Date 10/2025	**Brand drugs with a therapeutically equivalent (A-rated) generic drug currently available:** • The provider either verbally or in writing has submitted a medical or member specific reason why the brand name drug is required based on the member's condition or treatment history; **AND** if the member had side effects or a reaction to the generic drug, the provider has completed and submitted an FDA MedWatch form to justify the member's need to avoid this drug. The MedWatch form must be included with the prior authorization request Form FDA 3500 – Voluntary Reporting **Reference biologic drugs with either a biosimilar or interchangeable biologic drug currently available:** • The prescriber has verbally or in writing submitted a medical or member specific reason why the reference biologic is required based on the member's condition or treatment history; **AND** if the member had side effects or a reaction to two (if available) biosimilar or interchangeable biologics, the provider has completed and submitted an FDA MedWatch form to justify the member's need to avoid these drugs. The MedWatch form must be included with the prior authorization • The currently available biosimilar product(s) does not have the same appropriate use (per the references outlined in "Covered Uses") as the reference biologic drug being requested Form FDA 3500 – Voluntary Reporting **Reauthorization:** • Documentation of provider attestation that demonstrates a clinical benefit • The requested drug is for a medically accepted dose as outlined in Covered Uses **Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Diagnosis Code Requirement**
Drugs	Formulary/preferred medications that will pay at point of sale if the required ICD-10 code is submitted at the pharmacy
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criterion is met, the request will be approved for up to a 12 month duration (depending on the diagnosis and usual treatment duration).
Other Criteria	Provider has submitted a diagnosis that is FDA approved or referenced in disease state specific standard of care guidelines for the requested drug. (Please see covered uses section for appropriate sources)
Revision/Review Date 4/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Off-Label Uses Criteria**
Drugs	**Medications with off-label uses**
Covered Uses	Off-label uses: Medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criterion is met, the request will be approved for up to a 12 month duration (depending on the diagnosis and usual treatment duration).
Other Criteria	**Authorization:** 1. One of the following: a. Patient has had a documented trial and or intolerance with up to two preferred medications used to treat the documented diagnosis, or for medications where there is only one preferred agent, only that agent must have been ineffective or not tolerated. b. No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia **AND** 2. One of the following: a. Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Covered Uses section above) b. Requested use can be supported by at least two published peer reviewed clinical studies **AND**

Revision/Review Date 4/2025	3. Medication is being requested at an appropriate dose per literature **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group	**Oncology Drugs/Therapies**
Drugs	Oral and Injectable Oncology Medications (specialty or non-specialty) without product specific criteria when requested for an oncology diagnosis
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI) , and the Drug Package Insert, and/or per the National Comprehensive Cancer Network (NCCN)
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert or NCCN guidelines
Prescriber Restrictions	Prescribed by or in consultation with an oncologist, or specialist in type of cancer being treated
Coverage Duration	If the criteria are met, the request will be approved for up to 6 month duration.
Other Criteria	**All of the following criteria must be met:** • Requested use must be a labeled indication or be supported by NCCN Category 1 or 2A level of evidence. If the request is for an off-label use supported by NCCN as Category 2B recommendation then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g. allergic reaction, contraindication) • Documentation has been provided of the results of all required genetic testing where required per product package insert • Documentation has been provided of the results of all required laboratory values and patient specific information (e.g. weight, ALT/AST, Creatine Kinase, etc.) necessary to ensure the patient has no contraindications to therapy per product package insert • The product is being prescribed at a dose and duration that is within FDA approved/NCCN guidelines. • If the request is for a reference biologic drug with either a biosimilar or interchangeable biologic drug currently available, documentation of one of the following: o The provider has verbally or in writing submitted a member specific reason why the reference biologic is required based on the member's condition or treatment history; AND if the member had side effects or a reaction to the biosimilar or interchangeable biologic, the provider has completed and submitted an FDA MedWatch form to justify the member's need to avoid

Revision/Review 7/2025	these drugs. The MedWatch form must be included with the prior authorization request o The currently available biosimilar product does not have the same appropriate use (per the references outlined in "Covered Uses") as the reference biologic product being requested Form FDA 3500 – Voluntary Reporting • **If the request is for abiraterone (Zytiga) 500 mg tablet, a documented medical reason why two tablets of generic abiraterone acetate 250 mg cannot be used** **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Prior Authorization Exception Criteria**
Covered Uses	All medically accepted indications. Medically accepted indications are defined using the following compendia resources: the Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), American Hospital Formulary Service Drug Information (AHFS-DI), and DRUGDEX Information System. The reviewer may also reference disease state specific standard of care guidelines.
Scope	Requests for exception to the drug's prior authorization criteria requirements
Coverage Duration	12 months
Criteria	• The provider either verbally or in writing has submitted a medical or member specific reason why prior authorization criteria all or in part is not applicable to the member. o Medical and/or member specific reasons may include but are not limited to: ▪ Uniqueness of the member's condition or other physical characteristics of the member's condition. ▪ Psychiatric, intellectual, physical, cultural, and/or linguistic characteristics of the member which may inhibit the provider from obtaining all necessary prior authorization criteria requirements. **Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.**
Revision/Review Date:	10/2025

Field Name	Field Description
Prior Authorization Group Description	**Quantity Limit Exception Criteria**
Covered Uses	All medically accepted indications. Medically accepted indications are defined using the following compendia resources: the Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), American Hospital Formulary Service Drug Information (AHFS-DI), and DRUGDEX Information System. The reviewer may also reference disease state specific standard of care guidelines.
Scope	Requests for formulary drugs exceeding the health plan's published quantity limits
Criteria	• The provider has submitted a medical reason why the plan's quantity limit will be inadequate based on the member's condition and treatment history. • The provider has submitted justification for the approval of doubling (or higher) of the number of tablets/capsules per prescription for a medication that has a higher strength tablet/capsule available, stating why that higher dose tablet/capsule cannot be used (e.g. two lorazepam 0.5mg tablets to equal the dose of lorazepam 1mg, when lorazepam 1mg tablet exists) **AND one of the following:** o The member has a documented treatment failure with the drug prescribed at the health plan's quantity limit AND the dose requested is supported by the Medical Compendia or current treatment guidelines. o The member requires a dose within prescribing guidelines that exceeds the plan's quantity limit. **Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.**
Coverage Duration	12 Months
Revision/Review Date	10/2025

Field Name	Field Description
Prior Authorization Group Description	**Safety Edit Exception Criteria**
Covered Uses	All medically accepted indications. Medically accepted indications are defined using the following compendia resources: the Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), American Hospital Formulary Service Drug Information (AHFS-DI), and DRUGDEX Information System. The reviewer may also reference disease state specific standard of care guidelines.
Scope	Requests for formulary drugs and for previously approved non-formulary drugs: • Exceeding the Food and Drug Administration (FDA) or compendia max dose recommendations • Exceeding the FDA dosing or compendia administration frequency recommendations • Exceeding the FDA or compendia duration of therapy recommendations • Duplication of therapy error at Point of Service (POS) • Age Restriction error at POS • Day Supply Limit error at POS • Concurrent Use error at POS • Drug Drug Interaction error at POS
Criteria Revision/Review Date: 10/2025	**Exceeding the Food and Drug Administration (FDA) or compendia maximum dose, administration frequency or duration of therapy recommendations.** • The member must have a documented treatment failure with the drug at the maximum dose based on patient age/weight, administration frequency, or duration of therapy per FDA or compendia. AND • The provider must submit a medical reason why the maximum dose, administration frequency or duration of therapy needs to be exceeded based on the member's condition or treatment history. **Duplication of therapy** <u>Transition from one agent to another</u> • If a provider has outlined a plan to transition a member to a similar drug or provided a dose titration schedule, the requested drug is approved for one month*. <u>Concurrent Therapy with two similar agents</u>

	• The provider must submit a medical reason why treatment with more than one drug in the same class is required based on the member's condition and treatment history. OR • The provider must submit disease state specific standard of care guidelines supporting concurrent therapy. **Age Restriction** • The provider must submit a medical reason why the drug is needed for a member whose age is outside of the plan's minimum or maximum age limit. AND • The indication and dose requested is supported by the Medical Compendia or current treatment guidelines. **Day Supply Limit** • An additional fill exceeding the day supply limit is needed based on a dose increase or is needed to achieve a total daily dose OR • The provider must submit a medical reason why an additional fill is needed outside of the plan's day supply limit. AND • The indication and dose requested is supported by the FDA, Medical Compendia or current treatment guidelines. **Concurrent Use/Drug-Drug Interaction** • The provider must submit a medical reason why treatment with both drugs is necessary for the member AND • The increased risk for side effects when taking the drugs together has been discussed with the member **Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.**
Coverage Duration	*One month approval for Duplication of therapy when transitioning from one agent to another and Day Supply Limit due to a dose increase. All Other Scenarios: 12 months

Field Name	Field Description
Prior Authorization Group Description	**Step Therapy Exception Criteria**
Covered Uses	All medically accepted indications. Medically accepted indications are defined using the following compendia resources: the Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), American Hospital Formulary Service Drug Information (AHFS-DI), and DRUGDEX Information System. The reviewer may also reference disease state specific standard of care guidelines.
Scope	Requests for drugs on the plan's formulary with a step therapy restriction which do not meet step therapy requirements
Criteria	Requests for drugs on the plan's formulary with a step therapy restriction which do not meet step therapy requirements will be considered when the provider verbally or in writing has submitted a medical reason why: • Required step therapy drug(s) would be ineffective, or; • Required step therapy drug(s) have the potential to cause harm or deterioration of the member's condition, or; • The requested drug would be superior to the required prerequisite trial(s) with preferred drug(s). **Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.**
Coverage Duration	12 Months
Revision/Review Date:	10/2025

Field Name	Field Description
Prior Authorization Group Description	**5-Hydroxytryptamine-3 Serotonin Receptor Antagonists (5-HT3 RA), Substance P/Neurokinin 1 Receptor Antagonists (NK1 RA), and Combination Agents**
Drugs	Preferred (Step 1): 5-HT3 RA: ondansetron (Zofran) oral tablet, orally disintegrating tablet (ODT), oral solution, IV solution, injection (IV/SQ) solution or granisetron (Kytril) oral tablet, IV solution NK1 RA: aprepitant (Emend) oral capsule, fosaprepitant (Emend) IV emulsion Preferred (Step 2): 5-HT3 RA: palonosetron (Aloxi) IV solution Non-Preferred: Sustol (granisetron ER) SQ injection, Sancuso (granisetron ER) transdermal patch, Zuplenz (ondansetron) oral film, dolasetron (Anzemet) oral tablet, Cinvanti (aprepitant) IV emulsion, Emend (aprepitant) oral suspension, Varubi (rolapitant) oral capsule, Akynzeo (palonosetron/netupitant) oral capsule, IV solution, Focinvez (fosaprepitant), Posfrea (palonosetron) IV solution Any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	None
Required Medical Information	See "Other Criteria"
Age Restrictions	None
Prescriber Restrictions	Prescribed by a specialist in the field to treat the patient's respective medical condition
Coverage Duration	If all of the conditions are met, the request will be approved for up to 6 months or as long as recommended by the medical compendium and/or per the NCCN/ASCO standard of care guidelines.
Other Criteria	• The medication is being requested for a Food and Drug Administration (FDA) approved indication or a medical condition that is supported by the medical compendium, the National Comprehensive Cancer Network (NCCN), and/or American Society of Clinical Oncology (ASCO) standard of

	care guidelines for antiemetic therapy. • The requested dosing of the 5-HT3 RA and/or NK1 RA is within FDA approved, NCCN/ASCO or other medical compendia standard of care guidelines • Patients meeting one of the following criteria may receive the generic 5-HT3 RA palonosetron hydrochloride without prior trial and failure of ondansetron/granisetron o Adult patients receiving an antineoplastic agent with HIGH or MODERATE emetic risk per the NCCN Practice Guidelines o Pediatric patients receiving an antineoplastic agent with HIGH emetic risk per the NCCN Practice Guidelines who are unable to receive dexamethasone • For all other patients, if the medication request is for any 5-HT3 RA other than ondansetron, granisetron, or an NK1-RA other than aprepitant oral capsule or fosaprepitant IV emulsion: o The patient has a documented treatment failure after receiving an adequate trial of a preferred 5-HT3 RA and a preferred NK1 RA and/or has a documented medical reason (intolerance, hypersensitivity, contraindication, etc.) for not utilizing these medications to treat their medical condition.
Revision/Review Date 10/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Acute Migraine Treatments**
Drugs	**Reyvow (lasmiditan)** **Ubrelvy (ubrogepant)** **Nurtec ODT (rimegepant)** – If the request is for migraine prevention please refer to the Calcitonin Gene-Related Peptide (CGRP) Antagonists for Headache Prevention criteria **Zavzpret (zavegepant)**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Member is 18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, migraine specialist, pain specialist, or other specialist in the treatment of headaches
Coverage Duration	If all of the criteria are met, the initial request will be approved for 3 months. For continuation of therapy the request will be approved for 6 months.
Other Criteria	**Initial Authorization:** Nurtec ODT and Ubrelvy will be approved when all of the following criteria are met: • Diagnosis of migraine headache • Requested dose is within FDA approved dosing guidelines • Documented trial and failure of (or medical justification for not using) two triptan products • Medication will not be used in combination with another CGRP inhibitor for either acute or preventative treatment of migraine Reyvow and Zavzpret will be approved when all of the following criteria are met: • Diagnosis of migraine headache • Requested dose is within FDA approved dosing guidelines • Documented trial and failure of (or medical justification for not using) an analgesic medication and two triptan products

Revision/Review Date: 4/2025	• Reyvow only: Attestation the patient was counseled regarding not driving or operating machinery until at least 8 hours after taking each dose • Zavzpret only: Medication will not be used in combination with another CGRP inhibitor for either acute or preventative treatment of migraine **<u>Criteria for Re-Authorization:</u>** • Documentation of improvement in migraine pain and symptom(s) (e.g., photophobia, nausea, phonophobia) **Nurtec ODT QL of 8 units per month.** **Reyvow QL of 8 units per month.** **Ubrelvy QL of 16 units per month** **Zavzpret QL of 8 units per month** **<u>Criteria for exceeding the quantity limit</u> (note all of the above criteria must also be met)** • Documented trial and failure (or a medical justification for not using e.g. hypersensitivity, baseline bradycardia or hypotension, adverse events experienced from previous trial, etc.) with at least one drug from two categories below for at least 4 weeks EACH, at minimum effective doses: o Beta-adrenergic blockers o Topiramate or divalproex ER or DR o Amitriptyline or venlafaxine o Frovatriptan, zolmitriptan or naratriptan (for menstrual migraine prophylaxis) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Adakveo (crizanlizumab-tmca)**
Drugs	Adakveo (crizanlizumab-tmca)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	Member must be 16 years of age or older
Prescriber Restrictions	Prescriber must be a hematologist or sickle cell specialist
Coverage Duration	If the criteria are met, requests may be approved for 12 months.
Other Criteria Revision/Review Date: 7/2025	**Initial Authorization:** • Member has a confirmed diagnosis of sickle cell disease • Documentation was provided that the member has had 2 or more pain crises in the last 12 months • Documentation was provided that the member has been taking hydroxyurea at the maximum tolerated dose and has been compliant within the last 6 months (or a medical reason was provided why the patient is unable to use hydroxyurea) • Documentation of the member's current weight • Request is for an FDA-approved dose **Reauthorization:** • Documentation has been submitted that the member has demonstrated or maintained ONE of the following changes from baseline: o Reduction in pain crises o Increased time between crises o Decrease in days hospitalized • Documentation of the member's current weight • Request is for an FDA-approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Adenosine Triphosphate-Citrate Lyase (ACL) inhibitors**
Drugs	Nexletol (bempedoic acid) Nexlizet (bempedoic acid and ezetimibe)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	None
Required Medical Information	See "Other Criteria"
Age Restrictions	18 years or older
Prescriber Restrictions	Prescriber must be a cardiologist or specialist in the treatment of lipid disorders
Coverage Duration	If all of the conditions are met, the initial request will be approved with a 3-month duration and all reauthorization requests will be approved with a 12-month duration.
Other Criteria	**Initial Authorization:** **All Requests** • Member must have documentation of baseline low density lipoprotein cholesterol (LDL-C) • Member has tried and failed a high-intensity statin (i.e. atorvastatin 40-80 mg, rosuvastatin 20-40 mg) at maximum tolerated dose for 3 months via claim history or chart notes OR documentation has been provided that the member is not able to tolerate a statin. • Documentation was provided indicating provider has counseled member on smoking cessation and following a "heart healthy diet". **For Hyperlipidemia** • One of the following: o Member has a diagnosis of heterozygous familial hypercholesterolemia (FH) o Member has a diagnosis of primary hyperlipidemia • Member has tried and failed ezetimibe at a maximum tolerated dose or documentation has been provided that the patient is not able to tolerate ezetimibe.

Revision/Review Date 7/2025	**For Cardiovascular Risk Reduction** • Member has established cardiovascular disease (documented history of coronary artery disease, symptomatic peripheral arterial disease, and or cerebrovascular atherosclerotic disease) • Member does not have established cardiovascular disease but is considered high risk (one of the following): o Diabetes mellitus (type 1 or type 2) in females over 65 years of age or males over 60 years of age o A Reynolds Risk score > 30% or a SCORE Risk score > 7.5% over 10 years o A coronary artery calcium score >400 Agatston units at any time in the past. • Member has a fasting LDL-C ≥ 70 mg/dL **<u>Reauthorization:</u>** • Documentation provided that the member has obtained clinical benefit from medication (e.g. LDL-C lowering from baseline) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Adrenal Enzyme Inhibitors for Cushing's Disease**
Drugs	Isturisa (osilodrostat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be ≥ 18 years of age
Prescriber Restrictions	Prescribed by, or in consultation with, an endocrinologist or other specialist in the treatment of metabolic disorders
Coverage Duration	Initial Authorization: If the criteria are met, the request will be approved for a 6-month duration. Reauthorization: If the criteria are met, the request will be approved for a 12-month duration.
Other Criteria	**Initial Authorization:** • Member has confirmed diagnosis of Cushing's Disease • Pituitary surgery is not an option or has not been curative • Provider attests baseline electrocardiogram (ECG) has been obtained and hypokalemia and/or hypomagnesemia has been corrected prior to initiating therapy if present • The medication is being prescribed at a dose that is consistent with FDA-approved package labeling, nationally recognized compendia or peer-reviewed literature • Documented baseline urinary free cortisol (UFC) test ≥ 1.3upper limit of normal (ULN) o UFC Normal Range = 3.5-45 mcg/24 hrs (9.66-124.2 nmol/24 hrs) • Member has had a documented trial and failure of one of the following: o ketoconazole o Metopirone (metyrapone) o Lysodren (mitotane) o cabergoline o Signifor/Signifor LAR (pasireotide) o etomidate **OR** Member has a documented medical reason (e.g. contraindication, intolerance, hypersensitivity) as to why these medications cannot be used

Revision/Review Date: 2/2025	**<u>Reauthorization:</u>** • Member has responded to therapy as defined by a documented urinary free cortisol (UFC) test ≤ the upper limit of normal (ULN) • The medication is being prescribed at a dose that is consistent with FDA-approved package labeling, nationally recognized compendia **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Adrenal Enzyme Inhibitors for Cushing's Syndrome**
Drugs	Recorlev (levoketoconazole)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Patients with a non-endogenous source of hypercortisolism, such as exogenous source of glucocorticoids or therapeutic use of ACTH. • Patient has a diagnosis of pituitary or adrenal carcinoma
Required Medical Information	See "Other Criteria"
Age Restrictions	Per FDA approved package insert
Prescriber Restrictions	Prescriber must be an endocrinologist or in consultation with an endocrinologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 4/2025	**<u>Initial Authorization:</u>** • Patient has a diagnosis of endogenous Cushing's syndrome. • Patient is not a candidate for surgery, surgery is not an option, or prior surgery has not been curative. • Documented baseline urinary free cortisol (UFC) test ≥ 1.5 times ULN (within the past 30 days). • Patient has tried and failed, or has a medical reason for not using, ketoconazole. • Medication is prescribed at an FDA approved dose. **<u>Re-Authorization:</u>** • Documented or provider attestation of positive clinical response (i.e. decrease in urinary free cortisol from baseline.) • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Adrenergic, alpha-receptor-blocking agent**
Drug(s)	Phenoxybenzamine (Dibenzyline)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or specialist in the management of pheochromocytoma.
Coverage Duration	If the conditions are met, the request will be approved for up to a 14-day duration for perioperative management or up to a 6 month duration for non-surgical initial requests. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 2/2025	**Initial Authorization:** • Diagnosis of pheochromocytoma • Documented use for either perioperative management or long term use when surgery is contraindicated • Documented trial and failure, intolerance, or contraindication to doxazosin • Medication is prescribed at an FDA approved dose **Re-Authorization** • Documented long term use when surgery is contraindicated • Documentation or provider attestation that demonstrates a clinical benefit • Medication is prescribed at an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Adzynma**
Drugs	Adzynma (ADAMTS13, recombinant-krhn)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a hematologist, oncologist, intensive care specialist, or specialist in the treatment of rare genetic hematologic diseases
Coverage Duration	On-demand therapy: If all criteria are met, the request will be approved for 1 month. Prophylactic therapy: If all criteria are met, the initial request will be approved for 6 months. Reauthorization requests will be approved for 12 months.

Other Criteria	**Initial Authorization**
	• Diagnosis of congenital thrombotic thrombocytopenic purpura (cTTP) as confirmed by BOTH of the following:
	  o Molecular genetic testing
	  o ADAMTS13 activity <10%
	• Prescriber attestation that member has not been diagnosed with any other TTP-like disorder (i.e., microangiopathic hemolytic anemia, immune-mediated thrombotic thrombocytopenic purpura [iTTP])
	• If request is for prophylactic therapy, member must also have a history of at least one documented TTP event
	• Member's weight
	• Request is for an FDA-approved dose
	
	Reauthorization
	• Documentation of positive clinical response to therapy (i.e., improvement in acute and subacute TTP events, platelet counts, microangiopathic hemolytic anemia episodes, or clinical symptoms)
	• Member's weight
	• Request is for an FDA-approved dose

Revision/Review Date: 4/2025	**Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Agents for Atopic Dermatitis**
Drugs	**Adbry (tralokinumab), Cibinqo (abrocitinib), Dupixent (dupilumab), Ebglyss (lebrikizumab-lbkz), Eucrisa (crisaborole), Nemluvio (nemolizumab-ilto), Opzelura (ruxolitinib), pimecrolimus (Elidel), Rinvoq (upadacitinib), tacrolimus (Protopic), Vtama (tapinarof), Zoryve (roflumilast)**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Tacrolimus (Protopic), pimecrolimus (Elidel), and Opzelura (ruxolitinib): Immunocompromised members
Required Medical Information	See "other criteria"
Age Restrictions	Per package insert
Prescriber Restrictions	Provider must be a pediatrician, dermatologist, immunologist, or allergist
Coverage Duration	For Opzelura, Vtama, and Zoryve: If the criteria are met, the request will be approved with up to an 8 week duration and all reauthorization requests will be approved for up to a 6 month duration. For all others: If the criteria are met, the request will be approved with up to a 6 month duration.
Other Criteria	**Initial Authorization** **For pimecrolimus:** • Diagnosis of mild to moderate atopic dermatitis (AD) • For mild AD: trial and failure of one formulary medium to high potency topical corticosteroid • For moderate AD: Trial and failure of one formulary medium to high potency topical corticosteroid AND topical tacrolimus **For tacrolimus:** • Diagnosis of moderate to severe AD • Trial and failure of one formulary medium to high potency topical corticosteroid **For Eucrisa, Opzelura, Vtama, or Zoryve:** • Diagnosis of AD • Trial and failure of one formulary medium to high potency topical corticosteroid

Revision/Review Date 2/2025	• Trial and failure of topical tacrolimus or pimecrolimus (for members less than 2 years of age requesting Eucrisa, trial of topical tacrolimus of pimecrolimus is not required) ****A maximum of ONE 60 g tube of Opzelura may be approved per week**** **For Dupixent:** • Diagnosis of moderate to severe AD • Trial and failure to ONE of the following: o One formulary medium to high potency topical corticosteroid o Topical tacrolimus or pimecrolimus o Eucrisa (crisaborole) • Member must have atopic dermatitis involvement of at least 10% body surface area (BSA) **For Adbry or Nemluvio:** • Diagnosis of moderate to severe AD • Trial and failure of, or contraindication to, ONE of the following: o Eucrisa o Opzelura o Vtama o Zoryve **For Ebglyss:** • Diagnosis of moderate to severe AD • Trial and failure of, or contraindication to, ONE of the following: o Adbry o Dupixent o Nemluvio **For Cibinqo or Rinvoq:** • Diagnosis of refractory, moderate to severe, AD • Trial and failure of, or contraindication to another systemic drug product for AD **Reauthorization:** • Prescriber attests that the member has experienced improvement in symptoms (e.g. significant clearing of the skin, reduction in itching) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Agents for Graft versus Host Disease**
Drugs	Rezurock (belumosudil), Imbruvica (ibrutinib), Jakafi (ruxolitinib phosphate), Orencia (abatacept), Ryoncil (remestemcel-L-rknd) Niktimvo (axatilimab-csfr)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a hematologist, oncologist, or other specialist in the treatment of hematopoietic cell transplants
Coverage Duration	Jakafi, Niktimvo, Rezurock, and Imbruvica: If all of the conditions are met, the request will be approved for up to a 3 month duration for initial requests and up to a 6 month duration for renewal requests. Orencia: If all of the conditions are met, the request will be approved for 1 month duration (4 total infusions) Ryoncil: If all of the criteria are met, the initial request will be approved for a 2 month duration (12 infusions total). If all of the criteria are met, the reauthorization request will be approved for a 1 month duration (8 total infusions).
Other Criteria	****For oncological indications, please refer to the "Oncology Agents" policy**** **Initial Authorization:** • Imbruvica o Member has a diagnosis of chronic graft versus host disease o Member has tried and failed or cannot use a systemic corticosteroid or documentation is provided as to why a systemic corticosteroid cannot be used o The drug is prescribed at an FDA-approved dose • Jakafi o Member has a diagnosis of acute graft versus host disease or a diagnosis of chronic graft versus host disease o Member has tried and failed or cannot use a systemic corticosteroid or documentation is provided as to why a systemic corticosteroid cannot be used o The drug is prescribed at an FDA-approved dose • Rezurock or Niktimvo o Member has a diagnosis of chronic graft versus-host disease

Revision/Review Date: 4/2025	○ Member has tried and failed at least two lines of systemic immunosuppressive therapy (e.g. corticosteroids, calcineurin inhibitors, mycophenolate mofetil, ibrutinib, ruxolitinib), one of which must be a systemic corticosteroid, or documentation is provided as to why a systemic corticosteroid cannot be used ○ The drug is prescribed at an FDA-approved dose • Orencia ○ Orencia is being requested for prophylaxis against acute graft versus host disease ○ Member will be undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor ○ Member will be receiving Orencia in combination with a calcineurin inhibitor (e.g., tacrolimus, cyclosporine) and methotrexate ○ Member will be receiving antiviral prophylactic treatment for Epstein-Barr virus reactivation and will continue for 6 months following HSCT ○ Attestation provider has considered prophylactic antivirals for cytomegalovirus (CMV) infection/reactivation during treatment and for 6 months following HSCT ○ The drug is prescribed at an FDA-approved dose • Ryoncil ○ Member has a diagnosis of acute graft versus host disease ○ Member has tried and failed or cannot use a systemic corticosteroid or documentation is provided as to why a systemic corticosteroid cannot be used ○ Member's weight ○ Medication is prescribed at an FDA approved dose **<u>Re-Authorization:</u>** • Documentation is provided that the member has achieved a clinical benefit from medication (e.g. symptom improvement, reduction in corticosteroid dose) • For Ryoncil requests: documentation is provided that member has a recurrence of GvHD after achieving a complete response with initial therapy of Ryoncil • The drug is prescribed at an FDA-approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Agents for Primary Biliary Cholangitis**
Drugs	Iqirvo (elafibranor), Livdelzi (seladelpar)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restriction	Member must be 18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a hepatologist or gastroenterologist
Coverage Duration	If the criteria are met, the request will be approved for a 3 month duration for initial authorization and for up to a 12 month duration for reauthorization.
Other Criteria	**Initial Authorization:** • Diagnosis of primary biliary cholangitis (PBC) confirmed by at least two of the following tests: a) Positive antimitochondrial antibody test, or presence of other PBC-specific autoantibodies, including sp100 or gp210, if antimitochondrial antibody test is negative b) Elevated serum alkaline phosphatase (ALP) level c) Histologic evidence of primary biliary cholangitis from a liver biopsy • Drug is being requested in addition to ursodeoxycholic acid (UDCA) due to patient having an inadequate response to UDCA monotherapy for at least 1 year, OR member has a documented medical reason (e.g., contraindication, intolerance, hypersensitivity) why UDCA cannot be used and is taking the requested drug as monotherapy • Prescriber attests the patient does not have complete biliary obstruction, decompensated cirrhosis (e.g., Child-Pugh Class B or C) • • Submission of the following test results within 30 days of request: a) Serum ALP b) Total bilirubin **Reauthorization:** • Provider attests that the patient has not developed complete biliary obstruction, decompensated cirrhosis (e.g., Child-Pugh Class B or

Revision/Review Date 10/2025	C) • • Submission of lab tests confirming each of the following: ○ A decrease in ALP of ≥ 15% from baseline ○ ALP is less than 1.67 times the upper limit normal (ULN); defined as 118 U/L for females and 124 U/L for males ○ Total bilirubin ≤ ULN defined as 1.1 mg/dL for females and 1.5 mg/dL for males ○ **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Agents to Treat Constipation**
Drug(s)	**Preferred, PA Required**: Linzess (linaclotide) lubiprostone (Amitiza) Movantik (naloxegol) Symproic (naldemedine) **Non-Preferred, PA Required:** Trulance (plecanatide) prucalopride(Motegrity) Relistor (methylnaltrexone) Ibsrela (tenapanor) Or any newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the request will be approved for 6 months.
Other Criteria	**Criteria for Initial Authorization**: **For chronic idiopathic constipation (CIC), functional constipation, or irritable bowel syndrome with constipation (IBS-C):** 1. The member has tried and failed 2 different laxatives from 2 different classes (bulk-forming, osmotic, stimulant) **AND** 2. If the request is for a non-preferred agent, the member must also have tried and failed BOTH lubiprostone AND Linzess or have a medical reason (contraindication, intolerance etc.) as to why member is unable to use theses preferred products (note: lubiprostone is only indicated in women with IBS-C) **For opioid induced constipation (OIC):** 1. The member has tried and failed 2 different laxatives from 2 different classes (bulk-forming, osmotic, stimulant) **AND** 2. If the request is for a non-preferred agent, the member has tried and failed two of the following three agents, Symproic, Movantik, lubiprostone, or has a medical reason

Review/Revision Date: 7/2025	(contraindication, intolerance, etc.) as to why member is unable to use these products. **<u>Criteria for Reauthorization</u>**: 1. The member has been adherent with therapy (as determined through review of claims history). 2. Documentation that the member has experienced treatment efficacy. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Agents to Treat Gaucher's Disease**
Drugs	Cerdelga (eliglustat), Cerezyme (imiglucerase), Vpriv (velaglucerase alfa), Elelyso (taliglucerase alfa), miglustat (Zavesca)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	None
Required Medical Information	See "Other Criteria"
Age Restrictions	Per package insert
Prescriber Restrictions	Prescriber is a specialist in treatment of Gaucher's Disease (e.g. endocrinologist, hematologist or geneticist), or is in consultation with a specialist
Coverage Duration	If all of the conditions are met, the request will be approved with 6-month duration.
Other Criteria	**Initial Authorization:** Cerezyme, Vpriv, Elelyso, or miglustat initial authorization: • Patient has a confirmed diagnosis of Gaucher's disease, type 1 (GD1) • Request is for an FDA approved dose Cerdelga initial authorization: • Patient has a confirmed diagnosis of Gaucher's disease, type 1 (GD1) and is a CYP2D6 extensive metabolizer (EM), intermediate metabolizer (IM) or poor metabolizer (PM), as detected by an FDA-approved test. • Patient is not concomitantly taking Class IA (e.g. quinidine, procainamide) or Class III antiarrhythmic (e.g. amiodarone, sotalol). • For EMs or IMs, patient is not concomitantly taking a moderate or strong CYP2D6 inhibitor (e.g. fluoxetine, bupropion) WITH a moderate or strong CYP3A inhibitor (fluconazole, ketoconazole). • For IMs and PMs, patient is not concomitantly taking a strong CYP3A inhibitor. • Patient has no pre-existing cardiac disease or long QT syndrome. • For EM's, patient does not have moderate or severe hepatic impairment • For IM's or PMs, patient does not have any degree of hepatic impairment.

Revision/Review Date 4/2025	**<u>Re-Authorization criteria for all agents:</u>** • Documentation has been provided that patient has obtained clinical benefit from medication (e.g. increased platelet count, improvement in anemia, PFT's, improvement in radiographic scans, improved quality of life) • Request is for an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Agents for Homozygous Familial Hypercholesterolemia (HoFH)**
Drugs	**Preferred:** Evkeeza (evinacumab-dgnb) **Non-Preferred:** Juxtapid (lomitapide) ****Please refer to the "Proprotein Convertase Subtilisin/kexin 9 (PCSK9) Inhibitors" policy for requests for medications in that class****
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by cardiologist or specialist in treatment of lipid disorders.
Coverage Duration	If all of the above conditions are met, the initial request will be approved for up to a 6 month duration, and the reauthorization request will be approved for a 12 month duration.

Other Criteria	**Initial Authorization:**
	• Documentation of a diagnosis of homozygous familial hypercholesterolemia (HoFH) via either:
	  o Genetic confirmation of two mutant alleles at the LDL receptor, ApoB, PCSK9 or ARH adaptor protein gene locus; OR
	  o A clinical diagnosis of HoFH which includes: untreated LDL-C >500 mg/dL (>13 mmol/L) or treated LDL-C ≥300 mg/dL (>8 mmol/L), AND
	  ▪ Cutaneous or tendon xanthoma before age 10 years, OR
	  ▪ Elevated LDL-C levels consistent with heterozygous FH in both parents.
	• Patient has tried and failed atorvastatin 40mg-80mg or rosuvastatin 20-40mg (consistently for 3 months via claim history or chart notes). If patient is not able to tolerate atorvastatin or rosuvastatin, documentation was provided that patient is taking another statin at the highest tolerated dose, or a medical reason was provided why the member is not able to use these therapies.
	• If prescriber indicates member is "statin intolerant", documentation was provided including description of the side

Revision/Review Date 2/2025	effects, duration of therapy, “wash out”, re-trial, and then change of agents. • Patient has tried and failed ezetimibe at a maximal tolerated dose or a medical reason was provided why the member is not able to use ezetimibe • Member has documented trial and failure with PCSK9 inhibitor for at least 3 months, or a medical reason has been provided, why member is unable to use a PCSK9 inhibitor indicated for HoFH to manage their condition. • Documentation was provided indicating provider has counseled member on smoking cessation and following a “heart healthy diet”. • Documentation was provided of current LDL level • If the request is for Juxtapid the member has had documented trial and failure with Evkeeza for at least 6 month or a medical reason has been provided why the member is unable to use Evkeeza **Reauthorization:** • Documentation submitted indicates that the member has obtained clinical benefit from the medication including repeat fasting lipid panel lab report, and the member has achieved or maintained a LDL reduction from the levels immediately prior to initiation of treatment with Juxtapid or Evkeeza. • The patient’s claim history shows consistent therapy (monthly fills). **Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Agents for the Treatment of Postpartum Depression**
Drugs	Zurzuvae (zuranolone)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a psychiatrist or an obstetrician-gynecologist.
Coverage Duration	If all of the criteria are met, the initial request will be approved for a 14-day course of Zurzuvae per postpartum period. Reauthorization will not be permitted.
Other Criteria Revision/Review Date: 2/2025	**<u>Initial Authorization:</u>** • Prescriber attestation of severe postpartum depression (PPD) diagnosis and submission of validated screening tool result(s) (e.g. Edinburgh Postnatal Depression Scale, Hamilton Depression Rating Scale) that requires quick onset where the patient cannot wait 4-6 weeks for the standard of care antidepressants to take effect • Patient is ≤ 6 months postpartum with a major depressive episode without psychosis that began no earlier than the third trimester and no later than the first 4 weeks after delivery • Attestation that the provider warned the patient not to drive for at least 12 hours after each dose. • Medication is prescribed at an FDA approved dose **<u>Renewal Authorization:</u>** • Renewals will not be authorized **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Agents for Thrombocytopenia**
Drugs	**<u>Preferred Thrombocytopenia Agent(s)</u>:** • Promacta (eltrombopag) • Doptelet (avatrombopag) **<u>Non-Preferred Thrombocytopenia Agent(s)</u>:** • Alvaiz (eltrombopag) • Nplate (romiplostim) • Mulpleta (lusutrombopag) • Tavalisse (fostamatinib)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	Per package insert
Prescriber Restrictions	Prescriber must be a hematologist
Coverage Duration	If the criteria are met, the requests for Promacta, Alvaiz, Nplate, and Tavalisse will be approved for 12 months. Mulpleta will be approved for a maximum of 7 days. Doptelet will be approved for 12 months if the request is for ITP or for a maximum of 5 days if the request is for thrombocytopenia associated with chronic liver disease in adult patients requiring elective surgery.

Other Criteria	**Chronic immune (idiopathic) thrombocytopenia (ITP):**
	• Platelet count < 30,000 cells/microL
	• Documented trial and failure, or intolerance, contraindication, to ONE of the following:
	  • Glucocorticoids
	  • Intravenous immune globulin (IVIG)
	  • Rituximab
	  • splenectomy
	• If the request is for Alvaiz, Doptelet, Nplate or Tavalisse, the member has a documented trial and failure, intolerance, or contraindication to Promacta
	
	Severe aplastic anemia (Promacta and Alvaiz only):
	  • Being prescribed in conjunction with at least one immunosuppressive agent OR there is a documented trial and failure, intolerance, or contraindication to at least one immunosuppressive agent
	  • Platelet count < 20,000 cells/microL OR platelet cout < 30,000 cells/microL with bleeding OR reticulocyte count < 20,000 cells/microL OR absolute neutrophil count < 500 cells/microL
	  • If the request is for Alvaiz, the member has a documented trial

Revision/Review Date 4/2025	and failure, intolerance, or contraindication to Promacta **Thrombocytopenia in patients with Hepatitis C infection** (Promacta and Alvaiz only): • Diagnosis of chronic hepatitis C • Platelet count < 50,000 cells/microL • Documented treatment with interferon-based therapy AND patient's degree of thrombocytopenia prevents the initiation or limits the ability to maintain interferon-based therapy • If the request is for Alvaiz, the member has a documented trial and failure, intolerance, or contraindication to Promacta **Thrombocytopenia associated with chronic liver disease in *adult* patients requiring elective surgery** (Doptelet and Mulpleta only): • Patient has a diagnosis of chronic liver disease and is scheduled to undergo a procedure • Platelet count < 50,000 cells/microL • For Mulpleta, approve if there is documentation of trial and failure, intolerance, or contraindication to use Doptelet **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Alpha-1 Proteinase Inhibitors (Human)**
Drugs	**Preferred:** Prolastin-C **Non-Preferred:** Aralast NP Glassia Zemaira Or any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or specialist in the treatment of AAT
Coverage Duration	The request will be approved for up to a 12 month duration.
Other Criteria	**Initial Authorization:** • Documented diagnosis of a congenital deficiency of alpha-1 antitrypsin (AAT) (serum AAT level < 11 micromol/L [approximately 57 mg/dL using nephelometry or 80mg/dl by radial immunodiffusion]). • Documentation was submitted indicating the member has undergone genetic testing for AAT deficiency and is classified as phenotype PiZZ, PiSZ, PiZ(null) or Pi(null)(null) [NOTE: phenotypes PiMZ or PiMS are not candidates for treatment with Alpha1-Proteinase Inhibitors] • Documentation was submitted (member's pulmonary function test results) indicating airflow obstruction by spirometry (forced expiratory volume in 1 second [FEV_1] ≤ 65% of predicted), or provider has documented additional medical information demonstrating medical necessity • Documentation was submitted indicating member is a non-smoker or an ex-smoker (eg. smoking cessation treatment) • Documentation of the member's current weight • The Alpha-1 Proteinase Inhibitor (human) is being prescribed at an FDA approved dosage • If the medication request is for an Alpha1-Proteinase Inhibitor (human) product other than Prolastin-C, the patient has a

Revision/Review Date 2/2025	documented medical reason (intolerance, hypersensitivity, contraindication, treatment failure, etc.) for not using Prolastin-C to treat their medical condition **Reauthorization:** • Documentation of the member's current weight • Documentation was submitted indicating member is a non-smoker or an ex-smoker (e.g. smoking cessation treatment) • Documentation was submitted indicating the member has clinically benefited from therapy (i.e. stable lung function, improved PFTs, alpha-1 antitrypsin serum level maintained above 11 micromol/L [approximately 57 mg/dL using or 80 mg/dL by radial immunodiffusion], improved quality of life) • The Alpha-1 Proteinase Inhibitor (human) is being prescribed at an FDA approved dosage **Clinical reviewer/Medical Director must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Amifampridine**
Drugs	**Firdapse** (amifampridine)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Patients must be 6 years age or older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a neuromuscular specialist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy the request will be approved for 6 months.
Other Criteria Revision/Review Date 2/2025	**Initial Authorization:** • Diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) based on at least one electrodiagnostic study (i.e., repetitive nerve stimulation, nerve conduction studies, electromyography) OR anti-P/Q-type voltage-gated calcium channel antibody testing • Member has been screened for small cell lung cancer (SCLC) and/or other malignancies • Member does not have a history of seizures • Medication is being prescribed at an FDA approved dose or is supported by compendia or standard of care guidelines **Re-authorization:** • Medication is prescribed at an FDA-approved dose or is supported by compendia or standard of care guidelines • Documentation provided that prescriber has evaluated the member and recommends continuation of therapy **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Amtagvi (lifileucel)**
Drugs	Amtagvi (lifileucel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Uncontrolled brain metastases • Melanoma of uveal or ocular origin • Systemic steroid therapy for any reason
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be an oncologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for a one-time treatment.
Other Criteria Revision/Review Date: 4/2025	**<u>Initial Authorization:</u>** • Diagnosis of unresectable or metastatic melanoma (Stage IIIc or Stage IV) • Member must have progressed through at least one prior systemic therapy including a PD-1/PD-L1 blocking antibody and, if BRAF V600 mutation–positive, a BRAF inhibitor or BRAF inhibitor in combination with a MEK inhibitor • Member must have at least one resectable lesion (or aggregate of lesions resected) of a minimum 1.5 cm in diameter post-resection • Eastern Cooperative Oncology Group (ECOG) score of 0 or 1 • Medication is prescribed at an FDA approved dose **The safety and effectiveness of repeat administration of Amtagvi has not been evaluated and will not be approved.** **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Androgenic Agents**
Drug(s)	*****If the request is for gender dysphoria, please use the Medications without Drug or Class Specific Criteria***** **<u>Formulary Status: Formulary with quantity limit</u>** Testosterone Cypionate (Depo-Testosterone) vial – QL of 4mL per 28 days Testosterone Enanthate vial – QL of 5ml per 28 days **<u>Formulary Status: Formulary, PA Required</u>** *****Preferred Products***** Axiron (testosterone solution) (generic) Vogelxo (testosterone gel) (generic) Androgel 1.62% Pump (testosterone gel) (generic) ***Patient must meet criteria 1 and 2** **<u>Formulary Status: Non-Formulary:</u>** Androgel 1.62% gel packets Androderm Testim Testopel Natesto Aveed Methitest Jatenzo Xyosted Tlando Azmiro Undecatrex Kyzatrex Or any newly marketed testosterone agent ***Patient must meet criteria 1- 3**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert).
Exclusion Criteria	Men with carcinoma of the breast or known or suspected prostate cancer.

	Pregnant or breastfeeding women.
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	None
Coverage Duration	If all of the conditions are met, the initial request will be approved with 3 month duration and the renewal request will be approved with a 12 month duration.
Other Criteria: Review/Revision Date: 10/2025	**<u>For Initial Authorization</u>**: 1. Diagnosis of primary hypogonadism (congenital or acquired) or hypogonadotropic hypogonadism (congenital or acquired) 2. Documented low testosterone level (s) (<300 ng/dL for total testosterone; copy of laboratory result required) 3. Documented adequate trial and failure or intolerance with a preferred topical agent. **<u>For Re-Authorization:</u>** 1. Diagnosis of primary hypogonadism (congenital or acquired) or hypogonadotropic hypogonadism (congenital or acquired). 2. Documentation that the member is benefiting from use of the medication. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Angiotensin II Receptor Blocker and Renin Inhibitor Medications**
Drugs	**FORMULARY STATUS:** Preferred, Pays at Point-of-Sale (First Line) • losartan **(Cozaar)** Tablets • losartan/hydrochlorothiazide **(Hyzaar)** Tablets **FORMULARY STATUS:** Preferred, Requires Step Therapy (Second Line) • irbesartan **(Avapro)** Tablets • irbesartan/hydrochlorothiazide **(Avalide)** Tablets • olmesartan (**Benicar)** Tablets • olmesartan/ hydrochlorothiazide **(Benicar HCT)** Tablets • valsartan **(Diovan)** Tablets • valsartan/hydrochlorothiazide **(Diovan-HCT)** Tablets • amlodipine/valsartan (**Exforge)** Tablets • telmisartan **(Micardis)** Tablets **NOTE: Patient must meet criteria #1 for approval of initial PA request.** **FORMULARY STATUS:** Non-Preferred, Requires Prior Authorization (Third Line) • candesartan **(Atacand)** Tablets • candesartan/hydrochlorothiazide **(Atacand HCT)** Tablets • amlodipine /olmesartan **(Azor)** Tablets • **Edarbi** (azilsartan) Tablets • **Edarbyclor** (azilsartan/hydrochlorothiazide) Tablets • amlodipine/valsartan/hydrochlorothiazide **(Exforge HCT)** Tablets • telmisartan/hydrochlorothiazide **(Micardis-HCT)** Tablets • olmesartan/amlodipine/hydrochlorothiazide **(Tribenzor)** Tablets • telmisartan/amlodipine Tablets • aliskiren **(Tekturna)** Tablets **NOTE: Patient must meet criteria #1 & #2 for approval of initial PA request**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines
Exclusion Criteria	N/A
Required Medical	See “other criteria”

Information	
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with a 12 month duration.
Other Criteria Revision/Review Date: 7/2025	1. Documented adequate trial and failure or intolerance with a first line agent of at least 15 days of therapy 2. Documented adequate trial and failure or intolerance with a second line agent of at least 15 days of therapy **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Prior Authorization Group Description	**Anti-FGF23 Monoclonal Antibodies**
Drugs	Crysvita (burosumab) SQ solution, or any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: The Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	See Other Criteria
Required Medical Information	See Other Criteria
Age Restrictions	X-linked hypophosphatemia (XLH): 6 months of age or older Tumor-induced osteomalacia (TIO): 2 years of age and older
Prescriber Restrictions	Prescribed by, or in consultation with, an endocrinologist, nephrologist, molecular geneticist, or other specialist experienced in the treatment of metabolic bone disorders
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months and reauthorization requests will be approved for 12 months.
Other Criteria	**<u>Initial Authorization:</u>** **For X-linked hypophosphatemia (XLH):** • Diagnosis of XLH • Dosing is appropriate as per labeling or is supported by compendia or standard of care guidelines • Labs, as follows: o Serum phosphorus below normal for patient age o eGFR > 30 mL/min/1.73 m2 or CrCl ≥ 30 mL/min • Patient will not use concurrent oral phosphate and/or active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol) • Additionally, for adults: o Clinical signs and symptoms of XLH (e.g. bone/joint pain, fractures, osteomalacia, osteoarthritis, ensethopathies, spinal stenosis impaired mobility, presence or history of lower limb deformities, etc.) o Trial and failure of, or contraindication to, combination therapy with oral phosphate and active vitamin D (calcitriol) for a minimum of 8 weeks **For tumor-induced osteomalacia (TIO):** • Diagnosis of FGF23-related hypophosphatemia in TIO • Dosing is appropriate as per labeling or is supported by compendia or standard of care guidelines

Revision/Review Date: 7/2025	• The tumor(s) is/are not amenable to surgical excision or cannot be located
	• Labs, as follows:
	  o Serum phosphorus below normal for patient age
	  o eGFR > 30 mL/min/1.73 m2 or CrCl ≥ 30 mL/min
	• Patient will not use concurrent oral phosphate and/or active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol)
	
	<u>Re-authorization:</u>
	
	For XLH or TIO:
	• Documented effectiveness as evidenced by at least one of the following:
	  o Serum phosphorus within normal limits for patient age
	  o Clinical improvement (e.g. improved rickets, improved bone histomorphometry, increased growth velocity, increased mobility, decrease in bone fractures, improved fracture healing, reduction in bone-related pain)
	• 25-hydroxyvitamin D level and, if abnormally low, documented supplementation with cholecalciferol or ergocalciferol
	• Patient is not concurrently using oral phosphate and/or active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol)
	• Dosing continues to be appropriate as per labeling or is supported by compendia or standard of care guidelines
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	**Anti-Parkinson's Agents for OFF Episodes**
Drugs	Preferred (step 1): Ongentys (opicapone), Xadago (safinamide) Non-preferred (step 2): Nourianz (istradefylline), Inbrija (levodopa) inhalation, apomorphine (Apokyn) Non-preferred (step 3): Vyalev (foscarbidopa and foslevodopa), Onapgo (apomorphine), or any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: The Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Inbrija or Vyalev: Concurrent use with a nonselective monoamine oxidase (MAO) inhibitor (such as phenelzine or tranylcypromine) • Onapgo and Apokyn: Concurrent use with 5HT3 antagonists, including antiemetics (e.g. ondansetron, granisetron, dolasetron, palonosetron) and alosetron; concurrent use with other apomorphine products • Concurrent use of Vyalev and Onapgo
Required Medical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber is a neurologist or is working in consultation with a neurologist
Coverage Duration	If the criteria are met, the initial requests will be approved for up to a 6 month duration and reauthorization requests will be approved for 12 months.
Other Criteria	**Initial Authorization:** **All agents:** • Diagnosis of Parkinson's disease • Dosing is appropriate as per labeling or is supported by compendia or standard of care guidelines • Patient is currently taking and will continue to take carbidopa/levodopa (does not apply to Vyalev) • Attestation or documentation patient is experiencing symptom fluctuations or off episodes while taking carbidopa/levodopa where attempts have been made to adjust the carbidopa/levodopa dose and/or formulation in order to manage symptoms without success • Documented trial and failure (or contraindication) to **at least two** of the following adjunctive medication classes: o COMT-inhibitors (e.g., entacapone) o Dopamine agonists (e.g., ropinirole, pramipexole) o MAO-B inhibitors (e.g., rasagiline, selegiline) •

Revision/Review Date: 7/2025	**If the request is for a step 2 agent:** • Patient must also have a documented trial and failure or medical reason why a preferred step 1 agent cannot be used • If the request is for Inbrija, patient does not have asthma, COPD, or other chronic underlying lung disease **If the request is for a step 3 agent:** • Patient must have a documented trial and failure or medical reason why a preferred step 1 agent, and a non-preferred step 2 agent cannot be used • Prescriber attestation or documentation that the patient has advanced stage Parkinson's disease, and the patient is experiencing a minimum of 2.5 hours of "off" time per day • If the request is for Vyalev, patient is taking ≥400 mg of levodopa/day **<u>Re-authorization:</u>** • Documentation or provider attestation of positive clinical response (i.e. increase in "on" time without troublesome dyskinesia, decreased "off" time) • Dosing is appropriate as per labeling or is supported by compendia or standard of care guidelines **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Antifibrotic Respiratory Tract Agents

Drugs:
Ofev (nintedanib esylate)
pirfenidone (Esbriet)

Covered Uses: Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.

INITIAL CRITERIA:

For all requests:

- Patient is 18 years of age or older
- Prescriber is a pulmonologist or lung transplant specialist
- Provider attests that they have reviewed the patient's other medications, and have addressed all potential drug interactions
- Documentation has been provided that the patient does not smoke

If the request is for Idiopathic Pulmonary Fibrosis (IPF):

- Confirmed diagnosis of IPF
- Pulmonary function test indicate patient has Forced Vital Capacity (%FVC) ≥ 50% within 30 days of request

If the request is for Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) *(Ofev only)*:

- Confirmed diagnosis of SSc-ILD
- FVC ≥ 40% within 30 days of request
- Trial and failure of mycophenolate mofetil (MMF), cyclophosphamide or azathioprine.

If the request is for Chronic Fibrosing Intersitial Lung Diseases (ILDs) with a progressive phenotype *(Ofev only)*:

- Diagnosis of chronic fibrosing ILD (such as connective tissue disease [CTD]-associated ILD, chronic fibrosing hypersensitivity pneumonitis [HP], idiopathic non-specific interstitial pneumonia [iNSIP], unclassifiable idiopathic interstitial pneumonia [IIP]) of a progressive phenotype
- Recent (12 month) history of treatment with at least one medication to treat ILD (e.g., corticosteroid, azathioprine, MMF, n-acetylcysteine (NAC), rituximab, cyclophosphamide, cyclosporine, or tacrolimus).
- FVC ≥ 45% predicted within 30 days of request

If all of the above conditions are met, the request will be approved for a 6 month duration; if all of the above criteria are not met, the request is referred to a Medical/clinical reviewer for medical necessity review.

REAUTHORIZATION CRITERIA:

- Prescriber is a pulmonologist or lung transplant specialist

- Documentation submitted indicates that the member has obtained clinical benefit from the medication
- Documentation has been provided that the patient does not smoke

If all of the above conditions are met, the request will be approved for a 6 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

NOTE: Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Revision/Review Date: 7/2025

Field Name	Field Description
Prior Authorization Group Description	**Antihyperlipidemia Agents**
Drugs	**<u>FORMULARY STATUS</u>** Formulary, Pays at Point-of-Sale **SIMVASTATIN 5, 10, 20, 40 mg TABLETS** **LOVASTATIN TABLETS** **ATORVASTATIN TABLETS** **ROSUVASTATIN TABLETS** **PRAVASTATIN TABLETS** **<u>FORMULARY STATUS</u>** Requires Step Therapy **SIMVASTATIN 80 mg TABLETS** **Note: Patient must meet criteria #1 & #2 for approval of the PA request.** **<u>FORMULARY STATUS</u>** Non-Formulary, Prior Authorization Required **FLUVASTATIN** **FLUVASTATIN ER** **LIVALO (PITAVASTATIN)** **ZYPITAMAG (PITAVASTATIN)** **Note: Patient must meet criteria #1 & #3 for approval of the PA request.**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 10/2025	**<u>Initial Authorization:</u>** 1. Diagnosis of hypercholesterolemia and/or hyperlipidemia 2. Documented trial and failure of a lower strength of simvastatin 3. Documented trial and failure or intolerance with 3 preferred agents for a minimum of four weeks of therapy each

Field Name	Field Description
Prior Authorization Group Description	**Antisense Oligonucleotides for Duchenne Muscular Dystrophy**
Drugs	Exondys 51 (eteplirsen), Vyondys 53 (golodirsen), Viltepso (viltolarsen), Amondys 45 (casimersen)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Concomitant use with another antisense oligonucleotide
Required Medical Information	See "Other Criteria"
Age Restrictions	Age ≤ 20 years
Prescriber Restrictions	Prescribed by neurologist or provider who specializes in the treatment of DMD
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months and reauthorization requests will be approved for 12 months.

Other Criteria	**Initial Authorization:**
	• Member has a diagnosis of Duchenne muscular dystrophy (DMD) and lab test was submitted confirming the mutation of dystrophin gene amenable to ONE of the following:
	  o Exon 51 skipping for Exondys 51
	  o Exon 53 skipping for Vyondys 53 or Viltepso
	  o Exon 45 skipping for Amondys 45
	• Member is ambulatory
	• Baseline dystrophin levels AND results of motor function tests are provided [e.g. 6-Minute Walk Test (6MWT), Time to Stand Test (TTSTAND), Time to Run/Walk Test (TTRW), North Star Ambulatory Assessment (NSAA), Time to Climb 4 Steps Test (TTCLIMB)]
	• Member has stable pulmonary and cardiac function
	• ONE of the following applies:
	  o Member has been on a stable dose of corticosteroids for at least 3 months for Viltepso
	  o Member has been on a stable dose of corticosteroids for at least 6 months for Vyondys 53, Exondys 51, or Amondys 45
	• Attestation of renal function monitoring is provided with request
	• The request is for an FDA approved dose
	
	Reauthorization
	
	• Documentation is provided that the member had an increase in dystrophin levels from baseline

Revision/Review Date 4/2025	• Documentation is provided that the member had the expected clinical response (e.g. provider statement that the therapy has reduced the rate of further decline in function as demonstrated by 6MWT, TTSTAND, TTRW, NSAA, or TTCLIMB) • Member is ambulatory • Attestation of renal function monitoring is provided with request • The request is for an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	Anzupgo (delgocitinib)
Drugs	Anzupgo
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Current use of Opzelura (ruxolitinib), systemic JAK inhibitors, or potent immunosuppressants
Required Medical Information	See "Other Criteria"
Age Restrictions	Per FDA-approved labeling
Prescriber Restrictions	None
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Date: 10/2025	**Initial Authorization:** • Medication is prescribed at an FDA approved dose • Diagnosis of moderate to severe chronic hand eczema (CHE) • Documentation of hand eczema persisting for >3 months or recurring ≥2 times within 12-month time frame • Trial and failure, or contraindication to, ≥2 formulary moderate/high-potency topical corticosteroids **Re-Authorization:** • Documentation or provider attestation of positive clinical response (i.e. significant clearing of the skin, reduction in itching) • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Atovaquone Suspension**
Drugs	Atovaquone (Mepron) suspension
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 6 month duration.
Other Criteria Revision/Review Date 4/2025	<u>Treatment/Prevention of *Pneumocystis jirovecii* pneumonia</u> • Diagnosis of mild to moderate *Pneumocystis jirovecii* pneumonia (PCP) or diagnosis with the need to prevent PCP infection • Documented trial and failure with therapeutic doses or intolerance to trimethoprim- sulfamethoxazole (TMP-SMX). • Documented trial and failure with therapeutic doses or intolerance to dapsone. <u>Treatment/Prevention of *Toxoplasma gondii* encephalitis in patients with HIV</u>: • Diagnosis of *Toxoplasma gondii* encephalitis or documentation of supporting diagnosis for prophylaxis • Documented trial and failure with therapeutic doses or intolerance to trimethoprim- sulfamethoxazole (TMP-SMX). **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**BANZEL**
Drugs	**<u>FORMULARY STATUS</u>** Formulary, Pays at Point-of-Sale **CARBAMAZEPINE** **CLOBAZAM** **CLONAZEPAM** **CLORAZEPATE** **DIAZEPAM** **DIVALPROEX** **ETHOSUXIMIDE** **GABAPENTIN** **LAMOTRIGINE** **LEVETIRACETAM** **OXCARBAZEPINE** **PHENOBARBITAL** **PHENYTOIN** **PRIMIDONE** **TOPIRAMATE** **VALPROIC ACID** **ZONISAMIDE** **<u>FORMULARY STATUS</u>** Preferred, Requires Step Therapy with one prior step **RUFINAMIDE TABLETS** **RUFINAMIDE ORAL SUSPENSION** **Note: Patient must meet criteria #1 & #2 for approval of the PA request.**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	Member must be ≥ 1 year of age
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration.

Other Criteria Revision/Review Date 4/2025	1. Presumed or documented diagnosis of epilepsy or seizure disorder associated with Lennox-Gastaut Syndrome 2. Documented trial and failure or intolerance with an alternative preferred anticonvulsant for a minimum of 3 weeks

Field Name	Field Description
Prior Authorization Group Description	**Benlysta (belimumab)**
Drugs	Benlysta (belimumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	Severe active central nervous system lupus
Required Medical Information	See "other criteria"
Age Restrictions	Must be at least 5 years of age
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist or nephrologist
Coverage Duration	If all the criteria are met initial authorization requests may be approved for up to 6 months. Reauthorization requests may be approved for up to 12 months.
Other Criteria	**Initial Authorization**: • Active systemic lupus erythematosus (SLE) o Provider attestation that the patient is positive for autoantibodies (or antinuclear antibodies or anti–double-stranded DNA [anti-dsDNA] antibodies) o The member has tried and failed both of the following (or contraindication/inability to use these medications): ▪ Hydroxychloroquine ▪ One other immunosuppressant [e.g., methotrexate, azathioprine, calcineurin inhibitors or mycophenolate] • Active lupus nephritis o Provider attestation of diagnosis confirmed by kidney biopsy o The member has tried and failed, or has a medical reason for not using, both of the following ▪ Cyclophosphamide or tacrolimus ▪ Mycophenolate • Provider states the member will not be receiving concomitant therapy with the following: o B-cell targeted therapy including (but not limited to) rituximab o Interferon receptor antagonist, type 1 including (but not limited to) Saphnelo (anifrolumab) • Dosing is appropriate per labeling **Criteria for Reauthorization**: • Documentation or provider attestation of positive clinical response as indicated by one of the following: o Fewer flares that required steroid treatment

Revision/Review Date: 2/2025	○ Lower average daily oral prednisone dose ○ Improved daily function either as measured through a validated functional scale or through improved daily performance documented at clinic visits ○ Sustained improvement in laboratory measures of lupus activity • Dosing is appropriate per labeling **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Biologic Agents for Nasal Polyposis**
Drugs	**Dupixent** (dupilumab), **Xolair** (omalizumab), **Nucala** (mepolizumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Use of Dupixent, Xolair, or Nucala concomitantly or with another pulmonary biologic (e.g. Fasenra, Cinqair)
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be an allergist or otolaryngologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy the request will be approved for 6 months.
Other Criteria	****Xolair: For asthma and urticaria, please refer to the "Xolair for Asthma, Urticaria, and IgE-Mediated Food Allergy" policy**** ****Dupixent: For atopic dermatitis, please refer to the "Agents for Atopic Dermatitis" policy; For asthma, please refer to the "Pulmonary Biologics for Respiratory and Eosinophilic Conditions" policy**** ****Nucala: For asthma or other eosinophilic conditions, please refer to the "Pulmonary Biologics for Respiratory and Eosinophilic Conditions" policy**** **<u>Initial Authorization:</u>** • Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) • Medication is being prescribed at an FDA approved dosage • Documentation of ONE of the following: o Trial and failure, or medical reason for not using, all of the following therapies: ▪ an intranasal corticosteroid ▪ a systemic corticosteroid o Prior surgery for nasal polyps • Patient is currently using an intranasal corticosteroid, will be prescribed at an intranasal corticosteroid, or has a documented medical reason for not using an intranasal corticosteroid **<u>Re-authorization:</u>** • Medication is prescribed at an FDA-approved dosage • Member will continue to use an intranasal corticosteroid, or has a medical reason for not using an intranasal corticosteroid • Documentation has been provided that demonstrates a clinical

	benefit (e.g. improvements in symptom severity, nasal polyp score [NPS], sino-nasal outcome test-22 [SNOT-22], nasal congestion score [NCS], nasal obstruction symptom visual analogue scale [VAS])
Revision/Review Date 4/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Blincyto**
Drugs	Blincyto (blinatumomab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restriction	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist/hematologist
Coverage Duration	The request will be approved for up to a 12 month duration.
Other Criteria	**Initial Authorization:** • Patient has a diagnosis of one of the following forms of Acute Lymphoblastic Leukemia (ALL): a) Relapsed CD19-positive B-cell precursor ALL b) Refractory CD19-positive B-cell precursor ALL c) CD19-positive B-cell precursor ALL in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1% d) CD19-positive Philadelphia chromosome-negative B-cell precursor ALL in the consolidation phase of multiphase chemotherapy • Provider attests to monitor patient for Cytokine Release Syndrome (CRS) and neurological toxicities **Reauthorization:** • Provider attests to treatment response or stabilization of disease • Prescriber attests to monitor patient for Cytokine Release Syndrome (CRS) and neurological toxicities
Revision/Review Date 4/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Botulinum Toxins A&B**
Drugs	**Preferred Agents for FDA approved indications:** IncobotulinumtoxinA (Xeomin) AbobotulinumtoxinA (Dysport) **Non-preferred Agents:** OnabotulinumtoxinA (Botox) RimabotulinumtoxinB (Myobloc) DaxibotulinumtoxinA (Daxxify) Or any newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	According to package insert
Prescriber Restrictions	None
Coverage Duration	If all of the conditions are met, the request will be approved for 12 month duration.
Other Criteria	****The use of these medications for cosmetic purposes is NOT a covered benefit under the Medical Assistance program**** **For Initial Approval:** • The drug is being used for a medically accepted indication and dose as outlined in Covered Uses • The member has tried and failed standard first line therapy for their disease state and/or has a documented medical reason (intolerance, hypersensitivity, contraindication, etc.) for not using first line therapy • If the diagnosis is **Chronic Migraines** (≥15 days per month with headache lasting 4 hours a day or longer), the member has tried and failed, or has a medical reason for not using one drug from two of the following categories for at least 4 weeks each at a minimum effective dose: o Beta blockers (e.g. propranolol, timolol, etc.) o Amitriptyline or venlafaxine o Topiramate, divalproex ER or DR, or valproic acid

Revision/Review Date 10/2025	• If the diagnosis is **Overactive Bladder**, the member has tried and failed 2 formulary drugs (e.g. oxybutynin)
	• If the diagnosis is **Hyperhidrosis,** the member has tried and failed a prescription strength antiperspirant (e.g. 20% aluminum chloride hexahydrate)
	• If the diagnosis is **Chronic Sialorrhea,**
	  o Documentation is provided that the member has had sialorrhea lasting at least 3 months
	  o The member has tried and failed, or has a medical reason for not using, an anticholinergic medication (e.g. glycopyrrolate, hyoscyamine, benztropine)
	• If the request is for a non-preferred agent, the member tried and failed a preferred agent if appropriate for the requested indication
	
	For Reauthorization:
	• Documentation of provider attestation that demonstrates a clinical benefit
	• The requested drug is for a medically accepted dose as outlined in Covered Uses
	
	Physician/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	**Brineura (cerliponase alfa)**
Drugs	Brineura (cerliponase alfa)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert, and/or per the National Comprehensive Cancer Network (NCCN)
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	If the criteria are met, the request will be approved for 12 months.

Other Criteria	**Initial Authorization:**
	• Documentation of confirmed diagnosis of neuronal ceroid lipofuscinosis type 2 (CLN2) with one of the following:
	  o Lab results demonstrating deficient TPP1 enzyme activity
	  o Identification of causative mutations in the TPP1/CLN2 gene
	• Documentation of baseline CLN2 Clinical Rating Scale motor +language score. Baseline CLN2 score must be > 0.
	• Medication is prescribed at an FDA approved dose
	
	Re-authorization:
	• Documentation of CLN2 Clinical Rating Scale motor +language score has remained > 0
	• Medication is prescribed at an FDA approved dose

Revision/Review Date: 7/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	Brinsupri (brensocatib)
Drugs	Brinsupri (brensocatib)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist
Coverage Duration	If all the criteria are met, the initial and reauthorization request will be approved for 12 months
Other Criteria Revision/Review Date: 10/2025	**Initial Authorization:** • Diagnosis of bronchiectasis confirmed by chest CT scan • Documentation patient does not have Cystic Fibrosis • At least 2 exacerbations in the past 12 months requiring an antibiotic prescription, urgent care or emergency room visit, or hospitalization • Medication is prescribed at an FDA approved dose **Re-Authorization:** • Documentation or provider attestation of positive clinical response (i.e. decrease in cough, sputum production, exacerbations, etc.) • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Calcitonin Gene-Related Peptide (CGRP) Antagonists for Headache Prevention**
Drugs	**Preferred**: Emgality (galcanezumab) **Non-Preferred:** Aimovig (erenumab) Ajovy (fremanezumab) Vyepti (eptinezumab) Nurtec ODT (rimegepant) – if the request is for acute treatment of migraine please refer to the Acute Migraine Treatments criteria Qulipta (atogepant) and any newly marketed drug in the class
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Request for indication of chronic cluster headaches
Required Medical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, migraine specialist, pain specialist, or other specialist in the treatment of headaches
Coverage Duration	If the criteria are met, the initial authorization request will be approved for 6 months. Reauthorization may be approved for 6 months.
Other Criteria	**Criteria for Initial Authorization:** **Cluster Headache:** • Request for Emgality (galcanezumab) is for diagnosis of episodic cluster headache • If the request is for any other CGRP, do not approve; not indicated • Requested dose is within FDA approved dosing guidelines **Migraine Headache Prophylaxis**: • Diagnosis of episodic migraine as evidenced by number of headache days per month (4 to 14 migraine days per month) or chronic migraine (≥ 15 headache days per month with ≥ 8 migraine days per month). • Provider should note on the prior authorization request the number of headache days per month • Requested dose is within FDA approved dosing guidelines

Revision/Review Date: 4/2025	• Medication will not be used in combination with another CGRP inhibitor for either acute or preventative treatment of migraine
	
	AND
	
	• Trial and failure (or a medical justification for not using e.g. hypersensitivity, baseline bradycardia or hypotension, adverse events experienced from previous trial, etc.) with at least one of the following:
	  o Beta-adrenergic blockers
	  o Topiramate or divalproex ER or DR
	  o Amitriptyline or venlafaxine
	  o Frovatriptan, zolmitriptan or naratriptan (for menstrual migraine prophylaxis)
	
	AND
	
	• If the medication request is for a non-preferred CGRP Antagonist the patient has a documented medical reason (intolerance, hypersensitivity, contraindication, treatment failure etc.) for not using Emgality to treat their medical condition.
	
	<u>Criteria for Re-Authorization:</u>
	
	Episodic Cluster Headache:
	• Reduction in the frequency of headaches (clinical benefit)
	
	Migraine:
	• Reduction of ≥50% in the number of headache days per month relative to pre-treatment baseline (clinical benefit)
	• Provider should note on the prior authorization request the number of headache days per month
	• Medication will not be used in combination with another CGRP inhibitor for either acute or preventative treatment of migraine
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	**Camzyos**
Drugs	Camzyos (mavacamten)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	≥ 18 years
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.

Other Criteria	**Initial Authorization:**
	• Diagnosis of symptomatic New York Heart Association (NYHA) class II or III obstructive hypertrophic cardiomyopathy (oHCM)
	• Patient has a left ventricular ejection fraction (LVEF) ≥55%
	• Patient has a peak left ventricular outflow tract (LVOT) gradient ≥ 50 mmHg at rest or with provocation
	• Trial and failure or contraindication to ALL of the following:
	  o Beta blockers (i.e. metoprolol, propranolol, atenolol)
	  o Non-dihydropyridine calcium channel blockers (i.e. verapamil, diltiazem)
	• Prescriber attests that patient is not diagnosed with a disorder that causes cardiac hypertrophy that mimics oHCM (i.e., Fabry disease, amyloidosis, or Noonan syndrome with LV hypertrophy)
	• Prescriber attests that patient is not using moderate to strong CYP2C19 inducers, strong CYP2C19 inhibitors or CYP3A4 inducers
	• Medication is prescribed at an FDA approved dose
	Re-Authorization:
	• Documentation of clinical benefit as evidenced by an improvement in oHCM symptoms (i.e., improvement in shortness of breath, LVOT, peak oxygen consumption, etc.) from baseline OR improvement or no worsening of NYHA functional class from baseline
	• Patient has a left ventricular ejection fraction (LVEF) ≥50%
	• Medication is prescribed at an FDA approved dose

Revision/Review Date: 7/2025	**If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Carisoprodol**
Drugs	**Carisoprodol (Soma)**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Member 16 years of age or older.
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the requests for carisoprodol will be approved for a single fill for a maximum of 84 tablets for a 21 day supply.
Other Criteria Revision/Review Date 2/2025	**Initial Authorization**: • Member has had a trial and failure, or intolerance to, cyclobenzaprine, tizanidine, baclofen, or a nonsteroidal anti-inflammatory drug (NSAID) in the last 90 days; **AND** • If the member has previously received a carisoprodol containing drug within the past 90 days, then the provider attests the member has been screened for, and demonstrates no signs of, carisoprodol abuse **Re-Authorization**: • Documentation has been provided that states the member has been screened for, and demonstrates no signs of, carisoprodol abuse **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Chelating Agents**
Drugs	• **Chemet (succimer)** capsule, *up to a 19 day supply, pays at point of sale* • **Deferasirox (Exjade)** Tablet for Oral Suspension • **Deferasirox (Jadenu)** Tablet, Granule Pack • **Deferiprone (Ferriprox)** Tablet • **Ferriprox (Deferiprone)** solution • **Ferriprox (Twice a Day) (Deferiprone)** tablet • **Deferoxamine Mesylate (Desferal)** Vial • **Penicillamine (Cuprimine, Depen, D-penamine)** capsule, tablet • **Radiogardase (Prussian blue)** capsule • **Trientine (Syprine)** capsule • **Cuvrior (trientine tetrahydrochloride)** tablet • **Galzin (Zinc acetate)** capsule • **Pentetate calcium trisodium** ampule • **Pentetate zinc trisodium** ampule • **Calcium Disodium Versenate (edetate calcium disodium)** ampule
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	See "other criteria"
Prescriber Restrictions	N/A
Coverage Duration	If the above conditions are met, the request will be approved with a 6 month duration.
Other Criteria	**<u>Requests for deferasirox (Exjade, Jadenu) only:</u>** **Chronic iron overload due to blood transfusions:** <u>For Pediatric Population</u>**:** • Patient must be ≥ 2 years old and < 21 years old

	• Diagnosis of chronic iron overload due to blood transfusions • Patient receiving blood transfusions on a regular basis/participating in blood transfusion program • Serum Ferritin concentration is consistently > 1000 mcg/L. If the serum ferritin levels fall consistently below 500 mcg/L, deferasirox (Exjade, Jadenu) must be discontinued • If the request is for deferasirox oral granules in packet member has had a documented trial and failure of deferasirox dispersible tablets or medical reason why deferasirox dispersible tablets cannot be used • The medication requested is being prescribed at an FDA approved dose <u>For Adult Population</u>**:** • Patient must be ≥ 21 years old • Diagnosis of chronic iron overload due to blood transfusions • Patient receiving blood transfusions on a regular basis/participating in blood transfusion program • Serum Ferritin concentration is consistently > 1000 mcg/L. If the serum ferritin levels fall consistently below 500 mcg/L, deferasirox (Exjade, Jadenu) must be discontinued • Documented patient is unable to use deferoxamine (Desferal) parenterally • If the request is for deferasirox oral granules in packet member has had a documented trial and failure of deferasirox dispersible tablets or medical reason why deferasirox dispersible tablets cannot be used • The medication requested is being prescribed at an FDA approved dose **Chronic iron overload in non-transfusion dependent thalassemia Syndromes:** • Patient must be ≥ 10 years old • Diagnosis of thalassemia syndrome • Liver iron content (LIC) by liver biopsy of ≥ 5 mg Fe/g dry weight • ≥ 2 measurements of serum ferritin levels > 300mcg/L at least one month apart

	• If the request is for deferasirox oral granules in packet member has had a documented trial and failure of deferasirox dispersible tablets or medical reason why deferasirox dispersible tablets cannot be used • The medication requested is being prescribed at an FDA approved dose **<u>Requests for Ferriprox (deferiprone) only:</u>** **<u>Transfusion Iron overload due to thalassemia syndrome, sickle cell disease, or other anemias</u>** • Patient must be ≥ 3 years old for oral solution OR ≥ 8 years old for tablets • Diagnosis of thalassemia syndrome, sickle cell disease, or other anemia • Patient receiving blood transfusions on a regular basis/participating in blood transfusion program • Serum Ferritin concentration is consistently > 1000 mcg/L. If the serum ferritin levels fall consistently below 500 mcg/L, Ferriprox must be discontinued • Documentation patient is unable to use deferoxamine (Desferal) parenterally • Documented trial and failure of deferasirox (Exjade, Jadenu) or medical reason why deferasirox cannot be used • If the request is for deferiprone 1,000 mg tablet there is a documented medical reason why deferiprone 500 mg tablet cannot be used • If the request is for Ferriprox Twice a Day there is a documented medical reason why deferiprone 500 mg tablet and deferiprone 1,000 mg tablet cannot be used • The medication requested is being prescribed at an FDA approved dose **<u>Requests for Wilson's Disease:</u>** **Cuvrior (trientene tetrahydrochloride) only**: • Laboratory confirmed diagnosis of Wilson's disease supported by at least one appropriate diagnostic test (e.g., slit lamp examination, 24-urinary copper excretion, serum ceruloplasmin, serum copper concentration, liver biopsy, genetic testing, brain imaging, etc.)

	• Patient is de-coppered • Patient is tolerant to penicillamine and will discontinue penicillamine before starting therapy with Cuvrior • The medication requested is being prescribed at an FDA approved dose **Trientene (Syprine) only:** • Laboratory confirmed diagnosis of Wilson's disease supported by at least one appropriate diagnostic test (e.g., slit lamp examination, 24-urinary copper excretion, serum ceruloplasmin, serum copper concentration, liver biopsy, genetic testing, brain imaging, etc.) • Documented trial and failure, intolerance, or contraindication to penicillamine • The medication requested is being prescribed at an FDA approved dose **<u>Requests for all other drugs and indications:</u>** • The drug is requested for an appropriate use (per the references outlined in "Covered Uses") • The dose requested is appropriate for the requested use (per the references outlined in "Covered Uses") **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**
Revision/Review Date 7/2025	

Prior Authorization Group Description	**Cholbam**
Drugs	**Cholbam (cholic acid)**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	MD is a gastroenterologist OR hepatologist
Coverage Duration	If all of the conditions are met, the request will be approved for a 3 month duration for the first year of therapy, and then for a 6 month duration after one year of treatment.
Other Criteria	<u>Initial authorization:</u> • Patient has a confirmed diagnosis of: ➢ Bile acid synthesis disorder due to single enzyme defect (SEDs) OR ➢ Peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients that exhibit manifestations of liver disease, steatorrhea or complications from decreased fat soluble vitamin absorption • Current labs (within 30 days of request) have been submitted for the following: ➢ ALT/AST ➢ GGT (serum gamma glutamyltransferase) ➢ ALP (Alkaline phosphatase) ➢ Bilirubin ➢ INR <u>Re-authorization:</u> • Documentation has been submitted indicating clinical benefit/ liver function has improved since beginning treatment • For reauthorization after the first 3 months of treatment, lab results must show an improvement in liver function and there must be no evidence of biliary obstruction or cholestasis • Current labs (within 30 days of request) have been submitted for the following: ➢ ALT/AST

Revision/Review Date 10/2025	➢ GGT (serum gamma glutamyltransferase) ➢ ALP (Alkaline phosphatase) ➢ Bilirubin ➢ INR **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Chronic Dry Eye Agents**
Drugs	**<u>FORMULARY STATUS</u>** Preferred, Pays at Point-of-Sale **ARTIFICIAL TEARS (Glycerin-Peg) 1 %-0.3 % Eye Drops** **POLYVINYL ALCOHOL 1.4 % Eye drops** **REFRESH TEARS 0.5 % Eye Drops** **<u>FORMULARY STATUS</u>** Requires Step Therapy with one prior step **CYCLOSPORINE 0.05% (RESTASIS) DROPPERETTE** **Note: Patient must meet criteria #1 & #2 for approval of the PA request.** **<u>FORMULARY STATUS</u>** Requires Step Therapy with two prior steps **CEQUA 0.09% EYE DROPS** **MIEBO EYE DROPS** **TYRVAYA NASAL SPRAY** **XIIDRA 5% EYE DROPS** **Note: Patient must meet criteria #1, #2 & #3 for approval of the PA request.**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 7/2025	**<u>Initial Authorization:</u>** 1. Presumed or documented diagnosis of chronic dry eye 2. Documented trial and failure or intolerance with a formulary artificial tears product for a minimum of 3 weeks within past 60 days 3. Documented trial and failure or medical reason why member cannot use cyclosporine 0.05% dropperette

Field Name	Field Description
Prior Authorization Group Description	**Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Agents**
Drugs	Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase) **If the request is for an immunoglobulin for CIDP, please refer to the Immune Globulins criteria**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Per FDA-approved labeling
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or neuromuscular specialist.
Coverage Duration	If all of the criteria are met, the initial request will be approved for 3 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Date: 10/2025	**Initial Authorization:** • Diagnosis of CIDP confirmed by electrodiagnostic test results (e.g. electromyography or nerve conduction studies) • Patient has progressive or relapsing/remitting disease course for ≥2 months • Patient has an inadequate response, significant intolerance, or contraindication to intravenous immunoglobulin (IVIG) or subcutaneous immunoglobulin (SCIG) • Medication is prescribed at an FDA approved dose **Re-Authorization:** • Documentation or provider attestation of significant clinical improvement in neurologic symptoms or stabilization of disease • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Prior Authorization Group Description	**Ciprodex**
Drugs	**Ciprofloxacin/dexamethasone (Ciprodex) 0.3%-0.1%Otic Suspension**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restriction	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If criteria are met, the request will be approved for up to a 3 month duration.
Other Criteria Revision/Review Date: 10/2025	**<u>Acute otitis externa:</u>** • Documented trial and failure, contraindication, or intolerance to two of the following: ofloxacin otic, Acetic acid 2% ear solution or Neomycin/Polymixin B/Hydrocortisone otic drops. **OR** • Prescribing provider is an ear, eye, nose and throat (EENT) physician **<u>Acute otitis media in patients with tympanostomy tubes</u>:** • Documented trial and failure, contraindication, or intolerance to ofloxacin otic drops **OR** • Prescribing provider is an ear, eye, nose and throat (EENT) physician **NOTE: Medical Director/Clinical Reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary**

Field Name	Field Description
Prior Authorization Group Description	Cobenfy
Drugs	Cobenfy (xanomeline and trospium chloride)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescriber must be a psychiatrist or in consultation with a psychiatrist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Date: 2/2025	**Initial Authorization:** • Diagnosis of schizophrenia, consistent with the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) criteria. • Documented trial and failure with two alternative formulary/preferred antipsychotic agents, or a medical reason is provided for not using any typical or atypical antipsychotic agents. • Medication is prescribed at an FDA approved dose. • Provider attestation is provided patient does not have any of the following: o Moderate (Child-Pugh Class B) or severe (Child-Pugh Class C) hepatic impairment o Untreated Narrow-Angle Glaucoma o Urinary Retention o Gastric Retention **Re-Authorization:** • Documentation or provider attestation of positive clinical response (i.e. improvement in positive and/or negative symptoms of schizophrenia) • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Colchicine**
Drugs	**Formulary Status:** Preferred, requires step therapy Colchicine (Colcrys) tablets **Formulary Status:** Non-preferred, requires prior authorization Colchicine (Mitigare) capsules Gloperba (colchicine) solution
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 4/2025	*****For requests for Lodoco, please refer to the "Lodoco" policy***** • Presumed or documented diagnosis of gout • Documented trial and failure or intolerance with a preferred NSAID/COX-2 inhibitor, preferred oral corticosteroid, allopurinol, probenecid, probenecid/colchicine, or colchicine tablets for a minimum of one week of therapy in the previous 3 months • If the request if Gloperba there is a documented medical reason why colchicine tablets or capsules cannot be used **Note: Colchicine tablets may be approved as a first line agent if the request is for a diagnosis of Familial Mediterranean Fever or Pericarditis** **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Complement Inhibitors**
Drugs	Empaveli (pegcetacoplan), Fabhalta (iptacopan), Izervay (avacincaptad pegol injection), Soliris (eculizumab), Syfovre (pegcetacoplan injection), Ultomiris (ravulizumab), Voydeya (danicopan), PiaSky (crovalimab-akkz), BKEMV (eculizumab-aeeb), Epysqli (eculizumab-aagh)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a hematologist, nephrologist, neurologist, oncologist, ophthalmologist, or other appropriate specialist.
Coverage Duration	If the criteria are met, the criteria will be approved as follows: Initial Requests • 3 months: eculizumab (Soliris, BKEMV, Epysqli), Ultomiris (ravulizumab), Empaveli (pegcetacoplan), Voydeya (danicopan) • 6 months: Fabhalta (iptacopan). PiaSky (crovalimab-akkz) • 12 months: Syfovre (pegcetacoplan), Izervay (avacincaptad pegol) Reauthorization • 6 months: eculizumab (Soliris, BKEMV, Epysqli), Ultomiris (ravulizumab), Empaveli (pegcetacoplan), Voydeya (danicopan) • 12 months: Syfovre (pegcetacoplan), Fabhalta (iptacopan), PiaSky (crovalimab-akkz) No Reauthorization Izervay (avacincaptad pegol)
Other Criteria	**<u>Initial Authorization:</u>** • The request is for a dose that is FDA approved or in nationally recognized compendia in accordance with the patient's diagnosis, age, body weight, and concomitant medical conditions; **AND** • For Fabhalta (iptacopan), eculizumab (Soliris, BKEMV, Epysqli), Ultomiris (ravulizumab), Empaveli (pegcetacoplan), PiaSky (crovalimab-akkz), and Voydeya (danicopan) o Documentation patient complies with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria. • For Soliris or BKEMV, patient must have a documented trial and failure or intolerance to Epysqli or a medical reason why Epysqli cannot be used. **Paroxysmal Nocturnal Hemoglobinuria (PNH):** • Documentation of diagnosis by high sensitivity flow cytometry

Revision/Review Date 7/2025	• Presence of 1 or more of the following PNH-related signs or symptoms:
	  o Fatigue, hemoglobinuria, abdominal pain, shortness of breath (dyspnea), anemia, history of a major adverse vascular event (including thrombosis), dysphagia, erectile dysfunction, or history of pRBC transfusion due to PNH.
	•
	• Adults: For Ultomiris (ravulizumab), Empaveli (pegcetacoplan), Fabhalta (iptacopan), or PiaSky (crovalimab-akkz) patient must have a documented trial and failure or intolerance to Epysqli or a medical reason why Epysqli cannot be used.For Voydeya (danicopan):
	  o Member has been receiving eculizumab (Soliris, BKEMV, Epysqli) or Ultomiris (ravulizumab) therapy for at least 6 months
	  o Member has clinically evident extravascular hemolysis [defined as anemia (Hgb ≤9.5 gram/deciliter) with absolute reticulocyte count ≥120 x 10^9/liter] despite treatment with eculizumab (Soliris, BKEMV, Epysqli) or Ultomiris (ravulizumab)
	  o Voydeya (danicopan) will be used as add-on therapy to eculizumab (Soliris, BKEMV, Epysqli) or Ultomiris (ravulizumab)
	
	Generalized Myasthenia Gravis (gMG):
	• Refer to the "Myasthenia Gravis Agents" policy
	
	Neuromyelitis Optica Spectrum Disorder (NMOSD)
	• Refer to the "Neuromyelitis Optica Spectrum Disorder (NMOSD) Agents" policy
	
	IgA Nephropathy:
	• Refer to the "IgA Nephropathy Agents" policy
	
	Atypical Hemolytic Uremic Syndrome (aHUS)/Complement-Mediated HUS)
	• Documentation of confirmed diagnosis as evidenced by complement genotyping and complement antibodies; **OR**
	• Provider attestation treatment is being used empirically and delay in therapy will lead to unacceptable risk to the patient
	
	Geographic Atrophy (GA):
	• If the request is for Syfovre (pegcetacoplan injection), member must be ≥ 60 years of age
	• If the request is for Izervay (avacincaptad pegol injection), member must be ≥ 50 years of age
	• Diagnosis of GA secondary to age-related macular degeneration (AMD)
	• Absence of choroidal neovascularization (CNV) in treated eye

	• Best-corrected visual acuity (BCVA) of 24 letters (approximately 20/320) or better using Early Treatment Diabetic Retinopathy Study (ETDRS) • GA lesion size ≥ 2.5 and ≤ 17.5 mm^2 with at least 1 lesion ≥ 1.25 mm^2 **Complement 3 Glomerulopathy (C3G):** • Diagnosis of C3G as confirmed by renal biopsy • Patient's serum C3 level is reduced (defined as less than 0.85 x lower limit of the central laboratory normal range) • Patient's urine protein to creatinine ratio (UPCR) is ≥ 1.0 g/g • Patient has an eGFR ≥ 30 mL/min/1.73 m^2 • Patient has been taking maximally recommended or tolerated dose of an angiotensin converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB) for at least 90 days, or a medical reason is provided why this is inappropriate • Patient has a trial and therapy failure of mycophenolate and glucocorticoids, or a medical reason is provided why this is inappropriate. • Patient does not have recurrent C3G post kidney transplant **<u>Re-Authorization:</u>** • Re-authorization may be considered for all agents included in these criteria with the exception of Izervay (avacincaptad pegol injection), which is only indicated for a 12 month duration • Provider has submitted documentation of clinical response to therapy (e.g., reduction in disease severity, improvement in quality of life scores, increase in Hgb, reduced need for blood transfusions, slowing of growth rate of GA lesions, etc.); **AND** • The request is for a dose that is FDA approved or in nationally recognized compendia in accordance with the patient's diagnosis, age, body weight, and concomitant medical condition; **AND** • If the request is for aHUS/Complement Mediated HUS o Documentation of confirmed diagnosis as evidenced by complement genotyping and complement antibodies **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Continuous Glucose Monitors**
Drugs	Preferred: Freestyle Libre 14 Day, Freestyle Libre 2, FreeStyle Libre 3, Dexcom G6, Dexcom G7 Non-Preferred: Eversense (Sensor, Transmitter, and Reader components) And any newly marketed product in this class **This policy does not apply to continuous glucose monitor/insulin pump combination products reviewed and/or covered by the Medical Benefit including, but not limited to, the MiniMed. Requests for these products are referred to the plan's Utilization Management team for Review**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Patient must be age appropriate per prescribing information (PI)
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Other Criteria	• Diagnosis – diabetes • Meets criteria #1 or #2: o Treatment with insulin o Member has a risk for preventable complications of diabetes and there is clear medical benefit from full-time or episodic continuous glucose monitoring AND one of the following: ▪ HbA1C greater than 7% within the last 6 months ▪ History of recurring hypoglycemia, history of severe glycemic excursions, a wide fluctuation in blood glucose before mealtime or a marked early morning increase in fasting blood sugar • If the request is for a non-preferred product, trial and failure of or medical reason why patient cannot use a preferred product. • If member is continuing use of a non-preferred CGM, trial of a preferred CGM first is not required

Revision/Review Date 7/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Corlanor**
Drugs	Corlanor (ivabradine)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Pregnancy
Required Medical Information	See "Other Criteria"
Age Restrictions	See "Other Criteria"
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist
Coverage Duration	If all of the conditions are met, the request will be approved for 12 month duration.
Other Criteria	**Heart Failure in Adult Patients:** 1. Member is aged 18 years or older 2. Member has a diagnosis of stable symptomatic chronic heart failure (NYHA functional class II-IV) with a left ventricular ejection fraction ≤ 35% 3. Member is in sinus rhythm with a resting heart rate ≥ 70 beats per minute (bpm) 4. Member is currently being prescribed, or documentation has been provided that the member is not able to tolerate, an evidence based beta-blocker (i.e., bisoprolol, carvedilol, metoprolol succinate) at maximally tolerated dose **Heart Failure in Pediatric Patients:** 1. Member is aged 6 months to less than 18 years of age 2. Member has stable heart failure (NYHA/Ross functional class II-IV) due to dilated cardiomyopathy and a left ventricular ejection fraction ≤ 45% 3. Member is in sinus rhythm with an elevated resting heart rate
Revision/Review Date 2/2025	**Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Corticosteroids for Duchenne Muscular Dystrophy (DMD)**
Drugs	**Agamree (vamorolone)** **Deflazacort (Emflaza)**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Patient must be 2 years of age or older
Prescriber Restrictions	Prescribed by a neurologist, provider who specializes in the treatment of DMD, or in consultation with a neurologist of provider who specialized in the treatment of DMD
Coverage Duration	If all of the conditions are met, the initial request will be approved for a 6 month duration. For reauthorization, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 2/2025	**Initial Authorization:** • Confirmed diagnosis of Duchenne Muscular Dystrophy (such as documented mutation of dystrophin gene, genetic sequencing indicating mutations attributed to Duchene Muscular Dystrophy, muscle biopsy indicating absence of dystrophin protein, etc.), and copies of testing were submitted with request • Trial and failure with prednisone for at least 12 months, and documented medical reason why prednisone cannot be continued • The request is for an FDA approved dose **Reauthorization:** • Documentation or attestation of clinical benefit (such as improved muscle strength, muscle function, or overall symptom improvement) • The request is for an FDA approved dose **Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Corticotropin**
Drugs	**Preferred:** Cortrophin (corticotropin) **Non-Preferred:** Acthar (corticotropin)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• N/A
Required Medical Information	See "other criteria"
Age Restrictions	See "other criteria"
Prescriber Restrictions	See "other criteria"
Coverage Duration	If the criteria are met, the request will be approved for up to a 1 month duration.
Other Criteria	**Infantile Spasms (West Syndrome):** • Patient is < 2 years of age • The medication is being prescribed by a neurologist. • Documentation of the patient's current weight (in kg) and height/length (in cm) or body surface area (BSA) **Multiple Sclerosis:** • Documentation was submitted that patient is having an acute attack, with neurologic symptoms and increased disability or impairments in vision, strength or cerebellar function, and has failed therapy with intravenous (IV) methylprednisolone, or a medical reason has been submitted why patient is unable to use IV methylprednisolone. • The medication is being prescribed by a neurologist • If the request is for a non-preferred product, trial and failure of, contraindication to, or medical reason for not using the preferred product **All Other FDA Approved Conditions and Indications:** • Documented trial and failure of an IV corticosteroid AND an oral corticosteroid, or documented medical reason for why the patient cannot use these therapies for treatment • Documentation was provided that ALL other standard therapies have been used to treat the member's condition as described in the medical compendium (Micromedex, AHFS, Drug Points, and package insert) as defined in the Social Security Act and/or per recognized standard of care guidelines OR there is a

Revision/Review Date 7/2025	documented medical reason (i.e. medical intolerance, treatment failure, etc.) for why all other standard therapies could not be used to treat the member's condition. • Prescriber is a specialist in the condition they are treating. • If the request is for a non-preferred product, trial and failure of, contraindication to, or medical reason for not using the preferred product **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	Crenessity
Drugs	Crenessity (crinecerfont)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Patients with non-classic congenital adrenal hyperplasia (CAH) • Patients with adrenal insufficiency due to causes other than 21-hydroxylase deficiency
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by, or in consultation with, an endocrinologist or other specialist experienced in managing congenital adrenal hyperplasia
Coverage Duration	If all the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	**Initial Authorization:** • Medically confirmed diagnosis of classic 21-hydroxylase deficiency congenital adrenal hyperplasia (CAH) • Patient is currently on stable regimen of glucocorticoid therapy at a supraphysiological dose (i.e. >13 mg/m2/day in hydrocortisone dose equivalents for adults and >12 mg/m2/day in hydrocortisone dose equivalents for pediatric patients 4-17 years old) • Medication is prescribed at an FDA approved dose according to package insert (patient's current weight must be provided) • For all adults and pediatric patients weighing ≥55 kg or patients weighing ≥20 kg if CYP3A4 dose adjustment is required: capsule formulation is requested, or documentation is provided that patient is unable to swallow capsule whole • Dosing requests for capsule formulations will employ strategies to minimize the total number of capsules used daily (i.e. "doubling up" on lower strength capsules to achieve a higher dose when the requested dose strength exists will not be authorized). **Re-Authorization:** • Documentation is provided that patient has successfully achieved a reduction in glucocorticoid dosage from baseline.

Date: 4/2025	• Medication is prescribed at an FDA approved dose according to package insert (patient's current weight must be provided) • For all adults and pediatric patients weighing ≥55 kg or patients weighing ≥20 kg if CYP3A4 dose adjustment is required: capsule formulation is requested, or documentation is provided that patient is unable to swallow capsule whole • Dosing requests for capsule formulations will employ strategies to minimize the total number of capsules used daily (i.e. "doubling up" on lower strength capsules to achieve a higher dose when the requested dose strength exists will not be authorized). **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review**.

Field Name	Field Description
Prior Authorization Group Description	**Crinone**
Drugs	**Crinone (micronized progesterone)**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved for 30 single use applicators per 30 days until the end of pregnancy if the diagnosis is the prevention of spontaneous preterm delivery (singleton pregnancy and prior preterm birth or short cervix), or for up to 6 single use applicators if the diagnosis is secondary amenorrhea.
Other Criteria Revision/Review Date 7/2025	<u>Prevention of spontaneous preterm delivery:</u> • Patient has singleton pregnancy and prior preterm birth or short cervix <u>Secondary Amenorrhea:</u> • Patient has a diagnosis of secondary amenorrhea • Patient has tried and failed, or has contraindication or intolerance to, oral progestin therapy (e.g. medroxyprogesterone acetate, norethindrone acetate tablets, micronized progesterone) • If the request is for Crinone 8% gel the patient has tried and failed, or has a contraindication or intolerance to, Crinone 4% gel **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	Ctexli (chenodiol)
Drugs	Ctexli (chenodiol)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Concurrent use with Chobalm (cholic acid)
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, endocrinologist, or specialist in metabolic disorders.
Coverage Duration	If all the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Date: 7/2025	**Initial Authorization:** • Medication is prescribed at an FDA approved dose • Diagnosis of cerebrotendinous xanthomatosis (CTX) confirmed by genetic testing that detects variants in the CYP27A1 gene (copies of test must be submitted with request) **Re-Authorization:** • Documentation or provider attestation of positive clinical response (i.e. stabilization of cognitive development, improvement in laboratory abnormalities [i.e. urine 23S-pentol and plasma cholestanol], etc.) • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Prior Authorization Group Description	**Cystic Fibrosis transmembrane conductance regulator (CFTR) Modulators**
Drug(s)	Kalydeco, Kalydeco Granules (ivacaftor), Orkambi, Orkambi Granules (lumacaftor/ivacaftor), Symdeko (tezacaftor/ivacaftor), Trikafta (elexacaftor/tezacaftor/ivacaftor), Alyftrek (vanzacaftor/ tezacaftor/ deutivacaftor) or any newly marketed CFTR modulator to treat cystic fibrosis
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	See "Other Criteria"
Required Medical Information	See "Other Criteria"
Age Restrictions	See "Other Criteria"
Prescriber Restrictions	Prescriber is pulmonologist or specializes in the treatment of cystic fibrosis
Coverage Duration	If all of the conditions are met the initial request will be 6 months. Reauthorization requests will be 12 months.
Other Criteria Review/Revision Date 4/2025	<u>Initial criteria:</u> • Documentation provided includes a copy of the FDA-cleared cystic fibrosis (CF) mutation test OR documentation from the National Cystic Fibrosis Registry (e.g. screen shot) with member's genetic mutations • The request is for an FDA approved indication for the member's genotype and within dosing guidelines • The request is appropriate for member (e.g. age/weight) based on FDA-approved package labeling, peer reviewed medical literature and nationally-recognized compendia. <u>Reauthorization:</u> • Based on prescriber's assessment, patient continues to benefit from therapy • The request is within FDA dosing guidelines **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Dalfampridine**
Drugs	dalfampridine (Ampyra) tablets
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• History of seizures Moderate or severe renal impairment (creatinine clearance ≤ 50mL/minute)
Required Medical Information	See "other criteria"
Age Restrictions	Patient must be 18 years of age or older
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	If all of the conditions are met, the initial request will be approved for 6 month duration. Requests for reauthorization will be approve for 12 months.
Other Criteria	**Initial Authorization:** • Baseline creatinine clearance (within 60 days of request) • Patient has diagnosis of multiple sclerosis (MS) • Patient is ambulatory AND has a walking impairment • Baseline 25 foot walk was submitted with request • Documentation was submitted (consistent with pharmacy claims data, OR for new members to the health plan, consistent with chart notes) that patient is currently being treated with a disease modifying therapy (DMT) for MS (e.g. immunomodulator, interferon, immunosuppressive), or documentation of a medical reason (intolerance, hypersensitivity) as to why patient is unable to use one of these agents to treat their medical condition • Drug is being requested at an FDA approved dose **Re-authorization:** • Prescriber attests patient's walking has improved with dalfampridine therapy • Documentation was submitted patient is on a DMT for MS (e.g. immunomodulator, interferon, immunosuppressive), or documentation of a medical reason (intolerance, hypersensitivity) as to why patient is unable to use one of these agents to treat their medical condition • Drug is being requested at an FDA approved dose

Revision/Review Date 10/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Danazol**
Drugs	**Danazol** capsules
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Pregnancy
Required Medical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	See "other criteria"
Coverage Duration	If the criteria are met, the request will be approved with a 6 month duration for generic medication.
Other Criteria Revision/Review Date 10/2025	**ENDOMETRIOSIS** o Diagnosis of endometriosis o One of the following: o Documented trial and failure or medical reason for not using an analgesic pain reliever (e.g., NSAIDs, COX-2 inhibitors) taken in combination with a hormonal contraceptive (e.g. estrogen/progestin, progestin only) o Documented trial and failure of a gonadotropin-releasing hormone (GnRH) agonists or a GNRH antagonist. o Prescribing physician is a gynecologist. **HEREDITARY ANGIOEDEMA:** o Diagnosis of hereditary angioedema. o Prescriber is an immunologist, allergist, rheumatologist, or hematologist **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Daraprim**
Drugs	**pyrimethamine (Daraprim)**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Patients with documented megaloblastic anemia due to folate deficiency.
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be an appropriate specialist or documentation has been provided that prescriber has consulted with an appropriate specialist (i.e. infectious disease, OB/GYN).
Coverage Duration	If all of the conditions are met, congenital toxoplasmosis requests will be approved for 12 months, and all other requests will be approved for 3 months-at a time.
Other Criteria Revision/ Review Date 10/2025	**Congenital Toxoplasmosis** • Diagnosis of congenital toxoplasmosis **Acquired Toxoplasmosis** • Diagnosis of acquired toxoplasmosis • Prescribed in combination with leucovorin and either a sulfonamide or clindamycin **Patients with Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS)** • Diagnosis of Toxoplasmosis OR • Both of the following: o Medication is being prescribed for one of the following: ▪ Toxoplasmosis prophylaxis ▪ Cystoisosporiasis ▪ Pneumocystis jiroveci pneumonia prophylaxis/treatment o Documented medical reason why (e.g. intolerance, hypersensitivity, contraindication) sulfamethoxazole/trimethoprim cannot be used **Hematopoietic Cell Transplantation Recipients** • Medication prescribed for Toxoplasmosis prophylaxis • Documentation of medical reason why sulfamethoxazole/trimethorprim cannot be used **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Daybue (trofinetide)**
Drugs	Daybue (trofinetide)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or geneticist
Coverage Duration	If all the criteria are met, the initial request will be approved for 3 months. For continuation of therapy, the request will be approved for 6 months.
Other Criteria Revision/Review Date 7/2025	**Initial Authorization:** • Medication is prescribed at an FDA approved dose • Diagnosis of classic or typical Rett Syndrome (RTT) • Documentation or attestation of mutation of the MECP2 gene • Documentation of patient weight • Documentation or provider attestation of all the following: o RTT Clinical Severity Scale rating of 10–36 o Clinical Global Impression–Severity (CGI-S) score of ≥4 o Baseline Rett Syndrome Behavior Questionnaire (RSBQ) score **Re-Authorization:** • Documentation or provider attestation of positive clinical response (i.e., decrease from baseline in RSBQ score, decrease in Clinical Global Impression–Improvement (CGI-I, etc.) • Medication is prescribed at an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Dendritic Cell Tumor Peptide Immunotherapy**
Drugs	Provenge (sipuleucel-T)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Small cell/neuroendocrine prostate cancer
Required Medical Information	See "Other Criteria"
Age Restrictions	See "Other Criteria"
Prescriber Restrictions	Prescriber must be an oncologist or urologist
Coverage Duration	If all the criteria are met, the request will be approved for 3 doses per lifetime

Other Criteria
 	
Revision/Review Date 4/2025
	<u>Initial Authorization:</u>
	• Metastatic castrate resistant (hormone-refractory) prostate cancer (mCRPC) (consistent with medical chart history)
	  o Evidenced by soft tissue and/or bony metastases
	  o Patient does NOT have
	  ▪ M0CRPC (defined as CRPC whose only evidence of disseminated disease is an elevated serum PSA) is not authorized
	  ▪ Visceral metastases (e.g. liver, lung, adrenal, peritoneal, brain)
	• Patient is not currently being treated with systemic immunosuppressants (e.g. chemotherapy, corticosteroids) or, if the patient is being treated with immunosuppressants, the prescriber has provided a valid medical reason for combination therapy
	• Eastern Cooperative Oncology Group (ECOG) score 0-1
	• Serum testosterone <50 ng/dL (e.g. castration levels of testosterone)
	• Predicted survival of at least six months
	<u>Reauthorization:</u>
	• Treatment exceeding 3 doses per lifetime will not be authorized
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	**Desmopressin nasal spray**
Drugs	**Desmopressin** 1.5 mg/mL nasal spray
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	≥ 11 months
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 10/2025	**<u>Initial Authorization</u>** One of the following: • Diagnosis of Hemophilia A with Factor VIII coagulant activity levels greater than 5%. • Hemophilia A carrier • Diagnosis of mild to moderate Type 1 (classic) von Willebrand's disease with Factor VIII coagulant activity levels greater than 5%. • Diagnosis of mild to moderate Type 2A, 2M, or 2N von Willebrand's disease and documentation of a desmopressin trial and response o A single unit of desmopressin nasal spray will be approved for a desmopressin trial **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Dificid (fidaxomicin)**
Drugs	Dificid (fidaxomicin)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, an infectious disease specialist or gastroenterologist
Coverage Duration	If the criteria are met, the request will be approved for up to a 10-day duration.
Other Criteria Revision/Review Date: 7/2025	**<u>Authorization for initial Clostridium difficile infection:</u>** 1. Documentation provided for intolerance or medical reason why patient is unable to use oral vancomycin 2. Dose requested follows FDA labeling **<u>Authorization for recurrent Clostridium difficile infection:</u>** 1. Documentation provided that patient has tried oral vancomycin for management of Clostridium difficile infection 2. Dose requested follows FDA labeling **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Dojolvi**
Drugs	Dojolvi (triheptanoin)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescriber is a specialist in the treatment of the indicated condition
Coverage Duration	Initial: 6 months Renewal: 12 months

Other Criteria	**Initial Authorization:**
	• Member has a molecularly confirmed diagnosis of a long-chain fatty acid oxidation disorder (LC-FAOD)
	• Documentation of at least two of the following:
	  o Disease specific elevation of acylcarnitines on a newborn blood spot or in plasma
	  o Low enzyme activity in cultured fibroblasts
	  o One or more known pathogenic mutations in either the *CPT2, ACADVL, HADHA, or HADHB* gene
	• Attestation or documentation member will not be receiving any other medium-chain triglyceride products while taking Dojolvi
	• Documentation of member's daily caloric intake (DCI)
	• Dose is within FDA-indicated limits and does not exceed 35% of DCI
	
	Re-Authorization:
	• Documentation submitted indicating the member has experienced a clinical benefit (e.g. increased left ventricular ejection fraction, reduced left ventricular wall mass, reduced maximum heart rate, decreased incidence of rhabdomyolysis)
	• Documentation of member's DCI
	• Dose is within FDA-indicated limits and does not exceed 35% of DCI

Revision/Review Date: 2/2025	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	**Donepezil**
Drugs	**<u>FORMULARY STATUS</u>** Formulary, Pays at Point-of-Sale **DONEPEZIL TABLETS AND DISINTEGRATING TABLETS 5MG AND 10MG** **<u>FORMULARY STATUS</u>** Requires Step Therapy with one prior step **DONEPEZIL 23MG TABLET** **Note: Patient must meet criteria #1 & #2 for approval of the PA request.**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to 12 month duration for.
Other Criteria Revision/Review Date: 10/2025	**<u>Initial Authorization:</u>** 1. Presumed or documented diagnosis of dementia or Alzheimer disease 2. Documented trial and failure or intolerance with donepezil disintegrating or non-disintegrating 5 or 10mg tablet for a minimum of 3 weeks within past 60 days

Field Name	Field Description
Prior Authorization Group Description	**Dose Rounding Limit Exception Criteria**
Drugs	**Bevacizumab products (Avastin, Mvasi, Zirabev, Vegzelma, Alymsys)** ***for oncologic indications***
Covered Uses	All medically accepted indications. Medically accepted indications are defined using the following compendia resources: the Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), American Hospital Formulary Service Drug Information (AHFS-DI), and DRUGDEX Information System. The reviewer may also reference disease state specific standard of care guidelines.
Scope	Requests for drugs exceeding the health plan's dose rounding limits. For members 18 years of age and older, the dose will be rounded down to the nearest whole vial size if the rounded dose falls within 10% of the requested dose.
Criteria	• If the drug is subject to other criteria, the member must meet criteria for approval. • The provider has submitted justification why the dose-rounding will be inadequate based on the member's condition and treatment history. Exceptions may include but are not limited to: o Member previously demonstrated a suboptimal or partial response to therapy at a rounded dose o Rounded dose is unavailable due to manufacturer supply/shortage issues o Provider has a documented medical reason why dose rounding is inappropriate for the member **Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.**
Coverage Duration	6 months
Revision/Review Date	2/2025

Field Name	Field Description
Prior Authorization Group Description	**Doxylamine/Pyridoxine**
Drugs	Doxylamine 10 mg/Pyridoxine 10 mg (Diclegis) Bonjesta (doxylamine 20 mg/pyridoxine 20 mg)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be an obstetrician/gynecologist
Coverage Duration	If the criteria are met, the request will be approved for up to 9 (nine) months or the expected remaining duration of the pregnancy.
Other Criteria Revision/Review Date2/2025	**Initial authorization:** • Diagnosis of nausea and vomiting due to pregnancy. **AND** • The member has tried and failed, or has an intolerance to, combination therapy with pyridoxine (vitamin B_6) and doxylamine single-ingredient products. **AND** • If the request is for Bonjesta, the member has tried and failed, or has an intolerance to, doxylamine 10 mg/pyridoxine 10 mg **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Duvyzat**
Drugs	Duvyzat (givinostat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or provider who specializes in the treatment of Duchenne Muscular Dystrophy (DMD)
Coverage Duration	If all the criteria are met, the initial request will be approved for 12 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Review/Revision Date: 7/2025	**Initial Authorization:** • Medication is prescribed at an FDA approved dose according to body weight • Genetically confirmed diagnosis of DMD and copies of testing were submitted with request • Patient has been stable on baseline corticosteroids for at least 6 months • Patient is ambulatory • Patient's platelet count is $\geq 150 \times 10^9$/L **Re-Authorization:** • Documentation or provider attestation of positive clinical response (such as improved muscle function, muscle strength, or disease stabilization) • Patient is on concurrent corticosteroid treatment • Patient is ambulatory • Medication is prescribed at an FDA approved dose according to body weight **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Emergency Use Authorization (EUA) Drugs/Products for COVID-19**
Drugs	Any drug/product approved by EUA for COVID-19
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Emergency Use Authorization for the drug/product in question, and the Drug Package Insert (PPI).
Exclusion Criteria	See "Other Criteria"
Required Medical Information	See "Other Criteria"
Age Restrictions	As outlined within current FDA Emergency Use Authorization (EUA) guidelines
Prescriber Restrictions	N/A
Coverage Duration	As outlined within current FDA Emergency Use Authorization (EUA) guidelines
Other Criteria	Emergency Use Authorization for COVID-19 related drugs/products (all must apply): • The requested drug/product has a currently active Emergency Use Authorization as issued by the U.S. Food and Drug Administration. • Use of the requested drug/product is consistent with the current terms and conditions of the emergency use authorization (such as appropriate age/weight, formulation, disease severity, concurrent use with other medications or medical interventions, etc.). • Attestation that the provider is not requesting reimbursement for ingredient cost of drug when drug is provided by U.S. government at no charge
Revision/Review Date 2/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Endari**
Drugs	L-Glutamine (Endari)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a hematologist or sickle cell specialist
Coverage Duration	If all of the conditions are met, requests will be approved for a 12 months.
Other Criteria Revision/Review Date 10/2025	Initial: • Member has diagnosis of sickle cell disease • Documentation was provided that the patient had 2 or more crises in the last 12 months • Documentation was provided the member has been on hydroxyurea at the maximum tolerated dose and was compliant within the last 6 months (or a medical reason was provided why patient is unable to use hydroxyurea) • Request is for an FDA approved dose Reauthorization: • Prescriber attests member had reduction in number of sickle cell crises • Request is for an FDA approved dose **Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Enzyme Replacement Therapies for Fabry Disease**
Drugs	Fabrazyme (agalsidase beta) Elfabrio (peguniigalsidase alfa)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	According to the FDA approved prescribing information
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, cardiologist, nephrologist or specialist experienced in the treatment of Fabry disease
Coverage Duration	Initial Authorization: If the criteria are met, the request will be approved for a 6-month duration. Reauthorization: If the criteria are met, the request will be approved for a 12-month duration.
Other Criteria	**Initial Authorization:** • Male members must have a documented diagnosis of Fabry disease confirmed by one of the following: 1. An undetectable (<1%) alpha galactosidase A (alpha-Gal-A) activity level OR 2. A deficient alpha-Gal- activity level AND a documented detection of pathogenic mutations in the galactosidase alpha (*GLA*) gene by molecular genetic testing • Female members must have a documented diagnosis of Fabry disease confirmed by detection of pathogenic mutations in the *GLA* gene by molecular genetic testing AND evidence of clinical manifestation of the disease (e.g. kidney, neurologic, cardiovascular, gastrointestinal) • Member must not be using concurrently with Galafold (migalastat) • Documentation of the member's current weight • Request is for an FDA-approved dose **Re-Authorization:**

Revision/Review Date: 7/2025	• Documentation that member has experienced an improvement in symptoms from baseline including but not limited to: decreased pain, decreased gastrointestinal manifestations, decrease in proteinuria, stabilization of increase in eGFR, reduction of left ventricular hypertrophy (LVH) on echocardiogram, or improved myocardial function, or has remained asymptomatic • Member must not be using concurrently with Galafold (migalastat) • Documentation of the member's current weight • Request is for an FDA-approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Enzyme Replacement Therapy for Acid Sphingomyelinase Deficiency (ASMD)**
Drugs	Xenpozyme (olipudase alfa-rpcp)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, a specialist experienced in the treatment of ASMD
Coverage Duration	If all the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.

Other Criteria
 	
Date: 2/2025
	Initial Authorization:
	• Medication is prescribed at an FDA approved dose
	• Member has a diagnosis of ASMD confirmed by one of the following:
	  o Deficiency in acid sphingomyelinase (ASM) enzyme activity (as measured by peripheral blood leukocytes, cultured skin fibroblasts, or dried blood spots)
	  o Sphingomyelin phosphodiesterase-1 (SMPD1) gene mutation
	• Member has a clinical presentation consistent with ASMD type B or type A/B
	• Documentation of members height and weight
	• Documentation of baseline ALT and AST within 1 month prior to initiation of treatment
	
	Re-Authorization:
	• Documentation or provider attestation of positive clinical response (i.e. improvement in splenomegaly, hepatomegaly, pulmonary function, etc.)
	• Medication is prescribed at an FDA approved dose
	
	If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	**Eohilia**
Drugs	Eohilia (budesonide)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, allergist, immunologist, or other provider who specializes in the treatment of eosinophilic esophagitis (EoE)
Coverage Duration	If all criteria are met, the request will be approved for 3 months ***Reauthorization requests for maintenance therapy will not be approved as Eohilia has not been shown to be safe and effective for the treatment of EoE for longer than 12 weeks. Requests for subsequent courses for induction therapy will be handled on a case-by-case basis***
Other Criteria Revision/Review Date: 4/2025	• Diagnosis of EoE as confirmed by esophageal biopsy indicating ≥15 eosinophils per high-power field (eos/hpf) • Member must have experienced dysphagia for at least 4 days over a 2-week period • Documented trial and failure, intolerance, or contraindication to one proton pump inhibitor (PPI) at a maximally tolerated dose for a minimum of 8 weeks • Documented trial and failure, intolerance, or contraindication to an inhaled corticosteroid that can be swallowed (i.e., fluticasone, etc.) • Request is for an FDA-approved dose **Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Epidermolysis Bullosa Agents**
Drugs	Vyjuvek (beremagene geperpavec-svdt), Filsuvez (birch triterpenes)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Other forms of epidermolysis bullosa, such as epidermolysis bullosa simplex, kindler epidermolysis bullosa • Concurrent use of Vyjuvek and Filsuvez
Required Medical Information	See "Other Criteria"
Age Restrictions	Per prescribing information
Prescriber Restrictions	Prescriber must be a dermatologist, geneticist, or specialist experienced in the treatment of epidermolysis bullosa.
Coverage Duration	If all of the criteria are met, the initial request will be approved for two (2) months. Subsequent requests will be approved for six (6) months.
Other Criteria	**Initial Authorization:** • Patient has a diagnosis of dystrophic or junctional epidermolysis bullosa, with genetic mutation(s) confirmed via genetic testing. • Requested product is FDA approved for the patient's epidermolysis bullosa subtype • Documentation is provided that wound(s) to be treated are clean with adequate granulation tissue, excellent vascularization, and do not appear infected • Documentation is provided that there is no evidence of, or history of squamous cell carcinoma in the wound(s) to be treated • Medication is prescribed at an FDA approved dose, and maximum dispensable amount is not exceeded o Vyjuvek: Requests exceeding more than one vial per week will not be approved. o Filsuvez: documentation of size of treatment area(s) and frequency of dressing changes is required. One tube of Filsuvez covers up to 250 cm2 surface area per single use tube. Requests exceeding a quantity sufficient to cover the treatment area more than once daily will not be approved. Rounding to the next whole tube size necessary is allowed. **Re-Authorization:**

Revision/Review Date: 4/2025	• Documentation or provider attestation of positive clinical response (i.e. improvement in wound appearance, wound closure, healing, etc.)
	• Documentation indicating need for continued treatment is needed (either to partially healed wounds or to other wound sites)
	• Documentation is provided that wound(s) to be treated are clean with adequate granulation tissue, excellent vascularization, and do not appear infected
	• Documentation is provided that there is no evidence of, or history of squamous cell carcinoma in the wound(s) to be treated
	• Medication is prescribed at an FDA approved dose, and maximum dispensable amount is not exceeded.
	  o Vyjuvek: Requests exceeding more than one vial per week will not be approved.
	  o Filsuvez: documentation of size of treatment area(s) and frequency of dressing changes is required. One tube of Filsuvez covers up to 250 cm2 surface area per single use tube. Requests exceeding a quantity sufficient to cover the treatment area more than once daily will not be approved. Rounding to the next whole tube size necessary is allowed.
	
	If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Prior Authorization Group Description	**Epidiolex (cannabidiol)**
Drugs	**Epidiolex (cannabidiol)**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	Member must be ≥ 1 year old
Prescriber Restrictions	Prescriber must be neurologist or specialist in treatment of seizure disorder.
Coverage Duration	If the criteria are met, the request will be approved for a 6 month duration.
Other Criteria	<u>Initial:</u> • Clinical diagnosis of Lennox-Gastaut syndrome, Dravet syndrome or Tuberous Sclerosis complex • Member has a trial and failure of two antiepileptic drugs • Member is currently taking a stable dose of at least one other antiepileptic medication • Member's Weight • Dose is within FDA approved limits <u>Reauthorization:</u> • Documentation has been provided that demonstrates reduction or stabilization of seizure frequency • Dose is within FDA approved limits • Member's weight
Revision/Review Date: 10/2025	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Prior Authorization Group Description	**Erythropoiesis-Stimulating Agents (ESAs)**
Drugs	**Preferred:** Retacrit (epoetin alfa-epbx) Mircera (methoxy peg-epoetin beta) **Non-preferred:** Aranesp (darbepoetin alfa-polysorbate 80) Procrit (epoetin alfa) Epogen (epoetin alfa)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If criteria are met, the request will be approved for up to 1 month if the member is deficient in iron, vitamin B12, folate, or in the perisurgical setting, and up to 3 months for all other requests.

Other Criteria	**<u>Existing ESA users who are NEW to the plan:</u>**
	• Documentation of current dose
	• Drug is being prescribed for an FDA-approved indication at an FDA-approved dose or is otherwise supported by the compendia or standard-of-care guidelines
	• The member's HgB is within the following indication specific range:
	  o Anemia of CKD: ≤ 11 g/dL
	  o Anemia related to cancer: ≤ 12 g/dL
	  o Zidovudine-related anemia in members with HIV: ≤ 12 g/dL
	  o Ribavirin-induced anemia: ≤ 12g/dL
	
	<u>Initial Authorization for all requests:</u>
	• Drug is being prescribed for an FDA-approved indication at an FDA-approved dose or is otherwise supported by the compendia or standard-of-care guidelines
	• All submitted lab results have been drawn within 30 days of the request
	• The following lab results must be submitted:
	  o Hemoglobin (HgB)
	  o Hematocrit (HCT)

	• The following lab results must be submitted and demonstrate normal values, otherwise, the member MUST be receiving, or is beginning therapy, to correct the deficiency:
	  o Serum ferritin level (> 100ng/mL)
	  o Transferrin saturation (TSAT) (> 20%)
	  o Vitamin B12 level (> 223pg/mL)
	  o Folate level (> 3.1 ng/mL)
	• If the request is for a non-preferred ESA the member has tried and failed a preferred ESA or has a documented medical reason (e.g., intolerance, hypersensitivity, contraindication) why the preferred ESAs cannot be used.
	
	Requests for anemia of CKD:
	• HgB < 10 g/dL
	
	Requests for anemia related to chemotherapy in cancer patients:
	• The member must have a documented cancer diagnosis for which they will be receiving myelosuppressive therapy for palliative treatment for at least two additional months (members receiving myelosuppressive therapy with curative intent should not receive ESAs) **AND** documented symptomatic anemia with HgB < 10 g/dL
	OR
	• The member has symptomatic anemia related to myelodysplastic syndrome **AND** documented serum erythropoietin level ≤ 500 mU/mL
	
	Requests for zidovudine-related anemia in HIV:
	• The member is currently receiving highly active antiretroviral therapy (HAART) **AND** has a documented serum erythropoietin level ≤ 500 mU/mL
	
	Requests for ribavirin-induced anemia:
	• Member is currently receiving ribavirin and a documented attempt to reduce dose has been made
	• Hgb < 12 g/dL
	
	Requests for members undergoing surgery to reduce the need for allogenic blood transfusion:
	• Perioperative HgB < 13g/dL and > 10 g/dL.
	• The member is scheduled for an elective, non-cardiac, nonvascular surgery.
	
	Reauthorization:
	• All submitted lab results have been drawn within 30 days of the reauthorization request.

Revision/Review Date: 10/2025	• The following lab results must be submitted:
	  o Hemoglobin (HgB)
	• The following lab results must be submitted and demonstrate normal values, otherwise, the member MUST be receiving, or is beginning therapy, to correct the deficiency:
	  o Serum ferritin level (> 100ng/mL)
	  o Transferrin saturation (TSAT) (> 20%)
	  o Vitamin B12 level (> 223pg/mL)
	  o Folate level (> 3.1 ng/mL)
	• The members HgB is within the following indication specific range:
	  o Anemia of CKD: ≤ 11 g/dL
	  o Anemia related to cancer: ≤ 12 g/dL
	  o Zidovudine related anemia in members with HIV: ≤ 12 g/dL
	  o Ribavirin-induced anemia: ≤ 12g/dL
	
	For requests that fall outside of these parameters, or if the criteria are not met, the request will be referred to a Medical Director/clinical reviewer for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	**Fertility Agents** ***Requests for non-fertility related indications: refer to Medications without Drug or Class Specific Criteria***
Drugs	bromocriptine, cetrorelix (Cetrotide), ganirelix (Fyremadel), Clomid (clomiphene), chorionic gonadotropin (Novarel, Pregnyl), Ovidrel (choriogonadotropin alfa), Follistim AQ (follitropin beta), Gonal-f, Gonal-f RFF, Gonal-f RFF Rediject (follitropin alfa), leuprolide acetate, Menopur (menotropins), Synarel (nafarelin)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Pregnancy
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescriber is experienced in fertility treatment, such as OB/GYN, fertility specialist, endocrinologist, etc.
Coverage Duration	If all of the criteria are met, the initial request will be approved for a **lifetime maximum of three (3) treatment cycles**
Other Criteria Revision/Review Date: 4/2025	**<u>For authorization of Fertility Agents:</u>** • Medication is prescribed for treatment of infertility. • Medication is prescribed at an FDA approved or compendia supported dose and duration of therapy. **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Fecal Microbiota**
Drugs	Rebyota (fecal microbiota, live-jslm) Vowst (fecal micromiota spores, live-brpk)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Treatment of Clostridioides difficile infection (CDI)
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If all the criteria are met, the request will be approved for 1 treatment course
Other Criteria Date: 7/2025	• Medication is prescribed at an FDA approved dose • Diagnosis of at least 1 recurrent episode of CDI (≥2 total CDI episodes) • Current episode of CDI must be controlled (<3 unformed/loose stools/day for 2 consecutive days) • Positive stool test for C. difficile within 30 days before prior authorization request • Administration will occur 24–72 hours following completion of antibiotic course for CDI treatment • For Vowst only: attestation patient will bowel cleanse using magnesium citrate or polyethylene glycol electrolyte solution the day before the first dose of Vowst *Rebyota and Vowst are limited to 1 treatment course* **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Galafold**
Drugs	Galafold (migalastat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	Members should be greater than or equal to 18 years of age
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, cardiologist, nephrologist or specialist experienced in the treatment of Fabry disease
Coverage Duration	Initial Authorization: If the criteria are met, the request will be approved for a 6-month duration. Reauthorization: If the criteria are met, the request will be approved for a 12-month duration.
Other Criteria	**Initial Authorization:** • Member has a documented diagnosis of Fabry disease • Documentation member has an amenable galactosidase alpha (GLA) gene variant based on in vitro assay data • Member will not be using Galafold concurrently with enzyme replacement therapy (e.g., Fabrazyme) • Documented baseline eGFR ≥ 30 mL/min • Request is for an FDA-approved dose **Re-Authorization:** • Documentation that member has experienced an improvement in symptoms from baseline including but not limited to: decreased pain, decreased gastrointestinal manifestations, decrease in proteinuria, stabilization of increase in eGFR, reduction of left ventricular hypertrophy (LVH) on echocardiogram, or improved myocardial function • Member must not be using concurrently with other enzyme replacement therapy (e.g., Fabrazyme) • Documented eGFR ≥ 30 mL/min • Request is for an FDA-approved dose

Revision/Review Date: 10/2025	If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review. **Physician/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Generalized Pustular Psoriasis (GPP) Agents**
Drugs	Spevigo (spesolimab-abzo)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Per package insert
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist or geneticist
Coverage Duration	Acute Flares (IV vial): If all of the criteria are met, the request will be approved for up to 2 doses. Maintenance Treatment (SQ syringe): If all criteria are met, the initial request will be approved for 12 months. Reauthorization requests will be approved for 12 months.

Other Criteria	**<u>Initial Authorization</u>**
	• Diagnosis of generalized pustular psoriasis (GPP)
	• If request is for an acute GPP flare (IV vial), member must be experiencing an acute flare of GPP of moderate to severe intensity as defined by having all of the following:
	  o Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of 3 or greater
	  o Presence of fresh pustules (new appearance or worsening of pustules)
	  o GPPPGA pustulation sub score of 2 or greater
	  o At least 5% of body surface area covered with erythema and the presence of pustules
	• If request is for maintenance treatment of GPP (SQ syringe), member must have all of the following:
	  o History of at least two GPP flares in the past year of moderate to severe intensity
	  o GPPPGA score of 0 or 1
	  o Documented trial and failure, intolerance, or contraindication to TWO of the following: oral retinoids, methotrexate, and cyclosporine
	• Medication is prescribed at an FDA approved dose

Date: 7/2025	**<u>Reuathorization</u>** • If request is for an acute GPP flare (IV vial), member must have achieved a clinical response, defined as achieving a GPPPGA score of 0 or 1, to previous treatment but is now experiencing a new flare • If request is for maintenance treatment of GPP (SQ syringe), member must have documentation of positive clinical response to therapy (i.e. reduction in GPP flares) • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	GLP1 Receptor Agonists (Wegovy/Zepbound) for Non-Weight Loss Indications
Drugs	Wegovy (semaglutide) injection Zepbound (tirzepatide) injection
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Requests for a diagnosis of weight reduction and maintenance for overweight or obesity • Concurrent use of any glucagon-like-peptide-1 receptor agonist • Personal or family history of medullary thyroid carcinoma • Multiple Endocrine Neoplasia syndrome type 2
Required Medical Information	See "Other Criteria"
Age Restrictions	Wegovy for cardiovascular risk reduction: Member must be ≥ 45 years of age, all others per FDA approved labeling
Prescriber Restrictions	Provider is or treatment is in consultation with: • Wegovy for MASH: hepatologist, gastroenterologist, endocrinologist, or a specialist in the treatment of liver disease. • Wegovy for CVD risk reduction: N/A • Zepbound for Obstructive Sleep Apnea: specialist in the treatment of sleep disorders; or in consultation with a specialist in the treatment of sleep disorders.
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For re-authorizations, the request will be approved for 12 months.
Other Criteria	**<u>Initial Authorization for All Requests:</u>** • Requested dose is appropriate per labeling • Chart notes required confirming diagnosis **<u>Wegovy Requests:</u>** For **risk reduction of major adverse cardiovascular events** in adults with established CV disease, the following must be met: • Medication is prescribed for reducing the risk of adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with **established cardiovascular disease.** Documentation demonstrates patient has history of one or more of the following: o Prior myocardial infarction o Prior stroke o Symptomatic peripheral arterial disease, as evidenced by ≥1 of the following: ▪ Intermittent claudication with ankle brachial index <0.85 (at rest) ▪ Peripheral arterial revascularization procedure

Revision/ Review Date: 10/2025	▪ Amputation due to atherosclerotic disease • Documentation is provided that patient is overweight or obese, defined as a body mass index (BMI) ≥ 27 kg/m2 • Patient is receiving standard of care treatment of CVD, as appropriate/indicated, including an antiplatelet agent (ex. aspirin or P2Y12 inhibitor), lipid-lowering drug (ex. statin, otherwise ezetimibe, fibrate, and/or PCSK-9 inhibitor), antihypertensive (ex. beta blocker, ACE-I, ARB) • Prescriber attests medication therapy is part of a total treatment plan including diet and exercise/activity as appropriate for the patient's ability • Patient does not have a personal history of type 1 or type 2 diabetes • Documentation is provided patient's Hb A1c ≤ 6.5% For the treatment of **noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH)**, with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults, all of the following must be met: • Diagnosis of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH) with moderate to advanced liver fibrosis • Documentation of stage F2 to F3 fibrosis confirmed by biopsy or a noninvasive test (NIT) • Prescriber attestation to providing lifestyle counseling on nutrition and exercise • Prescriber attestation that member avoids excess alcohol intake **<u>Zepbound Requests:</u>** For treatment of **moderate to severe obstructive sleep apnea** in adults, the following must be met: • Patient's weight is provided • Patient's body mass index (BMI) is provided and is 30 kg/m2 or more • Documentation of current diagnosis of moderate to severe obstructive sleep apnea • Documentation of trial and failure regarding lifestyle changes and behavioral modification (e.g., healthy diet and increased physical activity) to reach a BMI < 30 kg/m^2 • One of the following: o Results of sleep testing showing patient's apnea hypopnea index (AHI) ≥ 15 while currently on PAP therapy o Results of sleep testing showing patient's apnea hypopnea index (AHI) ≥ 15 and patient had had a previous trial and failure of PAP therapy or a medical reason is provided why the patient is not able to use PAP therapy • Patient is not pregnant

	Re-Authorization: **Wegovy Requests:** For **risk reduction of major adverse cardiovascular events** in adults with established CV disease, the following must be met: • Patient is receiving standard of care treatment of CVD, as appropriate/indicated, including an antiplatelet agent (ex. aspirin or P2Y12 inhibitor), lipid-lowering drug (ex. statin, otherwise ezetimibe, fibrate, and/or PCSK-9 inhibitor), antihypertensive (ex. beta blocker, ACE-I, ARB) • Patient continues to not have Type 1 or Type 2 diabetes • Patient is adherent to therapy, as evidenced by claims records demonstrating ≥80% fill rate For the treatment of **noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH)**, with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults, all of the following must be met: • Requested dose is appropriate per labeling • The member continues to have a fibrosis stage of ≤ 3 • Patient is adherent to therapy, as evidenced by claims records demonstrating ≥80% fill rate **Zepbound Requests:** For treatment of **moderate to severe obstructive sleep apnea** in adults, the following must be met: • Documentation of positive clinical response to therapy (i.e., improvement patient's AHI, improvement in daytime sleepiness, sleep arousals, snoring). • Patient is adherent to therapy, as evidenced by claims records demonstrating ≥80% fill rate • Patient has achieved and/or maintained a 5% decrease in weight since baseline **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Glycopyrrolate (oral)**
Drugs	**Formulary Status**: Formulary; Pays at point-of-sale glycopyrrolate 1, 2 mg tablet **Formulary Status:** Requires prior authorization Glycopyrrolate (Cuvposa) 1 mg/5 mL oral solution Glycopyrrolate (Glycate) 1.5 mg tablet
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	Per package insert
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month.
Other Criteria	Requests for glycopyrrolate (Cuvposa) 1 mg/5 mL oral solution: • Documented diagnosis of chronic severe drooling **AND** • Documented neurological condition associated with problem drooling (e.g., cerebral palsy) **AND** • Member has tried and failed non-pharmacologic approaches to treatment (e.g., correction of situational factors, treatment of dental malocclusion and caries, orthodontic appliances, swallowing therapy, biofeedback and automatic cueing, positive and negative reinforcement) **AND** • Drug is being prescribed at FDA approved dose Requests for glycopyrrolate 1.5 mg tablet: • Documented diagnosis of peptic ulcer disease **AND** • Glycopyrrolate will be used as an adjunct to other therapies **AND** • Member has tried and failed glycopyrrolate 1 mg or 2 mg tablets or has a medical reason (e.g. intolerance,

Revision/Review Date 2/2025	hypersensitivity, contraindication, etc.) for not using glycopyrrolate 1 mg and 2 mg tablets **AND** • Drug is being prescribed at and FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Gonadotropin Releasing Hormone Agonists (GNRH)** **If diagnosis is Gender Dysphoria, use Medications without Drug or Class Specific Criteria** **If diagnosis is cancer, use Oncology Criteria**
Drug(s)	**Preferred GNRH Agonist(s) for their respective indications:** Zoladex (goserelin acetate), Lupron Depot (leuprolide acetate), Lupron Depot-Ped (leuprolide acetate) **Non-Preferred GNRH Agonist(s):** Fensolvi (leuprolide acetate), Supprelin LA (histrelin acetate), Synarel (nafarelin acetate), Trelstar (triptorelin pamoate), Triptodur (triptorelin pamoate), and any newly marketed GnRH agonist**.**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per the National Comprehensive Cancer Network (NCCN), the American Society of Clinical Oncology (ASCO), the American College of Obstetricians and Gynecologists (ACOG), or the American Academy of Pediatrics (AAP) standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert if not detailed in "Other Criteria"
Prescriber Restrictions	Prescriber must be a specialist in the field to treat the member's condition.
Coverage Duration	If all of the conditions are met, the request will be approved for up to 12 months if diagnosis is central precocious puberty, and up to 3-6 months as indicated below for other indications as recommended per FDA approved indications and/or as defined by the medical compendium or standard of care guidelines.
Other Criteria	**INITIAL AUTHORIZATION for ALL REQUESTS:** • The medication is being prescribed for an FDA approved/standard of care guideline indication and within FDA approved/standard of care dosing guidelines. AND the member meets the following for the respective diagnosis: Central precocious puberty (CPP) • Onset of secondary sexual characteristics occurred when member was aged less than 8 years for females or aged less than 9 years for males

	• Diagnosis is confirmed by a pubertal response to a GnRH stimulation test and/or measurement of gonadotropins (FSH/LH), and bone age advanced beyond chronological age.
	  o Patients with low or intermediate basal levels of LH should have a GnRH stimulation test to clarify the diagnosis.
	  ▪ *If basal levels of LH are markedly elevated [e.g. more than 0.3mlU/ml (where IU- International units)] in a child with precocious puberty, then a diagnosis of CPP can be made without proceeding to a GnRH stimulation test*.
	• Brain magnetic resonance imaging (MRI) has been performed for all boys with CPP and for girls with onset of secondary sexual characteristics before the age of six years of age to rule out a tumor.
	• If the request is for any agent other than Lupron Depot-Ped the member has had a documented trial and failure with Lupron Depot-Ped or a documented medical reason (e.g. intolerance, hypersensitivity, contraindication) was submitted why the member is not able to use Lupron Depot-Ped
	
	<u>Endometriosis</u>
	• For all therapies except Lupron, Lupron Depot, or Lupron Depot-Ped, member is ≥ 18 years of age
	• Member has a confirmed diagnosis (e.g. laparoscopy, etc.)
	• Documented trial and failure or medical reason for not using an analgesic pain reliever (e.g., NSAIDs, COX-2 inhibitors) taken in combination with combined estrogen progestin oral contraceptive pills (OCPs):
	  o If one of the following drugs has been tried previously, a trial of OCPs is not required: progestins, Orilissa (elagolix), danazol, or aromatase inhibitors (e.g. anastrozole, letrozole)
	• If the request is for any agent other than Zoladex or Lupron Depot/Ped the member has had a documented trial and failure with the preferred agents or a documented medical reason (e.g. intolerance, hypersensitivity, contraindication) was submitted why the member is not able to use these medications
	• Approval is 6 months
	
	<u>Uterine leiomyomas (Fibroids)</u>
	• Member has a confirmed diagnosis (e.g. pelvic examination, etc.)
	• If the request is for any agent other than Lupron Depot the member has had a documented trial and failure with Lupron Depot or a documented medical reason (e.g. intolerance, hypersensitivity, contraindication) was submitted why the member is not able to use Lupron Depot
	• Approval is 3 months

	Endometrial thinning • Member has a confirmed diagnosis (e.g. pelvic examination, etc.) • Documentation indicates patient is scheduled for endometrial ablation for dysfunctional uterine bleeding. • If the request is for any agent other than Zoladex the member has had a documented trial and failure with Zoladex or a documented medical reason (e.g. intolerance, hypersensitivity, contraindication) was submitted why the member is not able to use Zoladex • Approval is 3 months **REAUTHORIZATION for all requests:** • The medication is being prescribed for an FDA approved indication and within FDA approved dosing guidelines. • Documentation was provided supporting continued treatment (e.g. patient still has symptoms), and medication is being continued as recommended in package insert or standard of care guidelines. AND meets the following per diagnosis: Central precocious puberty (CPP) • If the medication reauthorization is for central precocious puberty, the child is male and < 12 years or female and < 11 years of age OR a documented medical reason to continue treatment was provided with request, and includes current height and bone age Endometriosis • Provider has evaluated patient for osteoporosis (e.g. Dexascan), and patient is receiving "add back" hormonal therapy (norethindrone acetate 5 mg daily alone or with conjugated estrogen therapy) or an oral bisphosphonate AND calcium and vitamin D supplementation. • The patient has not received cumulative doses of the GnRH agonist greater than 12 months of therapy. Fibroids • The patient has not received cumulative doses of the GnRH agonist greater than 6 months of therapy **NOTE: Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**
Review Date 10/2025	

Field Name	Field Description
Prior Authorization Group Description	**Gonadotropin Releasing Hormone Receptor Antagonists**
Drugs	Oriahnn (elagolix, estradiol, and norethindrone acetate), Myfembree (relugolix, estradiol, and norethindrone acetate), Orilissa (elagolix)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	• Pregnancy • History of osteoporosis • History of hepatic impairment (Myfembree, Oriahnn), or severe hepatic impairment (Orilissa)
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be ≥ 18 years of age
Prescriber Restrictions	Prescriber is an obstetrician/gynecologist
Coverage Duration	If the criteria are met, the request will be approved as outlined below**:** • Initial Authorization: 6 months • Reauthorization: 6 months • Eligible maximum lifetime treatment duration: 24 months
Other Criteria	**Initial Authorization for all requests:** • Medication is prescribed at an FDA approved dose • If patient is of childbearing potential, prescriber attests the patient is not currently pregnant • Prescriber attests the patient does not have a history of osteoporosis • Prescriber attests they have reviewed the patient's liver function **For a diagnosis of endometriosis associated with moderate to severe pain:** • Request is for Orilissa or Myfembree only • Documented trial and failure or medical reason for not using an analgesic pain reliever (e.g., NSAIDs, COX-2 inhibitors) taken in combination with combined estrogen progestin oral contraceptive pills (OCPs): o If one of the following drugs has been tried previously, a trial of OCPs is not required: progestins, gonadotropin-releasing hormone (GnRH) agonists, danazol, or aromatase inhibitors (e.g., anastrozole, letrozole) **For a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids):** • Request is for Oriahnn or Myfembree only • Documented trial and failure or medical reason for not using estrogen-progestin contraceptive therapy

Revision/Review Date: 2/2025	• If one of the following drugs has been tried previously, a trial of estrogen-progestin contraceptive therapy is not required:
	  o gonadotropin-releasing hormone (GnRH) agonists,
	  o progestin-releasing intrauterine device
	  o tranexamic acid
	• If the request is from Myfembree, there is a documented trial and failure of Oriahnn, or medical reason why Oriahnn cannot be used
	
	<u>Reauthorization:</u>
	• Maximum lifetime treatment duration based on previous dosing and/or hepatic functioning has not been exceeded.
	• Documentation or provider attestation of positive clinical response (e.g., reduction in pain, reduced menstrual bleeding).
	• Medication is prescribed at an FDA approved dose
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group	**Growth Hormone (GH) for Growth Failure or GH Deficiency**
Drug(s)	**Preferred:** Nutropin AQ NuSpin (somatropin) **Non-preferred:** Genotropin (somatropin) cartridge/MiniQuick, Humatrope (somatropin), Ngenla (somatrogon), Norditropin (somatropin) FlexPro, Omnitrope (somatropin), Sogroya (somapacitan), Zomacton (somatropin), Skytrofa (lonapegsomatropin-tcgd) and any newly marketed growth hormone agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Treatment of idiopathic short stature (ISS)-not a covered benefit and will not be approved
Required Medical Information	See other criteria
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or specialist in stated diagnosis
Coverage Duration	If all of the conditions are met, the initial request will be approved for 12 months.
Other Criteria	**Initial Authorization** • If diagnosis is for growth failure associated with chronic kidney disease (CKD), documentation that: either pretreatment height is < -1.88 standard deviations (SD) below the mean for age or a height velocity–for-age < 3rd percentile that persists beyond 3 months AND epiphyses are open • If diagnosis is for growth failure associated with Prader-Willi Syndrome, Noonan Syndrome, Turner's Syndrome, or short stature homeobox-containing gene (SHOX) mutation, or other underlying genetic cause, documentation of confirmatory genetic test • If diagnosis is adult-onset GH deficiency (AO-GHD), documentation of one of the following: o Insulin Growth Factor (IGF-1) deficiency (< -2 SD below reference range for age and gender)* and multiple (≥3) pituitary hormone deficiencies (MPHD) o Evidence of genetic defects affecting the hypothalamic pituitary axes (HPA) o Evidence of hypothalamic pituitary structural brain

Revision Date 2/2025	defects o Positive results of GH stimulatory test (e.g. insulin tolerance test [ITT], glucagon, or macimorelin) • If diagnosis is childhood-onset GH deficiency (CO-GHD) o And patient is currently pediatric, all of the following ▪ IGF-1 and insulin-like growth factor binding protein-3 (IGFBP-3) deficiency (< 0 SD below reference range for age and gender)* with prescriber attestation of growth failure; AND ▪ Provider attests that MRI or CT has been completed to exclude possibility of a pituitary tumor; AND ▪ Provider attests that member's epiphyses are open o And patient is currently adult, one of the following ▪ If diagnosis is idiopathic isolated GHD, documentation was provided that indicates GH therapy is still medically necessary (IGF-1 retesting during the transition period after a minimum 1 month of therapy discontinuation reveals continued GH deficiency) ▪ Diagnosis is GHD associated with MPHD, genetic defect affecting the HPA axes, or patient with hypothalamic pituitary structural brain defect • If the request is for a product other than Nutropin AQ, the provider submitted a documented medical reason (i.e. intolerance) why it is medically necessary to use another agent. **<u>Reauthorization</u>** • Documentation of diagnosis (Note: ISS is not a covered benefit) • Documented IGF-1 levels do not exceed upper limit of normal (ULN) (> 2 SD above reference range for age and gender)*, or if the IGF-1 levels exceed ULN, the dose has been reduced • In CO-GHD, growth response (as demonstrated by length/height and calculated height velocity within previous 6 months). *IGF-1 levels are highly age and gender specific. In the event the form provides a value and not the corresponding reference range, refer to published reference ranges for interpretation. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary**

Field Name	Field Description
Prior Authorization Group Description	**Healthcare professional (HCP) administered Disease Modifying Therapies (DMTs) for Multiple Sclerosis (MS)**
Drugs	**Ocrevus (ocrelizumab), Ocrevus Zunovo (ocrelizumab-hyaluronidase-ocsq), Riabni (rituximab), Ruxience (rituximab), Truxima (rituximab), Rituxan (rituximab), Rituxan Hycela (rituximab/hyaluronidase), Lemtrada (alemtuzumab), Tysabri (natalizumab), Tyruko (natalizumab-sztn), Briumvi (ublituximab)**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Tysabri, Tyruko, or Briumvi: • Primary Progressive MS (PPMS) Lemtrada: • PPMS • Clinically Isolated Syndrome (CIS)
Required Medical Information	See "Other Criteria"
Age Restrictions	Patients must be age appropriate per PPI, nationally recognized compendia, or peer-reviewed medical literature
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Other Criteria	**Initial Authorization** CIS, Relapsing Remitting MS (RRMS), Secondary Progressive MS (SPMS) • Diagnosis of CIS, RRMS, or SPMS • The medication is being prescribed at a dose consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature • Documented trial of at least TWO preferred agents [dimethyl fumarate, glatiramer, fingolimod (Gilenya)], or a documented medical reason (e.g. contraindication, intolerance, hypersensitivity, etc.) for not utilizing these therapies. OR For patients with "highly active" MS requesting Lemtrada (alemtuzumab), natalizumab, or rituximab, a trial with fingolimod (Gilenya) alone will be acceptable. • If the request is for any medication other the Briumvi (ublituximab) there is a documented trial and failure of Briumvi (ublituximab), or medical reason (e.g., intolerance, hypersensitivity, contraindication) why the patient cannot use Briumvi (ublituximab)

	• If the request is for Ocrevus (ocrelizumab), Ocrevus Zunovo (ocrelizumab-hyaluronidase-ocsq), Briumvi (ublituximab), or rituximab, documentation of the following:
	  o Attestation that the patient has been screened for and does not have active hepatitis B virus (HBV)
	• If the request is for a natalizumab product, documentation of the following
	  o Patient does not have a history of progressive multifocal leukoencephalopathy (PML)
	  o Documentation consistent with pharmacy claims data indicating the patient is not currently using any antineoplastic, immunosuppressant, or immunomodulating medications
	• If the request is for a rituximab product other than Ruxience (rituximab-pvvr), documented trial and failure of Ruxience (rituximab-pvvr), or medical reason (e.g. intolerance, hypersensitivity, contraindication) why the patient cannot use Ruxience (rituximab-pvvr)
	• If the request is for Tysabri (natalizumab), documented trial and failure of Tyruko (natalizumab-sztn), or medical reason (e.g. intolerance, hypersensitivity, contraindication) why the patient cannot use Tyruko (natalizumab-sztn)
	
	<u>Primary Progressive Multiple Sclerosis (PPMS)</u>
	• Diagnosis of PPMS
	• The medication is being prescribed at a dose consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature
	• If the request is for Ocrevus (ocrelizumab), Ocrevus Zunovo (ocrelizumab-hyaluronidase-ocsq), or rituximab, documentation of the following has been submitted
	  o Attestation that the patient has been screened for and does not have active HBV
	• If the request is for a rituximab product other than Ruxience (rituximab-pvvr), documented trial and failure of Ruxience (rituximab-pvvr), or medical reason (e.g. intolerance, hypersensitivity, contraindication) why the patient cannot use Ruxience (rituximab-pvvr)
	• If the request is for Rituxan Hycela (rituximab/hyaluronidase), all of the above AND documented medical reason why the patient cannot use Rituxan (rituximab).
	
	<u>Reauthorization</u>
	
	<u>CIS</u>

Revision/Review Date 10/2025	• The medication is being prescribed at a dose consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature
	• Documentation was provided that the prescriber has reviewed the risks and benefits of continuing DMT versus stopping.
	
	<u>RRMS, SPMS, or PPMS</u>
	• Documentation that the prescriber has evaluated the member and recommends continuation of therapy (clinical benefit)
	• The medication is being prescribed at a dose consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature
	• If the request is for Lemtrada (alemtuzumab), documentation of the following
	  o At least 12 months has or will have elapsed since previous treatment
	• If the request is for a natalizumab product, documentation of the following has been submitted
	  o Patient does not have a history of PML
	  o Documentation consistent with pharmacy claims data was submitted indicating the patient is not currently using any antineoplastic, immunosuppressant, or immunomodulating medications
	
	<u>Continuation of Therapy/ Provision:</u>
	
	Members with history (within the past 180 days or past 12 months for Lemtrada [alemtuzumab]) of a non-preferred product are not required to try a preferred agent prior to receiving the non-preferred product.
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	**Hemangeol (propranolol)**
Drugs	Hemangeol (propranolol HCl) oral solution, 4.28 mg/mL
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	See "Other Criteria"
Prescriber Restrictions	N/A
Coverage Duration	If all of the conditions are met, initial requests will be approved for up to 12 months. Subsequent authorizations will be approved for up to 6 months.
Other Criteria Revision/Review Date 10/2025	**<u>Initial Authorization (all must apply):</u>** • Member has a diagnosis of proliferating infantile hemangioma which requires systemic therapy • Member is at least 5 weeks corrected gestational age • Member's weight is at least 2 kg • Request is for FDA approved dose (member's weight must be provided with the request) **<u>Renewal Authorization (all must apply):</u>** • Request is for FDA approved dose (member's weight must be provided with the request) • Documentation is provided to support continued use of Hemangeol solution beyond the initial 12 month authorization period (ex. rebound growth or recurrence of infantile hemangioma, medical justification of extended length of therapy due to patient's condition, etc.) **Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Hemophilia Factor VIII Replacement Products for Hemophilia A**
Drugs	Preferred: Novoeight (antihemophilic factor, recombinant) Non-preferred: Advate, Afstyla, Kogenate FS, Kovaltry, Nuwiq, Recombinate, Xyntha/Solofuse (antihemophilic factor, recombinant); Adynovate, Esperoct, Jivi (antihemophilic factor, recombinant, pegylated); Alphanate, Humate P, Wilate (antihemophilic factor/Von Willebrand factor complex); Eloctate (antihemophilic factor, recombinant, Fc fusion protein); Altuviiio (antihemophilic factor, recombinant, Fc-VWF-XTEN fusion protein); Obizur (antihemophilic factor, recombinant, porcine sequence); Hemofil M, Koate (antihemophilic factor, human); And any newly marketed factor VIII replacement product
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Patient must be age appropriate per package insert
Prescriber Restrictions	Prescriber must be a hematologist
Coverage Duration	For chronic use, the request will be approved for 12 months. For intermittent use, the request will be approved for 1 month.
Other Criteria	• Patient has a diagnosis of Hemophilia A • The drug is being used for an FDA-approved indication at an FDA approved dose or the indication/dose are otherwise supported by treatment guidelines. • If the request is for any Factor VIII replacement product other than Novoeight, the member has a trial and failure or has a medical reason for not utilizing Novoeight, if appropriate based on the member's diagnosis
Revision/Review Date 2/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

HEPATITIS C TREATMENT

Preferred Agents, No Prior Authorization Required:
MAVYRET (Glecaprevir/Pibrentasvir)
SOFOSBUVIR/VELPATASVIR (Generic Epclusa)
LEDIPASVIR/SOFOSBUVIR (Generic Harvoni)

Non-Preferred Agents, Prior Authorization Required:
VOSEVI (sofosbuvir/ velpatasvir/voxilaprevir)
ZEPATIER (elbasvir/grazoprevir)
VIEKIRA PAK
SOVALDI (sofosbuvir)
HARVONI (ledipasvir/sofosbuvir)
PEG-INTRON/ PEGASYS (peginterferon alfa-2a)
RIBAVIRIN tablets or capsules
OR ANY OTHER NEWLY MARKETED AGENT for treatment of Hepatitis C

Where applicable and appropriate: MAVYRET (Glecaprevir/Pibrentasvir), SOFOSBUVIR/VELPATASVIR (GENERIC EPCLUSA), or LEDIPASVIR/SOFOSBUVIR (GENERIC HARVONI) are the PREFERRED AGENTS for Hepatitis C requests unless a documented medical reason has been provided (intolerance, hypersensitivity, contraindication, etc.) why the member is not able to use Mavyret, sofosbuvir/velpatasvir (generic Epclusa), or ledipasvir/sofosbuvir (generic Harvoni).

Initial requests must meet ALL of the following requirements:

1. Request must be for an appropriate FDA approved/AASLD guideline recommended indication, at an approved dose and duration, and for appropriate member (e.g. age/weight).
2. Member is 3 years of age or older
3. Provider attests that member does not have limited life expectancy of less than 12 months due to non-liver related comorbid conditions.
4. Provider attests that they have documentation of ALL the following:
    - A complete Hepatitis B immunization series OR Hepatitis B screening (sAb, sAg, and cAb)
    - Quantitative HBV DNA results if positive for hepatitis B sAg
    - If there is detectable HBV DNA, a treatment plan for Hepatitis B consistent with AASLD recommendations

- If negative for Hepatitis B sAb, a hepatitis B immunization plan or counseling to receive the hepatitis B immunization series

5. Provider attests that they have documented HIV screening (HIV Ag/Ab), and if confirmed positive by HIV-1/HIV-2 differentiation immunoassay, then one of the following:
    - Is being treated for HIV
    - Is not being treated for HIV and the medical record documents the rationale for not being treated
6. Provider attests that all potential drug interactions with concomitant medications have been addressed (including discontinuation of the interacting drug, dose reduction, or counseling of the member of the risks associated with the use of both medications).
7. Provider attests if member is actively abusing alcohol or IV drugs, or has a history of abuse that they have counseled member regarding the risks of alcohol or IV drug abuse, and an offer of referral for substance abuse disorder treatment has been made.
8. Provider attests that member is committed to treatment plan, including lab monitoring and SVR12 lab testing will be completed and submitted to health plan.
9. The beneficiary has agreed to participate in Hepatitis C monitoring, educational and counseling program provided by the health plan
10. The request includes the completed DC Medicaid Beneficiary Disclosure and Commitment to Take Hepatitis C Medications Form
11. The following lab testing is required before treatment (copies of labs required)
    - Genotype (and subtype if provided) must be provided for:
        - Patients who are not going to receive Mavyret or generic Epclusa
        - Generic Epclusa in treatment naive patients with compensated cirrhosis
        - Patients who do not qualify for simplified treatment (treatment-experienced, have or had decompensated cirrhosis (Child-Pugh B and C), have ESRD, are HIV positive, have current HBV infection (positive for HbsAg), are pregnant, have known or suspected hepatocellular carcinoma, or have had a liver transplant)
    - Has documentation of AASLD-recommended resistance-associated substitution (RAS) testing:
        - Zepatier requests: all members with genotype 1a
        - Harvoni requests: treatment-experienced members with genotype 1a
        - Epclusa: treatment naïve members with cirrhosis and treatment experienced members without cirrhosis with genotype 3
12. All approvals are for 28 days supply (see treatment summary that follows), and will be consistent with labeling or current guidelines, and are subject to change as guidelines are updated.

TREATMENT SUMMARY

****For unique patient populations such as pediatric patients, please refer to bottom of the page for links to guideline specific treatment regimens****

For all charts, Epclusa and Harvoni refer to their generic formulations

Treatment Naïve			
Genotype	**Treatment Option**	**Duration**	
		No Cirrhosis	**Compensated Cirrhosis (Child-Pugh A)**
1, 2, 3, 4, 5, or 6	**Mavyret**	**8 weeks**	**8weeks**
1, 2, 3, 4, 5, or 6	**Epclusa**	**12 weeks**	**12 weeks**
1, 4, 5, or 6	**Harvoni**	**8-12 weeks^**	**12 weeks**

*Patients with genotype 3 who have compensated cirrhosis and are being prescribed Epclusa must be negative for the Y93H RAS to qualify for treatment

^Treatment-naive patients with genotype 1 and without cirrhosis who have HCV RNA <6 million units/mL and are HIV-uninfected may be considered for therapy of 8 weeks duration with Harvoni.

Treatment Experienced		Duration	
Failed Regimen	Treatment Options	No Cirrhosis	Compensated Cirrhosis (Child-Pugh A)
Sofosbuvir-based (Sovaldi, Harvoni, and Epclusa) and Zepatier	Vosevi	12 weeks	12 weeks$^{\beta}$
	Mavyret*	16 weeks	16 weeks
Mavyret	Mavyret plus Sovaldi and ribavirin	16 weeks	16 weeks
	Vosevi	12 weeks	12 weeks^
Multiple including Vosevi or Sovaldi plus Mavyret	Mavyret plus Sovaldi and ribavirin	16 weeks$^{\mu}$	16 weeks$^{\mu}$
	Vosevi plus ribavirin	24 weeks$^{\mu}$	24 weeks

*Mavyret is an alternative regimen (Vosevi is preferred). Do not use for NS3/4 protease inhibitor inclusive therapies or genotype 3 infection with sofosbuvir/NS5A inhibitor experience.

$^{\beta}$Genotype 3: If the patient has compensated cirrhosis, weight-based ribavirin is recommended.

^If the patient has compensated cirrhosis, weight-based ribavirin is recommended.

$^{\mu}$May be extended to 24 weeks in difficult cases (e.g. genotype 3 with cirrhosis) or failure following Sovaldi plus Mavyret

Unique patient populations (e.g. Decompensated Cirrhosis, Post-

Transplant, etc. not addressed in previous tables)	
Decompensated Cirrhosis (Child-Pugh B or C)	Refer to current AASLD guidelines @ http://www.hcvguidelines.org/ **Note: If Mavyret, generic Epclusa, or generic Harvoni are a recommended treatment option in the guidelines, they are preferred** unless member has a trial and failure with a preferred product, or a documented medical reason has been provided (intolerance, hypersensitivity, contraindication, etc.) why the member is not able to use the preferred products.
Post-Transplant	
Hepatocellular Carcinoma	
Pediatrics	

Review/Revision Date: 10/2025

Field Name	Field Description
Prior Authorization Group Description	**HIF-PH Inhibitors for CKD Anemia**
Drugs	Vafseo (vadadustat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Diagnosis of uncontrolled hypertension
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be at least 18 years of age
Prescriber Restrictions	Prescriber must be a hematologist or nephrologist
Coverage Duration	If all conditions are met, the request will be approved with a 6-month duration.

Other Criteria	**Initial Authorization:**
	• Member has a diagnosis of chronic kidney disease (CKD) and has been undergoing dialysis for minimum time required by FDA-approved labeling
	• Member has a documented hemoglobin between 8.0 and 11.0 g/dL
	• Member has documentation of trial and failure, intolerance, contraindication, or inability to use erythropoietin stimulating agents (ESA)
	• The following lab results must be submitted and demonstrate normal values, otherwise, the member MUST be receiving, or is beginning therapy, to correct the deficiency:
	  o Serum ferritin level (> 100ng/mL)
	  o Transferrin saturation (TSAT) (> 20%)
	• Provider attests that member has no history of myocardial infarction, cerebrovascular event, or acute coronary syndrome in the past 3 months
	• Member will not be receiving concurrent treatment with an ESA
	• Request is for an FDA-approved dose
	• All submitted lab results have been drawn within 30 days of the request
	
	Reauthorization:
	• All submitted lab results have been drawn within 30 days of the reauthorization request.
	• Member has a documented increase in hemoglobin from baseline

Revision/ Review Date: 10/2025	• The following lab results must be submitted and demonstrate normal values, otherwise, the member MUST be receiving, or is beginning therapy, to correct the deficiency:
	  o Serum ferritin level (> 100ng/mL)
	  o Transferrin saturation (TSAT) (> 20%)
	• Member will not be receiving concurrent treatment with an ESA
	• Request is for an FDA-approved dose
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary

Field Name	Field Description
Prior Authorization Group Description	**Hormone Replacement Therapy** (estrogen-only oral and vaginal products)
Drugs	**FORMULARY STATUS** Preferred, Pays at Point-of-Sale **Estradiol** (Estrace) oral tablet **Estradiol** (Estrace) vaginal cream **Estradiol** (Vagifem, Yuvafem) vaginal tablet **FORMULARY STATUS** Preferred, Requires Step Therapy **Premarin** (estrogens, conjugated) oral tablet **Premarin** (estrogens, conjugated) vaginal cream **Menest** (estrogens, esterified) oral tablet
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 10/2025	**For all requests:** • The request is for an FDA approved indication. **Initial authorization for Premarin and Menest oral tablet** • Documented trial and failure or intolerance with estradiol oral tablet • If the request is for the treatment of moderate to severe symptoms of vulvar and vaginal atrophy or atrophic vaginitis due to menopause, must also have documented trial and failure or intolerance with estradiol vaginal cream OR estradiol vaginal tablet **Initial authorization for Premarin vaginal cream** • Documented trial and failure or intolerance with estradiol vaginal cream OR estradiol vaginal tablet **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Desc	**Hyaluronic Acid Derivatives**
Drug(s)	**Preferred:** Euflexxa **Non-Preferred:** Gel-One, Gelsyn-3, GenVisc 850, Hyalgan, Supartz FX, TriVisc, Visco-3, Durolane, Hymovis, Monovisc, Orthovisc, Synvisc, Synvisc-One, Triluron, or any newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), or the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See other criteria
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber is a rheumatologist, orthopedist, sports medicine specialist, or physiatrist
Coverage Duration	If all of the criteria are met, the request will be approved for one complete course of treatment (based on the FDA labeled dose of the drug requested).
Other Criteria	**Initial Authorization:** • A diagnosis of Osteoarthritis (OA)/Degenerative joint disease (DJD) of the knee. • Documentation (in claim history or provider statement) that the member has had trials of at least 2 oral alternatives (e.g. acetaminophen-containing products, oral NSAIDs, other oral analgesics, etc.) AND a topical NSAID without improvement in pain/function or has a medical reason (intolerance, hypersensitivity, contraindication, etc.) for not being able to utilize these therapies • Documentation has been provided that the member has tried and failed two intraarticular steroid injections, per affected knee, or the member has a medical reason for not being able to utilize steroid injections. • If the request is for any other product other than Euflexxa, the member has a documented medical reason (intolerance, hypersensitivity, contraindication, etc) for not using Euflexxa **Reauthorization:** • Documentation was submitted that the patient had a response to the treated knee(s) that lasted at least 6 months (e.g. decreased

Revision/Review Date: 2/2025	joint pain or stiffness, improved range of motion, etc.). • Documentation was submitted that the patient has a return of symptoms of osteoarthritis that has not responded to acetaminophen-containing products, oral or topical NSAIDs, or other oral analgesics or has a medical reason (intolerance, hypersensitivity, contraindication, etc.) for not being able to utilize these therapies. • If the request is for any other product other than Euflexxa, the member has a documented medical reason (intolerance, hypersensitivity, contraindication, etc) for not using Euflexxa. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Hydroxyprogesterone caproate (generic Delalutin)**
Drugs	Hydroxyprogesterone caproate (generic Delalutin)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Pregnancy
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a gynecologist or in consultation with a gynecologist
Coverage Duration	If all the criteria are met, the initial request will be approved for up to 6 months. For continuation of therapy, the request will be approved for up to 6 months.

Other Criteria
 	
Date: 4/2025
	<u>Initial Authorization:</u>
	• Medication is prescribed at an FDA approved dose
	• If request is for preterm birth, do not approve
	• Request is for one of the following indications:
	  o Amenorrhea or abnormal uterine bleeding due to hormonal imbalance
	  o Production of secretory endometrium and desquamation
	  o Test for endogenous estrogen production
	  o Advanced uterine adenocarcinoma
	
	<u>Re-Authorization:</u>
	• Documentation or provider attestation of clinical benefit
	• Medication is prescribed at an FDA approved dose
	
	If all the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	**Ileal bile acid transporter inhibitor (IBAT)**
Drugs	Bylvay (odevixibat), Livmarli (maralixibat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	Per prescribing information
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist or hepatologist
Coverage Duration	If the conditions are met, the request will be approved for a 6 month duration for initial requests and a 12 month duration for renewal requests.

Other Criteria	**<u>Initial Authorization:</u>**
	
	Progressive Familial Intrahepatic Cholestasis
	• Diagnosis of progressive familial intrahepatic cholestasis (PFIC)
	  o For Bylvay: PFIC type 1 or 2 with confirmed biallelic mutations via genetic testing
	  o For Livmarli: PFIC type 1, 2, 3, 4, or 6, with confirmed biallelic mutations via genetic testing
	• Documentation that patient does not have an *ABCB11* variant that results in non-functional or complete absence of bile salt export pump protein
	• Documented history of moderate to very severe pruritus
	• Documentation of patient's weight
	• Prescriber attests to monitor liver function tests and fat soluble vitamin (FSV) levels during treatment
	• Baseline serum bile acid level is provided
	• Documentation of trial and failure OR contraindication to at least TWO of the following:
	  o Ursodiol
	  o Cholestyramine or colesevelam
	  o Rifampin
	  o Fibrates (ex. fenofibrate)
	• The prescribed dose is within FDA approved dosing guidelines

Revision/Review Date: 7/2025	**Alagille Syndrome**
	• Diagnosis of Alagille syndrome (ALGS)
	• Documented history of moderate to very severe pruritus
	• Documentation of trial and failure OR contraindication to at least TWO of the following::
	  o Ursodiol
	  o Cholestyramine or colesevelam
	  o Rifampin
	  o Fibrates (ex. fenofibrate)
	• Prescriber attests that the member has cholestasis
	• Baseline serum bile acid level is provided
	• Documentation of patient's weight
	• Prescriber attests to monitor liver function tests and fat soluble vitamin (FSV) levels during treatment
	• The prescribed dose is within FDA approved dosing guidelines
	
	<u>Reauthorization:</u>
	• Documentation of clinical benefit indicating each of the following:
	  o An improvement in pruritus (e.g. improved observed scratching, decreased sleep disturbances/nighttime awakenings due to scratching, etc.)
	  o Reduction in serum bile acid level from baseline
	• Documentation of patient's weight
	• Prescriber attests to monitor liver function tests and FSV levels during treatment
	• Prescriber attests that patient has had no evidence of hepatic decompensation (e.g. variceal hemorrhage, ascites, hepatic encephalopathy, portal hypertension, etc.)
	• The prescribed dose is within FDA approved dosing guidelines
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Immunoglobulin A (IgA) Nephropathy Agents
Drugs	Fabhalta (iptacopan), Filspari (sparsentan), Tarpeyo (budesonide), Vanrafia (atrasentan)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	For Filspari and Vanrafia only: • Pregnancy
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist
Coverage Duration	If the criteria are met, the criteria will be approved as follows: Initial requests: • 6 months: Fabhalta • 9 months: Filspari, Tarpeyo, Vanrafia Reauthorization: • 12 months: Fabhalta, Filspari, Vanrafia • Reauthorization requests for Tarpeyo will not be allowed as the safety and efficacy of subsequent courses have not been established
Other Criteria	**<u>Initial Authorization:</u>** • Diagnosis of primary IgA nephropathy verified by biopsy • Member is on an ACE inhibitor or ARB at a maximally tolerated dose OR there is a medical reason that they cannot be on one • Member has proteinuria (defined as total urine protein ≥1 g/day) • Member has an estimated glomerular filtration rate (eGFR) ≥30 mL/min/1.73 m^2 • Medication is prescribed at an FDA approved dose • For Fabhalta: o Documentation patient complies with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria o Member is at risk for disease progression as defined by a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g • For Filspari: o Documentation of baseline liver function o Attestation that member will discontinue use of renin-

Date: 7/2025	angiotensin-aldosterone system (RAAS) inhibitors, endothelin receptor antagonists, and/or aliskiren upon initiation of Filspari • For Vanrafia: o Member is at risk for disease progression as defined by a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g **<u>Re-Authorization:</u>** • Documentation of positive clinical response (e.g. decrease in UPCR, stabilization of eGFR) • Medication is prescribed at an FDA approved dose • For Filspari: o Documentation of liver function ***Reauthorization requests will not be allowed as the safety and efficacy of subsequent courses of Tarpeyo have not been established*** **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Immune Globulins**
Drugs	Gamunex-C (IV or SQ) (Immune Globulin) Bivigam (IV) (Immune Globulin) Cuvitru (SQ) (Immune Globulin) Flebogamma (IV) (Immune Globulin) Gammagard liquid (IV or SQ) (Immune Globulin) Gammagard SD (IV) (Immune Globulin) Gammaked (IV or SQ) (Immune Globulin) Gammaplex (IV) (Immune Globulin) Hizentra (SQ) (Immune Globulin) Octagam (IV) (Immune Globulin) Privigen (IV) (Immune Globulin) Asceniv (IV) (Immune Globulin-slra) Cutaquig (SQ) (Immune Globulin-hipp) Panzyga (IV) (Immune Globulin-ifas) Hyqvia (SQ) (Immune Globulin Human/Recombinant Human Hyaluronidase) Xembify (SQ) (Immune Globulin-klhw) Alyglo (IV) (Immune Globulin-stwk) Or any newly marketed immune globulin ****Gamunex-C is the preferred product for the indications of primary immunodeficiency, chronic idiopathic thrombocytopenic purpura, and chronic inflammatory demyelinating polyneuropathy****
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	See “other criteria”
Coverage Duration	If the criteria are met the request will be approved for a 3 month duration unless otherwise specified in the diagnosis specific “Other Criteria” section below.
Other Criteria	**All Requests:** • Documentation of diagnosis confirmed by a specialist • Member has tried and failed, or has a documented medical reason

	for not using, all other standard of care therapies as defined per recognized guidelines • Member's height and weight are provided • Dosing will be calculated using ideal body weight (IBW), unless ONE of the following: o If the member's actual weight is less than their IBW, then dosing will be calculated using their actual weight o If the member's body mass index (BMI) is ≥30 kg/m^2 OR if their actual weight is greater than 20% of their IBW, then dosing will be calculated using adjusted body weight (adjBW) **Primary Immunodeficiency***: • Patient's IgG level is provided and below normal for requested indication, or a documented specific antibody deficiency is provided • Clinically significant deficiency of humoral immunity as evidenced by ONE of the following: o Inability to produce an adequate immunologic response to specific antigens. o History of recurrent infections despite prophylactic antibiotics • Dose is consistent with FDA approved package labeling, nationally recognized compendia, or peer-reviewed literature • If the request is for any medication other than Gamunex-C, the member has tried and failed, or has a documented medical reason for not using, Gamunex-C • If criteria is met, approve for 6 months. *Primary Immunodeficiency includes, but is not limited to, the following: Congenital agammaglobulinemia, hypogammaglobulinemia (Common Variable Immunodeficiency, CVID), severe combined immunodeficiency (SCID), Wiskott-Aldrich syndrome, X-linked agammaglobulinemia or Bruton's agammaglobulinemia, hypergammaglobulinemia, X-linked hyper IgM syndrome **Idiopathic Thrombocytopenic Purpura, acute and chronic**: • Acute: o Patient has active bleeding, requires an urgent invasive procedure, is deferring splenectomy, has platelet counts < 20,000/ul and is at risk for intra-cerebral hemorrhage or has life threatening bleeding, or has an inadequate increase in platelets from corticosteroids or is unable to tolerate corticosteroids o Dose does not exceed 1g/kg daily for up to 2 days, or

	400mg/kg daily for 5 days • Chronic: o Duration of illness is greater than 12 months o Member has documented trial and failure of corticosteroids and splenectomy, or has a documented medical reason why they are not able to use corticosteroids or member is at high risk for post-splenectomy sepsis. o Dose does not exceed 1g/kg daily for up to 2 days, or 400mg/kg daily for 5 days • If the request is for any medication other than Gamunex-C, the member has tried and failed, or has a documented medical reason for not using, Gamunex-C • If criteria is met, approve for up to 5 days. **Kawasaki disease:** • Immunoglobulin is being given with high dose aspirin unless contraindicated • Requested dose does not exceed a single 2g/kg dose • If criteria is met, approve for 1 dose **Chronic B-cell lymphocytic leukemia:** • The patient has had recurrent infections requiring IV antibiotics or hospitalization and has a serum IgG of <500 mg/dL • Dose does not exceed 500mg/kg every 3-4 weeks • If criteria is met, approve for 3 months. **Bone marrow transplantation:** • The patient has bacteremia or recurrent sinopulmonary infections and their IgG level is < 400mg/dL • Dose does not exceed 500mg/kg/wk for the first 100 days post-transplant • Dose does not exceed 500 mg//kg every 3-4 weeks 100 days after transplant • If criteria is met, approve for 3 months. **Pediatric HIV**: • Patient is < 13 years of age • Either patient's IgG level is < 400mg/dL or • If patient's IgG level is ≥ 400 mg/dL than significant deficiency of humoral immunity as evidenced by ONE of the following:

	○ Inability to produce an adequate immunologic response to specific antigens. ○ History of recurrent bacterial infections despite prophylactic antibiotics • Dose does not exceed 400mg/kg/dose every 2-4 weeks • If criteria is met, approve for 3 months. **Multifocal motor neuropathy (MMN)**: • Duration of symptoms has been at least 1 month with disability. • Nerve conduction studies were completed to rule out other possible conditions, and confirms the diagnosis of MMN. • Dose does not exceed 2.4 g/kg/month administered over 2 to 5 days. • If criteria is met, approve for up to 5 days for 6 months. **Chronic inflammatory demyelinating polyneuropathy (CIDP):** • Duration of symptoms has been at least 2 months with disability. • Nerve conduction studies or a nerve biopsy were completed in order to rule out other possible conditions, and confirms the diagnosis of CIDP. • Patient has tried and failed, or has a documented medical reason for not using, corticosteroids. ○ If the patient has severe and fulminant or pure motor CIDP a trial of corticosteroids is not required • Dose is consistent with FDA approved package labeling, nationally recognized compendia, or peer-reviewed literature • If the request is for any medication other than Gamunex-C, the member has tried and failed, or has a documented medical reason for not using, Gamunex-C **Guillain-Barre syndrome:** • Patient has severe disease with the inability to walk without aid • Onset of symptoms within the last 4 weeks • Dose does not exceed 2g/kg administered over 2-5 days • If criteria is met, approve for up to 5 days. **Myasthenia Gravis:** • Acute:

	○ Patient has an acute myasthenic exacerbation (i.e. acute episode of respiratory muscle weakness, difficulty swallowing, etc.) or is in preparation for thymoma surgery to prevent myasthenic exacerbation ○ Dose does not exceed 2 g/kg administered over 2-5 days ○ If criteria is met, approve for up to 5 days • Chronic: ○ Diagnosis of refractory generalized myasthenia gravis ○ Patient has tried and failed, or has a documented medical reason for not using 2 or more immunosuppressive therapies (i.e. corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil) ○ Dose does not exceed 2 g/kg/month administered over 2-5 days ○ If criteria is met, approve for 3 months **Dermatomyositis (DM):** • One of the following: ○ Bohan and Peter score of 3 (i.e. definite DM) ○ Bohan and Peter score of 2 (i.e. probable DM) AND concurring diagnostic evaluation by ≥ 1 specialist (e.g. neurologist, rheumatologist, dermatologist) • Patient does NOT have any of the following: ○ Cancer (CA) associated myositis defined as myositis within 2 years of CA diagnosis (except basal or squamous cell skin cancer or carcinoma in situ of the cervix that has been excised and cure) ○ Active malignancy ○ Malignancy diagnosed within the previous 5 years ○ Breast CA within the previous 10 years • For a diagnosis of DM, one of the following: ○ Member has tried and failed, or has a documented medical reason for not using both of the following: ▪ methotrexate (MTX) OR azathioprine ▪ rituximab. ○ Member has severe, life-threatening weakness or dysphagia • For a diagnosis of cutaneous DM (i.e. amyopathic DM, hypomyopathic DM): ○ Member has tried and failed, or has a documented medical reason for not using all of the following: MTX and mycophenolate mofetil. • Dose does not exceed 2 g/kg administered over 2-5 days every 4 weeks. • If criteria is met, approve for up to 3 months.
Revision/Review Date 10/2025	

	If criteria is met, the request will be approved for the duration listed above. If the criteria is not met, the request is referred to a Medical Director/Clinical reviewer for medical necessity review. **Medical Director/Clinical Reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary**

Field Name	Field Description
Prior Authorization Group Description	**Immunosuppressants for Lupus Nephritis**
Drugs	Lupkynis (voclosporin)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be 18 years of age or older
Prescriber Restrictions	Prescriber must be rheumatologist, nephrologist or other specialist in the treatment of autoimmune disorders
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Revision/Review Date 4/2025	**<u>Initial Authorization</u>** • Member must have a diagnosis of systemic lupus erythematosus (SLE) with a kidney biopsy indicating a histologic diagnosis of lupus nephritis (LN) Class III, IV, or V • Documentation that the member has a baseline eGFR > 45 mL/min/1.73m^2 • Documentation of the member's urine protein/creatinine ratio (UPCR) is provided • Member is concurrently being treated with background immunosuppressive therapy, or has a medical reason for not using background immunosuppressive therapy • Member is NOT concurrently being treated with cyclophosphamide • Medication is prescribed at an FDA approved dose **<u>Reauthorization</u>** • Documentation of improvement in renal function (i.e. reduction in UPCR or no confirmed decrease from baseline eGFR ≥ 20%) • Medication is prescribed at an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Increlex**
Drugs	Increlex (mecasermin [recombinant human insulin-like growth factor-1])
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	≥ 2 years to < 18 years
Prescriber Restrictions	Prescribed by or in consultation with an Endocrinologist or specialist in the treatment of pediatric growth disorders
Coverage Duration	If all of the conditions are met, the request will be approved for 12 months.

Other Criteria
 	
Revision/Review Date 7/2025
	<u>Initial Authorization</u>
	• Member has a diagnosis of one of the following
	  o Growth hormone (GH) gene deletion with the development of neutralizing antibodies to GH
	  o Severe primary insulin-like growth factor-1 (IGF-1) deficiency as defined as:
	  ▪ Height and basal IGF-1 standard deviation scores ≤ -3.0
	  ▪ Normal or elevated GH levels
	• Member does not have a closed epiphyses
	• Member does not have known or suspected malignancies
	• Request is for an FDA-approved dose
	
	<u>Reauthorization</u>
	• Growth velocity must be ≥ 2 cm in the past year
	• Member does not have a closed epiphyses
	• Member does not have known or suspected malignancies
	• Request is for an FDA-approved dose
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Prior Authorization Group Description	**Inhaled Antibiotics and Cystic Fibrosis Agents**
Drug(s)	Cayston (Aztreonam lysine), Pulmozyme (dornase alfa), Bronchitol (mannitol) Tobi, Tobi Podhaler, Bethkis, Kitabis (tobramycin), Arikayce (amikacin sulfate), or any newly marketed inhalation for treatment of cystic fibrosis
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	See "Other Criteria"
Prescriber Restrictions	Prescriber is pulmonologist or infectious disease specialist
Coverage Duration	If all of the conditions are met the request will be approved for 12 months.
Other Criteria Review/Revision Date: 4/2025	• Request is for an FDA approved indication and within dosing guidelines • The request is appropriate for member (e.g. age/weight) • If the request is for a brand name tobramycin product, documentation has been provided why member is unable to use generic tobramycin For all **Bronchitol (mannitol)** requests: • Member has documented trial and failure or medical reason for not using generic hypertonic saline nebulization solution (sodium chloride 3% or 7%) For all **Arikayce (amikacin sulfate)** requests: • Member has refractory Mycobacterium avium complex (MAC) lung disease **AND** there is a documented medical reason (e.g. contraindication, intolerance, hypersensitivity, etc.) why parenteral amikacin cannot be used **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Injectable/Infusible Bone-Modifying Agents for Osteoporosis and Paget's Disease**
Drugs	Pamidronate, ibandronate (Boniva), Prolia (denosumab), Prolia Biosimilars, zoledronic acid (Reclast), teriparatide (Forteo), teriparatide (biosimilar), Tymlos (abaloparatide), Evenity (romosozumab-aqqg) or any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	"See other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be an endocrinologist, rheumatologist, orthopedist, or obstetrician/gynecologist
Coverage Duration	If all of the conditions are met, requests will be approved for a 1 year. *** TERIPARATIDE/FORTEO/TYMLOS REQUESTS WILL ONLY BE APPROVED FOR A TOTAL DURATION OF 24 MONTHS*** ***EVENITY WILL ONLY BE APPROVED FOR A TOTAL DURATION OF 12 MONTHS***
Other Criteria	**For all Requests**: • The medication is FDA-approved for indication and is being requested at an FDA approved dose • If the request is for Prolia (denosumab) or a Prolia biosimilar, the member has a documented trial and failure with the biosimilar Bildyos (denosumab-nxxp), or a medical reason (e.g. intolerance, contraindication, etc.) as to why the member is unable to use this medication is provided If the diagnosis is postmenopausal or male osteoporosis: • If the request is for male osteoporosis or high risk postmenopausal osteoporosis with no prior fractures the member has a documented (consistent with pharmacy claims) adequate trial of an oral bisphosphonate or has a medical reason (e.g. intolerance, hypersensitivity, contraindication, etc.) for not using an oral bisphosphonate

	• If the request is for very high risk postmenopausal osteoporosis or postmenopausal osteoporosis with prior fractures a documented trial and failure of an oral bisphosphonate will not be required.
	  o Very high risk is defined as having one or more of the following:
	  ▪ History of fracture in the past 12 months
	  ▪ Multiple fractures
	  ▪ Fractures while on drugs causing skeletal harm (e.g. long-term glucocorticoids)
	  ▪ Very low T scores (< -3.0)
	  ▪ High risk for falls
	  ▪ History of injurious falls
	  ▪ Very high fracture probability as determined by fracture risk assessment tool (FRAX) (e.g. major osteoporosis fracture >30%, hip fracture > 4.5%)
	• Documentation was submitted indicating the member is a postmenopausal woman or a male member over 50 years of age and one of the following:
	  o A bone mineral density (BMD) value consistent with osteoporosis (T-scores equal to or less than –2.5)
	  o Has had an osteoporotic fracture
	  o A T-score between -1 and -2.5 at the femoral neck or spine and a 10 year hip fracture probability >3% or a 10 year major osteoporosis-related fracture probability >20% (based on the US-adapted WHO absolute fracture risk model)
	• If request is for teriparatide (Forteo), teriparatide (biosimilar), Tymlos (abaloparatide), or Evenity (romosozumab) one of the following applies to member:
	  o Documented trial and failure of a denosumab product **AND EITHER** ibandronate (Boniva) injection **OR** zoledronic acid (Reclast) or has a medical reason (e.g. intolerance, contraindication, etc.) why these therapies are not suitable to be used
	  o Has SEVERE osteoporosis (T-Score -3.5 or below, or T-Score of -2.5 or below plus a fragility fracture)
	• If request is for Evenity (romosozumab), Tymlos (abaloparatide), or teriparatide (biosimilar), a medical reason why member is unable to use teriparatide (Forteo) if appropriate based on diagnosis
	• If the request is for Evenity (romosozumab), the member does not have a history of heart attack or stroke within the preceding year
	<u>If the diagnosis is Paget's disease</u>:

Revision/Review Date: 10/2025	• The member has a documented (consistent with pharmacy claims) adequate trial of an oral bisphosphonate or has a medical reason (e.g. intolerance, hypersensitivity, contraindication, etc.) for not using an oral bisphosphonate • Documentation (within 60 days of request) was submitted including member's serum alkaline phosphatase level of ≥ two times the upper limit of normal AND the member is symptomatic OR there is documentation of active disease <u>If the diagnosis is glucocorticoid-induced osteoporosis</u>: • The member has a documented (consistent with pharmacy claims) adequate trial of an oral bisphosphonate or has a medical reason (e.g. intolerance, hypersensitivity, contraindication, etc.) for not using an oral bisphosphonate • For members ≥ 40 years of age on long-term glucocorticoid therapy: o Dosage of the oral glucocorticoid therapy is equivalent to a dose greater than 2.5 mg of prednisone daily o Member has a moderate to very high risk of fracture based on ONE of the following: ▪ History of osteoporotic fracture ▪ BMD less than or equal to -1 at the hip or spine ▪ FRAX 10-year risk for major osteoporotic fracture greater than or equal to10% (with glucocorticoid adjustment) ▪ FRAX 10-year risk for hip fracture greater than 1% (with glucocorticoid adjustment) • For adult members (all ages) receiving HIGH dose glucocorticoid therapy: o Member has a moderate to very high risk of fracture based on ONE of the following: ▪ History of prior fracture(s) ▪ Glucocorticoid dose ≥30mg/day or cumulative ≥5 grams/year ▪ Continuing glucocorticoid treatment ≥7.5mg/day for ≥6 months AND BMD Z score < -3 OR significant BMD loss (> least significant change of DXA) • If the request is for teriparatide (biosimilar), teriparatide (Forteo), or Tymlos (abaloparatide), the member has a documented trial and failure of zoledronic acid (Reclast) or a denosumab product or a medical reason (e.g. intolerance, contraindication, etc.) as to why the member is unable to use these medications is provided

	Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group	**Injectable/Infusible Bone-Modifying Agents for Oncology Indications**
Drugs	**Preferred Bone-Modifying Agent(s):** Pamidronate disodium, Zoledronic Acid **Non-preferred Bone-Modifying Agent(s):** Xgeva, Prolia (denosumab), Xgeva Biosimilars, Prolia Biosimilars
Covered Uses	The request is for an FDA approved indication or for a medically accepted indications as defined or as supported by the medical compendium (Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI) , Drug Package Insert) as defined in the Social Security Act 1927, or per the National Comprehensive Cancer Network (NCCN), the American Society of Clinical Oncology (ASCO), or the National Institutes of Health (NIH) Consensus Panel standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber is an oncologist
Coverage Duration	6 months
Other Criteria	• The request is for an approved/accepted indication at an approved dose • If the request is for Xgeva (denosumab) or an Xgeva biosimilar, the patient has a documented trial and failure of Bilprevda (denosumab-nxxp), or has a medical reason (intolerance, hypersensitivity, contraindication, renal insufficiency, etc.) for not utilizing this agent to manage their medical condition • If the request is for Prolia (denosumab) or a Prolia biosimilar, the patient has a documented trial and failure of Bildyos (denosumab-nxxp), or has a medical reason (intolerance, hypersensitivity, contraindication, renal insufficiency, etc.) for not utilizing this agent to manage their medical condition • If the request is for Xgeva (denosumab) or an Xgeva biosimilar for any of the indications below, the patient has a documented trial and failure of generic pamidronate OR zoledronic acid that is consistent with claims history, or has a documented medical reason (intolerance, hypersensitivity, contraindication, renal insufficiency, etc.) for not utilizing one of these agents to manage their medical condition o Bone metastases from solid tumors o Hypercalcemia of malignancy o Multiple myeloma osteolytic lesions

Revision/Review 10/2025	• If the request is for Xgeva (denosumab) or an Xgeva biosimilar for treating Giant cell tumor of bone, documentation has been submitted that the tumor is unresectable, that surgical resection is likely to result in morbidity (e.g. denosumab therapy is being used to aide in the possibility of resection with tumor shrinkage), or that disease has recurred. • If the request if for Prolia (denosumab) or a Prolia biosimilar for breast cancer, the patient has a documented trial and failure of generic pamidronate OR zoledronic acid that is consistent with claims history, or has a documented medical reason (intolerance, hypersensitivity, contraindication, renal insufficiency, etc.) for not utilizing one of these agents to manage their medical condition • If the request is for Prolia (denosumab) or a Prolia biosimilar for prostate cancer, approve. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**InPen**
Drugs	InPen
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	None
Required Medical Information	See "Other Criteria"
Age Restrictions	Age 7 years and older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	If all of the criteria are met, the request will be approved 1 system per year
Other Criteria Revision/Review Date: 2/2025	**<u>Initial Authorization</u>** • Patient has a diagnosis of diabetes and requires use of insulin • Treatment with multiple daily doses (≥ 3) of insulin • Medical justification supports necessity of the digital component (i.e., rationale why insulin dose/usage cannot be calculated/tracked manually such as member has an intellectual disability, or no caregivers are available to assist with insulin dose calculation) **<u>Reauthorization</u>** • Patient has a diagnoses of diabetes and requires use of insulin • Continued use of multiple daily doses (≥ 3) of insulin • Medical justification supports continued necessity of the digital component **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Insulin-Like Growth Factor-1 Receptor (Igf-1r) Antagonists For Thyroid Eye Disease**
Drugs	Tepezza (teprotumumab-trbw)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be 18 years age or older
Prescriber Restrictions	Prescriber must be an ophthalmologist, endocrinologist, or specialist with expertise in the treatment of Grave's disease with thyroid eye disease.
Coverage Duration	If all of the criteria are met, the request will be approved for up to 24 weeks of treatment (8 total infusions). Retreatment requests will not be allowed beyond the 8 dose limit.
Other Criteria	**Initial Authorization:** Tepezza is approved when all of the following are met: • Dosing does not exceed dosing guidelines as outlined in the package insert • Patient has a confirmed diagnosis of Graves' disease • Documentation of moderate-severe thyroid eye disease as evidenced by one or more of the following: o Lid retraction of >2mm o Moderate or severe soft-tissue involvement o Proptosis ≥3mm above normal values for race and sex o Periodic or constant diplopia • Patient must be euthyroid or thyroxine and free triiodothyronine levels are less than 50% above or below normal limits (submit laboratory results with request) • Patients of reproductive potential: attestation the patient is not pregnant, and appropriate contraception methods will be used before, during, and 6 months after the last infusion • Patient has had a trial and therapy failure of, or contraindication to: o For active disease: oral or IV glucocorticoids o For chronic/inactive disease: rehabilitative surgery

Revision/Review Date 7/2025	**<u>Re-authorization:</u>** • Retreatment or renewal requests beyond a total of 24 weeks of treatment (8 total infusions) will not be allowed. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Insulin Pumps**
Drugs	Omnipod Dash Intro Kit, Omnipod Dash Pods, Omnipod 5 G6 Intro Kit, Omnipod 5 G6 Pods, OmniPod GO **This policy does not apply to pumps reviewed and/or covered by the Medical Benefit including, but not limited to V-Go 24-hour disposable system and t:slim X2, and continuous glucose monitor/insulin pumps such as MiniMed. Requests for these products are referred to the plan's Utilization Management team for review.**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	None
Required Medical Information	See "Other Criteria"
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist, a certified diabetes care and education specialist (CDCES), or an obstetrician/gynecologist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Other Criteria	**Initial Authorization** • Diagnosis – diabetes • One of the following o Type 1 diabetes or other insulin-deficient forms of diabetes (e.g. cystic-fibrosis related diabetes) o Treatment with multiple daily doses (≥ 3) of insulin o Pregnancy o Continuation of therapy for patient new to plan o For OmniPod GO: trial and failure of a long-acting insulin or a medical reason why long-acting insulin cannot be used (adherence, etc.) **Reauthorization** • One of the following: o Type 1 diabetes or other insulin-deficient form of diabetes o Prescriber attests member has benefited from, and has continued need for, therapy with an insulin pump o Initial approval was based on continuation of therapy for patient new to plan. o For OmniPod GO: continuous use of approved insulin compatible with

Revision/Review Date 10/2025	device • Continuation of therapy based on a diagnosis of pregnancy alone is not eligible for reauthorization **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Janus Kinase Inhibitors for Nonsegmental Vitiligo**
Drugs	Opzelura (ruxolitinib)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI)
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	≥ 12 years of age
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist, immunologist, or specialist experienced in treatment of vitiligo
Coverage Duration	If criteria are met, the request will be approved with up to a 6 month duration. All reauthorization requests will be approved up to 12 months in duration.

Other Criteria	**Initial Authorization**
	o Diagnosis of nonsegmental vitiligo
	o Documentation of depigmented lesions including measurements and locations is provided
	o Prescriber attests that the total body vitiligo area (facial and nonfacial) being treated does not exceed 10% BSA
	o Trial and failure of, or intolerance to, ALL of the following:
	  o Topical corticosteroids
	  o Topical calcineurin inhibitors
	  o Targeted phototherapy
	o Prescriber attests that the member will not concomitantly use therapeutic biologics, other Janus kinase inhibitors, potent immunosuppressants, or phototherapy for repigmentation purposes
	o Request is for an FDA-approved dose
	
	****A MAXIMUM OF ONE 60 GRAM TUBE OF OPZELURA PER WEEK OR ONE 100 GRAM TUBE EVERY TWO WEEKS MAY BE APPROVED****
	
	Reauthorization
	o Prescriber attests that the member has experienced a clinical benefit (e.g. reduction in size or quantity of or stabilization of existing depigmented lesions; absence of new depigmented lesions)

Revision/Review Date 10/2025	○ Request is for an FDA-approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Joenja**
Drugs	Joenja (leniolisib)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Per prescribing information.
Prescriber Restrictions	Prescriber must be an immunologist, hematologist, medical geneticist, or other prescriber who specializes in the treatment of genetic or immunologic disorders.
Coverage Duration	If the criteria are met, requests will be approved with up to a 6-month duration. Thereafter, reauthorization requests will be approved with up to a 12-month duration.
Other Criteria Revision/Review Date 7/2025	**Initial Authorization:** • Documentation of APDS/PASLI-associated PIK3CD/PIK3R1 mutation, confirmed by genetic testing. • Documentation of nodal and/or extranodal lymphoproliferation, history of repeated oto-sino-pulmonary infections and/or organ dysfunction (e.g., lung, liver) • Prescriber attests that the member is not currently taking immunosuppressive medication • Prescriber attests that female patients have been advised of the potential risk to a fetus, will use effective contraception and have had a negative pregnancy test prior to initiation of treatment • Medication is being prescribed at an FDA approved dose **Reauthorization:** • Documentation has been submitted indicating member has experienced a clinical benefit from treatment (e.g., decreased lymph node size, increase in percentage of naïve B cells) • Prescriber attests that female patients will use effective contraception and have had a negative pregnancy test • Medication is being prescribed at an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Ketamine**
Drugs	Ketamine (Ketalar)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Depression: N/A Complex Regional Pain Syndrome (CRPS): pain management specialist
Coverage Duration	Initial: 4 weeks Continuation of therapy: 6 months

Other Criteria	**<u>Depression</u>**
	
	Initial Authorization:
	• Diagnosis of major depressive disorder (MDD) or treatment-resistant depression (TRD)
	• Documented trial and failure of two preferred oral antidepressants (e.g. SSRIs, SNRIs, TCAs) of at least a minimum effective dose for four (4) weeks or longer OR a medical justification as to why the patient cannot use preferred alternative(s).
	Re-authorization:
	• Documentation was submitted indicating the member has clinically benefited from therapy.
	
	<u>CRPS</u>
	
	Initial Authorization:
	• Diagnosis of CRPS (may also be termed reflex sympathetic dystrophy, algodystrophy, causalgia, Sudeck atrophy, transient osteoporosis, and acute atrophy of bone)
	• Patient has tried and failed at least 8 weeks treatment with or continues to receive physical therapy (PT) and/or occupational therapy (OT).
	• Patient has tried and failed at least two of the following:
	  ○ NSAIDs
	  ○ Anticonvulsants (e.g. gabapentin, pregabalin)
	  ○ Antidepressants (e.g. SNRIs, TCAs)
	  ○ Bisphosphonate (in the setting of abnormal uptake on bone scan)

Revision/Review Date 4/2025	**Re-authorization:** • Patient has demonstrated clinical benefit. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Kisunla**
Drugs	Kisunla (donanemab-azbt)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Patients with moderate to severe Alzheimer's Disease (AD) Patients with neurodegenerative disease caused by a condition other than AD
Required Medical Information	See "Other Criteria"
Age Restrictions	Age 60-85 years
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	For initial authorization: the request will be approved in accordance with the FDA-indicated titration schedule for up to 6 months For reauthorization: if all of the conditions are met, the request will be approved for 6 months.
Other Criteria	**Initial Authorization** • Diagnosis of mild cognitive impairment (MCI) caused by AD or mild AD dementia consistent with Stage 3 or Stage 4 Alzheimer's disease as evidenced by at least one of the following: o Clinical Dementia Rating Global (CDR-G) score of 0.5-1.0 o Mini-Mental State Examination (MMSE) score ≥ 20 and ≤ 28 o Montreal Cognitive Assessment (MoCA) score of ≥16 • The request is for an FDA approved dose • Documentation of BOTH of the following: o Recent, within past year, positive results for the presence of beta-amyloid plaques on a positron emission tomography (PET) scan or cerebrospinal fluid testing o Recent, within past year, baseline Magnetic Resonance Imaging (MRI) scan • Physician has assessed baseline disease severity utilizing an objective measure/tool (i.e., integrated Alzheimer's Disease Rating Scale [iADRS], Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog], Alzheimer's Disease Cooperative Study-instrumental Activities of Daily Living [ADCS-iADL], Clinical Dementia Rating-Sum of Boxes [CDR-SB], etc.)

Revision/Review Date 10/2025	• No recent (past 1 year) history of stroke, seizures or transient ischemic attack (TIA), or findings on neuroimaging that indicate an increased risk for intracerebral hemorrhage **Reauthorization** • The request is for an FDA approved dose • Patient continues to have a diagnosis of MCI caused by AD or mild AD dementia consistent with Stage 3 or Stage 4 Alzheimer's disease as evidenced by at least one of the following: o CDR-G score of 0.5-1.0 o MMSE score of 20-28 o MoCA score of ≥16 • Provider attestation of safety monitoring and management of amyloid related imaging abnormalities (ARIA) and intracerebral hemorrhage, as recommended per the manufacturer's prescribing information • Documentation that member has experienced clinical benefit from the medication (i.e., stabilization or decreased rate of decline in symptoms from baseline on CDR-SB, iADRS, ADAS-Cog, or ADCS-iADL scales) • No recent (past 1 year) history of stroke, seizures or TIA **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Lamzede**
Drugs	Lamzede (velmanase alfa-tycv)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	"See Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a specialist in the treatment of alpha-mannosidosis or other lysosomal storage disorders
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months

Other Criteria	**Initial Authorization**
	• Diagnosis of alpha-mannosidosis as confirmed by one of the following:
	  o Deficiency in alpha-mannosidase enzyme levels or activity in blood leukocytes
	  o DNA testing
	• Prescriber attests that medication will only be used to treat non-central nervous system manifestations of alpha-mannosidosis
	• Patient's weight
	• Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines
	
	Reauthorization
	• Patient has demonstrated a clinical response (i.e., reduction in serum oligosaccaride concentrations, stabilization or improvement in 3-minute stair climbing test [3MSCT], 6-minute walking test [6-MWT], forced vital capacity [FVC], etc.)
	• Prescriber attests that medication will only be used to treat non-central nervous system manifestations of alpha-mannosidosis
	• Patient's weight
	• Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines

Revision/Review Date 4/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Leqembi**
Drugs	Leqembi (lecanemab-irmb)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Patients with moderate to severe Alzheimer's Disease (AD) Patients with neurodegenerative disease caused by a condition other than AD
Required Medical Information	See "Other Criteria"
Age Restrictions	age 50-90 years
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	For initial and reauthorizations: if all of the conditions are met, the request will be approved for 6 months.
Other Criteria	**<u>Initial Authorization</u>** • Diagnosis of mild cognitive impairment (MCI) caused by AD or mild AD consistent with Stage 3 or Stage 4 Alzheimer's disease as evidenced by at least one of the following: o Clinical Dementia Rating Global (CDR-G) score of 0.5-1.0 and a Memory Box score of 0.5 or greater o Mini-Mental State Examination (MMSE) score ≥ 22 and ≤ 30 o Wechsler Memory Scale IV-Logical Memory (subscale) II (WMS-IV LMII) score at least 1 standard deviation below age-adjusted mean • The request is for an FDA approved dose • Documentation of BOTH of the following: o Recent, within past year, positive results for the presence of beta-amyloid plaques on a positron emission tomography (PET) scan or cerebrospinal fluid testing o Recent, within past year, baseline Magnetic Resonance Imaging (MRI) scan • Physician has assessed baseline disease severity utilizing an objective measure/tool (i.e., Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog-14], Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory-Mild Cognitive Impairment version [ADCS-ADL-MCI], Clinical Dementia Rating Sum of Boxes [CDR-SB], etc.) • No recent (past 1 year) history of stroke, seizures or transient ischemic attack (TIA), or findings on neuroimaging that indicate an increased risk for intracerebral hemorrhage. **<u>Reauthorization</u>**

Revision/Review Date 7/2025	• The request is for an FDA approved dose
	• Patient continues to have a diagnosis of mild cognitive impairment (MCI) caused by AD or mild AD consistent with Stage 3 or Stage 4 Alzheimer's disease as evidenced by at least one of the following:
	  o CDR-G score of 0.5-1.0 and a Memory Box score of 0.5 or greater
	  o MMSE score of 22-30
	  o Wechsler Memory Scale IV-Logical Memory (subscale) II (WMS-IV LMII) score at least 1 standard deviation below age-adjusted mean
	• Provider attestation of safety monitoring and management of amyloid related imaging abnormalities (ARIA) and intracerebral hemorrhage, as recommended per the manufacturer's prescribing information.
	• Documentation that member has experienced clinical benefit from the medication (such as: stabilization or decreased rate of decline in symptoms from baseline on CDR-SB, ADAS-Cog14, or ADCS MCI-ADL scales)
	• No recent (past 1 year) history of stroke, seizures, or TIA
	
	If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	**Levalbuterol for Inhalation**
Drugs	**FORMULARY STATUS** Preferred, Pays at Point-of-Sale (First line) **Albuterol HFA 90mcg/actuation** **Albuterol 0.63mg/3mL, 1.25mg/3mL, 2.5mg/3mL, 2.5mg/0.5mL inhalation solution** **FORMULARY STATUS** Preferred, Requires Step Therapy with one prior step (Second line) **Levalbuterol HFA 45mcg/actuation aerosol inhaler** **Levalbuterol 0.31mg/3mL, 0.63mg/3mL, 1.25/mg/3mL inhalation solution** **Note: Patient must meet criteria #1 & #2 for approval of the PA request.** **FORMULARY STATUS** Non-preferred, Requires prior authorization (Third line) **Albuterol 5mg/mL inhalation solution** **Levalbuterol 1.25mg/0.5mL inhalation solution** **Note: Patient must meet criteria #1 & #3 for approval of the PA request.**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to 12 month duration for.

Other Criteria Revision/Review Date 2/2025	**<u>Initial Authorization:</u>** 1. Presumed or documented diagnosis of dyspnea, asthma, or bronchospasm 2. Documented trial and failure or intolerance with an inhalation form of albuterol for a minimum of 3 weeks within past 60 days 3. Documented trial and failure or intolerance with a second line agent for a minimum of 3 weeks within past 60 days

Field Name	Field Description
Prior Authorization Group Description	**Lidocaine Topical Patch**
Drugs	Lidocaine 5% topical patch (Lidoderm) Ztlido 1.8% topical patch (lidocaine)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	Age 18 and older
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 6 month duration; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria Revision/Review Date 4/2025	**<u>Initial Authorization</u>** • Diagnosis of postherpetic neuralgia • If the request is for Ztlido there has been a documented trail and failure or intolerance to lidocaine 5% patch (Lidoderm) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Lodoco**
Drugs	Lodoco (colchicine) tablets
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Per FDA approved prescribing information
Prescriber Restrictions	Prescriber must be, or in consultation with a specialist in the treatment of cardiovascular disease, such as a cardiologist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.

Other Criteria
 	
Revision/Review Date: 2/2025
	• Patient has established atherosclerotic disease or multiple risk factors for cardiovascular disease
	• Patient is currently receiving statin therapy, or documentation has been provided that the member has a medical reason statin therapy is not appropriate
	• Documentation is provided that guideline directed medical therapies targeted to patient's specific risk factors are being maximized, such as medications targeted at reduction in cholesterol, blood pressure, antiplatelet therapies, and diabetes
	• Patient does not have pre-existing blood dyscrasias (ex. leukopenia, thrombocytopenia)
	• Patient does not have renal failure (CrCl less than 15 ml/min) or severe hepatic impairment
	• Patient is not currently taking medications contraindicated for concurrent use with Lodoco
	  o Strong CYP3A4 inhibitors (ex. atazanavir, clarithromycin, darunavir/ritonavir, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, tipranavir/ritonavir)
	  o P-glycoprotein inhibitors (ex. cyclosporine, ranolazine)
	
	Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group	**Long Acting Injectable Antipsychotics**
Drug(s)	**<u>Preferred, Pays at Point of Sale:</u>** **Abilify Maintena, Abilify Asimtufii** (aripiprazole monohydrate) **Aristada**, **Aristada Initio** (aripiprazole lauroxil) **Risperidone** (Risperdal Consta) **Uzedy** (risperidone) **<u>Non-Preferred:</u>** **Invega Sustenna, Invega Trinza** (paliperidone palmitate) **Invega Hafyera** (paliperidone palmitate) **Rykindo** (risperidone) Erzofri (paliperidone palmitate) **or any newly marketed long acting injectable antipsychotic**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be 18 years of age or older.
Prescriber Restrictions	Prescribed by or in consultation with a psychiatrist
Coverage Duration	If all of the conditions are met, the initial request will be approved for 6 month duration; reauthorization requests will be approved for 12 months.
Other Criteria	<u>Initial approval:</u> • Member has claims history or physician attestation that member has had prior use of an oral atypical antipsychotic • Member has demonstrated tolerability to the oral agent of the drug that is being requested • If the request is for any other product other than the preferred agents, the member has a documented trial (consistent with pharmacy claims or chart notes including 3 months or more of therapy) with one of the preferred agents, **<u>OR</u>** has a documented medical reason such as intolerance, hypersensitivity, contraindication, etc. **<u>OR</u>** documentation was provided indicating member was previously established on a non-preferred agent • If request is for Invega Trinza, documentation has been provided that the member has been stable on Invega Sustenna for 4 months, and at the same dose for the last 2 months

	• If the request is for Invega Hafyera, documentation has been provided that the member has been stable on Invega Sustenna for 4 months and at the same dose for the last 2 months OR has been stable on Invega Trinza for the last 3 months • Request is for FDA approved indication at an approved dose <u>Reauthorization:</u> • Member has been compliant with filling their medication **OR** documentation was provided indicating why member missed dosing • Documentation was provided that member is stable on medication • Request is for FDA approved indication at an approved dose
Revision/Review Date 4/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	MEK Inhibitors for Neurofibromatosis Type 1 (NF1)
Drugs	Gomekli (mirdametinib), Koselugo (selumetinib)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Prior use of a MEK inhibitor
Required Medical Information	See "Other Criteria"
Age Restrictions	Per package insert
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Date: 7/2025	**Initial Authorization:** • Documentation of neurofibromatosis type 1 (NF1) with symptomatic plexiform neurofibromas (PN) not amenable to complete resection • Drug will be given as monotherapy • Medication is prescribed at an FDA approved dose **Re-Authorization:** • Documentation or provider attestation of positive clinical response (i.e. no evidence of progressive disease) • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Ucopol Field Name	Field Description
Prior Authorization Group Description	**Mucopolysaccharidosis II (Hunter Syndrome) Agents**
Drugs	**Elaprase (idursulfase)**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	"See Other Criteria"
Age Restrictions	Patient is ≥ 16 months of age
Prescriber Restrictions	Prescribed by or in consultation with a specialist in the management Mucopolysaccharidosis II (geneticist, endocrinologist, neurologist, rheumatologist, etc.)
Coverage Duration	Initial Authorization: 6 months Reauthorization: 12 months
Other Criteria Revision/Review Date 7/2025	**Initial Authorization** • Diagnosis of Mucopolysaccharidosis II as confirmed by one of the following: o Enzyme assay demonstrating a deficiency of iduronate 2-sulfatase activity o Genetic testing • Patient's weight • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines **Reauthorization** • Patient has demonstrated a beneficial response (i.e., stabilization or improvement in 6-minute walk test [6-MWT], forced vital capacity [FVC]), urinary glycosaminoglycan (GAG) levels, liver volume, spleen volume, etc.) • Patient's weight • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Mucopolysaccharidosis VI (Maroteaux-Lamy Syndrome) Agents**
Drugs	**Naglazyme (galsulfase)**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	"See Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months Renewal: 12 months

Other Criteria	**Initial Authorization**
	• Diagnosis of Mucopolysaccharidosis VI as confirmed by one of the following:
	  o Enzyme assay demonstrating a deficiency in N-acetygalactosamine 4-sulfatase (arylsulfatase B) enzyme activity
	  o DNA testing
	• Patient's weight
	• Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines
	
	Reauthorization
	• Patient has demonstrated a beneficial response (i.e., stabilization or improvement in 12-minute walk test [12-MWT], 3-minute stair climb test, urinary glycosaminoglycan (GAG) levels, etc.)
	• Patient's weight
	• Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines

Revision/Review Date 10/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Multaq**
Drugs	**Multaq (dronedarone)**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Pregnancy
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	Request must be from a cardiologist or electrophysiologist.
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 4/2025	• Diagnosis of paroxysmal or persistent atrial fibrillation (AF) or atrial flutter (AFL) with a recent episode. • Must not have NYHA Class IV heart failure or symptomatic heart failure with recent decompensation requiring hospitalization or referral to a specialized heart failure clinic • Must have AF that can be cardioverted into normal sinus rhythm, or is currently in sinus rhythm • Prescriber attests women of childbearing potential have been counseled regarding appropriate contraceptives **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Myasthenia Gravis Agents**
Drugs	Rystiggo (rozanolixizumab), Soliris (eculizumab), Ultomiris (ravulizumab),Vyvgart (efgartigimod), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase), Zilbrysq (zilucoplan), BVEMV (eculizumab-aeeb), Epysqli (eculizumab-aagh), Imaavy (nipocalimab-aahu)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or rheumatologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.

Other Criteria	**Initial Authorization:**
	• Diagnosis of generalized myasthenia gravis (gMG)
	• Patient has a positive serological test for one of the following:
	  o Anti-AChR antibodies
	  o Anti-muscle-specific tyrosine kinase (MuSK) antibodies (Imaavy and Rystiggo only)
	• Patient has a Myasthenia Gravis Foundation of America (MGFA) clinical classification of class II, III or IV
	• For adults: patient has tried and failed, or has contraindication, to one of the following:
	  o Two (2) or more conventional therapies (i.e. acetylcholinesterase inhibitors, corticosteroids, non-steroidal immunosuppressive therapies)
	  o Failed at least 1 conventional therapy and required chronic plasmapheresis or plasma exchange or intravenous immunoglobulin
	• For eculizumab in patients 6-17 years: one of the following:
	  o Trial and failure of at least 1 conventional therapy (i.e. acetylcholinesterase inhibitors, corticosteroids, non-steroidal immunosuppressive therapies)
	  o Patient requires maintenance plasma exchange or intravenous immunoglobulin to control symptoms
	• Medication is prescribed at an FDA approved dose
	• Patient is not using agents covered by this policy concurrently (i.e. no concurrent use of Imaavy, Vyvgart, Vyvgart Hytrulo, Rystiggo, Soliris, Ultomiris, BKEMV, Epysqli or Zilbrysq)
	• For Vyvgart Hytrulo, patient has tried and failed, or has contraindication, to Vyvgart

Revision/Review Date: 7/2025	• Requests for Imaavy, Soliris (eculizumab), BKEMV (eculizimab-aeeb), Epysqli (eculizumab-aagh), Ultomiris (ravulizumab), and Zilbrysq (zilucoplan) will also require all of the following: o For adults: patient has tried and failed, or has contraindication, to Vyvgart, Vyvgart Hytrulo, or Rystiggo. ▪ Additionally, if the request is for Soliris or BKEMV, member must also have a documented trial and failure or intolerance to Epysqli or a medical reason why Epysqli cannot be used. o All ages: documentation patient complies with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against meningococcal infections in patients receiving a complement inhibitor**.** **<u>Re-Authorization:</u>** • Provider has submitted documentation of clinical response to therapy (e.g., reduction in disease severity, improvement in quality-of-life scores, MG-ADL scores, etc). • Medication is prescribed at an FDA approved dose. **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Neuromyelitis Optica Spectrum Disorder (NMOSD) Agents**
Drugs	Step 1: Rituximab (Rituxan, Truxima, Riabni, Ruxience), Step 2: Enspryng (satralizumab-mwge) Uplizna (inebilizumab-cdon) Step 3: Soliris (eculizumab) Ultomiris (ravulizumab-cwyz)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	For Enspryng, Uplizna, Soliris, Ultomiris: Anti-aquaporin-4 (AQP4) antibody **negative** neuromyelitis optica spectrum disorder (NMOSD)
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a specialist who is experienced in the treatment of NMOSD (such as immunologist, neurologist or hematologist)
Coverage Duration	If all of the conditions are met, requests will be approved for 12 months.
Other Criteria	**Initial Authorization:** For rituximab (Rituxan, Truxima, Riabni, or Ruxience): • Member has a diagnosis of NMOSD • Documentation indicating that the patient has been screened for HBV (hepatitis B virus) prior to initiation of treatment • Dosing is supported by compendia or standard of care guidelines • If the request is for any medication other than Ruxience (rituximab-pvvr) or Riabni (rituximab-arrx), there is a documented trial and failure of Ruxience or Riabni, or medical reason why (e.g. intolerance, hypersensitivity, contraindication) they cannot be used For Enspryng: • Member has a diagnosis of anti-aquaporin-4 (AQP4) antibody **positive** NMOSD • Provider attests to completion of the following assessments prior to the first dose of Enspryng as outlined in the prescribing information: o Hepatitis B virus screening o Tuberculosis screening

	○ Liver transaminase screening ○ Patient has not received live or attenuated-live virus vaccines within 4 weeks before the start of Enspryng therapy • Documented trial and failure of rituximab (Rituxan, Truxima, Riabni, or Ruxience), azathioprine, or mycophenolate mofetil, or medical reason why (e.g., intolerance, hypersensitivity, contraindication) they cannot be used • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines Exceptions: Requests for drugs in step 2 (Enspryng, Uplizna) may be approved without a trial and failure of rituximab (Rituxan, Truxima, Riabni, Ruxience), azathioprine, or mycophenolate if the member has been using Soliris or Ultomiris <u>For Uplizna:</u> • Member has a diagnosis of anti-aquaporin-4 (AQP4) antibody **positive** NMOSD • Provider attests to completion of appropriate assessments prior to the first dose of Uplizna as outlined in the prescribing information: ○ Hepatitis B virus screening ○ Quantitative serum immunoglobulins ○ Tuberculosis screening ○ Patient has not received live or attenuated-live virus vaccines within 4 weeks before the start of Uplizna therapy • Documented trial and failure of rituximab (Rituxan, Truxima, Riabni, or Ruxience), azathioprine, or mycophenolate mofetil or medical reason why (e.g., intolerance, hypersensitivity, contraindication) they cannot be used • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines Exceptions: Requests for drugs in step 2 (Enspryng, Uplizna) may be approved without a trial and failure of rituximab (Rituxan, Truxima, Riabni, Ruxience), azathioprine, or mycophenolate if the member has been using Soliris or Ultomiris <u>For Soliris/Ultomiris:</u> • Member has a diagnosis of anti-aquaporin-4 (AQP4) antibody **positive** NMOSD

	• Documentation patient complies with most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria.
	• Antimicrobial prophylaxis with oral antibiotics (penicillin, or macrolides if penicillin-allergic) for two weeks if the meningococcal vaccine is administered < 2 weeks before starting therapy or a documented medical reason why the patient cannot receive oral antibiotic prophylaxis.
	• Documented trial and failure of, or medical reason why (e.g. intolerance, hypersensitivity, contraindication) why the following cannot be used (one from each bullet below):
	  o Rituximab (Rituxan, Truxima, Riabni, or Ruxience), azathioprine, or mycophenolate mofetil
	  o Enspryng
	  o Uplizna
	• Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines
	
	<u>Reauthorization:</u>
	• Documentation that the prescriber has evaluated the member and recommends continuation of therapy (clinical benefit)
	• Request is for an FDA approved/medically accepted dose
	
	Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Revision/Review Date 10/2025	

Field Name	Field Description
Prior Authorization Group Description	**Natriuretic Peptides for Achondroplasia**
Drugs	Voxzogo (vosoritide)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Hypochondroplasia or short stature condition other than achondroplasia
Required Medical Information	See "Other Criteria"
Age Restrictions	According to FDA approved prescribing information
Prescriber Restrictions	Prescribed by, or in consultation with, an endocrinologist, medical geneticist, or other specialist for the treatment of achondroplasia
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 4/2025	**<u>Initial Authorization:</u>** • Member has a diagnosis of achondroplasia as confirmed via genetic testing • Prescriber attests patient has open epiphyses • Documentation of baseline growth velocity • Medication is prescribed at an FDA approved dose **<u>Re-Authorization:</u>** • Documentation of positive clinical response to therapy (as demonstrated by improvement over baseline in annualized growth velocity) • Prescriber attests patient has open epiphyses • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Nemluvio for Prurigo Nodularis**
Drugs	Nemluvio (nemolizumab-ilto)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescriber must be an allergist, immunologist, or a dermatologist.
Coverage Duration	If all the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.

Other Criteria
 	
Date: 2/2025
	<u>Initial Authorization:</u>
	• Diagnosis of severe prurigo nodularis (PN) with ≥ 6 weeks of pruritus
	• Member has ≥ 20 PN lesions
	• Documentation of member weight
	• Member has a ≥ 2-week trial of one of the following:
	  o Moderate potency or higher topical corticosteroid (TCS)
	  o Topical calcineurin inhibitor (TCI)
	• Medication is prescribed at an FDA approved dose
	<u>Re-Authorization:</u>
	• Documentation or provider attestation of positive clinical response (reduced nodular lesion count, decreased pruritis, etc.)
	• Documentation of member weight
	• Medication is prescribed at an FDA approved dose
	
	If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	**Niemann-Pick Disease Type C**
Drugs	Miplyffa (arimoclomol), Aqneursa (levacetylleucine)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Concomitant use of Miplyffa and Aqneursa
Required Medical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a neurologist, geneticist, or specialist in the treatment of Niemann-Pick disease type C (NPC)
Coverage Duration	If all criteria are met, the request will be approved for 12 months.

Other Criteria
 	
Revision/Review Date: 2/2025
	<u>Initial Authorization</u>
	• Diagnosis of NPC as confirmed by genetic testing demonstrating one of the following:
	  o Mutations in both alleles of NPC1 gene or NPC2 gene
	  o Mutation in one allele of NPC1 or NPC2 AND either a positive filipin-staining or elevated cholestane triol/oxysterols (>2x the upper limit of normal)
	• Documentation that member has at least one neurological sign of NPC (i.e., cognitive decline, vertical supranuclear gaze palsy, ataxia, seizures, etc.)
	• Documentation that member is ambulatory
	• For Miplyffa, prescriber must also attest that member will use in combination with miglustat
	• Member's weight
	• Request is for an FDA-approved dose
	
	<u>Reauthorization</u>
	• Documentation of positive clinical response to therapy (i.e., improvement or stabilization in ambulation, fine motor skills, swallowing, or speech)
	• Member's weight
	• Request is for an FDA-approved dose
	
	Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	**Nitisinone Products**
Drugs	Nitisinone (Orfadin) capsules Orfadin suspension Nityr (nitisinone) tablets Harliku (nitisinone) tablets
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	None
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a specialist in the diagnosis submitted
Coverage Duration	If all criteria are met, initial requests will be approved for up to 6 months and reauthorization requests will be approved for up to 12 months.

Other Criteria	**Initial Authorization for alkaptonuria (AKU) (Harliku and generic nitisinone only)**
	• Diagnosis of AKU confirmed by one of the following:
	  o Urinary homogentisic acid (HGA) excretion of >0.4 g/24 hours
	  o Genetic testing reveals variations in the homogentisate 1,2 dioxygenase (HGD) gene
	• Documented clinical manifestation of AKU (e.g. urine that darkens when exposed to air, ochronosis, chronic joint pain)
	• For Harliku, documented trial and failure, or intolerance to treatment with generic nitisinone prescribed at a dose for the treatment of AKU
	• For Harliku, the drug is prescribed at an FDA approved dose
	
	Initial Authorization for Hereditary Tyrosinemia Type 1 (all nitisinone products EXCEPT Harliku):
	• Diagnosis of Hereditary Tyrosinemia Type 1 confirmed by one of the following:
	  o DNA testing
	  o Detection of succinylacetone (SA) in urine or blood test
	• Documentation provided attesting to diet restricting tyrosine and phenylalanine

Revision/Review Date: 10/2025	• If request is for Nityr tablet or Orfadin suspension, documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use generic nitisinone (Orfadin) capsule • Drug is prescribed at an FDA approved dose **<u>Re-Authorization:</u>** • Attestation that member is achieving a clinical benefit from treatment o For Harliku, clinical benefit evidenced by decrease in urinary homogentisic acid [HGA] levels, decrease in visible ochronosis, and/or improvement/stabilization in joint-related symptoms • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Non-Preferred Inhaled Corticosteroid/Beta Agonist Combination Inhalers for Asthma and Chronic Obstructive Pulmonary Disease (COPD)**
Drugs	**Preferred, will pay at point of sale:** • fluticasone/salmeterol (AirDuo RespiClick) • fluticasone/salmeterol (Advair Diskus) **Non-preferred, Prior authorization required:** • Airsupra (albuterol/budesonide) • fluticasone/vilanterol (Breo Ellipta) • budesonide/formoterol (Symbicort HFA) • Breyna (budesonide/formoterol) • fluticasone/salmeterol (Advair HFA) • Wixela Inhub (Advair Diskus) • Dulera (mometasone/ formoterol) • Trelegy Ellipta (fluticasone/umeclidinium/vilanterol) • Breztri Aerosphere (budesonide/glycopyrrolate/formoterol) *and any other newly-marketed orally inhaled corticosteroid combination for asthma or COPD*
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved for one inhaler per month for 12 months or two budesonide/formoterol inhalers per month for 12 months if being used as the single inhaler for maintenance and reliever therapy.
Other Criteria	**Authorization:** 1. For budesonide/formoterol requests, documentation of one of the following: o Trial and failure, intolerance, inability to use or contraindication to generic AirDuo RespiClick or generic Advair Diskus (fluticasone/salmeterol) o Budesonide/formoterol will be used as the single inhaler for intermittent asthma o Budesonide/formoterol will be used as the single inhaler for maintenance and reliever therapy for asthma

Revision/Review Date: 2/2025	2. For Airsupra requests: o Trial and failure, intolerance, inability to use or contraindication to a budesonide/formoterol product 3. For all other non-preferred inhalers: o Documentation of trial and failure, intolerance, inability to use or contraindication to generic AirDuo RespiClick or generic Advair Diskus (fluticasone/salmeterol) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Ohtuvayre**
Drugs	Ohtuvayre (ensifentrine)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Primary diagnosis of asthma • Concomitant use of oral PDE4 inhibitors
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Ohtuvayre must be prescribed by or in consultation with a pulmonologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for a 6 month duration and reauthorization requests will be approved for up to a 12 month duration
Other Criteria Revision/Review Date: 10/2025	**<u>Initial Authorization:</u>** • Diagnosis of chronic obstructive pulmonary disease (COPD) • Documentation of a pre- and post-albuterol FEV1/FVC ratio of <0.70 • Documentation of a score of ≥ 2 on the Modified Medical Research Council (mMRC) Dyspnea Scale or a score of ≥ 10 on the COPD Assessment Test (CAT) • Documented trial, intolerance, or contraindication to treatment with a long-acting beta-2 agonist (LABA) plus a long-acting muscarinic antagonist (LAMA) (or a documented medical reason must be provided why the member is unable to use these therapies) • The drug is being prescribed at an FDA approved dose **<u>Re-Authorization:</u>** • The drug is being prescribed at an FDA approved dose • Documentation of clinical benefit from the medication (e.g. improvement in symptoms and exacerbations, improvement in mMRC or CAT, improvement in FEV1/FVC ratio, etc.) **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Ophthalmic Antihistamines**
Drugs	**<u>FORMULARY STATUS</u>** Preferred, Pays at Point-of-Sale **ketotifen 0.025% (Alaway, Zaditor)** eye drops **<u>FORMULARY STATUS</u>** Requires Step Therapy with one prior step **olopatadine 0.1% (Pataday Twice Daily)** eye drops **olopatadine 0.2% (Pataday Once Daily)** eye drops **Pataday Once Daily 0.7% (olopatadine)** eye drops **azelastine 0.05%** eye drops **Note: Patient must meet criteria #1 & #2 for approval of the PA request.**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 7/2025	1. Presumed or documented diagnosis of allergic conjunctivitis 2. Documented trial and failure or intolerance with ketotifen eye drops for a minimum of 2 weeks

Field Name	Field Description
Prior Authorization Group Description	**Opioid Containing Products**
Drugs	1. Opioids >90 Morphine Milligram Equivalents (MME) per day. 2. Opioids >7 days supply 3. All long acting opioid products regardless of dose or day supply
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Members taking buprenorphine-containing products for opioid dependence.
Required Medical Information	See "Other Criteria"
Age Restrictions	Patient must be age appropriate per package insert
Prescriber Restrictions	Pain Specialist, Oncologist, Hospice Physician, Hematologist, Surgeon, or attestation that the requesting prescriber is working in consultation with or has consulted with one of the above specialty types. If the prescriber is not one of the above specialties and is unable to consult with one of the above specialties, provider has attested that an attempt has been made to refer and/or transition patient to one of the above specialties.
Coverage Duration	If the criteria are met, the request will be approved for up to six months duration; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	*****If the member has cancer, sickle cell disease, is receiving hospice care or palliative care, or is a resident of a long-term care facility, please automatically authorize for up to 12 months (member must meet non-formulary criteria if request is for non-formulary medication)***** **Initial Authorization for Opioid Containing Products:** 1. The diagnosis is pain. For long-acting products, the diagnosis is chronic pain that requires daily, around the clock, opioid medication. 2. The patient has tried and failed non-pharmacologic treatment and two non-opioid containing pain medications (ex. acetaminophen, NSAIDs, selected antidepressants, anticonvulsants). 3. The prescriber has justified medical necessity for dosing above 90MME per day (i.e active tapering) and/or for request above day supply limits. 4. Member is not taking concurrent benzodiazepines. If member is taking benzodiazepines, prescriber has provided documentation as to why and has discussed risks of using opioids and benzodiazepines concurrently and has outlined plan for tapering if appropriate. 5. Member is not taking concurrent muscle relaxants. If member is taking muscle relaxants, prescriber has provided documentation as to why and has discussed risks of using opioids and muscle relaxants concurrently and has outlined plan for tapering if appropriate. 6. If patient has a high-risk condition stated in the CDC guidelines (ex. sleep apnea or other causes of sleep-disordered breathing, patients with

	renal or hepatic insufficiency, older adults, pregnant women, patients with depression or other mental health conditions, and patients with alcohol or other substance use disorders) prescriber attests to discussing heightened risks of opioid use and has educated patient on naloxone use and has considered prescribing naloxone. 7. Prescriber attests urine drug screens will be completed every 6 months and if illicit drugs are found, identifying the patient as high risk, the heightened risk of overdose will be explained to the patient. 8. Prescriber attests to discussing with the patient the level of risk for opioid abuse/overdose with the dose/duration prescribed to the patient. 9. Prescriber attests to discussing concomitant psychological disease and risks associated with opioid overdose/abuse. 10. Prescriber attests to discussing history of substance abuse and the risks associated with opioid overdose/abuse. 11. Prescriber has the patient's signature on file acknowledging education regarding the risks of opioid therapy as listed in items 8, 9, and 10 above. 12. Prescriber has provided a copy of a pain management agreement 13. Prescriber attests to checking the District's PDMP 14. If the request is for a non-formulary opioid, patient must meet criteria 1-13 AND one of the following conditions: a. Documented trial and failure or intolerance with two formulary medications used to treat the documented diagnosis. For medications where there is only one preferred agent, only that agent must have been ineffective or not tolerated. b. No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia. c. All other formulary medications are contraindicated based on the patient's diagnosis, other medical conditions, or other medication therapy. **<u>Reauthorization for Opioid Containing Products:</u>** 15. Dose requested is titrated down from initial authorization. a. If not, the prescriber has explained medical necessity for continued dosing above 90MME per day and/or above the day supply limit and proposed plan for titration going forward. b. If the requested dose is higher than that which was approved previously than the provider has submitted documentation of patient reassessment and medical justification explaining why the dose must be increased 16. Member is not taking concurrent benzodiazepines. If member is taking benzodiazepines, prescriber has provided documentation as to why and has discussed risks of using opioids and benzodiazepines concurrently and has outlined plan for tapering if appropriate. 17. Member is not taking concurrent muscle relaxants. If member is taking muscle relaxants, prescriber has provided documentation as to why and has discussed risks of using opioids and muscle relaxants concurrently and has outlined plan for tapering if appropriate. 18. Urine drug screen dates have been submitted every 6 months. If illicit drugs are found, prescriber has attested to identifying patient as high risk

	and explained heightened risk of overdose to patient. If opioids are not found on urine drug screen, prescriber attests to why member needs to continue therapy. 19. If patient has a high-risk condition stated in the CDC guidelines (ex. sleep apnea or other causes of sleep-disordered breathing, patients with renal or hepatic insufficiency, older adults, pregnant women, patients with depression or other mental health conditions, and patients with alcohol or other substance use disorders) prescriber attests to discussing heightened risks of opioid use and has educated patient on naloxone use and has considered prescribing naloxone. 20. Prescriber attests to checking the District's PDMP 21. If the request is for a non-formulary opioid, patient must meet criteria 15-20 AND one of the following conditions: a. Documented trial and failure or intolerance with two formulary medications used to treat the documented diagnosis. For medications where there is only one preferred agent, only that agent must have been ineffective or not tolerated. b. No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia. c. All other formulary medications are contraindicated based on the patient's diagnosis, other medical conditions, or other medication therapy.
Revision/Review Date: 4/2025	**<u>Requests for Opioid Containing Cough/Cold Products</u>** If the request is for an opioid containing cough/cold product, the prescriber has explained medical necessity for use of this product AND attests to checking the District's PDMP AND attests to being aware of all other opioid prescriptions the member is currently taking if applicable. If the product is non-formulary, there is a documented trial and failure or medical reason why member cannot use two formulary agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Oral Atypical Antipsychotics for Members Below the FDA Approved Minimum Age**
Drugs	**Formulary Status:** Preferred; Pays at Point-of-Sale Aripiprazole (Abilify) tablet, oral solution Clozapine (Clozaril) tablet Olanzapine (Zyprexa) tablet Quetiapine (Seroquel) tablet Quetiapine Extended Release (Seroquel XR) tablet Risperidone (Risperdal) tablet, oral solution Ziprasidone (Geodon) capsule **Formulary Status:**Non-preferred; Requires Prior Authorization Aripiprazole (Abilify) ODT Asenapine (Saphris) Caplyta (lumateperon) Clozapine (Fazaclo) ODT Fanapt (iloperidone) Lurasidone (Latuda) Lybalvi (olanzapine/samidorphan) Nuplazid (pimavanserin) Olanzapine (Zyrpexa Zydis) ODT Olanzapine/Fluoxetine (Symbyax) capsule Opipza (aripiprazole) oral film Paliperidone (Invega) tablet Rexulti (brexpiprazole) Risperidone (Risperdal M-tab) ODT Secuado (asenapine) Versacloz (clozapine) Vraylar (cariprazine)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	Aripiprazole (Abilify) ≥ 6 years old Caplyta (lumateperon) ≥ 18 years old Clozapine (Clozaril, Fazaclo, Versacloz) ≥ 18 years old Fanapt (iloperidone) ≥ 18 years old Lurasidone (Latuda) ≥ 10 years old Lybalvi (olanzapine/samidorphan) ≥ 18 years old Nuplazid (pimavanerin) ≥ 18 years old Olanzapine (Zyprexa) ≥ 10 years old Olanzapine/Fluoxetine (Symbyax) ≥ 10 years old Opipza (aripiprazole) oral film ≥ 6 years old Paliperidone (Invega) ≥ 12 years old

	Quetiapine (Seroquel) ≥ 10 years old Quetiapine Extended Release (Seroquel XR) ≥ 10 years old Risperidone (Risperdal) ≥ 5 years old Rexulti (brexpiprazole) ≥ 13 years old Saphris (asenapine) ≥ 10 years old Secuado (asenapine) ≥ 18 years old Vraylar (cariprazine) ≥ 18 years old Ziprasidone (Geodon) ≥ 18 years old
Prescriber Restrictions	Prescription is written by, or in consultation with, a Pediatric Neurologist, Child and Adolescent Psychiatrist, or a Child Development Pediatrician
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 4/2025	**For members below the FDA approved minimum age:** • Documentation of severe behavioral problems related to psychotic or neuro-developmental disorders (such as, but not limited to: autism, intellectual disability, bipolar disorder, tic disorder, or schizophrenia); **AND** • Documentation of a trial of non-pharmacologic therapies (e.g., behavioral, or cognitive); **AND** • If the request is for a non-preferred antipsychotic there has been a documented trial and failure or intolerance of 2 preferred antipsychotics for requested diagnosis **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Oxervate**
Drugs	Oxervate (cenegermin-bkbj)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, an ophthalmologist or optometrist
Coverage Duration	If all of the criteria are met, the request will be approved for a one-time 8-week treatment course. Additional treatment beyond 8-weeks will not be authorized.
Other Criteria Revision/Review Date 10/2025	• Documented diagnosis of Stage 2 or 3 neurotrophic keratitis • Documented treatment failure with at least one conventional non-surgical treatment for neurotrophic keratitis (i.e., artificial tear products, therapeutic soft contact lenses) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	**Field Description**
Prior Authorization Group Description	**Palynziq**
Drugs	Palynziq (pegvaliase-pqpz)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	None
Required Medical Information	See "other criteria"
Age Restrictions	None
Prescriber Restrictions	Specialist experienced in the treatment of phenylketonuria (PKU).
Coverage Duration	Initial Authorizations: 12 months Dose Increases (to 40 mg or 60 mg daily): 16 weeks Reauthorization: 12 months
Other Criteria	**INITIAL AUTHORIZATION:** • Documentation of a confirmed diagnosis of Phenylketonuria (PKU); **AND** • Documentation the member's blood phenylalanine (Phe) level is greater than 600 micromol/L(include lab results; must be within the past 90 days) • Documentation or prescriber attestation that the member has attempted control of PKU through a Phe restricted diet with Phe-free medical products/foods in conjunction with dietician or nutritionist. (Examples include Phenyl-Free [phenylalanine free diet powder], Loplex, Periflex, Phlex-10, PKU 2, PKU 3, XPhe Maxamaid, XPhe Maxamum) • Member has previously received sapropterin (Kuvan) and either had an inadequate response, was a non-responder (defined as members who were dosed at 20 mg/kg/day and did not have a decrease in blood Phe level after 1 month), or has a documented medical reason why sapropterin (Kuvan) cannot be used • The medication is being prescribed at a dose no greater than the FDA approved maximum initial dose of 20 mg SQ once daily. **DOSE INCREASES:** • Documentation of recent blood Phe level results (within the past 90 days). • Confirmation Phe control has not been achieved after adequate timeframe on the current dosing regimen: o For requests for a dose of 40 mg per day, the patient has been on 20 mg once daily continuously for at least 24 weeks and has not achieved adequate

Revision/Review Date: 4/2025	control o For requests for a dose of 60 mg per day, the patient has been on 40 mg once daily continuously for at least 16 weeks and has not achieved adequate control • The medication is being prescribed at an FDA approved dose (maximum of 60 mg once daily). **<u>REAUTHORIZATION:</u>** • Documentation of recent blood Phe level results (within the previous 90 days); **AND** • The medication is being prescribed at an FDA approved dose; **AND** • Member has achieved a reduction in blood phenylalanine concentration from pre-treatment baseline.. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Peanut Allergy Immunotherapy Agents (FDA Approved)**
Drugs	Palforzia [Peanut (Arachis hypogaea) Allergen Powder-dnfp] capsule/sachet
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Use of Palforzia concomitantly with Xolair
Required Medical Information	See "Other Criteria"
Age Restrictions	Initiation: Patient is age 4-17 years. Up dosing and maintenance: Patient is age ≥ 4 years
Prescriber Restrictions	Prescriber is a specialist in the area of allergy/immunology
Coverage Duration	6 months
Other Criteria	**Initial Authorization:** Palforzia is approved when all of the following criteria are met: • Patient has a confirmed diagnosis of peanut allergy • For patients starting initial dose escalation (new to therapy) o Patient has not had severe or life-threatening anaphylaxis within the previous 60 days • Patient will follow a peanut-avoidant diet • Patient has been prescribed and has acquired (as demonstrated by pharmacy claims or documentation) injectable epinephrine • No history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease • Patient does not have uncontrolled asthma **Criteria for Re-Authorization:** Palforzia is approved for re-authorization when all of the following criteria are met • Patient will follow a peanut-avoidant diet • Patient is able to tolerate at least the 3 mg dose daily • Patient is able to comply with the daily dosing requirements • Patient does not have recurrent asthma exacerbations or persistent loss of asthma control • Patient has been prescribed and has acquired (as demonstrated by pharmacy claims or documentation) injectable epinephrine **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**
Revision/Review Date	4/2025

Field Name	Field Description
Prior Authorization Group	**Pehnylalanine Hydroxylase Activators**
Drug(s)	sapropterin (Kuvan), Sephience (sepiapterin)
Covered Uses	*Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI) , and the Drug Package Insert).
Exclusion Criteria	None
Required Medical Information	See "Other Criteria"
Age Restrictions	None
Prescriber Restrictions	Specialist experienced in treating Phenylketonuria (PKU)
Coverage Duration	**Initial:** If the criterion is met, the request will be approved for a duration of 1 month; **Reauthorization:** If the criteria is met, the sapropterin requests will be approved for a duration of 1 month for patients who require a dose increase to 20 mg/kg/day due to non-responsiveness. Sephience requests will be approved for a duration of 1 month for patients who require a dose increase from their previous dose (up to a max dose of 60 mg/kg/day) due to non-responsiveness. For all other patients the request will be approved for a duration of 6 months;
Other Criteria	**INITIAL AUTHORIZATION:** • Documentation of a confirmed diagnosis of Phenylketonuria (PKU) • Documentation of the patient's baseline blood Phe level. (within 30 days of the request) • Documentation or prescriber attestation that the patient is currently utilizing a Phe-restricted diet • For Sephience: Documented trial and failure, intolerance, or contraindication to sapropterin in combination with Phe-restricted diet • Documentation of the patient's current weight. • The medication is being prescribed at an FDA approved dosage **PA CRITERIA FOR REAUTHORIZATION:** *For sapropterin: Patients that were dosed at 20mg/kg/day and did not have a decrease in Phe level of at least 30% from baseline, are considered NON RESPONDERS and NO ADDITIONAL TREATMENT will be authorized.* *For Sephience: Patients that were dosed at 60 mg/kg/day and did not have a decrease in Phe from baseline, are considered NON RESPONDERS and NO ADDITIONAL TREATMENT will be authorized* • Documentation of the patient's current weight.

Last review: 10/2025	• Documentation of updated blood Phe level results showing reduction in Phe level from baseline. • The medication is being prescribed at an FDA approved dosage. **NOTE: Clinical reviewer/Medical Director must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Pediculicides**
Drugs	**FORMULARY STATUS** Preferred, Pays at Point-of-Sale (Step One) • **Permethrin:** Lotion / cream rinse and liquid • **Pyrethrins/Piperonyl Butoxide OTC:** Shampoo **FORMULARY STATUS** Preferred, Requires Step Therapy (Step Two) • **Spinosad (**Natroba**):** Topical Suspension • **Ivermectin** (Sklice): Lotion **Note: Patient must meet #1 & #2 criteria for approval of initial PA request** **FORMULARY STATUS** Non-Preferred, Requires Prior Authorization (Step Three) • **Crotan, Pruradik** (crotamiton): Lotion • **Lindane:** Shampoo • **Malathion** (Ovide): Lotion • **or any newly marketed pediculicide** **Note: Patient must meet criteria #1, #2 & #3 for approval of initial PA request.**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If the criterion is met, the request will be approved for initial authorization. For re – authorization, a maximum of 2 treatments in a 30 day period will be approved.
Other Criteria	**Initial Authorization:** 1. Diagnosis of pediculus capitis (head lice and its eggs) or scabies

Revision/Review Date 10/2025	2. One of the following: a) Documented intolerance or hypersensitivity to a preferred step one agent, or a reason is provided as to why step one preferred agents cannot be used b) Documented trial and failure of a preferred agent within the previous 45 days, but no earlier than 7 days after the original fill. 3. One of the following: a) Documented intolerance or hypersensitivity to a preferred step two agent, or a reason is provided as to why a preferred step two agent cannot be used b) Documented trial and failure of a preferred step two agent within the previous 45 days, but no earlier than 7 days after the original fill **<u>Re - Authorization:</u>** 1. Formulary medications or malathion can be approved for a second treatment if live lice are present 7-9 days after the initial treatment. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group	**Pehnylalanine Hydroxylase Activators**
Drug(s)	sapropterin (Kuvan), Sephience (sepiapterin)
Covered Uses	*Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI) , and the Drug Package Insert).
Exclusion Criteria	None
Required Medical Information	See "Other Criteria"
Age Restrictions	None
Prescriber Restrictions	Specialist experienced in treating Phenylketonuria (PKU)
Coverage Duration	**Initial:** If the criterion is met, the request will be approved for a duration of 1 month; **Reauthorization:** If the criteria is met, the sapropterin requests will be approved for a duration of 1 month for patients who require a dose increase to 20 mg/kg/day due to non-responsiveness. Sephience requests will be approved for a duration of 1 month for patients who require a dose increase from their previous dose (up to a max dose of 60 mg/kg/day) due to non-responsiveness. For all other patients the request will be approved for a duration of 6 months;
Other Criteria	**INITIAL AUTHORIZATION:** • Documentation of a confirmed diagnosis of Phenylketonuria (PKU) • Documentation of the patient's baseline blood Phe level. (within 30 days of the request) • Documentation or prescriber attestation that the patient is currently utilizing a Phe-restricted diet • For Sephience: Documented trial and failure, intolerance, or contraindication to sapropterin in combination with Phe-restricted diet • Documentation of the patient's current weight. • The medication is being prescribed at an FDA approved dosage **PA CRITERIA FOR REAUTHORIZATION:** *For sapropterin: Patients that were dosed at 20mg/kg/day and did not have a decrease in Phe level of at least 30% from baseline, are considered NON RESPONDERS and NO ADDITIONAL TREATMENT will be authorized.* *For Sephience: Patients that were dosed at 60 mg/kg/day and did not have a decrease in Phe from baseline, are considered NON RESPONDERS and NO ADDITIONAL TREATMENT will be authorized* • Documentation of the patient's current weight.

Last review: 10/2025	• Documentation of updated blood Phe level results showing reduction in Phe level from baseline. • The medication is being prescribed at an FDA approved dosage. **NOTE: Clinical reviewer/Medical Director must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Pompe Disease Agents**
Drugs	Lumizyme (alglucosidase alfa) Nexviazyme (avalglucosidase alfa-ngpt) injection Pombiliti (cipaglucosidase alfa-atga) + Opfolda (miglustat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to FDA approved prescribing information
Prescriber Restrictions	Prescribed by, or in consultation with, a specialist in the treatment of Pompe disease, such as a genetic or metabolic specialist, neurologist, cardiologist, or pediatrician.
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.

Other Criteria	**Initial Authorization:**
	For infantile onset Pompe Disease (Lumizyme only):
	• Patient has a diagnosis of infantile-onset Pompe Disease, confirmed by one of the following:
	  o Enzyme assay showing a deficiency of acid alpha-glucosidase (GAA) activity in the blood, skin, or muscle
	  o Genetic testing showing a mutation in the GAA gene
	• Requested dose is appropriate per prescribing information (documentation of patient weight must be submitted with request)
	• Requested regimen will not be used in combination with other enzyme replacement therapies
	For late onset Pompe Disease (Lumizyme, Nexviazyme, or Pombiliti + Opfolda):
	• Patient has a diagnosis of late-onset (non-infantile) Pompe Disease, confirmed by one of the following:
	  o Enzyme assay showing a deficiency of acid alpha-glucosidase (GAA) activity in the blood, skin, or muscle
	  o Genetic testing showing a mutation in the GAA gene
	• Documentation patient has measurable signs or symptoms of Pompe disease
	• Results of a baseline 6-minute walk test (6MWT) and percent-predicted forced vital capacity (FVC) are provided (not required for patients who are not old enough to walk)
	• Requested dose is appropriate per prescribing information (documentation of patient weight must be submitted with request)

	• Requested regimen will not be used in combination with other enzyme replacement therapies (Exception: Pombiliti + Opfolda are to be used together)
	• Additionally for Nexviazyme: Patients < 30 kg must provide documentation of a trial and therapy failure of, or a medical reason why Lumizyme may not be used.
	• Additionally for Pombiliti + Opfolda: Patient must have trial and failure of another enzyme therapy (Lumizyme or Nexviazyme)
	Re-Authorization:
	• Documentation or provider attestation of positive clinical response to therapy
	  o Infantile onset: provider attestation of member benefit
	  o Late onset: improvement, stabilization, or slowing of progression of percent-predicted FVC and/or 6MWT
	• Requested dose is appropriate per prescribing information (documentation of patient weight must be submitted with request)
	• Requested regimen will not be used in combination with other enzyme replacement therapies (Exception: Pombiliti + Opfolda are to be used together)

Revision/Review Date: 2/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Potassium-removing agents**
Drugs	**Veltassa (patiromer), Lokelma (sodium zirconium cyclosilicate)**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber is a cardiologist or nephrologist or in consultation with one of these specialties
Coverage Duration	If the criteria are met, the request will be approved with up to a 3 month duration for initial requests and up to 6 months for renewal requests.
Other Criteria Revision/Review Date 4/2025	**<u>Initial Authorization</u>** • Diagnosis of hyperkalemia • Documentation patient has been counseled to follow a low potassium diet • Where clinically appropriate, documentation of medications known to cause hyperkalemia (e.g. angiotensin-converting enzyme inhibitor, angiotensin II receptor blocker, aldosterone antagonist, NSAIDs) have been discontinued or decreased to lowest effective dose **<u>Re-Authorization</u>** • Documentation that demonstrates member is receiving clinical benefit from treatment (e.g. potassium level returned to normal or significant decrease from baseline). **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Preferred Antidiabetic Agents**
Drugs	****For requests for Steglatro and Segluromet, please refer to the "Sodium Glucose CoTransporter-2 (SGLT-2) Inhibitors and Combination Products Containing SGLT-2 Inhibitors" policy**** **FORMULARY STATUS** Preferred, Pays at Point-of-Sale **METFORMIN** tablets **FORMULARY STATUS** Preferred, Requires Step Therapy with one prior step **TRULICITY (dulaglutide)** **OZEMPIC (semaglutide)** **MOUNJARO (tirzepatide)** **ALOGLIPTIN (generic Nesina)** **ALOGLIPTIN/METFORMIN (generic Kazano)** **ALOGLIPTIN/PIOGLITAZONE (generic Oseni)** **PIOGLITAZONE (generic Actos)** **PIOGLITAZONE/METFORMIN (generic Actoplus Met)** **SITAGLIPTIN (generic Zituvio)** **SITAGLIPTIN/METFORMIN (generic Zituvimet)** **Note: Member must meet criteria #1 & #2 for approval of the PA request.** **FORMULARY STATUS** Formulary, Requires Step Therapy with two prior steps **JANUVIA(sitagliptin)** **JANUMET (sitagliptin-metformin)** **JANUMET XR, ZITUVIMET ER (sitagliptin-metformin)** **Note: Member must meet criteria #1 & #2 and either criteria #3 or #4 for approval of the PA request.**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	According to package insert

Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration for; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria Revision/Review Date 2/2025	**<u>Initial Authorization:</u>** 1. Presumed or documented diagnosis of diabetes mellitus, type II. 2. One of the following: a. Documented trial and failure or intolerance with metformin at the maximally tolerated dose for a minimum of 3 months. b. If the request is for Trulicity or Ozempic, the member has established atherosclerotic cardiovascular disease (ASCVD) or is at high risk for ASCVD 3. Documented trial and failure or intolerance with a Step 2 alogliptin or sitagliptin for a minimum of 3 months. 4. Member is at risk for, or has documented history of, heart failure.

Field Name	Field Description
Prior Authorization Group Description	**Pregabalin**
Drugs	Pregabalin (Lyrica) capsule and oral solution & pregabalin ER (Lyrica CR) extended-release tablets
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	**Initial Authorization**: **Partial-Onset Seizures**: • Documented diagnosis of partial-onset seizures. • Request is for pregabalin capsule or solution **Postherpetic Neuralgia**: • Documented diagnosis of postherpetic neuralgia. • Documented trial and failure of one formulary alternatives (gabapentin, amitriptyline, nortriptyline) • If the request is for pregabalin ER there is a documented trial and failure of, or intolerance to, generic pregabalin capsule **Neuropathic Pain Associated with Diabetic Peripheral Neuropathy**: • Documented diagnosis of pain associated with diabetic peripheral neuropathy. • Documented trial and failure of one formulary alternative (i.e. gabapentin, duloxetine) • If the request is for pregabalin ER there is a documented trial and failure of, or intolerance to, generic pregabalin capsule **Neuropathic Pain Associated with Spinal Cord Injury**: • Documented diagnosis of neuropathic pain associated with spinal cord injury

Revision/Review Date4/2025	• Trial and failure of one formulary alternative (i.e. gabapentin, amitriptyline) • Request is for pregabalin capsule or solution **<u>Fibromyalgia</u>**: • Documented diagnosis of fibromyalgia. o Trial and failure of one formulary alternatives (i.e. gabapentin, duloxetine, amitriptyline) • Request is for pregabalin capsule or solution **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Presbyopia Agents**
Drugs	Vuity (pilocarpine HCl ophthalmic solution) Qlosi (pilocarpine HCl ophthalmic solution)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Vuity: 40-55 years Qlosi: 45-64 years
Prescriber Restrictions	Prescribed by or in consultation with an optometrist or ophthalmologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 2/2025	**Initial Authorization:** • Diagnosis of presbyopia • Trial and failure or contraindication to corrective lenses (i.e., eye glasses, contact lenses) • Medication is prescribed at an FDA approved dose **Re-Authorization:** • Documentation or provider attestation of positive clinical response • Medication is prescribed at an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Primary Hemophagocytic Lymphohistiocytosis (HLH) Agents**
Drugs	Gamifant (emapalumab-lzsg)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Members who have undergone hematopoietic stem cell transplantation (HSCT)
Required Medical Information	"See Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Hematologist, Oncologist, Immunologist, Transplant Specialist, or other specialist experienced in the treatment of immunologic disorders
Coverage Duration	Initial Authorization: 1 month Reauthorization: 3 months
Other Criteria Revision/Review Date 4/2025	***Gamifant will only be approved for members who have not yet received HSCT and will be discontinued at the initiation of HSCT*** **Initial Authorization** • Member has a diagnosis of Primary HLH • Prescriber attests that member has not achieved a satisfactory response to or is intolerant to conventional HLH therapy (e.g. etoposide, dexamethasone) or has recurrent disease • Prescriber attests that the member is a candidate for hematopoietic stem cell transplant (HSCT) • Member has been screened for latent tuberculosis infection • Member has or will receive prophylactic pre-medications (e.g. antivirals, antibiotics, antifungals) for Herpes Zoster, *Pneumocystis jirovecii*, and other fungal infections • Dosing is consistent with FDA approved labeling **Reauthorization** • Member continues to meet initial authorization criteria • Member is receiving prophylactic pre-medications (e.g. antivirals, antibiotics, antifungals) for Herpes Zoster, *Pneumocystis jirovecii*, and other fungal infections **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Primary Hyperoxaluria Agents**
Drugs	Oxlumo (lumasiran) Rivfloza (nedosiran)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a nephrologist, urologist, hepatologist, endocrinologist or consultation with one of these specialists
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.

Other Criteria	**Initial Authorization**
	• Diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by one of the following:
	  o Genetic testing confirming at least one mutation at the AGXT gene
	  o Liver biopsy demonstrating absent or significantly reduced AGT activity
	• Metabolic testing demonstrating one of the following:
	  o Oxlumo or Rivfloza
	  ▪ Increased urinary oxalate excretion (≥ 0.5 mmol/1.73 m^2per day[45 mg/1.73 m^2per day])
	  ▪ Increased urinary oxalate:creatinine ratio relative to normative values for age
	  o Oxlumo only: Increased plasma oxalate level (≥ 20 µmol/L)
	• For Rivfloza: member has relatively preserved kidney function (e.g., EGFR ≥ 30 mL/min/1.73 m2)
	• Member is concurrently using pyridoxine or has tried and failed previous pyridoxine therapy for at least 3 months, or has a medical reason for not using pyridoxine
	• Member has no history of liver transplant
	• Medication is prescribed at an FDA approved dose

Revision/Review Date 2/2025	• Patient is not using Oxlumo and Rivfloza concurrently **<u>Reauthorization</u>** • Members previously using pyridoxine will continue to use pyridoxine, or have a medical reason for not using pyridoxine • Documentation has been provided that demonstrates a clinical benefit (e.g. symptomatic improvement, reduction in urinary or plasma oxalate levels from baseline) • Medication is prescribed at an FDA approved dose • Patient is not using Oxlumo and Rivfloza concurrently **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Proprotein Convertase Subtilisin/kexin 9 (PCSK9) Monoclonal Antibodies (mAbs)**
Drugs	Preferred: Repatha (evolocumab), Praluent (alirocumab) Non-preferred: Leqvio (inclisiran), Any newly marketed PCSK9 inhibitor
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	See "Other Criteria"
Prescriber Restrictions	Prescriber must be cardiologist or specialist in treatment of lipid disorders
Coverage Duration	If the criteria are met, the initial request will be approved for up to a 3 month duration, and the reauthorization request will be approved for up to a 12 month duration; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	**Initial Authorization** **For All Requests:** • Request is appropriate for member (e.g. age) as indicated in package labeling or standard of care guidelines • Patient has tried and failed atorvastatin 40mg-80mg or rosuvastatin 20-40mg (consistently for 3 months via claim history or chart notes). If patient is not able to tolerate atorvastatin or rosuvastatin, documentation was provided that patient is taking another statin at the highest tolerated dose, or a medical reason was provided why the member is not able to use these therapies. • Patient has tried and failed ezetimibe at a maximal tolerated dose or a medical reason was provided why the member is not able to use this therapy. • If prescriber indicates member is "statin intolerant", documentation was provided including description of the side effects, duration of therapy, "wash out", re-trial, and then change of agents. • Documentation was provided indicating provider has counseled member on smoking cessation and following a "heart healthy diet". • If the request is for a non-preferred agent, documentation was provided of trial and failure, or a medical reason has been provided,

	why member is unable to use the preferred agent to manage their condition.
	
	AND the member meets the following for the respective diagnosis:
	
	<u>Familial Hypercholesterolemia (FH):</u>
	• Member has a diagnosis of familial hypercholesterolemia as evidenced by one of the following:
	  o Documentation provided including two fasting lipid panel lab reports with abnormal low density lipoprotein (LDL) levels ≥190 for FH in adults or ≥160 for FH in children.
	  o Results of positive genetic testing for an LDL-C-raising gene defect (LDL receptor, apoB, or PCSK9)
	  o LDL remains above goal despite maximally tolerated LDL-lowering therapy
	
	<u>Hyperlipidemia (Primary OR Secondary Atherosclerotic Cardiovascular Disease [ASCVD] Prevention)</u>
	• If the diagnosis is primary severe hyperlipidemia (i.e. LDL ≥190 mg/dL)
	  o LDL remains ≥ 100 mg/dL despite maximally tolerated LDL-lowering therapy
	• If the diagnosis is secondary ASCVD prevention
	  o LDL remains ≥ 55 mg/dL or non-HDL (i.e. total cholesterol minus HDL) ≥ 85 mg/dL despite maximally tolerated LDL-lowering therapy
	  o And ONE of the following:
	  ▪ Documented history of multiple major ASCVD events (acute coronary syndrome within past 12 months, history of myocardial infarction, history of ischemic stroke, symptomatic peripheral artery disease)
	  ▪ Documented history of 1 major ASCVD event (acute coronary syndrome within past 12 months, history of myocardial infarction, history of ischemic stroke, symptomatic peripheral artery disease) AND multiple high-risk conditions (age ≥ 65 years, history of coronary artery bypass graft or percutaneous coronary intervention, diabetes mellitus, hypertension, chronic kidney disease, current smoker, or congestive heart failure)
	
	<u>Reauthorization for all indications:</u>
	• Documentation submitted indicates that the member has obtained clinical benefit from the medication including repeat fasting lipid

Revision/Review Date 10/2025	panel lab report and the member has had a reduction in LDL from baseline • The patient's claim history shows consistent therapy (i.e. monthly fills) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Proton Pump Inhibitors (PPIs)**
Drugs	**<u>All PPIs are limited to an initial 3-month QL.</u>** **<u>FORMULARY STATUS</u>** Preferred, Pays at Point-of-Sale **Omeprazole** (Prilosec) capsule **Pantoprazole** (Protonix) tablet **Nexium DR** (esomeprazole magnesium) 2.5 mg, 5 mg packet for oral suspension (for members < 8 years old only) **Esomeprazole Magnesium** 10 mg, 20 mg, 40 mg packet for oral suspension (for members < 8 years old only) **<u>FORMULARY STATUS</u>** Preferred, Requires Step Therapy **Esomeprazole Magnesium** (Nexium/Nexium 24 HR OTC) capsule **Lansoprazole** (Prevacid/Prevacid 24 HR OTC) capsule **Omeprazole/Sodium Bicarbonate** (Zegerid OTC) capsule **Rabeprazole** 20mg (Aciphex) tablet **Prilosec DR** (omeprazole magnesium) packet for oral suspension (for members < 8 years old only) **Note: Patient must meet initial authorization criteria #1 for approval of the PA request.** **<u>FORMULARY STATUS</u>** Non-preferred, Requires Prior Authorization **Rabeprazole** 10 mg capsule sprinkle **Dexlansoprazole** (Dexilant) capsule **Lansoprazole** (Prevacid) orally disintegrating tablet **Esomeprazole Strontium** capsule **Nexium 24 HR** (esomeprazole magnesium) tablet **Omeprazole** 20 mg tablet (OTC) **Omeprazole magnesium** 20 mg capsule (OTC) **Omeprazole magnesium DR** (Prilosec OTC) 20.6 mg tablet **Omeprazole ODT** 20 mg orally disintegrating tablet (OTC) **Pantoprazole** packet for oral suspension **Omeprazole/Sodium Bicarbonate** (Zegerid) capsule, packet for oral suspension **Note: Patient must meet initial authorization criteria #1 and # 2 for approval of the PA request.**

Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If all the criteria are met, the initial request will be approved for up to 3 months. Reauthorization requests will be approved for up to 12 months. Reauthorization requests for doses greater than once daily will be approved for up to 12 months. If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	**Initial Authorization** 1. Documented trial and failure or intolerance with a first line agent for a minimum of 3 weeks of therapy within the previous 60 days, however, if the request is for Prilosec DR packets, only a trial of esomeprazole magnesium/Nexium DR packets will be accepted. 2. Documented trial and failure or intolerance with a second line agent for a minimum of 3 weeks-of therapy within the previous 60 days. **Reauthorization for use greater than 3 months after meeting criteria for PPI:** • Documented diagnosis of GERD complications (i.e. erosive esophagitis and Barrett's esophagus) or hypersecretory disease including Zollinger-Ellison syndrome. OR • Evaluation made by or in consultation with a gastroenterologist or otolaryngologist recommending continuation of treatment. OR • Documented medical [compendia supported] reason why long term use is appropriate for the member. **Doses Greater Than Once Daily After Meeting Criteria For PPI:** • Confirmed diagnosis of GERD, erosive esophagitis, *H. pylori* infection, or hypersecretory disease (e.g. Zollinger-Ellison syndrome). OR

Revision/Review Date: 10/2025	• Evaluation made by or in consultation with a gastroenterologist or otolaryngologist recommending higher doses of PPI. OR • Documented medical [compendia supported] reason why use greater than once per day is appropriate for the member. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Pulmonary Biologics for Respiratory and Eosinophilic Conditions**
Drugs	Nucala (mepolizumab), Fasenra (benralizumab), Cinqair (reslizumab), Dupixent (dupilumab), Tezspire (tezepelumab) or any newly marketed agents
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• When being used for relief of acute bronchospasm or status asthmaticus • When used in combination with another monoclonal antibody for the treatment of respiratory or eosinophilic conditions
Required Medical Information	See "other criteria"
Age Restrictions	Per Package Insert
Prescriber Restrictions	Prescriber must be an allergist, pulmonologist, immunologist, rheumatologist, gastroenterologist, dermatologist, or other provider who specializes in the treatment of asthma or eosinophilic conditions, or in consultation with one of these specialists
Coverage Duration	If the above conditions are met, the initial request will be approved with a 4 month duration. All subsequent requests will be approved with a 6 month duration.
Other Criteria	**Initial Authorization:** Asthma: • Confirmed diagnosis of one of the following: o Nucala, Fasenra, and Cinqair: Severe Eosinophilic Asthma o Dupixent: Moderate-to-Severe eosinophilic asthma o Tezspire: Severe Asthma • Documentation has been provided of blood eosinophil count within ONE of the following ranges: o Nucala and Dupixent: ≥ 150 cells/mcL (within 6 weeks of request) OR ≥ 300 cells/mcL (within the past 12 months) o Fasenra: ≥ 150 cells/mcL (within the past 12 months) o Cinqair: ≥ 400 cells/mcL (within the past 12 months) o Tezspire: No baseline blood eosinophil counts are required • The member has a documented baseline FEV_1 < 80% of predicted with evidence of reversibility by bronchodilator response. o Tezspire ONLY: If age is < 18 years, the member has a documented baseline FEV_1 < 90% of predicted with evidence of reversibility by bronchodilator response • Documentation has been provided indicating that that the member

	continues to experience significant symptoms while compliant on a maximally tolerated inhaled corticosteroid with long-acting beta2 agonist (ICS/LABA) AND long-acting muscarinic antagonist (LAMA) (or a documented medical reason must be provided why the member is unable to use these therapies) and ONE of the following: o Nucala: ≥ 2 exacerbations in the past 12 months o Fasenra: ≥ 1 exacerbation in the past 12 months o Cinqair: ≥ 1 exacerbation in the past 12 months requiring systemic corticosteroids o Dupixent: ≥ 1 exacerbation in the past 12 months requiring systemic corticosteroids or hospitalization o Tezspire: ≥ 2 exacerbations requiring systemic corticosteroids OR ≥ 1 exacerbation in the past 12 months requiring hospitalization • The prescribed dose is within FDA approved dosing guidelines <u>Chronic Obstructive Pulmonary Disease (COPD) *(Dupixent only)*</u>: • Confirmed diagnosis of COPD • Documentation has been provided of blood eosinophil count ≥ 300 cells/mcL • The member has a documented post-bronchodilator FEV_1/FVC ratio < 0.7 and post-bronchodilator FEV_1 of 30% to 70% predicted • Documentation has been provided indicating that that the member continues to experience significant symptoms (i.e., chronic productive cough) while compliant on maintenance triple therapy consisting of a long-acting muscarinic antagonist (LAMA), long-acting beta2 agonist (LABA), and inhaled corticosteroid (ICS) (or a documented medical reason must be provided why the member is unable to use these therapies) and ONE of the following: o ≥ 2 exacerbations in the past 12 months, where systemic corticosteroids were required for at least one of them o ≥ 1 exacerbation in the past 12 months requiring hospitalization • The prescribed dose is within FDA approved dosing guidelines <u>Oral Corticosteroid Dependent Asthma: *(Dupixent only)*</u> • Confirmed diagnosis of oral corticosteroid (OCS) dependent asthma with at least 5 mg oral prednisone or equivalent per day for at least 4 weeks within the last 3 months • The patient has a documented baseline FEV_1 < 80% of predicted with evidence of reversibility by bronchodilator response. • Documentation has been provided indicating patient still is having significant symptoms with ≥ 1 exacerbations in the previous 12 months requiring additional medical treatment, (emergency room

	visits, hospital admissions) while compliant on a high-dose inhaled corticosteroid with a long-acting B_2 agonist (ICS/LABA) AND a long-acting muscarinic antagonist (LAMA). If the patient has not utilized these therapies, a documented medical reason must be provided why patient is unable to do so. • The prescribed dose is within FDA approved dosing guidelines <u>Eosinophilic Esophagitis (EoE) (*Dupixent only):*</u> • Confirmed diagnosis of EoE by endoscopic biopsy • Documentation of baseline esophageal intraepithelial eosinophil count and Dysphagia Symptom Questionnaire (DSQ) scores • Member has a history of at least 2 episodes of dysphagia (with intakes of solids) per week in the last 4 weeks • Documented trial and failure, intolerance, or contraindication to one proton pump inhibitor at a maximally tolerated dose for a minimum of 8 weeks • The prescribed dose is within FDA approved dosing guidelines <u>Prurigo Nodularis (PN) (*Dupixent only*):</u> • Confirmed diagnosis of PN lasting for at least three months prior to request • Member has a Worst-itch Numeric Rating Scale (WI-NRS) score of 7 or higher indicating severe or very severe itching • Member has at least 20 PN lesions in total • Documented trial and failure, intolerance, or contraindication to at least two of the following for a minimum of two weeks: o One medium to super-high potency topical corticosteroid o One topical calcineurin inhibitor o UVB phototherapy or psoralen plus UVA phototherapy • The prescribed dose is within FDA approved dosing guidelines <u>Eosinophilic granulomatosis with polyangiitis (EGPA) (*Nucala & Fasenra only*):</u> • Confirmed diagnosis of EGPA and eosinophilic asthma lasting for ≥6 months • Member has a history of relapsing disease defined as at least one EGPA relapse requiring additional corticosteroids or immunosuppressant or hospitalization within the past 2 years OR member has a history of refractory disease defined as failure to attain remission in the prior 6 months following induction treatment with standard therapy • Member must be on a stable dose of oral corticosteroids for at least 4 weeks prior to request

	• Member has a blood eosinophil count ≥1,000 cells/mcL OR > 10% of total leukocyte count • Documented trial and failure, intolerance, or contraindication to cyclophosphamide, azathioprine, methotrexate, rituximab, OR mycophenolate mofetil • <u>If the request is for Nucala, member must also have a documented trial and failure, intolerance, or contraindication to Fasenra</u> • The prescribed dose is within FDA approved dosing guidelines <u>Hypereosinophilic Syndrome (HES) (*Nucala only*):</u> • Confirmed diagnosis of FIP1 like 1-platelet derived growth factor receptor alpha (FIP1L1-PDGFRA)-negative HES lasting for ≥6 months without an identifiable non-hematologic secondary cause • Member has a history of two or more HES flares (worsening of HES-related symptoms necessitating therapy escalation or ≥2 courses of rescue oral corticosteroids) within the past 12 months • Member has a blood eosinophil count ≥1,000 cells/mcL • Documented trial and failure, intolerance, or contraindication to oral corticosteroids AND at least one second-line agent (e.g. hydroxyurea, interferon, imatinib, methotrexate, cyclophosphamide, cyclosporine, azathioprine) (member must be on stable dose of at least one agent for at least 4 weeks prior to request) **<u>Re-Authorization:</u>** 1. Documentation submitted indicates the member has clinically benefited from the medication (e.g. Asthma & COPD: improved FEV_1, reduced exacerbations; HES: symptomatic improvement, reduced oral corticosteroid dose; EGPA: reduction in relapse frequency or severity, disease remission, symptomatic improvement, reduced oral corticosteroid dose; EoE: histological remission, improvement in DSQ scores; PN: improvement in WI-NRS score, symptomatic improvement) 2. The prescribed dose is within FDA approved dosing guidelines **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**
Revision/Review Date 2/2025	

Field Name	Field Description
Prior Authorization Group Description	**Pulmonary Hypertension (PH) Agents**
Drugs	**Endothelian Receptor Antagonists (ERA):** ambrisentan (Letairis), Opsumit (macitentan), bosentan (Tracleer) **ERA and Phosphodiesterase-5 (PDE-5) Inhibitor Combinations:** Opsynvi (macitentan and tadalafil) **PDE-5 Inhibitors:** tadalafil (Adcirca/Tadliq), sildenafil (Revatio/Liqrev) **Prostacyclin Receptor Agonists:** Uptravi (selexipag) **Prostaglandin Vasodilators:** epoprostenol (Flolan/Veletri), Orenitram/Tyvaso/Tyvaso DPI. (treprostinil), treprostinil sodium (Remodulin), Ventavis (Iloprost) **Soluble Guanylate Cyclase Stimulators:** Adempas (riociguat) **Transforming Growth Factor-beta (TGF-beta) Signaling Modulator:** Winrevair (sotatercept-csrk) **and any other newly marketed PAH treatment agents.**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or cardiologist
Coverage Duration	Orenitram, Tyvaso, Adempas, or Ventavis: 3 months for initial request Opsynvi: 4 months for initial request Uptravi: Request will be approved for the titration pack for 28 days until the highest tolerated dose (maintenance dose) is achieved. Once the member has achieved maintenance dosing, further refills can be approved for a 6 month duration. For all others, if all of the conditions are met, the initial request will be approved for a 6 month duration. All reauthorization requests will be approved for a 6 month duration

Other Criteria	**Initial Authorization:**
	• Member has a confirmed diagnosis that is indicated in the FDA approved package insert or has other medically-accepted use
	• For Uptravi, Orenitram, Tyvaso, Tyvaso DPI, Ventavis, Remodulin, Adempas, ONE of the following:
	  o Documented trial and failure of one PDE-5 inhibitor (e.g., sildenafil, tadalafil) AND one Endothelin Receptor Antagonist (bosentan, ambrisentan, or Opsumit)
	  o Diagnosis of WHO Group 1 FC III with evidence of rapid disease progression or FC IV (Uptravi, Orenitram, Tyvaso, Ventavis, Remodulin ONLY)
	  o Diagnosis of persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) WHO Group 4 after surgical treatment, or inoperable CTEPH (Adempas ONLY)
	  o Diagnosis of PH-ILD WHO Group 3 (Tyvaso ONLY)
	• If the request is for sildenafil oral suspension, Liqrev (sildenafil) oral suspension, Tracleer (bosentan) tablet for suspension, or Tadliq (tadalafil) oral suspension, documentation has been submitted as to why patient is unable to use the same ingredient in a tablet dosage form (e.g., difficulty swallowing)
	• If the request is for Opsumit the patient must have a documented trial and failure or intolerance to ambrisentan and bosentan, or provide a medical reason why these therapies are not appropriate.
	• If the request is for Opsynvi, BOTH of the following:
	  o Patient has been stable for at least 6 months on combination therapy consisting of a PDE-5 inhibitor AND an ERA
	  o Documentation is provided as to why patient is unable to take individual pills for combination therapy (e.g. adherence due to pill burden)
	• If the request is for Winrevair, ALL of the following:
	  o Documented trial and failure of, or contraindication tocombination therapy including one PDE-5 inhibitor AND one ERA OR Opsynvi
	  o Documentation of platelet count of $\geq$ 50,000/mm^3
	• Documentation of the patient's current weight, dosing, and titration schedule is provided (if applicable)
	• The medication is prescribed at a dose that is within FDA approved guidelines
	
	Re-authorization:
	• Documentation has been submitted indicating the clinical benefit of therapy (e.g. improvement in functional class, improvement in 6-minute walk test, exercise capacity, or hemodynamics).
	• Documentation of the patient's current weight, dosing, and titration schedule is provided (if applicable)
	• The medication is prescribed at a dose that is within FDA approved guidelines.

Revision/Review Date: 10/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Pyruvate Kinase Activators**
Drugs	Pyrukynd (mitapivat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Age ≥18 years
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	If the conditions are met, the request will be approved for a 6-month duration for initial requests and a 6-month duration for renewal requests. **If the conditions are not met: may approve up to 14 days of a Pyrukynd Taper Pack to allow for discontinuation tapering
Other Criteria	**Initial Authorization:** • The prescribed dose is within FDA approved dosing guidelines • Diagnosis of hemolytic anemia with pyruvate kinase deficiency (PKD) • Documentation of at least two variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, of which at least one is a missense variant • Documentation that the member is **not** homozygous for the R479H variant • Documentation that the member **does not have** two non-missense variants of the PKLR gene, without the presence of another missense variant in the PKLR gene • Documentation of ONE of the following: o The member does not regularly require blood transfusions (defined as requiring less than or equal to 3 red blood cell (RBC) transfusions in the past 52 weeks **and** no transfusions in the past 3 months) AND hemoglobin (Hb) level ≤ 10 g/dL o The member has required more than or equal to 6 RBC transfusions in the past 12 months ▪ Documentation of the number of transfusions and the number of red blood cell (RBC) units transfused

Revision/Review Date: 7/2025	• Prescriber attests that the member does not have moderate or severe hepatic dysfunction and will monitor liver function monthly for the first 6 months of treatment • Prescriber attests that the member does not have a history of a prior bone marrow or stem cell transplant • The member is not concurrently using hematopoietic-stimulating agents (e.g. Procrit or Retacrit) • Prescriber attests the member is taking at least 0.8mg of folic acid daily **<u>Reauthorization:</u>** • The prescribed dose is within FDA approved dosing guidelines • For the first reauthorization, documentation of benefit: increase in Hb ≥1.5 g/dL over baseline OR a reduction in transfusions, defined as ≥33% reduction in the number of red blood cell (RBC) units transfused over baseline • For subsequent reauthorizations: documentation of benefit: stabilization in Hb levels OR a sustained reduction in transfusions • If the reauthorization criteria are not met, may authorize up to 14 days of a Pyrukynd Taper Pack to allow for tapering. To reduce the risk of acute hemolysis, abrupt discontinuation of Pyrukynd should be avoided. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Qalsody**
Drugs	Qalsody (tofersen)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	See "Other Criteria"
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, neuromuscular specialist, or physician specializing in the treatment of amyotrophic lateral sclerosis (ALS)
Coverage Duration	If all the criteria are met, initial and renewal requests will be approved for 6 months
Other Criteria Review/Revision Date: 7/2025	**Initial Authorization:** • Diagnosis of ALS • Documentation of genetic test confirming a mutation in the superoxide dismutase 1 (SOD1) gene • Member is not dependent on invasive ventilation or tracheostomy • Documentation of slow vital capacity (SVC) ≥ 50% • Medication is prescribed at an FDA approved dose **Re-Authorization:** • Documentation or provider attestation of positive clinical response (e.g., reduction in the mean concentration of neurofilament light [NfL] chains in the plasma, reduction in concentration of SOD1 in cerebrospinal fluid (CSF), or improvement in the Revised ALS Functional Rating Scale (ALSFRS-R) total score) • Member is not dependent on invasive ventilation or tracheostomy • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Radicava**
Drugs	Edaravone (Radicava), Radivaca ORS (edaravone) and any other newly marketed agent *** riluzole (Rilutek) is Preferred and does not require prior authorization***
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	If the criteria are met, requests will be approved for up to 6 month duration
Other Criteria	**Initial Authorization:** • Member must have a diagnosis of ALS • Member must have a documented baseline evaluation of functionality using the revised ALS functional rating scale (ALSFRS-R) score ≥ 2 • Member's disease duration is 2 years or less • Member has a baseline forced vital capacity (FVC) of ≥ 80% • Member has been on riluzole (Rilutek), is beginning therapy as an adjunct to treatment with Radicava, or provider has provided a medical reason why patient is unable to use riluzole • Dose is within FDA approved limits **<u>Reauthorization:</u>** • Member is not ventilator-dependent • Provider documents clinical stabilization in symptoms (e.g. stabilization of ALSFRS-R score) • Dose is within FDA approved limits
Revision/Review Date 4/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Reblozyl (luspatercept-aamt)**
Drugs	Reblozyl (luspatercept-aamt) vial for subcutaneous injection
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Members are excluded if they have hemoglobin S/beta-thalassemia, isolated alpha-thalassemia
Required Medical Information	See "other criteria"
Age Restrictions	Member must be 18 years of age or older
Prescriber Restrictions	Prescriber must be a hematologist or oncologist
Coverage Duration	Initial and reauthorization requests will be approved for 6 months.

Other Criteria	**Criteria for initial approval:**
	• Requested dose is appropriate per labeling
	• The member's weight has been provided with the request
	• The member's most recent hemoglobin level (within the last month) has been provided with the request
	• Diagnosis appropriate per Covered Uses
	• For requests for anemia due to beta thalassemia, documentation of all of the following is required:
	  o Member requires regular red blood cell (RBC) transfusions (defined as at least 6 RBC units received over the last 6 months).
	• For requests for anemia due to myelodysplastic syndrome, documentation of all of the following is required:
	  o Myelodysplastic Syndrome Revised International Prognostic Scoring System (IPSS-R) categorization as very low, low, or intermediate risk of progression.
	  o Member has required transfusion of 2 or more RBC units within an 8 week period in the last 4 months
	  o Hemoglobin less than 10 g/dl
	Reauthorization:
	• For diagnosis of anemia due to beta thalassemia, documentation of the following:
	  o Fewer transfusions compared with baseline
	  AND
	  o A reduction in transfusion requirement of at least 2 RBC units compared with baseline
	• Diagnosis of anemia due to myelodysplastic syndrome: documentation of ONE of the following:
	  o Hemoglobin increase of at least 1.5 g/dl from baseline over a period of 8-12 weeks

Revision/ Review Date: 10/2025	OR o Reduction in red blood cell transfusion by at least 4 units over a period of 8-12 weeks compared with baseline transfusion requirement **If the above conditions are not met, the request will be referred to a Medical Director for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Retinoids (Dermatologic)**
Drugs	**FORMULARY STATUS** Requires Prior Authorization, Generically Available Agents Preferred: • **Claravis (isotretinoin)** • **Zenatane (isotretinoin)** • **Amnesteem (isotretinoin)** • **Isotretinoin** **FORMULARY STATUS** Requires Prior Authorization, Non-Preferred: • **Absorica (isotretinoin)** • **Absorica LD (isotretinoin)** • **Or any newly marketed oral retinoid product**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 6 month duration.
Other Criteria	**Initial Authorization** • Diagnosis of moderate to severe recalcitrant nodular acne **AND** • Documented treatment with a therapeutic trial and failure or intolerance to one or more first line topical therapies (e.g. topical antibiotics or topical retinoids) IN COMBINATION WITH one or more first line oral therapies (e.g. doxycycline, tetracycline, or minocycline) for at least 4 weeks (28 days) of therapy of each drug in the previous 180 days. • If the request is for a non-preferred drug, documentation has been provided that the member has tried and failed two preferred drugs or has a medical reason why these drugs cannot be used **Re-Authorization**

Revision/Review Date 10/2025	• Prescriber attests the member has experienced clinical benefit from therapy (e.g. perceived improvement of acne) and continued treatment with, or retreatment with, isotretinoin is necessary **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Rezdiffra**
Drugs	Rezdiffra (resmetirom)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Patients with decompensated cirrhosis ○
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a hepatologist, gastroenterologist, endocrinologist, or a specialist in the treatment of liver disease.
Coverage Duration	If all of the criteria are met, the initial and reauthorization requests will be approved for up to a 12 month duration
Other Criteria Review/Revision Date: 10/2025	**<u>Initial Authorization:</u>** • Diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis • Documentation of stage F2 to F3 fibrosis confirmed by biopsy or a noninvasive test (NIT) • Prescriber attestation to providing lifestyle counseling on nutrition and exercise • Prescriber attestation that member avoids excess alcohol intake • The drug is being prescribed at an FDA approved dose according to the member's weight **<u>Re-Authorization:</u>** • The member has clinically benefited from the medication (e.g. the resolution of steatohepatitis and no worsening of liver fibrosis, or at least one stage improvement in liver fibrosis and no worsening of steatohepatitis) • The member continues to have a fibrosis stage of ≤ 3 • The drug is being prescribed at an FDA approved dose according to the member's weight **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Rituximab

Drugs:

Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human, recombinant)
Truxima (rituximab-abbs)
Ruxience (rituximab-pvvr)
Riabni (rituximab-arrx)

RITUXIMAB WILL BE APPROVED IF THE FOLLOWING PRIOR AUTHORIZATION CRITERIA IS MET:

MULTIPLE SCLEROSIS:

- Refer to the "Healthcare Professional (HCP) administered/IV Disease Modifying Therapies (DMTs) for Multiple Sclerosis (MS)" policy

NEUORMYELITIS OPTICA SPECTRUM DISORDER (NMOSD):

- Refer to the "Neuromyelitis Optica Spectrum Disorder (NMOSD) Agents" policy

RHEUMATOID ARTHRITIS:

Initial Authorization

- The medication is being recommended and prescribed by a rheumatologist.
- The patient is an adult (≥18 y/o) and has a documented clinical diagnosis of rheumatoid arthritis.
- The patient has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trial (including dates and doses) of 3 months or more of therapy with one conventional (non-biologic) DMARD (e.g. methotrexate, leflunomide, sulfasalazine, hydroxychloroquine) or has a documented medical reason (e.g. intolerance, hypersensitivity) for not utilizing any of these therapies to manage their medical condition.
- The patient has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trial (including dates, doses) of 2 preferred biologics indicated for rheumatoid arthritis, or has documented medical reason (intolerance, hypersensitivity, etc.) for not taking the preferred therapies to manage their medical condition.
- Documentation indicating that rituximab is being used concurrently with methotrexate, or a medical reason why methotrexate cannot be used.

- Documentation indicating that the patient has been screened for Hepatitis B Virus (HBV) prior to initiation of treatment.
- Rituximab is being prescribed at an FDA approved dosage.
- If the request is for any medication other than Ruxience (rituximab-pvvr) or Riabni (rituximab-arrx), there is a documented trial and failure of Ruxience or Riabni, or medical reason why (e.g. intolerance, hypersensitivity, contraindication) they cannot be used.

If all of the above conditions are met, the request will be approved for up to a 1 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

Reauthorization

- The member has been receiving rituximab and documentation is provided that a rheumatologist has reevaluated the member and recommends continuation of therapy.
- Documentation was provided indicating that the patient had clinical benefit from receiving rituximab therapy.
- At least 16 weeks (4 months) has elapsed since the previous course of rituximab therapy.
- Documentation indicating that rituximab is being used concurrently with methotrexate, or a medical reason why methotrexate cannot be used.
- Rituximab is being prescribed at an FDA approved dosage.

If all of the above conditions are met, the request will be approved for up to a 1 year duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

PEMPHIGUS VULGARIS

Initial Authorization

- The medication is being recommended and prescribed by a rheumatologist or dermatologist
- The patient is ≥ 18 years with a diagnosis of moderate to severe pemphigus vulgaris
- Documentation the patient will be receiving P. jirovecii pneumonia (PJP) prophylaxis (ex. TMP/SMX, dapsone, atovaquone) or the prescriber has provided a medical reason for not prescribing PJP prophylaxis
- Documentation indicating that the patient has been screened for HBV prior to initiation

of treatment
- Rituximab is being prescribed at an FDA approved dose/frequency
- Rituximab is being used in combination with a tapering course of glucocorticoids

If all of the above conditions are met, the request will be approved for up to a 1 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

Reauthorization

- Documentation of clinical benefits (e.g., absence of new lesions) with rituximab therapy was provided by a rheumatologist or dermatologist
- Documentation the patient will continue to receive PJP prophylaxis (ex. TMP/SMX, dapsone, atovaquone) or the prescriber has provided a medical reason for not prescribing PJP prophylaxis
- Rituximab is being prescribed at an FDA approved dose/frequency

If all of the above conditions are met, the request will be approved for up to a 1 year duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

ONCOLOGY INDICATIONS

Initial Authorization:

- The medication is being recommended and prescribed by an oncologist.
- The medication is being requested for a labeled indication or an indication supported by a NCCN category 1 or 2A level of evidence.
- The requested indication is CD20 positive.
- Documentation indicating that the patient has been screened for HBV prior to initiation of treatment.
- Rituximab is being prescribed at a dose that is within FDA approved guidelines and/or is supported by the medical compendium as defined by the Social Security Act and/or the National Comprehensive Cancer Network (NCCN) or American Society of Clinical Oncology (ASCO) standard of care guidelines.
- If the request is for any medication other than Ruxience (rituximab-pvvr) or Riabni (rituximab-arrx), there is a documented trial and failure of Ruxience or Riabni, or medical reason why (e.g. intolerance, hypersensitivity, contraindication) they cannot be used.

- If the request is for Rituxan Hycela (rituximab/hyaluronidase human, recombinant), all of the following: the patient has received at least one full dose of a rituximab product by intravenous infusion, the medication is being requested for a malignant condition, and there is a medical reason why the alternative rituximab product cannot be continued.

If all of the above conditions are met, the request will be approved for up to a 3 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

Reauthorization

- The medication is being recommended and prescribed by an oncologist.
- Rituximab is being prescribed at a dose that is within FDA approved guidelines and/or is supported by the medical compendium as defined by the Social Security Act and/or per the NCCN or ASCO standard of care guidelines.

If all of the above conditions are met, the request will be approved for up to a 3 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

GRANULOMATOSIS WITH POLYANGIITIS (GPA) (WEGENER'S GRANULOMATOSIS) AND MICROSCOPIC POLYANGIITIS (MPA):

Initial Authorization:

- The medication is being recommended and prescribed by a rheumatologist or nephrologist.
- The patient is 2 years of age or older and has a documented clinical diagnosis of GPA (Wegener's Granulomatosis), eosinophilic granulomatosis with polyangiitis (EGPA), or MPA AND the prescriber indicates whether there is severe or non-severe disease.
- Documentation indicating that rituximab is being used concurrently with glucocorticoids.
- Documentation the patient will be receiving PJP prophylaxis (ex. TMP/SMX, dapsone, atovaquone) during treatment or the prescriber has provided a medical reason for not prescribing PJP prophylaxis
- Documentation indicating that the patient has been screened for HBV prior to initiation of treatment.
- Rituximab is being prescribed at an FDA approved dosage.
- If the patient is 18 years of age or older, and the request is for any medication other than

Ruxience (rituximab-pvvr) Riabni (rituximab-arrx), there is a documented trial and failure of Ruxience or Riabni, or medical reason why (e.g. intolerance, hypersensitivity, contraindication) they cannot be used.

If all of the above conditions are met, the request will be approved for up to a 1 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

Re-authorization:

- The medication is being recommended and prescribed by a rheumatologist or nephrologist.
- Documentation the patient will continue to receive PJP prophylaxis (ex. TMP/SMX, dapsone, atovaquone) or the prescriber has provided a medical reason for not prescribing PJP prophylaxis
- Rituximab is being prescribed at an FDA approved dose.

If all of the above conditions are met, the request will be approved for up to a 1 year duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

DERMATOMYOSITIS (DM) and POLYMYOSITIS (PM)

Initial Authorization:

- Rituximab is being recommended and prescribed by a neurologist, rheumatologist, or dermatologist.
- Patient meets one of the following:
    - Bohan and Peter score indicating definite DM or PM
    - Bohan and Peter score indicating probable DM or PM AND concurring diagnostic evaluation by ≥ 1 specialist (e.g. neurologist, rheumatologist, dermatologist)
- Patient does NOT have cancer associated myositis defined as myositis within 2 years of cancer diagnosis (except basal or squamous cell skin cancer or carcinoma in situ of the cervix that has been excised and cured)
- One of the following:
    - Patient has a documented trial and failure of, or has a documented medical reason for not using methotrexate (MTX) OR azathioprine
    - Patient has severe, life-threatening weakness or dysphagia
- Rituximab is prescribed at a dose per the medical compendia (Micromedex, American Hospital Formulary Service (AHFS), DrugPoints, the Drug Package Insert as defined in the Social Security Act and/or per the American Academy of Pediatrics (AAP) standard

of care guidelines and has a Class I or IIa recommendation).

- If the request is for any medication other than Ruxience (rituximab-pvvr) there is a documented trial and failure of Ruxience (rituximab-pvvr), or medical reason why (e.g. intolerance, hypersensitivity, contraindication) Ruxience (rituximab-pvvr) cannot be used.

If all of the above conditions are met, the request will be approved for up to a 1 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

Re-authorization:

- Rituximab is being recommended and prescribed by a neurologist, rheumatologist, or dermatologist.
- Documentation was provided indicating that the patient had clinical benefit from receiving rituximab therapy.
- Rituximab is prescribed at a medically accepted dose per the medical compendia.

If all of the above conditions are met, the request will be approved for up to a 3 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

OTHER MEDICALLY ACCEPTED INDICATIONS

Initial Authorization:

- The medication is prescribed for a non-FDA approved indication but is considered to be a medically accepted use of the medication per the medical compendia (Micromedex, American Hospital Formulary Service (AHFS), DrugPoints, the Drug Package Insert as defined in the Social Security Act and/or per the American Academy of Pediatrics (AAP) standard of care guidelines and has a Class I or Iia recommendation.
- The medication is prescribed at a medically accepted dose per the medical compendia as defined above.
- The medication is recommended and prescribed a specialist in the field to treat the member's respective medical condition.
- Documentation indicating that the patient has been screened for HBV prior to initiation of treatment.
- Documentation was submitted indicating that the member has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trial (including dates, doses of medications) of ALL first line medical therapies as recommended by the medical compendia and standard care

guidelines and/or has another documented medical reason (e.g. intolerance, contraindications, etc.) for not receiving or trying all first line medical treatment(s).

- If the request is for any medication other than Ruxience (rituximab-pvvr), there is a documented trial and failure of Ruxience (rituximab-pvvr), or medical reason why (e.g. intolerance, hypersensitivity, contraindication) Ruxience (rituximab-pvvr) cannot be used.

If all of the above conditions are met, the request will be approved for up to a 3 month duration.
If all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

Re-authorization:

- The medication is prescribed at a medically accepted dose per the medical compendia
- The medication is recommended and prescribed a specialist in the field to treat the member's respective medical condition.
- Documentation from medical chart was submitted indicating that the member has significantly clinically benefited from the medication.

If all of the above conditions are met, the request will be approved for up to a 3 month duration.
If all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

NOTE: Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Revision/Review Date: 7/2025

Field Name	Field Description
Prior Authorization Group Description	**Roflumilast**
Drugs	Roflumilast
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria	1. Documented diagnosis of chronic obstructive pulmonary disorder (COPD) with chronic bronchitis and a history of exacerbations 2. Documented trial and failure or intolerance with a preferred LABA/LAMA combination, or LABA/LAMA/ICS combination for a minimum of 4 weeks of therapy in the previous 60 days 3. Documented continuation of therapy with LABA or LAMA
Revision/Review Date 4/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Rytelo**
Drugs	Rytelo (imetelstat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be 18 years of age and older
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 6 months.
Other Criteria Revision/ Review Date: 10/2025	**<u>Initial Authorization:</u>** • Diagnosis of myelodysplastic syndromes (MDS) with transfusion-dependent anemia • Member has transfusion burden of 4 or more red blood cell (RBC) units within an 8-week period over the last 4 months • Prescriber attestation that complete blood cell count (CBC) will be obtained prior to initiation, weekly for first two cycles, and prior to each cycle thereafter • Member's weight has been provided with request • Medication is prescribed at an FDA approved dose **<u>Re-Authorization:</u>** • Documentation or provider attestation of reduction in RBC transfusion burden as compared with baseline • Provider attestation that patient is tolerating the medication and is not experiencing any serious adverse reactions • Member's weight has been provided with request • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Scopolamine Patch**
Drugs	Scopolamine Patch (Transderm-Scop)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved for the treatment of motion sickness and post-operative nausea and vomiting for a one (1) month duration and for the treatment of sialorrhea for a 12 month duration.
Other Criteria Revision/Review Date: 7/2025	**Initial Authorization:** Motion Sickness and Post-Operative Nausea and Vomiting: • Diagnosis of nausea and vomiting associated with motion sickness or nausea and vomiting associated with recovery from anesthesia and/or opiate analgesia and surgery. AND • Documented trial and failure at therapeutic doses of, intolerance to, or contraindication to two of the following: meclizine, diphenhydramine and dimenhydrinate. Sialorrhea • Documented trial and failure at therapeutic doses, intolerance or contraindication to glycopyrrolate. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Second Generation Antihistamines**
Drugs	**FORMULARY STATUS** Preferred, Pays at Point-of-Sale (Step One) **CLARITIN (loratadine) (generic)** tablets, oral solution **ZYRTEC (cetirizine) (generic)** tablets, oral solution **XYZAL (levocetirizine) (generic)** tablets **FORMULARY STATUS** Preferred, Requires Step Therapy (Step Two) **ALLEGRA (fexofenadine)** orally disintegrating tablets **ALLEGRA (fexofenadine) (generic)** **CLARINEX (desloratadine) (generic)** tablets **CLARITIN (loratadine) (generic)** orally disintegrating tablets, chewable tablets, capsules **ZYRTEC (cetirizine)** orally disintegrating tablets **ZYRTEC (cetirizine) (generic)** capsules **ALLEGRA-D 12 HOUR (fexofenadine/pseudoephedrine) (generic)** **ALLEGRA-D 24 HOUR (fexofenadine/pseudoephedrine) (generic)** **CLARITIN-D 12 HOUR (loratadine/pseudoephedrine) (generic)** **CLARITIN-D 24 HOUR (loratadine/pseudoephedrine) (generic)** **ZYRTEC-D 12 HOURS (cetirizine/pseudoephedrine) (generic)** ***Patient must meet criteria #1 and #2 for approval** **FORMULARY STATUS** Non-Preferred, Requires Prior Authorization (Third Line) **CLARINEX-D 12 HOUR (desloratadine/pseudoephedrine)** **CLARINEX (desloratadine) (generic)** orally disintegrating tablets **XYZAL (levocetirizine) (generic)** oral solution **ZYRTEC (cetirizine) (generic)** chewable tablets ***Patient must meet criteria #1, #2 and #3 for approval**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	N/A

Coverage Duration	If the criteria are met, the request will be approved with a 12 month duration; if the criteria are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity.
Other Criteria Revision/Review Date 2/2025	**<u>PA CRITERIA FOR APPROVAL:</u>** 1. Diagnosis of seasonal allergic rhinitis with or without nasal congestion, perennial allergic rhinitis with or without nasal congestion, or urticaria. 2. Documented trial and failure or intolerance to a step one agent 3. Documented trial and failure or intolerance to a step two agent **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Sedative Hypnotics for Insomnia**
Drugs	**FORMULARY STATUS** Preferred, Pays at Point-of-Sale (First Line) • **Zolpidem** (Ambien) tablet • **Zaleplon** capsule • **Eszopiclone** (Lunesta) tablet • **Zolpidem ER** (Ambien CR) tablet **Note: Patient must meet #1 & #2 criteria for approval of initial PA request** **FORMULARY STATUS:** Non-Preferred, Requires Prior Authorization • **Edluar** (zolpidem) sublingual tablet • **Zolpidem** sublingual tablet • **Ramelteon** (Rozerem) tablet • **Belsomra** (suvorexant) tablet • **Dayvigo** (lemborexant) tablet • **Quviviq** (daridorexant) tablet **Note: Patient must meet criteria #1 & #3 for approval of initial PA request.**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with a 12 month duration.

Other Criteria Revision/Review Date 10/2025	**PA CRITERIA FOR APPROVAL:** 1. Diagnosis of insomnia. 2. Documented trial and failure or intolerance to TWO preferred medications for at least 14 days of therapy EACH AND If the request is for Belsomra (suvorexant) or Quviviq (daridorexant), there must also be a documented trial and failure of Dayvigo (lemborexant) for at least 14 days. **NOTE:** Ramelteon can be approved as a first line agent if there is a history of substance abuse. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Self-administered Disease Modifying Therapies (DMTs) for Multiple Sclerosis (MS)**
Drugs	**Preferred:** dimethyl fumarate (TECFIDERA), fingolimod (GILENYA), glatiramer acetate (COPAXONE) **Non-preferred:** teriflunomide (AUBAGIO), MAYZENT (siponimod), PONVORY (ponesimod), VUMERITY (diroximel fumarate), TASCENSO ODT (fingolimod), AVONEX, REBIF (interferon beta-1a), BETASERON, EXTAVIA (interferon beta-1b), COPAXONE (glatiramer acetate), glatiramer acetate (GLATOPA), PLEGRIDY (peginterferon beta-1a), MAVENCLAD (cladribine), ZEPOSIA (ozanimod), BAFIERTAM (monomethyl fumarate), KESIMPTA (ofatumumab) or any other newly marketed self-administered DMT for MS indicated for the listed diagnoses
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Primary Progressive MS (PPMS) Mavenclad • Clinically Isolated Syndrome (CIS)
Required Medical Information	See "Other Criteria"
Age Restrictions	Patient must be age appropriate per prescribing information (PI)
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months for all agents except Mavenclad (cladribine). If all of the criteria for Mavenclad (cladribine) are met, the request will be approved for 1 course at a time with a lifetime maximum of 2 yearly treatment courses [1 course = (1 cycle per 30 days) two times].
Other Criteria	**Initial Authorization** • For all requests, the medication is being prescribed at a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed literature. Clinically Isolated Syndrome (CIS) • Diagnosis of CIS • If the request is for dimethyl fumarate or glatiramer approve. • If the request is for fingolimod (Gilenya) documentation of the following: o Healthcare Provider (HCP)-confirmed history of chickenpox, results of varicella zoster virus (VZV) antibody testing and, if negative, documentation of VZV vaccination

	• If the request is for Tascenso ODT (fingolimod) 0.25mg, the member must meet both of the following criteria: o Healthcare Provider (HCP)-confirmed history of chickenpox, results of varicella zoster virus (VZV) antibody testing and, if negative, documentation of VZV vaccination o Member weighs 40 kg or less • If the request is for any other agent, then the member must have a documented trial of TWO preferred agents or have a documented medical reason (e.g., contraindication, intolerance, hypersensitivity, etc.) for not utilizing two of these therapies **AND** o If the request is for Ponvory (ponesimod), Zeposia (ozanimod), Tascenso ODT (fingolimod), or Mayzent (siponimod), documentation of the following: ▪ Healthcare Provider (HCP)-confirmed history of chickenpox, results of varicella zoster virus (VZV) antibody testing and, if negative, documentation of VZV vaccination o Additionally, if the request is for Mayzent (siponimod), results of CYP2C9 genotyping A**ND** ▪ Patient does not have CYP2C9 *3/*3 (**CONTRAINDICATED**) ▪ if patient has CYP2C9 *1/*3 or *2/*3, dose does not exceed 1 mg daily o If the request is for Kesimpta (ofatumumab), documentation that immunizations are up-to-date. o If the request is for Bafiertam (monomethyl fumarate) or Vumerity (diroximel fumarate), the patient has a trial and failure of or documented medical reason for not using dimethyl fumarate (Tecfidera). o If the request is for Tascenso ODT (fingolimod) 0.5mg, the patient has a trial and failure of or documented medical reason for not using fingolimod (Gilenya) <u>Relapsing Remitting MS (RRMS) and Secondary Progressive MS (SPMS)</u> • Diagnosis of RRMS or SPMS • If the request is for dimethyl fumarate or glatiramer approve • If the request is for fingolimod (Gilenya) documentation of the following

	○ HCP-confirmed history of chickenpox, results of VZV antibody testing and, if negative, documentation of VZV vaccination • If the request is for Tascenso ODT (fingolimod) 0.25mg, the member must meet both of the following criteria: ○ Healthcare Provider (HCP)-confirmed history of chickenpox, results of varicella zoster virus (VZV) antibody testing and, if negative, documentation of VZV vaccination ○ Member weighs 40 kg or less • If the request is for any other agent, then the member must have a documented trial of TWO preferred agents or have a documented medical reason (e.g. contraindication, intolerance, hypersensitivity, etc.) for not utilizing two of these therapies AND ○ If the request is for Mavenclad (cladribine), documentation of the following: ▪ Patient's current weight ▪ Results of VZV antibody testing and, if negative, documentation of VZV vaccination ▪ If the patient has not tried at least one of the preferred therapies listed above but has a documented medical reason for not utilizing these therapies, the patient has tried and failed at least one other DMT for MS ○ If the request is for Ponvory (ponesimod), Zeposia (ozanimod), Tascenso ODT (fingolimod), or Mayzent (siponimod) documentation of the following: ▪ Healthcare Provider (HCP)-confirmed history of chickenpox, results of varicella zoster virus (VZV) antibody testing and, if negative, documentation of VZV vaccination ○ Additionally, if the request is for Mayzent (siponimod), results of CYP2C9 genotyping A**ND** ▪ Patient does not have CYP2C9 *3/*3 (**CONTRAINDICATED**) ▪ if patient has CYP2C9 *1/*3 or *2/*3, dose does not exceed 1 mg daily ○ If the request is for Kesimpta (ofatumumab), documentation that immunizations are up-to-date. ○ If the request is for Bafiertam (monomethyl fumarate) or Vumerity (diroximel fumarate), the patient has a trial and failure of or documented medical reason for not using dimethyl fumarate (Tecfidera). ○ If the request is for Tascenso ODT (fingolimod) 0.5mg, the patient has a trial and failure of or documented medical reason for not using fingolimod (Gilenya)

Revision/Review Date 10/2025	**Reauthorization**
	
	CIS
	• The medication is being prescribed at a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed literature
	• Documentation was provided that the prescriber has reviewed the risks and benefits of continuing DMT versus stopping.
	
	RRMS and SPMS
	• The medication is being prescribed at a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed literature
	• Documentation was provided that the prescriber has evaluated the member and recommends continuation of therapy (clinical benefit). **AND**
	• If the request is for Mavenclad (cladribine)
	  o Patient's current weight
	  o ****NO MORE THAN 2 COURSES IN TOTAL WILL BE APPROVED.****
	
	Continuation of Therapy:
	Members with history (within the past 90 days or past 12 months for Mavenclad [cladribine]) of a non-formulary product are not required to try a formulary agent prior to receiving the non-formulary product.
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	**Serostim (somatropin, mammalian derived)**
Drugs	Serostim (somatropin, mammalian derived)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be an HIV or infectious disease specialist
Coverage Duration	If all criteria are met, Serostim will be authorized for 12 weeks
Other Criteria	**Initial Authorization:** • Patient has been receiving optimal highly active antiretroviral therapy (HAART) for at least three months prior to initiation • Prescriber attests that the patient has been evaluated for other possible causes of wasting/cachexia (e.g. malignancies) or fat redistribution (e.g. diabetes mellitus, lipodystrophy, etc.) • Request is for the FDA approved or medically accepted dosing • Documentation supporting all of the following must be provided: o Baseline and repeated evaluation every 3 months of patient's weight (most recent weight measurement must be within the past 3 months) o BMI and lean body mass measured by X-ray absorptionmetry (DEXA/DXA) were provided with the request o Demonstrable weight loss of greater than 10% of the baseline body weight associated with either chronic diarrhea (two or more loose stools per day for greater than or equal to 1 month) or chronic weakness and fever for greater than or equal to 1 month o Patient has had an insufficient response to a three month trial of an anabolic steroid such as oxandolone o Patient has had an insufficient response to a three month trial of one of the following agents: megestrol acetate, cyproheptadine, or dronabinol **Re-authorization:** • The patient is receiving concomitant anti-HIV treatment

Revision/Review Date: 7/2025	• The prescriber has provided documentation of clinical benefit/response to Serostim. • Request is for FDA approved or medically accepted dosing **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Serotonin Receptor Agonists (Triptans)**
Drugs	**FORMULARY STATUS** Formulary, Pays at Point-of-Sale (First Line) • **Sumatriptan** (Imitrex) tablets, nasal spray, pen injector, syringe, and vial • **Rizatriptan** (Maxalt) tablets • **Rizatriptan** (Maxalt MLT) ODT **FORMULARY STATUS** Non-Formulary, Requires Prior Authorization (Second Line) • **Naratriptan** (Amerge) • **Almotriptan** (Axert) • **Frovatriptan** (Frova) • **Migranow Kit** (sumatriptan/menthol/camphor) • **Onzetra Xsail** (sumatriptan) • **Eletriptan** (Relpax) • **Sumatriptan/naproxen** (Treximet) • **Tosymra (sumatriptan)** • **Zolmitriptan** (Zomig) • **Zolmitriptan** (Zomig ZMT) • **Zembrace SymTouch** (sumatriptan) • **Any other newly marketed serotonin receptor agonists (triptans) treatment agents.** **Patients must meet criteria #1 and #2 for approval**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the above conditions are met, the request will be approved with a 12 month duration for quantities not to exceed 12 tablets per 30 days, 2 injections kits (4 injections) per 30 days, and 6 nasal spray units (1 box) per 30 days; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.

Other Criteria Revision/Review Date 4/2025	**<u>Initial Authorization:</u>** 1. Diagnosis of migraine or cluster headaches 2. Documented trial and failure, or intolerance to, preferred formulation of sumatriptan or rizatriptan at a therapeutic dose **<u>Quantities Greater Than Allowed Per 30 Days:</u>** If the patient requires doses greater than the set limits after meeting approval, the request will be referred to a Medical Director/clinical reviewer for medical necessity review. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Skyclarys**
Drugs	Skyclarys (omaveloxolone)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Per FDA-approved prescribing information
Prescriber Restrictions	Prescriber must be a neurologist or in consultation with a neurologist or specialist with expertise in treating patients with Friedreich's Ataxia.
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Revision/Review Date 7/2025	**Initial Authorization:** • Diagnosis of Friedreich's Ataxia, confirmed via genetic testing (must submit documentation) • Modified FARS score ≥20 and ≤80 • Medication is prescribed at an FDA approved dose **Re-Authorization:** • Documentation or provider attestation of positive clinical response to Skyclarys therapy (i.e. improvement in symptoms, slowing of disease progression, etc.) • Medication is prescribed at an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Sleep Disorder Therapy**
Drugs	**Formulary status**: Preferred, Prior Authorization Required • modafinil (Provigil) tablets • armodafinil (Nuvigil) tablets **Formulary status**: Non-preferred, Prior Authorization Required • Sunosi (solriamfetol) tablets • Wakix (pitolisant) tablets • Sodium oxybate solution • Xyrem (sodium oxybate) solution • Xywav (calcium, magnesium, potassium, and sodium oxybates) • Lumryz (sodium oxybate) packet
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Wakix: severe hepatic impairment (Child-Pugh class C) Sodium oxybate (Xyrem/Xyway/Lumryz): Succinic semialdehyde dehydrogenase deficiency
Required Medical Information	See "Other Criteria"
Age Restrictions	Per FDA approved prescribing information.
Prescriber Restrictions	Prescribed by or in consultation with a sleep specialist, neurologist, or other specialist in the treatment of the member's diagnosis (does not apply for diagnosis of shift-work disorder)
Coverage Duration	If the criteria are met, requests for modafinil, armodafinil, Sunosi, and Wakix will be approved with up to a 12 month duration. Requests for sodium oxybate products will be approved with up to a 3 month duration.
Other Criteria	**For all requests:** • Medication is being prescribed at an FDA approved dose **Modafinil/armodafinil initial authorization:** • For a diagnosis of obstructive sleep apnea (OSA) documentation that the member has been compliant with or is unable to use positive airway pressure [continuous positive airway pressure (CPAP), bilevel positive airway pressure (BPAP), or automatic positive airway pressure (APAP)]. **Sunosi initial authorization** • Documented trial and failure of modafinil or armodafinil or a documented medical reason for not utilizing these medications. • For members with OSA: o Documentation that the member has been compliant with or is unable to use positive airway pressure (CPAP, BPAP, or APAP) **Wakix initial authorization:**

	• For a diagnosis of narcolepsy without cataplexy: documented trial and failure of (or medical reason for not using), BOTH of the following:
	  o Modafinil or armodafinil
	  o Sunosi (solriamfetol)
	  For members under 18 years of age, no prerequisite medication trials are required
	• For a diagnosis of narcolepsy in members 18 years of age and older with cataplexy: documented trial and failure of, or medical reason for not using, the following:
	  o Dextroamphetamine
	
	<u>Sodium Oxybate (Xyrem/Xywav/Lumryz) initial authorization</u>
	• Medication is not being taken concurrently with sedative hypnotics
	• For a diagnosis of narcolepsy without cataplexy:
	  o Documented trial and failure of, or a medical reason for not using, ALL of the following:
	  ▪ Either modafinil or armodafinil (not required for members under 18)
	  ▪ Sunosi (solriamfetol) (not required for members under 18)
	  ▪ Wakix (pitolisant)
	  o For Xyrem or Xywav or Lumryz: documented trial and failure of, or medical reason for not using generic sodium oxybate.
	• For a diagnosis of narcolepsy with cataplexy:
	  o Documented trial and failure of each of, or medical reason for not using BOTH of the following:
	  ▪ Dextroamphetamine (no required for members under 18)
	  ▪ Wakix (pitolisant) (not required for members under 18)
	  o For Xyrem or Xywav or Lumyrz: documented trial and failure of, or medical reason for not using generic sodium oxybate.
	• For a diagnosis of idiopathic hypersomnia (Xywav only):
	  o Patient has a documented trial and failure of, or medical contraindication to, the following:
	  ▪ Modafinil or armodafinil
	
	<u>Reauthorization:</u>
	• Documentation has been submitted indicating member has experienced a clinical benefit from treatment (e.g. improvement on Epworth Sleepiness Score, reduction in frequency of cataplexy attacks)

Revision/Review Date: 10/2025	• For a diagnosis of obstructive sleep apnea (OSA) documentation that the member continues to be compliant with or is unable to use positive airway pressure (CPAP, BPAP, or APAP) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary**

Field Name	Field Description
Prior Authorization Group Description	SMN2 Splicing Modifiers for the Treatment of Spinal Muscular Atrophy (SMA)
Drugs	Evrysdi (risdiplam) Spinraza (nusinersen)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	• For Spinraza: patient has previously received treatment with Zolgensma • Concomitant use of Evrysdi and Spinraza
Required Medical Information	For Evrysdi: Patient's body weight
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	For Evrysdi: If all of the conditions are met, the request will be approved for 6 months for initial approval, followed by 12 months for reauthorization requests. For Spinraza: If all of the conditions are met, the request will be approved for 6 months for 5 doses (4 loading doses and 1st maintenance dose) for initial approval, and 12 months for 3 additional maintenance doses for reauthorization requests. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria	**Initial approval** • Member has a confirmed diagnosis of SMA types I, II or III and the molecular genetic test with mutation analysis was submitted that is positive for the genetic deletion of the exon 7 of the survival motor neuron (SMN1) • For Spinraza: Documentation of genetic testing confirming either two or three copies of the SMN2 gene **OR** four copies of the SMN2 gene with symptomology of SMA • For Evrysdi: Documentation of genetic testing confirming two to four copies of the SMN2 gene • Baseline motor function or motor milestone achievement was

Revision/Review Date 2/2025	submitted with request [e.g. CHOP Infant Test of Neuromuscular Disorders (CHOP-INTEND) or Hammersmith Infant Neurological Examination (HINE) for Type 1 or Hammersmith Functional Motor Scale Expanded Scores (HFMSE) for Type II and Type III, or 6 minute walk test in subjects able to walk] • The request is for an FDA approved dose **<u>Reauthorization</u>** • Documentation of clinical response was submitted with request (e.g. improvement in motor function/motor milestone achievement scores using CHOP-INTEND or HFMSE, 6 minute walk test or HINE improvement in more categories of motor milestones than worsening, patient remains permanent ventilation free if no prior ventilator support) • The request is for an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	Sodium Glucose CoTransporter-2 (SGLT-2) Inhibitors and Combinations
Drugs	**Step 1: Preferred with Step Through Metformin** Steglatro (ertugliflozin) Segluromet (ertugliflozin-metformin) **Step 2: Preferred – PA Required** dapagliflozin (Farxiga) **Step 3: Non-Preferred – PA Required** dapagliflozin-metformin /Xigduo XR Qtern (dapagliflozin-saxagliptin) Jardiance (empagliflozin) Synjardy/Synjardy XR (empagliflozin-metformin) Glyxambi (empagliflozin-linagliptin) Trijardy XR (empagliflozin-linagliptin-metformin) Steglujan (ertugliflozin-sitagliptin) Invokana (canagliflozin) Invokamet/Invokamet XR (canagliflozin-metformin) Inpefa (sotagliflozin) Brenzavvy (bexagliflozin)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Members with type 1 diabetes
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If all of the conditions are met, the request will be approved with a 12-month duration.

Other Criteria	**<u>Type 2 Diabetes</u>**
	• Member has a diagnosis of type 2 diabetes
	• For Steglatro and Segluromet
	  o Documentation has been provided that the member has had a 3 month trial of metformin at the maximally tolerated dose or has a medical reason why metformin cannot be used
	• If the request is for a preferred Step 2 agent:
	  o Documentation has been provided that the member has had a 3 month trial of metformin at maximally tolerated

	dose in combination with Steglatro (or the combination agent Segluromet) or has a medical reason why these medications cannot be used (e.g., intolerance, established cardiovascular disease, at high risk for cardiovascular disease, or diabetic nephropathy with albuminuria) • If the request is for a non-preferred Step 3 agent: o Documentation has been provided that the member has tried and failed or has a medical reason why (e.g., intolerance, established cardiovascular disease, at high risk for cardiovascular disease, or diabetic nephropathy with albuminuria) they cannot use one preferred Step 1 agent and a preferred Step 2 agent • Medication is prescribed at an FDA approved dose **Heart Failure** • Member has a diagnosis of symptomatic heart failure (NYHA functional class II-IV) • If left ventricular ejection fraction (LVEF) is reduced (i.e. ≤ 40%) the member is currently being prescribed or will be prescribed the following treatment regimen or documentation has been provided that the member is not able to tolerate these agents: o Angiotensin-Converting Enzyme (ACE) Inhibitor OR Angiotensin Receptor Blocker (ARB) OR Angiotensin Receptor/Neprilysin Inhibitor (ARNI) o Evidenced-based beta-blocker (i.e., bisoprolol, carvedilol, metoprolol succinate) o Mineralocorticoid receptor antagonists (MRA) • Medication is prescribed at an FDA approved dose • If the request is for any non-preferred Step 3 agent, documentation has been provided that the member has had a trial and failure of dapagliflozin or has a medical reason why this medication cannot be used **Chronic Kidney Disease** • Member has a diagnosis of chronic kidney disease Member has eGFR ≥20 to <45 mL/min/1.73m² or eGFR ≥45 to <90 mL/min/1.73m² with urinary albumin:creatinine ratio ≥200 mg/g (or protein:creatinine ratio ≥300 mg/g) • For members with documented albuminuria, an ACE or ARB is currently being prescribed, will be prescribed, or documentation has been provided that the member is not able to tolerate these agents. • Medication is prescribed at an FDA approved dose

Revision/Review Date 2/2025	• If the request is for any non-preferred Step 3 agent, documentation has been provided that the member has had a trial and failure of dapagliflozin or has a medical reason why this medication cannot be used **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	Sohonos
Drugs	Sohonos (palovarotene)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Pregnancy • Use in patients younger than 8 years of age for females and 10 years of age for males
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with an orthopedic specialist or provider who specializes in rare connective tissue diseases
Coverage Duration	If all of the criteria are met, the initial or reauthorization request will be approved for up to 6 months taking into account patient specific scenarios.
Other Criteria Revision/Review Date: 2/2025	**Initial Authorization:** • Documented diagnosis of fibrodysplasia ossificans progressiva (FOP) • Documented genetic testing of ACVR1 R206H mutation • Attestation that patient is not pregnant and appropriate contraception methods will be used at least 1 month before treatment, during treatment, and 1 month after the last dose (if applicable) • Documentation of weight for patients younger than 14 years old • Medication is prescribed at an FDA approved dose **Re-Authorization:** • Documentation or provider attestation of clinical benefit (i.e. volume reduction of heterotopic ossification) or worsening (i.e. flare-up presence and/or worsening of flare-ups) • Attestation that patient is not pregnant and appropriate contraception methods will be used at least 1 month before treatment, during treatment, and 1 month after the last dose (if applicable) • Documentation of weight for patients younger than 14 years old • Medication is prescribed at an FDA approved dose **Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Somatostatin Analogs and Growth Hormone Receptor Antagonists**
Drugs	Octreotide (Sandostatin) Sandostatin LAR (octreotide) Lanreotide 120 mg/0.5 mL Lanreotide (Somatuline Depot) () 60 mg/0.2 mL, 90 mg/0.3 mL, 120 mg/0.5mL Mycapssa (octreotide) Signifor (pasireotide) Signifor LAR (pasireotide) Somavert (pegvisomant)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA) Drug Package Insert (PPI). ** Non-FDA approved (i.e. off-label) uses; refer to the "Off-Label Use" policy for non-oncology indications, and the "Oncology Drugs" policy for off-label oncology uses**
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Per FDA approved package insert
Prescriber Restrictions	Prescriber must be a specialist with appropriate expertise in treating the condition in question (such as an endocrinologist, neurologist/neurosurgeon, oncologist, etc.). Consultation with appropriate specialist for the condition in question is also acceptable.
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	**Initial Authorization** For all FDA approved indications (including FDA-approved oncology related uses) • Medication requested is for an FDA approved indication and dose • If the provider is requesting therapy with more than one somatostatin analog or a somatostatin analog and a growth hormone receptor antagonist, then documentation must be submitted as to why patient is unable to be treated with monotherapy, or a medical reason was provided why monotherapy is not appropriate. For Acromegaly • Patient has had an inadequate response to, or medical reason why, surgical treatment cannot be used.

	• If the patient mild disease (e.g. mild signs and symptoms of growth hormone excess, modest elevations in IGF-1) there is a documented trial of a dopamine agonist (e.g. bromocriptine mesylate, cabergoline) at a therapeutically appropriate dose or a documented medical reason why a dopamine agonist cannot be used
	• **Additionally for Mycapssa:**
	  o Patient has showed clinical response to and tolerates treatment with octreotide or lanreotide therapy
	  o Clinical justification is provided as to why patient cannot continue use of injectable somatostatin analog therapy
	• **Additionally for Somavert:**
	  o Patient has had an inadequate response to therapy with a somatostatin analog, or has a documented medical reason why a somatostatin analog cannot be used
	• **Additionally for Signifor LAR:**
	  o Patient has had an inadequate response to therapy with either lanreotide (Somatuline Depot) or octreotide (Sandostain, Sandostatin LAR), or has a documented medical reason why these somatostatin analogs cannot be used.
	
	<u>For Cushing's Disease (pasireotide products only)</u>
	• Patient must have had inadequate response, or medical reason why surgical treatment cannot be used
	
	<u>Reauthorization</u>
	• Medication requested is for an FDA approved indication and dose
	• Documentation has been provided that demonstrates a clinical benefit (e.g. improvement in laboratory values, improvement or stabilization of clinical signs/symptoms, etc.)

Revision/Review Date 4/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Specialty Biologic Agents**
Drugs	<u>Step 1: Preferred (pays at point-of-sale)</u> Hadlima (adalimumab-bwwd) Adalimumab-fkjp (unbranded Hulio) Adalimumab-aaty Simlandi (adalimumab-ryvk) <u>Step 2: Preferred (PA required)</u> Avsola (infliximab-axxq) Enbrel (etanercept) Entyvio (Vedolizumab) Inflectra (infliximab-dyyb) Infliximab Kevzara (sarilumab) Kineret (anakinra) Olumiant (baricitinib) Orencia (abatacept) Otezla (Apremilast) Otulfi (ustekinumab-aauz) Renflexis (infliximab-abda) Siliq (brodalumab) Simponi, Simponi Aria (golimumab) Avtozma (tocilizumab-anoh) Tyenne (tocilizumab-aazg) Tofidence (tocilizumab-bavi) Xeljanz, Xeljanz XR (tofacitinib) Yesintek (ustekinumab-kfce) Imuldosa (ustekinumab-srlf) Tyruko (natalizumab-sztn) <u>Step 3: Non-Preferred (PA required)</u> All adalimumab biosimilar agents not listed in step 1 (ex. Amjevita, Cyltezo, Hyrimoz, Yuflyma, Hulio, etc.) All Stelara biosimilars not listed in step 2 (ex. Steqeyma, Selarsdi, etc.) Actemra (tocilizumab) Arcalyst (rilonacept) Bimzelx (bimekizumab) Cimzia (certolizumab) Cosentyx (secukinumab) Humira (adalimumab) Ilaris (canakinumab) Ilumya (tildrakizumab-asmn)

	Litfulo (ritlecitinib) Omvoh (mirikizumab) Remicade (infliximab) Rinvoq (upadacitinib) Rinvoq LQ (upadacitinib) Skyrizi (isankizumab) Sotyktu (deucravacitinib) Stelara (ustekinumab) Taltz (ixekizumab)Tremfya (guselkumab)Tysabri (natalizumab) Zeposia (ozanimod) Zymfentra (infliximab) Or any newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines. ** Non-FDA approved (i.e. off-label) uses; refer to the "Off-Label Use" policy**
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by, or in consultation with, a specialist in the field to treat the member's respective medical condition
Coverage Duration	If all of the conditions are met, requests will be approved for 12 months.
Other Criteria	• The drug is being requested for an appropriate use (per the references outlined in "Covered Uses") • The dose requested is appropriate for the requested use (per the references outlined in "Covered Uses") • If the request is for a preferred Step 2 agent, documentation has been provided that the member has tried and failed or has a medical reason why (e.g. intolerance, contraindication) they cannot use a preferred Step 1 agent appropriate for the requested use (per the references outlined in "Covered Uses") • If the request is for a non-preferred Step 3 agent, documentation has been provided that the member has tried and failed or has a medical reason why (e.g. intolerance, contraindication) they cannot use one preferred step 1 agent and one preferred step 2 agent appropriate for the requested use (per the references outlined in covered uses) AND: • If the request is for a reference biologic drug with a biosimilar or

Revision/Review Date: 10/2025	interchangeable biologic drug (ex. Humira, Remicade, Stelara), documentation of one of the following: • The provider has verbally, or in writing, submitted a member-specific reason why the reference biologic is required based on the member's condition or treatment history; AND if the member had side effects or a reaction to the biosimilar or interchangeable biologic, the provider has completed and submitted an FDA MedWatch form to justify the member's need to avoid these drugs. MedWatch form must also be included with the prior authorization request. Form FDA 3500 – Voluntary Reporting • The currently available biosimilar product does not have the same appropriate use (per the references outlined in "Covered Uses") as the reference biologic drug being requested *NOTE: • Requests for Humira 10 mg/0.1 mL in pediatric patients may be approved without a trial of a step 1 or step 2 agent, when requested for an appropriate use (per the references outlined in "Covered Uses") **Reauthorization:** • Documentation submitted indicates that the member has obtained clinical benefit from the medication. • The drug is being requested for an appropriate use and dose (per the references outlined in "Covered Uses") **Continuation of Therapy Provision (does not apply to Remicade, Humira, Stelara or non-preferred adalimumab and non-preferred Stelara biosimilar agents)**: • Members with history (within the past 90 days) of a non-preferred Step 3 biological agent are not required to try a Step 1 and a Step 2 biological agent prior to receiving the non-preferred agent. • Members with history (within the past 90 days) of a preferred Step 2 biological agent are not required to try a Step 1 biological agent prior to receiving the Step 2 agent. **Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Spiriva Respimat**
Drugs	Spiriva Respimat (tiotropium bromide)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	Asthma: 6 years of age or older COPD: N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration. If the criteria are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria	**Initial authorization:** Asthma: • Documented diagnosis of asthma • The request is for 1.25 mcg/inhalation strength • At least ONE of the following is true: o Member has had ≥ 1 serious exacerbation in the past year requiring hospitalization o Member has had ≥ 2 exacerbations in the past year requiring oral corticosteroids o Member remains symptomatic despite treatment with a combination of an inhaled corticosteroid (ICS) and long acting beta agonist (LABA), or has a documented medical reason (e.g. contraindication, intolerance, hypersensitivity) why that treatment cannot be used • Member will continue to receive treatment with a combination of an ICS and LABA • Dose is within FDA approved limits Chronic Obstructive Pulmonary Disease (COPD): 1. Documented diagnosis of COPD 2. The request is for the 2.5 mcg/inhalation strength 3. Member has tried and failed one preferred single agent inhaled long acting muscarinic antagonists (LAMA) (e.g. Incruse Ellipta) or has a documented medical reason (e.g. contraindication, intolerance, hypersensitivity) why those

Revision/Review Date 2/2025	treatments cannot be used 4. Dose is within FDA approved limits **<u>Reauthorization</u>:** 1. Member has experienced a clinical benefit from therapy (e.g. improved lung function, reduced exacerbations, improved symptoms) 2. Dose is within FDA approved limits **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Spravato**
Drugs	**Spravato** (esketamine)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Patients must be 18 years age or older
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the initial request will be approved for 4 weeks. For continuation of therapy the request will be approved for 6 months.

Other Criteria
 	
Revision/Review Date 4/2025
	Initial Authorization:
	• Member has a diagnosis of at least one of the following:
	  o Major depressive disorder with treatment-resistant depression
	  o Major depressive disorder with acute suicidal ideation or behavior
	• Medication is being prescribed at an FDA approved dosage.
	• If Spravato is being requested for a diagnosis of major depressive disorder with treatment-resistant depression (i.e. without suicidal ideation or behavior) the member has either:
	  o Documented trial and failure of two preferred oral antidepressants (eg. SSRIs, SNRIs, TCAs) of at least a minimum effective dose for four (4) weeks or longer
	  OR
	  o Medical justification as to why the patient cannot use preferred alternative(s).
	• Requests for a diagnosis of major depressive disorder with acute suicidal ideation or behavior (not required for treatment resistant depression):
	  o Prescriber attests Spravato will be used in conjunction with an oral antidepressant
	
	Re-authorization:
	• Medication is prescribed at an FDA-approved dosage.
	• Medication is being used in conjunction with an oral antidepressant (not required for diagnosis of treatment resistant depression).
	• Documentation was submitted indicating the member has clinically benefited from therapy.

	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Prior Authorization Group Description	**Subcutaneous Treatments for Hemophilia**
Drugs	Hemlibra (emicizumab-kxwh), Hympavzi (marstacimab-hncq), Alhemo (concizumab-mtci), Qfitlia (fitusiran)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a hematologist
Coverage Duration	If the criteria are met, requests will be approved for 6 months. If the provider states that the requested medication is for a chronic or long-term condition for which the medication may be necessary for the life of the patient, the request will be approved for 12 months.

Other Criteria	**Initial Authorization:**
	Documentation submitted indicates the following:
	• The member's weight
	• The drug is being requested for an FDA-approved indication and the dose is within FDA-indicated limits
	• Diagnosis of hemophilia A or hemophilia B AND one of the following
	  o Member has tried Factor VIII or Factor IX products and is not well-managed due to limited venous access or treatment failure (attestation must be submitted from prescriber)
	  o Request is for routine prophylaxis in patients with a diagnosis of hemophilia A or hemophilia B **WITH** inhibitors and history of spontaneous or traumatic bleeding episode
	  o Request is for routine prophylaxis in patients with a diagnosis of hemophilia A or hemophila B ***WITHOUT*** inhibitors and patient requires management with Factor VIII or Factor IX products at a total weekly dose of >100 U/kg (attestation must be submitted by prescriber)
	• If the request is for Hympavzi, Alhemo, or Qfitlia for hemophila A, the member must also have a trial and failure or intolerance to Hemlibra
	• If the request is for Qfitlia, prescriber must also attest to monitoring member antithrombin (AT) levels, signs and symptoms of thrombotic

Revision/Review Date: 7/2025	events, and signs and symptoms of acute and recurrent gallbladder disease as recommended per the manufacturer's prescribing information **<u>Re-Authorization:</u>** • Documentation submitted indicating the member has experienced a clinical benefit from the medication (e.g. reduction in bleeding episodes, improved quality of life) • The member's weight • Dose is within FDA-indicated limits **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Sublingual Allergenic Extracts**
Drugs	**Grastek** (timothy grass pollen allergen extract) **Odactra** (house dust mite allergen extract) **Oralair** (sweet vernal/orchard/rye/timothy/Kentucky blue grass mixed pollen allergenic extract) **Ragwitek** (Short ragweed pollen allergenic extract)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	According to Package Insert
Prescriber Restrictions	Prescriber is an allergist or immunologist
Coverage Duration	If all of the conditions are met, the request will be approved for a 12 month duration.

Other Criteria	**Initial authorization**:
	
	For all requests:
	• Requested allergenic extract is being used to treat allergic rhinitis with or without conjunctivitis
	• Member has had a document trial and failure of, or intolerance to, an intranasal corticosteroid (e.g. fluticasone) used in combination with at least one of the following:
	  o Oral antihistamine (e.g. cetirizine)
	  o Intranasal antihistamine (e.g. azelastine)
	  o Oral leukotriene receptor antagonist (montelukast)
	• Patient has been prescribed (as demonstrated by pharmacy claims or documentation) injectable epinephrine
	
	Grastek:
	• Diagnosis has been confirmed by positive skin or in vitro testing to Timothy Grass, or cross reactive, pollen
	
	Odactra:
	• Diagnosis has been confirmed by either positive skin test to house dust mite allergen extract **OR** positive in vitro testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssiunus*

Revision/Review Date 10/2025	Oralair: • Diagnosis has been confirmed by positive skin, or in vitro, testing to Sweet Vernal, Orchard, Rye, Timothy, Kentucky Blue Grass, or cross reactive, pollen Ragwitek: • Diagnosis has been confirmed by positive skin, or in vitro, testing to Short Ragweed pollen **Reauthorization:** For all requests: • Member has experienced a reduction in symptoms associated with allergic rhinitis **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Synagis (palivizumab)**
Drugs	Synagis (palivizumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	A maximum of 5 doses may be approved within the Respiratory Syncytial Virus (RSV) season. Requests for additional doses will be reviewed on a case-by case basis based on CDC surveillance reports, state/local health department recommendations, and other current medical literature.
Other Criteria	<u>Must have documented medical reason for not using Beyfortus (niresvimab) AND</u> <u>Infants less than 1 year of age at the onset of the respiratory syncytial virus (RSV) season (which typically starts November 1st, but may vary seasonally)</u> **<u>AND</u>** <u>have one of the following indications</u>: • Born at less than 29 weeks, 0 days gestation • Born at less than 32 weeks, 0 days gestation AND had chronic lung disease of prematurity defined as greater than 21% oxygen for at least 28 days after birth • Born at any gestational age with hemodynamically significant heart disease including: o Cyanotic heart disease in consultation with a pediatric cardiologist o Acyanotic Heart disease with one of the following: ▪ On heart failure medication and expected to require cardiac surgical procedure ▪ Moderate to severe pulmonary hypertension • Cystic fibrosis with clinical evidence of chronic lung disease (CLD) and/or nutritional compromise in the first year of life • Born at any gestational age with pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the lower airway <u>Infants less than 2 years of age at the onset of the RSV season (which typically starts November 1st, but may vary seasonally)</u> **<u>AND</u>** <u>have one</u>

Revision/Review Date: 7/2025	of the following indications: • Born at less than 32 weeks, 0 days AND had a diagnosis of chronic lung disease of prematurity at birth as defined above **AND** had continued need for one of the following respiratory interventions in the 6 months preceding RSV season: Chronic steroids, chronic diuretics, supplemental oxygen • Cystic fibrosis with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) or weight for length less than the 10th percentile • Born at any gestational age and will be profoundly immunocompromised during the RSV season, including: o Solid organ or hematopoietic stem cell transplant recipient o Chemotherapy recipient • Born at any gestational age and receiving a cardiac transplant **Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Tavneos**
Drugs	Tavneos (avacopan)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Not Applicable
Required Medical Information	See "Other Criteria"
Age Restrictions	≥18 years old
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist or hematologist
Coverage Duration	If the conditions are met, the request will be approved for a 6-month duration for initial requests and a 12-month duration for renewal requests.
Other Criteria Revision/Review Date: 2/2025	**<u>Initial Authorization:</u>** • Diagnosis of one of the following subtypes of severe active antineutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis: granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) • Prescriber attestation that Tavneos will be prescribed in combination with corticosteroids AND cyclophosphamide or rituximab, unless there is documented trial and failure, intolerance, inability to use, or contraindication to these therapies • The prescribed dose is within FDA-approved dosing guidelines • Documentation of baseline Birmingham Vasculitis Activity Score (BVAS) score • Prescriber attestation that the patient will have liver function tests before treatment (ALT, AST, alkaline phosphate, and total bilirubin) and every 4 weeks after start of therapy for the first 6 months of treatment • Prescriber attestation that the patient has been screened for and does not have active hepatitis B virus (HBV) infection at baseline **<u>Reauthorization:</u>** • Documentation of remission (BVAS score of 0) OR improvement in BVAS score • Prescriber attestation that patient has no abnormality in liver function tests (abnormality: ALT or AST >3 times the upper limit of normal and bilirubin >2 times the upper limit of normal) • Prescriber attestation that patient has no active HBV infection • The prescribed dose is within FDA approved dosing guidelines **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Topical Agents for Psoriasis**
Drugs	**FORMULARY STATUS** Preferred, Step Therapy with one prior step Calcipotriene (Dovonex) 0.005% topical cream Tazarotene (Tazorac) 0.1% topical cream **Note: Patient must meet criteria #1 & #2 for approval of the PA request.** **FORMULARY STATUS:** Non-Preferred, Requires Prior Authorization Vtama (tapinarof) Zoryve (roflumilast) **Note: Patient must meet criteria #1 & #3 for approval of the PA request.**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved for up to a 12 month duration.
Other Criteria Revision/Review Date 10/2025	1. Presumed or documented diagnosis of psoriasis 2. Documented trial and failure or intolerance with a topical corticosteroid 3. Documented trial and failure with, or intolerance to, topical corticosteroid used in combination with either calcipotriene or tazarotene

Field Name	Field Description
Prior Authorization Group Description	**Topical Antiviral Treatment**
Drugs	**FORMULARY STATUS:** Preferred, pays at the point of sale • **Docosanol** (Abreva) • **Acyclovir** (Zovirax) ointment **FORMULARY STATUS:** Non-Preferred, Prior Authorization Required • **Acyclovir** (Zovirax) cream • **Penciclovir** (Denavir) • **Xerese** (acyclovir/hydrocortisone) • **or any newly marketed topical antiviral agent**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 10/2025	**Initial Authorization** For the treatment of herpes labialis (cold sores): • Documented trial and failure or intolerance to a preferred oral antiviral, such as acyclovir or valacyclovir tablet. • Documented trial and failure or intolerance to a preferred topical antiviral (e.g. docosanol) For the treatment of genital herpes: • Documented trial and failure or intolerance to a preferred oral antiviral, such as acyclovir or valacyclovir tablet. • Documented trial and failure of a preferred topical antiviral (e.g. acyclovir ointment) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Topical mTOR Kinase Inhibitors**
Drugs	Hyftor (sirolimus topical gel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	Member concomitantly taking an oral mTOR inhibitor
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be 6 years or older
Prescriber Restrictions	Prescriber must be a dermatologist, medical geneticist, neurologist, or other prescriber who specializes in the treatment of genetic or dermatologic disorders.
Coverage Duration	If the criteria are met, requests will be approved with up to a 3 month duration. Thereafter, reauthorization requests will be approved with up to a 6 month duration.
Other Criteria Revision/Review Date 4/2025	**Initial Authorization:** • Member has a confirmed diagnosis of tuberous sclerosis complex (TSC) • Member has at least 3 facial angiofibromas measuring 2 mm or larger in diameter • Documentation of a comprehensive dermatologic evaluation has been provided • Prescriber attests that the member is not a candidate for laser therapy or surgery • Medication is being prescribed at an FDA approved dose **Reauthorization:** • Documentation has been provided indicating that the member has experienced a clinical benefit from treatment (e.g. improvement in size and color of angiofibromas) • Documentation of a comprehensive dermatologic evaluation has been provided • Prescriber attests that the member is not a candidate for laser therapy or surgery • Medication is being prescribed at an FDA approved dose

Field Name	Field Description
Prior Authorization Group Description	**Transthyretin-mediated Amyloidosis Agents**
Drugs	**Preferred:** Polyneurpathy – Onpattro (patisiran), Amvuttra (vutrisiran), Wainua (eplontersen) Cardiomyopathy – Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis), Attruby (acoramidis) **Non-preferred**: Cardiomyopathy – Amvuttra (vutrisiran) Or any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Patient must be 18 years of age or older
Prescriber Restrictions	Prescriber must be neurologist, cardiologist, or specialist in the treatment of amyloidosis
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy the request will be approved for 6 months.
Other Criteria	**Initial Authorization**: • Regimen does not exceed FDA-approved dose/frequency • Patient has not undergone a liver or heart transplant • Requests for use multiple agents (different mechanism of action) in this policy for mixed polyneuropathy-cardiomyopathy phenotypes will only be considered if patient meets clinical criteria requirements for each section. **Polyneuropathy-Type** If the request is for Onpattro, Amvuttra, or Wainua: • Patient has diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis as evidenced by documented transthyretin variant by genotyping • One of the following: o Patient has baseline polyneuropathy disability (PND) score ≤ IIIb o Patient has a baseline FAP Stage 1 or 2

	○ Patient has baseline neuropathy impairment (NIS) score ≥ 5 and ≤ 130 • Patient has clinical signs/symptoms of neuropathy **Cardiomyopathy-Type** If the request is for Vyndaqel, Vyndamax, Attruby, or Amyuttra: • Patient has a confirmed diagnosis of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis • Documented amyloid deposit by biopsy or positive technetium 99m pyrophosphate (Tc 99m PYP) cardiac imaging • Patient has New York Heart Association (NYHA) functional class I, II, or III heart failure symptoms. • For Amvuttra, patient has contraindication to/or previous trial and failure or continued clinical progression with use of Vyndaqel, Vyndamax or Attruby **<u>Re-authorization (for continuing and new patients to the plan)</u>** : • Patient's regimen does not exceed FDA-approved dose/frequency for the agent • Patient has not undergone a liver or heart transplant • Requests for use multiple agents (different mechanism of action) in this policy for mixed polyneuropathy-cardiomyopathy phenotypes will only be considered if patient meets clinical criteria requirements for each section. • Documented positive clinical response to therapy from baseline (stabilization/slowing of disease progression, improved neurological impairment, motor functions, improved NIS score, stabilization/reduced rate of decline in 6 minute walk test, etc.) • If the request is for Vyndaqel/Vyndamax/Attruby/Amyuttra ○ Patient has continued NYHA functional class I, II, or III heart failure symptoms
Revision/Review Date:4/2025	**<u>Continuation of Therapy Provision:</u>** Members with history (within the past 90 days) of a non-formulary product are not required to try a formulary agent prior to receiving the non-formulary product. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Prior Authorization Group Description	**Treatment of Hereditary Angioedema (HAE)**
Drugs	**<u>Preferred:</u>** Berinert (C1 esterase inhibitor, human) Haegarda (C1 esterase inhibitor, human) Ruconest (C1 esterase inhibitor, recombinant) icatibant (Firazyr) **<u>Non-preferred:</u>** Cinryze (C1 esterase inhibitor, human) Kalbitor (ecallantide) Takhzyro (lanadelumab-flyo) Orladeyo (berotralstat) Ekterly (sebetralstat) Andembry (garadacimab-gxii) Dawnzera (donidalorsen) For danazol requests, refer to the "Danazol" policy
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be an immunologist, allergist, rheumatologist, or hematologist

Coverage Duration	If criteria are met, the request will be approved as follows:
	• Acute treatment: 1 + 5 refills
	• Pre procedural prophylaxis: 1 treatment
	• Long-term prophylaxis:
	  o Initial: 6 months
	  o Reauthorization: 12 months

Other Criteria	**<u>Initial Requests:</u>**
	• Documentation submitted indicates the medication is being prescribed at FDA approved dose.
	• The patient is not taking ACE inhibitors or estrogen containing oral contraceptives/hormone replacement therapy
	• Diagnosis of one of the following**:**
	  o HAE with deficient or dysfunctional C1INH (e.g. type I, type II, or acquired C1NH deficiency
	  o HAE with normal C1INH:
	  ▪ If known origin, documentation of results of confirmatory genetic test (e.g. mutations in gene for factor XII,

	angiopoietin-1, plasminogen, kininogen-1, myoferlin, heparan sulfate-glucosamine 3-O-sulfotransferase 6) ▪ If unknown origin (U-HAE), documentation of a prolonged trial of high-dose non-sedating antihistamines **For acute treatment (Ruconest, Berinert, Kalbitor, icatibant, Ekterly):** o The patient is receiving only one agent for the treatment of acute attacks o If the request is for a non-preferred agent, the member has documented trial and failure of, or intolerance to a preferred agent or medical reason why the member cannot use a preferred agent **For prophylaxis (Haegarda, Takhzyro, Cinryze, Orladeyo, Andembry, Dawnzera):** • Pre-procedural o Documentation that patient will be undergoing a medical, surgical, or dental procedure associated with mechanical impact to the upper aerodigestive tract • Long-term o The patient has a history of at least two severe attacks/month (e.g. with swelling of the face, throat, or GI tract) or at least one laryngeal attack, and chart notes have been submitted indicating the date and severity of attack. o The patient is only receiving one medication for long-term prophylaxis • If the request is for a non-preferred agent o And the patient has a C1INH deficiency or dysfunction, documented trial and failure of or medical reason why patient cannot use a preferred agent o And the patient has HAE with normal C1INH, documented trial and failure of, or documented medical reason why patient cannot use danazol (note: danazol may require prior authorization) **<u>Renewal Criteria:</u>** **For acute treatment (Ruconest, Berinert, Kalbitor, icatibant, Ekterly):** • Documentation was submitted that the patient has clinically benefited from medication • The patient is receiving no other medications for acute treatment • The medication is being prescribed at FDA approved dose. **For prophylaxis (Haegarda, Takhzyro, Cinryze, Orladeyo, Andembry, Dawnzera):**

Revision/Review Date: 10/2025	• Documentation was submitted that the patient has clinically benefited from prophylactic therapy as demonstrated by a reduced number of attacks • The medication is being prescribed at an FDA approved dose • The patient is receiving no other medications for prophylaxis **NOTE: Medical Director/Clinical Reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary**

Field Name	Field Description
Prior Authorization Group Description	**Treatments for Plasminogen Deficiency Type 1 (PLD1)**
Drugs	Ryplazim (human plasma-derived plasminogen)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a hematologist, medical geneticist, or other specialist in the treatment of rare blood or genetic disorders
Coverage Duration	If all of the criteria are met, the initial request will be approved for 12 weeks. Reauthorization requests will be approved for 12 weeks if the member has not had a documented positive response to therapy and for 12 months if the member has had a documented positive response to therapy.

Other Criteria	**Initial Authorization**
	• Member must have a diagnosis of PLD1 (i.e. hypoplasminogenemia)
	• Member must have a documented history of lesions or other symptoms consistent with the diagnosis (e.g. ligneous conjunctivitis, oral, respiratory, gastrointestinal, urogenital, integumentary, or central nervous system manifestations)
	• Member must have baseline plasminogen activity levels ≤ 45%
	  o If the member received plasminogen supplementation with fresh frozen plasma, prescriber attests that a 7-day washout period was performed before obtaining baseline plasminogen activity levels.
	• The request is for an FDA approved dose
	
	Reauthorization
	• ONE of the following is true:
	  o Member has a documented positive response to therapy (e.g. reduction in number or size of lesions, no new or recurring lesions)
	  o Member has not had a documented positive response to therapy and ONE of the following:
	  ▪ If confirmed plasminogen activity levels are ≥ 10% above baseline, then appropriate dosing frequency adjustments must be made.
	  ▪ If confirmed plasminogen activity levels are < 10% above baseline, then appropriate dosing frequency adjustments must be made AND the prescriber must provide a medical justification as to why therapy should be continued.
	• The request is for an FDA approved dose

Revision/Review Date 4/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Tryngolza (olezarsen)**
Drugs	Tryngolza (olezarsen) injection, for subcutaneous use
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be 18 years of age or older
Prescriber Restrictions	Prescriber must be an endocrinologist, lipidologist, or cardiologist experienced in, or in consultation with a specialist experienced in, familial chylomicronemia syndrome (FCS).
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.

Other Criteria
 	
Date: 4/2025
	Initial Authorization:
	• Medication is prescribed at an FDA approved dose
	• The member has undergone genetic testing to confirm a diagnosis of FCS with ONE of the following results:
	  o The member has a pathogenic gene mutation in FCS-causing genes (e.g., *LPL*, *GPIHBP1*, *APOA5*, *APOC2*, or *LMF1*)
	  o The member has inconclusive genetic results and has documentation supporting the diagnosis of FCS by ONE of the following:
	  ▪ North America Familial Chylomicronemia Syndrome (NAFCS) score ≥ 45
	  ▪ FCS score ≥ 10
	  ▪ History of acute pancreatitis
	  ▪ History of recurrent abdominal pain without other known causes
	• The member's most recent triglyceride level is ≥880 mg/dL (10 mmol/L)
	• The prescriber attests the member will follow a low-fat diet
	Re-Authorization:
	• Medication is prescribed at an FDA approved dose
	• Documentation of a positive clinical benefit (e.g., reduction in fasting triglyceride level from baseline, fewer acute pancreatitis events)
	• The prescriber attests the member will continue to follow a low-fat diet
	If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	**Type I Interferon (IFN) Receptor Antagonist**
Drugs	Saphnelo (anifrolumab-fnia)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Severe active central nervous system lupus • Active lupus nephritis
Required Medical Information	See "Other Criteria"
Age Restrictions	≥ 18 years
Prescriber Restrictions	Prescriber must be a rheumatologist or in consultation with a rheumatologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.

Other Criteria
 	
Date: 10/2025
	<u>Initial Authorization:</u>
	• Diagnosis of active moderate to severe systemic lupus erythematosus (SLE)
	• Member has tried all of the following (or there is a medical reason they cannot use these therapies) before Saphnelo:
	  o Hydroxychloroquine + Glucocorticoids
	  o One other immunosuppressant (i.e., methotrexate, azathioprine, calcineurin inhibitors, or mycophenolate)
	  o Benlysta (belimumab), if member has autoantibody-positive SLE
	• Prescriber attests member will not be using Saphnelo concurrently with Benlysta
	• Medication is prescribed at an FDA approved dose
	
	<u>Re-Authorization:</u>
	• Documentation or provider attestation of positive clinical response (i.e., reduction in signs and symptoms of SLE, fewer flares, reduced oral corticosteroid use, etc.)
	• Prescriber attests member will not be using Saphnelo concurrently with Benlysta
	• Medication is prescribed at an FDA approved dose
	
	If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	Tzield (teplizumab-mzwv)
Drugs	Tzield (teplizumab-mzwv)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Type 2 diabetes (T2D)
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	If all the criteria are met, the initial request will be approved for a **one-time treatment.**

Other Criteria
 	
Review/Revision Date: 2/2025
	<u>Initial Authorization:</u>
	• Medication is prescribed at an FDA approved dose
	• Diagnosis of stage 2 type 1 diabetes (T1D) confirmed by presence of at least two of the following autoantibodies:
	  o Glutamic acid decarboxylase 65 (GAD) autoantibody
	  o Insulin autoantibody (IAA)
	  o Insulinoma-associated antigen 2 autoantibody (IA-2A)
	  o Zinc transporter 8 autoantibody (ZnT8A)
	  o Islet cell autoantibody (ICA)
	• Abnormal glucose on an oral glucose-tolerance test (or alternative glycemic test if an oral glucose-tolerance test is not available)
	
	If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	**Urea Cycle Disorder Agents**
Drugs	<u>Preferred (PA required)</u> sodium phenylbutyrate (Buphenyl) <u>Non-Preferred (PA required)</u> Pheburane (sodium phenylbutyrate) Olpruva (sodium phenylbutyrate) Ravicti (glycerol phenylbutyrate)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Ravicti: N-Acetylglutamate Synthetase (NAGS) deficiency is not a covered diagnosis
Required Medical Information	See "Other Criteria"
Age Restrictions	Per FDA approved prescribing information
Prescriber Restrictions	Prescriber must be (or have prescribed in consultation with) a metabolic disease specialist or healthcare provider experienced in the treatment of urea cycle disorders.
Coverage Duration	If all of the criteria are met, the initial request will be approved for 3 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	**<u>Initial Authorization (for all agents):</u>** • Medication is prescribed at an FDA approved dose. • Documentation of member's current weight or body surface area (depending on agent and patient in question). • Diagnosis of a urea cycle disorder confirmed by genetic testing or enzyme analysis. • Provider attests patient's condition is unable to be managed solely with dietary protein restriction and/or amino acid supplementation. • Provider attests the requested medication will be used in conjunction with ongoing dietary protein restriction and amino acid supplementation (if appropriate). • Patient has not received a liver transplant. **Additionally for Pheburane:** • Trial and failure of a preferred urea cycle disorder agent, or a medical reason why this would be inappropriate must be provided. **Additionally for Olpruva:** • Trial and failure of a preferred urea cycle disorder agent, or a medical reason why this would be inappropriate must be provided.

Review Date: 7/2025	• Trial and failure of Pheburane is required before Olpruva will be considered, or a medical reason why this would be inappropriate must be provided. Requests for Olpruva due only to convenience of packaging will not be considered. **Additionally for Ravicti:** • Trial and failure of a preferred urea cycle disorder agent. • Trial and failure of Pheburane or Olpruva is required before Ravicti will be considered, or a medical reason why this would be inappropriate must be provided. Reasons of taste/palatability will not be considered as a medical reason for waiving trial of Pheburane or Olpruva **<u>Re-Authorization:</u>** • Documentation or provider attestation of positive clinical response (i.e. stabilization of patient's plasma ammonia levels). • Medication is prescribed at an FDA approved dose. **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Veopoz**
Drugs	Veopoz (pozelimab-bbfg)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Patients with unresolved Neisseria meningitidis infection • Concurrent use of another complement inhibitor (i.e. Soliris)
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a physician with experience in managing complement related disorders (i.e., gastroenterologist, immunologist, cardiologist, etc.)
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 10/2025	**Initial Authorization:** • Medication is prescribed at an FDA approved dose • Diagnosis of CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease • Documentation of hypoalbuminemia (serum albumin <3.5 g/dL) • Documentation of patient weight **Re-Authorization:** • Documentation or provider attestation of positive clinical response (i.e. symptom improvement, normalization of labs such as serum albumin (3.5-5.5 g/dL) and IgG concentrations, reduced hospitalizations and severe adverse events, increased quality of life, etc.) • Documentation of patient weight • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Verquvo**
Drugs	Verquvo (vericiguat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Pregnancy
Required Medical Information	See "Other Criteria"
Age Restrictions	Patient must be 18 years or older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist
Coverage Duration	If all of the conditions are met, the request will be approved for 12 month duration.
Other Criteria Revision/Review Date 7/2025	1. Medication is prescribed at an FDA approved dose 2. The medication is being used for the treatment of symptomatic chronic heart failure with reduced ejection fraction (less than 45%) 3. Documentation that the patient has had a previous hospitalization for heart failure or has required outpatient IV diuretics 4. Member is currently being prescribed the following treatment regimens, or documentation has been provided that the member is not able to tolerate or has a contraindication to any of these agents: a. Angiotensin-converting enzyme (ACE) inhibitor OR angiotensin receptor blocker (ARB) OR angiotensin receptor/neprilysin inhibitor b. Mineralocorticoid receptor antagonist (e.g. spironolactone) c. Evidence based beta-blocker (i.e., bisoprolol, carvedilol, metoprolol succinate) d. Farxiga or Jardiance 5. Patient is not concomitantly using a phosphodiesterase-5 (PDE-5) enzyme inhibitor (e.g. sildenafil) 6. Negative pregnancy test (for females of reproductive age; as indicated) within 30 days of request 7. Prescriber attests to discussing with females of reproductive potential the need to use effective forms of contraception during treatment and for one month after stopping treatment **Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors**
Drugs	Austedo/Austedo XR (deutetrabenazine) Ingrezza (valbenazine) tetrabenazine (Xenazine) Any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Concurrent use of monoamine oxidase inhibitors (MAOIs)
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by, or in consultation with, a neurologist or psychiatrist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	**Initial Authorization:** • Dose is within FDA-approved limits • Prescriber attests patient will not be receiving treatment with any other VMAT2 inhibitor **For approval for use in Tardive Dyskinesia (TD):** • Member must have clinical diagnosis of tardive dyskinesia that has persisted for the last 90 days, with documented baseline evaluation (e.g., Abnormal Involuntary Movement Scale (AIMS), the Tardive Dyskinesia Rating Scale (TDRS), etc.) • For members on antipsychotics, the antipsychotic dose(s) must have been stable for a continuous 90 day period at some point prior to the request • Prescriber has attempted at least ONE of the following strategies to manage the patient's condition, or has provided a clinical reason why NONE of the following are possible: o Reducing the dose of the drug responsible for causing dyskinesia o Discontinuing the drug responsible for causing dyskinesia o For members on first generation antipsychotics, switching to a second generation antipsychotic o Trial of benzodiazepines • For VMAT2 inhibitors other than tetrabenazine, member has a documented medical reason (e.g., treatment failure, intolerance,

Revision/Review Date: 10/2025	hypersensitivity, contraindication) for not using tetrabenazine AND o For Austedo requests: ▪ Prescriber attests patient has no signs of hepatic impairment ▪ For patients at risk for QT prolongation, prescriber attests a baseline ECG has been obtained o For Ingrezza requests: ▪ Must be dosed at one capsule per day **For approval for use in chorea associated with Huntington's Disease (HD):** • Patient must have diagnosis of moderate to severe Huntington's with chorea, with documented baseline Total Maximal Chorea (TMC) score provided • For VMAT2 inhibitors other than tetrabenazine, member has a documented medical reason (e.g., treatment failure, intolerance, hypersensitivity, contraindication) for not using tetrabenazine AND o For Austedo requests: ▪ Prescriber attests patient has no signs of hepatic impairment ▪ For patients at risk for QT prolongation, prescriber attests a baseline ECG has been obtained o For Ingrezza requests: ▪ Must be dosed at one capsule per day **<u>Re-Authorization:</u>** • Documentation or provider attestation of positive clinical response (e.g., improvement from baseline in average scores on the previously submitted symptom rating scale, decrease in symptoms, etc.) • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Vijoice**
Drugs	Vijoice (alpelisib)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	≥ 2 years
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, dermatologist, vascular surgeon, hematologist/oncologist, or other specialist in the treatment of PIK3CA-Related Overgrowth Spectrum (PROS)
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 7/2025	**Initial Authorization:** • Diagnosis of PROS • Documented evidence of a mutation in the PIK3CA gene • Patient has at least one target lesion identified on imaging • Prescriber attests the patient's condition is severe or life-threatening and necessitates systemic treatment • Medication is prescribed at an FDA approved dose **Re-Authorization:** • Documentation of a positive clinical response defined as the patient achieving ALL of the following: o At least a 20% reduction in the sum of measurable target lesion volume (1 to 3 lesions, via central review of imaging scans) o None of the individual target lesions have ≥ 20% increase from baseline o Absence of progression of non-target lesions o Absence of any new lesions • Prescriber attests the patient does not have any serious adverse events or unacceptable toxicity • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Vimizim (elosulfase alfa)**
Drugs	Vimizim (elosulfase alfa)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	Patient must be 5 years of age or older.
Prescriber Restrictions	Prescriber is, or is collaborating with another provider who is, a specialist in the treatment of Morquio A syndrome or other lysosomal storage disorders.
Coverage Duration	6 months
Other Criteria	**Initial Authorization (new to therapy):** • Patient has confirmed diagnosis of mucopolysaccharidosis IVA (MPS IVA, or Morquio A syndrome) via one of the following: o Genetic testing o Analysis of N-Acetylgalactosamine 6-sulfatase (GALNS) activity in leukocytes or fibroblasts • Documentation of patient weight Patient must have completed a 6-minute walk test for baseline evaluation (must submit results with request) and be able to walk a minimum of 30 meters at baseline. **Re-Authorization:** • Patient shows signs of improvement from baseline in a 6-minute walk test (must submit results with request) Re-authorization for members new to the plan previously treated with Vimizim: • Patient has confirmed genetic diagnosis of mucopolysaccharidosis IVA (MPS IVA, or Morquio A syndrome) via one of the following: o Genetic testing o Analysis of N-Acetylgalactosamine 6-sulfatase (GALNS) activity in leukocytes or fibroblasts • Documentation of patient weight Patient must have completed a 6-minute walk test for baseline evaluation, and patient shows signs of improvement from baseline in a recent 6-minute walk test (must submit both results with request). • If a baseline 6-minute walk test was not completed prior to initiation of Vimizim therapy, then:

Revision/Review Date 7/2025	o A current test must be completed and patient must be able to walk a minimum of 30 meters (must submit results with request). o Continued authorizations for Vimizim for patients without a completed baseline 6-minute walk test evaluation prior to initiation of therapy must continue to be able to walk a minimum of 30 meters in subsequent evaluations. o If patient is established on Vimizim therapy prior to enrollment on the plan, but is not able to walk a minimum of 30 meters, then medical justification is required as to how the patient continues to receive benefit from Vimizim therapy. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Voquezna**
Drugs	Voquezna (vonoprazan), Voquezna Dual Pack (vonoprazan; amoxicillin), Voquezna Triple Pack (vonoprazan; amoxicillin; clarithromycin)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Per package insert
Prescriber Restrictions	Prescribed by, or in consultation with, a gastroenterologist, infectious disease specialist, or other specialist with expertise in the treatment of erosive esophagitis or H. pylori infection
Coverage Duration	If the criteria are met, the request will be approved for up to the following: Healing of erosive esophagitis: Voquezna 20 mg once daily for up to 8 weeks Maintenance of healed erosive esophagitis: Voquezna 10 mg once daily for up to 6 months Treatment of H. pylori infection: 14 days For heartburn associated with non-erosive gastroesophageal reflux disease: Voquezna 10 mg once daily for 4 weeks
Other Criteria	**Initiation of Therapy:** <u>For erosive esophagitis (healing or maintenance of healed erosive esophagitis):</u> • Patient has a diagnosis of endoscopy-confirmed erosive esophagitis (all grades) • Patient is H. pylori negative • Patient has a trial and failure of treatment with ≥ 8 weeks with two different formulary proton pump inhibitors at optimized dosing (double-dose or twice daily dosing), or a medical reason is provided why this is inappropriate. <u>For the treatment of Helicobacter pylori (H. pylori) infection:</u> • Patient has a confirmed H. pylori positive infection, plus one of the following clinical conditions: o dyspepsia lasting at least 2 weeks, functional dyspepsia, recent/new diagnosis of peptic ulcer, or a stable dose of long-term NSAID treatment

Revision/Review Date: 7/2025	• Patient has a trial and failure of a generic, guideline recommended, first-line regimen for H. pylori infection such as bismuth quadruple therapy (PPI + bismuth subcitrate or subsalicylate + tetracycline + metronidazole), or a medical reason is provided why this would be inappropriate. <u>For the relief of heartburn associated with non-erosive gastroesophageal reflux disease:</u> • Patient has a diagnosis of symptomatic gastroesophageal reflux disease (GERD) with heartburn as the predominant symptom • Patient has a history of heartburn lasting at least 6 months, with symptoms on at least four days per week • Patient is H. pylori negative, and endoscopy has confirmed patient has no esophageal erosions • Prescriber attests patient has been educated about lifestyle modifications related to GERD management (i.e. avoidance of trigger foods, weight loss in overweight and obese patients, avoiding meals within 2-3 hours of bedtime, tobacco cessation, etc.) • Patient has a trial and failure of treatment with ≥ 8 weeks with two different formulary proton pump inhibitors at optimized dosing (double-dose or twice daily dosing), or a medical reason is provided why this is inappropriate. **Renewal Requests:** Use of Voquezna for longer than 8 weeks for healing of erosive esophagitis, longer than 6 months for maintenance of healing in erosive esophagitis, or longer than 4 weeks for heartburn associated with non-erosive gastroesophageal reflux disease will not be approved. Renewal requests for Voquezna for treatment of H. pylori infection will not be approved. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Voriconazole (Vfend)**
Drugs	Voriconazole (Vfend) tablets, oral suspension
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	2 years of age and older.
Prescriber Restrictions	N/A
Coverage Duration	If the above conditions are met, the request will be approved with up to a 3 month duration depending upon the severity of the infection.
Other Criteria	**<u>Initial Authorization</u>**: 1. Voriconazole is being used to treat invasive aspergillosis or a serious fungal infection caused by Scedosporium apiospermum and Fusarium species **OR** 2. Voriconazole is being used to treat esophageal candidiasis, candidemia (nonneutropenics), or disseminated candidiasis of the skin, abdomen, kidney, bladder wall or wounds; **AND** o Documented trial and failure with a formulary treatment option (i.e. fluconazole or nystatin) or documented medical reason (e.g., recent discharge from hospital on oral voriconazole, intolerance, hypersensitivity, contraindication) for not using a formulary treatment option for relevant indications
Revision/Review Date 7/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	Vykat XR (diazoxide choline)
Drugs	Vykat XR (diazoxide choline)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist, psychiatrist, or other physician with expertise in the treatment of Prader-Willi syndrome (PWS)
Coverage Duration	If all the criteria are met, the initial and reauthorization requests will be approved for 6 months.
Other Criteria Revision/Review Date: 7/2025	**Initial Authorization:** • Medication is prescribed at an FDA approved dose • Documentation of patient's body weight • Diagnosis of PWS confirmed by genetic testing (copies of test must be submitted with request) • Documentation patient experiences symptoms of hyperphagia related to PWS (e.g. food-seeking behaviors, food aggression, etc.) **Re-Authorization:** • Documentation of positive clinical response in hyperphagic symptoms (i.e. decrease in food-related aggression or food-seeking behavior, etc.) • Medication is prescribed at an FDA approved dose • Documentation of patient's body weight **If all the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**White Blood Cell Stimulators**
Drugs	**FORMULARY STATUS** **Short-Acting G-CSFs:** **Zarxio** (filgrastim-sndz) – PREFERRED AGENT **Releuko** (filgrastim-ayow)– PREFERRED AGENT **Nivestym** (filgrastim-aafi) **Granix** (TBO-filgrastim) **Neupogen** (filgrastim) **Nypozi** (filgrastim-txid) Or any newly market agent **Long-Acting G-CSFs:** **Ziextenzo** (pegfilgrastim-bmez) – PREFERRED AGENT **Fulphila** (pegfilgrastim-jmdb)– PREFERRED AGENT **Fylnetra** (pegfilgrastim-pbbk) **Nyvepria** (pegfilgrastim-apgf) **Neulasta** (pegfilgrastim) **Neulasta Onpro** (pegfilgrastim) **Rolvedon** (eflapegrastim-xnst) **Stimufend** (pegfilgrastim-fpgk) **Udenyca** (pegfilgrastim-cbqv) **Udenyca Onbody** (pegfilgrastim-cbqv) Or any newly market agent **Additional Agents:** **Aphexda** (motixafortide) **Plerixafor (**Mozobil) **Leukine** (Sargramostim) Or any newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USPDI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a hematologist, an oncologist, or an infection disease specialist
Coverage Duration	Initial authorization requests for all indications will be approved for 12 weeks. Reauthorization requests for all indications, with the exception of chronic

	neutropenia, will be approved for 12 weeks. Reauthorization requests for chronic neutropenia will be approved for 24 weeks.
Other Criteria	**<u>Initial Authorization</u>:** • The drug is being used for an appropriate indication at an appropriate dose per "Covered Uses". • ***For ALL requests for treatment or prophylaxis of febrile neutropenia:*** Documentation of the patient's absolute neutrophil count (ANC) within the last 30 day has been provided. **<u>Short-Acting G-CSFs:</u>** • ***For all requests for non-preferred agents:*** The patient has a documented treatment failure {i.e. failure to reach and/or maintain target ANC, prolonged febrile neutropenia, unplanned hospitalization or infection requiring prolonged anti-infective use} with an adequate trial (including dates, doses of therapy) of both Zarxio AND Releuko or has another documented medical reason (intolerance, hypersensitivity, stem cell collection, etc.) for not using Zarxio AND Releuko to treat their medical condition. **<u>Long-Acting G-CSFs:</u>** • ***For Fylnetra, Udenyca, Undenyca Onbody, Nyvepria, Rolvedon, or Stimufend requests:*** The patient has a documented treatment failure (i.e. failure to reach and/or maintain target ANC, prolonged febrile neutropenia or infection requiring prolonged anti-infection use) with the use of Ziextenzo orFulphila, or has a documented medical reason (intolerance, hypersensitivity, stem cell collection, etc.) for not using Ziextenzo or Fulphila • ***For Neulasta or Neulasta Onpro requests:*** The patient has a documented treatment failure (i.e. failure to reach and/or maintain target ANC, prolonged febrile neutropenia or infection requiring prolonged anti-infection use) with the use of Ziextenzo AND Fulphila PLUS either Fylnetra, Udenyca, Undenyca Onbody, Stimufend, or Nyvepria or has a documented medical reason (intolerance, hypersensitivity, stem cell collection, etc.) for not using these therapies **<u>Additional Agents:</u>** • ***For Leukine requests***: Documentation is submitted of the patient's current diagnosis, current body weight, body surface area (within 30 days of the request). • ***For plerixafor & Aphexda requests:*** Documentation is submitted of the patient's current diagnosis, current body weight, and that the patient is using drug in combination with a granulocyte-colony stimulating factor (G-CSF) agent (e.g. Zarxio, Nivestym). Requests for Aphexda must also have a documented treatment failure (i.e. failure to reach and/or maintain target ANC, prolonged febrile neutropenia or infection requiring prolonged anti-infection use) with plerixafor

Revision/Review Date: 7/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary**.

Field Name	Field Description
Prior Authorization Group Description	**Xifaxan (rifaximin)**
Drugs	Xifaxan (rifaximin)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	For Travelers' Diarrhea Treatment: Patient must be 12 years of age or older For Hepatic Encephalopathy or Irritable Bowel Syndrome with diarrhea (IBS-D): Patient must be 18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Hepatic Encephalopathy: If the criteria are met, for initial authorization, the request will be approved for 6 months. For re-authorization, the request will be approved for 12 months. Travelers diarrhea: If the criteria are met, the request will be approved for a one-time, 3 day regimen Irritable Bowel Syndrome with diarrhea (IBS-D): If the criteria are met, the request will be approved for 14 days. For re-authorization, the request may be approved up to 2 more times for a 14 day duration.
Other Criteria	**Initial Authorization**: Hepatic Encephalopathy • Patient has the diagnosis of hepatic encephalopathy • Patient will be using lactulose concurrently or has a medical reason for being unable to use lactulose Traveler's Diarrhea Treatment • Patient has the diagnosis of traveler's diarrhea • Patient has tried and failed therapy with one formulary antibiotic or has a medical reason for not trying a formulary antibiotic (e.g., levofloxacin, azithromycin, sulfamethoxazole-trimethoprim) Irritable Bowel Syndrome with diarrhea (IBS-D) • Patient has the diagnosis of moderate to severe IBS-D

Revision/Review 7/2025	• Patient has tried and failed or has a contraindication or intolerance to one formulary tricyclic antidepressant **<u>Re-Authorization (Hepatic Encephalopathy and IBS-D only)</u>**: • Documentation indicating the member has clinically benefited from therapy. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Xolair for Asthma, Urticaria, and IgE-Mediated Food Allergy**
Drugs	Xolair (omalizumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	• Use of Xolair concomitantly with another pulmonary biologic (e.g. Fasenra, Nucala, Cinqair, Dupixent, Tezspire) • Use of Xolair concomitantly with Palforzia • Use of Xolair for emergency treatment of allergic reactions, including anaphylaxis
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by, or in consultation with, an allergist/immunologist, pulmonologist, or dermatologist
Coverage Duration	If all of the conditions are met, the initial and reauthorization request will be approved for up to a 6 month duration for renewal requests.
Other Criteria	****For nasal polyposis, please refer to the "Biologic Agents for Nasal Polyposis" policy**** **Initial Authorization:** Asthma: • Member has at least a 6 month history of moderate to severe asthma • The drug is being prescribed at an approved dose according to member's weight and IgE level • Member is taking maximally tolerated ICS/LABA combination in addition to a LAMA (e.g. tiotropium) for at least 3 months, or there is a documented medical reason why the member is unable to take these medications • Member's asthma is uncontrolled as defined by having one of the following: o Frequent severe exacerbations requiring two or more bursts of systemic glucocorticoids (more than three days each) in the previous year o History of serious exacerbation: at least one hospitalization, intensive care unit stay, or mechanical ventilation in the previous year o Airflow limitation defined as a forced expiratory volume in 1 second (FEV1) less than 80% of predicted o Poor symptom control including at least THREE of the following:

	▪ Asthma Control Questionnaire (ACQ) consistently > 1.5 or Asthma Control Test (ACT) < 20 ▪ Daytime asthma symptoms more than twice per week ▪ Use of an inhaled short acting B-2 agonist to relieve asthma symptoms more than twice per week (not including use prior to exercise) ▪ Limited physical activity due to asthma symptoms ▪ Nighttime awakening due to asthma symptoms • Member has a positive immediate response on RAST test and/or skin prick test to at least 1 common allergen (e.g. dermatophagoides farinae, dermatop hagoides pteronyssinus, dog, cat, or cockroach) that is an asthma trigger (copy of results required). • Pre-treatment serum IgE levels must be greater than or equal to 30 IU/mL <u>Chronic Idiopathic Urticaria:</u> • The drug is prescribed at an approved dose • Member has at least a 6 week history of urticaria • Member requires oral corticosteroids to control symptoms • The patient remains symptomatic despite a minimum two week trial (or has medical reason for not utilizing) of two preferred second generation H1 antihistamines at the maximum tolerated dose <u>IgE-Mediated Food Allergy</u>: • Diagnosis of IgE-mediated food allergy with documented allergy to one or more of the following foods: o Peanut, milk, egg, wheat, cashew, hazelnut, or walnut • Attestation Xolair will be used in conjunction with food allergen avoidance • The drug is being prescribed at an FDA approved dose according to the member's weight and IgE level **<u>Re-Authorization:</u>** • The drug is being prescribed at an approved dose • The member has experienced a clinical benefit from medication (e.g. decrease exacerbations, reduction in use of oral steroids, decrease in skin manifestations or severe itching, improvement in pulmonary function tests, etc.)

Review/Revision Date: 4/2025	**If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Xolremdi**
Drugs	Xolremdi (mavorixafor)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	12 years of age and older
Prescriber Restrictions	Prescriber must be an immunologist or a hematologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Date: 7/2025	**Initial Authorization:** • Diagnosis of WHIM (warts, hypogammaglobulinemia, infections and myelokathexis) syndrome confirmed by genotype variant of chemokine receptor 4 (CXCR4) and absolute neutrophil count (ANC) of ≤ 400 cells/μL • Documentation of baseline ANC and absolute lymphocyte count (ALC) • Documentation of member weight • Medication is prescribed at an FDA approved dose **Re-Authorization:** • Documentation or provider attestation of positive clinical response (i.e. improvement from baseline in ANC and/or ALC) • Documentation of member weight • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Yorvipath**
Drugs	Yorvipath (palopegteriparatide)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Members with acute postsurgical hypoparathyroidism (HP) or those who are at increased risk for osteosarcoma
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be 18 years of age or older
Prescriber Restrictions	Prescriber must be an endocrinologist or in consultation with an endocrinologist.
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.

Other Criteria
 	
Date: 2/2025
	Initial Authorization:
	• Confirmed diagnosis of chronic HP of postsurgical, autoimmune, genetic, or idiopathic origins, for at least 6 months
	• Provider attestation that patient is currently receiving conventional therapy, including active vitamin D (calcitriol) and elemental calcium, and that patient's disease cannot be adequately controlled on conventional therapy alone
	• Current labs (within 60 days of request) have been submitted for the following:
	  o Albumin-corrected serum calcium (must be ≥ 7.8mg/dL to start therapy)
	  o Serum vitamin D level (must be ≥ 20 ng/mL to start therapy)
	• Medication is prescribed at an FDA approved dose
	Re-Authorization:
	• Documentation of a recent albumin-corrected serum calcium in the lower-half of the normal reference range or just below the normal reference range (~8–9 mg/dL)
	• ONE of the following:
	  o Patient no longer requires active vitamin D or therapeutic doses of calcium, OR
	  o Patient has had a significant reduction in required dosages of active vitamin D or therapeutic doses of calcium and is still actively titrating doses of Yorvipath
	• Medication is prescribed at an FDA approved dose
	
	If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	**Zoryve Foam**
Drugs	Zoryve (roflumilast) topical foam
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist
Coverage Duration	If the criteria are met, the request will be approved for up to 12 months.

Other Criteria
 	
Review/Revision Date:
10/2025
	<u>Initial Authorization:</u>
	For the diagnosis of seborrheic dermatitis:
	• Diagnosis of seborrheic dermatitis
	• Documented trial and failure of or intolerance to at least two of the following therapies:
	  o Topical antifungals (i.e., ketoconazole, ciclopirox)
	  o Topical corticosteroids (i.e., betamethasone valerate, clobetasol propionate, fluocinolone)
	For the diagnosis of plaque psoriasis:
	• Diagnosis of plaque psoriasis
	• Documented trial and failure (minimum duration of 4 weeks) of or intolerance to a topical steroid (e.g. betamethasone, clobetasol, fluocinonide, desonide) AND
	• Documented trial and failure of or intolerance to the use of a topical corticosteroid in combination with one of the following topical agents:
	  o Vitamin D analogs (e.g. calcitriol, calcipotriene)
	  o Tazarotene
	  o Calcineurin inhibitors (e.g. tacrolimus, pimecrolimus)
	
	<u>Re-Authorization:</u>
	• Documented positive clinical response to treatment (i.e., improvement in symptoms)
	
	If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.