Healthy DC

Prior Authorization Criteria

Effective 4/1/2026

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 Drugs (no PA required):
	• 5-HT3 RA:
	  o Granisetron tablet
	  o Ondansetron oral tablet, orally disintegrating tablet, oral solution
	• NK1 RA
	  o Aprepitant oral capsule
	
	Non-Preferred Drugs (PA Required):
	• Akynzeo (palonosetron/netupitant) oral capsule
	• Emend oral suspension
	• Varubi (rolapitant) oral capsule
	
	Medical Benefit Drugs:
	• Preferred (1st Line):
	  o Fosaprepitant (Emend) IV emulsion
	  o Granisetron IV solution
	  o Ondansetron IV solution, injection (IV/SQ) solution
	• Non-Preferred:
	  o Akynzeo (palonsetron/netupitant) IV solution
	  o Cinvanti (aprepitant) IV emulsion
	  o Focinvez (fosaprepitant) IV solution
	  o Palonosetron (Aloxi) 0.25 mg/2mL IV solution
	  o palonosetron (Aloxi) 0.25 mg/5 mL IV solution
	  o Sustol (granisetron ER) SQ injection
	  o Posfrea (palonosetron) IV solution
	
	Non-Formulary:
	Sancuso (granisetron) patch
	Any other marketed agent within 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, the National Comprehensive Cancer Network (NCCN), and/or American Society of Clinical Oncology (ASCO) standard of care guidelines for antiemetic therapy.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by a specialist in the field to treat the member’s respective medical condition
Coverage Duration	If all of the criteria are met, the request will be approved for up to 12 months.
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.

Revision/Review Date 08/2025	• 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
	• If the medication request is for a non-preferred agent:
	  o The member has a documented treatment failure of 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
	  o Members meeting one of the following criteria may receive palonosetron hydrochloride IV solution without prior trial and failure of preferred options:
	  ▪ Adults receiving an antineoplastic agent with HIGH or MODERATE emetic risk per the NCCN Practice guidelines
	  ▪ Pediatric members receiving an antineoplastic with high-emetic-risk per the NCCN Practice guidelines who are unable to receive dexamethasone
	  o If the request is for Emend oral suspension, trial and failure of a preferred agent if the member meets one of the following:
	  ▪ Age 6 months to 12 years old
	  ▪ Documentation of inability to swallow capsules
	  o If the request is for Posfrea, the member has documented treatment failure of palonosetron IV solution
	• If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated.
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Prior Authorization Group Description	**Acitretin**
Drugs	Acitretin
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	must be 18 years age or older
Prescriber Restrictions	Prescribed by, or in consultation with, a dermatologist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.

Other Criteria
 	
Revision/Review Date 02/2026
	<u>Initial Authorization</u>
	• Diagnosis of plaque psoriasis
	• Documented trial and failure to at least TWO of the following:
	  o Topical corticosteroids (i.e., betamethasone, triamcinolone, etc.)
	  o Topical vitamin D analogs (i.e., calcipotriene, calcitrol)
	  o Topical tacrolimus or pimecrolimus
	  o Tazarotene
	  o Methotrexate
	  o Cyclosporine
	• Requested dose is within FDA approved dosing guidelines
	
	<u>Reauthorization</u>
	• Requested dose is within FDA approved dosing guidelines
	• Member has been receiving the medication and documentation was provided that the prescriber has evaluated the member and recommends continuation of therapy (clinical benefit)
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Prior Authorization Group Description	**Adenosine Triphosphate-Citrate Lyase (ACL) inhibitors**
Drugs	Formulary: Nexletol (bempedoic acid) Nexlizet (bempedoic acid/ezetimibe) Non-Formulary: Any other marketed agent within 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), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by a cardiologist or specialist in the treatment of lipid disorders
Coverage Duration	If all of the criteria are met, the request 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". • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. For Hyperlipidemia: • Member meets 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 and LDL-C is not at goal, or documentation has been provided that the patient is not able to tolerate ezetimibe. 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. **Reauthorization:** • 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.**
Revision/Review Date: 05/2025	

Prior Authorization Group Description	**Acute Migraine Treatments**
Drugs	<u>Formulary:</u> Nurtec ODT (rimegepant) – if the request is for preventative treatment of migraine, please refer to the Calcitonin Gene-Related Peptide (CGRP) Antagonists for Headache Prevention criteria Ubrelvy (ubrogepant) <u>Non-Formulary:</u> Zavzpret (zavegepant) Any other marketed agent within 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	N/A
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 all of the criteria are met, the request will be approved for 12 months.
Other Criteria	**<u>Initial Authorization:</u>** For Ubrelvy: • Diagnosis of migraine • Requested dose is within FDA approved dosing guidelines • Trial and failure of two formulary triptan products • Medication will not be used in combination with another CGRP inhibitor for either acute or preventative treatment of migraine For Nurtec ODT: • 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 • Documented trial and failure or (or medical justification for not using) Ubrelvy • Medication will not be used in combination with another CGRP inhibitor for either acute or preventative treatment of migraine If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated.

Revision/Review Date: 08/2025	**<u>Reauthorization:</u>** • Documentation of improvement in pain and symptom (s) (e.g., photophobia, nausea, phonophobia) • Medication will not be used in combination with another CGRP inhibitor for either acute or preventative treatment of migraine **<u>Criteria for exceeding the quantity limit</u> (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	16 years of age or older
Prescriber Restrictions	Prescribed by a hematologist or provider with expertise in the treatment of sickle cell disease
Coverage Duration	If all of the criteria are met, the initial request may be approved for up to a 6-month duration. Reauthorization requests may be approved for 12 months.
Other Criteria Revision/Review Date: 02/2026	**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 member 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.**

Prior Authorization Group Description	**Adrenal Enzyme Inhibitors for Cushing's Syndrome**
Drugs	Recorlev (levoketoconazole) Isturisa (osilodrostat)
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	Prescribed by 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 reauthorization, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 02/2026	**<u>Initial Authorization:</u>** • Member has a diagnosis of endogenous Cushing's syndrome. • Member 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 ≥ 1.3 times ULN (within the past 30 days). • Medication is prescribed at an FDA approved dose. • For Isturisa, provider must also attest that baseline electrocardiogram (ECG) has been obtained and hypokalemia and/or hypomagnesemia has been corrected prior to initiating therapy if present • 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 **<u>Re-Authorization:</u>** • Documentation or provider attestation of positive clinical response (i.e. decrease in urinary free cortisol from baseline.) • 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.**

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	Prescribed by a hematologist, oncologist, intensive care specialist, or specialist in the treatment of rare genetic hematologic diseases
Coverage Duration	On-demand therapy: If all of the criteria are met, the request will be approved for 1 month. Prophylactic therapy: If all of the criteria are met, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 02/2026	**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 **Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Agents for Atopic Dermatitis**
Drugs	**Formulary Products with ST:** tacrolimus (Protopic) pimecrolimus (Elidel) **Formulary Products with PA:** Cibinqo (abrocitinib) Dupixent (dupilumab) Eucrisa (crisaborole) Opzelura (ruxolitinib) Rinvoq (upadicitinib) **Non-Formulary:** Adbry (tralokinumab) Ebglyss (lebrikizumab-lbkz) Nemluvio (nemolizumab-ilto) Vtama (tapinarof) Zoryve 0.15% cream Any other marketed agent within 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	Tacrolimus (Protopic), pimecrolimus (Elidel), and Opzelura (ruxolitinib): Immunocompromised members
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by a pediatrician, dermatologist, immunologist, or allergist
Coverage Duration	For Opzelura, Zoryve, and Vtama: If all the criteria are met, the request will be approved with up to an 8 week duration, and reauthorization requests will be approved for up to a 6 month duration. For all other products: If all the criteria are met, the request will be approved for up to a 6 month duration.

Other Criteria	**<u>Initial Authorization</u>**
	
	For pimecrolimus and tacrolimus:
	• Trial and failure of one formulary medium to high potency topical corticosteroid
	
	For Eucrisa, Opzelura, Vtama, and Zoryve 0.15% cream:
	• Diagnosis of atopic dermatitis
	• Trial and failure of, or contraindication to, ALL of the following:
	  o One formulary medium to high potency topical corticosteroid
	  o One formulary topical calcineurin inhibitor
	
	<u>A MAXIMUM of ONE 60 g TUBE of OPZELURA MAY BE APPROVED PER WEEK**</u>**

	For Adbry or Nemluvio: • Diagnosis of moderate to severe AD • Trial and failure, or contraindication to, ONE of the following: o Eucrisa o Opzelura o Vtama o Zoryve **For Dupixent and Rinvoq for atopic dermatitis:** • Trial and failure, or contraindication/intolerance to ONE of the following: o One formulary topical medium to high potency topical corticosteroid o Topical tacrolimus or pimecrolimus (for members less than 2 years of age requesting Dupixent, trial of topical tacrolimus or pimecrolimus is not required) o Eucrisa (crisaborole) or Zoryve (roflumilast) 0.15% cream **For Cibinqo:** • Diagnosis of refractory, moderate to severe, AD • Trial and failure of, intolerance to, or contraindication to another systemic drug product **For Ebglyss:** o Diagnosis of moderate to severe AD o Trial and failure of, or contraindication to, ONE of the following: o Adbry o Dupixent o Nemluvio If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **Reauthorization:** o Prescriber attests that the member has experienced improvement (e.g., significant clearing of the skin, reduction in itching)
Revision/Review Date 11/2025	**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 Graft versus Host Disease**
Drugs	Formulary: Imbruvica (ibrutinib) Jakafi (ruxolitinib) Rezurock (belumosudil) Orencia (abatacept) Non-Formulary: Ryoncil (remestemcel-L-rknd) Niktimvo (axatilimab-csfr) Any other marketed agent within the class
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	Prescribed by a hematologist, oncologist, or other specialist in the treatment of hematopoietic cell transplants
Coverage Duration	Jakafi, Niktimvo, Rezurock, and Imbruvica: If all of the criteria are met, the request will be approved for up to a 12 month duration. Orencia: If all the criteria are met, the request will be approved for a 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 Drugs/Therapies" 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

Revision/Review:
Date: 05/2025
	• Rezurock or Niktimvo
	  ○ Member has a diagnosis of chronic graft versus host disease
	  ○ 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
	  ○ For Niktimvo requests, member's weight
	
	• Orencia
	  ○ Orencia is being requested for prophylaxis against acute graft versus host disease
	  ○ Member will be underdoing 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
	
	• If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated.
	
	<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 **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 Homozygous Familial Hypercholesterolemia (HoFH)**
Drugs	Formulary**:** Juxtapid (lomitapide) Medical Benefit: Evkeeza (evinacumab-dgnb) Non-Formulary: Any other marketed agent within the class ****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 criteria are met, the requests will be approved for up to 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.
	• Member has tried and failed atorvastatin 40mg-80mg or rosuvastatin 20-40mg (consistently for 3 months via claim history or chart notes). If member is not able to tolerate atorvastatin or rosuvastatin, documentation was provided that member 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 effects, duration of therapy, "wash out," re-trial, and then change of agents.
	• Member 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 the 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."

Revision/Review Date: 02/2026	• 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 months or a medical reason has been provided why the member is unable to use Evkeeza • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **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 an LDL reduction from the levels immediately prior to initiation of treatment with Juxtapid or Evkeeza. • The member'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.**

Prior Authorization Group Description	**Agents for Primary Biliary Cholangitis**
Drugs	Formulary: Livdelzi (seladelpar) Non-Formulary: Iqirvo (elafibranor) Any other marketed agent within 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	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 all of 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) with confirmation of diagnosis by the following tests: a) Positive antimitochondrial antibody (AMA) test, or presence of other PBC-specific autoantibodies, including sp100 or gp210, if AMA test is negative b) Elevated serum alkaline phosphatase (ALP) level c) Histologic evidence of PBC from a liver biopsy • Drug is being requested in addition to ursodeoxycholic acid (UDCA) due to member 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 member does not have complete biliary obstruction or 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 If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **Reauthorization:** • Provider attests that the member has not developed complete biliary obstruction or decompensated cirrhosis (e.g., Child-Pugh Class B or C) • Submission of lab tests confirming each of the following: o A decrease in ALP of ≥ 15% from baseline o ALP is less than 1.67 times the upper limit normal (ULN);
Revision/Review Date 11/2025	

	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.**

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 the criteria are met, the initial request will be approved for a one 14-day course of Zurzuvae per postpartum period. Reauthorization will not be permitted.
Other Criteria Revision/Review Date 02/2026	• Physician attestation of moderate to severe postpartum depression (PPD) diagnosis and submission of validated screening tool result(s) (e.g., Edinburgh Postnatal Depression Scale, Hamilton Rating Scale for Depression (HAM-D)) that requires quick onset where the member cannot wait 4-6 weeks for the standard of care antidepressants to take effect • Member 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 member not to drive for at least 12 hours after each dose . • 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.**

Prior Authorization Group Description	**Agents for Thrombocytopenia**
Drugs	Formulary: eltrombopag (Promacta) Doptelet (avatrombopag) Non-Formulary: Alvaiz (eltrombopag) Mulpleta (lusutrombopag) Nplate (romiplostim) Tavalisse (fostamatinib) Wayrilz (rilzabrutinib) Any other marketed agent within 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	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by a hematologist
Coverage Duration	• If all of the criteria are met, the request for eltrombopag, Alvaiz, Nplate, Tavlisse, and Wayrilz will be approved for 12 months. • 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. • Mulpleta will be approved for a maximum of 7 days.
Other Criteria	**Chronic immune (idiopathic) thrombocytopenia (ITP):** • Platelet count < 30,000 cells/ microL within the past 6 months • Documentation of trial and failure, or intolerance or contraindication, to glucocorticoids AND one of the following: intravenous immune globulin (IVIG), Rituxan, or splenectomy • For Doptelet, Nplate, Alvaiz, Tavalisse, or Wayrilz, member must also have a documented trial and failure, intolerance, or contraindication to eltrombopag **Severe aplastic anemia** (eltrombopag and Alvaiz only): • 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; **AND** • Platelet count < 20,000 cells/microL OR platelet count < 30,000 cells/microL with bleeding OR reticulocyte count < 20,000 cells/microL OR absolute neutrophil count < 500 cells/microL within the past 6 months

Revision/Review Date 11/2025	• For Alvaiz, member must also have a documented trial and failure, intolerance, or contraindication to eltrombopag **Thrombocytopenia in members with Hepatitis C infection** (eltrombopag and Alvaiz only): • Diagnosis of chronic hepatitis C • Platelet count < 50,000 cells/microL within the past 6 months • Documented treatment with interferon-based therapy AND member's degree of thrombocytopenia prevents the initiation or limits the ability to maintain interferon-based therapy • For Alvaiz, member must also have a documented trial and failure, intolerance, or contraindication to eltrombopag **Thrombocytopenia associated with chronic liver disease in ***adult*** members requiring elective surgery** (Doptelet and Mulpletaonly): • Member has a diagnosis of chronic liver disease and is scheduled to undergo a procedure • Platelet count < 50,000 cells/microL within the past 6 months • For Mulpleta: documentation of trial and failure, intolerance, or contraindication to use Doptelet If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Agents to Treat Constipation**
Drug(s)	<u>Formulary, Step Therapy Required:</u> Movantik (naloxegol) Linzess (linaclotide) Trulance (plecanatide) <u>Formulary, PA Required:</u> Relistor (methylnaltrexone) Non-Formulary: prucalopride (Motegrity) Ibsrela (tenapanor) Symproic (naldemedine) Any other marketed agent within 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	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	**<u>Initial Authorization</u>**: Requests for Linzess, Movantik, or Trulance: • The member has tried and failed ONE of the following or has a medical reason (contraindication, intolerance, etc.) as to why member is unable to use: polyethylene glycol or lactulose Requests for Relistor: • The member has a diagnosis of OIC with chronic, non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent opioid dosage escalation OR the member has a diagnosis of OIC with advanced illness • The member has tried and failed 2 different laxatives from 2 different classes (bulk-forming, osmotic, stimulant) • The member has tried and failed or has a medical reason (contraindication, intolerance, etc.) as to why member is unable to use both of the following: lubiprostone and Movantik If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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

Review/Revision Date: 11/2025	medications where there is only one formulary agent, only that agent must have been ineffective or not tolerated. **<u>Reauthorization</u>**: • 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.**

Prior Authorization Group Description	**Agents to Treat Gaucher's Disease**
Drugs	Formulary: Cerdelga (eliglustat) Cerezyme (imiglucerase) Elelyso (taliglucerase alfa) Miglustat (Zavesca) Vpriv (velaglucerase alfa) Non-Formulary: Any other marketed agent within 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), and the Drug Package Insert (PPI).
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 treatment of Gaucher's Disease (e.g., endocrinologist, hematologist or geneticist)
Coverage Duration	If all of the criteria are met, the request will be approved with a 12-month duration.
Other Criteria	**Initial Authorization:** Cerezyme, Vpriv, Elelyso, or miglustat: • Member has a confirmed diagnosis of Gaucher's disease, type 1 (GD1) • Request is for an FDA approved dose Cerdelga: • Member 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. • Member is not concomitantly taking Class IA (e.g., quinidine, procainamide) or Class III antiarrhythmic (e.g., amiodarone, sotalol). • For EMs or IMs, member 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, member is not concomitantly taking a strong CYP3A inhibitor. • Member has no pre-existing cardiac disease or long QT syndrome. • For EMs, member does not have moderate or severe hepatic impairment • For IMs or PMs, member does not have any degree of hepatic impairment. • Request is for an FDA approved dose If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary medications appropriate for the requested use (per the references outlined in "Covered Uses" or has a

Revision/Review Date: 05/2025	medical reason why these drug(s) cannot be used (e.g., intolerance, contraindication). For medications where there is only one formulary agent, only that agent must have been ineffective or not tolerated. **<u>Re-Authorization criteria for all agents:</u>** • Documentation has been provided that member 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.**

Prior Authorization Group Description	**Alpha-1 Proteinase Inhibitors (Human)**
Drugs	**Non-Formulary:** Prolastin-C – 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	Members who have undergone liver transplantation
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	If all of the criteria are met, 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 and 80 mg/dL by radial immunodiffusion)] • Documentation was submitted indicating the member has undergone genetic testing for AAT deficiency and is classified as phenotype PiZZ, PiZ(null) or Pi(null)(null) [NOTE: phenotypes PiSZ, 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 [FE_{V1}] < 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 (e.g., 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 member has a 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 the member has clinically benefited from therapy (i.e., stable lung function, improved PFTs, alpha-1 antitrypsin serum level maintained above 11 micromol/L, improved quality of life)

Revision/Review Date 11/2025	• Documentation was submitted indicating member is a non-smoker or an ex-smoker (e.g., smoking cessation treatment) • The Alpha-1 Proteinase Inhibitor (human) is being prescribed at an FDA approved dosage **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Prior Authorization Group Description	**Amantadine**
Drugs	Formulary: Gocovri (amantadine) oral capsule Non-Formulary: Any other marketed agent within 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	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	If all of the criteria are met, the request will be approved for a 12-month duration.

Other Criteria
 	
Revision/Review Date 05/2025
	<u>Initial Authorization</u>
	• Medication requested is for an FDA approved dose
	• For Gocovri requests, member is receiving concomitant levodopa-based therapy
	• For requests for treatment of Parkinson's disease:
	  o Member has trial and failure or intolerance/contraindication to two (2) alternative formulary dopamine agonists (e.g., pramipexole, ropinirole, etc.)
	  o Member has trial and failure of or intolerance/contraindication to an immediate-release amantadine product
	• For requests for drug-induced extrapyramidal symptoms:
	  o Member has trial and failure of or intolerance/contraindication to an immediate-release amantadine product
	• If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated.
	
	<u>Reauthorization</u>
	• The medication is prescribed at an FDA-approved dosage.
	• The member has been receiving the medication and documentation was provided that the prescriber has evaluated the member and recommends continuation of therapy (clinical benefit).
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

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	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a neuromuscular specialist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 02/2026	**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 a dose that is FDA-approved or is supported by compendia or standard of care guidelines **Re-authorization:** • Medication is being prescribed at a dose that is FDA-approved or is supported by compendia or standard of care guidelines • Documentation 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.**

Prior Authorization Group Description	**Amlodipine-Atorvastatin Combination Step Therapy**
Drugs	Amlodipine-atorvastatin oral 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 all of the criteria are met, the request will be approved for up to a 12 month duration
Other Criteria Revision/Review Date 2/2026	• Prior use of both amlodipine AND atorvastatin single-ingredient products required. **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents.

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	Prescribed by an oncologist
Coverage Duration	If all of the criteria are met, the request will be approved for a one-time treatment.
Other Criteria Review/Revision Date: 05/2025	• 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.**

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*** **Formulary:** Methyltestosterone oral capsule Testosterone (Axiron) 30 mg/actuation transdermal solution in metered pump Testosterone (Androgel 1%) transdermal gel packet Testosterone (Vogelxo, Testim) 1% (50 mg/ 5 g) transdermal gel packet, 12.5 mg/actuation pump Testosterone (Androgel 1.62%) transdermal gel packet, 20.25 mg/actuation pump, 40.5 mg/2.5 g transdermal gel **Non-Formulary:** Aveed (testosterone) 750 mg/3 ml (250 mg/ml) intramuscular solution Azmiro (testosterone cypionate) intramuscular syringe Jatenzo (testosterone undecanoate) capsules Kyzatrex (testosterone undecanoate) capsules Methitest (methyltestosterone) 10 mg tablet Natesto (testosterone) 5.5 mg/0.122 g/actuation nasal gel pump Testopel (testosterone) 75 mg implant pellet testosterone (Fortesta) 2% transdermal gel pump Tlando (testosterone undecanoate) capsules Undecatrex (testosterone undecanoate) capsules Xyosted (testosterone) subcutaneous auto-injector Any other marketed agent within 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), 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	N/A
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Other Criteria:	**Initial Authorization**: 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) on two occasions with at least one level in the past 6 months 3. If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated.

Review/Revision Date: 08/2025	**<u>Re-Authorization:</u>** 1. Diagnosis of primary hypogonadism (congenital or acquired) or hypogonadotropic hypogonadism (congenital or acquired). 2. Documentation that the member experienced a clinical benefit as a result of the medication. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Anti-FGF23 Monoclonal Antibodies**
Drugs	Non-Formulary: Crysvita (burosumab) SQ solution Any other marketed agent within 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	N/A
Required Medical Information	N/A
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 request 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 • Member will not use concurrent oral phosphate and/or active vitamin D analogs (e.g., calcitriol, paricalcitol, doxercalciferol, calcifediol) • 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 • 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

Revision/Review Date: 05/2025	• Member 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 member's 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
	• Member 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.

Prior Authorization Group Description	**Antifibrotic Respiratory Tract Agents**
Drugs	Formulary: Ofev (nintedanib esylate) pirfenidone (Esbriet) Non-Formulary: Any other marketed agent within 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	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by a pulmonologist or lung transplant specialist
Coverage Duration	If all of the criteria are met, the request will be approved for up to a 12 month duration.
Other Criteria	**For All Requests:** • Provider attests that they have reviewed the member's other medications, and have addressed all potential drug interactions • Documentation has been provided that the member does not smoke • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **If the request is for Idiopathic Pulmonary Fibrosis (IPF):** • Confirmed diagnosis of IPF • Pulmonary function tests indicate member has Forced Vital Capacity (%FVC) greater than or equal to 50% within 30 days of request. • If the request is for Ofev, the member has a documented trial and failure or intolerance with pirfenidone. **If the request is for Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD):** • The request is for Ofev (nintedanib) only • Confirmed diagnosis of SSc-ILD • FVC greater than or equal to 40% within 30 days of request • Trial and failure of mycophenolate mofetil (MMF) or cyclophosphamide **If the request is for Chronic Fibrosing Interstitial Lung Disease (ILDs) with a progressive phenotype:**

Revision/Review Date: 08/2025	• The request is for Ofev (nintedanib) 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 or reason why other medications are contraindicated for the member (e.g., corticosteroid, azathioprine, MMF, rituximab, cyclophosphamide, cyclosporine, or tacrolimus). • FVC greater than or equal to 45% predicted within 30 days of request • Member is not taking pirfenidone **<u>Reauthorization Criteria</u>** • Documentation submitted indicates that the member has obtained clinical benefit from the medication • Documentation has been provided that the member does not smoke **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Anti-Infective Ear Drops Step Therapy**
Drugs	Ciprofloxacin-dexamethasone otic suspension Ciprofloxacin (Cetraxal) otic solution Ciprofloxacin-fluocinolone (Otovel) preservative-free otic 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 all of the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 11/2025	Prior use of one of the following is required: ofloxacin 0.3% OR neomycin-polymyxin-HC suspension/solution **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Anti-Parkinson's Agents for OFF Episodes**
Drugs	Formulary: apomorphine (Apokyn) Ongentys (opicapone) Xadago (safinamide) Non-Formulary: Nourianz (istradefylline) Inbrija (levodopa) inhalation Onapgo (apomorphine) Vyalev (foscarbidopa and foslevodopa) Any other marketed agent within 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	• 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	Prescribed by or in consultation with a neurologist
Coverage Duration	If all of the criteria are met, the request will be approved for up to 12 months.
Other Criteria	**<u>Initial Authorization:</u>** • Diagnosis of Parkinson's disease • Member is currently taking and will continue to take carbidopa/levodopa (does not apply to Vyalev) • Member 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) • Dosing is appropriate as per labeling or is supported by compendia or standard of care guidelines • If the request is for Inbrija, member does not have asthma, COPD, or other chronic underlying lung disease

Revision/Review Date 02/2026	• If the request is for apomorphine (Apokyn) or any other newly marketed agent, member must also have a documented trial and failure or intolerance to Ongentys and Xadago • If the request is for Vyalev, member is taking ≥400 mg of levodopa/day • If the request is for Vyalev or Onapgo, 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 a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **Re-authorization:** • 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.**

Prior Authorization Group Description	**Antisense Oligonucleotides for Duchenne Muscular Dystrophy**
Drugs	Non-Formulary: Amondys 45 (casimersen) Exondys 51 (eteplirsen) Viltepso (viltolarsen) Vyondys 53 (golodirsen) Any other marketed agents within 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	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 requests and reauthorization requests will be approved for up to 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.
	• 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

Revision/Review Date 02/2026	• 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.**

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	According to package insert
Prescriber Restrictions	None
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For reauthorization, the request will be approved for 12 months.
Other Criteria Review/Revision Date: 11/2025	**<u>Initial Authorization:</u>** • 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 **<u>Re-Authorization:</u>** • 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 **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist or nephrologist
Coverage Duration	If all of 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
 	
Revision/Review Date: 11/2025
	Initial Authorization:
	• Active systemic lupus erythematosus (SLE)
	  o Provider attestation that the member 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 I including (but not limited to) Saphnelo (anifrolumab)
	• Dosing is appropriate per labeling
	
	Reauthorization:
	• Documentation or provider attestation of positive clinical response such as
	  o Fewer flares that required steroid treatment
	  o Lower average daily oral prednisone dose
	  o Improved daily function either as measured through a validated functional scale or through improved daily performance documented at clinic visits
	  o 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.

Prior Authorization Group Description	**Biologic Agents for Nasal Polyposis**
Drugs	Formulary: Dupixent (dupilumab) Nucala (mepolizumab) Xolair (omalizumab) Tezspire (mepolizumab) Non-Formulary: Any other marketed agent within 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	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	Prescribed by or in consultation with an allergist/immunologist, pulmonologist, or otolaryngologist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Other Criteria	****Xolair: For asthma, urticaria, and IgE-mediated food allergy, 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 and COPD, please refer to the "Pulmonary Biologics for Respiratory & Eosinophilic Conditions" policy**** ****Nucala & Tezspire: For asthma, COPD, or other eosinophilic conditions, please refer to the "Pulmonary Biologics for Respiratory & Eosinophilic Conditions" policy**** **<u>Initial Authorization:</u>** • Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) • Medication is being prescribed at an FDA approved dosage • Member is currently using an intranasal corticosteroid and will continue therapy, will be prescribed an intranasal corticosteroid with request, or has a medical reason for not using an intranasal corticosteroid • Documentation of ONE of the following: o Trial and failure or has a medical reason for not using ALL of the following therapies: ▪ intranasal corticosteroids ▪ systemic corticosteroid o Member had prior surgery for nasal polyps • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary medications

Revision/Review Date 02/2026	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 formulary agent, only that agent must have been ineffective or not tolerated. **<u>Re-authorization:</u>** • Member will continue to use 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]) • Medication is being prescribed at an FDA-approved dosage **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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	If all the criteria are met, request will be approved for up to a 12 month duration.
Other Criteria	**Initial Authorization:** • Member 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 member for Cytokine Release Syndrome (CRS) and neurological toxicities **Reauthorization:** • Provider attests to treatment response or stabilization of disease • Prescriber attests to monitor member for Cytokine Release Syndrome (CRS) and neurological toxicities
Revision/Review Date 11/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Botulinum Toxins A&B**
Drugs	**Formulary:** IncobotulinumtoxinA (Xeomin) AbobotulinumtoxinA (Dysport) **Non-Formulary:** 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	Concomitant use of botulinum toxin and calcitonin gene-related peptide antagonist (e.g., Emgality, Ajovy, Aimovig, Quilipta, Nurtec ODT) for chronic migraine prevention.
Required Medical Information	N/A
Age Restrictions	According to package insert
Prescriber Restrictions	None
Coverage Duration	If all of the criteria are met, the request will be approved for 12 month duration.

Other Criteria
 	
Revision/Review Date: 11/2025
	****The use of these medications for cosmetic purposes is NOT a covered benefit****
	Initial Authorization:
	• 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 condition 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 (i.e., propranolol, timolol, metoprolol, nadolol, or atenolol)
	  o Amitriptyline or venlafaxine
	  o Topiramate, divalproex ER or DR, or valproic acid
	  o Candesartan or a CGRP antagonist (e.g., Emgality)
	• 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-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **Reauthorization Criteria:** • Documentation of provider attestation that demonstrates a clinical benefit • The requested drug is for a medically accepted dose as outlined in Covered Uses **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Brenzavvy**
Drugs	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	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 08/2025	• 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 of 3 months or more of therapy with Jardiance or has a documented medical reason (e.g. intolerance, contraindication) for not utilizing Jardiance. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Brineura (cerliponase alfa)**
Drugs	Non-Formulary: 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	Prescribed by a neurologist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.

Other Criteria
 	
Revision/Review Date: 08/2025
	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
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

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 of the criteria are met, the request will be approved for 12 months.
Other Criteria Review/Revision Date: 11/2025	**<u>Initial Authorization:</u>** • Diagnosis of bronchiectasis confirmed by chest CT scan • Documentation member 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 **<u>Re-Authorization:</u>** • 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 **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Calcipotriene-Betamethasone Dipropionate Ointment Step Therapy**
Drugs	Calcipotriene-Betameth Diprop Ointment 0.005-0.064 % External
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 of the criteria are met, the request will be approved for up to a 12 month duration.
Other Criteria Revision/Review Date 02/2026	• Prior use of one of the following is required: 1. calcipotriene 0.005% ointment or cream 2. betamethasone dipropionate 0.05% cream, gel, ointment, or lotion **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents.

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 request will be approved for 12 months.

Other Criteria
 	
Revision/Review Date: 08/2025
	Initial Authorization:
	• Diagnosis of symptomatic New York Heart Association (NYHA) class II or III obstructive hypertrophic cardiomyopathy (oHCM)
	• Member has a left ventricular ejection fraction (LVEF) ≥55%
	• Member 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 member 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 member is not using moderate to strong CYP2C19 inducers, strong CYP2C19 inhibitors, or moderate to strong CYP3A4 inducers
	• Medication is prescribed at an FDA approved dose
	
	Re-Authorization:
	• Documentation of clinical benefit as evidenced by an improvement from baseline in oHCM symptoms (i.e., improvement in fatigue, chest pain, shortness of breath, LVOT, peak oxygen consumption, etc.) OR improvement or no worsening of NYHA functional class
	• Member has a left ventricular ejection fraction (LVEF) ≥50%
	• 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.

Prior Authorization Group Description	**Carbonic Anhydrase Inhibitor Step Therapy**
Drugs	Brinzolamide Suspension 1% Ophthalmic
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 of the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 08/2025	1. Prior use of dorzolamide ophthalmic required. **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Carisoprodol Products**
Drugs	Formulary: Carisoprodol 350 mg tablets Non-Formulary: Any other marketed agent in this 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	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 08/2025	• Prior use of all of the following is required: a. Baclofen tablets b. Cyclobenzaprine tablets c. Tizanidine tablets d. Methocarbamol tablets e. Chlorzoxazone tablets • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Cystic Fibrosis transmembrane conductance regulator (CFTR) Modulators**
Drug(s)	Formulary: Alyftrek (vanzacaftor/tezacaftor/deutivacaftor) Kalydeco, Kalydeco Granules (ivacaftor) Orkambi, Orkambi Granules (lumacaftor/ivacaftor) Symdeko (tezacaftor/ivacaftor) Trikafta (elexacaftor/tezacaftor/ivacaftor) Non-Formulary: Any other marketed agent within 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), 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	Prescribed by a pulmonologist or specialist in the treatment of cystic fibrosis
Coverage Duration	If all of the criteria are met, the request will be approved for up to 12 months.
Other Criteria Review/Revision Date 02/2026	<u>Initial authorization:</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., screenshot) 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. • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. <u>Reauthorization:</u> • Based on prescriber's assessment, member 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.

Prior Authorization Group Description	**Calcitonin Gene-Related Peptide (CGRP) Antagonists for Headache Prevention**
Drugs	**Formulary:** Emgality (galcanezumab) - preferred Aimovig (erenumab) Qulipta (atogepant) Nurtec ODT (rimegepant) – if the request is for acute treatment of migraine please refer to the Acute Migraine Treatments criteria **Non-Formulary:** Vyepti (eptinezumab)-Medical Benefit Product Ajovy (fremanezumab) Any other marketed agent within 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 or concomitant use of botulinum toxin and calcitonin gene-related peptide antagonist (e.g,, Emgality, Ajovy, Aimovig, Quilipta, Nurtec ODT) for chronic migraine prevention.
Required Medical Information	See "Other Criteria"
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 up to 12 months.
Other Criteria	**<u>Initial Authorization:</u>** **Cluster Headache:** • Request for Emgality (galcanezumab) 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 • 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 verapamil. **Migraine Headache Prophylaxis**: • Diagnosis of episodic migraine (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 • Medication will not be used in combination with another CGRP inhibitor for either acute or preventative treatment of migraine • Trial and failure (or a medical justification for not using e.g., hypersensitivity, baseline bradycardia or hypotension, adverse events

Revision/Review Date: 05/2025	experienced from previous trial, etc.) with at least two of the following for at least 2 months: o Beta-adrenergic blockers o Topiramate or divalproex ER or DR o Amitriptyline or venlafaxine o Frovatriptan, zolmitriptan, or naratriptan (for menstrual migraine prophylaxis) • If the medication request is for a non-preferred CGRP Antagonist, the member has a documented medical reason (intolerance, hypersensitivity, contraindication, treatment failure etc.) for not using Emgality to treat their medical condition. If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **<u>Reauthorization:</u>** **Episodic Cluster Headache:** • Documented reduction in the frequency of headaches (clinical benefit) **Migraine:** • Documented 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**.

Prior Authorization Group Description	**Chelating Agents**
Drugs	**Pharmacy Benefit:** Deferasirox (Exjade) Tablet for Oral Suspension Deferasirox (Jadenu) Tablet, Granule Pack Deferiprone (Ferriprox) Tablet Ferriprox (Twice-a-Day) (deferiprone) Tablet Penicillamine (Cuprimine) capsule Penicillamine (Depen Titratabs) tablet Trientine (Syprine) capsule **Medical Benefit:** Calcium Disodium Versenate (edetate calcium disodium) ampule Deferoxamine mesylate (Desferal) vial Pentetate calcium trisodium ampule Pentetate zinc trisdoium ampule **Non-Formulary:** Chemet (succimer) capsule Cuvrior (trientine tetrahydrochloride) tablet Ferriprox (deferiprone) solution Galzin (zinc acetate) capsule Any other marketed agent within 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	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	See "Other Criteria"
Prescriber Restrictions	N/A
Coverage Duration	If all the criteria are met, the request will be approved with a 12 month duration.
Other Criteria	**Requests for deferasirox (Exjade, Jadenu) only:** **Chronic iron overload due to blood transfusions:** For Pediatric Population**:** • Member must be ≥ 2 years old and < 21 years old • Diagnosis of chronic iron overload due to blood transfusions • Member receiving blood transfusions on a regular basis/participating in blood transfusion program • Documentation of serum Ferritin concentration is consistently > 1000 mcg/L within the past 3 months. 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>**:** • Member must be ≥ 21 years old • Diagnosis of chronic iron overload due to blood transfusions • Member receiving blood transfusions on a regular basis/participating in blood transfusion program • Documentation of serum Ferritin concentration is consistently > 1000 mcg/L within the past 3 months. If the serum ferritin levels fall consistently below 500 mcg/L, deferasirox (Exjade, Jadenu) must be discontinued • Documentation that member 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:** • Member must be ≥ 10 years old • Diagnosis of thalassemia syndrome • Documentation of liver iron content (LIC) by liver biopsy of ≥ 5 mg Fe/g dry weight within the past 6 months. • Documentation of ≥ 2 measurements of serum ferritin levels > 300mcg/L at least one month apart with the most recent level within the past 3 months • 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 deferiprone (Ferriprox) only:</u>** **<u>Transfusion Iron overload due to thalassemia syndrome, sickle cell disease, or other anemias</u>** • Member must be ≥ 3 years old for oral solution OR ≥ 8 years old for tablets • Diagnosis of thalassemia syndrome, sickle cell disease, or other anemia • Member receiving blood transfusions on a regular basis/participating in blood transfusion program • Documentation of serum Ferritin concentration is consistently > 1000 mcg/L within the past 3 months. If the serum ferritin levels fall consistently below 500 mcg/L, Ferriprox must be discontinued

Revision/Review Date 08/2025	• Documentation that member 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 Ferriprox Twice a Day, there is a documented medical reason why deferiprone 500 mg or 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**: • Diagnosis of Wilson's disease • Member is de-coppered • Member 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:** • Diagnosis of Wilson's disease • Documented trial and failure, intolerance, or contraindication to penicillamine • The medication requested is being prescribed at an FDA approved dose **Penicillamine capsules only:** • Documentation of trial and failure, intolerance, or medical reason why member is unable to use penicillamine tablets is required. **<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") • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Agents**
Drugs	Non-Formulary: Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase) Any other marketed agent within the class **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	According to package insert
Prescriber Restrictions	Prescribed by a neurologist or neuromuscular specialist.
Coverage Duration	If all of the criteria are met, the initial request will be approved for 3 months. For reauthorization requests, the request will be approved for 12 months.
Other Criteria Review/Revision Date: 11/2025	**Initial Authorization:** • Diagnosis of CIDP confirmed by electrodiagnostic test results (e.g., electromyography or nerve conduction studies) • Member has progressive or relapsing/remitting disease course for ≥2 months • Member has an inadequate response, significant intolerance, or contraindication to intravenous immunoglobulin (IVIG) or subcutaneous immunoglobulin (SCIG) • Medication is prescribed at an FDA approved dose **Reauthorization:** • Documentation or provider attestation of significant clinical improvement in neurologic symptoms or stabilization of disease • 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.**

Prior Authorization Group Description	**Cobenfy (xanomeline and trospium chloride)**
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	Prescribed by, or in consultation with a psychiatrist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 02/2026	**<u>Initial Authorization:</u>** • 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 that the member 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 **<u>Re-Authorization:</u>** • 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 **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Complement Inhibitors**
Drugs	**Formulary:** Empaveli (pegcetacoplan) **Non-Formulary:** BKEMV (eculizumab-aeeb) Epysqli (eculizumab-aagh) Fabhalta (iptacopan) Izervay (avacincaptad pegol injection) Soliris (eculizumab) Syfovre (pegcetacoplan) Ultomiris (ravulizumab) Voydeya (danicopan) PiaSky (crovalimab-akkz) Any other marketed agent within the class
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	Prescribed by a hematologist, nephrologist, neurologist, oncologist, ophthalmologist, or other appropriate specialist.
Coverage Duration	If all of the criteria are met, the request will be approved as follows: Initial requests: • 3 months: eculizumab (Soliris, BKEMV, Epysqli), Ultomiris (ravulizumab), Voydeya (danicopan) • 6 months: Fabhalta (iptacopan), PiaSky (crovalimab-akkz), Empaveli (pegcetacoplan) • 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), 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 Empaveli, Fabhalta, eculizumab (Soliris, BKEMV, Epysqli) Ultomiris, PiaSky (crovalimab-akkz), and Voydeya: o Documentation member complies with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria.

Revision/Review Date 11/2025	• For Soliris or BKEMV, member must have a documented trial and failure or intolerance to Epysqli or a medical reason why Epysqli cannot be used. • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **Paroxysmal Nocturnal Hemoglobinuria (PNH):** • Documentation of diagnosis by high sensitivity flow cytometry • 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), member 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, member must be 60 years of age or older. • If the request is for Izervay, member must be 50 years of age or older • 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) and Immune-Complex Membranoproliferative Glomerulonephritis (IC-MPGN):** • Diagnosis of primary C3G or IC-MPGN as confirmed by renal biopsy • Member's urine protein to creatinine ratio (UPCR) is ≥ 1.0 g/g • Member has an eGFR ≥ 30 mL/min/1.73 m^2 • Member 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 • For Fabhalta: Member does not have recurrent C3G post kidney transplant **<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, increase in Hgb, reduced need for blood transfusions, slowing of growth rate of GA lesions, improvement in UPCR, etc); **AND** • The request is for a dose that is FDA approved or in nationally recognized compendia in accordance with the member's diagnosis, age, body weight, and concomitant medication conditions ; **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.**

Prior Authorization Group Description	**Compound Products**
Drugs	Compounds over $300
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	N/A
Prescriber Restrictions	N/A
Coverage Duration	If all criteria are met, the request will approved for up to a 12 month duration (depending on the diagnosis and usual treatment duration).
Other Criteria Revision/Review Date 05/2025	**Initial Authorization:** • Compound contains at least one active drug ingredient that is FDA approved • Requested compound product is not a copy of a commercially available FDA approved product • Clinical rationale for using a compound product instead of an FDA approved product has been provided • Peer reviewed medical literature supporting use of compounded product for the indication being requested has been provided **Reauthorization:** • Provider attests that member has clinical improvement associated with use of compound product • Requested compound product is not a copy of a commercially available FDA approved product **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Continuous Glucose Monitors Step Therapy**
Drugs	Freestyle Libre 14-Day Freestyle Libre 2, 2 Plus Freestyle Libre 3, 3 Plus Dexcom G6 Dexcom G7
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 of the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 08/2025	• Member is being treated with insulin therapy. **Continuation of Therapy Provision:** Members with history (within the past 90 days) of CGM use are not required to demonstrate treatment with insulin. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Ivabradine (Corlanor)**
Drugs	Ivabradine (Corlanor)
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 the package insert
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist
Coverage Duration	If all of the criteria are met, requests will be approved for up to 12 months.
Other Criteria	**Initial Authorization** For all requests • Member is not currently using strong CYP3A4 inhibitor (e.g. clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin) Adults with Heart Failure with Reduced Ejection Fraction (HFrEF) • Documentation has been provided of the following: o Member has a diagnosis of stable symptomatic chronic heart failure (NYHA functional class II-IV) with a reduced left ventricular ejection fraction (LVEF) ≤35% o Member is in sinus rhythm with a resting heart rate ≥70 beats per minute (BPM) o Member is currently prescribed, or documentation has been provided that member is not able to tolerate an evidence based beta-blocker (i.e., bisoprolol, carvedilol, metoprolol succinate) at maximally tolerated dose o The medication is being prescribed at an FDA approved dosage Pediatrics with Heart Failure due to Dilated Cardiomyopathy (DCM) • Member has stable heart failure (NYHA/Ross functional class II-IV) due to dilated cardiomyopathy and a left ventricular ejection fraction ≤45% • Member is in sinus rhythm with an elevated resting heart rate • The medication is being prescribed at an FDA approved dosage Inappropriate Sinus Tachycardia • Member is currently prescribed, or documentation has been provided that member is not able to tolerate a beta-blocker at maximally tolerated dose • Dose consistent with guidelines/compendia Postural Tachycardia Syndrome • Member is NOT taking norepinephrine reuptake inhibitors concurrently • Trial and failure of or medical reason for not being able to use two of the following: fludrocortisone, pyridostigmine, beta-blocker (e.g., propranolol), midodrine, clonidine, methyldopa.

Revision/Review Date: 02/2026	• Dose consistent with guidelines/compendia **<u>Reauthorization</u>** • Dose consistent with package insert or guidelines/compendia • Attestation that member has experienced clinical benefit **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Corticosteroids for Duchenne Muscular Dystrophy (DMD)**
Drugs	Non-Formulary: deflazacort (Emflaza) Agamree (vamorolone) Any other marketed agent within 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	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	2 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, provider who specializes in the treatment of DMD
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 02/2026	**<u>Initial Authorization:</u>** • 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 **<u>Reauthorization:</u>** • 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 **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Prior Authorization Group Description	**Corticotropin**
Drugs	**Preferred:** Cortrophin (cortictropin) **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 all the criteria are met, the request will be approved for up to a 1 month duration.
Other Criteria Revision/Review Date: 02/2026	**<u>Infantile Spasms (West Syndrome):</u>** • Member is <2 years of age • The medication is being prescribed by a neurologist. • Documentation of the member's current weight (in kg) and height/length (in cm) or body surface area (BSA) **<u>Multiple Sclerosis:</u>** • Documentation was submitted that member is having acute attack, with neurologic symptoms and increased disability or impairments in vision, strength or cerebellar function, and has failed therapy with IV methylprednisolone, or a medical reason has been submitted why member 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. **<u>All Other FDA Approved Conditions and Indications:</u>** • Documented trial and failure of IV AND oral corticosteroids, or documented medical reason for why the member 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 medical compendia (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 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.

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	• Members with non-classic congenital adrenal hyperplasia (CAH) • Members 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 of the criteria are met, the request will be approved for 12 months.
Other Criteria	**Initial Authorization:** • Medically confirmed diagnosis of classic 21-hydroxylase deficiency congenital adrenal hyperplasia (CAH) • Member 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 • Member's current weight • For adults and pediatric members weighing ≥55 kg, or members weighing ≥20 kg if CYP3A4 dose adjustment is required: capsule formulation is requested OR documentation is provided that member 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 member has successfully achieved a reduction in glucocorticoid dosage from baseline. • Medication is prescribed at an FDA approved dose according to package insert • Member's current weight • For all adults and pediatric members weighing ≥55 kg or members weighing ≥20 kg if CYP3A4 dose adjustment is

Review/Revision Date: 05/2025	required: capsule formulation is requested OR documentation is provided that member 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). **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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 of the criteria are met, the request will be approved for 12 months.
Other Criteria Review/Revision Date: 05/2025	**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 **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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	According to package insert
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. Reauthorization requests will be approved for 12 months.
Other Criteria Revision/Review Date 02/2026	**<u>Initial Authorization:</u>** • Baseline creatinine clearance (within 60 days of request) above 50 mL/min • Member has diagnosis of multiple sclerosis (MS), • Member is ambulatory AND has a walking impairment • Baseline 25-foot walk test 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 member 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 member is unable to use DMT agents to treat their medical condition • Drug is being requested at an FDA approved dose **<u>Re-authorization:</u>** • Member is ambulatory • Member has experienced 10% or greater improvement from baseline in the timed 25-foot walk test (T25FW) • Documentation was submitted member is on DMT MS treatment, or initial approval was on the basis of member being unable to use DMT agents to treat their medical condition • Drug is being requested at 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	**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 of the criteria are met, the request will be approved for up to a 12 month duration.
Other Criteria Revision/Review Date 08/2025	**<u>Initial Authorization:</u>** • 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 member's weight • Documentation or provider attestation of all the following: o Clinical Global Impression–Severity (CGI-S) score of ≥4 o Baseline Rett Syndrome Behavior Questionnaire (RSBQ) score **<u>Re-Authorization:</u>** • 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.**

Prior Authorization Group Description	**Dendritic Cell Tumor Peptide Immunotherapy**
Drugs	Non-Formulary: 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	Prescribed by an oncologist or urologist
Coverage Duration	If all of the criteria are met, the request will be approved for 3 doses per lifetime

Other Criteria
 	
Revision/Review Date: 05/2025
	Initial Authorization:
	• Metastatic castrate resistant (hormone-refractory) prostate cancer (mCRPC) (consistent with medical chart history)
	  o Evidenced by soft tissue and/or bony metastases
	  o Member 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)
	• Member is not currently being treated with systemic immunosuppressants (e.g., chemotherapy, corticosteroids) or, if the member 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
	
	Reauthorization:
	• 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.

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	For First Occurrence of CDI: If the criteria are met, the request will be approved for up to a 10-day duration. For First Recurrent CDI: If the criteria are met, the request will be approved for up to a 25-day duration.
Other Criteria Revision/Review Date: 02/2026	• Diagnosis of *Clostridium* (or *Clostridioides*) *difficile* infection (CDI) • If this is the first occurrence or the FIRST recurrent episode of CDI, documentation of treatment failure, intolerance, or medical reason why member is unable to use oral vancomycin • 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	**Dose Rounding Limit Exception Criteria**
Drugs	**Bevacizumab products (Avastin, Mvasi, Zirabev, Vegzelma, Alymsys, Jobevne)** ***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 (e.g., lab values, rapidly fluctuating body weight, curative treatment) **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	02/2026

Prior Authorization Group Description	**Doxepin Cream Step Therapy**
Drugs	Doxepin (Prudoxin, Zonalon) cream
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 of the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 11/2025	Prior use of one topical corticosteroid is required. **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Doxylamine/Pyridoxine**
Drugs	Formulary: doxylamine 10 mg/pyridoxine 10 mg (Diclegis) Non-Formulary: Any other marketed agent within 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
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 all of the criteria are met, the request will be approved for up to 9 months or the expected remaining duration of the pregnancy.
Other Criteria Revision/Review Date: 02/2026	• The member has a diagnosis of nausea and vomiting due to pregnancy. • The member has tried and failed, or has an intolerance to, combination therapy with pyridoxine (vitamin B6) and doxylamine single-ingredient products. • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Dry Eye Disease Agents**
Drugs	Formulary – Step Therapy Required: Cyclosporine emulsion 0.05% (Restasis) ophthalmic Formulary – Prior Authorization Required: Xiidra (lifitegrast) 5% ophthalmic Non-Formulary: Cequa 0.09% (cyclosporine) Restasis multidose 0.05% Tyrvaya (varenicline) 0.03mg nasal spray Miebo (perfluorohexyloctane) solution 1.338g/ml Vevye 0.1% (cyclosporine) ophthalmic solution Any other marketed agent within 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	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 with up to a 12 month duration.

Other Criteria
 	
Revision/Review Date 08/2025
	Initial Authorization:
	• For cyclosporine emulsion 0.05%:
	  o Prior use of an artificial tear product is required.
	• For Restasis Multidose, Cequa, Xiidra, Vevye, or Tyrvaya:
	  o Prior use of cyclosporine emulsion 0.05% ophthalmic is required.
	• If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated.
	
	Reauthorization:
	• Documentation provided that the member has obtained clinical benefit from medication
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Prior Authorization Group Description	**Duavee Step Therapy**
Drugs	Duavee (conjugated estrogens/bazedoxifene)
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 of the criteria are met, the request will be approved for up to a 12 month duration.
Other Criteria Revision/Review Date 11/2025	For prevention of postmenopausal osteoporosis: Prior use of raloxifene is required For treatment of vasomotor symptoms: Prior use of oral estrogen is required **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Duvyzat (givinostat)**
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 a neurologist or provider who specializes in the treatment of Duchenne Muscular Dystrophy (DMD)
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Other Criteria Review/Revision Date: 08/2025	**<u>Initial Authorization:</u>** • 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 • Member has been stable on baseline corticosteroids for at least 6 months • Member is ambulatory • Member's platelet count is ≥ 150 x 109/L **<u>Re-Authorization:</u>** • Documentation or provider attestation of positive clinical response (such as improved muscle function, muscle strength, or disease stabilization) • Member is on concurrent corticosteroid treatment • Member is ambulatory • Medication is prescribed at an FDA approved dose according to body weight **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Egrifta (tesamorelin)**
Drugs	Egrifta SV vial Egrifta WR subcutaneous kit
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, an endocrinologist or HIV specialist
Coverage Duration	If all of the criteria are met, the request will be approved for up to 6 months duration and renewal requests will be approved for 12 months.

Other Criteria
 	
Revision/Review Date 11/2025
	Initial Authorization:
	• Member has a diagnosis of HIV infection with abdominal lipodystrophy
	• Documentation provided indicating the one of the following within the past 12 months:
	  o CT scan indicating visceral fat accumulation
	  o Waist circumference of ≥95 cm [37.4 inches] and a waist-to-hip ratio of ≥0.94 for men; OR
	  o Waist circumference of ≥94 cm [37.0 inches] and ≥0.88 for women
	• Physician attests member does not currently have active malignancy, does not have disruption of the hypothalamic-pituitary axis, and is not pregnant
	• Medication is being prescribed at an FDA-approved dosage
	
	Reauthorization:
	• The member has experienced a positive clinical response as documented by a reduction in visceral adipose tissue on CT scan or a decrease in waist circumference
	• The medication is being prescribed at an FDA-approved dosage
	
	Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Prior Authorization Group Description	**Elmiron**
Drugs	Elmiron (pentosan polysulfate sodium)
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	16 years or older
Prescriber Restrictions	Prescribed by a urologist, obstetrician/gynecologist, or other specialist in the treatment of genitourinary disorders
Coverage Duration	If all of the criteria are met, the initial request will be approved for up to 6 months, and the reauthorization request will be approved for up to 12 months.
Other Criteria Revision/Review Date 11/2025	**Initial Authorization** • Member has a confirmed diagnosis of bladder pain or discomfort associated with interstitial cystitis • The member has tried and failed treatment with amitriptyline or has a documented medical reason why amitriptyline is not appropriate treatment. • Documentation of baseline Genitourinary Pain Index (GUPI) and urinary frequency or urgency • Requested dose is within FDA approved guidelines **Reauthorization** • Documentation is provided that the member has obtained a clinical benefit (e.g., reduction in GUPI, reduced pelvic or bladder pain, reduced urinary frequency or urgency) • Requested dose is within FDA approved guidelines **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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	Prescribed by a hematologist or sickle cell specialist
Coverage Duration	If all of the criteria are met, requests will be approved for 12 months.
Other Criteria Revision/Review Date 02/2026	**Initial authorization:** • Member has diagnosis of sickle cell disease • Documentation was provided that the member 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 member 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 **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Enzyme Replacement Therapies for Fabry Disease**
Drugs	Non-Formulary: Fabrazyme (agalsidase beta) Elfabrio (peguniigalsidase alfa) Any other marketed agent within 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), and the Drug Package Insert (PPI).
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 geneticist, cardiologist, nephrologist, or specialist experienced in the treatment of Fabry disease
Coverage Duration	If all of the criteria are met, the request will be approved for a 12-month duration.
Other Criteria	****Drug is being requested through the member's medical benefit**** **<u>Initial Authorization</u>:** • 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 **<u>Re-Authorization:</u>** • 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

Revision/Review Date: 08/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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 of the 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: 05/2025	• 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 propionate) • 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.**

Prior Authorization Group Description	**Epidermolysis Bullosa Agents**
Drugs	Non-Formulary: Filsuvez (birch triterpenes) Any other marketed agent within 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	• Other forms of epidermolysis bullosa, such as epidermolysis bullosa simplex, junctional epidermolysis bullosa, kindler epidermolysis bullosa • Concurrent use of Vyjuvek and Filsuvez
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by a dermatologist, geneticist, or specialist experienced in the treatment of epidermolysis bullosa.
Coverage Duration	If all of the criteria are met, the request will be approved for up to 12 months.
Other Criteria	**<u>Initial Authorization:</u>** • Member has a diagnosis of dystrophic or junctional epidermolysis bullosa, with genetic mutation(s)confirmed via genetic testing. • Requested product is FDA approved for the member'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. Filsuvez covers up to 250 cm^2 surface area per single tube. Requests exceeding use more than once daily will not be approved. Rounding to the next whole tube size necessary is allowed. • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **<u>Re-Authorization:</u>** • Documentation or provider attestation of positive clinical response (i.e., improvement in wound appearance, wound closure, healing, etc.)

Review/Revision Date: 05/2025	• 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 weekly dispensing 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. Filsuvez covers up to 250 cm^2 surface area per single tube. Requests exceeding use more than once daily will not be approved. Rounding to the next whole tube size necessary is allowed. **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	**Formulary, Preferred:** Retacrit (epoetin alfa-epbx): Preferred for pharmacy or medical benefit requests **Formulary, Non-preferred:** Aranesp (darbepoetin alfa-polysorbate 80) **Non-formulary:** Epogen, Procrit (epoetin alfa) Any other marketed agent within the class **Medical benefit:** Mircera (methoxy peg-epoetin beta): requests for anemia of chronic kidney disease (CKD) only
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 criteria are met, the request will be approved for up to • 1 month if the member is deficient in iron, vitamin B12 or folate, and in the peri-surgical setting • 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 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 **<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 lab results submitted must have been drawn within 30 days of 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 <u>MUST</u> 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 medication is being requested through the pharmacy benefit: o Retacrit is the preferred ESAs for all indications. For requests for all other ESAs, documentation must be provided as to why Retacrit is not medically appropriate for the member • If the medication is being requested though the medical benefit: o Retacrit is the preferred ESAs for all indications EXCEPT anemia due to CKD. Mircera is the preferred ESA for anemia due to CKD. For requests for all other ESAs not addressed in this policy, documentation must be provided as to why Retacrit, Aranesp, or Mircera is not medically appropriate for the member • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. <u>Requests for anemia of CKD:</u> • HgB < 10 g/dL <u>Requests for anemia related to chemotherapy in cancer patients:</u> • 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 <u>curative intent</u> should <u>not</u> receive ESAs) **AND** documented <u>symptomatic</u> anemia with HgB < 10 g/dL **OR** • The member has symptomatic anemia related to myelodysplastic syndrome **AND** documented serum erythropoietin level ≤ 500 mU/mL <u>Requests for zidovudine-related anemia in HIV</u>: • The member is currently receiving highly active antiretroviral therapy (HAART) **AND** has a documented serum erythropoietin level ≤ 500 mU/mL • Member is receiving a dose of zidovudine ≤ 4,200 mg/week <u>Requests for ribavirin-induced anemia:</u> • Member is currently receiving ribavirin and a documented attempt to reduce dose has been made • Hgb < 12 g/dL <u>Requests for members undergoing surgery to reduce the need for allogenic blood transfusion:</u> • Perioperative HgB < 13g/dL and > 10 g/dL. • The member is scheduled for an elective, non-cardiac, nonvascular surgery. **<u>Reauthorization:</u>**

Revision/Review Date: 11/2025	• All submitted lab results have been drawn within 30 days of the reauthorization request.
	• 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 (> 100 ng/mL)
	  o Transferrin saturation (TSAT) (> 20%)
	  o Vitamin B12 level (> 223 pg/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: HgB ≤ 12 g/dL
	  o Ribavirin-induced anemia: HgB ≤ 12g/dL
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Prior Authorization Group Description	**Emergency Use Authorization (EUA) Drugs/Products for COVID-19**
Drugs	Any drugs/products 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 or through a patient assistance program at no charge
Revision/Review Date 02/2026	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Febuxostat (Uloric) Step Therapy**
Drugs	Febuxostat (Uloric)
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 of the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 11/2025	Documented trial and failure of or intolerance to allopurinol **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Fecal Microbiota**
Drugs	Non-Formulary: Rebyota (fecal microbiota, live-jslm) Vowst (fecal micromiota spores, live-brpk) Any other marketed agent within 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	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 of the criteria are met, the request will be approved for 1 treatment course
Other Criteria Review Revision Date: 08/2025	• 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 6 weeks before prior authorization request • Administration will occur 24 to 72 hours (for Rebyota only) or 2 to 4 days (for Vowst only) 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* **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Fertility Agents** ***Requests for non-fertility related indications: refer to Medication without Drug or Class Specific criteria***
Drugs	Formulary: cetrorelix (Cetrotide) clomiphene (Clomid) Follistim AQ (follitropin beta) ganirelix (Fyremadel) Gonal-F, Gonal-F RFF, Gonal-F RFF Rediject (follitropin alfa) Menopur (menotropins) Novarel 5000 unit (chorionic gonadotropin) chorionic gonadotropin 10000 unit Ovidrel (choriogonadotropin alfa) Pregnyl (choriogonadotropin alfa) Non-Formulary: Any other marketed agent for fertility
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 request will be approved for 12 months.

Other Criteria	**For authorization of Fertility Agents:**
	• Medication is prescribed for an FDA-approved indication **for treatment of infertility.**
	• Medication is prescribed at an FDA approved or compendia supported dose and duration of therapy.
	• Requests for Novarel or Ovidrel:
	  o Documentation of a trial and therapy failure, intolerance, or medical reason why member cannot use Pregnyl.
	• Requests for Cetrotide:
	  o Documentation of a trial and therapy failure, intolerance, or medical reason why member cannot use ganirelix.
	• If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated.

Revision/Review Date: 08/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Fluoxetine and Venlafaxine ER Tablets Step Therapy**
Drugs	Fluoxetine HCl Tablet Venlafaxine HCl Extended-Release 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 all of the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 05/2025	Requests for fluoxetine tablet: • Prior use of fluoxetine capsules is required. Requests for venlafaxine ER tablet: • Prior use of venlafaxine extended-release capsules is required. **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Forzinity (elamipretide)**
Drugs	Forzinity (elamipretide)
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	N/A
Prescriber Restrictions	Prescribed by a cardiologist, endocrinologist, hematologist, geneticist, neurologist, or other provider specializing in the treatment of Barth Syndrome.
Coverage Duration	If all of the criteria are met, the request will be approved for up to a 12 month duration.
Other Criteria Revision/Review Date: 02/2026	**Initial Authorization:** • Diagnosis of Barth Syndrome confirmed via identification of mutations in the TAZ gene per genetic testing • Member's current weight is provided with the request and is ≥ 30 kg • Pediatrics: patient does not have renal impairment • Adults: patient is not on dialysis • Requested dose is within FDA approved dosing guidelines **Reauthorization:** • Member has not experienced a serious hypersensitivity reaction to Forzinity • Documentation or provider attestation of clinical benefit (i.e. 6-minute walk test, Total Fatigue Score on the Barth syndrome Symptom Assessment, muscle strength, cardiac function, etc.) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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	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	If all of the criteria are met, the request will be approved for a 12-month duration.
Other Criteria Revision/Review Date: 08/2025	**Initial Authorization:** • Member has a documented diagnosis of Fabry disease • Member has a documented amenable galactosidase alpha (GLA) gene variant based on in vitro assay data • Member will not be using concurrently with enzyme replacement therapy (e.g., Fabrazyme) • Member has a documented baseline eGFR ≥ 30 mL/min/1.73 m^2 • Request is for an FDA-approved dose **Re-Authorization:** • Member has a documented 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 enzyme replacement therapy (e.g., Fabrazyme) • Member has a documented eGFR ≥ 30 mL/min /1.73 m^2 • 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	**Gattex**
Drugs	Gattex (teduglutide)
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	Members with active gastrointestinal neoplasia
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by a gastroenterologist or other specialist in the treatment of gastrointestinal disorders
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Other Criteria Revision/Review Date 02/2026	**Initial Authorization** • Member has a confirmed diagnosis of short bowel syndrome (SBS) • Members must be dependent on parenteral nutrition at least 3 days a week for at least 12 months. • Documentation of baseline parenteral nutrition frequency and fluid volume • Requested dose is within FDA approved guidelines. **Reauthorization** • Documentation is provided that the member has obtained a clinical benefit (e.g., reduction in parenteral fluid volume, reduction in number of days receiving parenteral nutrition) • Requested dose is within FDA approved guidelines. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Generalized Pustular Psoriasis (GPP) Agents**
Drugs	Non-Formulary: Spevigo (spesolimab-abzo) Any other marketed agent within 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	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to 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, requests will be approved for 12 months.

Other Criteria	**Initial Authorization:**
	• 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
	
	Reauthorization:
	• 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 and 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

Revision/Review Date: 05/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Glucagon-Like Peptide-1 Receptor Agonist (GLP-1) for Diabetes**
Drugs	Formulary: Mounjaro (tirzepatide) Ozempic (semaglutide) Rybelsus (semaglutide) Trulicity (dulaglutide) Non-Formulary: Exenatide (Byetta) Liraglutide (Victoza) Any other marketed agent in this 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	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the request will be approved with up to a 12 month duration.

Other Criteria
 	
Revision/Review Date 11/2025
	Initial authorization:
	• Diagnosis of Type 2 Diabetes Mellitus
	• Documentation of laboratory results that meet one of the following values:
	  o A1C >= 6.5
	  o Fasting plasma glucose (FPG) >= 126mg/dL
	  o 2-hour plasma glucose (PG) >= 200 mg/dL during OGTT (oral glucose tolerance test)
	  o Random Plasma Glucose >= 200 mg/dL
	• Medication is prescribed at an FDA approved dose
	• If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated.
	
	Reauthorization:
	• Diagnosis of Type 2 Diabetes Mellitus
	• Documentation of baseline laboratory results that meet one of the following values:
	  o A1C >= 6.5
	  o Fasting plasma glucose (FPG) >= 126mg/dL

	○ 2-hour plasma glucose (PG) >= 200 mg/dL during OGTT (oral glucose tolerance test) ○ Random Plasma Glucose >= 200 mg/dL • Documentation of positive clinical response to therapy (e.g., A1C lab results) • 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.**

Prior Authorization Group Description	**GLP-1 Receptor Agonists (Wegovy, Zepbound) for Non-Weight Loss Indications**
Drugs	Wegovy (semaglutide) injection, tablet 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 (GLP-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: ≥45 years of age All others: according to package insert
Prescriber Restrictions	Prescribed by or in consultation with: • Wegovy for MASH/NASH: 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
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. Re-authorization requests will be approved for 12 months.
Other Criteria	**<u>Initial Authorization:</u>** • All requests: Requested dose and formulation (injection, tablet) is appropriate per labeling **Wegovy Requests:** • For Wegovy tablet requests, member has a documented medical reason (e.g., allergy to inactive ingredient) for not using Wegovy injection • For risk reduction of major adverse cardiovascular events in adults with established CV disease, the following must be met: o Medication is requested for reducing the risk of adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with **established cardiovascular disease (CVD).** Chart notes demonstrating member has history of one or more of the following: ▪ Prior myocardial infarction ▪ Prior stroke ▪ 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

	• Amputation due to atherosclerotic disease o Chart notes provided that member is overweight or obese, defined as a body mass index (BMI) ≥27 kg/m2 o Member is receiving standard of care treatment for CVD, as appropriate/indicated, including an antiplatelet agent (ex: aspirin or P2Y12 inhibitor), lipid-lowering drug (ex: statin, ezetimibe, fibrate, PCSK-9 inhibitor), antihypertensive (ex: beta blocker, ACE-I, ARB) o Prescriber attests medication therapy is part of a total treatment plan including diet and exercise/activity as appropriate for the member's ability o Member does not have a personal history of type 1 or type 2 diabetes o Chart notes provided that member'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: o Diagnosis of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH) with moderate to advanced liver fibrosis o Documentation of stage F2 to F3 fibrosis confirmed by biopsy or a noninvasive test (NIT) o Prescriber attestation to providing lifestyle counseling on nutrition and exercise o Prescriber attestation that member avoids excess alcohol intake **Zepbound Requests:** • For treatment of **moderate to severe obstructive sleep apnea** in adults, the following must be met: o Medication is requested for moderate to severe obstructive sleep apnea. o Member's weight taken within the past 30 days is provided o Member's body mass index (BMI) is provided and is 30 kg/m2 or more o Chart notes demonstrating current diagnosis of moderate to severe obstructive sleep apnea o 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 o Documentation of one the following: ▪ Results of sleep testing (e.g., polysomnography or recording time) showing member's apnea hypopnea index (AHI) ≥ 15 while currently on PAP therapy ▪ Results of sleep testing (e.g., sleep study or device report) showing member's apnea hypopnea index (AHI) ≥ 15 and member had had a previous trial and failure of PAP therapy or a medical reason is provided why the member is not able to use PAP therapy

	○ If member is currently on PAP therapy or had a previous trial and failure of PAP therapy, documentation of a device report demonstrating compliance with positive airway pressure (e.g., device used for 70% of nights for four or more hours per night, for two or more months) ○ Chart notes demonstrating member has practiced sleep hygiene modifications (e.g., avoiding a nonsupine sleeping position, avoiding alcohol and sedatives before bed) for at least six months prior to initiation of Zepbound ○ Member is not pregnant **<u>Re-Authorization:</u>** **Wegovy Requests:** • For Wegovy tablet requests, member has a documented medical reason (e.g., allergy to inactive ingredient) for not using Wegovy injection • For **risk reduction of major adverse cardiovascular events** in adults with established CV disease, the following must be met: ○ Medication is requested for reducing the risk of adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with **established cardiovascular disease (CVD).** Chart notes demonstrating member has history of one or more of the following: ▪ Prior myocardial infarction ▪ Prior stroke ▪ 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 • Amputation due to atherosclerotic disease ○ Member is receiving standard of care treatment for CVD, as appropriate/indicated, including an antiplatelet agent (ex: aspirin or P2Y12 inhibitor), lipid-lowering drug (ex: statin, ezetimibe, fibrate, 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 member's ability ○ Member continues to not have Type 1 or Type 2 diabetes ○ Chart notes provided that member is overweight or obese, defined as a body mass index (BMI) ≥27 kg/m2 ○ Member 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 ○ Member is adherent to therapy, as evidenced by claims records demonstrating ≥80% fill rate **<u>Zepbound Requests:</u>** • For treatment of **moderate to severe obstructive sleep apnea** in adults, the following must be met: ○ Requested dose is appropriate per labeling and meets one of the following: ▪ Dose does not exceed 15 mg once weekly ▪ After the initial dose escalation period, maintenance dose is ≥ 5 mg once weekly ○ Medication is requested for moderate to severe obstructive sleep apnea. ○ Chart notes demonstrating member has a current diagnosis of moderate to severe obstructive sleep apnea. ○ Documentation of positive clinical response to therapy as demonstrated by one of the following: ▪ For the first renewal request, member meets ONE of the following: • AHI reduction from baseline • Improvement in the sleep apnea-specific hypoxic burden (SASHB) score • Improvement in one of the sleep-related patient reported outcomes scores (e.g., Epworth sleepiness scale (ESS), Calgary sleep apnea QOL index (SAQLI), functional outcomes of sleep Questionnaire (FOSQ), patient-reported outcomes measurement information system (PROMIS) sleep-related impairment or sleep disturbance) ▪ For second or subsequent renewal requests, stabilization or improvement in one of the following: • AHI • SASHB • Sleep-related patient reported outcomes scores (e.g., Epworth sleepiness scale (ESS), Calgary sleep apnea QOL index (SAQLI), functional outcomes of sleep Questionnaire (FOSQ), patient-reported outcomes measurement information system (PROMIS) sleep-related impairment or sleep disturbance) ○ Documentation that member is actively enrolled in a weight loss program that involves a reduced calorie diet, increased physical activity, and behavioral modification adjunct to therapy ○ Member is adherent to therapy, as evidenced by claims records demonstrating ≥80% fill rate

Review/Revision Date: 02/2026	○ Member has achieved and/or maintained a 5% decrease in weight since baseline **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Glucagon-Like Peptide-1 (GLP-1) Receptor Agonist/Basal Insulin Combination Products Step Therapy**
Drugs	Soliqua (insulin glargine/lixisenatide) Xultophy (insulin degludec/liraglutide)
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 of the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 08/2025	Requests for Soliqua: • Documented trial and failure of or intolerance to one of the following is required: insulin degludec, insulin glargine-yfgn, Rezvoglar, Lantus, Levemir, Toujeo, Trulicity, Ozempic, Victoza, Rybelsus, or Mounjaro Requests for Xultophy: • Documented trial and failure of or intolerance to Soliqua (insulin glargine/lixisenatide) **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Gonadotropin Releasing Hormone (GNRH) Agonist/Antagonists** ****If diagnosis is gender dysphoria, use Medications without Drug or Class Specific Criteria **** ****If diagnosis is cancer, use Oncology Drugs/Therapies criteria****
Drugs	Formulary: Lupron Depot (leuprolide acetate) intramuscular injection Lupron Depot-PED (leuprolide acetate) intramuscular injection Orilissa (elagolix) tablet Synarel (nafarelin acetate) nasal spray Trelstar Mixject (triptorelin pamoate) Non-Formulary: Fensolvi (leuprolide acetate) Myfembree (relugolix, estradiol, and norethindrone acetate) Oriahnn (elagolix, estradiol, and norethindrone acetate) Supprelin LA (histrelin acetate) Triptodur (triptorelin pamoate) Zoladex (goserelin acetate) Any other marketed agent within 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	For Oriahnn, Myfembree, and Orilissa: pregnancy, history of osteoporosis, history of severe hepatic impairment (Orilissa only), history of hepatic impairment (Myfembree and Oriahnn only)
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by, or in consultation with, a specialist in the condition being treated (such as OB/GYN, endocrinologist, etc.)

Coverage Duration	If all of the criteria are met, the request will be approved as outlined below.
	• Central precocious puberty (CPP): 12 months (no maximum total duration)
	• Endometriosis: maximum duration 6 months total, except for the following -
	  o Lupron Depot: maximum duration of 12 months total
	  o Oriahnn, Myfembree, and Orilissa: maximum duration of 24 months total (12 month duration per authorization)
	• Endometriosis with dyspareunia (Orilissa only): maximum duration of 6 months (200 mg twice daily)
	• Uterine fibroids: maximum duration of 6 months total
	• Endometrial thinning to prepare for endometrial ablation: 3 months
	•

Other Criteria	**Initial Authorization:** • Member has a confirmed diagnosis that is indicated in the FDA approved package insert OR is a medically-accepted indication

	• Request is for an appropriate age and dose/duration of therapy based on FDA-approved package insert or supported by relevant standard of care guidelines • There is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, medical contraindication, etc.) to use an appropriate first-line therapy to treat the member's respective condition, based on current standard of care guidelines (if applicable). o For a diagnosis of endometriosis, first-line therapy may include agents such as: hormonal contraceptives, progestins, NSAIDs, etc. o For a diagnosis of uterine fibroids, first-line therapy may include agents such as: hormonal contraceptives, NSAIDS, etc. o For a diagnosis of central precocious puberty: N/A • Requests for a GNRH agonist for use for endometriosis, the member will receive one of the following in conjunction with the GNRH agonist: o Norethindrone acetate 5 mg daily o Conjugated estrogen therapy o Oral bisphosphonate AND calcium and vitamin D supplementation • Requests for Synarel or Trelstar Mixject for endometriosis: o Member has had a documented trial and failure with Lupron Depot OR Orilissa OR a documented medical reason (e.g., intolerance hypersensitivity, contraindication) as to why the member is unable to use these therapies. • Requests for Synarel for CPP o Member has had a documented trial and failure with Lupron Depot or a documented medical reason (e.g., intolerance hypersensitivity, contraindication) as to why the member is unable to use Lupron Depot. • Requests for Orilissa, Oriahnn, or Myfembree: o If member is of childbearing potential, prescriber attests the member is not currently pregnant o Prescriber attests the member does not have a history of osteoporosis o Prescriber attests they have reviewed the member's liver function o For a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids), the request is for Oriahnn or Myfembree only. o For a diagnosis of endometriosis associated with moderate to severe pain, the request is for Orilissa or Myfembree only. • For a diagnosis of endometrial thinning, documentation submitted indicating the member is scheduled for endometrial ablation for dysfunctional uterine bleeding • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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

Revision/Review Date: 08/2025	formulary agent, only that agent must have been ineffective or not tolerated. **Re-authorization:** • Member has a confirmed diagnosis that is indicated in the FDA approved package insert OR is a medically-accepted indication • Request is for an appropriate age and dose/duration of therapy based on FDA-approved package insert or supported by relevant standard of care guidelines • Maximum lifetime treatment duration based on previous dosing and/or hepatic functioning has not been exceeded. • Documentation or provider attestation of positive clinical response (i.e., reduction in pain, reduced menstrual bleeding, slowed puberty, etc.) and medication is being continued as recommended in package insert or standard of care guidelines. • <u>Additionally for Endometriosis renewal requests for GNRH agonists</u>: Negative effects associated with use have been assessed (bone loss/osteoporosis) and appropriate hormonal add-back therapy (such as norethindrone acetate 5 mg daily or conjugated estrogen therapy) or bisphosphonate and calcium + vitamin D is being used to mitigate these effects in combination with GNRH agonist treatment, unless otherwise medically contraindicated. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group	**Growth Hormone (GH) for Growth Failure or GH Deficiency**
Drug(s)	**Formulary:** Omnitrope (somatropin) – preferred agent Genotropin (somatropin) cartridge/MiniQuick Humatrope (somatropin) Norditropin (somatropin) FlexPro Nutropin (somatropin) AQ NuSpin Non-Formulary: Any other marketed agent within 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	Treatment of idiopathic short stature (ISS) is 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 criteria are met, the request will be approved for up to 12 months.
Other Criteria	**<u>Initial Authorization</u>** • If diagnosis is for growth failure associated with chronic kidney disease (CKD), documentation that: either pretreatment height is less than -1.88 standard deviations (SD) below the mean for age or a height velocity-for-age less than 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, the confirmatory genetic test has been documented with the request • If diagnosis is adult-onset GH deficiency (AO-GHD), documentation of one of the following: o Insulin Growth Factor (IGF-1) deficiency (less than -2 SD below reference range for age and sex)* 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 defects o Positive results of stimulatory test (e.g., insulin tolerance test [ITT], glucagon, or macimorelin) • If diagnosis is childhood-onset GH deficiency (CO-GHD): o And member 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 sex)* with prescriber attestation of growth

Review/Revision Date 02/2026	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 member 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 Omnitrope, the provider submitted a documented medical reason (i.e., intolerance) why it is medically necessary to use another agent. • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **<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 sex)*, or if the IGF-1 levels do not 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 sex 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.**

Prior Authorization Group Description	**Healthcare professional (HCP) administered/IV Disease Modifying Therapies (DMTs) for Multiple Sclerosis (MS)**
Drugs	Formulary: Ruxience (rituximab-pvvr) Truxima (rituximab-abbs) Non-Formulary: Briumvi (ublituximab) Lemtrada (alemtuzumab) Ocrevus (ocrelizumab) Ocrevus Zunovo (ocrelizumab/hyaluronidase-ocsq) Riabni (rituximab-arrx) Rituxan (rituximab) Rituxan Hycela (rituximab/hyaluronidase) Tysabri (natalizumab) Tyruko (natalizumab-sztn) Any other marketed agent within 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	Lemtrada: Clinically Isolated Syndrome (CIS), Primary Progressive MS (PPMS) Tysabri, Tyruko, or Briumvi: Primary Progressive MS (PPMS)
Required Medical Information	See "Other Criteria"
Age Restrictions	Members must be age appropriate per prescribing information, 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	**<u>Initial Authorization</u>** <u>Clinically Isolated Syndrome (CIS), Relapsing Remitting MS (RRMS), Secondary Progressive MS (SPMS)</u> • 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] or a documented medical reason (e.g., contraindication, intolerance, hypersensitivity, etc.) for not utilizing these therapies. OR • For members with "highly active" MS requesting Lemtrada (alemtuzumab), Tysabri (natalizumab), Tyruko (natalizumab), or rituximab, a trial with one preferred agent will be acceptable. • If the request is for any medication other than Briumvi (ublituximab), there

	is a documented trial and failure of Briumvi (ublituximab), or medical reason (e.g., intolerance, hypersensitivity, contraindication) why the member cannot use Briumvi • If the request is for Ocrevus (ocrelizumab), Ocrevus Zunovo, Briumvi (ublituximab) or rituximab, documentation of the following o Attestation that the member has been screened for and does not have active hepatitis B virus (HBV) o If the request is for a rituximab product, other than Ruxience documented reason why the member cannot use Ruxience (rituximab) or Truxima (rituximab) • If the request is for Tysabri (natalizumab) or Tyruko (natalizumab-sztn), documentation of the following: o Member does not have a history of progressive multifocal leukoencephalopathy (PML) o Documentation consistent with pharmacy claims data indicating the member is not currently using any antineoplastic, immunosuppressant, or immunomodulating medications • If the request is for Rituxan Hycela (rituximab/hyaluronidase), all of the above AND documented medical reason why the member cannot use Rituxan (rituximab). <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, or rituximab, documentation of the following has been submitted o Attestation that the member has been screened for and does not have active HBV • If the request is for a rituximab product other than Ruxience (rituximab), documented reason why the member cannot use Ruxience (rituximab) or Truxima (rituximab) • If the request is for Rituxan Hycela (rituximab/hyaluronidase), all of the above AND documented medical reason why the member cannot use Rituxan (rituximab). **<u>Reauthorization</u>** <u>CIS</u> • 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)

Revision/Review Date: 02/2026	• 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 that at least 12 months has or will have elapsed since previous treatment
	• If the request is for Tysabri (natalizumab) or Tyruko (natalizumab-sztn), documentation of the following has been submitted:
	  o Member does not have a history of PML
	  o Documentation consistent with pharmacy claims data was submitted indicating the member is not currently using any antineoplastic, immunosuppressant, or immunomodulating medications
	
	<u>Continuation of Therapy Provision:</u>
	Members with history of a non-formulary product (within the past 180 days or past 12 months for Lemtrada [alemtuzumab]) 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.

HEPATITIS C TREATMENT

MAVYRET (Glecaprevir/Pibrentasvir) – PREFERRED AGENT
SOFOSBUVIR/VELPATASVIR (GENERIC EPCLUSA) – PREFERRED AGENT
LEDIPASVIR/SOFOSBUVIR (GENERIC HARVONI) – PREFERRED AGENT
VOSEVI (sofosbuvir/ velpatasvir/voxilaprevir) – PREFERRED AGENT
PEG-INTRON/ PEGASYS (peginterferon alfa-2a)
OR ANY OTHER MARKETED AGENT for treatment of Hepatitis C

Where applicable and appropriate: MAVYRET (Glecaprevir/Pibrentasvir), SOFOSBUVIR/VELPATASVIR (GENERIC EPCLUSA), LEDIPASVIR/SOFOSBUVIR (GENERIC HARVONI), or VOSEVI (sofosbuvir/ velpatasvir/voxilaprevir) 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), ledipasvir/sofosbuvir (generic Harvoni), or Vosevi (sofosbuvir/ velpatasvir/voxilaprevir).

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. The drug is being prescribed by a specialist in hepatology/gastroenterology/infectious disease/HIV/or liver transplant.
3. Member is 3 years of age or older.
4. Provider attests that member does not have limited life expectancy of less than 12 months due to non-liver related comorbid conditions.
5. Provider attests that they have documentation of ALL of 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
6. 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
7. 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).
8. 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.
9. Provider attests that member is committed to treatment plan, including lab monitoring and sustained virologic response (SVR12) lab testing will be completed and submitted to health plan.
10. The following lab testing is required before treatment (copies of labs required)
    - Genotype (and subtype if provided) must be provided for:
        - Members who are not going to receive Mavyret or generic Epclusa
        - Generic Epclusa in treatment naive members with compensated cirrhosis
        - Members 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 for:

- 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

11. 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 (sofosbuvir/velpatasvir) and Harvoni (ledipasvir/sofosbuvir) 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**	**8 weeks**
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 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 for patients with genotype 1.

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^**
	Mavyret*	**16 weeks**	**16 weeks**
Mavyret	**Mavyret plus Sovaldi and ribavirin**	**16 weeks**	**16 weeks**
	Vosevi	**12 weeks**	**12 weeks$^{\beta}$**
Multiple including Vosevi or Sovaldi plus Mavyret	**Mavyret plus Sovaldi and ribavirin**	**16 weeks$^{\mu}$**	**16 weeks$^{\mu}$**
	Vosevi plus ribavirin	**24 weeks**	**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.

^If the member has genotype 3 and compensated cirrhosis, add weight-based ribavirin if no contraindications.

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

$^{\beta}$Addition of weight-based ribavirin is recommended for compensated cirrhosis

For unique patient populations, (e.g. Decompensated Cirrhosis, Post-Transplant, etc. not addressed in previous tables), refer to current AASLD guidelines @ http://www.hcvguidelines.org/ **NOTE**: If Mavyret, Epclusa, or Harvoni are recommended treatment options, they are preferred unless medical reason is provided that member is unable to use Mavyret, Epclusa, or Harvoni.	
Decompensated Cirrhosis (Child-Pugh B or C)	
Post-Transplant	
Hepatocellular Carcinoma	
Pediatrics	*If member is at least 35 kg and the request is for Harvoni or Sovaldi, the medication is being prescribed no more than one tablet daily. * If member is at least 35 kg and the request is for Harvoni or Sovaldi oral pellets, medical reasoning is required as to why member is unable to use oral tablets at a one tablet daily dosage. *If member is between 17 and 30 kg and the request is for Brand Epclusa 200 mg/100, the request can be approved without providing medical justification for not using sofosbuvir/velpatasvir (generic Epclusa). *If member is between 17 and 35 kg and the request is for Brand Harvoni 45 mg/200 mg oral tablets or pellets, or patient is under 17 kg and the request is for Brand Harvoni 33.75/150 mg oral pellets, the request can be approved without providing medical justification for not using ledipasvir/sofosbuvir (generic Harvoni). *If member is at least 45 kg or 12 years of age and the request is for Mavyret 50/20 mg pellet packs, medical reasoning is required as to why member is unable to use Mavyret 100 mg/40 mg oral tablets. *If member is less than 45 kg or under 12 years of age, the request for Mavyret 50/20 mg pellet packs can be approved without providing medical justification for not using Mavyret 100 mg/40 mg tablets.

Review/Revision Date: 08/2025

Prior Authorization Group Description	**Hetlioz (tasimelteon)**
Drugs	tasimelteon (Hetlioz) capsules Hetlioz LQ (tasimelteon) 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	According to package insert
Prescriber Restrictions	Prescribed by a sleep specialist or specialist in the treatment of the disease of the member, or documentation has been provided that prescriber has consulted with a sleep specialist or other specialist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Other Criteria Revision/Review Date 08/2025	**<u>Initial Authorization</u>** Non-24-Hour Sleep-Wake Disorder (N24SWD)-**Hetlioz Only** • Member has a diagnosis of N24SWD AND is blind • Member has attempted a 3-month treatment course of melatonin or has intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) • The request is for an FDA approved dose Nighttime Sleep Disturbances in Smith-Magenis Syndrome (SMS) • Member has a diagnosis of SMS with a history of nighttime sleep disturbances • Member has attempted a 3-month treatment course of melatonin or has intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) • If less than 15 years of age, documentation of member's weight has been provided • The request is for an FDA approved dose **<u>Reauthorization</u>** • Provider attests that member has had an improvement of overall sleep quality • If less than 15 years of age, documentation of member's weight has been provided • 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.**

Prior Authorization Group Description	**HIF-PH Inhibitors**
Drugs	Vafseo (vadadustat) Any other marketed agent within 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	Diagnosis of uncontrolled hypertension
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be at least 18 years of age
Prescriber Restrictions	Prescribed by a hematologist or nephrologist
Coverage Duration	If all of the criteria are met, the request will be approved with a 12 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 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 • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **Reauthorization:** • All submitted lab results have been drawn within 30 days of the reauthorization request. • Member has a documented increase in hemoglobin from baseline • 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%)

Revision/Review Date: 02/2026	• 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**

Prior Authorization Group Description	**High Potency Topical Steroids Step Therapy**
Drugs	Desoximetasone 0.25% Liquid Desoximetasone 0.05% Gel Halcinonide 0.1% Cream
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 of the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 08/2025	1. Prior use of three of the following is required: a. Betamethasone dipropionate 0.05% augmented cream b. Betamethasone dipropionate 0.05% ointment c. Desoximetasone 0.25% cream, ointment d. Fluocinonide 0.05% cream, ointment, gel, or solution **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Desc	**Hyaluronic Acid Derivatives**
Drug(s)	**Formulary:** Euflexxa, Gelsyn-3 **Non-Formulary:** Durolane, Gel-One, GenVisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz FX, TriVisc, Visco-3, 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 physical medicine/rehabilitation physician (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 a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **Reauthorization:** • Documentation was submitted that the member had a response in the treated knee(s) that lasted at least 6 months (e.g., decreased joint pain or stiffness, improved range of motion, etc.). • Documentation was submitted that the member 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 a non-formulary agent, the member has a documented trial

Revision/Review Date: 02/2026	and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

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 of the criteria are met, the request will be approved for up to 12 months.

Other Criteria
 	
Revision/Review Date: 02/2026
	<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
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Prior Authorization Group Description	**Insulin-Like Growth Factor-1 Receptor (Igf-1r) Antagonists For Thyroid Eye Disease**
Drugs	Non-Formulary: Tepezza (teprotumumab-trbw) Any other marketed agent within this 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	See "Other Criteria"
Age Restrictions	Member must be 18 years age or older
Prescriber Restrictions	Prescribed by 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
 	
Revision/Review Date 02/2026
	<u>Initial Authorization:</u>
	• Dosing does not exceed dosing guidelines as outlined in the package insert
	• Member has a confirmed diagnosis of Graves' disease
	• One of the following:
	  o Moderate to severe active TED with CAS ≥4 and at least one of the following:
	  ▪ Eyelid retraction of ≥2mm
	  ▪ Moderate or severe soft-tissue involvement
	  ▪ Proptosis ≥3mm above normal values for race and sex
	  ▪ Periodic or constant diplopia
	  o Chronic TED with one of the following:
	  ▪ ≥3-mm increase in proptosis from before diagnosis of TED
	  ▪ Proptosis ≥3 mm above normal values for race and sex
	• Member must be euthyroid or thyroxine and free triiodothyronine levels are less than 50% above or below normal limits (submit laboratory results with request)
	• Members of reproductive potential: attestation the member is not pregnant, and appropriate contraception methods will be used before, during, and 6 months after the last infusion
	• For active disease: Member has had a trial and therapy failure of, or contraindication to oral or IV glucocorticoids
	
	<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.

Prior Authorization Group Description	**Ileal bile acid transporter inhibitor (IBAT)**
Drugs	Formulary: Bylvay (odevixibat) Livmarli (maralixibat) Non-Formulary: Any other marketed agent within 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	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist or hepatologist
Coverage Duration	If all of the criteria are met, the request will be approved for a 12 month duration.

Other Criteria	**Initial Authorization:**
	
	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 member 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 member's weight
	• Prescriber attests to monitor liver function tests and fat soluble vitamin (FSV) levels during treatment
	• Baseline serum bile acid level
	• Documentation of trial and failure ORcontraindication 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
	
	Alagille Syndrome
	• Diagnosis of Alagille syndrome (ALGS)
	• Documented history of moderate to very severe pruritus
	• Baseline serum bile acid level is provided

Revision/Review Date: 08/2025	• Documentation of member's weight
	• Prescriber attests to monitor liver function tests and fat soluble vitamin (FSV) levels during treatment
	• 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
	• The prescribed dose is within FDA approved dosing guidelines
	
	If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated.
	
	Reauthorization:
	• Documentation of clinical benefit indicated by the following:
	  o An improvement in pruritus (e.g., improved observed scratching, decreased sleep disturbances/nighttime awakenings due to scratching, etc.) AND
	  o Reduction in serum bile acid level from baseline
	• Documentation of member's weight
	• Prescriber attests to monitor liver function tests and FSV levels during treatment
	• Prescriber attests that member 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.

Prior Authorization Group Description	**Immune Globulins**
Drugs	Formulary: Gamunex-C (IV or SQ) (Immune Globulin) - *Preferred for all applicable indications* Alyglo (IV) (Immune Globulin-stwk) Asceniv (IV) (Immune Globulin-slra) Bivigam (IV) (Immune Globulin) Cutaquig (SQ) (Immune Globulin-hipp) 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) Hyqvia (SQ) (Immune Globulin Human/Recombinant Human Hyaluronidase) Octagam (IV) (Immune Globulin) Panzyga (IV) (Immune Globulin-ifas) Privigen (IV) (Immune Globulin) Xembify (SQ) (Immune Globulin-klhw) Non-Formulary: Any other marketed agent within 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), substantially accepted peer reviewed medical literature, 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 specialist in the disease state being treated
Coverage Duration	If all of 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	**<u>All Requests:</u>** • 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

	○ 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) • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **Primary Immunodeficiency***: • Member's IgG level is provided and below normal for requested indication, or a documented specific antibody deficiency • Clinically 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 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 are 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, and X-linked Hyper IgM syndrome **Idiopathic Thrombocytopenic Purpura, acute and chronic**: • Acute: ○ Member has active bleeding, is requiring an urgent invasive procedure, is deferring splenectomy, has platelet counts < 20,000/ul at risk for intra-cerebral hemorrhage or life-threatening bleeding, or has inadequate increase in platelets from corticosteroids or unable to tolerate corticosteroids. ○ Dose does not exceed 1g/kg daily for up to 2 days, or 400mg/kg daily for 5 days • Chronic: ○ Duration of illness is greater than 12 months ○ 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 are met, approve for up to 5 days. **<u>Kawasaki disease</u>:** • Immunoglobulin is being given with high dose aspirin unless contraindicated • Requested dose does not exceed a single 2g/kg dose • If criteria are met, approve for 1 dose **<u>Chronic B-cell lymphocytic leukemia</u>:** • The member has had recurrent infections requiring IV antibiotics or hospitalization and has a serum IgG level of < 500 mg/dL • Dose does not exceed 500mg/kg every 4 weeks • If criteria are met, approve for 3 months. **<u>Bone marrow transplantation:</u>** • The member has bacteremia or recurrent sinopulmonary infections and their IgG level is < 400mg/dL • Dose does not exceed 500 mg/kg/wk for the first 100 days post-transplant • Dose does not exceed 500 mg/kg/dose every 3-4 weeks 100 days after transplant • If criteria are met, approve for 3 months. **<u>Pediatric HIV</u>**: • Member is < 13 years of age • Either member's IgG level is < 400mg/dL OR if member's IgG level is ≥ 400 mg/dL then 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 bacterial infections despite prophylactic antibiotics • Dose does not exceed 400mg/kg/dose every 2 to 4 weeks • If criteria are met, approve for 3 months. **<u>Multifocal motor neuropathy (MMN)</u>**: • 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 are 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.
	• Member has tried and failed, or has a documented medical reason for not using corticosteroids.
	  o If the member 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
	• If criteria are met, approve for 3 months
	
	Guillain-Barre syndrome:
	• Member 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 are met, approve for up to 5 days.
	
	Myasthenia Gravis:
	• Acute:
	  o Member 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
	  o Dose does not exceed 2 g/kg administered over 2-5 days
	  o If criteria are met, approve for up to 5 days
	• Chronic:
	  o Diagnosis of refractory generalized myasthenia gravis
	  o Member 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)
	  o Dose does not exceed 2 g/kg/month administered over 2-5 days
	  o If criteria are met, approve for 3 months.
	
	Dermatomyositis (DM):
	• One of the following:
	  o Bohan and Peter score of 3 (i.e., definite DM)

Revision/Review Date 11/2025	○ Bohan and Peter score of 2 (i.e., probable DM) AND concurring diagnostic evaluation by ≥ 1 specialist (e.g., neurologist, rheumatologist, dermatologist) • Member 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. **Medical Director/Clinical Reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Immunoglobulin A (IgA) Nephropathy Agents**
Drugs	Non-Formulary: Fabhalta (iptacopan) Filspari (sparsentan) Tarpeyo (budesonide) Vanrafia (atrasentan) Voyxact (sibeprenlimab-szsi) Any other marketed agent within 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	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 all of the criteria are met, the criteria will be approved as follows: Initial requests: • 6 months: Fabhalta • 9 months: Filspari, Tarpeyo, Vanrafia, Voyxact Reauthorization: • 12 months: Fabhalta, Filspari, Vanrafia, Voyxact • 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 is on an SGLT2 inhibitor 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 ≥0.5 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 member 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 o Documentation of trial and failure, intolerance or contraindication to Filspari • For Filspari:

Review/Revision Date: 02/2026	○ Documentation of baseline liver function ○ Attestation that member will discontinue use of renin-angiotensin-aldosterone system (RAAS) inhibitors, endothelin receptor antagonists, and/or aliskiren upon initiation of Filspari • For Vanrafia: ○ Member is at risk for disease progression as defined by a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g ○ Documentation of trial and failure, intolerance or contraindication to Filspari • For Voyxact: ○ Documentation of trial and failure, intolerance or contraindication to Tarpeyo **<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: ○ Documentation of liver function ***Reauthorization requests will not be allowed as the safety and efficacy of subsequent courses of Tarpeyo have not been established*** **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Immunosuppressants for Lupus Nephritis**
Drugs	Formulary: Lupkynis (voclosporin) Non-Formulary: Any other marketed agent within this 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), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by rheumatologist, nephrologist, or other specialist in the treatment of autoimmune disorders
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 05/2025	**<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 >45mL/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 • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **<u>Reauthorization</u>** • Documentation of improvement in renal function (i.e., reduction in UPCR or no confirmed decrease from baseline eGFR ≥ 20%) • Prescriber attestation that eGFR will be assessed quarterly • 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.**

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	According to package insert
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 criteria are met, the request will be approved for 12 months.

Other Criteria	**Initial Authorization**
	• 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 by both of the following:
	  ▪ 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
	
	Reauthorization
	• 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

Revision/Review Date 05/2025	**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)	Formulary: Cayston (aztreonam lysine) Pulmozyme (dornase alfa) Tobramycin 300 mg/5ml (Tobi) Non-Formulary: Bronchitol (mannitol) Kitabis Pak (tobramycin) Tobi/Tobi Podhaler (tobramycin) tobramycin 300mg/4mL (Bethkis) Any other marketed agent within 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), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by a pulmonologist or infectious disease specialist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Other Criteria Review/Revision Date: 02/2026	• Request is for an FDA approved indication and within dosing guidelines • If the request is for Pulmozyme (dornase alfa) for a member with **mild** disease, a trial of generic hypertonic saline nebulization solution (sodium chloride 3% or 7%) is required • If the request is for Bronchitol (mannitol), a trial of generic hypertonic saline nebulization solution (sodium chloride 3% or 7%) is required • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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 Any other marketed agent within the class
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), substantially accepted peer reviewed medical literature, 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	Prescribed by an oncologist
Coverage Duration	If all of the criteria are met, the request will be approved for up to 6 months.
Other Criteria	• If the request is for Xgeva (denosumab) or an Xgeva biosimilar, the member 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 member 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 • The request is for an approved/accepted indication at an approved dose • If the request is for Xgeva (denosumab) or an Xgeva biosimilar for any of the indications below, the member 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 • 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

Revision/Review 11/2025	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 is for Prolia (denosumab) or a Prolia biosimilar for breast cancer, the member 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	**Injectable/Infusible Bone-Modifying Agents for Osteoporosis and Paget's Disease**
Drugs	**Formulary, Pharmacy Benefit:** teriparatide (Forteo biosimilar) Tymlos (abaloparatide) Bildyos (denosumab-nxxp) **Non-Formulary, Pharmacy Benefit:** Prolia (denosumab) Prolia biosimilars Any other marketed agent within the class **Medical Benefit:** Pamidronate Ibandronate (Boniva) Zoledronic acid (Reclast) Evenity (romosuzumab-aqqg)
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, rheumatologist, orthopedist, or obstetrician/gynecologist
Coverage Duration	If all of the criteria are met, requests will be approved for 12 months. *** TERIPARATIDE /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	**<u>For all Requests</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 • The member is taking calcium and vitamin D • 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 request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. <u>If the diagnosis is postmenopausal or male osteoporosis</u>: • 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 the request is for very high risk postmenopausal osteoporosis or postmenopausal osteoporosis with prior fractures, a documented trial and failure of an oral bisphosphonate is not 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%) • If request is for Forteo, teriparatide biosimilars, Tymlos (abaloparatide), or Evenity (romosozumab) **ONE** of the following applies: o Documented trial and failure of denosumab product **AND EITHER** ibandronate (Boniva) injection **OR** zoledronic acid (Reclast) or a medical reason (e.g. intolerance, contraindication, etc.) why these therapies are not suitable is provided o Has SEVERE osteoporosis (T-Score -3.5 or below, or T-Score of -2.5 or below plus a fragility fracture) • 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>: • 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>:

Revision/Review Date: 11/2025	• For members ≥ 40 years of age on long-term glucocorticoid therapy:
	  o Dosage of the glucocorticoid therapy is equivalent to a dose greater than 2.5 mg of prednisone per day
	  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 to 10% (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
	  ▪ 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) 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.) 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.

Prior Authorization Group Description	**Janus Kinase Inhibitors for Nonsegmental Vitiligo**
Drugs	Formulary: Opzelura (ruxolitinib) Non-Formulary: Any other marketed agent within 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), 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 all of the criteria are met, the request will be approved with up to a 6 month duration and reauthorization requests will be approved up to a 12 month duration.

Other Criteria
 	
Revision/Review Date 11/2025
	Initial Authorization
	• Diagnosis of nonsegmental vitiligo
	• Documentation of depigmented lesions including measurements and locations is provided
	• Prescriber attests that the total body vitiligo area (facial and nonfacial) being treated does not exceed 10% BSA
	• Trial and failure of, or intolerance to, ALL of the following:
	  o Topical corticosteroids
	  o Topical calcineurin inhibitors
	  o Targeted phototherapy
	• Prescriber attests that the member will not concomitantly use therapeutic biologics, other Janus kinase inhibitors, potent immunosuppressants, or phototherapy for repigmentation purposes
	• Request is for an FDA-approved dose
	• If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated.
	
	****A MAXIMUM OF ONE 60 GRAM TUBE OF OPZELURA PER WEEK OR ONE 100 GRAM TUBE EVERY TWO WEEKS MAY BE APPROVED****
	
	Reauthorization
	• 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)
	• 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	**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	According to package insert
Prescriber Restrictions	Prescribed by an immunologist, hematologist, medical geneticist, or other prescriber who specializes in the treatment of genetic or immunologic disorders.
Coverage Duration	If all of the criteria are met, the request will be approved for a 12-month duration.
Other Criteria Revision/Review Date 08/2025	**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.**

Prior Authorization Group Description	**Ketamine**
Drugs	Non-Formulary: 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	If all of the criteria are met, initial authorization and reauthorization requests may be approved for up to 12 months.
Other Criteria Revision/Review Date 02/2026	**<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 member cannot use preferred alternative(s). **Re-authorization:** • Documented or attestation 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) • Member has tried and failed at least 8 weeks treatment with or continues to receive physical therapy (PT) and/or occupational therapy (OT). • Member has tried and failed at least two of the following: o NSAIDs o Anticonvulsants (e.g., gabapentin, pregabalin) o Antidepressants (e.g., SNRIs, TCAs) o Bisphosphonate (in the setting of abnormal uptake on bone scan) **Re-authorization:** • Documented or attestation 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	**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	Prescribed by a neurologist
Coverage Duration	For initial authorization: if all of the criteria are met, the request will be approved in accordance with the FDA-indicated titration schedule for up to 6 months For reauthorization: if all of the criteria 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.) • 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

Revision/Review Date: 05/2025	• Member 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.

Prior Authorization Group Description	**Long-acting muscarinic antagonist (LAMA) and Long-acting Beta(2) Agonists (LABA) and Inhaled Corticosteroid (ICS)/LAMA/LABA Products Step Therapy**
Drugs	Umeclidinium/vilanterol (Anoro Ellipta)
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 of the criteria are met, the request will be approved for up to a 12 month duration.
Other Criteria	For LAMA/LABA (Anoro Ellipta): 1. Prior use of BOTH of the following is required: a. Bevespi Aerosphere (glycopyrrolate/formoterol) b. Stiolto Respimat (tiotropium/olodaterol) **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents.
Revision/Review Date 11/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Lantidra (donislecel)**
Drugs	Lantidra (donislecel)
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	Prescribed by or in consultation with an endocrinologist
Coverage Duration	If all of the criteria are met, the request will be approved for one infusion. A member may only receive a maximum of 3 infusions per lifetime as there is no data regarding the efficacy or safety for treatment with more than 3 infusions.

Other Criteria	**<u>Initial Authorization</u>**
	• Documentation of Type 1 Diabetes diagnosis for more than 5 years
	• Documentation of blood glycated hemoglobin (HbA1c) above target goal
	• Documentation of intensive insulin management efforts (i.e., adjusting insulin regimen to multiple daily injections, frequently monitoring blood glucose levels daily, the use of devices such as a continuous glucose monitor, etc.)
	• Member has at least one of the following, despite intensive insulin management efforts:
	  o Inability to sense hypoglycemia until the blood glucose falls to less than 54 mg/dL
	  o At least 1 or more episodes of severe hypoglycemia (blood glucose below 50 mg/dL) in the past 3 years
	• Provider must confirm the following:
	  o Blood glycosylated hemoglobin (HbA1c) is not higher than 12%
	  o Member has an insulin requirement of no more than 0.7 International Units (IU)/kilogram/day
	  o Member has a Body Mass Index (BMI) less than 27 kg/m^2
	  o Member is not diagnosed with a psychiatric disorder (i.e., schizophrenia, bipolar disorder, or major depression)
	  o Member does not have severe cardiac disease as defined by: Recent myocardial infarction within the past 6 months, angiographic evidence of non-correctable coronary artery disease, or evidence of ischemia on a functional cardiac exam
	• Provider attests that member will be receiving concomitant immunosuppression therapy
	• Drug is being requested at an FDA-approved dose
	• Member's weight
	
	<u>Reauthorization</u>
	• Member has not achieved independence from exogenous insulin within one year of infusion OR member has lost independence from

Revision/Review Date: 11/2025	exogenous insulin within one year after a previous infusion • Provider attests that member will be receiving concomitant immunosuppression therapy • Drug is being requested at an FDA-approved dose • Member's weight **Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Leqembi (lecanemab-irmb)**
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	50-90 years old
Prescriber Restrictions	Prescribed by a neurologist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.

Other Criteria	**Initial Authorization**
	• 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.
	
	Reauthorization
	• The request is for an FDA approved dose

Revision/Review Date: 05/2025	• Member 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
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Prior Authorization Group Description	**Leukotriene Modifiers Step Therapy**
Drugs	Zafirlukast oral tablets Zileuton ER oral 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 all of the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 02/2026	1. For Zafirlukast requests, prior use of montelukast is required 2. For Zileuton ER requests, prior use of both montelukast and zafirlukast is required **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Levalbuterol Nebulization Solution Step Therapy**
Drugs	Levalbuterol 0.31 mg/3 mL, 0.63 mg/3 mL, 1.25 mg/3 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	N/A
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 08/2025	1. Prior use of albuterol required **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Lidocaine Topical Patch**
Drugs	Formulary: Lidocaine 5% topical patch (Lidoderm) Ztlido 1.8% topical patch (lidocaine) Non-Formulary: Any other marketed agent within 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	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 08/2025	• 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) • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Lodoco (colchicine)**
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	According to package insert
Prescriber Restrictions	Prescribed 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
 	
Review/Revision Date: 11/2025
	• Member has established atherosclerotic disease or multiple risk factors for cardiovascular disease
	• Member 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 member's specific risk factors are being maximized, such as medications targeted at reduction in cholesterol, blood pressure, antiplatelet therapies, and diabetes
	• Member does not have pre-existing blood dyscrasias (ex. leukopenia, thrombocytopenia)
	• Member does not have renal failure (CrCl less than 15 ml/min) or severe hepatic impairment
	• Member is not currently taking medications contraindicated for concurrent use with Lodoco
	  ○ Strong CYP3A4 inhibitors (ex. atazanavir, clarithromycin, darunavir/ritonavir, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, tipranavir/ritonavir)
	  ○ P-glycoprotein inhibitors (ex. cyclosporine, ranolazine)
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Prior Authorization Group	**Long Acting Injectable Antipsychotics**
Drug(s)	Formulary: Erzofri (paliperidone palmitate) Invega Sustenna, Invega Trinza, Invega Hafyera (paliperidone palmitate) Rykindo, Uzedy (risperidone) Non-Formulary: Any other marketed agent within 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), and the Drug Package Insert.
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 psychiatrist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 month duration.
Other Criteria Revision/Review Date 08/2025	<u>Initial authorization:</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 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 received a least one three-month cycle of Invega Trinza OR the member has been stable on Invega Sustenna for 4 months and at the same dose for the last 2 months. • If request is for Aristada Initio, only a single dose will be approved if documentation has been provided that the member is initiating Aristada • If request is for Risperdal Consta, Rykindo, or Uzedy, documentation of trial and failure, intolerance or contraindication to risperidone (generic for Risperdal Consta • Request is for FDA approved indication at an approved dose • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. <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 **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Prior Authorization Group Description	**Low Potency Topical Steroids Step Therapy**
Drugs	Desonide Lotion 0.05% External Fluocinolone 0.01% Cream
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 of the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 08/2025	1. Prior use of three of the following is required: a. Alclometasone 0.05% ointment or cream b. Betamethasone valerate 0.1% lotion c. Desonide 0.05% cream d. Fluocinolone 0.01% solution e. Triamcinolone acetonide 0.025% cream, lotion **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Lower-Mid Potency Topical Steroids Step Therapy**
Drugs	Fluticasone Propionate Lotion 0.05% Hydrocortisone butyrate 0.1% lotion, ointment, solution, cream
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 of the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 08/2025	1. Prior use of three of the following is required: a. Betamethasone dipropionate 0.05% lotion b. Betamethasone valerate 0.1% cream c. Desonide 0.05% ointment d. Fluocinolone 0.025% cream e. Hydrocortisone valerate 0.2% cream f. Triamcinolone 0.025% ointment g. Triamcinolone 0.1% lotion **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Medications for Use in ADHD Treatment for Members 21 and Older**
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	Preferred drugs will pay for members 20 and younger; PA required for members 21 and older
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Other Criteria	• Prescriber attests that the Diagnostic and Statistical Manual of Mental Disorders V (DSM-5) criteria for diagnosis of ADHD in adults has been met. • Appropriate dose of medication based on age and indication. • Behavioral modification techniques have been tried prior to medication being prescribed • The member is not on another stimulant with the same duration of action (i.e., short-acting or long-acting) simultaneously. • The member is not concurrently taking a benzodiazepine with the exception of medication required for a seizure diagnosis. If a benzodiazepine is required, appropriate documentation has been provided by the prescriber indicating justification. • If the request is for a non-preferred or non-formulary medication, documented trial and failure or intolerance to two preferred medications used to treat the documented diagnosis.
Revision/Review Date: 02/2026	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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/Therapies 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 criteria are met, the request will be approved for up to a 12 month duration (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") • Member meets one of the three following criteria: o Documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. o No other formulary medication has a medically accepted use for the member's specific diagnosis as referenced in the medical compendia. o All other formulary medications are contraindicated based on the member's diagnosis, other medical conditions, or other medication therapy. **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:** o 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 o 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 **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**
Revision/Review Date 11/2025	

Prior Authorization Group Description	**Medium Potency Topical Steroids Step Therapy**
Drugs	Clocortolone Pivalate Cream 0.1 % Hydrocortisone valerate 0.2% ointment
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 of the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 08/2025	1. Prior use of three of the following is required: a. Fluocinolone 0.025% ointment b. Fluticasone propionate 0.05% cream c. Mometasone furoate 0.1% cream, solution d. Triamcinolone 0.05% ointment e. Triamcinolone 0.1% ointment or cream **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Medium-High Potency Topical Steroids Step Therapy**
Drugs	Desoximetasone 0.05% Cream, Ointment
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 of the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 08/2025	1. Prior use of three of the following is required: a. Betamethasone dipropionate 0.05% cream b. Betamethasone valerate 0.1% ointment c. Fluticasone propionate 0.005% ointment d. Mometasone 0.1% ointment e. Triamcinolone 0.5% ointment or cream **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**MEK Inhibitors for Neurofibromatosis Type 1 (NF1)**
Drugs	**Formulary:** Koselugo (selumetinib) **Non-Formulary:** Gomekli (mirdametinib) Any other marketed agent in this 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	Prior use of a MEK inhibitor
Required Medical Information	See "Other Criteria"
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 12 months.
Other Criteria Review/Revision Date: 05/2025	**<u>Initial Authorization:</u>** • 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 • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **<u>Re-Authorization:</u>** • Documentation or provider attestation of positive clinical response (i.e. no evidence of progressive disease) • 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.**

Prior Authorization Group Description	**Mucopolysaccharidosis II (Hunter Syndrome) Agents**
Drugs	Non-Formulary: Elaprase (idursulfase) Any other marketed agent within 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	N/A
Required Medical Information	"See Other Criteria"
Age Restrictions	Member is ≥ 16 months of age
Prescriber Restrictions	Prescribed by or in consultation with a specialist experienced in the management of Mucopolysaccharidosis II (geneticist, endocrinologist, neurologist, rheumatologist, etc)
Coverage Duration	If all of the criteria are met, requests will be approved for up to 12 months.

Other Criteria	**<u>Initial Authorization</u>**
	• 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
	• Member's weight
	• Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines
	• If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated.
	
	<u>Reauthorization</u>
	• Member 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.)
	• Member's weight
	• Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines

Revision/Review Date 05/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Mucopolysaccharidosis VI (Maroteaux-Lamy Syndrome) Agents**
Drugs	Non-Formulary: Naglazyme (galsulfase) Any other marketed agent within 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	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, initial authorization requests may be approved for up to 6 months and reauthorization requests may be approved for up to 12 months.

Other Criteria
 	
Revision/Review Date 11/2025
	<u>Initial Authorization</u>
	• 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
	• Member's weight
	• Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines
	
	<u>Reauthorization</u>
	• Member 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.)
	• Member'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.

Prior Authorization Group Description	**Multi-drug Resistant (MDR) Tuberculosis (TB) Antibacterials**
Drugs	Formulary: Sirturo (bedaquiline) Pretomanid Non-Formulary: Any other marketed agent within 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	Drug-sensitive (DS) TB Latent TB infection
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a TB expert (TB experts can be found through CDC-supported TB Centers of Excellence for Training, Education, and Medical Consultation (http://www.cdc.gov/tb/education/rtmc/default.htm), through local health department TB control programs (https://www.cdc.gov/tb/links/tboffices.htm), and through international MDR-TB expert groups such as the Global TB Network.
Coverage Duration	Sirturo (bedaquiline): If all of the criteria are met, requests will be approved for up to12 months with a maximum of one additional 12 month authorization period (24 months total). Pretomanid: If all of the criteria are met, the request will be approved for up to 9 months.
Other Criteria	**Initial Authorization** Request for Sirturo (bedaquiline) • Diagnosis is laboratory confirmed pulmonary MDR-TB or RR-TB with an isolate showing genotypic or phenotypic resistance to RIF Is being prescribed in combination with other medications to treat TB Request for Pretomanid • Diagnosis is laboratory confirmed pulmonary extensively drug resistant (XDR)-TB or MDR-TB or RR-TB with an isolate showing genotypic or phenotypic resistance to RIF. • Is being used in combination with other medications to treat TB All requests • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent

Revision/Review Date 02/2026	must have been ineffective or not tolerated. **<u>Reauthorization</u>** • Provider attests that member is having a positive response to treatment. • Medial justification (e.g., extensively drug resistant [XDR]-TB) for requests exceeding "Coverage Duration" limits. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Myasthenia Gravis Agents**
Drugs	Non-Formulary: Vyvgart (efgartigimod), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase), Rystiggo (rozanolixizumab), Soliris (eculizumab), Ultomiris (ravulizumab), Zilbrysq (zilucoplan), BKEMV (eculizumab-aeeb), Epysqli (eculizumab-aagh), Imaavy (nipocalimab-aahu) Any other marketed agent within 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	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 request will be approved for 12 months.
Other Criteria	****Drug is being requested through the member's medical benefit**** **<u>Initial Authorization:</u>** • For diagnosis of Chronic Inflammatory Demyelinating Polyneuropathy, refer to the "Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Agents" policy • Diagnosis of generalized myasthenia gravis (gMG) • Member has a positive serological test for one of the following: o Anti-AChR antibodies o Anti-muscle-specific tyrosine kinase (MuSK) antibodies (Rystiggo and Imaavy only) • Member has a Myasthenia Gravis Foundation of America (MGFA) clinical classification of class II, III or IV • Member has tried and failed, or has contraindication, to one of the following: o Trial and failure of at least 1 conventional therapy (i.e. acetylcholinesterase inhibitors, corticosteroids, non-steroidal immunosuppressive therapies) o Member requires maintenance plasma exchange or intravenous immunoglobulin to control symptoms • Medication is prescribed at an FDA approved dose • Member is not using agents covered by this policy concurrently (i.e., no concurrent use of Vyvgart, Vyvgart Hytrulo, Rystiggo, Soliris, BKEMV, Epysqli, Zilbrysq, Imaavy, or Ultomiris) • For Vyvgart Hytrulo, member has tried and failed, or has

Revision/Review Date: 08/2025	contraindication, to Vyvgart • Requests for Imaavy, Soliris, BKEMV, Epysqli, Ultomiris, and Zilbrysq will also require all of the following: o For adults: member has tried and failed, or has contraindication, to Vyvgart, Vyvgart Hytrulo, or Rystiggo. o All ages: documentation member complies with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against meningococcal infections in members receiving a complement inhibitor. • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **<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. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Nemluvio (nemolizumab-ilto)**
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 of the criteria are met, the request will be approved for 12 months.

Other Criteria
 	
Revision/Review Date: 02/2026
	<u>Initial Authorization:</u>
	• Diagnosis of severe prurigo nodularis (PN) with ≥ 6 weeks of pruritus
	• Member has ≥ 20 PN lesions
	• Documentation of member's 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's weight
	• 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.

Prior Authorization Group Description	**Niemann-Pick Disease Type C**
Drugs	Non-Formulary: Aqneursa (levacetylleucine) Miplyffa (arimoclomol) Any other marketed agent within 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	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 of the criteria are met, the request will be approved for 12 months.

Other Criteria	**Initial Authorization**
	• 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
	
	Reauthorization
	• 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

Revision/Review Date: 02/2026	**Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Nitisinone Products**
Drugs	Formulary: Nitisinone (Orfadin) capsules Orfadin suspension Nityr (nitisinone) tablets Non-Formulary: Harliku (nitisinone) tablets Any other marketed agent within this 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	None
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by a specialist in the diagnosis submitted
Coverage Duration	If all of the 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	**<u>Initial Authorization</u>** • For alkaptonuria (AKU) (Harliku and generic nitisinone only): o Diagnosis of AKU confirmed by one of the following: ▪ Urinary homogentisic acid (HGA) excretion of >0.4 g/24 hours ▪ Genetic testing reveals variations in the homogentisate 1,2 dioxygenase (HGD) gene o Documented clinical manifestation of AKU (e.g. urine that darkens when exposed to air, ochronosis, chronic joint pain) o For Harliku, documented trial and failure, or intolerance to treatment with generic nitisinone prescribed at a dose for the treatment of AKU o Drug is prescribed at an FDA-approved dose or dose is supported by compendia or standard of care guideline • For hereditary tyrosinemia type 1 (all nitisinone products EXCEPT Harliku): o Diagnosis of hereditary tyrosinemia type 1 confirmed by one of the following: ▪ DNA testing ▪ Detection of succinylacetone (SA) in urine or blood test o Documentation provided attesting to diet restricting tyrosine and phenylalanine o 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 o Drug is prescribed at an FDA approved dose

Revision/Review Date: 11/2025	• If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **<u>Reauthorization</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 • Drug 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.**

Prior Authorization Group Description	**Neuromyelitis Optica Spectrum Disorder (NMOSD) Agents**
Drugs	Step 1: Rituximab (Rituxan, Truxima, Ruxience, Riabni) Step 2: Enspryng (satralizumab-mwge) Uplizna (inebilizumab-cdon) Step 3: Soliris (eculizumab) Ultomiris (ravulizumab-cwvz) Any other marketed agent within 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	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 criteria are met, requests will be approved for 12 months.
Other Criteria	**Initial Authorization:** For rituximab (Rituxan, Truxima, Ruxience, or Riabni): • Member has a diagnosis of NMOSD • Documentation indicating that the member 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 Truxima (rituximab-abbs), there is a documented trial and failure of both Ruxience (rituximab-pvvr) and Truxima (rituximab-abbs), or medical reason why (e.g., intolerance, hypersensitivity, contraindication) it 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 o Liver transaminase screening o Member has not received live or attenuated-live virus vaccines within 4 weeks before the start of Enspryng therapy • Documented trial and failure to rituximab (Rituxan, Truxima, Ruxience, or Riabni), azathioprine, or mycophenolate mofetil, or a

	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, Ruxience, Riabni), 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: o Hepatitis B virus screening o Quantitative serum immunoglobulins o Tuberculosis screening o Member has not received live or attenuated-live virus vaccines within 4 weeks before the start of Uplizna therapy • Documented trial and failure to rituximab (Rituxan, Truxima, Ruxience, or Riabni), azathioprine, or mycophenolate mofetil, or a 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, Ruxience, or Riabni), azathioprine, or mycophenolate if the member has been using Soliris or Ultomiris <u>For Soliris or Ultomiris:</u> • Member has a diagnosis of anti-aquaporin-4 (AQP4) antibody **positive** NMOSD • Documentation member complies with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria • Antimicrobial prophylaxis with oral antibiotics (such as penicillin, macrolides, etc.) for two weeks if the meningococcal vaccine is administered < 2 weeks before starting therapy or a documented medical reason why the member cannot receive oral antibiotic prophylaxis. • Documented trial and failure or medical reason (e.g., intolerance, hypersensitivity, contraindication) why member cannot use the following (one from each bullet below): o Rituximab (Rituxan, Truxima, Ruxience or Riabni), azathioprine, or mycophenolate mofetil

Revision/Review Date 11/2025	○ Enspryng ○ Uplizna • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines **Reauthorization:** • Documentation that the prescriber has evaluated the member and recommends continuation of therapy (clinical benefit) • Request is for an FDA approved/medically accepted dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Prior Authorization Group Description	**Non-Preferred Anticonvulsants Step Therapy**
Drugs	Aptiom (eslicarbazepine) Briviact (brivaracetam) Diacomit (stiripentol) Epidiolex (cannabidiol) Fintepla (fenfluramine) Fycompa (perampanel) Rufinamide (Banzel) Sympazan (clobazam) Vigabatrin (Sabril, Vigadrone, Vigpoder) Xcopri (cenobamate)
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 of the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 05/2025	Prior use of two of the following is required: • Carbamazepine/carbamazepine ER • Clobazam • Divalproex sodium/divalproex sodium ER • Ethosuxamide • Felbamate • Gabapentin • Lamotrigine/lamotrigine ER • Levetiracetam/levetiracetam ER • Oxcarbazepine • Phenobarbital • Phenytoin/phenytoin ER • Primidone • Topiramate • Valproic acid • Zonisamide **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Non-Preferred Antipsychotics Step Therapy**
Drugs	Asenapine (Saphris) Caplyta (lumateperone) Fanapt (iloperidone) lurasidone (Latuda) Nuplazid (pimavanserin) Paliperidone ER (Invega) Rexulti (brexpiprazole) Secuado (asenapine) 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	N/A
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the request will be approved for up to a 12 month duration.
Other Criteria Revision/Review Date: 11/2025	If the request is for Rexulti: 1. Prior use of aripiprazole is required. If the request is for Nuplazid: 1. Prior use of both of the following is required: o Clozapine o Quetiapine/quetiapine ER If the request is for any other non-preferred antipsychotic: 1. Prior use of two of the following is required: o Aripiprazole o Olanzapine o Quetiapine/quetiapine ER o Risperidone o Ziprasidone **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Non-Preferred Basal Insulins Step Therapy**
Drugs	Tresiba (Insulin degludec) Subcutaneous Solution, Flextouch Pen
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 of the criteria are met, the request will be approved for up to a 12 month duration.
Other Criteria Revision/Review Date: 02/2026	1. Prior use of Lantus is required. **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Non-Preferred Insomnia Agents Step Therapy**
Drugs	Ramelteon (Rozerem) Dayvigo (lemborexant) Belsomra (suvorexant)
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 of the criteria are met, the request will be approved with a 12 month duration.
Other Criteria Revision/Review Date 05/2025	Prior use of at least one of the following medications: • Zolpidem/Zolpidem ER • Zaleplon • Eszopiclone **NOTE:** Ramelteon can be approved as a first line agent if there is a history of substance abuse. Continuation of Therapy Provision: Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Non-Preferred Medications for Treatment of Attention-Deficit/ Hyperactivity Disorder (ADHD) Step Therapy**
Drugs	Adzenys XR ODT (amphetamine) tablets Amphetamine tablets Methylphenidate chewable 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	21 years (maximum; see "Medications for Use in ADHD Treatment for Members 21 and Older" criteria)
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 11/2025	Requests for amphetamine tablets: • Documented trial and failure of or intolerance to at least two of the following: methylphenidate tablets, dexmethylphenidate tablets, or amphetamine-dextroamphetamine tablets Requests for methylphenidate chewable tablets: • Documented trial and failure of or intolerance to methylphenidate tablets Requests for Adzenys XR: • Documented trial and failure of or intolerance to at least two of the following: methylphenidate extended-release tablets, methylphenidate extended-release capsules, dextroamphetamine capsules, or amphetamine-dextroamphetamine extended-release capsules **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Non-Preferred Rapid Insulins Step Therapy**
Drugs	Novolog (insulin aspart) Kirsty (insulin aspart-xjhz) Merilog (insulin aspart-szjj)
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 of the criteria are met, the request will be approved for up to a 12 month duration.
Other Criteria Revision/Review Date: 02/2026	1. Prior use of insulin lispro or Humalog is required. **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Non-Preferred Triptans Step Therapy**
Drugs	Almotriptan tablets Eletriptan tablets Frovatriptan tablets Naratriptan tablets Zolmitriptan tablets Sumatriptan Nasal, 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	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date: 08/2025	Prior use of both sumatriptan AND rizatriptan tablets is required. **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Non-Preferred Urinary Antispasmodics Step Therapy**
Drugs	Darifenacin ER Tolterodine ER (Detrol LA) Trospium ER
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 of the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 11/2025	Prior use of two of the following is required: fesoterodine ER, oxybutynin/oxybutynin ER, trospium, tolterodine, or solifenacin. **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Off-Label Uses**
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 all of the criteria are met, the request will be approved for up to a 12 month duration (depending on the diagnosis and usual treatment duration).
Other Criteria Revision/Review Date 08/2025	1. One of the following: a. Member has had a documented trial and or intolerance with 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 member'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** 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.**

Prior Authorization Group Description	**Ohtuvayre (ensifentrine)**
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	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 Review/Revision Date: 11/2025	**<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.) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Omisirge**
Drugs	Omisirge (omidubicel-onlv)
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	Member has previously received this medication
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	If all of the criteria are met, the request will be approved for a one-time treatment.
Other Criteria Review/Revision Date: 08/2025	****Drug is being requested through the member's medical benefit**** • Member has a hematologic malignancy planned for umbilical cord blood transplantation (UCBT) following myeloablative conditioning • Prescriber attests that the member is eligible for myeloablative allogeneic hematopoietic stem cell transplantation (HSCT) AND does not have a readily available matched related donor, matched unrelated donor, mismatched unrelated donor, or haploidentical donor • Member has not received a prior allogenic HSCT • Member does not have known allergy to dimethyl sulfoxide (DMSO), Dextran 40, gentamicin, human serum albumin, or bovine material **The safety and effectiveness of repeat administration of Omisirge have 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.**

Prior Authorization Group	**Oncology Drugs/Therapies**
Drugs	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	N/A
Prescriber Restrictions	Prescriber is an oncologist, or specialist in the type of cancer being treated.
Coverage Duration	If all of the criteria are met, the request will be approved for up to a 12 month duration.
Other Criteria	**All of the following criteria must be met:** • The product is being requested for a FDA labeled indication or is supported by NCCN Category 1 or 2A level of evidence. If the request is for an off-label 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) if such treatment exists; **AND** • Documentation has been provided of the results of all required genetic testing where required per product package insert; **AND** • Documentation has been provided of the results of all required laboratory values and member-specific information (e.g., weight, ALT/AST, Creatinine Kinase, etc.) necessary to ensure the member has no contraindications to therapy per product package insert; **AND** • The product is being prescribed at a dose 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 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 drug being requested **Form FDA 3500 – Voluntary Reporting**

Revision/Review Date 02/2026	• 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.**

Prior Authorization Group Description	**Ophthalmic Alpha-Agonist Step Therapy**
Drugs	Apraclonidine 0.5% Ophthalmic Solution Brimonidine-timolol 0.2-0.5% 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	N/A
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 08/2025	<u>For apraclonidine requests:</u> 1. Prior use of brimonidine ophthalmic solution required. <u>For brimonidine-timolol requests:</u> 1. Prior use of both single-agent brimonidine ophthalmic solution and timolol ophthalmic solution are required. **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Ophthalmic Corticosteroids Step Therapy**
Drugs	Loteprednol (Lotemax) 0.5% Difluprednate (Durezol)
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 of the criteria are met, the request will be approved for up to a 12 month duration.
Other Criteria Revision/Review Date 11/2025	Documented trial and failure of or intolerance to one of the following: prednisolone acetate 1% or fluorometholone 0.1% drops **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Ophthalmic Histamine Antagonists Step Therapy**
Drugs	Epinastine 0.05% ophthalmic solution Bepotastine 1.5% 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	N/A
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the request will be approved for up to a 12 month duration.
Other Criteria Revision/Review Date: 11/2025	Prior use of either ophthalmic cromolyn or azelastine is required. **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Ophthalmic Prostaglandins Step Therapy**
Drugs	Formulary – Generic, Pays at Point-of-Sale (Step One) Latanoprost 0.005% ophthalmic solution Formulary – Generic, Requires Step Therapy (Step Two) Tafluprost 0.00015% ophthalmic solution Travoprost 0.004% ophthalmic solution Formulary – Preferred Brand, Pays at Point-of-Sale (Step Three) Lumigan ophthalmic solution Non-Formulary – Requires Prior Authorization (Step Four) Vyzulta ophthalmic solution Non-Formulary – Requires Prior Authorization (Step Five) Iyuzeh ophthalmic solution Zioptan ophthalmic solution Any other marketed agent within 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	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the request will be approved for up to a 12 month duration.
Other Criteria Revision/Review Date: 08/2025	1. Step two agents must have documented trial and failure or intolerance to a step one agent 2. Step four agents must have documented trial and failure or intolerance with a step one agent, step two agent, and step three agent. 3. Step five agents must have documented trial and failure or intolerance to a step one agent, step two agent, step three agent, and step four agent. **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Opioid Containing Cough & Cold Products**
Drugs	Schedule II-V Opioid Containing Cough & Cold Products > 5 days 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), and the Drug Package Insert (PPI).
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 criteria are met, the request will be approved for 10 days.
Other Criteria Revision/Review Date 02/2026	• Prescriber has explained medical necessity for use of this product • Prescriber attests to checking the appropriate state Controlled Substances Reporting System (CSRS) and to being aware of all other opioid prescriptions the member is currently taking if applicable **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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 4. Opioids exceeding plan defined quantity limits
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	According to 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 all of the criteria are met, the request will be approved for up to 6 months.
Other Criteria	*****If the member has cancer, sickle cell disease, or is receiving hospice care or palliative care, please automatically authorize for up to 12 months (member must meet non-formulary criteria if request is for non-formulary medication)***** **Initial Authorization:** 1. The diagnosis is pain. For long-acting products, the diagnosis is chronic pain that requires daily, around the clock, opioid medication. 2. The member has tried and failed non-pharmacologic treatment and two non-opioid containing pain medications (ex. acetaminophen, NSAIDs, selected antidepressants, anticonvulsants). 3. For long-acting products, the member has tried and failed short-acting opioid agents. If a member has not attempted short-acting opioid agents, documentation as to why they are unable to use. 4. The prescriber has justified medical necessity for dosing above 90 MME per day (i.e., active tapering) and/or for request above day supply or quantity limits. 5. 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. 6. 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. 7. If member has a high-risk condition stated in the CDC guidelines (ex. sleep apnea or other causes of sleep-disordered breathing, members

	with renal or hepatic insufficiency, older adults, pregnant women, members with depression or other mental health conditions, and members with alcohol or other substance use disorders) prescriber attests to discussing heightened risks of opioid use and has educated member on naloxone use and has considered prescribing naloxone. 8. Prescriber attests urine drug screens will be completed every 6 months and if illicit drugs are found, identifying the member as high risk, the heightened risk of overdose will be explained to the member. 9. Prescriber attests to discussing with the member the level of risk for opioid abuse/overdose with the dose/duration prescribed to the member. 10. Prescriber attests to discussing concomitant psychological disease and risks associated with opioid overdose/abuse. 11. Prescriber attests to discussing history of substance abuse and the risks associated with opioid overdose/abuse. 12. Prescriber has the member's signature on file acknowledging education regarding the risks of opioid therapy as listed in items 8, 9, and 10 above. 13. Prescriber has provided a copy of a pain management agreement 14. Prescriber attests to checking the applicable state Prescription Drug Monitoring Program (PDMP) 15. If the request is for a non-formulary opioid, member must meet criteria 1-14 AND one of the following conditions: a. Documented trial and failure or intolerance with two formulary medications used to treat the documented diagnosis. b. No other formulary medication has a medically accepted use for the member's specific diagnosis as referenced in the medical compendia. c. All other formulary medications are contraindicated based on the member's diagnosis, other medical conditions, or other medication therapy. **<u>Reauthorization:</u>** 1. 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 member reassessment and medical justification explaining why the dose must be increased 2. 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. 3. 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.

Revision/Review Date: 02/2026	4. Urine drug screen dates have been submitted every 6 months. If illicit drugs are found, prescriber has attested to identifying member 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. 5. If member has a high-risk condition stated in the CDC guidelines (ex. sleep apnea or other causes of sleep-disordered breathing, members with renal or hepatic insufficiency, older adults, pregnant women, members with depression or other mental health conditions, and members with alcohol or other substance use disorders) prescriber attests to discussing heightened risks of opioid use and has educated member on naloxone use and has considered prescribing naloxone. 6. Prescriber attests to checking the applicable state Prescription Drug Monitoring Program (PDMP) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Oral Antifungals**
Drugs	Formulary: • Itraconazole capsule, solution • Voriconazole tablets, suspension • Posaconazole delayed release-tablet, oral suspension • Cresemba (isavuconazonium) capsule • Flucytosine capsule Non-Formulary: Any other marketed agent within 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), and the Drug Package Insert (PPI).
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 criteria are met, the request will be approved for 12 months.
Other Criteria	**Initial Authorization** • For **itraconazole**, approve if one of the following: o Diagnosis of blastomycosis or histoplasmosis o For oropharyngeal or esophageal candidiasis, there is documentation of trial and failure, intolerance, or contraindication to fluconazole o For aspergillus infections, there is documentation of trial and failure, intolerance, or contraindication to voriconazole o For onychomycosis, there is documentation of trial and failure, intolerance, or contraindication to terbinafine or fluconazole tablets • For **voriconazole**, approve if one of the following: o Diagnosis of one of the following: ▪ Fungal infection by Scedosporium apiospermum or Fusarium species ▪ Treatment of invasive candidiasis in critically ill patients ▪ Invasive pulmonary aspergillus infections ▪ Primary prophylaxis for aspergillus infections for special populations such as lung transplant, acute myeloid leukemia (AML), allo-stem cell transplant with prolonged neutropenia from chemotherapy AND high risk for infection o For esophageal candidiasis or candidemia in nonneutropenic patients: documentation of trial and failure, intolerance, or contraindication to fluconazole

Revision/Review Date 08/2025	○ For blastomycosis or histoplasmosis: documentation of trial and failure, intolerance, or contraindication to itraconazole • For **posaconazole tablets**, approve if one of the following: ○ For prophylaxis of invasive aspergillus or candida in patients at high risk of developing invasive aspergillus or candida due to being severely immunocompromised: trial and failure or inability to use voriconazole ○ For the treatment of invasive aspergillosis: trial and failure or inability to use voriconazole • For **posaconazole suspension,** approve if: ○ For oropharyngeal candidiasis, there is documentation of trial and failure, intolerance, or contraindication to fluconazole • For **Cresemba**, approve if one of the following: ○ Diagnosis of invasive mucormycosis in adults ○ For invasive aspergillosis in adults, there is documentation of trial and failure, intolerance, or contraindication to voriconazole • For **flucytosine**, approve if: ○ Diagnosis of cryptococcal meningitis or cryptococcosis ○ Diagnosis of candidiasis with CNS involvement, symptomatic urinary tract infections (e.g. cystitis, pyelonephritis, or fungal masses), endocarditis or infected cardiac devices, endophthalmitis, septicemia, or pulmonary infections • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **Reauthorization** • Documentation is provided that the member has responded to therapy • Additional therapy is medically necessary and clinically appropriate **NOTE**: • Requests for itraconazole solution require a documented trial and failure, or intolerance to itraconazole oral capsules unless the oral solution is being requested for diagnosis of oropharyngeal or esophageal candidiasis. • Requests for voriconazole suspension require a documented trial and failure, or intolerance to voriconazole tablets • Requests for flucytosine require combination therapy with amphotericin B for systemic candidiasis, cryptococcal meningitis, or cryptococcosis

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

Prior Authorization Group Description	**Oral Estrogens Step Therapy**
Drugs	Menest (esterified estrogens) Premarin (conjugated equine estrogens)
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 of the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 11/2025	Prior use of oral estradiol is required. **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Otezla (apremilast) for Behçet's Disease**
Drugs	Otezla, Otezla XR (apremilast) 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	N/A
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by, or in consultation with, a rheumatologist
Coverage Duration	If all of the criteria are met, initial requests and reauthorizations will be approved for a 12 month duration.
Other Criteria Revision/Review Date 02/2026	**Initial Authorization:** • The member has a diagnosis of oral ulcers associated with Behçet's disease AND • The medication is being prescribed at an appropriate FDA approved dose (for age and weight) AND • The member has an adequate trial (consistent with pharmacy claims/medical record data/provider attestation) with at least one topical corticosteroid and colchicine OR • Member has a documented medical reason (e.g., allergy, intolerance, contraindication) for not using topical corticosteroids and colchicine to manage their condition. **Reauthorization:** • The medication is being prescribed at an FDA-approved dosage. • The member has been receiving the medication and documentation was provided that the prescriber has evaluated the member and recommends continuation of therapy (clinical benefit). **Continuation of Therapy Provision**: • Members with history (within the past 90 days) of Otezla use are not required to demonstrate trial of conventional treatments. **Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

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 02/2026	1. Documented diagnosis of Stage 2 or 3 neurotrophic keratitis 2. 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.**

Prior Authorization Group Description	**Peanut Allergy Immunotherapy Agents (FDA Approved)**
Drugs	Non-Formulary: Palforzia [Peanut (Arachis hypogaea) Allergen Powder-dnfp] capsule/sachet Any other marketed agent within 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	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Initiation: age 1-17 years. Up dosing and maintenance: age ≥ 1 year
Prescriber Restrictions	Prescribed by a specialist in the area of allergy/immunology
Coverage Duration	If all of the criteria are met, the request will be approved for a 12 month duration.
Other Criteria Revision/Review Date: 08/2025	**<u>Initial Authorization:</u>** • Member has a confirmed diagnosis of peanut allergy • For members starting initial dose escalation (new to therapy) o Member has not had a severe or life-threatening anaphylaxis within the previous 60 days • Member will follow a peanut-avoidant diet • Member 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 • Member does not have uncontrolled asthma **<u>Re-Authorization:</u>** • Member will follow a peanut-avoidant diet • Member is able to tolerate initial dose escalation per the prescribing information • Member is able to comply with the daily dosing requirements • Member does not have recurrent asthma exacerbations or persistent loss of asthma control • Member 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.**

Prior Authorization Group	**Phenylalanine Hydroxylase Activators**
Drug(s)	Formulary: Sapropterin dihydrochloride (Kuvan) Non-Formulary: Sephience (sepiapterin) Any other marketed agent within 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) , and the Drug Package Insert).
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by specialist experienced in treating PKU
Coverage Duration	**Initial:** If all of the criteria are met, the request will be approved for 1 month. **Reauthorization:** If all of the criteria are met, sapropterin requests will be approved for a duration of 1 month for members 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 members the request will be approved for a duration of 3 months
Other Criteria Revision/Review Date: 11/2025	**Initial Authorization:** • Documentation of a confirmed diagnosis of Phenylketonuria (PKU) • Documentation of the member's baseline blood Phe level. (within 30 days of the request) • Documentation consistent with order forms, receipts, or chart notes (within 30 days of request) that the member 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 member's current weight. • The medication is being prescribed at an FDA approved dosage • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **Reauthorization:** *For sapropterin: Members that were dosed at 20mg/kg/day and did not have a decrease in Phe from baseline, are considered NON RESPONDERS and NO ADDITIONAL TREATMENT will be authorized.*

	For Sephience: Members 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 member's current weight. • Documentation of at least **two** separate blood Phe level results after initiation of therapy (within 30 days of request). • The medication is being prescribed at an FDA approved dosage. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Prior Authorization Group Description	**Phosphate Binders**
Drugs	**Formulary:** Sevelamer carbonate (Renvela) powder packet Lanthanum carbonate (Fosrenol) chewable tablet Fosrenol (lanthanum carbonate) powder packet Velphoro (sucroferric oxyhydroxide) chewable tablet **Non-Formulary:** Auryxia (ferric citrate) tablet Sevelamer HCl (Renagel) tablet Any other marketed agent within 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), and 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 criteria are met, requests will be approved for a 12-month duration.

Other Criteria
 	
Revision/Review Date: 05/2025
	• For sevelamer carbonate powder pack, or lanthanum chewable tablet for hyperphosphatemia with ESRD, approve if:
	  o There is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use sevelamer carbonate tablet
	• For Velphoro or Fosrenol powder packet for hyperphosphatemia with ESRD, approve if:
	  o There is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use sevelamer carbonate tablet or powder pack AND lanthanum carbonate chewable tablet
	• If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated.
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Prior Authorization Group Description	**Pompe Disease Agents**
Drugs	Non-Formulary: Lumizyme (alglucosidase alfa) Nexviazyme (avalglucosidase alfa-ngpt) injection Pombiliti (cipaglucosidase alfa-atga) + Opfolda (miglustat) Any other marketed agent in this 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	See "Other Criteria"
Age Restrictions	According to package insert
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):
	• Member 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 member's 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):
	• Member 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 member 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 members who are not old enough to walk)
	• Requested dose is appropriate per prescribing information (documentation of member's 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: Members < 30 kg must provide documentation of a trial and therapy failure of, or a medical reason why Lumizyme may not be used.

Review/Revision Date: 02/2026	• Additionally for Pombiliti + Opfolda: Member must have trial and failure of another enzyme therapy (Lumizyme or Nexviazyme)
	
	<u>Re-Authorization:</u>
	• 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 member's 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)
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Prior Authorization Group Description	**Potassium-Removing Agents**
Drugs	Formulary: Lokelma (sodium zirconium cyclosilicate) Veltassa (patiromer) Non-Formulary: Any other marketed agent within 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	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist, nephrologist, or transplant specialist
Coverage Duration	If all of the criteria are met, the request will be approved for up to a 12 month duration.
Other Criteria Revision/Review Date 05/2025	**Initial Authorization** • Diagnosis of hyperkalemia • Documentation member 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 • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **Re-Authorization** • 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.**

Prior Authorization Group Description	**Presbyopia Agents**
Drugs	Formulary: Qlosi (pilocarpine HCl ophthalmic solution) Vuity (pilocarpine HCl ophthalmic solution) Non-Formulary: Any other marketed agent within 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	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Qlosi: 45-64 years Vuity: 40-55 years
Prescriber Restrictions	Prescribed by or in consultation with an optometrist or ophthalmologist
Coverage Duration	If all of the criteria are met, requests will be approved for 12 months.
Other Criteria Revision/Review Date: 02/2025	**Initial Authorization:** • Diagnosis of presbyopia • Trial and failure or contraindication to corrective lenses (i.e., eyeglasses, contact lenses) • Medication is prescribed at an FDA approved dose • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **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.**

Prior Authorization Group Description	**Primary Hemophagocytic Lymphohistiocytosis (HLH) Agents**
Drugs	Non-Formulary: Gamifant (emapalumab-lzsg) Any other marketed agent within 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	Members who have undergone hematopoietic stem cell transplantation (HSCT)
Required Medical Information	"See Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by a Hematologist, Oncologist, Immunologist, Transplant Specialist, or other specialist experienced in the treatment of immunologic disorders
Coverage Duration	If all of the criteria are met, initial and reauthorization requests will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 02/2026	***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.**

Prior Authorization Group Description	**Primary Hyperoxaluria Agents**
Drugs	Non-Formulary: Oxlumo (lumasiran) Rivfloza (nedosiran) Any other marketed agent 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), and the Drug Package Insert (PPI).
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 nephrologist, urologist, hepatologist, endocrinologist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.

Other Criteria
 	
Revision/Review Date: 02/2026
	<u>Initial Authorization</u>
	• Diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by one of the following:
	  o At least one mutation at the AGXT gene
	  o Liver biopsy demonstrating absent or significantly reduced AGT activity
	• Metabolic testing demonstrating the following:
	  o For Oxlumo (one of the following):
	  ▪ Increased urinary oxalate excretion (≥ 0.5 mmol/1.73 m^2 per day[45 mg/1.73 m^2 per day])
	  ▪ Increased urinary oxalate:creatinine ratio relative to normative values for age
	  ▪ Increased plasma oxalate level (≥ 20 μmol/L)
	  o For Rivfloza (one of the following):
	  ▪ Increased urinary oxalate excretion (≥ 0.5 mmol/1.73 m^2 per day[45 mg/1.73 m^2 per day])
	  ▪ Increased urinary oxalate:creatinine ratio relative to normative values for age
	• 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
	• Member 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 oxalate, urinary oxalate:creatinine ratio, or plasma oxalate levels from baseline)
	• Medication is prescribed at an FDA approved dose
	• Member 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.

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 Revision/Review Date 11/2025	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. • Medical and/or member-specific reasons may include but are not limited to: o Uniqueness of the member's condition or other physical characteristics of the member's condition. o Psychiatric, intellectual, physical, cultural, and/or linguistic characteristics of the member which may prohibit 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.**

Prior Authorization Group Description	**Proprotein Convertase Subtilisin/kexin 9 (PCSK9) Inhibitors**
Drugs	**Formulary Pharmacy Benefit Agents** Repatha (evolocumab) Praluent (alirocumab) **Non-Formulary Pharmacy Benefit Agents** Any other marketed agent within the class **Medical Benefit Agents** Leqvio (inclisiran)
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 cardiologist or specialist in treatment of lipid disorders
Coverage Duration	If all of 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

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
	• One of the following:
	  ○ Provider indicates member's LDL-C is above goal OR
	  ○ Genetic test submitted with request (for diagnosis of familial hypercholesterolemia (FH) only)
	• Member has tried and failed atorvastatin 40mg-80mg or rosuvastatin 20-40mg (consistently for 3 months via claim history or chart notes). If member is not able to tolerate atorvastatin or rosuvastatin, documentation was provided that member 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 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."
	• Member has tried and failed ezetimibe at a maximal tolerated dose OR one of the following:

Revision/Review Date 11/2025	○ Member has an LDL-C that is >25% above goal LDL-C while adherent to treatment with highest-tolerated intensity statin (if clinically appropriate) consistently for 3 months ○ Documentation has been provided that the member is not able to tolerate ezetimibe • If the request is for Leqvio (inclisiran), documentation was provided of trial and failure or a medical reason has been provided, why member is unable to use Repatha or Praluent to manage their condition. • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **<u>Reauthorization for all indications:</u>** • Repeat fasting lipid panel shows reduction in LDL from baseline (prior to starting PCSK9 inhibitor) • The member's claim history shows consistent therapy (e.g. monthly fills) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Proton Pump Inhibitors (PPIs)**
Drugs	**Formulary -** Preferred, Pays at Point-of-Sale Omeprazole (Prilosec) capsule Pantoprazole (Protonix) tablet **Formulary -** Non-Preferred, Requires Step Therapy Esomeprazole Magnesium (Nexium) capsule Lansoprazole (Prevacid) capsule Omeprazole/Sodium Bicarbonate (Zegrid) capsule, packet Rabeprazole (Aciphex) tablet **Note: Member must meet criteria #1 & # 2 for approval of the ST request.** **Formulary** Non-Preferred, Requires Prior Authorization Dexlansoprazole (Dexilant) **Non-Formulary** Any other marketed agent within the class **Note: Member 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 all of the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria	1. Presumed or documented diagnosis of duodenal ulcer, *H. pylori* infection, gastritis, gastric ulcer, GERD, erosive esophagitis, Barrett's disease or hypersecretory disease including Zollinger-Ellison syndrome. 2. Documented trial and failure or intolerance with two preferred agents for a minimum of 3 weeks of therapy each. 3. Documented trial and failure or intolerance with a non-preferred generic agent for a minimum of 3 weeks-of therapy each. **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents.

Revision/Review Date 11/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Pulmonary Biologics for Respiratory and Eosinophilic Conditions**
Drugs	Formulary: Dupixent (dupilumab) Fasenra (benralizumab) Nucala (mepolizumab) Tezspire (tezepelumab) Medical Benefit Only: Cinqair (resilizumab) Non-Formulary: Any other marketed agent within 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), and the Drug Package Insert (PPI).
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	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with an allergist, pulmonologist, immunologist, rheumatologist, gastroenterologist, dermatologist, or other provider who specializes in the treatment of eosinophilic conditions
Coverage Duration	If all of the criteria are met, the initial request will be approved with a 4 month duration and reauthorization 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: ≥150 cells/mcL (within 6 weeks of request) OR ≥300 cells/mcL (within the past 12 months)
	  o Dupixent and Fasenra: ≥150 cells/mcL
	  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 FEV1 < 80% of predicted with evidence of reversibility by bronchodilator response.
	  o Tezspire ONLY: If age is < 18 years, the member has a documented baseline FEV1 <90% of predicted with evidence of reversibility by bronchodilator response.
	• Documentation has been provided indicating that the member continues to have significant symptoms while compliant on a maximally tolerated inhaled corticosteroid with a long-acting B2 agonist (ICS/LABA) (or a documented

	medical reason must be provided why the member is unable to use these therapies) • The member has experienced ONE of the following: o Nucala: ≥2 exacerbations in the previous 12 months o Fasenra: ≥2 exacerbations in the previous 12 months o Cinqair: ≥1 exacerbation in the previous 12 months requiring systemic corticosteroids o Dupixent: ≥1 exacerbation in the previous 12 months requiring systemic corticosteroids or hospitalization o Tezspire: ≥2 exacerbations requiring systemic corticosteroids OR ≥1 exacerbation in the previous 12 months requiring hospitalization • The prescribed dose is within FDA approved dosing guidelines **Chronic Obstructive Pulmonary Disease (COPD) *(Dupixent & Nucala only)*:** • Confirmed diagnosis of COPD • Documentation has been provided of blood eosinophil count within one of the following ranges: o Dupixent: ≥ 300 cells/mcL o Nucala: ≥ 150 cells/mcL (within 6 weeks of request) OR ≥ 300 cells/mcL (within the past 12 months) • The member has a documented post-bronchodilator FEV_1/FVC ratio < 0.7 and post-bronchodilator FEV_1 of 20% to 80% 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 all three therapies, OR if ICS are contraindicated, a LAMA and a LABA can be used • Documentation has been provided that the member meets 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 **Oral Corticosteroid Dependent Asthma (*Dupixent only*):** • 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 member has a documented baseline FEV1 < 80% of predicted with evidence of reversibility by bronchodilator response. • Documentation has been provided indicating that the member 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 B2 agonist (ICS/LABA) AND a long-acting muscarinic antagonist (LAMA). If the member has not utilized these therapies, a documented medical reason must be provided why member 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 or symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, heartburn, abdominal pain) • Documented trial and failure, intolerance, or contraindication to one proton pump inhibitor at a maximally tolerated dose, or topical esophageal corticosteroids 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 • 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 one medium to super-high potency topical corticosteroid for a minimum of two weeks • The prescribed dose is within FDA approved dosing guidelines **<u>Chronic Spontaneous Urticaria (CSU) (*Dupixent only):*</u>** • Confirmed diagnosis of CSU • Documented history of urticaria for at least 6 weeks • Member remains symptomatic despite a minimum two-week trial of a formulary second generation H1 antihistamine at the maximum tolerated dose; or has a medical reason for not utilizing a second-generation antihistamine • The p drug is prescribed at an FDA approved dose

Revision/Review Date 11/2025	**<u>Bullous Pemphigoid (*Dupixent only):*</u>**
	• Confirmed diagnosis of bullous pemphigoid
	• Member has a Bullous Pemphigoid Disease Area Index (BPDAI) activity score ≥24
	• Member has a Peak Pruritus Numeric Rating Scale (NRS) score ≥4
	• Documented trial and failure, intolerance, or contraindication to at least one of the following:
	  ○ High potency topical corticosteroids
	  ○ Oral corticosteroids
	  ○ Doxycycline
	  ○ Immunosuppressive therapies (ex. azathioprine, mycophenolate, methotrexate, etc.)
	• The prescribed dose is within FDA approved dosing guidelines

	Eosinophilic granulomatosis with polyangiitis (EGPA) (*Fasenra & Nucala only*): • 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 one of the following: cyclophosphamide, rituximab, azathioprine, methotrexate, OR mycophenolate mofetil • The prescribed dose is within FDA approved dosing guidelines **Hypereosinophilic Syndrome (HES) (*Nucala only*):** • 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) If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **Reauthorization:** • Documentation submitted indicates the member has had a positive clinical response (e.g., Asthma and COPD: improved FEV1, 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; CSU: decrease in severe itching or urticaria activity; bullous pemphigoid: sustained remission, improvement in Peak Pruritus NRS score) • 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.

Prior Authorization Group Description	**Pulmonary Hypertension (PH) Agents**
Drugs	**Endothelian Receptor Antagonists:** ambrisentan (Letairis), bosentan (Tracleer), Opsumit (macitentan) **ERA and Phosphodiesterase-5 (PDE-5) Inhibitor Combinations:** Opsynvi (macitentan and tadalafil) **Prostacyclin Receptor Agonists:** Uptravi (selexipag) **PDE-5 Inhibitors:** tadalafil (Adcirca/Tadliq), sildenafil (Revatio/Liqrev) **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) 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: If all of the criteria are met, initial requests will be approved for 3 months. Opsyvni: If all of the criteria are met, initial requests will be approved for 4 months. 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 other agents, if all of the criteria are met, the request 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)

Revision/Review Date 11/2025	• 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 member is unable to use the same ingredient in a tablet dosage form (e.g., difficulty swallowing)
	• If the request is for Opsumit, the member 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 Opsyvni, BOTH of the following:
	  o Member 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 member 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 to, f combination therapy including one PDE-5 inhibitor AND one ERA OR Opsyvni
	  o Documentation of platelet count of > 50,000/mm3
	• If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated.
	• Documentation of the member's current weight, dosing, and titration schedule is provided (if applicable)
	• The medication is prescribed at a dose that is within FDA approved guidelines
	
	<u>Re-authorization:</u>
	• 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 member's current weight, dosing, and titration schedule is provided (if applicable)
	• The medication is prescribed at a dose that is within FDA approved guidelines.
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Prior Authorization Group Description	**Pyrimethamine**
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	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, an appropriate specialist (i.e., infectious disease, OB/GYN).
Coverage Duration	Toxoplasmosis: • Treatment – 6 weeks at a time • Primary prophylaxis – 3 months at a time • Secondary prophylaxis (i.e., chronic maintenance) – 3 months at a time • Congenital toxoplasmosis requests may be approved for up 12 months • Toxoplasmosis in pregnancy requests may be approved for up to 22 weeks Cystoisosporiasis: • Treatment – 1 month at a time • Secondary prophylaxis – 3 months at a time Pneumocystis pneumonia - 3 months at a time
Other Criteria	**ALL REQUESTS** forpyrimethamine should be accompanied by a prescription for leucovorin **Toxoplasmosis:** • Treatment: o Adolescents and adults – must be used in combination with a sulfonamide or clindamycin ▪ For toxoplasmosis in pregnancy requests, the member must have reached at least 18 weeks gestation AND pyrimethamine must be used in combination with sulfadiazine o Pediatrics (congenital and acquired toxoplasmosis) – must be used in combination with sulfadiazine • Primary Prophylaxis: o For adults or pediatric members with HIV: ▪ A medical reason as to why the member is not able to use trimethoprim-sulfamethoxazole (TMP/SMX) or atovaquone o For adults with HIV: documentation of CD4 count <200 cells/µL • Secondary Prophylaxis (i.e., chronic maintenance treatment): o In members **not** initially treated with a pyrimethamine regimen, a medical reason as to why the member is not able to continue with an alternative regimen for maintenance

	<u>Cystoisosporiasis:</u>
	• Treatment:
	  ○ For adults or pediatric members with HIV, a medical reason as to why the member is not able to be treated with TMP/SMX
	• Secondary Prophylaxis:
	  ○ For adults and pediatric members with HIV:
	  ▪ The member was previously diagnosed with, and completed a treatment regimen for cystoisosporiasis
	  ▪ If member was not previously treated with a pyrimethamine regimen for the treatment of cystoisosporiasis, a medical reason why the member is not able to continue the medications used for treatment
	  ▪ For adults with HIV: CD4 count ≤200 cells/µL or CD4 count has been >200 cells/µL for 6 months or less
	
	<u>Pneumocystis Pneumonia:</u>
	• Primary Prophylaxis:
	  ○ For adults with HIV:
	  ▪ Documentation of CD4 count <200 cells/µL or CD4 percentage <14% or documentation that antiretroviral treatment initiation is delayed
	  ▪ Documentation must be submitted with a medical reason for not utilizing TMP/SMX, dapsone, aerosolized pentamidine, or atovaquone.
	• Secondary Prophylaxis:
	  ○ For adults with HIV:
	  ▪ The member was previously diagnosed with, and completed a treatment regimen for, pneumocystis pneumonia
	  ▪ If member was not previously treated with a pyrimethamine regimen, a medical reason why the member is not able to continue the medications used for treatment

Revision/Review Date: 05/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Pyruvate Kinase Activators**
Drugs	Formulary: Pyrukynd (mitapivat) Non-Formulary: Any other marketed agent within 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	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 all of the criteria are met, the request will be approved for a 6-month duration. **If all of the criteria 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 • 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 0.8 mg of folic acid daily

Revision/Review Date: 08/2025	• If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **Reauthorization:** • 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.**

Prior Authorization Group Description	**Qalsody (tofersen)**
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 of the criteria are met, the request will be approved for a 12-month duration.
Other Criteria Review/Revision Date: 08/2025	****Drug is being requested through the member's medical benefit**** **<u>Initial Authorization:</u>** • 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 **<u>Re-Authorization:</u>** • 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 **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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
Coverage Duration	12 Months
Criteria Revision/Review Date 11/2025	• 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). • 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. • **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. **OR** 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.**

Prior Authorization Group Description	**Radicava**
Drugs	Pharmacy Benefit: Radicava ORS (edaravone) Medical Benefit: edaravone (Radicava)
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 all of the criteria are met, the request will be approved for up to a 12 month duration.
Other Criteria Revision/Review Date: 02/2026	**<u>Initial Authorization:</u>** • 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 member is unable to use riluzole • Dose is within FDA approved limits **<u>Reauthorization</u>** • Member has a documented positive response to therapy (e.g., improvement or stabilization of ALSFRS-R score) • 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.**

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 or isolated alpha-thalassemia.
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be 18 years of age or older
Prescriber Restrictions	Prescribed by a hematologist or oncologist
Coverage Duration	If all of the criteria are met, requests will be approved for 6 months.

Other Criteria
 	
Revision/Review Date: 11/2025
	Initial Authorization:
	• 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 both of the following:
	  o Fewer transfusions compared with baseline
	  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 to 12 weeks
	  OR
	  o Reduction in RBC transfusion by at least 4 units over an 8 to 12 week period compared with baseline transfusion requirement
	• Prescriber states that the member did not experience a Grade 3 or 4 hypersensitivity reaction

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

Prior Authorization Group Description	**Retinoids (Dermatologic)**
Drugs	Formulary: Isotretinoin capsules Non-Formulary: Absorica, Absorica LD (isotretinoin) Accutane (isotretinoin) Amnesteem (isotretinoin) Claravis (isotretinoin) Zenatane (isotretinoin) Any other marketed agent in this 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	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the request will be approved with up to a 12 month duration. Maximum of two courses of therapy will be approved with a minimum of 2 months off in between therapy courses.
Other Criteria Revision/Review Date 08/2025	**<u>Initial Authorization</u>** • Diagnosis of moderate to severe recalcitrant nodular acne • Documented treatment with a therapeutic trial and failure, intolerance to, or medical contraindication 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. • Dose is appropriate for member • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **<u>Re-Authorization</u>** • Documentation that 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.**

Prior Authorization Group Description	**Rezdiffra (resmetirom)**
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	Members with decompensated cirrhosis
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by a hepatologist, gastroenterologist, endocrinologist, or a specialist in the treatment of liver disease.
Coverage Duration	If all of the criteria are met, the requests will be approved for up to a 12 month duration.
Other Criteria Review/Revision Date: 11/2025	**<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 • In patients without diabetes, or patients not taking another GLP1 receptor agonist: Documentation of trial and failure, or documented medical reason for not using Wegovy **<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 **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Rhapsido**
Drugs	Rhapsido (remibrutinib)
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 allergist, immunologist, or dermatologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For reauthorization, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 02/2026	**<u>Initial Authorization:</u>** • Medication is prescribed at an FDA approved dose • Diagnosis of chronic spontaneous urticaria for at least 6 weeks with uncontrolled symptoms • Member has had at least a 2-week trial and failure of, or has a contraindication to, at least two different H1 antihistamines (e.g. cetirizine, levocetirizine, loratadine, desloratadine, fexofenadine) at four times the standard FDA-approved dose • Member has had at least a 2-month trial and failure of, or has a contraindication to, Xolair or Dupixent **<u>Re-Authorization:</u>** • Documentation or provider attestation of positive clinical response (i.e. change from baseline in weekly itch severity score, 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.**

Prior Authorization Group Description	**Rituximab Agents**
Drugs	Formulary: Ruxience (rituximab-pvvr) Truxima (rituximab-abbs) Non-Formulary: Riabni (rituximab-arrx) Rituxan (rituximab) Rituxan Hycela (rituximab / human hyaluronidase) Any other marketed agent within 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	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	See "Other Criteria"
Prescriber Restrictions	See "Other Criteria"
Coverage Duration	See "Other Criteria"
Other Criteria	**Rituximab agents 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 member is an adult (≥18 y/o) and has a documented clinical diagnosis of rheumatoid arthritis. • 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 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 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 all

	preferred biologics indicated for rheumatoid arthritis, or has documented medical reason (intolerance, hypersensitivity, etc.) for not taking ALL of these therapies to manage their medical condition. • Documentation indicating that the member 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 Truxima (rituximab-abbs) there is a documented trial and failure of Truxima (rituximab-abbs), or medical reason why (e.g. intolerance, hypersensitivity, contraindication) Truxima (rituximab-abbs) cannot be used. • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. If all of the above conditions are met, the request will be approved for up to a 1-month duration **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 member had clinical benefit from receiving rituximab therapy. • At least 16 weeks (4 months) has elapsed since the previous course of rituximab therapy. • 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 12-month duration **PEMPHIGUS VULGARIS** **Initial Authorization** • The medication is being recommended and prescribed by a rheumatologist or dermatologist • The member is ≥ 18 years with a diagnosis of moderate to severe pemphigus vulgaris • Documentation the member will be receiving P. jirovecii pneumonia (PCP) prophylaxis (ex. TMP/SMX, dapsone, atovaquone) or the prescriber has provided a medical reason for not prescribing PCP prophylaxis • Documentation indicating that the member 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 the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. If all of the above conditions are met, the request will be approved for up to a 1 month duration. **Reauthorization** • Documentation of clinical benefits (e.g., absence of new lesions) with rituximab therapy was provided by a rheumatologist or dermatologist • Documentation the member will continue to receive PCP prophylaxis (ex. TMP/SMX, dapsone, atovaquone) or the prescriber has provided a medical reason for not prescribing PCP 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 12 month duration **ONCOLOGY INDICATIONS** **Initial Authorization:** • The medication is being recommended and prescribed by an oncologist. • The medication is being requested for a labeled indication, an indication supported by a NCCN category 1 or 2A level of evidence, or an indication supported by substantially accepted peer reviewed medical literature • The requested indication is CD20 positive • Documentation indicating that the member 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) 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 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 the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. If all of the above conditions are met, the request will be approved for up to a 3-month duration **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 **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 member is 2 years of age or older and has a documented clinical diagnosis of GPA (Wegener's Granulomatosis), 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 member will be receiving PCP prophylaxis (ex. TMP/SMX, dapsone, atovaquone) during treatment or the prescriber has provided a medical reason for not prescribing PCP prophylaxis • Documentation indicating that the member has been screened for HBV prior to initiation of treatment. • Rituximab is being prescribed at an FDA approved dosage. • If the member is 18 years of age or older, and 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 the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. If all of the above conditions are met, the request will be approved for up to a 1-month duration **Re-authorization:** • The medication is being recommended and prescribed by a rheumatologist or nephrologist. • Documentation the member will continue to receive PCP prophylaxis (ex. TMP/SMX, dapsone, atovaquone) or the prescriber has provided a medical reason for not prescribing PCP prophylaxis • Rituxan 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 12 month duration. **DERMATOMYOSITIS (DM) and POLYMYOSITIS (PM)** **Initial Authorization:** • Rituximab is being recommended and prescribed by a neurologist, rheumatologist, or dermatologist. • Member meets one of the following: o Bohan and Peter score indicating definite DM or PM o Bohan and Peter score indicating probable DM or PM AND concurring diagnostic evaluation by ≥ 1 specialist (e.g., neurologist, rheumatologist, dermatologist) • Member 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: o Member has a documented trial and failure of, or has a documented medical reason for not using methotrexate (MTX) OR azathioprine o 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).

Revision/Review Date: 11/2025	• 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 the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. If all of the above conditions are met, the request will be approved for up to a 1-month duration **Re-authorization:** • Rituximab is being recommended and prescribed by a neurologist, rheumatologist, or dermatologist. • Documentation was provided indicating that the member 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 **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 member 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 the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. If all of the above conditions are met, the request will be approved for up to a 3-month duration. **<u>Re-authorization:</u>** • 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. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Prior Authorization Group Description	**Rivastigmine Patch Step Therapy**
Drugs	Rivastigmine (Exelon) patch
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 of the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 11/2025	Prior use of rivastigmine capsule required. **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Roflumilast (Daliresp)**
Drugs	Roflumilast (Daliresp)
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 pulmonologist
Coverage Duration	If all of the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 02/2026	• Documented diagnosis of severe chronic obstructive pulmonary disorder (COPD) associated with chronic bronchitis and a history of exacerbations. • Documented trial and failure or intolerance with a preferred inhaled LABA/LAMA combination, or LABA/LAMA/ICS combination for a minimum of 4 weeks of therapy in the previous 60 days. • Documented continuation of therapy with LABA or LAMA. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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	Prescribed by a hematologist or oncologist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Other Criteria Review/Revision Date: 08/2025	**Initial Authorization:** • Diagnosis of myelodysplastic syndromes (MDS) with transfusion-dependent anemia • Myelodysplastic Syndrome Revised International Prognostic Scoring System (IPSS-R) categorization as low or intermediate-1 risk of progression • 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 **Re-Authorization:** • Documentation or provider attestation of reduction in RBC transfusion burden as compared with baseline • Provider attestation that member 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 **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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
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
Criteria	**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 member 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

Revision/Review Date: 11/2025	• The provider must submit disease state specific standard of care guidelines supporting concurrent therapy. **<u>Age Restriction</u>** • 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. **<u>Day Supply Limit</u>** • 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. **<u>Concurrent Use/Drug-Drug Interaction</u>** • 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.**

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), AVONEX, REBIF (interferon beta-1a), BETASERON, EXTAVIA (interferon beta-1b), GLATOPA (glatiramer acetate), PLEGRIDY (peginterferon beta-1a), MAVENCLAD (cladribine), MAYZENT (siponimod), ZEPOSIA (ozanimod), PONVORY (ponesimod), BAFIERTAM (monomethyl fumarate), VUMERITY (diroximel fumarate), KESIMPTA (ofatumumab), TASCENSO ODT (fingolimod)
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	Member 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	**<u>Initial Authorization</u>** • 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. <u>Clinically Isolated Syndrome (CIS)</u> • Diagnosis of CIS • If the request is for dimethyl fumarate, or glatiramer approve. • If the request is for fingolimod, documentation of the following: o Healthcare Provider (HCP)-confirmed history of chickenpox, results of varicella zoster (VZV) antibody testing and, if negative, documentation of VZV vaccination • If the request is for a non-preferred 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 Gilenya, Ponvory (ponesimod), Mayzent (siponimod), Zeposia (ozanimod), or Tascenso ODT (fingolimod), HCP-confirmed history of chickenpox, results of VZV antibody testing and, if negative, documentation of VZV vaccination

	▪ Additionally, if the request is for Mayzent (siponimod), results of CYP2C9 genotyping. **AND** • Member does not have CYP2C9 *3/*3 (**CONTRAINDICATED**) • If member has CYP2C9 *1/*3 or *2/*3, dose does not exceed 1 mg daily ▪ Additionally, if the request is for Tascenso ODT (fingolimod), documentation of member's current weight. o If the request is for Kesimpta (ofatumumab), documentation that immunizations are up-to-date. <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, documentation of the following: o Healthcare Provider (HCP)-confirmed history of chickenpox, results of varicella zoster (VZV) antibody testing and, if negative, documentation of VZV vaccination • If the request is for a non-preferred 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 Mavenclad (cladribine), documentation of the following: ▪ Member's current weight ▪ Results of VZV antibody testing and, if negative, documentation of VZV vaccination ▪ If the member has not tried at least one of the preferred therapies listed above but has a documented medical reason for not utilizing these therapies, the member has tried and failed at least one other DMT for MS o If the request is for Ponvory (ponesimod), Mayzent (siponimod), Zeposia (ozanimod) or Tascenso ODT (fingolimod), HCP-confirmed history of chickenpox, results of VZV antibody testing and, if negative, documentation of VZV vaccination ▪ Additionally, if the request is for Mayzent (siponimod), results of CYP2C9 genotyping. **AND** • Member does not have CYP2C9 *3/*3 (**CONTRAINDICATED**) • if member has CYP2C9 *1/*3 or *2/*3, dose does not exceed 1 mg daily. ▪ Additionally, if the request is for Tascenso ODT (fingolimod), documentation of members current weight. o If the request is for Kesimpta (ofatumumab), documentation that immunizations are up-to-date. **<u>Reauthorization</u>**

Revision/Review Date 02/2026	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 Member's current weight o ****NO MORE THAN 2 COURSES IN TOTAL WILL BE APPROVED.**** **Continuation of Therapy Provision:** Members with history (within the past 90 days or past 12 months for Mavenclad [cladribine]) 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.**

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	Prescribed by an HIV or infectious disease specialist
Coverage Duration	If all of the criteria are met, the request will be approved for up to a 12 week duration
Other Criteria	**<u>Initial Authorization</u>:** • Member has been receiving optimal highly active antiretroviral therapy (HAART) for at least three months prior to initiation • Prescriber attests that the member 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 member'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) 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 Member has had an insufficient response to a three month trial of one of the following agents: megestrol acetate, cyproheptadine, or dronabinol **<u>Re-authorization:</u>** • The member is receiving concomitant anti-HIV treatment • The prescriber has provided documentation of clinical benefit/response to Serostim. • Request is for FDA approved or medically accepted dosing
Revision/Review Date: 08/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Silodosin (Rapaflo) Step Therapy**
Drugs	Silodosin (Rapaflo)
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 of the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 05/2025	Documented trial and failure of or intolerance to alfuzosin ER, and at least one of the following: doxazosin, tamsulosin, or terazosin **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Skyclarys (omaveloxolone)**
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	According to package insert
Prescriber Restrictions	Prescribed by 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 request will be approved for a 12 month duration.
Other Criteria Revision/Review Date 08/2025	**<u>Initial Authorization:</u>** • 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 **<u>Re-Authorization:</u>** • 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.**

Prior Authorization Group Description	**Sleep Disorder Therapy**
Drugs	Formulary: modafinil (Provigil) tablets armodafinil (Nuvigil) tablets Sunosi (solriamfetol) tablets sodium oxybate (Xyrem) solution Xywav (oxybate salts) solution Non-Formulary: Lumryz (sodium oxybate) Wakix (pitolisant) tablets Any other marketed agents within 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	Sodium oxybate (Xyrem)/Xywav/Lumryz: Succinic semialdehyde dehydrogenase deficiency
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
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 all of the criteria are met, requests will be approved with up to a 12 month duration.
Other Criteria	**<u>For all requests:</u>** • Medication is being prescribed at an FDA approved dose • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **<u>Modafinil/armodafinil initial authorization:</u>** • 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)]. • For all diagnoses, requests for armodafinil require a trial and failure of modafinil or a medical reason why (e.g., contraindication, intolerance, hypersensitivity, age) modafinil cannot be used **<u>Sunosi initial authorization</u>**

Revision/Review Date 08/2025	• Documented trial and failure of modafinil or armodafinil or a documented medical reason why (e.g., contraindication, intolerance, hypersensitivity, age) these cannot be used • For members with OSA, documentation that the member has been compliant with or unable to use positive airway pressures (CPAP, BPAP, or APAP) • Medication is not being taken concurrently or within 14 days of an MAOI **<u>Wakix initial authorization:</u>** • For a diagnosis of narcolepsy **without cataplexy**, documented trial and failure of, or medical reason for not utilizing, each of the following: o Modafinil or armodafinil **AND** o Sunosi **<u>*For members under 18 years of age, no prerequisite medication trials are required*</u>** • 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 utilizing dextroamphetamine **<u>Sodium Oxybate (Xyrem)/Xywav/Lumryz initial authorization</u>** • Medication is not being taken concurrently with sedative hypnotics • If member has a history of substance abuse, documentation has been provided that prescriber has referred the member for substance abuse disorder treatment. ***For members under 18 years of age, no prerequisite medication trials are required*** • For diagnosis of narcolepsy without cataplexy: o Documented trial and failure of, or medical reason why (e.g., contraindication, intolerance, hypersensitivity, age) ALL of the following cannot be used: ▪ Modafinil or armodafinil ▪ Sunosi (solriamfetol) o For Xyrem, Xywav, or Lumryz: documented trial and failure of, or medical reason for not using generic sodium oxybate • For diagnosis of narcolepsy with cataplexy: o Documented trial and failure of or medical reason why (e.g., contraindication, intolerance, hypersensitivity, age) the following cannot be used ▪ Dextroamphetamine o For Xyrem, Xywav, or Lumryz: documented trial and failure of, or medical reason for not using generic sodium oxybate • For diagnosis of idiopathic hypersomnia (Xywav only):

	○ Documented trial and failure of or medical reason why (e.g., contraindication, intolerance, hypersensitivity, age) the following cannot be used ▪ 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) • 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**

Prior Authorization Group Description	**SMN2 Splicing Modifiers for the Treatment of Spinal Muscular Atrophy (SMA)**
Drugs	Formulary: Evrysdi (risdiplam) Non-Formulary: Spinraza (nusinersen) Any other marketed agent within 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), and the Drug Package Insert (PPI).
Exclusion Criteria	Concomitant use of Evrysdi and Spinraza
Required Medical Information	For Evrysdi: Member's body weight
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by a neurologist
Coverage Duration	For Evrysdi: If all of the criteria are met, the request will be approved for 6 months for initial authorization, followed by 12 months for reauthorization requests. For Spinraza: If all of the criteria are met, the request will be approved for 6 months for 5 doses (4 loading doses and 1st maintenance dose) for initial authorization, and 12 months for 3 additional maintenance doses for reauthorization requests.
Other Criteria	**Initial authorization** • 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 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, Revised Upper Limb Module (RULM), or Motor Function Measure 32 (MFM-32)] • The request is for an FDA approved dose • Member has not previously received treatment with Zolgensma or Itvisma • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary medications appropriate for the requested use (per the references outlined in "Covered Uses" or has a medical reason why

Revision/Review Date 02/2026	these drug(s) cannot be used (e.g., intolerance, contraindication). For medications where there is only one formulary agent, only that agent must have been ineffective or not tolerated. **<u>Reauthorization</u>** • Documentation of clinical response was submitted with request (e.g., improvement or stabilization 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, RULM, MFM-32, 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.**

Prior Authorization Group Description	**Sohonos (palovarotene)**
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 members 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 request will be approved for up to 12 months
Other Criteria Review/Revision Date: 11/2025	**<u>Initial Authorization:</u>** • Documented diagnosis of fibrodysplasia ossificans progressiva (FOP) • Documented genetic testing of ACVR1 R206H mutation • Attestation that member 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 members younger than 14 years old • Medication is prescribed at an FDA approved dose **<u>Re-Authorization:</u>** • 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 member 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 members younger than 14 years old • 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.**

Prior Authorization Group Description	**Solosec Step Therapy**
Drugs	Solosec 2 gm 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	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 08/2025	1. Prior use of metronidazole tablets required. **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Somatostatin Analogs and Growth Hormone Receptor Antagonists**
Drugs	Formulary: Lanerotide 120 mg/ 0.5 mL (Somatuline Depot) Somatuline Depot 60 mg/0.2 mL. 90 mg/0.3 mL (lanreotide) Octreotide (Sandostatin, Sandostatin LAR) Signifor (pasireotide) Somavert (pegvisomant) Non-Formulary: Palsonify (paltusotine) Any other marketed agent within the class
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA) Drug Package Insert (PPI).
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 with appropriate expertise in treating the condition in question (such as an endocrinologist, neurologist/neurosurgeon, oncologist, etc.).
Coverage Duration	If all of the criteria are met, 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 combination therapy with an immediate release somatostatin analog and a long-acting somatostatin analog OR a somatostatin analog and growth hormone receptor antagonist (e.g., pegvisomant), then documentation must be submitted as to why member is unable to be treated with monotherapy, or a medical reason was provided why monotherapy is not appropriate.
	• If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated.
	
	For Acromegaly
	• Member must have had inadequate response to, or medical reason why patient cannot use one of the following:
	  o surgical treatment
	  o trial of a dopamine agonist (ex: bromocriptine mesylate, cabergoline) at a therapeutically appropriate dose
	• If request is for pegvisomant, member must have trial and failure or medical reason for being unable to use a somatostatin analog (e.g., octreotide, lanreotide).

	• Requests for use of a somatostatin analog or growth hormone receptor antagonist in combination with radiotherapy will be approved. <u>For Cushing's Disease (pasireotide products only)</u> • Member must have had inadequate response or medical reason why member cannot undergo surgical treatment. • Requests for use of a somatostatin analog or growth hormone receptor antagonist in combination with radiotherapy will be approved. **<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 02/2026	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Specialty Biological Agents for Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis**
Drugs	**Preferred Pharmacy Benefit Agents:** Abrilada (adalimumab-afzb) Adalimumab-aaty (unbranded Yuflyma) Adalimumab-fkjp (unbranded Hulio) Enbrel (etanercept) Hadlima (adalimumab-bwwb) Rinvoq/Rinvoq LQ (upadacitinib) Simlandi (adalimumab-ryvk)Taltz (ixekizumab) Xeljanz/Xeljanz XR (tofacitinib) Yusimry (adalimumab-aqvh) **Non-Preferred Pharmacy Benefit Agents:** Cimzia (certolizumab) Cosentyx SC (secukinumab) Simponi (golimumab) **Non-Formulary Pharmacy Agents:** All adalimumab biosimilar agents not listed as preferred (e.g., Amjevita, Cyltezo, Hyrimoz) Bimzelx (bimekizumab-bkzx) Humira (adalimumab) Any other marketed agent within the class **Medical Benefit Agents:** Infliximab--**Preferred Infliximab** Avsola (infliximab-axxq) Inflectra (infliximab-dyyb) Remicade (infliximab) Renflexis (infliximab-abda) Simponi Aria (golimumab) Cosentyx IV (secukinumab) Any other marketed IV agent within 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	N/A
Required Medical Information	N/A
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by, or in consultation with, a rheumatologist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 month duration.
Other Criteria	**Initial Authorization:** • The member has a diagnosis of ankylosing spondylitis or nonradiographic axial spondyloarthritis AND

	• The medication is being prescribed at an appropriate FDA approved dose (for age and weight) or dose referenced in compendia/guidelines • The member has an adequate trial (consistent with pharmacy claims/medical record data/physician attestation) with at least two different nonsteroidal anti-inflammatory drugs (NSAIDs) OR • Member has a documented medical reason (e.g., allergy, intolerance, contraindication) for not using two NSAIDs to manage their condition. • If the request is for Xeljanz/XR (tofacitinib) or Rinvoq (upadacitinib), there is documented (consistent with pharmacy claims/medical record data/physician attestation), adequate trial of a preferred tumor necrosis factor (TNF) inhibitor. • If the request is for Cimzia for nr-axSpA, documented (consistent with pharmacy claims/medical record data/physician attestation), adequate trial of two preferred products or documentation that a TNFi is medically necessary and no other TNFi is indicated. • If the request is for a non-preferred or non-formulary biologic agent, documented (consistent with pharmacy claims/medical record data/physician attestation), adequate trial of at least two preferred products or a medical reason as to why the member is unable to utilize the preferred products. o If the request is for Cosentyx or Bimzelx, documented (consistent with pharmacy claims/medical record data) adequate trial of Taltz or medical reason as to why member is unable to utilize the product. • If the request is for a reference brand with therapeutically equivalent biosimilars (e.g., Humira or Stelara), documented adequate trial of all formulary biosimilars or a medical reason as to why the member is unable to utilize the formulary products. • If the request is for Avsola, Renflexis, or Inflectra, documented (consistent with pharmacy claims/medical record data/chart notes/physician attestation), adequate trial of infliximab. • If the request is for Remicade, documented (consistent with pharmacy claims/medical record data/chart notes/physician attestation), adequate trial of infliximab, Avsola, Renflexis, AND Inflectra. **Reauthorization:** • The medication is being prescribed at an appropriate FDA approved dose or dose referenced in compendia/guidelines • The member has been receiving the medication and documentation was provided that the prescriber has evaluated the member and recommends continuation of therapy (clinical benefit). • If the request is for a reference brand with therapeutically equivalent biosimilars (e.g., Humira or Stelara), documented adequate trial of all formulary biosimilars or a medical reason as to why the member is unable to utilize the formulary products. **Continuation of Therapy Provision**:

Revision/Review Date 08/2025	• Members with history (within the past 90 days) of a preferred biological agent are not required to try the above mentioned conventional therapies prior to receiving the preferred biological agent. • Members with history (within the past 90 days) of a non-preferred biological product are not required to demonstrate trial of preferred biological agents nor the above mentioned conventional therapies prior to receiving the non-preferred agent. **Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Prior Authorization Group Description	**Specialty Biological Agents for Crohn's Disease**
Drugs	**Preferred Pharmacy Benefit Agents:** Abrilada (adalimumab-afzb) Adalimumab-aaty (unbranded Yuflyma) Adalimumab-fkjp (unbranded Hulio) Hadlima (adalimumab-bwwb) Rinvoq/Rinvoq LQ (upadacitinib) Simlandi (adalimumab-ryvk) Skyrizi (risankizumab) Yusimry (adalimumab-aqvh) **Non-Preferred Pharmacy Benefit Agents:** Cimzia (certolizumab) Imuldosa (ustekinumab-srlf) Steqeyma (ustekinumab-stba) Yesintek (ustekinumab-kfce) Otulfi (ustekinumab-aauz) Selarsdi (ustekinumab-aekn) Tremfya (guselkumab) **Non-Formulary Pharmacy Benefit Agents:** All adalimumab biosimilar agents not listed as preferred (e.g., Amjevita, Cyltezo, Hyrimoz) Stelara SC (ustekinumab) Entyvio SC (vedolizumab) Humira (adalimumab) Omvoh SC (mirikizumab) All ustekinumab biosimilar agents not listed as preferred (e.g., Pyzchiva, Wezlana) Any other marketed agent within the class **Medical Benefit Agents:** Infliximab-**Preferred Infliximab** Avsola (infliximab-axxq) Entyvio IV (vedolizumab) Inflectra (infliximab-dyyb) Omvoh IV (mirikizumab) Remicade (infliximab) Renflexis (infliximab-abda) Stelara IV (ustekinumab) All ustekinumab biosimilars IV Tysabri (natlizumab) Any other marketed IV agent within 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	N/A

Required Medical Information	N/A
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by, or in consultation with, a gastroenterologist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 month duration.

Other Criteria	**Initial Authorization:**
	• Documentation of one of the following:
	  o Request is for induction of remission in moderate-severe/high risk Crohn's disease, severe/fulminant Crohn's disease, or perianal/fistulizing Crohn's disease
	  o Request is for use in mild/low risk Crohn's disease for a member who has been unable to achieve or maintain remission after an adequate trial (consistent with pharmacy claims/medical record data/physician attestation) of a systemic corticosteroid AND traditional immunomodulatory therapy (e.g., sulfasalazine, azathioprine, 6-mercaptopurine, or methotrexate) or the member has a documented medical reasons (e.g., allergy, intolerance, or contraindication) for not using these therapies to manage the condition
	  o Request is for maintenance of remission achieved with use of biologic therapy
	• If the request is for a non-preferred or non-formulary biologic agent, documented (consistent with pharmacy claims/medical record data/physician attestation), adequate trial of at least two preferred products or a medical reason as to why the member is unable to utilize the preferred products.
	• If the request is for a reference brand with therapeutically equivalent biosimilars (e.g., Humira or Stelara), documented adequate trial of all formulary biosimilars or a medical reason as to why the member is unable to utilize the formulary products.
	• If the request is for Rinvoq (upadicitinib), there is documented (consistent with pharmacy claims/medical record data/physician attestation), adequate trial of a preferred tumor necrosis factor (TNF) inhibitor.
	• If the request is for Avsola, Renflexis, or Inflectra, documented (consistent with pharmacy claims/medical record data/chart notes/physician attestation), adequate trial of infliximab.
	• If the request is for Remicade, documented (consistent with pharmacy claims/medical record data/chart notes/physician attestation), adequate trial of infliximab, Avsola, Renflexis, AND Inflectra.
	
	Reauthorization:
	• The medication is being recommended and prescribed by a gastroenterologist at an FDA-approved dosage.
	• The member has been receiving the medication and documentation was provided that the prescriber has evaluated the member and recommends continuation of therapy (clinical benefit).
	• If the request is for a reference brand with therapeutically equivalent biosimilars (e.g., Humira or Stelara), documented adequate trial of all formulary biosimilars or a medical reason as to why the member is unable to utilize the formulary products.
	
	Continuation of Therapy Provision:

Revision/Review Date: 08/2025	• Members with history (within the past 90 days) of a preferred biological agent are not required to try the above mentioned conventional therapies prior to receiving the preferred biological agent. • Members with history (within the past 90 days) of a non-preferred biological product are not required to demonstrate trial of preferred biological agents nor the above mentioned conventional therapies prior to receiving the non-preferred agent. **Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Prior Authorization Group Description	**Specialty Biological Agents for Inflammatory Conditions**
Drugs	***Two preferred biological agents must be tried and failed, prior to approval of non-preferred and/or non-formulary biological agents, unless not FDA indicated*** **Please refer to each indication-based policy below for coverage requirements.** **Preferred Pharmacy Benefit Agents:** Abrilada (adalimumab-afzb) Adalimumab-aaty (unbranded Yuflyma) Adalimumab-fkjp (unbranded Hulio) Enbrel (etanercept) Hadlima (adalimumab-bwwb) Rinvoq/Rinvoq LQ (upadicitinib) Simlandi (adalimumab-ryvk) Skyrizi (risankizumab) Taltz (ixekizumab) Xeljanz/Xeljanz XR (tofacitinib) Yusimry (adalimumab-aqvh) **Non-Preferred Pharmacy Benefit Agents:** Actemra SC (tocilizumab) Cimzia (certolizumab) Cosentyx SC (secukinumab) Ilumya (tildrakizumab-asmn) Imuldosa (ustekinumab-srlf) Kevzara (sarilumab) Kineret (anakinra) Olumiant (baricitinib) Orencia SC (abatacept) Otezla (apremilast) Siliq (brodalimumab) Simponi (golimumab) Steqeyma (ustekinumab-stba) Yesintek (ustekinumab-kfce) Otulfi (ustekinumab-aauz) Selarsdi (ustekinumab-aekn) Sotyktu (deucravacitinib) Tremfya SC (guselkumab) **Non-Formulary Pharmacy Benefit Agents:** All adalimumab biosimilar agents not listed as preferred (e.g., Amjevita, Cyltezo, Hyrimoz) Bimzelx (bimekizumab-bkzx) Entyvio SC (vedolizumab) Humira (adalimumab) Ilaris (canakinumab) Omvoh SC (mirikizumab) Stelara SC (ustekinumab) Tyenne SC (tocilizumab-aazg)

Revision/Review Date: 07/2025	Velsipity (etrasimod) Zymfentra (infliximab-dyyb) All ustekinumab biosimilar agents not listed as preferred (e.g., Pyzchiva, Wezlana) Any other marketed agent within the class **Medical Benefit Agents:** Infliximab-**Preferred Infliximab** Actemra IV (tocilizumab) Avsola (infliximab-axxq) Cosentyx IV (secukinumab) Entyvio IV (vedolizumab) Inflectra (infliximab-dyyb) Omvoh IV (mirikizumab) Orencia IV (abatacept) Remicade (infliximab) Renflexis (infliximab-abda) Simponi Aria (golimumab) Stelara IV (ustekinumab) Tofidence (tocilizumab-bavi) Tremfya IV (guselkumab) Tyenne IV (tocilizumab-aazg) Tysabri (natalizumab) All ustekinumab biosimilars IV Any other marketed IV agent within the class

Prior Authorization Group Description	**Specialty Biologic Agents for Juvenile Idiopathic Arthritis**
Drugs	**<u>Pharmacy Benefit Agents</u>** Abrilada (adalimumab-afzb) Actemra SC (tocilizumab) Adalimumab-aaty (unbranded Yuflyma) Adalimumab-fkjp (unbranded Hulio) Cimzia (certolizumab pegol) Cosentyx SC (secukinumab) Enbrel (etanercept) Hadlima (adalimumab-bwwb) Humira (adalimumab) Imuldosa (ustekinumab-srlf) Kevzara (sarilumab) Kineret (anakinra) Orencia SC (abatacept) Rinvoq/Rinvoq LQ (upadacitinib) Simlandi (adalimumab-ryvk) Stelara SC (ustekinumab) All ustekinumab biosimilars SC (e.g., Steqeyma, Yesintek, Otulfi, Selarsdi) Xeljanz/Xeljanz XR (tofacitinib) Yusimry (adalimumab-aqvh) Any other marketed agent within the class **<u>Medical Benefit Agents</u>** Actemra IV (tocilizumab) Avsola (infliximab-axxq) Cosentyx IV (secukinumab) Inflectra (infliximab-dyyb) Infliximab -**Preferred Infliximab** Orencia IV (abatacept) Remicade (infliximab) Renflexis (infliximab-abda) Simponi Aria (golimumab) Stelara IV (ustekinumab) Tyenne IV (tocilizumab-aazg) Tofidence (tocilizumab-bavi) All ustekinumab biosimilars IV Any other IV marketed agent within 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	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert

Prescriber Restrictions	Prescribed by, or in consultation with, a rheumatologist or dermatologist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Other Criteria	**Initial Authorization:** **For a diagnosis of polyarticular juvenile idiopathic arthritis:** Preferred Pharmacy Benefit Agents: Hadlima (adalimumab-bwwb) Abrilada (adalimumab-afzb) Adalimumab-aaty (unbranded Yuflyma) Adalimumab-fkjp (unbranded Hulio) Enbrel (etanercept) Simlandi (adalimumab-ryvk) Xeljanz/Xeljanz XR (tofacitinib) Rinvoq/Rinvoq LQ (upadacitinib) Yusimry (adalimumab-aqvh) Non-Preferred Pharmacy Benefit Agents Actemra Prefilled Syringe/Auto-Injector (tocilizumab) Cimzia (certolizumab pegol) Kevzara (sarilumab) Orencia SC (abatacept) Non-Formulary Pharmacy Benefit Agents All adalimumab biosimilar agents not listed as preferred (e.g., Amjevita, Cyltezo, Hyrimoz) Humira (adalimumab) Tyenne SC (tocilizumab-aazg) Medical Benefit Agents Actemra IV (tocilizumab) Simponi Aria (Golimumab) Orencia IV (abatacept) Tyenne IV (tocilizumab-aazg) Tofidence (tocilizumab-bavi) • The medication is being prescribed at an appropriate FDA approved dose (for age and weight) • The member has an adequate trial (consistent with pharmacy claims/medical record data/physician attestation) with one disease modifying anti-rheumatic drug (DMARD) (e.g., methotrexate) or leflunomide or sulfasalazine, or one of the following is true: o Member has a documented medical reason (e.g., allergy, intolerance, contraindication) for not using conventional therapy to manage their condition. o Member has one or more of the following: Risk factors (ex. positive rheumatoid factor, positive anti-cyclic citrullinated peptide antibodies, joint damage) and have involvement of high-risk joints, high disease activity, and/or those judged to be at high-risk of disabling joint damage

	• If the request is for Rinvoq (upadacitinib) or Xeljanz (tofacitinib), there is documented (consistent with pharmacy claims/medical record data/physician attestation), adequate trial of a preferred tumor necrosis factor (TNF) inhibitor. • If the request is for a non-preferred or non-formulary agent, documented (consistent with pharmacy claims/medical record data/chart notes, physician attestation) adequate trial of two preferred biological agents. • If the request is for a reference brand with therapeutically equivalent biosimilars (e.g., Humira or Stelara), documented adequate trial of all formulary biosimilars or a medical reason as to why the member is unable to utilize the formulary products. **For a diagnosis of systemic juvenile idiopathic arthritis:** <u>Preferred Pharmacy Benefit Agents:</u> Hadlima (adalimumab-bwwb) Abrilada (adalimumab-afzb) Adalimumab-aaty (unbranded Yuflyma) Adalimumab-fkjp (unbranded Hulio) Simlandi (adalimumab-ryvk) Yusimry (adalimumab-aqvh) <u>Non-Preferred Pharmacy Benefit Agents:</u> Actemra SC (tocilizumab) Orencia SC (abatacept) Kineret (anakinra) <u>Non-Formulary Pharmacy Benefit Agents</u> Humira (adalimumab) Ilaris (canakinumab) <u>Medical Benefit Agents:</u> Actemra IV (tocilizumab) Orencia IV (abatacept) Tyenne IV (tocilizumab-aazg) Tofidence (tocilizumab-bavi) • The medication is being prescribed at an appropriate FDA approved, or compendia supported, dose (for age and weight). • One of the following is true: o The member has an adequate trial (consistent with pharmacy claims/medical record data/physician attestation) with one of the following: ▪ Non-steroidal anti-inflammatory drug (NSAID) ▪ Systemic glucocorticoids ▪ Methotrexate ▪ Leflunomide ▪ Cyclosporine or tacrolimus o The member has a documented medical reason (e.g., allergy,

	intolerance, contraindication) for not using conventional therapy to manage their condition. o The member has a diagnosis of sJIA with macrophage activation syndrome (MAS) • If the request is for a non-preferred or non-formulary agent, documented (consistent with pharmacy claims/medical record data/chart notes, physician attestation) adequate trial of two preferred biological agents. • If the request is for a reference brand with therapeutically equivalent biosimilars (e.g., Humira or Stelara), documented adequate trial of all formulary biosimilars or a medical reason as to why the member is unable to utilize the formulary products. **For a diagnosis of juvenile psoriatic arthritis:** <u>Preferred Pharmacy Benefit Agents:</u> Enbrel (etanercept) Rinvoq/Rinvoq LQ (upadacitinib) <u>Non-Preferred Pharmacy Benefit Agents:</u> Cosentyx SC (secukinumab) Imuldosa (ustekinumab-srlf) Orencia SC (abatacept) Steqeyma (ustekinumab-stba) Yesintek (ustekinumab-kfce) Otulfi (ustekinumab-aauz) Selarsdi (ustekinumab-aekn) <u>Non-Formulary Pharmacy Benefit Agents:</u> Stelara SC (ustekinumab) <u>Medical Benefit Agents:</u> Cosentyx IV (secukinumab) Orencia IV (abatacept) Simponi Aria (golimumab) Stelara IV (ustekinumab) All ustekinumab biosimilars IV • The medication is being prescribed at an appropriate FDA approved dose (for age and weight). • One of the following is true: o The member has an adequate trial (consistent with pharmacy claims/medical record data/physician attestation) with nonsteroidal anti-inflammatory drugs (NSAIDs) or a cyclooxygenase-2 (COX-2) inhibitor and then a conventional DMARD (e.g., leflunomide, methotrexate or sulfasalazine) o Member has a documented medical reason (e.g., allergy, intolerance, contraindication) for not using NSAIDs or COX-2 inhibitors, then a DMARD to manage their condition. o There is documentation of severe erosive disease with

	functional limitation. o Member has axial disease (i.e., involving the sacroiliac joints and spine) or enthesitis (i.e., involving the plantar fascia and Achilles tendon insertion) and has tried and failed NSAIDs or COX-2 inhibitor therapy. • If the request is for Rinvoq (upadacitinib), there is documented (consistent with pharmacy claims/medical record data/physician attestation), adequate trial of a preferred tumor necrosis factor (TNF) inhibitor. • If the request is for a non-preferred or non-formulary agent, documented (consistent with pharmacy claims/medical record data/chart notes, physician attestation) adequate trial of two preferred biological agents. • If the request is for a reference brand with therapeutically equivalent biosimilars (e.g., Humira or Stelara), documented adequate trial of all formulary biosimilars or a medical reason as to why the member is unable to utilize the formulary products. **For a diagnosis of enthesitis-related arthritis:** <u>Preferred Pharmacy Benefit Agents:</u> Hadlima (adalimumab-bwwb) Abrilada (adalimumab-afzb) Adalimumab-aaty (unbranded Yuflyma) Adalimumab-fkjp (unbranded Hulio) Enbrel (etanercept) Simlandi (adalimumab-ryvk) Yusimry (adalimumab-aqvh) <u>Non-Preferred Pharmacy Benefit Agents:</u> Cosentyx SC (secukinumab) <u>Non-Formulary Pharmacy Benefit Agents</u> Humira (adalimumab) <u>Medical Benefit Agents:</u> Simponi Aria (golimumab) Infliximab-**Preferred Infliximab** Avsola (infliximab-axxq) Remicade (infliximab) Renflexis (infliximab-abda) Inflectra (infliximab-dyyb) Cosentyx IV (secukinumab) • The medication is being prescribed at an appropriate FDA approved, or compendia supported, dose (for age and weight). • The member has an adequate trial with a nonsteroidal anti-inflammatory drug (NSAID) or a cyclooxygenase-2 (COX-2) inhibitor, or member has a documented medical reason (e.g., allergy, intolerance, contraindication) for not using one of these agents.

Revision/Review Date: 08/2025	• If the request is for a TNF inhibitor other than adalimumab or Enbrel, one of the following:
	  o Documented (consistent with pharmacy claims/medical record data/chart notes/physician attestation), adequate trial of adalimumab and Enbrel.
	  o Member has a documented medical reason (e.g., allergy, intolerance, contraindication) for not using adalimumab and Enbrel to manage their condition.
	• If the request is for Renflexis, Inflectra, or Avsola; documented (consistent with pharmacy claims/medical record data/chart notes/physician attestation), adequate trial of infliximab.
	• If the request is for Remicade, documented (consistent with pharmacy claims/medical record data/chart notes/physician attestation), adequate trial of infliximab, Avsola, Renflexis, AND Inflectra.
	• If the request is for a reference brand with therapeutically equivalent biosimilars (e.g., Humira or Stelara), documented adequate trial of all formulary biosimilars or a medical reason as to why the member is unable to utilize the formulary products.
	
	Re-Authorization:
	• The medication is being prescribed at an appropriate FDA approved, or compendia supported, dose (for age and weight)
	• The member has been receiving the medication and documentation was provided that the prescriber has evaluated the member and recommends continuation of therapy (clinical benefit).
	• If the request is for a reference brand with therapeutically equivalent biosimilars (e.g., Humira or Stelara), documented adequate trial of all formulary biosimilars or a medical reason as to why the member is unable to utilize the formulary products.
	
	Continuation of Therapy Provision:
	• Members with history (within the past 90 days) of a preferred biological agent are not required to try the above mentioned conventional therapies prior to receiving the preferred biological agent.
	• Members with history (within the past 90 days) of a non-preferred biological product are not required to demonstrate trial of preferred biological agents nor the above mentioned conventional therapies prior to receiving the non-preferred agent.
	
	Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Prior Authorization Group Description	**Specialty Biological Agents for Psoriasis**
Drugs	**Preferred Pharmacy Benefit Agents:** Abrilada (adalimumab-afzb) Adalimumab-aaty (unbranded Yuflyma) Adalimumab-fkjp (unbranded Hulio) Enbrel (etanercept) Hadlima (adalimumab-bwwb) Simlandi (adalimumab-ryvk) Skyrizi (risankizumab-rzaa) Taltz (ixekizumab) Yusimry (adalimumab-aqvh) **Non-Preferred Pharmacy Benefit Agents:** Cimzia (certolizumab pegol) Cosentyx SC (secukinumab) Ilumya (tildrakizumab-asmn) Imuldosa (ustekinumab-srlf) Otezla (apremilast) Siliq (brodalumab) Sotyktu (deucravacitinib) Steqeyma (ustekinumab-stba) Yesintek (ustekinumab-kfce) Otulfi (ustekinumab-aauz) Selarsdi (ustekinumab-aekn) Tremfya SC (guselkumab) **Non-Formulary Pharmacy Benefit Agents:** All adalimumab biosimilar agents not listed as preferred (e.g., Amjevita, Cyltezo, Hyrimoz) Bimzelx (bimekizumab-bkzx) Humira (adalimumab) Stelara SC (ustekinumab) All ustekinumab biosimilar agents not listed as preferred (e.g., Pyzchiva, Wezlana) Any other marketed agent within the class **Medical Benefit Agents** Infliximab- **Preferred Infliximab** Avsola (infliximab-axxq) Cosentyx IV (secukinumab) Inflectra (infliximab-dyyb) Remicade (infliximab) Renflexis (infliximab-abda) Stelara IV (ustekinumab) Tremfya IV (guselkumab) All ustekinumab biosimilars IV Any other marketed IV agent within 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	N/A
Required Medical Information	N/A
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by, or in consultation with, a dermatologist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 month duration.
Other Criteria	**Initial Authorization:** • Member has a diagnosis of plaque psoriasis AND the medication is being prescribed at an appropriate FDA approved dose (for age and weight) • The member has an adequate-trial (consistent with pharmacy claims/medical record data/ physician attestation) of a therapy in 3 of the following categories, at least one of which must be either a systemic therapy or phototherapy: o Topical steroids o Topical tacrolimus or pimecrolimus o Topical calcipotriene, calcitriol, or Tazorac (tazarotene) o Topical anthralin, coal tar, or salicylic acid o Oral methotrexate or cyclosporine o Oral acitretin o UVB phototherapy or PUVA (psoralen-oral or topical methoxsalen plus UVA therapy) **OR** • Member has a documented medical reason (e.g., allergy, intolerance, contraindication) for not using 3 of these therapies to manage their condition. • If the request is for a non-preferred or non-formulary agent, documented (consistent with pharmacy claims/medical record data) adequate trial of at least two preferred products or medical reason as to why member is unable to utilize the products. o If the request is for Cosentyx, Bimzelx, or Siliq, documented (consistent with pharmacy claims/medical record data) adequate trial of Taltz or medical reason as to why member is unable to utilize the product. • If the request is for a reference brand with therapeutically equivalent biosimilars (e.g., Humira or Stelara), documented adequate trial of all formulary biosimilars or a medical reason as to why the member is unable to utilize the formulary products. • If the request is for Renflexis, Inflectra, or Avsola documented (consistent with pharmacy claims/medical record data/chart notes/physician attestation), adequate trial of infliximab. • If the request is for Remicade, documented (consistent with pharmacy claims/medical record data/chart notes/physician attestation), adequate trial of infliximab, Avsola, Renflexis, AND Inflectra. **Reauthorization:**

Revision/Review Date: 08/2025	• The medication is being recommended or prescribed by a dermatologist at an FDA-approved dosage. • The member has been receiving the medication and documentation was provided that the prescriber has evaluated the member and recommends continuation of therapy (clinical benefit). • If the request is for a reference brand with therapeutically equivalent biosimilars (e.g., Humira or Stelara), documented adequate trial of all formulary biosimilars or a medical reason as to why the member is unable to utilize the formulary products. **Continuation of Therapy Provision**: • Members with history (within the past 90 days) of a preferred biological agent are not required to try the above mentioned conventional therapies prior to receiving the preferred biological agent. • Members with history (within the past 90 days) of a non-preferred biological product are not required to demonstrate trial of preferred biological agents nor the above mentioned conventional therapies prior to receiving the non-preferred agent. **Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Prior Authorization Group Description	**Specialty Biological Agents for Psoriatic Arthritis (PsA)**
Drugs	**Preferred Pharmacy Benefit Agents:** Abrilada (adalimumab-afzb) Adalimumab-aaty (unbranded Yuflyma) Adalimumab-fkjp (unbranded Hulio) Enbrel (etanercept) Hadlima (adalimumab-bwwb) Rinvoq/Rinvoq LQ (upadicitinib) Simlandi (adalimumab-ryvk) Skyrizi (risankizumab) Taltz (ixekizumab) Xeljanz/Xeljanz XR (tofacitinib) Yusimry (adalimumab-aqvh) **Non-Preferred Pharmacy Benefit Agents:** Cimzia (certolizumab) Cosentyx SC (secukinumab) Imuldosa (ustekinumab-srlf) Orencia SC (abatacept) Otezla (apremilast) Simponi (golimumab) Steqeyma (ustekinumab-stba) Yesintek (ustekinumab-kfce) Otulfi (ustekinumab-aauz) Selarsdi (ustekinumab-aekn) Tremfya SC (guselkumab) **Non-Formulary Pharmacy Benefit Agents:** All adalimumab biosimilar agents not listed as preferred (e.g., Amjevita, Cyltezo, Hyrimoz) Humira (adalimumab) Stelara SC (ustekinumab) All ustekinumab biosimilar agents not listed as preferred (e.g., Pyzchiva, Wezlana) Any other marketed agent within the class **Medical Benefit Agents** Infliximab-**Preferred Infliximab** Avsola (infliximab-axxq) Cosentyx IV (secukinumab) Inflectra (infliximab-dyyb) Orencia IV (abatacept) Remicade (infliximab) Renflexis (infliximab-abda) Simponia Aria (golimumab) Stelara IV (ustekinumab) Tremfya IV (guselkumab) All ustekinumab biosimilars IV Any other marketed IV agent within 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	N/A
Required Medical Information	N/A
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by, or in consultation with, a rheumatologist or dermatologist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 month duration.
Other Criteria	**Initial Authorization:** • The member has a diagnosis of psoriatic arthritis • The medication is being prescribed at an appropriate FDA approved dose (for age and weight) • If there is documentation of severe erosive disease with functional limitation, a preferred biologic agent may be approved • For all other members, one of the following must apply: o The member has an adequate trial (consistent with pharmacy claims/medical record data/physician attestation) with nonsteroidal anti-inflammatory drugs (NSAIDs) or a cyclooxygenase-2 (COX-2) inhibitor and then a conventional DMARD (e.g., leflunomide, methotrexate or sulfasalazine) OR o Member has axial disease (i.e., involving the sacroiliac joints and spine) or enthesitis (i.e., involving the plantar fascia and Achilles tendon insertion) and has tried and failed NSAID therapy ORhas a documented medical reason (e.g., allergy, intolerance, contraindication) for not using NSAIDs, then a DMARD to manage their condition. • If the request is for a non-preferred or non-formulary biologic agent, documented adequate trial (consistent with pharmacy claims/medical record data) of at least two preferred products or a medical reason as to why the member is unable to utilize the preferred products. o If the request is for Cosentyx or Bimzelx, documented (consistent with pharmacy claims/medical record data) adequate trial of Taltz or medical reason as to why member is unable to utilize the product. • If the request is for a reference brand with therapeutically equivalent biosimilars (e.g., Humira or Stelara), documented adequate trial of all formulary biosimilars or a medical reason as to why the member is unable to utilize the formulary products. • If the request is for Rinvoq (upadicitinib) or Xeljanz (tofacitinib), there is documented adequate trial (consistent with pharmacy claims/medical record data) of a preferred tumor necrosis factor (TNF) inhibitor. • If the request is for Avsola, Renflexis, or Inflectra, documented (consistent with pharmacy claims/medical record data/chart notes/physician attestation), adequate trial of infliximab.

Revision/Review Date: 08/2025	• If the request is for Remicade, documented (consistent with pharmacy claims/medical record data/chart notes/physician attestation), adequate trial of infliximab, Avsola, Renflexis, AND Inflectra **Reauthorization:** • The medication is being prescribed at an FDA-approved dosage. • The member has been receiving the medication and documentation was provided that the prescriber has evaluated the member and recommends continuation of therapy (clinical benefit). • If the request is for a reference brand with therapeutically equivalent biosimilars (e.g., Humira or Stelara), documented adequate trial of all formulary biosimilars or a medical reason as to why the member is unable to utilize the formulary products. **Continuation of Therapy Provision**: • Members with history (within the past 90 days) of a preferred biological agent are not required to try the above mentioned conventional therapies prior to receiving the preferred biological agent. • Members with history (within the past 90 days) of a non-preferred biological product are not required to demonstrate trial of preferred biological agents nor the above mentioned conventional therapies prior to receiving the non-preferred agent. **Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Prior Authorization Group Description	**Specialty Biological Agents for Rheumatoid Arthritis**
Drugs	**Preferred Pharmacy Benefit Agents:** Abrilada (adalimumab-afzb) Adalimumab-aaty (unbranded Yuflyma) Adalimumab-fkjp (unbranded Hulio) Enbrel (etanercept) Hadlima (adalimumab-bwwb) Rinvoq/Rinvoq LQ (upadacitinib) Simlandi (adalimumab-ryvk) Xeljanz/Xeljanz XR (tofacitinib) Yusimry (adalimumab-aqvh) **Non-Preferred Pharmacy Benefit Agents:** Actemra SC (tocilizumab) Cimzia (certolizumab) Kevzara (sarilumab) Kineret (anakinra) Olumiant (baricitinib) Orencia SC (abatacept) Simponi (golimumab) **Non-Formulary Pharmacy Benefit Agents:** All adalimumab biosimilar agents not listed as preferred (e.g., Amjevita, Cyltezo, Hyrimoz) Humira (adalimumab) Any other marketed agent within the class **Medical Benefit Agents** Infliximab-**Preferred Infliximab** Actemra IV (tocilizumab) Avsola (infliximab-axxq) Inflectra (infliximab-dyyb) Orencia IV (abatacept) Remicade (infliximab) Renflexis (infliximab-abda) Simponi Aria (golimumab) Tofidence (tocilizumab-bavi) Tyenne IV (tocilizumab-aazg) Any other marketed IV agent within 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	N/A
Required Medical Information	N/A
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by, or in consultation with, a rheumatologist

Coverage Duration	If all of the criteria are met, the request will be approved for 12 month duration.
Other Criteria	**Initial Authorization:** • The member has a diagnosis of rheumatoid arthritis • The medication is being prescribed at an appropriate FDA approved dose for age and weight • The member has an adequate trial (consistent with pharmacy claims/medical record data/physician attestation), or documented medical reason (e.g., allergy, intolerance, contraindication) with at least one non-biologic disease modifying anti-rheumatic drug (DMARD) (e.g., methotrexate, leflunomide, sulfasalazine or hydroxychloroquine) • If the request is for a non-preferred or non-formulary biological agent, documented (consistent with pharmacy claims/medical record data/physician attestation), adequate trial of at least two preferred products or medical reason as to why member is unable to utilize the preferred products • If the request is for a reference brand with therapeutically equivalent biosimilars (e.g., Humira or Stelara), documented adequate trial of all formulary biosimilars or a medical reason as to why the member is unable to utilize the formulary products. • If the request is for Rinvoq (upadicitinib) or Xeljanz (tofacitinib), there is documented (consistent with pharmacy claims/medical record data/physician attestation), adequate trial of a preferred tumor necrosis factor (TNF) inhibitor. • If the request is for Avsola, Renflexis, or Inflectra, documented (consistent with pharmacy claims/medical record data/chart notes/physician attestation), adequate trial of infliximab. • If the request is for Remicade, documented (consistent with pharmacy claims/medical record data/chart notes/physician attestation), adequate trial of infliximab, Avsola, Renflexis, AND Inflectra. • For members who require adalimumab (Humira or biosimilar) 40 mg SC weekly or 80 mg SC every other week, documentation must be submitted indicating that the member has a medical reason (e.g., intolerance, hypersensitivity, contraindication) for not receiving concomitant methotrexate. **Reauthorization:** • The medication is prescribed at an FDA-approved dosage. • The member has been receiving the medication and documentation was provided that the prescriber has evaluated the member and recommends continuation of therapy (clinical benefit). • If the request is for a reference brand with therapeutically equivalent biosimilars (e.g., Humira or Stelara), documented adequate trial of all formulary biosimilars or a medical reason as to why the member is unable to utilize the formulary products. **Continuation of Therapy Provision**:

Revision/Review Date: 08/2025	• Members with history (within the past 90 days) of a preferred biological agent are not required to try the above mentioned conventional therapies prior to receiving the preferred biological agent. • Members with history (within the past 90 days) of a non-preferred biological product are not required to demonstrate trial of preferred biological agents nor the above mentioned conventional therapies prior to receiving the non-preferred agent. **Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Prior Authorization Group Description	**Specialty Agents for Ulcerative Colitis**
Drugs	**<u>Preferred Pharmacy Benefit Agents</u>:** Abrilada (adalimumab-afzb) Adalimumab-aaty (unbranded Yuflyma) Adalimumab-fkjp (unbranded Hulio) Hadlima (adalimumab-bwwb) Rinvoq/Rinvoq LQ (upadacitinib) Simlandi (adalimumab-ryvk) Skyrizi (risankizumab) Xeljanz/Xeljanz XR (tofacitinib) Yusimry (adalimumab-aqvh) **<u>Non-Preferred Pharmacy Benefit Agents</u>:** Imuldosa (ustekinumab-srlf) Simponi (golimumab) Steqeyma (ustekinumab-stba) Yesintek (ustekinumab-kfce) Otulfi (ustekinumab-aauz) Selarsdi (ustekinumab-aekn) Tremfya SC (guselkumab) Zeposia (ozanimod) **Non-Formulary Pharmacy Benefit Agents:** All adalimumab biosimilar agents not listed as preferred (e.g., Amjevita, Cyltezo, Hyrimoz) Entyvio SC (vedolizumab) Humira (adalimumab) Omvoh SC (mirikizumab) Stelara SC (ustekinumab) Velsipity (etrasimod All ustekinumab biosimilar agents not listed as preferred (e.g., Pyzchiva, Wezlana) Zymfentra (infliximab-dyyb) Any other marketed agent within the class **<u>Medical Benefit Agents:</u>** Infliximab- **Preferred Infliximab** Avsola (infliximab-axxq) Entyvio IV (vedolizumab) Inflectra (infliximab-dyyb) Omvoh IV (mirikizumab) Remicade (infliximab) Renflexis (infliximab-abda) Stelara IV (ustekinumab) All ustekinumab biosimilars IV Tremfya IV (guselkumab) Any other marketed IV agent within this 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, or in consultation with, a gastroenterologist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 month duration.
Other Criteria	**Initial Authorization:** • The member has a diagnosis of moderate to severely active ulcerative colitis AND the medication is being prescribed at an appropriate FDA approved dose (for age and weight) • ONE of the following: o Request is for a member who has been unable to achieve remission after an adequate trial (consistent with pharmacy claims/medical record data/physician attestation) of a corticosteroid (e.g., budesonide or oral/IV corticosteroids) or the member has a documented medical reason (e.g., allergy, intolerance, contraindication) for not using corticosteroids to manage their condition. o Request is for a member who has been unable to achieve remission after induction with corticosteroids AND one conventional therapy (e.g., sulfasalazine, mesalamine, 6-mercaptopurine, budesonide, or oral corticosteroids) consistent with pharmacy claims/medical record data/physician attestation or the member has a documented medical reason (e.g., allergy, intolerance, contraindication) for not using conventional therapies to manage their condition. o Request is for maintenance of remission achieved with use of biologic therapy • If the request is for Xeljanz/XR (tofacitinib) or Rinvoq (upadacitinib), there is documented (consistent with pharmacy claims/medical record data/physician attestation), adequate trial of a preferred tumor necrosis factor (TNF) inhibitor. • If the request is for a non-preferred or non-formulary pharmacy agent, documented (consistent with pharmacy claims/medical record data/chart notes/physician attestation), adequate trial of two preferred biologic agents. o If the request is for Velsipity or Zeposia, documentation of healthcare-provider confirmed history of chickenpox, results of varicella zoster virus (VZV) antibody testing and, if negative, documentation of VZV vaccination. • If the request is for a reference brand with therapeutically equivalent biosimilars (e.g., Humira or Stelara), documented adequate trial of all formulary biosimilars or a medical reason as to why the member is unable to utilize the formulary products.

Revision/Review Date: 08/2025	• If the request is for Avsola, Renflexis, Zymfentra, or Inflectra, documented (consistent with pharmacy claims/medical record data/chart notes/physician attestation), adequate trial of infliximab. • If the request is for Remicade, documented (consistent with pharmacy claims/medical record data/chart notes/physician attestation), adequate trial of infliximab, Avsola, Renflexis, AND Inflectra. **Reauthorization:** • The medication is being prescribed at an FDA-approved dosage. • The member has been receiving the medication and documentation was provided that the prescriber has evaluated the member and recommends continuation of therapy (clinical benefit). • If the request is for a reference brand with therapeutically equivalent biosimilars (e.g., Humira or Stelara), documented adequate trial of all formulary biosimilars or a medical reason as to why the member is unable to utilize the formulary products. **Continuation of Therapy Provision**: • Members with history (within the past 90 days) of a preferred biological agent are not required to try the above mentioned conventional therapies prior to receiving the preferred biological agent. • Members with history (within the past 90 days) of a non-preferred biological product are not required to demonstrate trial of preferred biological agents nor the above mentioned conventional therapies prior to receiving the non-preferred agent. **Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Prior Authorization Group Description	**Specialty Biologic Agents for FDA (if no indication-specific criteria) and NON-FDA Approved Medically-Accepted Indications**
Drugs	**Preferred Pharmacy Benefit Agents:** Abrilada (adalimumab-afzb) Adalimumab-aaty (unbranded Yuflyma) Adalimumab-fkjp (unbranded Hulio) Hadlima (adalimumab-bwwb) Enbrel (etanercept) Rinvoq, Rinvoq LQ (upadicitinib) Simlandi (adalimumab-ryvk) Skyrizi (risankizumab) Taltz (ixekizumab) Xeljanz/Xeljanz XR (tofacitinib) Yusimry (adalimumab-aqvh) **Non-Preferred Pharmacy Benefit Agents:** Actemra Prefilled Syringe/Auto-injector (tocilizumab) Cimzia (certolizumab) Cosentyx SC (secukinumab) Ilumya (tildrakizumab-asmn) Kevzara (sarilumab) Kineret (anakinra) Olumiant (baricitinib) Orencia SC (abatacept) Otezla (apremilast) Siliq (brodalimumab) Simponi (golimumab) Starjemza (ustekinumab-hmny) Ustekinumab-aauz (unbranded Otulfi) Sotyktu (deucravacitinib) Stelara SC (ustekinumab) Tremfya (guselkumab) Velsipity (etrasimod) Zeposia (ozanimod) **Non-Formulary Pharmacy Agents:** All adalimumab biosimilar agents not listed as preferred (e.g., Amjevita, Cyltezo, Hyrimoz) Bimzelx (bimekizumab-bkzx) Entyvio SC (vedolizumab) Humira (adalimumab) Ilaris (canakinumab) Omvoh SC (mirikizumab) Stelara SC (ustekinumab) Tyenne SC (tocilizumab-aazg) Velsipity (etrasimod) Zymfentra (infliximab-dyyb) All ustekinumab biosimilar agents not listed as preferred (e.g., Pyzchiva, Wezlana) Any other marketed agent within the class **Medical Benefit Agents:**

	Infliximab-**Preferred Infliximab** Actemra IV (tocilizumab) Avsola (infliximab-axxq) Inflectra (infliximab-dyyb) Remicade (infliximab) Renflexis (infliximab-abda) Actemra (tocilizumab) Cosentyx IV (secukinumab) Entyvio IV (vedolizumab) Ilaris (canakinumab) Omvoh IV (mirikizumab) Orencia IV (abatacept) Simponia Aria (golimumab) Stelara IV (ustekinumab) Tofidence (tocilizumab-bavi) Tremfya IV (guselkumab) Tyenne IV (tocilizumab-aazg) Tysabri (natalizumab) All ustekinumab biosimilars IV Any other marketed agent within 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	N/A
Required Medical Information	N/A
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 criteria are met, the request will be approved for a 12 month duration.
Other Criteria	**<u>Initial Authorization:</u>** • Request is for a medically accepted use per the medical compendia or standard of care guidelines for member • Dose is appropriate for member (e.g., age/weight) • The member has had an adequate trial of all first line therapies (when available) as recommended by the medical compendia or standard of care guidelines consistent with pharmacy claims/medical record data/chart notes/physician attestation (including dates and dosing of all first line therapies) OR member has a documented medical reason (e.g., allergy, intolerance, contraindication) for not using first line therapies to manage the condition • If the request is for a non-preferred or non-formulary biologic agent, documented (consistent with pharmacy claims/medical chart data) adequate trial of at least two preferred products (with different mechanisms of action where applicable) with a medically-accepted use for the member's condition

Revision/Review Date: 02/2026	per standard of care guidelines, or medical reason as to why member is unable to utilize the preferred products • If the request is for a reference brand with therapeutically equivalent biosimilars (e.g., Humira or Stelara), documented adequate trial of all formulary biosimilars or a medical reason as to why the member is unable to utilize the formulary products. **<u>Reauthorization:</u>** • Documentation submitted indicates member has obtained clinical benefit from the medication. • The medication is prescribed at a compendia/guideline/FDA-approved dosage • If the request is for a reference brand with therapeutically equivalent biosimilars (e.g., Humira or Stelara), documented adequate trial of all formulary biosimilars or a medical reason as to why the member is unable to utilize the formulary products. **Continuation of Therapy Provision**: • Members with history (within the past 90 days) of a preferred biological agent are not required to try the above mentioned conventional therapies prior to receiving the preferred biological agent. • Members with history (within the past 90 days) of a non-preferred biological product are not required to demonstrate trial of preferred biological agents nor the above mentioned conventional therapies prior to receiving the non-preferred agent. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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	Prescribed by or in consultation with a psychiatrist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 4 weeks. For reauthorization, the request will be approved for 6 months.

Other Criteria
 	
Revision/Review Date 02/2026
	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
	• Requests 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 (e.g.. SSRIs, SNRIs, TCAs) of at least a minimum effective dose for four (4) weeks or longer
	  OR
	  o Medical justification as to why the member 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
	• Medication is being prescribed at an FDA-approved dose
	• Prescriber attests urine drug screens for illicit drugs will be completed every 6 months.
	
	Re-authorization:
	• Medication is prescribed at an FDA-approved dose.
	• 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.
	• Urine drug screen dates have been submitted every 6 months.
	
	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	Non-Formulary: Alhemo (concizumab-mtci) Hemlibra (emicizumab-kxwh) Hympavzi (marstacimab-hncq) Qfitlia (fitusiran) Any other marketed agent in this 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	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by a hematologist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.

Other Criteria
 	
Revision/Review Date: 08/2025
	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 members 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 members with a diagnosis of hemophilia A or hemophilia 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 Qfitlia, Hympavzi, or Alhemo for hemophilia 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 events, and signs and symptoms of acute and recurrent gallbladder disease as recommended per the manufacturer's prescribing information
	
	Re-Authorization:

	• 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.**

Prior Authorization Group Description	**Sucraid**
Drugs	Sucraid (sacrosidase)
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 a gastroenterologist or other specialist in the treatment of metabolic disorders
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Other Criteria	**Initial Authorization** • Member has a diagnosis of congenital sucrase-isomaltase deficiency or sucrase deficiency confirmed through genetic testing or breath test • Prescriber attests that the member is attempting to reduce the amount of sucrose and maltose in their diet • Requested dose is within FDA approved guidelines **Reauthorization** • Documentation is provided that the member has obtained a clinical benefit (e.g., fewer total stools, greater number of hard and formed stools, fewer watery and soft stools, decrease in breath hydrogen output) • Requested dose is within FDA approved guidelines
Revision/Review Date 05/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Super-High Potency Topical Steroids Step Therapy**
Drugs	Halobetasol Propionate Foam 0.05%
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 of the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 08/2025	Prior use of three of the following is required: 1. Betamethasone dipropionate augmented 0.05% gel, lotion, or ointment 2. Clobetasol propionate 0.05% cream, gel, ointment, or solution 3. Clobetasol propionate emollient 0.05% cream 4. Halobetasol 0.05% cream or ointment **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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	Members who have received Beyfortus (nirsevimab-alip) for the current respiratory syncytial virus (RSV) season
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

Other Criteria	Infants less than 1 year of age at the onset of the RSV season (e.g., November 1st) must have a documented reason for not being able to use Beyfortus (nirsevimab-alip) **AND** have one of the following indications:
	• 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
	
	Infants less than 2 years of age at the onset of the RSV season (November 1st) must have a documented reason for not being able to use Beyfortus (nirsevimab-alip) **AND** have one 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

Revision/Review Date: 05/2025	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.**

Prior Authorization Group Description	**Tavneos (avacopan)**
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	N/A
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 all of the criteria are met, the request will be approved for 12 months.
Other Criteria	**Initial Authorization:** • 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 standard therapy (i.e. rituximab, cyclophosphamide, glucorticoids, etc.) 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 member 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 member has been screened for and does not have active hepatitis B virus (HBV) infection at baseline **Reauthorization:** • Documentation of remission (BVAS score of 0) OR improvement in BVAS score • Prescriber attestation that member 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 member has no active HBV infection • The prescribed dose is within FDA approved dosing guidelines
Revision/Review Date: 02/2026	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Topical Antifungal Agents**
Drugs	Formulary: Julia (efinaconazole) 10% solution Luliconazole (Luzu) 1% cream Naftifine HCl (Naftin) 1%, 2% cream Oxiconazole Nitrate (Oxistat) 1% cream Non-Formulary: Naftifine HCl (Naftin) 2% gel Any other marketed agent within 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	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	For luliconazole, naftifine, and oxiconazole requests: If all of the criteria are met, the request will be approved for a 3 month duration. For Julia requests: If all of the criteria are met, the request will be approved for a 12 month duration.

Other Criteria
 	
Revision/Review Date 08/2025
	• Request is for an FDA approved indication
	• For luliconazole, naftifine, and oxiconazole requests:
	  o Member has had a documented trial and failure of, or intolerance to, an over-the-counter topical antifungal product (such as terbinafine, tolnaftate, or miconazole) for a clinically appropriate duration for the member's diagnosis, or a medical reason is provided why these products cannot be used
	  o Member has had a documented trial and failure of, or intolerance to, topical clotrimazole (Rx or OTC), or a medical reason is provided why it cannot be used
	• For Julia requests:
	  o Member has had a documented trial and failure of, or intolerance to oral terbinafine AND oral itraconazole, or a medical reason is provided why these products cannot be used
	  o Member has had a documented trial and failure of, or intolerance to, topical ciclopirox 8% solution, or a medical reason is provided why it cannot be used
	• If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Topical Antiviral Treatment**
Drugs	Formulary: Acyclovir (Zovirax) cream Penciclovir (Denavir) cream Non-Formulary: Any other marketed agent within 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	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the request will be approved for up to a 12 month duration
Other Criteria Revision/Review Date 11/2025	<u>For the treatment of herpes labialis (cold sores) or genital herpes:</u> • Documented trial and failure or intolerance to a formulary oral antiviral (e.g., acyclovir, valacyclovir, or famciclovir) • Documented trial and failure or intolerance to a preferred topical antiviral (e.g., acyclovir ointment) • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Topical Ivermectin Step Therapy**
Drugs	Ivermectin Cream 1% External
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 of the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date: 11/2025	Prior use of metronidazole 0.75% cream or gel is required. **Continuation of Therapy Provision:** Members with history (within the past 90 days) of second line agents are not required to demonstrate trial of first line agents. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Topical mTOR kinase inhibitors**
Drugs	Formulary: Hyftor (sirolimus topical gel) Non-Formulary: Any other marketed agent within 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), 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, neurologist, medical geneticist, or other prescriber who specializes in the treatment of genetic or dermatologic disorders.
Coverage Duration	If all of the criteria are met, initial requests will be approved with up to a 3 month duration and reauthorization requests will be approved with up to a 6 month duration.
Other Criteria Revision/Review Date 11/2025	**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 within the past 12 months • Prescriber attests that the member is not a candidate for laser therapy or surgery • Medication is being prescribed at an FDA approved dose • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **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 within the past 12 months • Prescriber attests that the member is not a candidate for laser therapy or surgery • 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.

Prior Authorization Group Description	**Topical Wound Treatment Agents**
Drugs	Formulary: Regranex (becaplermin) gel Santyl (collagenase) ointment Non-Formulary: Any other marketed agent within this 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	Regranex: • Treatment of pressure ulcers and venous stasis ulcers • Treatment of diabetic neuropathic ulcers that do not extend through the dermis into subcutaneous tissue • Treatment of ischemic diabetic ulcers • Use on exposed joints, tendons, ligaments, and bone • Use on wounds that close by primary intention
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the request will be approved for up to 12 months.

Other Criteria	**Initial Authorization:**
	
	<u>For Santyl (collagenase) ointment</u>
	• Type of wound is one of the following:
	  o Wounds to be debrided, severe burns, or chronic dermal ulcers
	• Verification that the requested amount does not exceed the amount on the Santyl dosing calculator: https://www.santyl.com/hcp/dosing
	  o Dimension of wound and duration of treatment required for calculation of dose and amount
	
	<u>For Regranex (becaplermin) gel</u>
	• Type of wound is the following:
	  o Lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply.
	• Wound has failed to adequately respond to 4 weeks of standard wound therapy
	• Prescriber attests Regranex use in conjunction with good ulcer care practices (including initial sharp debridement, pressure relief, and infection control)
	• Prescriber attests member does not have a known neoplasm(s) at the site(s) of application

	• Verification that the requested amount does not exceed the amount per the prescribing information
	  o Dimension of wound and duration of treatment required for calculation of dose and amount (number of tubes requested is based on calculation where each 15 gm tube provides a total of 60 cm length of ointment)
	
	If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated.
	
	Reauthorization:
	• Documentation submitted indicates a clinical benefit was observed (e.g., reduction in wound size, decrease in wound-related pain, etc)
	• For Santyl: Verification that the requested amount does not exceed the amount on the Santyl dosing calculator: https://www.santyl.com/hcp/dosing
	  o Dimension of wound and duration of treatment required for calculation of dose and amount
	• For Regranex: Verification that the requested amount does not exceed the amount per the prescribing information
	  o Dimension of wound and duration of treatment required for calculation of dose and amount (number of tubes requested is based on calculation where each 15 gm tube provides a total of 60 cm length of ointment)

Revision/Review Date: 02/2026	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Transthyretin-mediated Amyloidosis Agents**
Drugs	**<u>Formulary Pharmacy Benefit Agents</u>:** Cardiomyopathy – Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis), Attruby (acoramidis) Polyneuropathy –Wainua (eplontersen) **<u>Medical Benefit Agents:</u>** Polyneuropathy – Onpattro (patisiran) Polyneuropathy or Cardiomyopathy - Amvuttra (vutrisiran) **Non-Formulary:** Any other marketed agent within 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	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by a neurologist, cardiologist, or specialist in the treatment of amyloidosis
Coverage Duration	If all of the criteria are met, the requests will be approved for 12 months.
Other Criteria	**<u>Initial Authorization</u>**: • Regimen does not exceed FDA-approved dose/frequency • Member has not undergone a liver or heart transplant • Requests for use of multiple agents (different mechanism of action) in this policy for mixed polyneuropathy-cardiomyopathy phenotypes will only be considered if member meets clinical criteria requirements for each section. • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **Polyneuropathy-Type** • If the request is for Onpattro, Wainua, or Amvuttra, the member has diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis as evidenced by: o Documented transthyretin variant by genotyping o One of the following: ▪ Member has baseline polyneuropathy disability (PND) score ≤ IIIb ▪ Member has a baseline Familial Amyloid Polyneuropathy (FAP) Stage 1 or 2 ▪ Patient has baseline neuropathy impairment (NIS) score ≥ 5 and ≤ 130 o Member has clinical signs/symptoms of neuropathy

Revision/Review Date: 05/2025	**Cardiomyopathy-Type** • If the request is for Vyndaqel, Vyndamax, Attruby, or Amvuttra: member has diagnosis of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis as evidenced by: o Documented transthyretin variant by genotyping or wild-type amyloidosis o Documented amyloid deposit by biopsy or positive technetium 99m pyrophosphate (Tc 99m PYP) cardiac imaging o Member has New York Heart Association (NYHA) functional class I, II, or III heart failure symptoms. o For Amvuttra, member 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>**: • Member's regimen does not exceed FDA-approved dose/frequency for the agent • Member has not undergone a liver or heart transplant • Requests for use of multiple agents (different mechanism of action) in this policy for mixed polyneuropathy-cardiomyopathy phenotypes will only be considered if member 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/Amvuttra o Member has continued NYHA functional class I, II, or III heart failure symptoms **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>Formulary:</u>** <u>Preferred:</u> Berinert (C1 esterase inhibitor, human) Haegarda (C1 esterase inhibitor, human) icatibant (Firazyr) Orladeyo (berotralstat) Ruconest (C1 esterase inhibitor, recombinant) <u>Non-preferred:</u> Cinryze (C1 esterase inhibitor, human) Kalbitor (ecallantide) Takhzyro (lanadelumab-flyo) Ekterly (sebetralstat) Andembry (garadacimab-gxii) Dawnzera (donidalorsen) **Non-Formulary:** Sajazir (branded generic of icatibant) Any other marketed agent within 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	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by an immunologist, allergist, rheumatologist, or hematologist
Coverage Duration	If all of criteria are met, the request will be approved as follows: • Acute treatment: 1 + 5 refills • Pre-procedural prophylaxis: 1 treatment • Long-term prophylaxis: Initial request for 6 months, reauthorization requests for 12 months.
Other Criteria	**<u>Initial Criteria</u>** • Documentation submitted indicates the medication is being prescribed at FDA approved dose. • The member is not taking ACE inhibitors, estrogen containing oral contraceptives, or hormone replacement therapy. • Documented diagnosis of one of the following: o HAE with deficient or dysfunctional C1INH (e.g., type I, type II, or acquired C1INH 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 (Berinert, icatibant, Kalbitor, Ruconest, Sajazir, Ekterly):** o The member 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 o If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **For prophylaxis (Cinryze, Haegarda, Orladeyo, Takhzyro, Andembry, Dawnzera):** o Pre-procedural ▪ Documentation that member will be undergoing a medical, surgical, or dental procedure associated with mechanical impact to the upper aerodigestive tract and anticipated date of the procedure. o Long-term ▪ The member has a history of at least two severe attacks per 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. ▪ The member is receiving one prophylactic HAE medication only. ▪ 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. o If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated.

Revision/Review Date: 11/2025	**<u>Reauthorization Criteria:</u>** **For acute treatment (Berinert, icatibant, Kalbitor, Ruconest, Sajazir, Ekterly):** • Documentation was submitted that the member has clinically benefited from medication. • The medication is being prescribed at FDA approved dose. • The member is receiving no other medications for acute treatment. **For prophylaxis (Cinryze, Haegarda, Orladeyo, Takhzyro, Andembry, Dawnzera):** • Documentation was submitted that the member has clinically benefited from prophylactic therapy as demonstrated by a reduced number of attacks. • The medication is being prescribed at an FDA approved dose • For Takhzyro: o If the member is 6 years of age or older and the member has been well controlled (e.g., attack free) for 6 months or more while receiving Takhzyro, the member will be on a dosing interval of every four weeks, or a medical reason has been provided why continued therapy with a dosing interval of every two weeks is necessary. • The member is receiving no other medications for prophylaxis. **Medical Director/Clinical Reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary**

Prior Authorization Group Description	**Familial Chylomicronemia Syndrome**
Drugs	Non-Formulary: Tryngolza (olezarsen) Redemplo (plozasiran) Any other marketed agent within 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	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, an endocrinologist, lipidologist, or cardiologist or specialist experienced in familial chylomicronemia syndrome (FCS)
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.

Other Criteria	**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:
	  ○ The member has a pathogenic gene mutation in FCS-causing genes (e.g., *LPL*, *GPIHBP1*, *APOA5*, *APOC2*, or *LMF1*)
	  ○ 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 member is refractory to standard triglyceride lowering therapies (e.g., statins, fibrates, omega-3 fatty acids, and niacin)
	• The prescriber attests the member will follow a low-fat diet
	• If the request is for Tryngolza, member must also have a trial and failure, intolerance, or contraindication to Redemplo
	
	Re-Authorization:
	• Medication is prescribed at an FDA approved dose

Review/Revision Date: 02/2026	• 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 **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Type I Interferon (IFN) Receptor Antagonist**
Drugs	Non-Formulary: Saphnelo (anifrolumab-fnia) Any other marketed agent within 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	• Severe active central nervous system lupus • Active lupus nephritis
Required Medical Information	See "Other Criteria"
Age Restrictions	≥ 18 years
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months and the reauthorization request will be approved for 12 months.
Other Criteria Revision/Review Date: 11/2025	**<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 **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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 request will be approved for a **one-time treatment.**

Other Criteria
 	
Revision/Review Date: 02/2026
	• 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)
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Prior Authorization Group Description	**Vaginal Progesterone**
Drugs	Formulary: Crinone (micronized progesterone) Endometrin (micronized progesterone) Non-Formulary: Any other marketed agent within 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	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by an OBGYN specialist
Coverage Duration	Prevention of spontaneous preterm delivery: • Crinone and Endometrin will be approved for 30 single use applicators/inserts per 30 days until the end of pregnancy Secondary Amenorrhea: • Crinone will be approved for up to 6 single use applicators Assisted Reproductive Technology (ART) • Crinone and Endometrin will be approved for: 12 months
Other Criteria Revision/Review Date: 08/2025	**Initial Authorization:** Prevention of spontaneous preterm delivery: • Member has singleton pregnancy and short cervix • Member has tried and failed, or has a contraindication or intolerance to micronized progesterone (Prometrium) capsules • If the request is for Crinone, the member has tried and failed, has a contraindication or intolerance to, or other medical justification for not using Endometrin Secondary Amenorrhea: • Member has a diagnosis of secondary amenorrhea • Member 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 member has tried and failed, or has a contraindication or intolerance to, Crinone 4% gel. Assisted Reproductive Technology (ART) [ONLY for states with Infertility Treatment Benefit] • Member requires intravaginal progesterone as part of an ART treatment plan

	If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Vascepa**
Drugs	Icosapent ethyl (Vascepa)
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	Cardiovascular risk reduction: See "Other Criteria" Triglyceride reduction: N/A
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.

Other Criteria	**Initial Authorization**
	
	Cardiovascular risk reduction
	• Member has a diagnosis of moderate hypertriglyceridemia (pre-treatment triglyceride ≥ 150 mg/dL) and ONE of the following is true:
	  o Member is ≥ 45 years of age and has established cardiovascular disease as evidenced by a history of at least ONE of the following:
	  ▪ Myocardial infarction or acute coronary syndrome
	  ▪ Stroke or transient ischemic attack
	  ▪ Coronary artery disease with stable angina
	  ▪ Coronary or other arterial revascularization
	  ▪ Peripheral vascular disease
	  ▪ Aortic aneurism
	  o Member is ≥ 50 years of age, has diabetes mellitus and at least TWO of the following:
	  ▪ Men ≥ 55 years or women ≥ 65 years
	  ▪ Cigarette smoker or stopped smoking within the past 3 months
	  ▪ Hypertension (pretreatment blood pressure ≥ 140 mmHg systolic or ≥ 90 mmHg diastolic)
	  ▪ HDL-C ≤ 40 mg/dL for men or ≤ 50 mg/dL for women
	  ▪ High-sensitivity C-reactive protein > 3.0 mg/L
	  ▪ Renal dysfunction (CrCl > 30 mL/min and < 60 mL/min)
	  ▪ Retinopathy
	  ▪ Micro- or macro-albuminuria
	  ▪ Ankle-brachial index (ABI) < 0.9 without symptoms of intermittent claudication
	• Member is taking and will continue on maximum tolerated statin dose while receiving icosapent ethyl (Vascepa), or documentation has been provided that the member is not able to tolerate a statin.
	• If request is for brand Vascepa, member has tried generic icosapent ethyl
	• Documentation was provided indicating provider has counseled member on smoking cessation (if applicable) and following a "heart healthy diet."
	• The request is for an FDA approved dose.

Revision/Review Date: 02/2026	**Triglyceride reduction** • Member has a diagnosis of severe hypertriglyceridemia (pre-treatment triglyceride level ≥ 500 mg/dL). • Member has tried and failed an OTC fish oil or omega-3-acid ethyl ester (generic Lovaza) • If request is for brand Vascepa, member has tried generic icosapent ethyl • Documentation was provided indicating provider has counseled member on smoking cessation (if applicable) and following a "heart healthy diet." • The request is for an FDA approved dose. **<u>Reauthorization</u>** • Documentation was provided that the member has obtained clinical benefit from medication (e.g., triglyceride lowering from baseline) • For cardiovascular risk reduction, the member will continue on maximum tolerated statin dose, or documentation has been provided that the member is not able to tolerate a statin. • 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.**

Prior Authorization Group Description	**Vasopressin Antagonists**
Drugs	Formulary: Jynarque (tolvaptan) tolvaptan (Samsca) Non-Formulary: Any other marketed agent within this 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	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	See "Other Criteria"
Coverage Duration	Initial request: • Jynarque (tolvaptan) – 12 months • Tolvaptan (Samsca) – 30 days Reauthorization request: • Jynarque (tolvaptan) – 12 months • Tolvaptan (Samsca) – 12 months

Other Criteria	**Initial Authorization**
	All indications
	• Member is not currently using a strong CYP3A4 inhibitor (e.g., clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin)
	• If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated.
	
	Autosomal Dominant Polycystic Kidney Disease (ADPKD)
	• Request is for Jynarque (tolvaptan)
	• Prescribed by or in consultation with a nephrologist
	• Medication is being prescribed at an FDA approved dose
	• Confirmed diagnosis of ADPKD (e.g., ultrasound, MRI, CT scan, genetic test)
	• Sodium within normal limits (Na 135 to 147 mEq/L)
	• One of the following
	  o Estimated glomerular filtration rate (eGFR) ≥ 25 mL/min
	  o Creatinine clearance (CrCl) ≥ 60 mL/min

Revision/Review Date 02/2026	• Total kidney volume (TKV) ≥ 750 mL
	
	Hypervolemic or Euvolemic Hyponatremia
	• Request is for tolvaptan (Samsca)
	• Medication is being prescribed at an FDA approved dose
	• Trial and failure of or contraindication to fluid restriction and other therapies (e.g., diuretics)
	• Therapy will be or has been initiated in the hospital
	
	Reauthorization
	ADPKD
	• Medication is being prescribed at a FDA approved dose
	• One of the following
	  ○ eGFR ≥ 25 mL/min
	  ○ CrCl ≥ 60 mL/min
	
	Hypervolemic or Euvolemic Hyponatremia
	• Medication is being prescribed at an FDA approved dose
	• Medical justification for duration of therapy > 30 days
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Prior Authorization Group Description	**Vascular Endothelial Growth Factor (VEGF) Inhibitors for Ophthalmic Conditions**
Drugs	Preferred Vascular Endothelial Growth Factor (VEGF) Inhibitor(s) [Step 1]: • **Avastin** (bevacizumab) • **Byooviz** (ranibizumab-nuna) • **Cimerli** (ranibizumab-eqrn) Non-Preferred Vascular Endothelial Growth Factor (VEGF) Inhibitor(s) [Step 2]: • **Beovu** (brolucizumab) • **Eylea/Eylea HD** (aflibercept) • **Lucentis** (ranibizumab) • **Pavblu** (aflibercept-ayyh) • **Susvimo** (ranibizumab) Non-Preferred Vascular Endothelial Growth Factor (VEGF) Inhibitor(s) [Step 3]: • **Vabysmo** (faricimab) • Any other marketed agent in this 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	See "Other Criteria"
Age Restrictions	Approvable for adults 18 years of age and older only Eylea: Approvable in pediatric patients for diagnosis of retinopathy of prematurity
Prescriber Restrictions	Prescribed by an ophthalmologist
Coverage Duration	If all of the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria	**Initial Authorization:** **Avastin:** • Request is for compendia supported dosing for an ophthalmic indication **Byooviz & Cimerli:** • Request is for an FDA-approved dosing regimen **Non-Preferred VEGF Inhibitor:** • Requests for Step 3 agents require documented trial and failure with both a preferred VEGF inhibitor (step 1) and a non-preferred (step 2) VEGF inhibitor agent. • Request is for an FDA-approved dosing regimen; **AND**

Revision/Review Date: 02/2026	• Requests for Step 2 agents require documented trial and failure with a preferred VEGF inhibitor for all FDA-approved indications OR a medical justification for not using a preferred VEGF inhibitor (e.g., experienced a severe ADR such as hypersensitivity, arterial thromboembolism, cerebrovascular accident, raised intraocular pressure, retinal detachment). • Requests for Eylea (aflibercept) may be approved for a diagnosis of retinopathy of prematurity without a trial and failure of a preferred VEGF inhibitor. Members must have a diagnosis of retinopathy of prematurity in at least one eye with one of the following retinal findings: o ROP Zone 1 Stage 1+, 2+, 3 or 3+, or o ROP Zone II Stage 2+ or 3+, or o AP-ROP (aggressive posterior ROP) **Reauthorization:** • Prescriber attests that member has obtained a clinical benefit from medication • Request is for FDA-approved dosing regimen **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Veopoz (pozelimab-bbfg)**
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	• Members 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, and the reauthorization request will be approved for 12 months.
Other Criteria Revision/Review Date: 11/2025	**<u>Initial Authorization:</u>** • 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 member's weight **<u>Re-Authorization:</u>** • 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 member's weight • 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.**

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	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.

Other Criteria
 	
Revision/Review Date 08/2025
	• Medication is prescribed at an FDA approved dose
	• The medication is being used for the treatment of symptomatic chronic heart failure with reduced ejection fraction (less than 45%)
	• Documentation that the member has had a previous hospitalization for heart failure or has required outpatient IV diuretics
	• 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 these agents:
	  o Angiotensin-converting enzyme (ACE) inhibitor OR angiotensin receptor blocker (ARB) OR angiotensin receptor/neprilysin inhibitor
	  o Mineralocorticoid receptor antagonist (e.g., spironolactone)
	  o Beta-blocker (i.e., bisoprolol, carvedilol, metoprolol succinate)
	  o Sodium-glucose cotransporter 2 (SGLT2) inhibitor (e.g., Farxiga, Jardiance)
	• Member is not concomitantly using a phosphodiesterase-5 (PDE-5) enzyme inhibitor (e.g., sildenafil)
	• Negative pregnancy test (for females of reproductive age; as indicated) within 30 days of request.
	• 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 judgement, the requested item is medically necessary.

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	5 years of age or older.
Prescriber Restrictions	Prescribed by or in consultation with a specialist in the treatment of Morquio A syndrome 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 (new to therapy):**
	• Member 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
	• Medication is prescribed at an FDA approved dose.
	• Documentation of member's weight
	• Member 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:
	• Medication is prescribed at an FDA approved dose.
	• Documentation of member's weight
	• Member 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:
	• Member 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
	• Medication is prescribed at an FDA approved dose.
	• Documentation of member's weight
	• Member must have completed a 6-minute walk test for baseline evaluation, and member 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 08/2025	○ A current test must be completed and member must be able to walk a minimum of 30 meters (must submit results with request). ○ Continued authorizations for Vimizim for members 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. ○ If member 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 member 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.**

Prior Authorization Group Description	**Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors**
Drugs	Formulary: Austedo, Austedo XR (deutetrabenazine) Ingrezza (valbenazine) Non-Formulary: 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 and the reauthorization request will be approved for 12 months.
Other Criteria	**<u>Initial Authorization:</u>** • Dose is within FDA-approved limits • Prescriber attests member will not be receiving treatment with any other VMAT2 inhibitor • If the request is for a non-formulary agent, the member has a documented trial and failure or intolerance with two alternative formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. **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), Extrapyramidal Symptom Rating Scale (ESRI), Schooler and Kane's Research Diagnoses for Tardive Dyskinesia (RD-TD), the Tardive Dyskinesia Rating Scale (TDRS), the Dyskinesia Identification System-Condensed User Scale (DISCUS), or the Texas Research Institute of Mental Sciences Dyskinesia Rating Scale (TRIMS)) • 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 member's condition, or has provided a clinical reason why NONE of the following are possible:

	○ Reducing the dose of the drug responsible for causing dyskinesia ○ Discontinuing the drug responsible for causing dyskinesia ○ For members on first generation antipsychotics, switching to a second generation antipsychotic ○ Trial of tetrabenazine or benzodiazepines • Member has a documented medical reason (e.g., treatment failure, intolerance, hypersensitivity, contraindication) for not using tetrabenazine AND ○ For Austedo, Austedo XR requests: ▪ Prescriber attests member has no signs of hepatic impairment ▪ For members at risk for QT prolongation, prescriber attests a baseline ECG has been obtained ○ For Ingrezza requests: ▪ Must be dosed at one capsule per day **For approval for use in chorea associated with Huntington's Disease (HD):** • Member must have diagnosis of moderate to severe Huntington's with chorea, with documented baseline Total Maximal Chorea (TMC) score provided • Member has a documented medical reason (e.g., treatment failure, intolerance, hypersensitivity, contraindication) for not using tetrabenazine AND ○ For Austedo, Austedo XR requests: ▪ Prescriber attests member has no signs of hepatic impairment ▪ For members at risk for QT prolongation, prescriber attests a baseline ECG has been obtained ○ 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 or stabilization from baseline in average scores on the previously submitted symptom rating scale, decrease in symptoms, etc.) • Member will not be receiving treatment with any other vesicular monoamine transporter 2 (VMAT2) inhibitor • 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.**
Revision/Review Date: 11/2025	

Prior Authorization Group Description	**Voquezna (vonoprazan)**
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	According to 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 all of 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	**Initial Authorization:** <u>For erosive esophagitis (healing or maintenance of healed erosive esophagitis):</u> • Member has a diagnosis of endoscopy-confirmed erosive esophagitis (all grades) • Member is H. pylori negative • Member 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> • Member has a confirmed H. pylori positive infection, plus one of the following clinical conditions: ○ dyspepsia lasting at least 2 weeks, functional dyspepsia, recent/new diagnosis of peptic ulcer, or a stable dose of long-term NSAID treatment • Member 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> • Member has a diagnosis of symptomatic gastroesophageal reflux disease (GERD) with heartburn as the predominant symptom • Member has a history of heartburn lasting at least 6 months, with symptoms on at least four days per week • Member is H. pylori negative, and endoscopy has confirmed member has no esophageal erosions • Prescriber attests member 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.) • Member 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. **Re-Authorization:** 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.
Revision/Review Date: 08/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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 of the criteria are met, the initial and reauthorization requests will be approved for 12 months.
Other Criteria Review/Revision Date: 08/2025	**<u>Initial Authorization:</u>** • Medication is prescribed at an FDA approved dose • Documentation of member's body weight • Diagnosis of PWS confirmed by genetic testing (copies of test must be submitted with request) • Documentation member experiences symptoms of hyperphagia related to PWS (e.g. food-seeking behaviors, food aggression, etc.) **<u>Re-Authorization:</u>** • 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 member's body weight **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**White Blood Cell Stimulators**
Drugs	**Short-Acting G-CSFs:** **Nivestym** (filgrastim-aafi)-**Preferred** **Zarxio** (filgrastim-sndz) **Granix** (TBO-filgrastim) **Neupogen** (filgrastim) **Releuko** (filgrastim-ayow) -**Preferred** **Nypozi** (filgrastim-txid) **Long-Acting G-CSFs:** **Ziextenzo** (pegfilgrastim-bmez) **Neulasta** (pegfilgrastim) **Neulasta Onpro** (pegfilgrastim) **Nyvepria** (pegfilgrastim-apgf) **Fulphila** (pegfilgrastim-jmdb) -**Preferred** **Udenyca** (pegfilgrastim-cbqv) **Udenyca Onbody** (pegfilgrastim-cbqv) **Fylnetra** (pegfilgrastim-pbbk) **Rolvedon** (eflapegrastim-xnst) **Stimufend** (pegfilgrastim-fpgk) **Ryzneuta** (efbemalenograstim alfa-vuxw) **Additional Agents:** **Leukine** (Sargramostim) plerixafor (Mozobil) Aphexda (motixafortide)
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 or other specialist for submitted diagnosis
Coverage Duration	If all criteria are met, requests will be approved for 12 months.
Other Criteria	**Initial Authorization:** • ***For ALL requests for treatment or prophylaxis of febrile neutropenia:*** Documentation of the member's absolute neutrophil count (ANC) within the last 30 day has been provided. • 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 **Short-Acting G-CSFs:** • ***For all requests for non-preferred agents:*** The member has a documented treatment failure (i.e., failure to reach and/or maintain target

Revision/Review Date: 02/2026	ANC, prolonged febrile neutropenia, unplanned hospitalization or infection requiring prolonged anti-infective use) with an adequate trial (including dates, doses of therapy) of both Nivestym AND Releuko or has another documented medical reason (intolerance, hypersensitivity, stem cell collection, etc.) for not using Nivestym AND Releuko to treat their medical condition. • ***For Neupogen requests,*** The member 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 Zarxio, Granix, Releuko, Nypozi AND Nivestym or has another documented medical reason (intolerance, hypersensitivity, stem cell collection, etc.) for not using Zarxio, Granix, Releuko, Nypozi, AND Nivestym to treat their medical condition. **<u>Long-Acting G-CSFs:</u>** • ***For Ziextenzo, Udenyca, Udenyca Onbody, Nyvepria, Rolvedon, Ryzneuta, Stimufend, or Fylnetra requests:*** The member 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 Fulphila, or has a documented medical reason (intolerance, hypersensitivity, stem cell collection, etc.) for not using Fulphila • ***For Neulasta or Neulasta Onpro requests:*** The member 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 Fulphila, Ziextenzo AND either Fylnetra, Udenyca, Udenyca 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 member's current diagnosis, current body weight, body surface area and absolute neutrophil count (within 30 days of the request). • ***For Plerixafor & Aphexda requests:*** Documentation is submitted of the member'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). o 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 **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary**.

Prior Authorization Group Description	**Xermelo**
Drugs	Xermelo (telotristat ethyl)
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 oncologist.
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Other Criteria Revision/Review Date 02/2026	**Initial Authorization** • Medication requested is for an FDA approved indication and dose. • Diagnosis is carcinoid syndrome diarrhea. • Documentation is provided that diarrhea is inadequately controlled with somatostatin analog therapy at a stable dose for at least 3 months. • Xermelo will be used concurrently with somatostatin analog therapy. **Reauthorization** • Medication requested is for an FDA approved indication and dose. • Documentation has been provided that demonstrates a clinical benefit (e.g., improvement in diarrhea). • Member continues to use Xermelo concurrently with somatostatin analog therapy as evidenced by clinical documentation or pharmacy claims history. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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 criteria are met, the requests will be approved for up to a 6 month duration.
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 FDA approved dose according to the 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

Review/Revision Date: 11/2025	• 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 Spontaneous Urticaria (CSU):</u> • Confirmed diagnosis of CSU • The drug is being prescribed at an FDA approved dose • Documented history of urticaria for at least 6 weeks • Member remains symptomatic despite a minimum two week trial (or has medical reason for not utilizing) of a formulary second generation H1 antihistamine 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 clinically benefited from medication (e.g., decreased exacerbations, reduction in use of oral steroids, decrease in skin manifestations or severe itching, improvement in pulmonary function tests, etc.) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Xolremdi (mavorixafor)**
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	Prescribed by an immunologist or a hematologist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Other Criteria Review/Revision Date: 08/2025	**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 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 **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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	Prescribed by, or in consultation with an endocrinologist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.

Other Criteria	**<u>Initial Authorization:</u>**
	• Confirmed diagnosis of chronic hypoparathyroidism (HP) of postsurgical, autoimmune, genetic, or idiopathic origins, for at least 6 months
	• Provider attestation that member 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
	
	<u>Re-Authorization:</u>
	• 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)
	• Member meets ONE of the following:
	  o Member no longer requires active vitamin D or therapeutic doses of calcium, OR
	  o Member 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

Revision/Review Date: 02/2026	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Zontivity**
Drugs	Zontivity (vorapaxar)
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	18 years age or older
Prescriber Restrictions	Prescribed by, or in consultation with, a cardiologist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 08/2025	**<u>Initial Authorization</u>** • Member has a history of myocardial infarction (MI) OR has peripheral arterial disease (PAD) • Medication will be used concurrently with aspirin and/or clopidogrel • Member does not have a history of stroke, transient ischemic attack (TIA), intracerebral hemorrhage (ICH), or active pathological bleeding • Medication is prescribed at an FDA approved dose **<u>Reauthorization</u>** • Documentation of positive clinical response to therapy • Medication is being used concurrently with aspirin and/or clopidogrel • 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.**