PRIOR AUTHORIZATION

CRITERIA Effective

1/02/2024

DEPARTMENT OF HUMAN SERVICES

Nonpreferred Drug Prior Authorization Criteria

April 2022

Approval criteria

A request for coverage of a non-preferred drug may be approved if the following criteria are met:

- The drug is not excluded from coverage (for example, drugs for erectile dysfunction) **AND**
- The drug is prescribed for a medically accepted indication as defined in Section 1927 of the Social Security Act **AND**
- The member has been taking the requested nonpreferred drug to treat a mental illness or emotional disturbance as defined by Minnesota Statute, 62Q.527 for at least 90 days **OR**
- The preferred drugs are experiencing documented drug shortages or recalls from a wholesaler, manufacturer, the ASHP (American Hospital of Health-System Pharmacist) Drug Shortage web page or the US Food and Drug Administration **OR**
- The requested drug is being prescribed within recommended dosing guidelines **AND**
- The member has had a trial of at least two preferred chemically unique drugs within the same drug class on the Preferred Drug List, or a trial of at least one preferred drug within the same drug class if there are not two chemically unique preferred drugs within the same drug class. The use of free goods or pharmaceutical samples will not be considered as meeting any step of the nonpreferred drug prior authorization criteria **AND (at least one of the following)**
    - The prescriber must provide documentation (for example, pharmacy dispensing record, medication orders in members' health record, and so forth) at the time of request showing that:
        - the member adhered to the previous therapies during the trial(s) AND
        - the trial period was sufficient to allow for a positive treatment outcome, or that the drug was discontinued due to an adverse event OR
    - The member is currently taking the requested nonpreferred drug and is experiencing a positive therapeutic outcome AND the prescriber provides documentation that switching the member to a preferred drug is expected to cause harm to the member, or that the preferred drug would be ineffective OR
    - The preferred drug is contraindicated pursuant to the pharmaceutical manufacturer's prescribing information or, due to a documented adverse event or medical condition, is likely to result in the following:
        - cause an adverse reaction OR
        - decrease the ability of the member to achieve or maintain reasonable functional ability in performing daily activities OR
        - cause physical or mental harm to the member

Duration of Approval

- Requests due to drug shortages:
    - The Department of Human Services (DHS) may approve the request up to 3 months or up to the estimated known and verifiable resolution date, if the documented drug shortages are from the wholesaler (for example, wholesaler invoice, screenshot of wholesaler electronic ordering system, and so forth).
    - DHS may approve the request up to 6 months or up to the estimated known and verifiable resolution date, if the documented drug shortages are from the manufacturer (for example, manufacturer press release, screenshot of manufacturer web page, and so forth).
    - DHS may approve the request up to 12 months or up to the estimated known and verifiable resolution date, if the documented drug shortages are from the ASHP Drug Shortages web page or US Food and Drug Administration

- DHS may approve requests due to other reasons up to 12 months

Quantity Limits

- Quantity limits pursuant to the FDA-approved label will apply

Note

- If applicable, the nonpreferred drug prior authorization criteria does not replace the requirement for a clinical prior authorization for a specific drug
- The inability or unwillingness of the enrolled pharmacy to order or stock the preferred drug will not be considered as a basis for requests due to drug shortages

Definition

Free goods or pharmaceutical samples: medication samples, medications obtained from any patient assistance programs or any discount programs, medications obtained through free trial programs, manufacturer vouchers, coupons or debit cards while the member is on Medical Assistance.

For Questions

MHCP Provider Resource Center (651) 431-2700 or 1-800-366-5411

DEPARTMENT OF HUMAN SERVICES

Continuation of Therapy Prior Authorization Criteria

February 2019

Definition:

Biosimilar Substitution: Dispensing a biosimilar product rather than the reference biologic product.

Cash Pay: Allowing a member to pay for the entire cost of a non-covered prescription, after a member, in consultation with the prescriber and the pharmacist, has decided that covered alternatives are not options. A member may pay for the entire cost of a non-covered controlled substance prescription, including gabapentin, only when the member meets all conditions specified in the Advanced Recipient Notice of Non-Covered Prescription Form (DHS-3641-ENG)

Continuation of Therapy: Allowing a member who has been stabilized on a medication that requires prior authorization, but was previously covered by another payer (i.e., commercial insurance, MCO Medicaid plans), to continue the therapy without the prescriber having to satisfy the Fee-for-Service prior authorization criteria.

Free goods/pharmaceutical samples: medication samples, medications obtained from any patient assistance programs, medications obtained through free trial programs, manufacturer vouchers, coupons or debit cards.

Generic Substitution: Dispensing a generically equivalent drug rather than the brand name drug.

Continuation of Therapy criteria:

Continuation of Therapy override may be approved for non-preferred or restricted drugs if the following conditions are met:

- The requested non preferred or restricted drugs are not excluded from coverage (e.g., drugs for weight loss, drugs for erectile dysfunction); AND
- The requested non-preferred or restricted drugs are prescribed for a medically accepted indication as defined in Sec. 1927 of the Social Security Act, AND
- The member has been treated with a non-preferred or restricted drugs at a consistent dosage for at least 90 days and the prescriber indicates (orally or in writing) that the prescribed medication will best treat the member's condition; AND
- The pharmacy or prescriber must provide an attestation that the medication was covered by another payer and not obtained via cash pay, drug manufacturer-issued debit cards, or via free goods/pharmaceutical samples.

Continuation of Therapy may be approved for the following duration:

- Continuation of Therapy override may be approved for up to 90 days. After 90 days, the prescriber must obtain prior authorization for the non-preferred or restricted drug or transition the member to an alternative therapy. Multiple Continuation of Therapy overrides will not be approved for the same drug; OR
- If the member has an existing approved prior authorization (PA) for the non-preferred or restricted drugs, then the member's previously approved PA will be approved until the PA expires; OR
- If the member has received a prescribed drug to treat a mental illness or emotional disturbance as defined by Minnesota Statute 62Q.527, the member may continue to receive coverage for such prescribed drugs for up to one year.

Continuation of Therapy criteria overrides are not available to bypass generic or biosimilar substitution (if applicable).

Free goods/Pharmaceutical Samples Policy:

The use of free goods or pharmaceutical samples will not be considered as meeting the 90-day treatment requirement for Continuation of Therapy overrides. A member, after meeting all conditions for cash pay, must pay for the entire cost of the non-covered prescription.

Prior Authorization Group Description	**Off-Label Uses**
Medications	Drugs with off-label uses
Covered Uses	Off-Label indications (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" below
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the conditions are met, the request will be approved for 12 months (depending on the diagnosis and usual treatment duration).

Other Criteria
 	
Revision/Review Date: 9/2023
	Documentation requirements for approval:
	• Drug is being requested at an appropriate dose per literature
	• One of the following:
	  o No other formulary drug has a medically accepted use for the member's specific diagnosis as referenced in the medical compendia
	  o Member has had a documented trial and or intolerance with two formulary 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
	• One of the following:
	  o Drug is being requested for an accepted off-label use listed in the standard clinical decision support resources (as noted in Covered Uses section above)
	  o Requested use can be supported by at least two published peer-reviewed clinical studies
	
	If the conditions are not met, the request will be sent to a clinical reviewer for medical necessity review.

Prior Authorization Group Description	**Prior Authorization Exception Criteria**
Covered Uses	All medically accepted indications. Medically accepted indications are defined using the following compendia resources: the Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), American Hospital Formulary Service Drug Information (AHFS-DI), and DRUGDEX Information System. The reviewer may also reference disease state specific standard of care guidelines.
Scope	Requests for exception to the drug's prior authorization criteria requirements
Coverage Duration	12 months
Criteria	The provider either verbally or in writing has submitted a medical or member specific reason why prior authorization criteria all or in part is not applicable to the member. • 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.**
Revision/Review Date:	12/2023

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	• 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. **AND one of the following:** o The member has a documented treatment failure with the drug prescribed at the health plan's quantity limit AND the dose requested is supported by the Medical Compendia or current treatment guidelines. **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.**
Revision/Review Date	12/2023

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 patient age/weight, administration frequency, or duration of therapy per FDA or compendia. AND • The provider must submit a medical reason why the maximum dose, administration frequency or duration of therapy needs to be exceeded based on the member's condition or treatment history. **Duplication of therapy** <u>Transition from one agent to another</u> • If a provider has outlined a plan to transition a member to a similar drug or provided a dose titration schedule, the requested drug is approved for one month*. <u>Concurrent Therapy with two similar agents</u>

	• The provider must submit a medical reason why treatment with more than one drug in the same class is required based on the member's condition and treatment history. OR • The provider must submit disease state specific standard of care guidelines supporting concurrent therapy. **Age Restriction** • The provider must submit a medical reason why the drug is needed for a member whose age is outside of the plan's minimum or maximum age limit. AND • The indication and dose requested is supported by the Medical Compendia or current treatment guidelines. **<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.**
Revision/Review Date:	12/2023

Field Name	Field Description
Prior Authorization Group Description	**Step Therapy Exception Criteria**
Covered Uses	All medically accepted indications. Medically accepted indications are defined using the following compendia resources: the Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), American Hospital Formulary Service Drug Information (AHFS-DI), and DRUGDEX Information System. The reviewer may also reference disease state specific standard of care guidelines.
Scope	Requests for drugs on the plan's formulary with a step therapy restriction which do not meet step therapy requirements
Coverage Duration	12 Months
Criteria	The provider verbally or in writing has submitted a medical reason why: • Required step therapy drug(s) would be ineffective, OR; • Required step therapy drug(s) have the potential to cause harm or deterioration of the member's condition, OR; • The requested drug would be superior to the required prerequisite trial(s) with the preferred drug(s), **Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.**
Revision/Review Date:	12/2023

Prior Authorization Group Description	**Specialty Drugs**
Drugs	Oral and injectable specialty drugs without drug or class specific prior authorization criteria *** 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	N/A
Prescriber Restrictions	N/A
Coverage Duration	If all of the conditions are met, requests will be approved for 6 months.
Other Criteria	• The drug is being requested for an appropriate use (per the references outlined in "Covered Uses") • The dose requested is appropriate for the requested use (per the references outlined in "Covered Uses") • If the request is for a non-formulary/non-preferred drug, documentation has been provided that the member has tried and failed two formulary/preferred agents 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) • If the request is for a reference biologic drug with a biosimilar or interchangeable biologic drug, 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. MedWatch form must also be included with the prior authorization request. Form FDA 3500 – Voluntary Reporting • The currently available biosimilar product does not have the same appropriate use (per the references outlined in "Covered Uses") as the reference biologic drug being requested
Revision/Review Date: 09/2023	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Prior Authorization Group Description	**Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors**
Drugs	Nexletol (bempedoic acid), Nexlizet (bempedoic acid/ezetimibe), or any newly-approved drug in the class
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	None
Required Medical Information	See "Other Criteria"
Age Restrictions	18 years or older
Prescriber Restrictions	Prescriber must be a cardiologist or specialist in the treatment of lipid disorders
Coverage Duration	If all of the conditions are met, the initial request will be approved for 3 months. Reauthorization requests will be approved for 12 months.

Other Criteria	**<u>Initial Authorization:</u>**
	• Member must have documentation of baseline low density lipoprotein cholesterol (LDL-C)
	• One of the following is true:
	  o Member has a diagnosis of heterozygous familial hypercholesterolemia (FH)
	  o Member has a diagnosis of hyperlipidemia and atherosclerotic cardiovascular disease (ASCVD) as evidenced by a fasting LDL-C ≥ 70 mg/dL AND a history of 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, or
	  ▪ Aortic aneurysm
	  ▪ Clinically significant CHD diagnosed by invasive or non-invasive testing (such as coronary angiography, stress test using treadmill, stress echocardiography, or nuclear imaging)
	• 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.
	• Member has tried and failed ezetimibe at a maximum tolerated dose or documentation has been provided that the patient is not able to tolerate ezetimibe.
	• Member will continue on maximum tolerated statin dose while receiving Nexletol/Nexlizet 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".
	
	<u>Reauthorization:</u>
	• Documentation was provided that the member has experienced a clinical benefit from the medication (e.g. LDL-C lowering from baseline)
	• One of the following is true:
	  o Member will continue on maximum tolerated statin dose while receiving Nexlizet, or documentation has been provided that the member is not able to tolerate a statin
	  o Member will continue on maximum tolerated statin and ezetimibe dose while receiving Nexletol, or documentation has been provided that the member is not able to tolerate a statin and/or ezetimibe.

Revision/Review Date: 6/2023	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Acute Migraine Treatments**
Drugs	Preferred: Ubrelvy (ubrogepant) Non-preferred: Reyvow (lasmiditan) Nurtec ODT (rimegepant) - If the request is for migraine prevention please refer to the Calcitonin Gene-Related Peptide (CGRP) Antagonists for Headache Prevention 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	Member is 18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 3 months. For continuation of therapy the request will be approved for 6 months.
Other Criteria Revision/Review Date: 06/2023	**Initial Authorization:** Reyvow, Ubrelvy or Nurtec ODT will be approved when all of the following criteria are met: • Diagnosis of migraine headache • Requested dose is within FDA approved dosing guidelines • Documented trial and failure of (or medical justification for not using) an analgesic medication and two triptan products • If the request is for a non-preferred medication, documentation of trial/failure of, or a medical justification for not using, Ubrelvy. • For Reyvow requests: Attestation the patient was counseled regarding not driving or operating machinery until at least 8 hours after taking each dose **Criteria for Re-Authorization:** • Documentation of improvement in migraine pain and symptom(s) (e.g., photophobia, nausea, phonophobia) **Reyvow QL of 8 units per month.** **Ubrelvy QL of 16 units per month** **Nurtec ODT QL of 15 units per month** **Criteria for exceeding the quantity limit (note all of the above criteria must also be met)** • Documented trial and failure (or a medical justification for not using e.g. hypersensitivity, baseline bradycardia or hypotension, adverse events experienced from previous trial, etc.) with at least one drug from two categories below for at least 4 weeks EACH, at minimum effective doses: o Beta-adrenergic blockers o Topiramate or divalproex ER or DR o Amitriptyline or venlafaxine o Frovatriptan, zolmitriptan or naratriptan (for menstrual migraine prophylaxis) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Acyclovir (Zovirax)**
Drugs	Preferred: acyclovir 5% ointment Non-preferred: acyclovir 5% 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 the conditions are met, the request will be approved for up to 12 months.
Other Criteria Revision/Review Date: 12/2023	Criteria for approval of acyclovir cream: • Diagnosis of herpes labialis (cold sores) • Documented trial and failure or intolerance to an oral antiviral medication (acyclovir, valacylovir, famciclovir) AND acyclovir 5% ointment. Criteria for approval of acyclovir ointment: • Diagnosis of genital herpes OR non-life-threatening mucocutaneous herpes simplex virus infections • Documented trial and failure or intolerance to an oral antiviral medication (acyclovir, valacylovir, famciclovir) If the above conditions are not met, the request will be referred to a Medical Director for medical necessity review.

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 Restriction	Member must be 16 years of age or older
Prescriber Restriction	Prescriber must be a hematologist or provider with expertise in the treatment of sickle cell disease
Coverage Duration	If 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: 06/2023	**Initial Authorization:** • Member has a confirmed diagnosis of sickle cell disease • Documentation was provided that the member has had 2 or more pain crises in the last 12 months • Documentation was provided that the member has been taking hydroxyurea at the maximum tolerated dose and has been compliant within the last 6 months (or a medical reason was provided why the patient is unable to use hydroxyurea) • Documentation of the member's current weight • Request is for an FDA-approved dose **Reauthorization:** • Documentation has been submitted that the member has demonstrated or maintained ONE of the following changes from baseline: o Reduction in pain crises o Increased time between crises o Decrease in days hospitalized • Documentation of the member's current weight • Request is for an FDA-approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Adrenal Enzyme Inhibitors for Cushing's Disease**
Drugs	Isturisa (osilodrostat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be ≥ 18 years of age
Prescriber Restrictions	Prescribed by, or in consultation with, an endocrinologist or other specialist in the treatment of metabolic disorders
Coverage Duration	Initial Authorization: If the criteria are met, the request will be approved for a 6-month duration. Reauthorization: If the criteria are met, the request will be approved for a 12-month duration.

Other Criteria
 	
Revision/Review Date: 03/2023
	<u>Initial Authorization:</u>
	• Member has confirmed diagnosis of Cushing's Disease
	• Pituitary surgery is not an option or has not been curative
	• Provider attests baseline electrocardiogram (ECG) has been obtained and hypokalemia and/or hypomagnesemia has been corrected prior to initiating therapy if present
	• The medication is being prescribed at a dose that is consistent with FDA-approved package labeling, nationally recognized compendia or peer-reviewed literature
	• Documentation of baseline urinary free cortisol (UFC)
	• 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>Reauthorization:</u>
	• Member has responded to therapy as defined by a documented urinary free cortisol (UFC) test ≤ the upper limit of normal (ULN)
	• The medication is being prescribed at a dose that is consistent with FDA-approved package labeling, nationally recognized compendia
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Prior Authorization Group Description	**Aduhelm (aducanumab)**
Drugs	Aduhelm (aducanumab) *****Initial authorizations and reauthorizations must be approved by a Medical Director*****
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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	None
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	For initial authorization: the request will be approved in accordance with the FDA-indicated titration schedule for up to 6 months For reauthorization: if all of the conditions are met, the request will be approved for 6 months.
Other Criteria	**Initial Authorization** • Diagnosis of mild cognitive impairment (MCI) caused by AD or mild AD as evidenced by at least one of the following: o Clinical Dementia Rating Global (CDR-G) score of 0.5 (very mild dementia) o Repeatable Battery for Assessment of Neuropsychological Status (RBANS) delayed memory index (DMI) score ≤ 85 (low average) o Mini-Mental State Examination (MMSE) score ≥ 24 (questionably significant impairment) • 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 • Not currently using blood thinners (except aspirin)

Revision/Review Date: 9/2023	• No recent (past 1 year) history of stroke or transient ischemic attack (TIA) **<u>Reauthorization</u>** • The request is for an FDA approved dose • Provider attestation of safety monitoring and management of amyloid related imaging abnormalities (ARIA) and intracerebral hemorrhage, as recommended per the manufacturer's prescribing information. • Patient continues to have a diagnosis of mild cognitive impairment (MCI) caused by AD or mild AD consistent with Stage 3 or Stage 4 Alzheimer's disease as evidenced by at least one of the following: o CDR-G score of 0.5 (very mild dementia) o RBANS DMI score ≤ 85 (low average) o MMSE score of 24-30 • Not currently using blood thinners (except aspirin) • No recent (past 1 year) history of stroke or TIA • Recent, within past year, positive results for the presence of beta-amyloid plaques on a positron emission tomography (PET) scan **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 Atopic Dermatitis**
Drugs	Preferred: Dupixent (dupilumab) tacrolimus ointment pimecrolimus cream Non-preferred/Non-formulary: Eucrisa (crisaborole) Opzelura (ruxolitinib) Rinvoq (upadacitinib) Adbry (tralokinumab) Cibinqo (abrocitinib) Protopic ointment (BRAND) Elidel cream (BRAND)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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, pimecrolimus, and Opzelura should not be used in immunocompromised patients
Required Medical Information	See "other criteria"
Age Restrictions	Per prescribing information
Prescriber Restrictions	Adbry, Cibinqo, Rinvoq, Dupixent and Opzelura requests: Prescriber must be a pediatrician, dermatologist, or allergist
Coverage Duration	For Opzelura: Initial requests will be approved for 8 weeks and reauthorization requests will be approved for 6 months. For all other products: Initial requests will be approved for 6 months and reauthorization requests will be approved for 12 months.
Other Criteria	**Initial Authorization** **For pimecrolimus (Elidel):** • Diagnosis of mild to moderate atopic dermatitis • Member has a trial and failure of, contraindication to, intolerance to, or medical reason for not using, one formulary medium to high potency topical corticosteroid for at least 4 weeks **For tacrolimus (Protopic):** • Member has a trial and failure of, contraindication to, intolerance to, or medical reason for not using, one formulary medium to high potency topical corticosteroid for at least 4 weeks **For Eucrisa:** • Diagnosis of mild to moderate atopic dermatitis • Trial and failure of, contraindication to, intolerance to, or medical reason for not using the following: o A formulary medium to high potency topical corticosteroid AND o tacrolimus (Protopic) or pimecrolimus (Elidel) (not required for members less than 2 years of age) • Request is for a 60g tube/30 days. If a larger quantity is requested, documentation of clinical reason for the quantity is required. **For Dupixent or Adbry:** • Diagnosis of moderate to severe atopic dermatitis • Trial and failure of, contraindication to, intolerance to, or medical reason for not using the following: o A formulary medium to high potency topical corticosteroid AND o Topical tacrolimus (Protopic) or pimecrolimus (Elidel) (not required for members less than 2 years of age requesting Dupixent) AND

Revision/Review Date: 12/2023	o Eucrisa (not required for members with severe disease) **For Opzelura:** o Diagnosis of mild to moderate atopic dermatitis o Member must have 3% to 20% of body surface area (BSA) atopic dermatitis involvement (excluding scalp) o Trial and failure contraindication to, intolerance to, or medical reason for not using ALL of the following: o One formulary medium to high potency topical corticosteroid o Topical tacrolimus or pimecrolimus o Eucrisa (crisaborole) **A MAXIMUM OF ONE 60g TUBE PER WEEK OR ONE 100g TUBE PER 2 WEEKS OF OPZELURA MAY BE APPROVED** **For Rinvoq or Cibinqo:** o Diagnosis of refractory, moderate to severe AD o Trial and failure of, intolerance to, or contraindication to another systemic immunomodulatory drug product (e.g. cyclosporine, methotrexate, corticosteroids, biologics) o If the request is for Cibinqo for a new start, member is not using antiplatelets (excepting aspirin </= 81 mg/day) **Reauthorization:** • Provider attests that the member has experienced improvement in symptoms (e.g. significant clearing of the skin, reduction in itching) due to 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	**Agents for Thrombocytopenia**
Drugs	Non-formulary: • Nplate (romiplostim) • Doptelet (avatrombopag) • Tavalisse (fostamatinib) • Promacta (eltrombopag) • Mulpleta (lusutrombopag)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	For Doptelet, Mulpleta, and Tavalisse, member must be 18 years or older ITP: For Promacta and Nplate, member must be 1 year or older Severe aplastic anemia: For Promacta, member must be 2 years or older
Prescriber Restrictions	Prescriber must be a hematologist
Coverage Duration	• If the criteria are met, the request will be approved for 12 months for Promacta, Nplate and Tavalisse. • Doptelet will be approved for a maximum of 5 days for thrombocytopenia associated with chronic liver disease in adult patients requiring elective surgery and 12 months for immune thrombocytopenia (ITP) • Mulpleta will be approved for a maximum of 7 days.

Other Criteria Revision/Review Date: 9/2023	• **Chronic immune (idiopathic) thrombocytopenia (ITP):** o For Promacta, approve if there is a documentation of trial and failure, intolerance or contraindication to use ONE of the following: glucocorticoids, intravenous immune globulin (IVIG), Rituxan (if appropriate) or splenectomy AND platelet level < 30,000 mm^3 o For Nplate, Doptelet, or Tavalisse, approve if there is documentation of all of the following: ▪ Platelet level < 30,000 mm^3 ▪ Trial and failure, intolerance or contraindication to use ONE of the following: glucocorticoids, intravenous immune globulin (IVIG), Rituxan (if appropriate) or splenectomy ▪ Trial and failure, intolerance, or contraindication to use Promacta • **Severe aplastic anemia** (Promacta only): o Documented trial and failure, intolerance or contraindication to use at least one immunosuppressive agent o Platelet level < 20,000 cells/microL OR platelet level < 30,000 cells/microL with bleeding OR reticulocyte level < 20,000 cells/microL OR absolute neutrophil level < 500 cells/microL • **Thrombocytopenia in patients with Hepatitis C infection** (Promacta only): o Diagnosis of chronic hepatitis C o Documentation of treatment with interferon-based therapy AND patient's degree of thrombocytopenia prevents the initiation or limits the ability to maintain interferon-based therapy o Medical reason for why patient needs to be treated with interferon over direct acting antiviral (DAA) medication o Platelet level < 50,000/mm^3 • **Thrombocytopenia associated with chronic liver disease in ***adult*** patients requiring elective surgery** (Doptelet and Mulpleta only): o Patient has a diagnosis of chronic liver disease and is scheduled to undergo a procedure o Platelet level < 50,000/mm^3 o **For Mulpleta:** documentation of trial and failure, intolerance, or contraindication to use Doptelet **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Agents to Treat Constipation**
Drugs	**Formulary, PA Required:** lubiprostone (Amitiza) Linzess (linaclotide) Movantik (naloxegol) **Non-Formulary, PA Required:** Trulance (plecanatide) Motegrity (prucalopride) Relistor (methylnaltrexone) Symproic (naldemedine) Ibsrela (tenapanor) Or any newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Per package insert
Prescriber Restrictions	N/A
Coverage Duration	Initial request = 6 months Reauthorization request = 12 months
Other Criteria	**For chronic idiopathic constipation (CIC) or irritable bowel syndrome with constipation (IBS-C) or pediatric functional constipation, all of the following apply:** • The member has a diagnosis of CIC or a diagnosis of IBS-C • The member has tried and failed 2 different laxatives from 2 different classes (bulk-forming, osmotic, stimulant) • The medication is prescribed at an FDA-approved dose • If the request is for a non-formulary agent, the member must also have a trial and failure of (or medical reason for not using) two formulary/preferred products for the requested indication **For opioid induced constipation (OIC), all of the following apply:** • 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 medication is prescribed at an FDA-approved dose • If the request is for a non-formulary agent, the member must also have a trial and failure of (or medical reason for not using) two formulary/preferred products for the requested indication **Criteria for Reauthorization**:

	• The member has been adherent with therapy (as determined through review of claims history) • Documentation that the member has experienced treatment efficacy • The medication is prescribed at an FDA-approved dose
Revision/Review Date: 9/2023	**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 Gaucher's Disease**
Drugs	Cerdelga (eliglustat tartrate), Cerezyme (imiglucerase), Vpriv (velaglucerase alfa), Elelyso (taliglucerase alfa), miglustat (Zavesca)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	None
Required Medical Information	See "Other Criteria"
Age Restrictions	Per package insert
Prescriber Restrictions	Prescriber is a specialist in treatment of Gaucher's Disease (e.g. hematologist, orthopedist, endocrinologist, or geneticist), or is working in consultation with a specialist.
Coverage Duration	If all of the conditions are met, the request will be approved for 6 months.

Other Criteria Revision/Review Date: 06/2023	**<u>Initial Authorization:</u>** <u>Cerezyme, Vpriv, Elelyso, or miglustat initial criteria:</u> • Member has a confirmed diagnosis of Gaucher's disease, type 1 (GD1) • Request is for an FDA-approved dose <u>Cerdelga Initial Criteria:</u> • Member has a confirmed diagnosis of Gaucher's disease, type 1 (GD1) • The member has been designated a Cytochrome P450 2D6 (CYP2D6) extensive metabolizer (EM), intermediate metabolizer (IM) or poor metabolizer (PM) by an FDA-approved test. • Member is not concomitantly taking a Class IA (e.g. quinidine, procainamide) or Class III (e.g. amiodarone, sotalol) antiarrhythmic. • For EMs or IMs, member is not concomitantly taking a moderate or strong CYP2D6 inhibitor (e.g. fluoxetine, bupropion) WITH a moderate or strong Cytochrome P450 3A (CYP3A) inhibitor (fluconazole, ketoconazole). • For IMs and PMs, member is not concomitantly taking a strong CYP3A inhibitor • For EM's, patient does not have moderate or severe hepatic impairment • For IM's or PMs, patient does not have any degree of hepatic impairment • Request is for an FDA approved dose **<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, pulmonary function tests (PFTs), 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	**Agents for graft versus host disease**
Drugs	**Non-preferred/Non-formulary** Imbruvica (ibrutinib) Jakafi (ruxolitinib) Rezurock (belumosudil) Orencia (abatacept)
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	Per prescribing information
Prescriber Restrictions	Prescriber must be a hematologist, oncologist, or other specialist in the treatment of hematopoietic cell transplants
Coverage Duration	Jakafi, Rezurock, and Imbruvica: If all of the conditions are met, the request will be approved for up to a 3 month duration for initial requests and up to a 6 month duration for renewal requests. Orencia: If all the conditions are met, the request will be approved for a 1 month duration (4 total infusions)
Other Criteria Revision/Review Date: 12/2023	****For oncological indications, please refer to the "Oncology Agents" policy**** **Initial Authorization:** • Imbruvica o Member has a diagnosis of chronic graft versus host disease o Member has tried and failed or cannot use a systemic corticosteroid or immunosuppressant, or documentation is provided as to why a systemic corticosteroid or immunosuppressant cannot be used o The drug is prescribed at an FDA-approved dose • Jakafi o Member has a diagnosis of acute graft versus host disease or a diagnosis of chronic graft versus host disease o Member has tried and failed or cannot use a systemic corticosteroid or documentation is provided as to why a systemic corticosteroid cannot be used o The drug is prescribed at an FDA-approved dose • Rezurock o Member has a diagnosis of chronic graft versus host disease o 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 o The drug is prescribed at an FDA-approved dose • Orencia o Orencia is being requested for prophylaxis against acute graft versus host disease o Member will be underdoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor o 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 **<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) • The drug is prescribed at an FDA-approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

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	6 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a neuromuscular specialist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy the request will be approved for 12 months.
Other Criteria Revision/Review Date: 3/2023	**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 provided that prescriber has evaluated the member and recommends continuation of therapy **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Androgenic Agents**
Drug(s)	<u>Preferred (PA required):</u> testosterone cypionate intramuscular oil testosterone (generic Androgel) 1.62% transdermal gel pump <u>Non-preferred (PA required):</u> testosterone (generic Androgel) 1.62% transdermal gel packet testosterone (generic Androgel) 1% transdermal gel packet testosterone (Vogelxo) 1% (50 mg/5 g) transdermal gel packet, 12.5 mg/actuation pump methyltestosterone 10 mg capsule testosterone (Fortesta) 2% transdermal gel pump Methitest (methyltestosterone) 10 mg tablet Aveed (testosterone) 750 mg/3 ml (250 mg/ml) intramuscular solution Testim (testosterone) 1% gel Testopel (testosterone) 75 mg implant pellet Natesto (testosterone) 5.5 mg/0.122 g/actuation nasal gel pump testosterone enanthate 200 mg/ml intramuscular oil Xyosted (testosterone) subcutaneous auto-injector Jatenzo (testosterone undecanoate) capsules Tlando (testosterone undecanoate) capsules Or any newly marketed testosterone agent <u>Non-formulary</u> Androgel 1.62% transdermal gel packet Androgel 1% transdermal gel packet testosterone (Axiron) 30 mg/actuation transdermal solution in metered pump Striant (testosterone) 30 mg buccal system, sustained release
Covered Uses	Medically accepted indications are defined using the following 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	None
Prescriber	None
Coverage Duration	Initial authorization: 3 months Reauthorization duration: 12 months

Other Criteria	<u>For Initial Authorization:</u> • Diagnosis of primary hypogonadism (congenital or acquired) or hypogonadotropic hypogonadism (secondary hypogonadism) • Documented total testosterone level less than 300 ng/dl on two occasions in the last 18 months (copies of laboratory results required) • If a non-preferred drug is being requested, the member has had a trial of at least two preferred chemically unique drugs within the same drug class, or a trial of at least one preferred drug within the same drug class if there are not two chemically unique preferred drugs within the same drug class; or documentation was provided as to why the member cannot use preferred drugs <u>For Re-Authorization:</u> • Diagnosis of primary hypogonadism (congenital or acquired) or hypogonadotropic hypogonadism (congenital or acquired). • Documentation indicating the member has experienced a clinical benefit as a result of therapy
Revision/Review Date: 9/2023	**Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Prior Authorization Group Description	**Anti-CD19 CAR-T Immunotherapies**
Drugs	Breyanzi (lisocabtagene maraleucel), Kymriah (tisagenlecleucel), Yescarta (axicabtagene ciloleucel), Tecartus (brexucabtagene autoleucel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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 primary central nervous system lymphoma
Required Medical Information	See "Other Criteria"
Age Restrictions	See "Other Criteria"
Prescriber Restrictions	Prescriber must be an oncologist, hematologist or other appropriate specialist.
Coverage Duration	If all the criteria are met, the initial request will be approved for a one – time infusion per lifetime.
Other Criteria	**Initial authorization:** • Patient must not have received prior anti-CD19 CAR-T therapy. • Patient will be screened for HBV, HCV, and HIV in accordance with clinical guidelines. • Patient does not have an active infection or inflammatory disorder. • Patient has a life expectancy >12 weeks. • Patient will not receive live virus vaccines for at least 6 weeks prior to the start of lymphodepleting chemotherapy and until immune recovery following treatment. **Leukemia** **B-cell precursor Acute Lymphoblastic Leukemia (ALL):** • If the request is for Kymriah o Patient is 25 years of age or younger o ALL that is refractory or in second or later relapse • If the request is for Tecartus o Patient is 18 years of age or older o ALL that is relapsed or refractory **Non-Hodgkin's Lymphoma (NHL)** **Mantle Cell Lymphoma (MCL):** • If the request is for Tecartus: o Patient is 18 years of age or older o Patient has relapsed/refractory disease defined as failure of BOTH the following lines of therapy: ▪ Chemoimmunotherapy such as an anti-CD20 monoclonal antibody (e.g. Rituxan) + any chemotherapeutic agent ▪ Bruton Tyrosine Kinase (BTK) Inhibitor (e.g. Calquence, Imbruvica, Brukinsa) **For other forms of NHL:** • If the request is for Breyanzi (lisocabtagene maraleucel), Kymriah (tisagenlecleucel), Yescarta (axicabtagene ciloleucel) o Use is supported by a labeled indication or NCCN guidelines o Patient is 18 years of age or older

Revision/Review Date: 06/2023	○ For Breyanzi: ONE of the following: ▪ Patient is refractory to first-line chemoimmunotherapy or relapsed within 12 months of first-line chemoimmunotherapy ▪ Patient is refractory to first-line chemoimmunotherapy or relapsed after first-line chemoimmunotherapy and is not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age ○ Patient has failed two or more lines of systemic therapyFor Kymriah: Patient has relapsed/refractory disease defined as failure of two or more lines of systemic therapy ○ For Yescarta: Patient is refractory to first-line chemoimmunotherapy or relapses within 12 months of firth-line chemoimmunotherapy OR has failed two or more lines of systemic therapy. **<u>Re-authorization</u>:** • Treatment exceeding 1 dose 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	**Antifibrotic Respiratory Tract Agents**
Drug(s)	Ofev (nintedanib esylate) pirfenidone (Esbriet)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See other criteria
Age Restrictions	Member must be 18 years or older
Prescriber Restrictions	Prescriber must be a pulmonologist or lung transplant specialist
Coverage Duration	If all of the criteria are met, the request will be approved for 6 months.
Other Criteria Review/Revision Date: 9/2023	**Initial Authorization:** For All Requests: • Provider attests that they have reviewed 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 Idiopathic Pulmonary Fibrosis: • Confirmed diagnosis of idiopathic pulmonary fibrosis • 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 Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD): • The request is for Ofev (nintedanib) only • Confirmed diagnosis of SSc-ILD • FVC ≥ 40% within 30 days of request • Trial and failure of mycophenolate mofetil (MMF), cyclophosphamide, or azathioprine, or a medical reason was submitted as to why these therapies are not appropriate for the patient. If the request is for Chronic Fibrosing Interstitial Lung Diseases (ILDs) with a progressive phenotype: • 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, environmental/occupational lung disease, or sarcoidosis) • History of treatment in the last 12 months with at least one conventional medication used to treat ILD (e.g. corticosteroid, azathioprine, MMF, n-acetylcysteine (NAC), rituximab, cyclophosphamide, cyclosporine, tacrolimus), or a medical reason was submitted as to why these therapies are not appropriate for the patient. • FVC ≥ 45% predicted within 30 days of request

	Reauthorization: • 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-Parkinson's Agents for OFF Episodes**	
Drugs	Nourianz (istradefylline), Inbrija (levodopa) inhalation, Apokyn (apomorphine), Xadago (safinamide), Ongentys (opicapone), or any other newly marketed agent	
Covered Uses	Medically accepted indications are defined using the following sources: The Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.	
Exclusion Criteria	N/A	
Required Medical Information	See Other Criteria	
Age Restrictions	N/A	
Prescriber Restrictions	Prescriber is a neurologist or is working in consultation with a neurologist	
Coverage Duration	**Initial Authorization**	If the criteria are met, the request will be approved for 6 months
	Reauthorization	If the criteria are met, the request will be approved for 12 months

Other Criteria
 	
Revision/Review Date: 3/2023
	<u>Initial Authorization:</u>
	• Diagnosis of Parkinson's disease
	• Patient is currently taking and will continue to take carbidopa/levodopa
	• Patient is experiencing symptom fluctuations or off episodes while taking carbidopa/levodopa where attempts have been made to adjust the carbidopa/levodopa dose and/or formulation in order to manage symptoms without success
	• Documented trial and failure (or contraindication) to **at least two** of the following adjunctive medication classes:
	  o COMT-inhibitors (e.g. entacapone)
	  o Dopamine agonists (e.g. ropinirole, pramipexole)
	  o MAO-B inhibitors (e.g. rasagiline, selegiline)
	• Dosing is appropriate as per labeling or is supported by compendia or standard of care guidelines
	• If the request is for Inbrija, patient does not have asthma, COPD, or other chronic underlying lung disease
	• If the request is for Nourianz, Inbrija, Apokyn, Kynmobi, or any other newly marketed agent, patient must also have a documented trial and failure or intolerance to Ongentys and Xadago
	
	<u>Re-authorization:</u>
	• Documentation of positive clinical response
	• 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	**Antipsychotic Drugs**
Drugs	**Preferred:** Abilify Maintena aripiprazole oral solution aripiprazole tablet chlorpromazine tablet clozapine tablet clozapine ODT fluphenazine tablet fluphenazine decanoate injection haloperidol tablet haloperidol decanoate injection haloperidol lactate injection Invega Sustenna Invega Trinza Invega Hafyera Latuda (lurasidone) Invega Trinza lithium oral solution lithium capsule lithium ER tablet loxapine capsule olanzapine intramuscular injection olanzapine tablet perphenazine tablet perphenazine/amitriptyline pimozide tablet quetiapine tablet quetiapine ER tablet Risperdal Consta risperidone tablet risperidone oral solution risperidone ODT thioridizine tablet trifluoroperazine tablet thiothixene capsule ziprasidone capsule **Non-Preferred:** aripiprazole ODT Abilify tablet asenapine (Saphris) Abilify Mycite (aripiprazole) Aristada, Aristada Initio (aripiprazole lauroxil) Caplyta (lumateperone) Clozaril (clozapine) Fanapt (iloperidone) Geodon (ziprasidone) Invega tablet Lybalvi (olanzapine and samidorphan) molindone tablet Nuplazid (pimavanserin) olanzapine ODT olanzapine-fluoxetine capsule paliperidone tablet Perseris (risperidone) Rexulti (brexpiprazole) Risperdal ODT, solution, tablet Saphris Secuado (asenapine) Seroquel, Seroquel XR (quetiapine) Symbyax Versacloz (clozapine) Vraylar (cariprazine) ziprasidone intramuscular inj. Zyprexa, Zyprexa Zydis (olanzapine) Zyprexa Relprevv (olanzapine) any newly marketed product
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request may be approved for 12 months.

Other Criteria	**<u>Criteria For Initial Approval:</u>** • Diagnosis appropriate per Covered Uses **AND** • For non-preferred drugs, prescriber documents that preferred formulary drugs have been tried or were considered **AND** it was determined that the drug prescribed will best treat the condition. **AND** • If the request is for a long-acting injectable antipsychotic, documentation that the member has tolerated and experienced a favorable response with oral dosage form **<u>Criteria for Continuation of Care (reauthorization and members on existing therapy including members new to the plan):</u>** • If the request is for a mental illness or emotional disturbance, documentation that the patient has been treated with the drug for at least 90 days prior to a change in SCHA's drug formulary or prior to becoming a SCHA member • Diagnosis appropriate per Covered Uses **NOTE: Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary**
Revision/Review Date: 9/2023	

Prior Authorization Group Description	**Antiviral Agents for Hepatitis B**	
Drugs	Preferred: entecavir tablet Baraclude oral solution lamivudine (Epivir HBV) tenofovir disoproxil fumarate (Viread)	Non-preferred/Non-formulary: adefovir (Hepsera) Baraclude tablet Vemlidy (tenofovir alafenamide fumarate) Viread 40 mg/g oral powder any newly-approved agent for Hepatitis B
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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 consistent with compendia data for the requested drug	
Prescriber Restrictions	Prescribed by (or working in consultation with) a gastroenterologist, hepatologist, or infectious disease specialist	
Coverage Duration	Initial Requests: If criteria are met, 6 months of therapy will be approved. Reauthorization requests: • For requests for patients undergoing chemotherapy: HBV prophylactic treatment is approved for 12 months upon completion of chemotherapy. • Reauthorization requests will not be considered for perinatal prophylaxis after 3 months postpartum; refer to other criteria categories to determine eligibility for continued treatment. • All other reauthorization requests will be approved for 12 months.	

Other Criteria	**<u>Initial criteria for all diagnoses in the adult population:</u>** • Diagnosis of hepatitis B • Medication is being prescribed at an appropriate FDA-approved dose (for age and weight) • For non-preferred drug requests, the member has had a trial of at least two preferred chemically unique drugs within the same drug class, or a trial of at least one preferred drug within the same drug class if there are not two chemically unique preferred drugs within the same drug class; or documentation was provided as to why the member cannot use preferred products • If the request is for an oral solution/oral powder, medical justification for use (i.e. difficulty swallowing) must be provided **For immune-active Chronic Hepatitis B:** • Laboratory values submitted are consistent with immune-active disease as outlined below: o HBV DNA > 2000 IU/ml (if HBeAg negative) or HBV DNA > 20,000 IU/ml (if HBeAg positive) o ALT > 66 U/L in males or > 50 U/L in females OR evidence of histological disease (significant inflammation and/or fibrosis) **For decompensated cirrhosis:** Presence of decompensated cirrhosis and detectable serum HBV DNA. **For compensated cirrhosis:** Presence of elevated HBV DNA ≥ 2000 IU/mL **Prophylaxis for Transplant Recipients with Hepatitis B:** o Patient is HBsAg-positive and undergoing liver transplantation, regardless of HBeAg status or HBV-DNA level pre-transplant; OR o Patient is HBsAg-negative and received a HBsAg-negative but anti-HBc–positive graft; OR o Patient has received a HBsAg-positive (non-liver) organ transplant. **Pregnant Women (for perinatal transmission prophylaxis only; patient does not meet other eligibility categories):** Patient is in the third trimester of pregnancy and is HBsAg-positive with HBV DNA level > 200,000 IU **Undergoing Chemotherapy or Will Be Initiating Cytotoxic Chemotherapy:** o Patient is HBsAg-positive, anti-HBc–positive regardless of baseline serum HBV DNA levels; OR o Patient is HBsAg-negative, anti-HBc–positive; AND 1) Receiving anti-CD20 antibody therapy (e.g., rituximab); OR 2) Undergoing stem cell transplantation.

Revision/Review Date: 9/2023	**Immune-tolerant disease (normal ALT)**
	Patient is an adult over 40 with elevated HBV DNA ≥ 1,000,000 IU/ml and liver biopsy showing significant necroinflammation or fibrosis
	
	Acute Symptomatic Hepatitis B
	• Patient has acute hepatitis B and one of the following:
	  o Acute liver failure OR
	  o Severe disease as indicated by one of the following: total bilirubin >3 mg/dL (or direct bilirubin >1.5 mg/dL), international normalized ratio (INR) >1.5, encephalopathy, or ascites
	
	INITIAL CRITERIA for Treatment of Chronic Hepatitis B in children (<18 years of age):
	• Diagnosis of hepatitis B
	• Medication is being prescribed at an appropriate FDA approved dose (for age and weight)
	• Patient is HBeAg-positive with both of the following:
	  o Elevated ALT
	  o Measurable HBV-DNA levels
	• For non-preferred drug requests, the member has had a trial of at least two preferred chemically unique drugs within the same drug class, or a trial of at least one preferred drug within the same drug class if there are not two chemically unique preferred drugs within the same drug class; or documentation was provided as to why the member cannot use preferred products
	• If request is for oral solution/oral powder, medical justification for use (i.e. difficulty swallowing) must be provided.
	
	Reauthorization Criteria
	• Documented positive response to treatment as evidenced by decrease or normalization of ALT/AST and reduced HBVDNA levels
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Prior Authorization Group Description	**Arikayce (amikacin sulfate)**
Drug(s)	Arikayce (amikacin sulfate)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, a pulmonologist or infectious disease specialist
Coverage Duration	If all of the conditions are met the request will be approved for 6 months.

Other Criteria
 	
Review/Revision Date: 6/2023
	Initial Authorization:
	• Member has a diagnosis of *mycobacterium avium complex* (MAC) lung disease with a documented positive sputum culture
	• Member has failed guideline-based therapy with continued positive sputum cultures after 6 months or more of treatment
	• Member will continue to receive guideline-based treatment throughout use of Arikayce
	
	Reauthorization:
	• Member has documentation of one of the following:
	  ○ Sputum conversion (three consecutive monthly negative sputum cultures)
	  ○ Documentation indicating the member has experienced a clinical benefit as a result of therapy (e.g. improvement in six minute walk test (6MWT), improvement seen on imaging, improvement in respiratory symptom score)
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

BPrior Authorization Group Description	**B-Cell Maturation Antigen (BCMA) Directed Chimeric Antigen Receptor (CAR) T-Cell Therapy**
Drugs	Abecma (idecabtagene vicleucel), Carvykti (ciltacabtagene autoleucel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be 18 years or older
Prescriber Restrictions	Prescriber must be a hematologist, an oncologist, or other appropriate specialist
Coverage Duration	If all the criteria are met, the initial request will be approved for a one – time infusion per lifetime.

Other Criteria
 	
Revision/Review Date: 06/2023
	<u>Initial Authorization</u>
	• Member has a diagnosis of relapsed or refractory multiple myeloma (RRMM)
	• Member must have received at least 4 prior lines of therapy, which must include ALL of the following:
	  o An immunomodulatory agent (e.g. lenalidomide, pomalidomide, thalidomide)
	  o A proteasome inhibitor (e.g. bortezomib, carfilzomib, ixazomib)
	  o An anti-CD38 monoclonal antibody (e.g. daratumumab, isatuximab)
	• Member does not have an active infection
	• Member will be screened for cytomegalovirus (CMV), hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines
	• Member will not receive live virus vaccines for at least 6 weeks prior to the start of lymphodepleting chemotherapy and until immune recovery following treatment
	• Member has not previously received a BCMA CAR-T therapy
	
	<u>Re-authorization:</u>
	• Treatment exceeding 1 dose 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	**Biologic Agents for Nasal Polyposis**
Drugs	**Dupixent** (dupilumab), **Xolair** (omalizumab), **Nucala** (mepolizumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Use of Dupixent, Xolair, and Nucala concomitantly or with another pulmonary biologic (e.g. Fasenra, , Cinqair)
Required Medical Information	See "Other Criteria"
Age Restrictions	Patients must be 18 years age or older
Prescriber Restrictions	Prescriber must be an allergist/immunologist or otolaryngologist, or working in consultation with one of these specialists
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy the request will be approved for 6 months.
Other Criteria Revision/Review Date: 9/2023	****Xolair:** For asthma and urticaria, please refer to the "Xolair for Asthma and Urticaria" policy****** ****Dupixent:** For atopic dermatitis, please refer to the "Agents for Atopic Dermatitis" policy; For asthma, please refer to the "Pulmonary Biologics for Asthma and Eosinophilic Conditions" policy****** ****Nucala:** For asthma or other eosinophilic conditions, please refer to the "Pulmonary Biologics for Asthma and Eosinophilic Conditions" policy** **<u>Initial Authorization:</u>** • Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) • Medication is being prescribed at an FDA approved dose • Patient 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 Patient had prior surgery for nasal polyps OR o Trial and failure or intolerance, or a medical reason has been provided, for not using ALL of the following therapies: ▪ intranasal corticosteroids ▪ systemic corticosteroid **<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 dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Bleeding Disorder Blood Products**
Drugs	**Preferred:** Advate, Adynovate, Afstyla, Alphanate, Alphanine SD, Alprolix, Benefix, Coagadex, Corifact, Eloctate, Esperoct, Feiba, Hemofil M, Humate-P, Idelvion, Ixinity, Jivi, Koate, Kogenate FS, Kovaltry, Mononine, Novoeight, Novoseven RT, Nuwiq, Obizur, Profilnine SD, Rebinyn, Recombinate, Rixubis, Tretten, Vonvendi, Wilate, Xyntha, Xyntha Solofuse **Non-Formulary/Non-preferred:** any newly marketed blood product indicated for a bleeding disorder
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Patient must be age appropriate per package insert
Prescriber Restrictions	Prescriber must be a hematologist
Coverage Duration	If all of the criteria are met, the request will be approved for 3 months.
Other Criteria Revision/Review Date: 12/2023	• Patient has a diagnosis of a bleeding disorder and the type of deficiency has been provided • The drug is being used for an FDA-approved indication at an FDA-approved dose or the indication/dose are otherwise supported by treatment guidelines • Requests for non-formulary/non-preferred products: Member has a documented treatment failure with at least two of the preferred agents OR has a documented medical reason (intolerance, hypersensitivity, contraindication, etc.) why they are not able to use preferred agents **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	**Preferred Agents for FDA approved indications:** abobotulinumtoxin A (Dysport) incobotulinumtoxin A (Xeomin) **Non-preferred Agents:** onabotulinumtoxin A (Botox) rimabotulinumtoxin B (Myobloc) DaxibotulinumtoxinA (Daxxify) or any newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	According to prescribing information
Prescriber Restrictions	None
Coverage Duration	If all of the conditions are met, the request will be approved 6 months.
Other Criteria Revision/Review Date: 12/2023	****The use of these medications for cosmetic purposes is NOT a covered benefit under the Medical Assistance program.**** <u>Criteria for approval:</u> • The drug is being used for a medically accepted indication and dose as outlined in the Covered Uses section • The member has tried and failed standard first line therapy and/or has a documented medical reason (intolerance, hypersensitivity, contraindication, etc) for not using the 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 **all** of the following categories for at least 4 weeks each at a minimum effective dose: o a beta blocker (e.g. propranolol, timolol, metoprolol, nadolol, or atenolol) o amitriptyline, nortriptyline, duloxetine, desvenlafaxine or venlafaxine o valproic acid/divalproex sodium or topiramate • If the diagnosis is **Overactive Bladder**, the member has tried and failed, or has a medical reason for not using at least 2 formulary medications (e.g. oxybutynin, tolterodine, trospium) • If the diagnosis is **Hyperhidrosis**, the patient has tried and failed a prescription strength antiperspirant (e.g. 20% aluminum chloride hexahydrate) • If the diagnosis is **Chronic Sialorrhea**, o Documentation is provided that the member has had sialorrhea lasting at least 3 months o The member has tried and failed, or has a medical reason for not using, an anticholinergic medication (e.g., glycopyrrolate, hyoscyamine, benztropine)

	• If the request is for a non-preferred agent, the member tried and failed a preferred agent if appropriate for the requested indication Physician/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	**Brineura (cerliponase alfa)**
Drugs	Brineura (cerliponase alfa)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert, and/or per the National Comprehensive Cancer Network (NCCN)
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	Member must be 3 years of age or older
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	If the criteria are met, the request will be approved for 6 months.
Other Criteria Revision/Review Date: 9/2023	**<u>Initial Authorization:</u>** • Documentation of confirmed diagnosis of late infantile 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. • Prescribed dose is consistent with FDA-approved labeling **<u>Re-authorization:</u>** • Documentation of CLN2 Clinical Rating Scale motor +language score has remained > 0 • Prescribed dose is consistent with FDA-approved labeling **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Prior Authorization Group Description	**Budesonide Nebulization Solution (Pulmicort Respules)**
Drugs	Preferred: budesonide inhalation suspension Non-preferred: BRAND Pulmicort Respules
Covered Uses	Medically accepted indications are defined using the following sources the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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	Budesonide suspension for nebulization will pay at point of sale for members $\leq$ 11 years of age.
Prescriber Restrictions	N/A
Coverage Duration	If the conditions are met, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 6/2023	For diagnosis of asthma in children 12 and older and adults: • Documentation as to why the member cannot use an inhaled corticosteroid via inhaler • Total daily dose should not exceed 2 mg. Doses beyond 2 mg/day should be reviewed for medical necessity. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Carisoprodol**
Drugs	carisoprodol (Soma, Vanadom) 250 mg, 350 mg tablets carisoprodol-aspirin-codeine 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	Member is 16 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, requests for carisoprodol will be approved for a single fill for a maximum of 84 tablets for a 21 day supply with one refill per year and requests for carisoprodol-aspirin will be approved for a single fill for a maximum of 168 tablets for a 21 day supply; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria Revision/Review Date: 12/2023	The member has tried and failed, or has a documented medical reason for not using, all of the following: • tizanidine • cyclobenzaprine • baclofen

Prior Authorization Group Description	**Cystic Fibrosis transmembrane conductance regulator (CFTR) Modulators**
Drug(s)	Kalydeco, Kalydeco Granules (ivacaftor) Orkambi, Orkambi Granules (lumacaftor/ivacaftor) Symdeko (tezacaftor/ivacaftor) Trikafta (elexacaftor/tezacaftor/ivacaftor) any newly marketed CFTR modulator to treat cystic fibrosis
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	See "Other Criteria"
Required Medical Information	See "Other Criteria"
Age Restrictions	See "Other Criteria"
Prescriber Restrictions	Prescriber is pulmonologist or specializes in the treatment of cystic fibrosis
Coverage Duration	If all of the conditions are met the initial request will be 6 months. Reauthorization requests will be 12 months. If all of the criteria are not met, the request is referred to a Medical director/clinical reviewer for medical necessity review.
Other Criteria Review/Revision Date 12/2023	<u>Initial criteria:</u> • Documentation provided includes a copy of the FDA-cleared cystic fibrosis (CF) mutation test OR documentation from the National Cystic Fibrosis Registry (e.g., screen shot) with member's genetic mutations • The request is for an FDA approved indication for the member's genotype and within dosing guidelines • The request is appropriate for member (e.g., age/weight) based on FDA-approved package labeling, peer reviewed medical literature and nationally-recognized compendia. <u>Reauthorization:</u> • Based on prescriber's assessment, patient continues to benefit from therapy • The request is within FDA dosing guidelines **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Calcitonin Gene-Related Peptide (CGRP) Antagonists for Headache Prevention**
Drugs	<u>Preferred</u> • Emgality (galcanezumab-gnlm) • Ajovy (fremanezumab-vfrm) <u>Non-preferred/Non-formulary</u> • Aimovig (erenumab-aooe) • Vyepti (eptinezumab) • Nurtec ODT (if the request is for acute treatment of migraine please refer to the Acute Migraine Treatments criteria) • Qulipta (atogepant) • Any newly approved CGRP Antagonist for headache prevention
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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 diagnosis of CHRONIC cluster headaches
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescriber is a neurologist or is working in consultation with a neurologist.
Coverage Duration	If the criteria are met, the initial authorization request will be approved for 6 months. Reauthorization may be approved for 6 months.
Other Criteria	**<u>Criteria for Initial Authorization</u>** **Migraine Headache Prophylaxis:** • Diagnosis of episodic migraine or chronic migraine • Documentation of the number of headache days per month should be provided with the request • 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 blocker

Revision/Review Date: 9/2023	o Topiramate or divalproex/valproate/valproic acid o Tricyclic antidepressant or venlafaxine o For menstrual migraine prophylaxis only: frovatriptan, zolmitriptan or naratriptan • If the medication request is for a non-preferred CGRP receptor antagonist, the member has a documented medical reason (intolerance, hypersensitivity, contraindication, treatment failure etc) for not using a preferred CGRP receptor antagonist • Requested dose is within FDA approved dosing guidelines **Episodic Cluster Headache** • Documented diagnosis of episodic cluster headache and requested medication is indicated for episodic cluster headache • Requested dose is within FDA approved dosing guidelines • Documented trial and failure of (or a medical justification for not using) verapamil for at least 4 weeks, at minimum effective dose **<u>Criteria for Re-Authorization</u>** **Migraine Headache Prophylaxis:** • Reduction in number of headache days per month by 50% relative to pre-treatment baseline o Documentation of the number of headache days per month should be provided with the request **Episodic Cluster Headache** • Documented reduction in the frequency of headaches **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Camzyos**
Drugs	Camzyos (mavacamten)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	≥ 18 years
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 9/2023	**<u>Initial Authorization:</u>** • Diagnosis of symptomatic New York Heart Association (NYHA) class II or III obstructive hypertrophic cardiomyopathy (oHCM) • Patient has a left ventricular ejection fraction (LVEF) ≥55% • Patient has a peak left ventricular outflow tract (LVOT) gradient ≥ 50 mmHg at rest or with provocation • Trial and failure or contraindication to ALL of the following: o Beta blockers (i.e. metoprolol, propranolol, atenolol) o Non-dihydropyridine calcium channel blockers (i.e. verapamil, diltiazem) • Prescriber attests that patient is not diagnosed with a disorder that causes cardiac hypertrophy that mimics oHCM (i.e., Fabry disease, amyloidosis, or Noonan syndrome with LV hypertrophy) • Prescriber attests that patient is not using moderate to strong CYP2C19 or CYP3A4 inhibitors or inducers • Medication is prescribed at an FDA approved dose **<u>Re-Authorization:</u>** • 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 • Patient has a left ventricular ejection fraction (LVEF) ≥50% • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Prior Authorization Group Description	**Chelating Agents**
Drugs	Preferred: deferasirox (Jadenu) tablets Chemet (succimer) capsules (pays at point of sale without PA) Non-preferred: deferasirox (Jadenu) oral granules, deferasirox (Exjade) tablets for oral suspension, deferiprone (Ferriprox) tablets, Ferriprox (deferiprone) solution, penicillamine capsules, radiogardase capsules, trientine capsules, Galzin (zinc acetate) capsules, Bal in Oil (dimpercaprol), Pentetate calcium trisodium, Pentetate zinc trisodium, Calcium Disodium Versenate (edetate calcium disodium)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	See "Other Criteria"
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved for 6 months.
Other Criteria	**Requests for deferasirox (Exjade, Jadenu)** **Chronic iron overload due to blood transfusions:** • Member is 2 years of age or older • Diagnosis of chronic iron overload due to blood transfusions • Member is receiving blood transfusions on a regular basis/participating in blood transfusion program • Serum ferritin concentration is consistently > 1000 mcg/L. If the serum ferritin levels fall consistently below 500 mcg/L, deferasirox therapy must be interrupted • The medication requested is being prescribed at an FDA-approved dose • If the request is not for deferasirox tablets, documentation was provided as to why the member cannot use deferasirox tablets whole or crushed **Chronic iron overload in non-transfusion-dependent thalassemia syndromes:** • Member must be ≥ 10 years old • Diagnosis of thalassemia syndrome • Liver iron content (LIC) by liver biopsy of ≥ 5 mg Fe/g dry weight • Serum ferritin level > 300mcg/L on ≥ 2 measurements one month apart • The medication requested is being prescribed at an FDA-approved dose If the request is not for deferasirox tablets, documentation was provided as to why the member cannot use deferasirox tablets whole or crushed **<u>Requests for Ferriprox (deferiprone)</u>** **Transfusional iron overload:** • Member must be ≥ 3 years old for oral solution or ≥ 8 years old for tablets • Diagnosis of thalassemia, sickle cell disease, or other anemia

Revision/Review Date: 9/2023	• Member is receiving blood transfusions on a regular basis/participating in blood transfusion program • Serum Ferritin concentration is consistently > 1000 mcg/L. If the serum ferritin levels fall consistently below 500 mcg/L, Ferriprox must be discontinued • The medication requested is being prescribed at an FDA approved dose • Documentation was provided as to why the member cannot use deferasirox tablets whole or crushed **Requests for all other drugs and indications:** • The drug is requested for an appropriate use (per the references outlined in "Covered Uses") • The dose requested is appropriate for the requested use (per the references outlined in "Covered Uses") Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Prior Authorization Group Description	**Cholbam**
Drugs	Cholbam (cholic acid)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescriber is a gastroenterologist or hepatologist
Coverage Duration	If all of the conditions are met, the request will be approved for a 3 month duration for the first year of therapy, and then for a 6 month duration after one year of treatment.
Other Criteria Revision/Review Date: 12/2023	<u>Initial authorization:</u> • Patient has a confirmed diagnosis of: o Bile acid synthesis disorder due to single enzyme defect (SEDs) OR o Peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients that exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat soluble vitamin absorption • Current labs (within 30 days of request) have been submitted for the following: o ALT/AST o GGT (serum gamma glutamyltransferase) o ALP (alkaline phosphatase) o Bilirubin o INR <u>Re-authorization:</u> • Documentation has been submitted indicating clinical benefit/liver function has improved since beginning treatment • For reauthorization after the first 3 months of treatment, lab results must show an improvement in liver function and there must be no evidence of biliary obstruction or cholestasis • Current labs (within 30 days of request) have been submitted for the following: o ALT/AST o GGT (serum gamma glutamyltransferase) o ALP (alkaline phosphatase) o Bilirubin o INR **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 (CGMs)**
Products	Eversense Guardian Connect Enlite Freestyle Libre 10-day Any other newly-marketed CGM **Note: Dexcom G6, Freestyle Libre 2, Freestyle Libre 3 Sensor, and Freestyle Libre 14-day are preferred and will pay at POS without a prior authorization**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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	See "Other Criteria"
Coverage Duration	If the conditions are met, the request will be approved for the following: • one meter and one reader (as applicable) for 12 months • up to 5 sensors per 30 days may be approved for 12 months • one (1) Eversense transmitter for 12 months • one (1) Guardian Connect transmitter for 12 months

Other Criteria
 	
Revision/Review Date: 3/2023
	• Diagnosis of diabetes
	• One of the following:
	  o Prescribed by, or in consultation with, and endocrinologist
	  o Member is assisted by a certified diabetes care and education specialist (CDCES)
	• One of the following:
	  o Member is using an insulin pump/continuous subcutaneous insulin infusion
	  o Member is using multiple (≥3) daily insulin injections
	  o Member is a child or adolescent with type 1 diabetes mellitus (DM)
	  o Member is diagnosed with gestational DM and treated with insulin
	  o Member is a pregnant woman with type 1 or type DM treated with intensive insulin therapy
	  o Recent (past 6 months) history of problematic hypoglycemia (e.g. frequent or severe hypoglycemia, nocturnal hypoglycemia, hypoglycemia unawareness)
	  o Continuation of therapy with existing CGM
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	**Corlanor**
Drugs	Corlanor (ivabradine)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Pregnancy
Required Medical Information	See "Other Criteria"
Age Restrictions	See "Other Criteria"
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist
Coverage Duration	If all of the conditions are met, the request will be approved for 12 month duration.
Other Criteria Revision/Review Date: 03/2023	**Heart Failure in Adult Patients:** 1. Member is aged 18 years or older 2. Member has a diagnosis of stable symptomatic chronic heart failure (NYHA functional class II-IV) with a left ventricular ejection fraction ≤ 35% 3. Member is in sinus rhythm with a resting heart rate ≥ 70 beats per minute (bpm) 4. Member is currently being prescribed, or documentation has been provided that the member is not able to tolerate, an evidence based beta-blocker (i.e., bisoprolol, carvedilol, metoprolol succinate) at maximally tolerated dose **Heart Failure in Pediatric Patients:** 1. Member is aged 6 months to less than 18 years of age 2. Member has stable heart failure (NYHA/Ross functional class II-IV) due to dilated cardiomyopathy and a left ventricular ejection fraction ≤ 45% 3. Member is in sinus rhythm with an elevated resting heart rate **Reauthorization** 1. Dose consistent with package insert or guidelines/compendia 2. Attestation that patient has experienced clinical benefit **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	Acthar (corticotropin) Cortitrophin (corticotropin)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	See "other criteria"
Prescriber Restrictions	See "other criteria"
Coverage Duration	If the criteria are met, the request will be approved for up to a 1 month duration.
Other Criteria Revision/Review Date: 6/2023	**Infantile Spasms (West Syndrome):** • Patient is < 2 years of age • The medication is being prescribed by a neurologist. • Documentation of the patient's current weight (in kg) and height/length (in cm) or body surface area (BSA) **Multiple Sclerosis:** • Documentation was submitted that patient is having acute attack, with neurologic symptoms and increased disability or impairments in vision, strength or cerebellar function, and has failed therapy with intravenous (IV) methylprednisolone, or a medical reason has been submitted why patient is unable to use IV methylprednisolone. • The medication is being prescribed by a neurologist • If the request is for Acthar, trial and failure of, contraindication to, or medical reason for not using Cortitrophin. **All Other FDA Approved Conditions and Indications:** • Documented trial and failure of parenteral AND enteral corticosteroids, or documented medical reason for why the patient cannot use these therapies for treatment **AND** • 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. **AND** • Prescriber is a specialist in the condition they are treating. • If the request is for Acthar, trial and failure of, contraindication to, or medical reason for not using Cortitrophin. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Crinone**
Drugs	Crinone (micronized progesterone)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Treatment of infertility
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met for prevention of spontaneous preterm delivery, the request will be approved for 30 single use applicators per 30 days until the end of pregnancy. If the criteria are met for secondary amenorrhea, the request will be approved for 6 doses.
Other Criteria Revision/Review Date: 9/2023	**<u>Criteria for Authorization:</u>** • **Requests for prevention of spontaneous preterm delivery**: o Member is pregnant with one fetus (singleton) and is less than or equal to 24 weeks gestation AND o Member has history of preterm birth of a singleton OR a short cervix • **Requests for secondary amenorrhea** o Documented diagnosis of secondary amenorrhea AND o Member has tried and failed or has a documented allergy/ contraindication/intolerance to oral progestin therapy (e.g. micronized progesterone capsules, medroxyprogesterone acetate tablets, norethindrone tablets) o If the request is for Crinone 8% gel, documentation is required that the member has tried and failed Crinone 4% gel. **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)
Covered Uses	Medically accepted indications are defined using the following 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	• History of seizures • Moderate or severe renal impairment (creatinine clearance $\leq$ 50 mL/minute)
Required Medical Information	See "other criteria"
Age Restrictions	Patient must be 18 years of age or older
Prescriber Restrictions	Prescriber must be a neurologist or other specialist in the treatment of multiple sclerosis
Coverage Duration	Initial Authorization: If all the criteria are met, the request will be approved for 6 months. Reauthorization: If all of the criteria are met, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 6/2023	**Criteria for Initial Authorization:** • Member has a diagnosis of multiple sclerosis (MS) • Member is ambulatory but has walking impairment. Documentation of objective measure of walking ability (e.g. 25 foot walk test, 6 minute walk distance, Multiple Sclerosis Walking Scale (MSWS-12)) must be submitted with the request. • Documentation of baseline creatinine clearance (within 60 days of request) above 50 mL/min • Documentation was submitted (consistent with pharmacy claims data or for new members to the health plan, consistent with chart notes) that patient is currently receiving disease-modifying therapy for MS or documentation of a medical reason (intolerance, hypersensitivity) as to why patient is unable to use MS disease-modifying therapy • Drug is being requested at an FDA-approved dose **Criteria for Re-authorization:** • Documentation of improvement in objective measure of walking ability from baseline was submitted with request • Member is receiving disease-modifying therapy for MS or documentation of a medical reason (intolerance, hypersensitivity) for not using MS disease-modifying therapy has been submitted • Drug is being requested 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	**Danazol**
Drugs	danazol capsules
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Pregnancy-see "other criteria"
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	See "other criteria"
Coverage Duration	If the criteria are met, the request will be approved with for 6 months.

Other Criteria
 	
Revision/Review Date: 3/2023
	<u>ENDOMETRIOSIS</u>
	• Diagnosis of endometriosis
	• Documentation of one of the following:
	  o Trial and failure of (or documented medical reason for not using) first line therapy of combined estrogen/progestin or progestin-only contraceptive therapy in combination with an NSAID.
	  o Trial and failure of gonadotropin-releasing hormone (GnRH) agonists or GnRH antagonists (e.g. Orilissa [elagolix] or Myfembree (relugolix, estradiol, and norethindrone acetate)).
	• Prescriber must be a gynecologist
	• Negative pregnancy test is documented
	
	<u>HEREDITARY ANGIOEDEMA:</u>
	• Diagnosis of hereditary angioedema
	• Prescriber must be an immunologist, allergist, rheumatologist, or hematologist
	• Negative pregnancy test is documented
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Daybue (trofinetide)
Drugs	Daybue (trofinetide)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	If all the criteria are met, the initial request will be approved for 3 months. For continuation of therapy, the request will be approved for 6 months.
Other Criteria Revision/Review Date 9/2023	**Initial Authorization:** • Medication is prescribed at an FDA approved dose • Diagnosis of classic or typical Rett Syndrome (RTT) • Documentation or attestation of mutation of the MECP2 gene • Documentation of patient weight • Documentation or provider attestation of all the following: o RTT Clinical Severity Scale rating of 10–36 o Clinical Global Impression–Severity (CGI-S) score of ≥4 o Baseline Rett Syndrome Behavior Questionnaire (RSBQ) score **Re-Authorization:** • Documentation or provider attestation of positive clinical response (i.e., decrease from baseline in RSBQ score, decrease in Clinical Global Impression–Improvement (CGI-I, etc.) • Medication is prescribed at an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Diabetic Testing Supplies**
Products	**Preferred Glucose Monitors:** Accu-Chek Aviva Plus Accu-Chek Guide Accu-Chek Guide Me Accu-Chek Nano Smartview Contour Contour Next Contour Next EZ Contour Next ONE **Preferred Test Strips:** Accu-Chek Aviva Plus Accu-Chek Compact Plus Accu-Chek Guide Accu-Chek Smartview Contour Contour Next *Preferred products pay at POS within quantity limits without prior authorization*
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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 criteria are met, requests will be approved for 12 months. A maximum of 102 test strips per month will be approved (depending on package size). A maximum of one meter per year will be approved.

Other Criteria Revision/Review Date: 6/2023	Criteria for approval of **Non-Preferred** products: • Member is legally blind or has reduced visual acuity so that they are unable to see the numbers on ALL of the preferred products and the requested product has a feature that enables the member to use the meter that is not available on any of the preferred meters. The member (not a caregiver) must be the one using the monitor/strips OR • Member is currently using an insulin pump that needs specific meter compatibility to accurately dose insulin OR • Preferred meter is not compatible with insulin pump member is using OR • Member is unable to change to a preferred meter and strip combination due to a cognitive or developmental disability OR • Changing to a preferred meter and strip combination would create undue hardship for the member Criteria for approval over the **Quantity Limit for Test Strips**: • The member has been stabilized on the current regimen. Stabilization on the current regimen is defined as having the prescription filled at least two times in the past 90 days AND the plan has paid for the previous two fills in excess of the quantity limit. OR • The member has a diagnosis of type 1 diabetes AND approved quantity will not exceed 306 strips per 30 days OR • The member has a diagnosis of type 2 diabetes AND • The member needs to test more than 3 times per day due to one of the following: o The member has not been prescribed test strips previously OR o The member's diabetes medication regimen (including insulin) is undergoing changes AND • Approved quantity will not exceed 204 strips per 30 days *Quantity limit overrides are not available for glucose monitors, continuous glucose monitors, transmitters or sensors* **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Diacomit (stiripentol)**
Drugs	**Diacomit** (stiripentol): Non-preferred
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	Member must be 6 months of age or older
Prescriber Restrictions	Prescriber must be neurologist or specialist in treatment of seizure disorder
Coverage Duration	Initial authorization: 6 months Reauthorization: 12 months
Other Criteria Revision/Review Date: 6/2023	<u>Criteria for Initial Authorization:</u> • Diagnosis of Dravet syndrome • Documentation of member's weight (must be ≥ 7kg) • Trial and failure with <u>concurrent</u> use of both clobazam and valproate within the member's lifetime, or documented contraindication to these medications • Member is currently taking a stable dose of clobazam • Dose is within FDA-approved limits <u>Criteria for Reauthorization:</u> • Documentation has been provided that demonstrates reduction or stabilization of seizure frequency • Member is currently taking a stable dose of clobazam • Documentation of patient's weight • 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	**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), or the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Per FDA labeling
Prescriber Restrictions	Prescriber must be a specialist in infectious disease, or working in consultation with a specialist in infectious disease
Coverage Duration	For First Occurrence of CDI: If all of the criteria are met, the request may be approved for up to 10 days 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: 9/2023	**For Adult Patients:** • 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 with oral vancomycin is required • Dose requested follows FDA labeling **For Pediatric Patients:** • Diagnosis of *Clostridium* (or *Clostridioides*) *difficile* infection (CDI) • Documentation of current body weight • If this is the first occurrence or the FIRST OR SECOND recurrent episode of CDI, documentation of treatment failure, contraindication, or intolerance with oral vancomycin is required • Dose requested follows FDA labeling If all the criteria are not met, the request will be referred to a Medical Director or clinical reviewer for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	Durysta (bimatoprost) intracameral implant
Drugs	Durysta (bimatoprost) intracameral implant
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Any of the following conditions: • Active or suspected ocular or periocular infection • Corneal endothelial cell dystrophy (e.g., Fuchs' Dystrophy) • Prior corneal transplantation, or endothelial cell transplants [e.g., Descemet's Stripping Automated Endothelial Keratoplasty (DSAEK)] • Patients whose posterior lens capsule is absent or ruptured
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be ≥ 18 years of age
Prescriber Restrictions	Must be prescribed by, or in consultation with, an ophthalmologist
Coverage Duration	If all of the criteria are met, the request will be approved for one implant per affected eye. Requests for repeat administration into an eye which has previously received a Durysta implant will not be approved.
Other Criteria Date: 12/2023	**Initial Authorization:** • Durysta is prescribed for a diagnosis of open angle glaucoma or ocular hypertension • Documentation has been provided that the member has tried and failed or has a medical reason why (e.g. intolerance, contraindication) they cannot use a topical eye drop for treatment (ex. prostaglandin analogs, beta-blockers, alpha agonists, etc.) **Re-Authorization:** • Requests for repeat administration into an eye which has previously received a Durysta implant will not be approved. **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	Elevidys (delandistrogene moxeparvovec)
Drugs	Elevidys (delandistrogene moxeparvovec)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Any deletion in exon 8 and/or exon 9 in the Duchenne muscular dystrophy (DMD) gene • Concurrent use with an exon skipping drugs, such as Exondys 51, Amondys 45, Vyondys 53, Viltepso
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by neurologist or provider who specializes in the treatment of DMD
Coverage Duration	If all the criteria are met, the initial request will be approved for a **one-time treatment.**
Other Criteria Review/Revision Date: 12/2023	**<u>Initial Authorization:</u>** • Medication is prescribed at an FDA approved dose • Documentation of weight • Diagnosis of DMD with a confirmed mutation in the *DMD* gene • Attestation patient is ambulatory • Member has been on a stable dose of corticosteroids for at least 3 months • Baseline micro-dystrophin protein level **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, 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), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	16 years and older
Prescriber Restrictions	Prescriber must be a urologist, obstetrician/gynecologist, or other specialist in the treatment of genitourinary disorders
Coverage Duration	If the conditions are met, the request will be approved for up to 6 months. For continuation of therapy, the request will be approved for up to 12 months.
Other Criteria	<u>Initial Authorization</u> Documentation of all of the following is required: • Diagnosis of bladder pain or discomfort associated with interstitial cystitis • The member has tried and failed all of the following: o Self-care practices and behavior modification (e.g., fluid management, bladder training, avoidance of activities/food/ beverages that exacerbate symptoms) o Amitriptyline (or a documented medical reason why amitriptyline is not appropriate for the member, e.g., age over 65) • Documentation of baseline Genitourinary Pain Index (GUPI) and urinary frequency or urgency • Requested dose is within FDA approved guidelines <u>Reauthorization</u> • 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
Revision/Review Date: 12/2023	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Prior Authorization Group Description	**Emflaza**
Drugs	Emflaza (deflazacort)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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 age is appropriate per labeling
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or specialist in Duchenne Muscular Dystropy (DMD)
Coverage Duration	If all of the conditions are met, the approval will be for 6 months.
Other Criteria Revision/Review Date: 6/2023	**Initial Authorization:** • Confirmed diagnosis of Duchenne Muscular Dystrophy (documented mutation of dystrophin gene, genetic sequencing indicating mutations attributed to Duchenne Muscular Dystrophy, OR muscle biopsy indicating absence of dystrophin protein), and copies of testing were submitted with request • Patient has onset of weakness before 5 years of age, and serum creatine kinase activity of at least 10 times the upper limit of normal (ULN) at some stage in their illness • Provider attests patient has had a baseline eye examination • Provider attests patient has had a baseline bone mineral density (BMD) screening completed • Patient is or will be taking adequate calcium and vitamin D supplementation if dietary intake is less than recommended for age according to Institute of Medicine Guidelines • Patient has trial and failure with prednisone or prednisolone for at least 12 months • Documented medical reason why prednisone or prednisolone are not able to be continued, why Emflaza is medically necessary, and why Emflaza is not expected to have the same side effect profile as the preferred agents • The request is for an FDA approved dose **Reauthorization:** • Physician attests that the patient's muscle strength has stabilized or improved since starting treatment • Patient's claim history shows consistent therapy (monthly fills) • Physician attests patient has had repeat eye and BMD screenings as appropriate • The request is for an FDA approved dose **Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Prior Authorization Group Description	**Empaveli (pegcetacoplan)**
Drugs	Empaveli (pegcetacoplan)
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 Infortion	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a hematologist or other appropriate specialist
Coverage Duration	Initial Request: 3 months Reauthorization: 6 months
Other Criteria Revision/Review Date: 9/2023	**<u>Initial Authorization:</u>** • Documentation of diagnosis paroxysmal nocturnal hemoglobinuria (PNH) by high sensitivity flow cytometry • The request is for a dose that is appropriate according to labeling or nationally recognized compendia in accordance with the patient's diagnosis, age and concomitant medical conditions • Documentation of vaccination against meningococcal disease or a documented medical reason why the patient cannot receive vaccination or vaccination needs to be delayed o Antimicrobial prophylaxis with oral antibiotics (penicillin, or macrolides if penicillin-allergic) for two weeks if the meningococcal vaccine is administered < 2 weeks before starting therapy or a documented medical reason why the patient cannot receive oral antibiotic prophylaxis **<u>Re-Authorization:</u>** • Provider has submitted documentation of clinical response to therapy (e.g. increased Hgb, reduced need for blood transfusions, improved score on disease severity scale) • The request is for an appropriate dose per compendia **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Endari**
Drugs	Endari (L-Glutamine)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a hematologist, or is working in consultation with a hematologist.
Coverage Duration	If all of the conditions are met, requests will be approved for a 12 months. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria Revision/Review Date 12/2023	Initial approval: • Member has diagnosis of sickle cell disease • Documentation was provided that the patient had 2 or more crises in the last 12 months • Documentation was provided the member has been on hydroxyurea at the maximum tolerated dose and was compliant within the last 6 months (or a medical reason was provided why patient is unable to use hydroxyurea) • Request is for an FDA approved dose Reauthorization: • Prescriber attests member had reduction in number of sickle cell crises • Request is for an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Prior Authorization Group Description	**Epidiolex (cannabidiol)**
Drugs	Epidiolex (cannabidiol)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	Member must be ≥ 1 year old
Prescriber Restrictions	Prescriber must be neurologist or specialist in treatment of seizure disorder.
Coverage Duration	If the criteria are met, the request will be approved for 6 months.
Other Criteria Revision/Review Date: 12/2023	Criteria for Initial Approval: • Diagnosis of Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex • Member has had a trial and failure of two antiepileptic drugs • Member is currently taking a stable dose of at least one other antiepileptic medication • Member's weight has been provided with the request • Dose is within FDA approved limits Reauthorization: • Documentation has been provided that demonstrates reduction or stabilization of seizure frequency • Member's weight has been provided with the request • 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	**Erythropoiesis-Stimulating Agents (ESAs)**
Drugs	Preferred: Epogen (epoetin alfa) Retacrit (epoetin alfa-epbx) Aranesp (darbepoetin alfa-polysorbate 80) Mircera (methoxy peg-epoetin beta) –available under medical benefit only for requests for anemia of CKD Non-preferred: Procrit (epoetin alfa)
Covered Uses	Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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 criteria are met, the request will be approved as follows: • For 1 month if the member is deficient in iron, vitamin B12, or folate and in the peri-surgical setting • Up to 3 months for all other requests • If the provider states that the requested medication is for a chronic or long-term condition, reauthorization will be approved for 12 months
Other Criteria	**Existing ESA users who are NEW to the plan:** • 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 • Documentation of current dose • The member's hemoglobin (Hgb) is within the following indication-specific range: o Anemia of CKD: Hgb < 11 g/dl o Anemia related to cancer: Hgb ≤ 12 g/dl o Zidovudine-related anemia in members with HIV: Hgb ≤ 12 g/dl o Ribavirin-induced anemia: Hgb ≤ 12 g/dl **Requests for Initial Therapy:** • Drug is being prescribed for an FDA-approved indication at an FDA approved dose or is otherwise supported by compendia or standard of care guidelines. • All required labs must have been drawn within 30 days of the request • The following lab values have been submitted: o hemoglobin (Hgb) o hematocrit (HCT) • The following lab results must be submitted and demonstrate normal values, otherwise, the member MUST be receiving, or is beginning, therapy to correct the deficiency: o Serum ferritin ≥ 100 ng/mL o Transferrin saturation (TSAT ≥ 20% o Vitamin B12 level > 223 pg/mL o Folate level > 3.1 ng/mL • If a non-preferred drug is being requested, the member has had a trial of at least two preferred chemically unique drugs within the same drug class, or a trial of at least one preferred drug within the same drug class if there are not two

	chemically unique preferred drugs within the same drug class; or documentation was provided as to why the member cannot use preferred drugs r **Additional Requirements:** For anemia of chronic kidney disease: • Hgb < 10 g/dL For ribavirin-induced anemia: • Member is currently receiving ribavirin and there was a documented attempt at ribavirin dose reduction • Hgb < 12 g/dL For zidovudine-related anemia in members with HIV: • The member must currently receiving highly active antiretroviral therapy (HAART) • Erythropoietin level ≤ 500 mU/mL • Member is receiving a dose of zidovudine ≤ 4,200 mg/week
Revision/Review Date: 12/2023	For anemia related to cancer: • One of the following is true: o Member is receiving myelosuppressive therapy for palliative treatment for at least two months (members receiving myelosuppressive therapy with curative intent should not receive ESAs) AND has documented symptomatic anemia with Hgb <10 g/dL; or o Member has symptomatic anemia related to myelodysplastic syndrome AND documented serum erythropoietin level ≤ 500 mU/ml For members undergoing surgery to reduce the need for allogenic blood transfusion: • Perioperative Hgb must be less than ≤13 g/dL and > 10 g/dL • The member is scheduled for an elective, non-cardiac, nonvascular surgery **Reauthorization:** • All submitted lab results have been drawn within 30 days of the reauthorization request • 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 ≥ 100 ng/mL o transferrin saturation (TSAT) ≥ 20% o vitamin B12 level > 223 pg/mL o folate level > 3.1 ng/mL • The member's hemoglobin is within the following indication-specific range: o For anemia of CKD: Hgb ≤ 11 g/dL o For anemia related to cancer: Hgb ≤ 12 g/dL o For zidovudine-related anemia in members with HIV: Hgb ≤ 12 g/dL o For ribavirin-induced anemia: Hgb ≤ 12 g/dL • An increase in dose has not occurred more than once every 4 weeks **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 drug/product approved by EUA for COVID-19
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Emergency Use Authorization for the drug/product in question, and the Drug Package Insert (PPI).
Exclusion Criteria	See "Other Criteria"
Required Medical Information	See "Other Criteria"
Age Restrictions	As outlined within current FDA Emergency Use Authorization (EUA) guidelines
Prescriber Restrictions	N/A
Coverage Duration	As outlined within current FDA Emergency Use Authorization (EUA) guidelines
Other Criteria Revision/Review Date: 3/2023	Emergency Use Authorization for COVID-19 related drugs/products (all must apply): • The requested drug/product has a currently active Emergency Use Authorization as issued by the U.S. Food and Drug Administration. • Use of the requested drug/product is consistent with the current terms and conditions of the emergency use authorization (such as appropriate age/weight, formulation, disease severity, concurrent use with other medications or medical interventions, etc.). • Attestation that the provider is not requesting reimbursement for ingredient cost of drug when drug is provided by U.S. government at no change **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	Fabrazyme (agalsidase beta) Elfabrio (peguniigalsidase alfa)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	According to the FDA approved prescribing information
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, cardiologist, nephrologist or specialist experienced in the treatment of Fabry disease
Coverage Duration	Initial Authorization: If the criteria are met, the request will be approved for a 6-month duration. Reauthorization: If the criteria are met, the request will be approved for a 12-month duration.
Other Criteria Revision/Review Date: 9/2023	**<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 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 **Physician/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	Fecal Microbiota
Drugs	Rebyota (fecal microbiota, live-jslm) Vowst (fecal micromiota spores, live-brpk)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Treatment of Clostridioides difficile infection (CDI)
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If all the criteria are met, the request will be approved for 1 treatment course
Other Criteria Date: 09/2023	• 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 to72 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* **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Prior Authorization Group Description	**Fintepla (fenfluramine)**
Drugs	Fintepla (fenfluramine)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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 ≥ 2 years of age
Prescriber Restrictions	Prescriber must be neurologist or specialist in treatment of seizure disorder
Coverage Duration	If the criteria are met, the request will be approved for a 6 month duration
Other Criteria	**Initial Authorization** • Diagnosis of Lennox-Gastaut or Dravet syndrome • Documented trial and failure or intolerance of at least two antiepileptic drugs • Member is currently taking a stable dose of at least one other antiepileptic medication • Member's weight • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines **Reauthorization** • Documentation has been provided that demonstrates reduction or stabilization of seizure frequency • Member's weight • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines
Revision/Review Date 9/2023	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Galafold**
Drugs	Galafold (migalastat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	Members should be greater than or equal to 18 years of age
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, cardiologist, nephrologist or specialist experienced in the treatment of Fabry disease
Coverage Duration	Initial Authorization: If the criteria are met, the request will be approved for a 6-month duration. Reauthorization: If the criteria are met, the request will be approved for a 12-month duration.
Other Criteria Revision/Review Date: 9/2023	**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.**

Field Name	Field Description
Prior Authorization Group Description	**Gene Therapy for Hemophilia**
Drugs	Hemgenix (etranacogene dezaparvovec)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Patient has previously received this medication
Required Medical Information	See "Other Criteria"
Age Restrictions	Patient must be 18 years of age or older
Prescriber Restrictions	Prescriber must be a hematologist
Coverage Duration	If all the criteria are met, the initial request will be approved for a one-time treatment.

Other Criteria
 	
Revision/Review Date: 12/2023
	<u>Initial Authorization:</u>
	• Diagnosis of Hemophilia B (congenital Factor IX deficiency) with ONE of the following:
	  o Currently using Factor IX prophylaxis therapy
	  o Has current or historical life-threatening hemorrhage
	  o Has repeated, serious spontaneous bleeding episodes
	• Documentation that patient has ≤2% of normal circulating Factor IX
	• Prescriber attests they have performed liver function assessments
	• Documented Factor IX inhibitor titer test showing the patient is negative for Factor IX inhibitors
	• Patient's weight
	• Medication is prescribed at an FDA approved dose
	
	The safety and effectiveness of repeat administration of Hemgenix 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.

Field Name	Field Description
Prior Authorization Group Description	**Generalized Pustular Psoriasis (GPP) Agents**
Drugs	Spevigo (spesolimab-abzo)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	≥ 18 years
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist or geneticist
Coverage Duration	If all of the criteria are met, the request will be approved for up to 2 doses.

Other Criteria
 	
Revision/Review Date: 03/2023
	• Diagnosis of generalized pustular psoriasis (GPP)
	• Member is experiencing an acute flare of GPP of moderate to severe intensity as defined by the patient having all of the following:
	  ○ Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of 3 or greater
	  ○ Presence of fresh pustules (new appearance or worsening of pustules)
	  ○ GPPPGA pustulation sub score of 2 or greater
	  ○ At least 5% of body surface area covered with erythema and the presence of pustules
	• If member has previously received Spevigo treatment for a prior GPP flare, member must have achieved a clinical response, defined as achieving a GPPPGA score of 0 or 1, to previous treatment but is now experiencing a new flare
	• Medication is prescribed at an FDA approved dose
	
	If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Prior Authorization Group Description	Gene Therapy for Regular Red Blood Cell (RBC) Transfusion Dependent Beta-Thalassemia
Drugs	Zynteglo (betibeglogene autotemcel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a hematologist
Coverage Duration	If all the criteria are met, the initial request will be approved for a one-time treatment. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.

Other Criteria
 	
Revision/Review: Date: 12/2023
	<u>Initial Authorization:</u>
	
	• Medication is prescribed at an FDA approved dose
	• Member has a diagnosis of transfusion dependent beta-thalassemia
	• Member requires regular RBC transfusions defined as ONE of the following:
	  o History of ≥100 mL/kg/year of packed red blood cell (pRBCs) in the past 2 years
	  o History of ≥8 transfusions of pRBCs per year in the past 2 years
	• Prescriber attests that the member does not have accessibility to a family matched hematopoietic stem-cell transplantation (HSCT)
	• Negative pregnancy test (if applicable)
	
	The safety and effectiveness of repeat administration of Zynteglo have not been evaluated and will not be approved.

Field Name	Field Description
Prior Authorization Group Description	**Givlaari**
Drugs	Givlaari (givosiran)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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	N/A
Coverage Duration	If all criteria are met, the initial request will be approved for up to 6 months and reauthorization will be approved for up to 12 months.
Other Criteria Date: 12/2023	**Initial Authorization:** • Documented diagnosis of acute hepatic porphyria (AHP) • Documentation of one of the following: o Elevation of urinary or plasma porphobilinogen (PBG) ≥ 4 times the upper limit of normal (ULN) o Elevation of aminolevulinic acid (ALA) values ≥ 4 times the ULN o Mutation in an affected gene as identified on molecular genetic testing • Documentation of active disease, with at least 2 porphyria attacks OR 1 severe attack with central nervous system involvement within the last 6 months, resulting in hospitalization, urgent health care or intravenous administration of hemin • Member has not had a liver transplant • Documentation of the member's current weight • Medication is prescribed at an FDA approved dose **Reauthorization:** • Documentation of positive clinical response as represented by one of the following: o Reduction in hemin administration o Reduction in number of porphyria attacks (acute episode of neurovisceral pain in the abdomen, back, chest, extremities and/or limbs) • Member has not had a liver transplant • Documentation of the member's current weight • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Prior Authorization Group Description	**Gonadotropin Releasing Hormone (GNRH) Agonists** **If diagnosis is cancer, use oncology drugs/therapies criteria**
Drug(s)	**Preferred GnRH Agonists for their respective indications:** Zoladex (goserelin acetate) Lupron Depot (leuprolide acetate) Lupron Depot-Ped (leuprolide acetate) **Non-Preferred GnRH Agonists** Fensolvi (leuprolide acetate) Supprelin LA (histrelin acetate) Synarel (nafarelin) Trelstar (triptorelin pamoate) Triptodur (triptorelin pamoate) And any newly marketed GnRH agonist
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per the National Comprehensive Cancer Network (NCCN), the American Society of Clinical Oncology (ASCO), the American College of Obstetricians and Gynecologists (ACOG), or the American Academy of Pediatrics (AAP) standard of care guidelines.
Exclusion Criteria	None
Required Medical Information	See Other Criteria
Age Restrictions	See Other Criteria
Prescriber Restrictions	Gynecologist, Endocrinologist, or any Specialist in the field that treats the member's condition
Coverage Duration	If all of the conditions are met, the request will be approved for 12 months, except for the following medical conditions: • Endometriosis: 6 months • Uterine leiomyomas (fibroids): 3 months • Endometrial thinning to prepare for endometrial ablation: 3 months
Other Criteria	**<u>INITIAL AUTHORIZATION for ALL REQUESTS:</u>** • The medication is prescribed for an FDA approved or standard of care guideline indication and within FDA approved or standard of care dosing guidelines. **AND the member meets the following for the respective diagnosis:** <u>Central precocious puberty (CPP)</u> • Onset of secondary sexual characteristics less than age 8 in females and age 9 in males • Diagnosis is confirmed by a pubertal response to a GnRH stimulation test and/or measurement of gonadotropins (FSH/LH), and bone age advanced beyond chronological age. o Patients with low or intermediate basal levels of LH should have a GnRH stimulation test to clarify the diagnosis ▪ *If basal levels of LH are markedly elevated [e.g. more than 0.3mlU/ml (where IU- International units)] in a child with*

	precocious puberty, then a diagnosis of CPP can be made without proceeding to a GnRH stimulation test. • Brain magnetic resonance imaging (MRI) has been performed for all boys with CPP and for girls with onset of secondary sexual characteristics before the age of six years of age to rule out a tumor. • If the request is for any agent other than Lupron Depot-Ped the member has a documented trial and failure with Lupron Depot-Ped or medical reason (e.g. contraindication, hypersensitivity, intolerance) as to why the member is not able to use Lupron-Depot Ped <u>Endometriosis</u> • Confirmed diagnosis of endometriosis and all of the following: o Documented trial and failure or medical reason for not using an analgesic pain reliever (e.g., NSAIDs, COX-2 inhibitors) taken in combination with combined estrogen progestin oral contraceptive pills (OCPs) ▪ <u>If one of the following drugs has been tried previously, a trial of OCPs is not required: progestins, Orilissa (elagolix), danazol, or an aromatase inhibitor (e.g. anastrozole, letrozole)</u> o If the request is for any agent other than Lupron Depot or Zoladex, the member has had a documented trial and failure with Lupron Depot or Zoladex or a documented medical reason (e.g., intolerance, hypersensitivity, contraindication) was submitted why the member is not able to use Lupron Depot or Zoladex o If the request is not for a leuprolide agent, member must be 18 years of age or older o Member will receive one of the following in conjunction with GNRH agonist therapy: ▪ norethindrone acetate 5 mg daily ▪ conjugated estrogen therapy ▪ oral bisphosphonate AND calcium and vitamin D supplementation <u>Uterine leiomyomas (Fibroids)</u> • Documented diagnosis of uterine fibroids and the following apply: o The member requires the medication to decrease uterine volume as a result of uterine fibroids for symptom management (e.g. pelvic pressure, urinary frequency or urgency, cramping, constipation, etc.) and for shrinkage of size to allow for surgical intervention o If the request is for any agent other than Lupron Depot, the member has had a documented trial and failure with Lupron Depot or a documented medical reason (e.g., intolerance, hypersensitivity, contraindication) was submitted why the member is not able to use Lupron Depot <u>Endometrial thinning</u> • Documentation was submitted indicating the member is scheduled for endometrial ablation for dysfunctional uterine bleeding • If the request is for any agent other than Zoladex, the member has a

	documented trial and failure with Zoladex or a documented medical reason (e.g., intolerance, hypersensitivity, contraindication) was submitted why the member is not able to use Zoladex **REAUTHORIZATION criteria for all requests:** • The medication is being prescribed for an FDA approved or standard of care guideline indication and within FDA approved or standard of care dosing guidelines. • Documentation was provided supporting continued treatment (e.g. patient still has symptoms), and medication is being continued as recommended in package insert or standard of care guidelines. **AND meets the following per diagnosis:** Central precocious puberty (CPP) • If the medication reauthorization is for central precocious puberty, the child is male and < 12 years or female and < 11 years of age OR a documented medical reason to continue treatment was provided with request, and includes current height and bone age Endometriosis • Prescriber has evaluated member for osteoporosis (e.g. Dexa scan) • Member will receive one of the following in conjunction with GNRH agonist therapy: o norethindrone acetate 5 mg daily o conjugated estrogen therapy o oral bisphosphonate AND calcium and vitamin D supplementation • The member has not received cumulative doses of the GnRH agonist greater than 12 months of therapy. Fibroids • The member has not received cumulative doses of the GnRH agonist greater than 6 months of therapy **NOTE: Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**
Revision/Review Date: 9/2023	

Prior Authorization Group	**Growth Hormone (GH) for Growth Failure or GH Deficiency**
Drug(s)	**Preferred:** Norditropin FlexPro, Nutropin AQ NuSpin **Non-preferred:** Humatrope**,** Genotropin/Genotropin MiniQuick, Omnitrope, Saizen/Saizen Click Easy, Zomacton and any newly marketed growth hormone agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Treatment of idiopathic short stature (ISS) is not a covered benefit and will not be approved
Required Medical Information	See other criteria
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, an endocrinologist or specialist in the stated diagnosis
Coverage Duration	If all of the conditions are met, the initial request will be approved for 12 months.
Other Criteria	**Initial Authorization** • If a non-preferred drug is being requested, the member has had a trial of at least two preferred chemically unique growth hormone drugs or documentation was provided as to why the member cannot use preferred growth hormone drugs • The requested dose is appropriate per compendia • If diagnosis is 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 **growth failure associated with chronic kidney disease (CKD)**, documentation has been provided for the following: o Pretreatment height is less than -1.88 standard deviations (SD) below the mean for age OR height velocity for age is less than 3rd percentile and has persisted for more than 3 months AND o Epiphyses are open • If diagnosis is **adult-onset growth hormone 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 gender*) in a patient with organic pituitary disease and multiple (>3) pituitary hormone deficiencies (MPHD) o Evidence of genetic defects affecting the hypothalamic pituitary adrenal (HPA) axis o Evidence of hypothalamic pituitary structural brain defects o Positive results of GH stimulatory test (e.g. insulin tolerance test (ITT), glucagon stimulation test, or macimorelin stimulation test) • If diagnosis is **childhood-onset GH deficiency (CO-GHD)**: o And patient is currently pediatric, documentation of all of the following is required: ▪ IGF-1 and insulin-like growth factor binding protein-3 (IGFBP-3) deficiency (level below reference range for age and gender)* with prescriber attestation of growth failure ▪ Provider attests that MRI has been completed to exclude possibility of

Revision/Review Date: 3/2023	a pituitary tumor ▪ Provider attests that member's epiphyses are open ○ And patient is currently adult, documentation of one of the following is required: ▪ 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 **Reauthorization** • Documentation of diagnosis (Note: idiopathic short stature is not a covered benefit) • Documented IGF-1 do not exceed upper limit of normal (ULN) (>2 SDs above reference range for age and gender)*, or if the IGF-1 levels do exceed ULN, the dose has been reduced • In CO-GHD patients, the prescriber indicates a positive growth response has occurred with growth hormone therapy *IGF-1 levels are highly age and gender specific. In the event the lab report provides a value and not the corresponding reference range, refer to published reference ranges for interpretation. (example: https://www.labcorp.com/tests/010363/insulin-like-growth-factor-1-igf-1) **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	**Non-preferred/non-formulary:** Ocrevus (ocrelizumab), Riabni (rituximab), Ruxience (rituximab), Truxima (rituximab), Rituxan (rituximab), Rituxan Hycela (rituximab/hyaluronidase), Lemtrada (alemtuzumab), Tysabri (natalizumab), Briumvi (ublituximab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Lemtrada: Clinically Isolated Syndrome (CIS), Primary Progressive MS (PPMS) Tysabri or Briumvi: Primary Progressive MS (PPMS)
Required Medical Information	See "Other Criteria"
Age Restrictions	Patients 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 • If a non-preferred drug is being requested, the member has had a trial of at least two preferred conventional multiple sclerosis drugs (Aubagio, Avonex, Betaseron, Copaxone 20 mg, Gilenya, Rebif); or documentation was provided as to why the member cannot use preferred drugs OR For patients with "highly active" MS requesting Lemtrada (alemtuzumab), Tysabri (natalizumab), or rituximab, a trial with one preferred agent will be acceptable. • If the request is for Ocrevus (ocrelizumab), Briumvi or rituximab, documentation of the following o Attestation that the patient 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 (rituximab), documented medical reason why the patient cannot use Ruxience (rituximab). • If the request is for Tysabri (natalizumab), documentation of the following: o Patient does not have a history of progressive multifocal leukoencephalopathy

Revision/Review Date: 6/2023	(PML) o Documentation consistent with pharmacy claims data indicating the patient is not currently using any antineoplastic, immunosuppressant, or immunomodulating medications Primary Progressive Multiple Sclerosis (PPMS) • 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) or rituximab, documentation of the following has been submitted o Attestation that the patient has been screened for and does not have active HBV o If the request is for a rituximab product other than Ruxience (rituximab), documented reason why the patient cannot use Ruxience (rituximab). **Reauthorization** CIS • 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. RRMS, SPMS, or PPMS • Documentation that the prescriber has evaluated the member and recommends continuation of therapy (clinical benefit) • The medication is being prescribed at a dose consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature o 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), documentation of the following has been submitted o Patient does not have a history of PML o Documentation consistent with pharmacy claims data was submitted indicating the patient is not currently using any antineoplastic, immunosuppressant, or immunomodulating medications **Continuation of Therapy Provision:** 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.**

/Prior Authorization Group Description	**Hemlibra**
Drugs	Hemlibra (emicizumab-kxwh)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a hematologist
Coverage Duration	If the criteria are met, requests will be approved for 6 months.
Other Criteria Revision/Review Date: 9/2023	**<u>Initial Authorization</u>:** Documentation submitted indicates the following: • The patient's weight • Dose is within FDA-indicated limits **AND one of the following:** • Request is for routine prophylaxis in a member with a diagnosis of hemophilia A **WITH** Factor VIII inhibitors • Request is for routine prophylaxis in a member with a diagnosis of hemophilia A ***withOUT*** Factor VIII inhibitors and o Patient requires management with Factor VIII products at a total weekly dose of > 100 U/kg **OR** o Patient has tried Factor VIII products and is not well managed due to limited venous access-OR o Patient required frequent episodic treatment or prophylaxis with a bypassing agent **<u>Re-Authorization:</u>** • Documentation submitted indicating the member has experienced a clinical benefit from the medication (e.g. reduction in bleeding episodes, improved quality of life) and has discontinued factor VIII inhibitor or BPA prophylaxis (where applicable) • The patient'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.

Drugs - **Epclusa, Harvoni, lepidasvir-sofosbuvir, Mavyret, Sovaldi, sofusbuvir-valpatasvir, Viekira Pak, Vosevi, Zepatier**

March 2023
Effective date for Fee-for-Service and all Managed Care Medical Assistance Plans: March 1, 2023

Therapeutic area - Hepatitis C Direct-Acting Antivirals

Criteria

- All drugs used to treat Hepatitis C infections require prior authorization.
- Hepatitis C drug authorization criteria will vary by patient's genotype.
- Preferred drugs require patients to meet preferred drug authorization criteria before payment.
- Nonpreferred drugs require patients to meet nonpreferred drug authorization criteria before payment.
- A tiered approach is used for genotypes where there are multiple nonpreferred treatment options.
- Certain requested regimen with no FDA-approved treatment duration will be evaluated on a case-by-case basis. All other requested regimens must meet treatment duration described in the FDA-approved label.
- Prior authorization requests for patients with mixed genotypes will be evaluated on a case-by-case basis.
- Providers should fax the completed Hepatitis C Drug Prior Authorization Form (DHS-7085) to the MHCP Prescription Drug Prior Authorization Agent.

Exclusion Criteria (applies to all drugs and genotypes)

- Clinically significant drug interactions with patient's existing medications that cannot be mitigated
- Pregnancy
- Severe end organ disease and not eligible for transplant (e.g. liver, heart, lung, kidney)
- Clinically-significant illness or any other major medical disorder that may interfere with patients' abilities to complete a course of treatment
- Patients who, in the professional judgment of the primary treating clinician, would not achieve a long term clinical benefit from HCV treatment (e.g. patients with multisystem organ failure; receiving palliative care or in hospice; significant pulmonary or cardiac disease; and malignancy outside of the liver not meeting oncologic criteria for cure)
- Decompensated liver disease with CPT > 12 or MELD > 20
- MELD ≤ 20 and one of the following:
    - Cardiopulmonary disease that cannot be corrected and is a prohibitive risk for surgery
    - Malignancy outside the liver not meeting oncologic criteria for cure
    - Hepatocellular carcinoma
    - Intrahepatic cholangiocarcinoma
    - Hemangiosarcoma
- Contraindication to requested drug or drug combination
- Requested duration of therapy is longer or shorter than therapy duration listed in FDA-approved label of requested drug
- Indeterminate HCV genotype

Continuity of Care (applies to all drugs and genotypes)

At the time of treatment initiation, patient must have evidence of Minnesota Health Care Programs (MHCP) insurance coverage for the duration of treatment.

Table 1: MHCP Preferred Drug List - Hepatitis C Direct-Acting Antivirals; all require prior authorization

Genotype 1 Treatment-Naïve Patients

Preferred	Nonpreferred
Mavyret	Zepatier Sofosbuvir-velpatasvir Epclusa Lepidasvir-sofosbuvir Harvoni tablet Harvoni pellet Sovaldi tablet Sovaldi pellet Viekira Pak

Genotype 1 Treatment-Experienced Patients

Preferred	Nonpreferred
Mavyret Vosevi	None

Genotype 2 Treatment-Naïve Patients

Preferred	Nonpreferred
Mavyret	Sofosbuvir-velpatasvir Epclusa Sovaldi tablet Sovaldi pellet

Genotype 2 Treatment-Experienced Patients

Preferred	Nonpreferred
Mavyret Vosevi	None

Genotype 3 Treatment-Naïve Patients

Preferred	Nonpreferred
Mavyret	Sofosbuvir-velpatasvir Epclusa Sovaldi tablet Sovaldi pellet

Genotype 3 Treatment-Experienced Patients

Preferred	Nonpreferred
Mavyret Vosevi	None

Genotype 4 Treatment-Naïve Patients

Preferred	Nonpreferred
Mavyret	Zepatier Sofosbuvir-velpatasvir Epclusa Lepidasvir-sofosbuvir Harvoni tablet Harvoni pellet Sovaldi tablet Sovaldi pellet

Genotype 4 Treatment-Experienced Patients

Preferred	Nonpreferred
Mavyret Vosevi	None

Genotype 5 or 6 Treatment-Naïve Patients

Preferred	Nonpreferred
Mavyret	Sofosbuvir-velpatasvir Epclusa Lepidasvir-sofosbuvir Harvoni tablet Harvoni pellet

Genotype 5 or 6 Treatment-Experienced Patients

Preferred	Nonpreferred
Mavyret Vosevi	None

Criteria for Genotype 1 – all drugs require prior authorization

Hepatitis C Genotype 1: Sofosbuvir-velpatasvir, Epclusa, Harvoni, lepidasvir-sofosbuvir, Mavyret, Sovaldi, Vosevi, Zepatier

Treatment-Naïve Patients

Preferred	Nonpreferred
Mavyret	Zepatier Sofosbuvir-velpatasvir Epclusa Lepidasvir-sofosbuvir Harvoni tablet Harvoni pellet Sovaldi tablet Sovaldi pellet Viekira Pak

Treatment-Experienced Patients

Preferred	Nonpreferred
Mavyret Vosevi	None

Preferred Drug Prior Authorization Criteria for Treatment-Naïve Patients, Genotype 1

Prescriber Requirements

Criteria 1: The regimen may be prescribed by a primary care provider, a gastroenterologist, hepatologist, or infectious disease specialist

OR

If the patient has any ONE of the following, the regimen must be prescribed by a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist:

- Patient is treatment-experienced OR
- Patient has Hepatitis B and/or HIV co-infection OR
- Patient has undergone liver transplantation OR
- Patient has liver cancer OR
- Patient has severe liver disease defined as:
    - APRI > 1.5 OR
    - FibroSURE > 0.49 OR
    - Fibroscan > 9.5 kPa OR
    - FIB-4 > 3.25 OR

- MR Elastography > 6 kPa OR
- Fibrospect > 42 OR
- Liver Biopsy > F3 AND

Criteria 2: If the patient has a substance use disorder or IV drug use, the patient must:

- Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request OR
- Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request AND
- Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:
  - Condom distribution (e.g. written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)
  - Access to sterile syringes (e.g. written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)
  - Naloxone training and distribution (e.g. written prescription for naloxone, copy of current naloxone training protocol etc.)
  - Medication-assisted treatment options (e.g. provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) OR
- Not be candidate for ANY of the harm reduction services above; and provider provides the reason the patient is not a candidate for each of the harm reduction services above

Criteria 3: The treating clinician must provide documentation to attest the patient is screened for evidence of current or prior hepatitis B virus (HBV) infection before starting treatment with direct-acting antivirals. The treating clinician must also have a monitoring plan in place for HBV flare-ups or reactivation during treatment and post-treatment follow up **AND**

- Where indicated, the treating clinician must provide documentation that the patient has been counseled on the HBV reactivation adverse events management plan AND the risk of HBV reactivation including serious liver injury and death **AND**

Criteria 4: Clinical documentation of patient's liver cirrhosis status (e.g. no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**

Criteria 5: Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request **AND**

Criteria 6: Provider attests to submit SVR12 results to the Department via fax at 651-431-7424 upon request **AND**

Criteria 7: Patient meets the age limit and has the diagnosis described in the FDA-approved label

Nonpreferred Drug Prior Authorization Criteria for Treatment-Naïve Patients, Genotype 1

- Patient is NOT a candidate for Mavyret **AND**
- Patient has met Criteria 1 through 7 of the Preferred Drug Criteria **AND**
- Patient's prescribed regimen must align with the dosage recommendation described in the FDA-approved label or in AASLD/IDSA HCV guidelines; **AND**

Patient has HCV infection with **at least ONE** of the four conditions listed below:

- Decompensated liver disease as defined by Child-Pugh-Turcotte classification score 7-12 and MELD is ≤20.
- Abdominal imaging where radiologist determines findings are suggestive of cirrhosis (e.g. nodules; enlarged liver, especially in the left lobe; tortuous hepatic arteries; ascites; portal hypertension)
- Evidence of one or more noninvasive tests indicating a fibrosis score of ≥ F3, such as:
  - APRI (AST to platelet ratio index) ≥ 1.5
  - FibroSURE ≥ 0.49
  - FibroScan ≥ 9.5
  - Fibrosis-4 index (FIB-4) > 3.25
  - MR Elastography ≥ 6 kPa
  - Fibrospect ≥ 42
- HCV infections with one of the following:

- Post solid organ transplant (e.g. heart; kidney; liver)
- Awaiting liver transplant
- Stage I-III hepatocellular carcinoma meeting Milan criteria
- HCV infection post liver transplant
- Severe complications of HCV as defined below:
  - Type 2 or Type 3 essential mixed cryoglobulinemia with end organ manifestations
  - HCV-induced renal disease (e.g. nephrotic syndrome or mebranoproliferative glomerulonephritis (MPGN)

Preferred Drug Prior Authorization Criteria for Treatment-Experienced Patients, Genotype 1

Prescriber Requirements

Criteria 1: If the patient has any ONE of the following, the regimen must be prescribed by a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist:

- Patient is treatment-experienced OR
- Patient has Hepatitis B and/or HIV co-infection OR
- Patient has undergone liver transplantation OR
- Patient has liver cancer OR
- Patient has severe liver disease defined as:
  - APRI > 1.5 OR
  - FibroSURE > 0.49 OR
  - Fibroscan > 9.5 kPa OR
  - FIB-4 > 3.25 OR
  - MR Elastography > 6 kPa OR
  - Fibrospect > 42 OR
  - Liver Biopsy > F3 **AND**

Criteria 2: If the patient has a substance use disorder or IV drug use, the patient must:

- Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request OR
- Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request AND
- Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:
  - Condom distribution (e.g. written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)
  - Access to sterile syringes (e.g. written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)
  - Naloxone training and distribution (e.g. written prescription for naloxone, copy of current naloxone training protocol etc.)
  - Medication-assisted treatment options (e.g. provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) OR
- Not be candidate for ANY of the harm reduction services above; and provider provides the reason the patient is not a candidate for each of the harm reduction services above

Criteria 3: The treating clinician must provide documentation to attest that the patient is screened for evidence of current or prior hepatitis B virus (HBV) infection before starting treatment with direct-acting antivirals AND the provider has a monitoring plan for HBV flare-ups or reactivation during treatment and post-treatment follow-up **AND**

- Where indicated, the treating clinician must provide documentation that the patient has been counseled on the HBV reactivation adverse events management plan AND the risk of HBV reactivation including serious liver injury and death **AND**

Criteria 4: Clinical documentation of patient's liver cirrhosis status (e.g. no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**

Criteria 5: Clinical documentation of patient's prior treatment including drug name and date(s) of therapy **AND**

Criteria 6: Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request **AND**

Criteria 7: Provider attests to submit SVR12 results to the Department via fax at 651-431-7424 upon request **AND**

Criteria 8: Patient meets the age limit and has the diagnosis described in the FDA-approved label

Criteria for Genotype 2 – all drugs require prior authorization

Hepatitis C Genotype 2: Sofosbuvir-velpatasvir, Epclusa, Mavyret, Sovaldi, Vosevi

Treatment-Naïve Patients

Preferred	Nonpreferred
Mavyret	Sofosbuvir-velpatasvir Epclusa Sovaldi tablet Sovaldi pellet

Treatment-Experienced Patients

Preferred	Nonpreferred
Mavyret Vosevi	None

Preferred Drug Prior Authorization Criteria for Treatment-Naïve Patients, Genotype 2

Prescriber Requirements

Criteria 1: The regimen may be prescribed by a primary care provider, a gastroenterologist, hepatologist, or infectious disease specialist

OR

If the patient has any ONE of the following, the regimen must be prescribed by a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist:

- Patient is treatment-experienced OR
- Patient has Hepatitis B and/or HIV co-infection OR
- Patient has undergone liver transplantation OR
- Patient has liver cancer OR
- Patient has severe liver disease defined as:
    - APRI > 1.5 OR
    - FibroSURE > 0.49 OR
    - Fibroscan > 9.5 kPa OR

- FIB-4 > 3.25 OR
- MR Elastography > 6 kPa OR
- Fibrospect > 42 OR
- Liver Biopsy > F3 **AND**

Criteria 2: If the patient has a substance use disorder or IV drug use, the patient must:

- Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request OR
- Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request AND
- Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:
  - Condom distribution (e.g. written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)
  - Access to sterile syringes (e.g. written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)
  - Naloxone training and distribution (e.g. written prescription for naloxone, copy of current naloxone training protocol etc.)
  - Medication-assisted treatment options (e.g. provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) OR
- Not be candidate for ANY of the harm reduction services above; and provider provides the reason the patient is not a candidate for each of the harm reduction services above

Criteria 3: The treating clinician must provide documentation to attest the patient is screened for evidence of current or prior hepatitis B virus (HBV) infection before starting treatment with direct-acting antivirals. The treating clinician must also have a monitoring plan in place for HBV flare-ups or reactivation during treatment and post-treatment follow up **AND**

- Where indicated, the treating clinician must provide documentation that the patient has been counseled on the HBV reactivation adverse events management plan AND the risk of HBV reactivation including serious liver injury and death **AND**

Criteria 4: Clinical documentation of patient's liver cirrhosis status (e.g. no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**

Criteria 5: Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request **AND**

Criteria 6: Provider attests to submit SVR12 results to the Department via fax at 651-431-7424 upon request **AND**

Criteria 7: Patient meets the age limit and has the diagnosis described in the FDA-approved label

Nonpreferred Drug Prior Authorization Criteria for Treatment-Naïve Patients, Genotype 2

- Patient is NOT a candidate for Mavyret **AND**
- Patient has met Criteria 1 through 7 of the Preferred Drug Criteria **AND**
- Patient's prescribed regimen must align with the dosage recommendation described in the FDA-approved label or in AASLD/IDSA HCV guidelines; **AND**

Patient has HCV infection with at least ONE of the four conditions listed below:

- Decompensated liver disease as defined by Child-Pugh-Turcotte classification score 7-12 and MELD is ≤20
- Abdominal imaging where radiologist determines findings are suggestive of cirrhosis (e.g. nodules; enlarged liver, especially in the left lobe; tortuous hepatic arteries; ascites; portal hypertension)
- Evidence of one or more noninvasive tests indicating a fibrosis score of ≥ F3, such as:
  - APRI (AST to platelet ratio index) ≥ 1.5
  - FibroSURE ≥ 0.49
  - FibroScan ≥ 9.5
  - Fibrosis-4 index (FIB-4) > 3.25
  - MR Elastography ≥ 6 kPa
  - Fibrospect ≥ 42

HCV infections with one of the following:

- Post solid organ transplant (e.g. heart; kidney; liver)
- Awaiting liver transplant
- Stage I-III hepatocellular carcinoma meeting Milan criteria
- HCV infection post liver transplant
- Severe complications of HCV as defined below:
  - Type 2 or Type 3 essential mixed cryoglobulinemia with end organ manifestations
  - HCV-induced renal disease (e.g. nephrotic syndrome or mebranoproliferative glomerulonephritis (MPGN)

Preferred Drug Prior Authorization Criteria for Treatment-Experienced Patients, Genotype 2

Prescriber Requirements

Criteria 1: If the patient has any ONE of the following, the regimen must be prescribed by a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist:

- Patient is treatment-experienced OR
- Patient has Hepatitis B and/or HIV co-infection OR
- Patient has undergone liver transplantation OR
- Patient has liver cancer OR
- Patient has severe liver disease defined as:
  - APRI > 1.5 OR
  - FibroSURE > 0.49 OR
  - Fibroscan > 9.5 kPa OR
  - FIB-4 > 3.25 OR
  - MR Elastography > 6 kPa OR
  - Fibrospect > 42 OR
  - Liver Biopsy > F3 **AND**

Criteria 2: If the patient has a substance use disorder or IV drug use, the patient must:

- Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request OR
- Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request AND
- Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:
  - Condom distribution (e.g. written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)
  - Access to sterile syringes (e.g. written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)
  - Naloxone training and distribution (e.g. written prescription for naloxone, copy of current naloxone training protocol etc.)
  - Medication-assisted treatment options (e.g. provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) OR
- Not be candidate for ANY of the harm reduction services above; and provider provides the reason the patient is not a candidate for each of the harm reduction services above

Criteria 3: The treating clinician must provide documentation to attest that the patient is screened for evidence of current or prior hepatitis B virus (HBV) infection before starting treatment with direct-acting antivirals **AND** the provider has a monitoring plan for HBV flare-ups or reactivation during treatment and post-treatment follow-up **AND**

- Where indicated, the treating clinician must provide documentation that the patient has been counseled on the HBV reactivation adverse events management plan AND the risk of HBV reactivation including serious liver injury and death **AND**

Criteria 4: Clinical documentation of patient's liver cirrhosis status (e.g. no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**

Criteria 5: Clinical documentation of patient's prior treatment including drug name and date(s) of therapy **AND**

Criteria 6: Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request **AND**

Criteria 7: Provider attests to submit SVR12 results to the Department via fax at 651-431-7424 upon request **AND**

Criteria 8: Patient meets the age limit and has the diagnosis described in the FDA-approved label

Criteria for Genotype 3 – all drugs require prior authorization

Hepatitis C Genotype 3: Epclusa, Mavyret, Sovaldi, Vosevi, sofosbuvir-velpatasvir

Treatment-Naïve Patients

Preferred	Nonpreferred
Mavyret	Sofosbuvir-velpatasvir Epclusa Sovaldi tablet Sovaldi pellet

Treatment-Experienced Patients

Preferred	Nonpreferred
Mavyret Vosevi	None

Preferred Drug Prior Authorization Criteria for Treatment-Naïve Patients, Genotype 3

Prescriber Requirements

Criteria 1: The regimen may be prescribed by a primary care provider, a gastroenterologist, hepatologist, or infectious disease specialist

OR

If the patient has any ONE of the following, the regimen must be prescribed by a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist:

- Patient is treatment-experienced OR
- Patient has Hepatitis B and/or HIV co-infection OR
- Patient has undergone liver transplantation OR
- Patient has liver cancer OR
- Patient has severe liver disease defined as:
    - APRI > 1.5 OR

- FibroSURE > 0.49 OR
- Fibroscan > 9.5 kPa OR
- FIB-4 > 3.25 OR
- MR Elastography > 6 kPa OR
- Fibrospect > 42 OR
- Liver Biopsy > F3 **AND**

Criteria 2: If the patient has a substance use disorder or IV drug use, the patient must:

- Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request OR
- Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request AND
- Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:
  - Condom distribution (e.g. written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)
  - Access to sterile syringes (e.g. written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)
  - Naloxone training and distribution (e.g. written prescription for naloxone, copy of current naloxone training protocol etc.)
  - Medication-assisted treatment options (e.g. provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) OR
- Not be candidate for ANY of the harm reduction services above; and provider provides the reason the patient is not a candidate for each of the harm reduction services above

Criteria 3: The treating clinician must provide documentation to attest the patient is screened for evidence of current or prior hepatitis B virus (HBV) infection before starting treatment with direct-acting antivirals. The treating clinician must also have a monitoring plan in place for HBV flare-ups or reactivation during treatment and post-treatment follow up **AND**

- Where indicated, the treating clinician must provide documentation that the patient has been counseled on the HBV reactivation adverse events management plan, including the risks of HBV reactivation, including serious liver injury and death **AND**

Criteria 4: Clinical documentation of patient's liver cirrhosis status (e.g. no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**

Criteria 5: Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request **AND**

Criteria 6: Provider attests to submit SVR12 results to the Department via fax at 651-431-7424 upon request **AND**

Criteria 7: Patient meets the age limit and has the diagnosis described in the FDA-approved label

Nonpreferred Drug Prior Authorization Criteria for Treatment-Naïve Patients, Genotype 3

- Patient is NOT a candidate for Mavyret **AND**
- Patient has met Criteria 1 through 7 of the Preferred Drug Criteria **AND**
- Patient's prescribed regimen must align with the dosage recommendation described in the FDA-approved label or in AASLD/IDSA HCV guidelines; **AND**

Patient has HCV infection with at least ONE of the four conditions listed below:

- Decompensated liver disease as defined by Child-Pugh-Turcotte classification score 7-12 and MELD is ≤20
- Abdominal imaging where radiologist determines findings are suggestive of cirrhosis (e.g. nodules; enlarged liver, especially in the left lobe; tortuous hepatic arteries; ascites; portal hypertension)
- Evidence of one or more noninvasive tests indicating a fibrosis score of ≥ F3, such as:
  - APRI (AST to platelet ratio index) ≥ 1.5
  - FibroSURE ≥ 0.49
  - FibroScan ≥ 9.5
  - Fibrosis-4 index (FIB-4) > 3.25

    - MR Elastography ≥ 6 kPa
    - Fibrospect ≥ 42
- HCV infections with one of the following:
    - Post solid organ transplant (e.g. heart; kidney; liver)
    - Awaiting liver transplant
    - Stage I-III hepatocellular carcinoma meeting Milan criteria
    - HCV infection post liver transplant
    - Severe complications of HCV as defined below:
        - Type 2 or Type 3 essential mixed cryoglobulinemia with end organ manifestations
        - HCV-induced renal disease (e.g. nephrotic syndrome or mebranoproliferative glomerulonephritis (MPGN)

Preferred Drug Prior Authorization Criteria for Treatment-Experienced Patients, Genotype 3

Prescriber Requirements

Criteria 1: If the patient has any ONE of the following, the regimen must be prescribed by a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist:

- Patient is treatment-experienced OR
- Patient has Hepatitis B and/or HIV co-infection OR
- Patient has undergone liver transplantation OR
- Patient has liver cancer OR
- Patient has severe liver disease defined as:
    - APRI > 1.5 OR
    - FibroSURE > 0.49 OR
    - Fibroscan > 9.5 kPa OR
    - FIB-4 > 3.25 OR
    - MR Elastography > 6 kPa OR
    - Fibrospect > 42 OR
    - Liver Biopsy > F3 **AND**

Criteria 2: If the patient has a substance use disorder or IV drug use, the patient must:

- Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request OR
- Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request AND
- Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:
    - Condom distribution (e.g. written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)
    - Access to sterile syringes (e.g. written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)
    - Naloxone training and distribution (e.g. written prescription for naloxone, copy of current naloxone training protocol etc.)
    - Medication-assisted treatment options (e.g. provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) OR
- Not be candidate for ANY of the harm reduction services above; and provider provides the reason the patient is not a candidate for each of the harm reduction services above

Criteria 3: The treating clinician must provide documentation to attest that the patient is screened for evidence of current or prior hepatitis B virus (HBV) infection before starting treatment with direct-acting antivirals **AND** the provider has a monitoring plan for HBV flare-ups or reactivation during treatment and post-treatment follow-up **AND**

- Where indicated, the treating clinician must provide documentation that the patient has been counseled on the HBV reactivation adverse events management plan AND the risk of HBV reactivation including serious liver injury and death **AND**

Criteria 4: Clinical documentation of patient's liver cirrhosis status (e.g. no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**

Criteria 5: Clinical documentation of patient's prior treatment including drug name and date(s) of therapy **AND**

Criteria 6: Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request **AND**

Criteria 7: Provider attests to submit SVR12 results to the Department via fax at 651-431-7424 upon request **AND**

Criteria 8: Patient meets the age limit and has the diagnosis described in the FDA-approved label

Criteria for Genotype 4 – all drugs require prior authorization

Hepatitis C Genotype 4: Sofosbuvir-velpatasvir, Epclusa, Harvoni, lepidasvir-sofosbuvir, Mavyret, Sovaldi, Vosevi, Zepatier

Treatment-Naïve Patients

Preferred	Nonpreferred
Mavyret	Zepatier Sofosbuvir-velpatasvir Epclusa Lepidasvir-sofosbuvir Harvoni tablet Harvoni pellet Sovaldi tablet Sovaldi pellet

Treatment-Experienced Patients

Preferred	Nonpreferred
Mavyret Vosevi	None

Preferred Drug Prior Authorization Criteria for Treatment-Naïve Patients, Genotype 4

Prescriber Requirements

Criteria 1: The regimen may be prescribed by a primary care provider, a gastroenterologist, hepatologist, or infectious disease specialist

OR

If the patient has any ONE of the following, the regimen must be prescribed by a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist:

- Patient is treatment-experienced OR
- Patient has Hepatitis B and/or HIV co-infection OR
- Patient has undergone liver transplantation OR
- Patient has liver cancer OR
- Patient has severe liver disease defined as:
    - APRI > 1.5 OR
    - FibroSURE > 0.49 OR
    - Fibroscan > 9.5 kPa OR
    - FIB-4 > 3.25 OR
    - MR Elastography > 6 kPa OR
    - Fibrospect > 42 OR
    - Liver Biopsy > F3 **AND**

Criteria 2: If the patient has a substance use disorder or IV drug use, the patient must:

- Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request OR
- Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request AND
- Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:
    - Condom distribution (e.g. written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)
    - Access to sterile syringes (e.g. written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)
    - Naloxone training and distribution (e.g. written prescription for naloxone, copy of current naloxone training protocol etc.)
    - Medication-assisted treatment options (e.g. provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) OR
- Not be candidate for ANY of the harm reduction services above; and provider provides the reason the patient is not a candidate for each of the harm reduction services above

Criteria 3: The treating clinician must provide documentation to attest the patient is screened for evidence of current or prior hepatitis B virus (HBV) infection before starting treatment with direct-acting antivirals. The treating clinician must also have a monitoring plan in place for HBV flare-ups or reactivation during treatment and post-treatment follow up **AND**

- Where indicated, the treating clinician must provide documentation that the patient has been counseled on the HBV reactivation adverse events management plan, including the risks of HBV reactivation, including serious liver injury and death **AND**

Criteria 4: Clinical documentation of patient's liver cirrhosis status (e.g. no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**

Criteria 5: Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request **AND**

Criteria 6: Provider attests to submit SVR12 results to the Department via fax at 651-431-7424 upon request **AND**

Criteria 7: Patient meets the age limit and has the diagnosis described in the FDA-approved label

Nonpreferred Drug Prior Authorization Criteria for Treatment-Naïve Patients, Genotype 4

- Patient is NOT a candidate for Mavyret **AND**
- Patient has met Criteria 1 through 7 of the Preferred Drug Criteria **AND**
- Patient's prescribed regimen must align with the dosage recommendation described in the FDA-approved label or in AASLD/IDSA HCV guidelines; **AND**

Patient has HCV infection with **at least ONE** of the four conditions listed below:

- Decompensated liver disease as defined by Child-Pugh-Turcotte classification score 7-12 and MELD is ≤20.

- Abdominal imaging where radiologist determines findings are suggestive of cirrhosis (e.g. nodules; enlarged liver, especially in the left lobe; tortuous hepatic arteries; ascites; portal hypertension)
- Evidence of one or more noninvasive tests indicating a fibrosis score of ≥ F3, such as:
    - APRI (AST to platelet ratio index) ≥ 1.5
    - FibroSURE ≥ 0.49
    - FibroScan ≥ 9.5
    - Fibrosis-4 index (FIB-4) > 3.25
    - MR Elastography ≥ 6 kPa
    - Fibrospect ≥ 42
- HCV infections with one of the following:
    - Post solid organ transplant (e.g. heart; kidney; liver)
    - Awaiting liver transplant
    - Stage I-III hepatocellular carcinoma meeting Milan criteria
    - HCV infection post liver transplant
    - Severe complications of HCV as defined below:
        - Type 2 or Type 3 essential mixed cryoglobulinemia with end organ manifestations
        - HCV-induced renal disease (e.g. nephrotic syndrome or mebranoproliferative glomerulonephritis (MPGN)

Preferred Drug Prior Authorization Criteria for Treatment-Experienced Patients, Genotype 4

Prescriber Requirements

Criteria 1: If the patient has any ONE of the following, the regimen must be prescribed by a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist:

- Patient is treatment-experienced OR
- Patient has Hepatitis B and/or HIV co-infection OR
- Patient has undergone liver transplantation OR
- Patient has liver cancer OR
- Patient has severe liver disease defined as:
    - APRI > 1.5 OR
    - FibroSURE > 0.49 OR
    - Fibroscan > 9.5 kPa OR
    - FIB-4 > 3.25 OR
    - MR Elastography > 6 kPa OR
    - Fibrospect > 42 OR
    - Liver Biopsy > F3 **AND**

Criteria 2: If the patient has a substance use disorder or IV drug use, the patient must:

- Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request OR
- Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request AND
- Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:
    - Condom distribution (e.g. written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)
    - Access to sterile syringes (e.g. written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)
    - Naloxone training and distribution (e.g. written prescription for naloxone, copy of current naloxone training protocol etc.)
    - Medication-assisted treatment options (e.g. provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) OR
- Not be candidate for ANY of the harm reduction services above; and provider provides the reason the patient is not a candidate for each of the harm reduction services above

Criteria 3: The treating clinician must provide documentation to attest that the patient is screened for evidence of current or prior hepatitis B virus (HBV) infection before starting treatment with direct-acting antivirals AND the provider has a monitoring plan for HBV flare-ups or reactivation during treatment and post-treatment follow-up **AND**

- Where indicated, the treating clinician must provide documentation that the patient has been counseled on the HBV reactivation adverse events management plan AND the risk of HBV reactivation including serious liver injury and death **AND**

Criteria 4: Clinical documentation of patient's liver cirrhosis status (e.g. no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**

Criteria 5: Clinical documentation of patient's prior treatment including drug name and date(s) of therapy **AND**

Criteria 6: Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request **AND**

Criteria 7: Provider attests to submit SVR12 results to the Department via fax at 651-431-7424 upon request **AND**

Criteria 8: Patient meets the age limit and has the diagnosis described in the FDA-approved label

Criteria for Genotype 5 or 6 – all drugs require prior authorization

Hepatitis C Genotype 5 or 6: Sofosbuvir-velpatasvir, Epclusa, Mavyret, Harvoni, lepidasvir-sofosbuvir, Vosevi

Treatment-Naïve Patients

Preferred	Nonpreferred
Mavyret	Sofosbuvir-velpatasvir Epclusa Lepidasvir-sofosbuvir Harvoni tablet Harvoni pellet

Treatment-Experienced Patients

Preferred	Nonpreferred
Mavyret Vosevi	None

Preferred Drug Prior Authorization Criteria for Treatment-Naïve Patients, Genotype 5 or 6

Prescriber Requirements

Criteria 1: The regimen may be prescribed by a primary care provider, a gastroenterologist, hepatologist, or infectious disease specialist

OR

If the patient has any ONE of the following, the regimen must be prescribed by a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist:

- Patient is treatment-experienced OR
- Patient has Hepatitis B and/or HIV co-infection OR
- Patient has undergone liver transplantation OR
- Patient has liver cancer OR
- Patient has severe liver disease defined as:
    - APRI > 1.5 OR
    - FibroSURE > 0.49 OR
    - Fibroscan > 9.5 kPa OR
    - FIB-4 > 3.25 OR
    - MR Elastography > 6 kPa OR
    - Fibrospect > 42 OR
    - Liver Biopsy > F3 **AND**

Criteria 2: If the patient has a substance use disorder or IV drug use, the patient must:

- Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request OR
- Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request AND
- Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:
    - Condom distribution (e.g. written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)
    - Access to sterile syringes (e.g. written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)
    - Naloxone training and distribution (e.g. written prescription for naloxone, copy of current naloxone training protocol etc.)
    - Medication-assisted treatment options (e.g. provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) OR
- Not be candidate for ANY of the harm reduction services above; and provider provides the reason the patient is not a candidate for each of the harm reduction services above

Criteria 3: The treating clinician must provide documentation to attest the patient is screened for evidence of current or prior hepatitis B virus (HBV) infection before starting treatment with direct-acting antivirals. The treating clinician must also have a monitoring plan in place for HBV flare-ups or reactivation during treatment and post-treatment follow up **AND**

- Where indicated, the treating clinician must provide documentation that the patient has been counseled on the HBV reactivation adverse events management plan, including the risks of HBV reactivation, including serious liver injury and death **AND**

Criteria 4: Clinical documentation of patient's liver cirrhosis status (e.g. no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**

Criteria 5: Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request **AND**

Criteria 6: Provider attests to submit SVR12 results to the Department via fax at 651-431-7424 upon request **AND**

Criteria 7: Patient meets the age limit and has the diagnosis described in the FDA-approved label

Nonpreferred Drug Prior Authorization Criteria for Treatment-Naïve Patients, Genotype 5 or 6

- Patient is NOT a candidate for Mavyret **AND**
- Patient has met Criteria 1 through 7 of the Preferred Drug Criteria **AND**
- Patient's prescribed regimen must align with the dosage recommendation described in the FDA-approved label or in AASLD/IDSA HCV guidelines; **AND**

Patient has HCV infection with **at least ONE** of the four conditions listed below:

- Decompensated liver disease as defined by Child-Pugh-Turcotte classification score 7-12 and MELD is ≤20.
- Abdominal imaging where radiologist determines findings are suggestive of cirrhosis (e.g. nodules; enlarged liver, especially in the left lobe; tortuous hepatic arteries; ascites; portal hypertension)
- Evidence of one or more noninvasive tests indicating a fibrosis score of ≥ F3, such as:
    - APRI (AST to platelet ratio index) ≥ 1.5
    - FibroSURE ≥ 0.49
    - FibroScan ≥ 9.5
    - Fibrosis-4 index (FIB-4) > 3.25
    - MR Elastography ≥ 6 kPa
    - Fibrospect ≥ 42
- HCV infections with one of the following:
    - Post solid organ transplant (e.g. heart; kidney; liver)
    - Awaiting liver transplant
    - Stage I-III hepatocellular carcinoma meeting Milan criteria
    - HCV infection post liver transplant
    - Severe complications of HCV as defined below:
        - Type 2 or Type 3 essential mixed cryoglobulinemia with end organ manifestations
        - HCV-induced renal disease (e.g. nephrotic syndrome or mebranoproliferative glomerulonephritis (MPGN)

Preferred Drug Prior Authorization Criteria for Treatment-Experienced Patients, Genotype 5 or 6

Prescriber Requirements

Criteria 1: If the patient has any ONE of the following, the regimen must be prescribed by a gastroenterologist, hepatologist, infectious disease specialist, or a nurse practitioner or physician assistant working with a gastroenterologist, hepatologist, or infectious disease specialist:

- Patient is treatment-experienced OR
- Patient has Hepatitis B and/or HIV co-infection OR
- Patient has undergone liver transplantation OR
- Patient has liver cancer OR
- Patient has severe liver disease defined as:
    - APRI > 1.5 OR
    - FibroSURE > 0.49 OR
    - Fibroscan > 9.5 kPa OR
    - FIB-4 > 3.25 OR
    - MR Elastography > 6 kPa OR
    - Fibrospect > 42 OR
    - Liver Biopsy > F3 **AND**

Criteria 2: If the patient has a substance use disorder or IV drug use, the patient must:

- Be enrolled in a substance use disorder treatment program and provider's attestation of enrollment is provided at time of request OR
- Be counseled about measures to reduce the risk of HCV transmission to others; and evidence of counseling is provided at time of request AND
- Be offered at least TWO of the following harm reduction services, as described in AASLD/IDSA HCV guidelines:
    - Condom distribution (e.g. written prescription for condoms, clinic receipt of condom purchase for distribution within the past 12 months, etc.)
    - Access to sterile syringes (e.g. written prescription for needles and syringes, copy of educational materials on syringe access and disposal provided to the patient, etc.)
    - Naloxone training and distribution (e.g. written prescription for naloxone, copy of current naloxone training protocol etc.)
    - Medication-assisted treatment options (e.g. provider's attestation of methadone program enrollment, prescription for buprenorphine substantiated by pharmacy claims data.) OR
- Not be candidate for ANY of the harm reduction services above; and provider provides the reason the patient is not a candidate for each of the harm reduction services above

Criteria 3: The treating clinician must provide documentation to attest that the patient is screened for evidence of current or prior hepatitis B virus (HBV) infection before starting treatment with direct-acting antivirals **AND** the provider has a monitoring plan for HBV flare-ups or reactivation during treatment and post-treatment follow-up **AND**

- Where indicated, the treating clinician must provide documentation that the patient has been counseled on the HBV reactivation adverse events management plan AND the risk of HBV reactivation including serious liver injury and death **AND**

Criteria 4: Clinical documentation of patient's liver cirrhosis status (e.g. no cirrhosis, compensated cirrhosis, etc.) that corresponds to the requested therapy duration **AND**

Criteria 5: Clinical documentation of patient's prior treatment including drug name and date(s) of therapy **AND**

Criteria 6: Pretreatment detectable HCV RNA viral load value, measured within 1 year of treatment start date, is provided at time of request **AND**

Criteria 7: Provider attests to submit SVR12 results to the Department via fax at 651-431-7424 upon request **AND**

Criteria 8: Patient meets the age limit and has the diagnosis described in the FDA-approved label

Questions?

MHCP Provider Resource Center 651-431-2700 or 800-366-5411

<table>
<tr><td>Prior Authorization Group Description</td><td>Treatment of Hereditary Angioedema (HAE)</td></tr>
<tr><td>Drugs</td><td>Preferred:
Berinert (C1 esterase inhibitor, human)
Cinryze (C1 esterase inhibitor, human)

Non-preferred:
Haegarda (C1 esterase inhibitor, human)
Ruconest (C1 esterase inhibitor, recombinant)
icatibant (Firazyr)
Kalbitor (ecallantide)
Takhzyro (lanadelumab-flyo)
Orladeyo (berotralstat)
or any newly marketed agent

If the request is for danazol, please refer to the danazol PA criteria</td></tr>
<tr><td>Covered Uses</td><td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td></tr>
<tr><td>Exclusion Criteria</td><td>N/A</td></tr>
<tr><td>Required Medical Information</td><td>See “Other Criteria”</td></tr>
<tr><td>Age Restrictions</td><td>According to package insert</td></tr>
<tr><td>Prescriber Restrictions</td><td>Prescriber must be an immunologist, allergist, rheumatologist, or hematologist</td></tr>
<tr><td>Coverage Duration</td><td>If criteria are met, the request will be approved as follows:
• Acute treatment: Initial fill + 5 refills
• Pre-procedural prophylaxis: 1 treatment
• Long-term prophylaxis:
o Initial: 6 months
o Reauthorization: 12 months</td></tr>
<tr><td>Other Criteria</td><td><u>Initial Criteria</u>
• Dose is appropriate for indication per compendia
• The member is not taking ACE inhibitors or estrogen-containing oral contraceptives or hormone replacement therapy
• Documented diagnosis of one of the following:
1. HAE with deficient or dysfunctional C1INH (e.g. type I, type II, or acquired C1INH deficiency):
<table>
<tr><td>Deficiency Type</td><td>C4</td><td>C1INH antigenic level</td><td>C1INH functional level</td></tr>
<tr><td>Type I (deficiency of C1INH)</td><td>Low</td><td>Low</td><td>Low</td></tr>
<tr><td>Type II (dysfunction of C1INH)</td><td>Low</td><td>Normal or elevated</td><td>Low</td></tr>
<tr><td>Acquired C1INH deficiency</td><td>Low</td><td>Low or normal</td><td>Low</td></tr>
</table>
2. 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)</td></tr>
</table>

	▪ If unknown origin (U-HAE), documentation of a prolonged trial of high-dose non-sedating antihistamines **For acute treatment:** • The patient is receiving only one agent for the treatment of acute attacks. • If the request is for a non-preferred drug, the member has documented trial and failure of, or intolerance to, Berinert **For pre-procedural prophylaxis:** • Documentation that patient will be undergoing a medical, surgical, or dental procedure associated with mechanical impact to the upper aerodigestive tract and anticipated date of the procedure **For long-term prophylaxis:** • The patient has a history of at least two severe attacks per month (e.g swelling of the face, throat, or GI tract) or at least one laryngeal attack • The patient is only receiving one HAE medication for long-term prophylaxis • If the patient has a C1INH deficiency or dysfunction, documented trial and failure of, or intolerance to, Haegarda **<u>Renewal Criteria:</u>** **For acute treatment:** • Dose is appropriate for indication per compendia • Documentation was submitted that the patient has clinically benefited from medication • The patient is receiving no other medications for acute treatment **For prophylaxis:** • Dose is appropriate for indication per compendia • Documentation was submitted that the patient has clinically benefited from prophylactic therapy as demonstrated by a reduced number of attacks • If the request is for Takhzyro and the patient has been well controlled (e.g. attack-free) for 6 months or more while receiving Takhzyro the patient will be receiving 300 mg every four weeks, or a medical reason has been provided why continued therapy with 300 mg every two weeks is necessary **Medical Director/Clinical Reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary**
Revision/Review Date: 03/2023	

Prior Authorization Group Description	**Hyaluronic Acid Derivatives**
Drug(s)	**EUFLEXXA (preferred agent),** Gel-One, Gelsyn-3, GenVisc 850, Hyalgan, Monovisc, Orthovisc, Supartz FX, Synvisc One, Synvisc, Durolane, Visco-3, Hymovis, Triluran, 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), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Specialist, or working in consultation with a specialist in, orthopedic surgery, sports medicine, physiatry, or rheumatology
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 • The member has had adequate trials without improvement or has a medical reason (intolerance, hypersensitivity, contraindication, etc.) for not being able to use ALL of the following: o Two different oral acetaminophen-containing analgesics, oral NSAIDs, or other oral analgesics o A topical NSAID • Documentation that the members has tried and failed two intra-articular steroid injections, per affected knee or has a medical reason (intolerance, hypersensitivity, contraindication, etc) for not being able to utilize steroid injections • If the request is for any product other than Euflexxa, the member has a medical reason (intolerance, hypersensitivity, contraindication, etc) for not using Euflexxa **Reauthorization:** • Documentation was submitted that the member had a response to the hyaluronic acid injection that lasted at least 6 months (e.g. decreased joint pain or stiffness, improved knee range of motion, decrease in midpatellar knee circumference in millimeters, or synovial effusion absent or volume decreased) • Documentation was submitted that symptoms of osteoarthritis have returned and have not responded to oral analgesics or topical NSAIDs; or a medical reason was provided as to why these therapies are not appropriate (intolerance, hypersensitivity, contraindication, etc)

Review/Revision Date: 03/2023	• If the request is for any product other than Euflexxa, the member has a medical reason (intolerance, hypersensitivity, contraindication, etc) for not using Euflexxa **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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

Other Criteria
 	
Revision/Review Date:
Date: 6/2023
	<u>Initial Authorization:</u>
	• Medication is prescribed at an FDA approved dose
	• If request is for preterm birth, do not approve
	• Request is for one of the following indications:
	  o Amenorrhea or abnormal uterine bleeding due to hormonal imbalance
	  o Production of secretory endometrium and desquamation
	  o Test for endogenous estrogen production
	  o Advanced uterine adenocarcinoma
	
	<u>Re-Authorization:</u>
	• Documentation or provider attestation of clinical benefit
	• Medication is prescribed at an FDA approved dose
	
	If all the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	**Ileal bile acid transporter (IBAT) inhibitors**
Drugs	Bylvay (odevixibat), Livmarli (maralixibat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	Bylvay: 3 months and older Livmarli: 1 year and older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist or hepatologist
Coverage Duration	If the conditions are met, the request will be approved for a 6 month duration for initial requests and a 12 month duration for renewal requests.
Other Criteria	**<u>Initial Authorization:</u>** **Progessive Familial Intrahepatc Cholestasis (Bylvay ONLY)** • Diagnosis of progressive familial intrahepatic cholestasis (PFIC) type 1, 2, or 3 with genetic confirmation • Documentation that patient does not have an *ABCB11* variant that results in non-functional or complete absence of bile salt export pump protein (BSEP-3) • Documented history of moderate to very severe pruritus • Documentation of patient's weight • Prescriber attests to monitor liver function tests and fat soluble vitamin (FSV) levels during treatment • Baseline serum bile acid level • Documentation of trial and failure OR medical reason why the member is unable to use ALL of the following: o Ursodiol o Cholestyramine or colesevelam • The prescribed dose is within FDA approved dosing guidelines **<u>Alagille Syndrome (Livmarli ONLY)</u>** • Diagnosis of Alagille syndrome (ALGS) • Documented history of moderate to very severe pruritus • Prescriber attests that member has cholestasis

	• Baseline serum bile acid level is provided
	• Documentation of patient's weight
	• Prescriber attests to monitor liver function tests and fat soluble vitamin (FSV) levels during treatment
	• Documentation of trial and failure OR medical reason why the member is unable to use ALL of the following:
	  o Ursodiol
	  o Cholestyramine or colesevelam
	  o Rifampin
	• The prescribed dose is within FDA approved dosing guidelines
	
	<u>Reauthorization:</u>
	• 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 patient's weight
	• Prescriber attests to monitor liver function tests and FSV levels during treatment
	• Prescriber attests that patient has had no evidence of hepatic decompensation (e.g. variceal hemorrhage, ascites, hepatic encephalopathy, portal hypertension, etc.)
	• The prescribed dose is within FDA approved dosing guidelines

Revision/Review Date: 3/2023	**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	Gamunex-C (IV or SQ) (Immune Globulin) – preferred for all applicable indications Bivigam (IV) (Immune Globulin) Cuvitru (SQ) (Immune Globulin) Flebogamma (IV) (Immune Globulin) Gamastan (IM) (Immune Globulin) Gamastan SD (IM) (Immune Globulin) Gammagard liquid (IV or SQ) (Immune Globulin) Gammagard SD (IV) (Immune Globulin) Gammaked (IV or SQ) (Immune Globulin) Gammaplex (IV) (Immune Globulin) Hizentra (SQ) (Immune Globulin) Octagam (IV) (Immune Globulin) Privigen (IV) (Immune Globulin) Asceniv (IV) (Immune Globulin-slra) Cutaquig (SQ) (Immune Globulin-hipp) Panzyga (IV) (Immune Globulin-ifas) Hyqvia (SQ) (Immune Globulin Human/Recombinant Human Hyaluronidase) Xembify (SQ) (Immune Gobulin-klhw) or any newly-approved immune globulin product
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber is a specialist in disease state being treated
Coverage Duration	If the criteria are met the request will be approved for a 3 month duration unless otherwise specified in the diagnosis specific “Other Criteria” section below.
Other Criteria	**<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 o If the member’s body mass index (BMI) is ≥30 kg/m^2 OR if their actual weight is greater than 20% of their IBW, then dosing will be calculated using adjusted body weight (adjBW) **<u>Primary Immunodeficiency*</u>**: • Patient’s IgG level is provided and is below normal level for indication

- 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, X-linked hyper IgM syndrome

Idiopathic Thrombocytopenic Purpura, acute and chronic:

- Acute:
    - Patient 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 an inadequate increase in platelets from corticosteroids or unable to tolerate corticosteroids
    - Dose does not exceed 1000 mg/kg daily for up to 2 days, or 400 mg/kg daily for 5 days
- Chronic:
    - Duration of illness is greater than 12 months
    - Patient 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.
    - Dose does not exceed 1000 mg/kg daily for up to 2 days, or 400 mg/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.

Kawasaki disease:

- Immune globulin is being given with high dose aspirin, unless contraindicated
- Requested dose does not exceed a single 2 g/kg dose. If criteria are met, approve for up to 1 dose

Chronic B-cell lymphocytic leukemia:

- Patient's IgG level is <500 mg/dL
- The patient has had recurrent infections requiring IV antibiotics or hospitalization
- Dose does not exceed 500 mg/kg every 4 weeks
- If criteria are met, approve for 3 months.

Bone marrow transplantation:

	• The patient has bacteremia or recurrent sinopulmonary infections and their IgG level is < 400mg/dL • Dose does not exceed 500 mg/kg/week for the first 100 days post-transplant • Dose does not exceed 500 mg/kg every 3-4 weeks 100 days after transplant • If criteria are met, approve for 3 months. **Pediatric HIV**: • Patient is < 13 years of age • Either patient's IgG level is < 400mg/dL or if patient's IgG level is ≥ 400 mg/dL than significant deficiency of humoral immunity as evidenced by ONE of the following: o Inability to produce an adequate immunologic response to specific antigens. o History of recurrent bacterial infections despite prophylactic antibiotics • Dose does not exceed 400 mg/kg/dose every 2 to 4 weeks • If criteria are met, approve for 3 months. **Multifocal motor neuropathy (MMN)**: • Duration of symptoms has been at least 1 month with disability. • Nerve conduction studies were completed to rule out other possible conditions, and confirms the diagnosis of MMN. • Dose does not exceed 2 g/kg/month administered over 2-5 days. • If criteria are met, approve for up to 5 days per course for 3 months. **Chronic inflammatory demyelinating polyneuropathy (CIDP):** • Duration of symptoms has been at least 2 months with disability. • Nerve conduction studies or a nerve biopsy were completed in order to rule out other possible conditions, and confirms the diagnosis of CIDP. • Patient has a documented trial and failure of, or has a documented medical reason for not using, corticosteroids o If the patient has severe and fulminant CIDP, a trial of corticosteroids is not required o In pure motor CIPD a trial of corticosteroids in 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 up to 5 days for 3 months **Guillain-Barre syndrome:** • Patient has severe disease with the inability to walk without aid • Onset of symptoms within the last 4 weeks • Dose does not exceed 2 g/kg given over 5 days per month • If criteria are met, approve for up to 5 days. **Myasthenia Gravis:** • Acute: o Patient has an acute myasthenic exacerbation (i.e., acute episode of respiratory muscle weakness, difficulty swallowing, etc.) or is in

Revision/Review Date: 12/2023	preparation for thymoma surgery to prevent myasthenic exacerbation o Dose does not exceed 2 g/kg administered over 2-5 days o If criteria is met, approve for up to 5 days • <u>Chronic:</u> o Diagnosis of refractory generalized myasthenia gravis o Patient has a documented trial and failure of, 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 is met, approve for 3 months. **<u>Dermatomyositis (DM):</u>** • One of the following: o Bohan and Peter score of 3 (i.e. definite DM) o Bohan and Peter score of 2 (i.e. probable DM) AND concurring diagnostic evaluation by ≥ 1 specialist (e.g. neurologist, rheumatologist, dermatologist) • Patient does NOT have any of the following: o 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 cure) o Active Malignancy o Malignancy diagnosed within the previous 5 years o Breast cancer within the previous 10 years • For a diagnosis of DM, one of the following: o Patient has a documented trial and failure of, or has a documented medical reason for not using both of the following: ▪ methotrexate (MTX) OR azathioprine ▪ rituximab o Patient has severe, life-threatening weakness or dysphagia • For a diagnosis of cutaneous DM (i.e. amyopathic DM, hypomyopathic DM): o Patient has a documented trial and failure of, or has a documented medical reason for not using, all of the following: ▪ MTX ▪ 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. If criteria is met, the request will be approved for the duration listed above**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	Lupkynis (voclosporin)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be 18 years of age or older
Prescriber Restrictions	Prescriber must be rheumatologist, nephrologist or other specialist in the treatment of autoimmune disorders
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 6/2023	**<u>Initial Authorization</u>** • Member must have a diagnosis of systemic lupus erythematosus (SLE) with a kidney biopsy indicating a histologic diagnosis of lupus nephritis (LN) Class III, IV, or V • Documentation that the member has a baseline eGFR > 45 mL/min/1.73m^2 • Documentation of the member's urine protein/creatinine ratio (UPCR) is provided • Member is concurrently being treated with background immunosuppressive therapy, or has a medical reason for not using background immunosuppressive therapy • Member is NOT concurrently being treated with cyclophosphamide • Medication is prescribed at an FDA approved dose **<u>Reauthorization</u>** • Documentation of improvement in renal function (i.e. reduction in UPCR or no confirmed decrease from baseline eGFR ≥ 20%) • Medication is prescribed at an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Inhaled Cystic Fibrosis Agents**
Drug(s)	<u>Preferred:</u> Bethkis Kitabis Pak <u>Non-preferred:</u> Cayston (aztreonam lysine) Tobi/Tobi Podhaler generic tobramycin Non-formulary: Bronchitol (mannitol) Pulmozyme (dornase alfa) or any newly marketed inhaled antibiotic or cystic fibrosis treatment
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug 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	Member's current weight
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a pulmonologist or infectious disease specialist
Coverage Duration	If all of the conditions are met, the request will be approved for 12 months
Other Criteria Review/Revision Date: 3/2023	• Request is for an FDA-approved indication and within dosing guidelines • The request is appropriate for member based on age and weight • 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 Pulmozyme (dornase) 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 a PDL non-preferred product, documentation that the member has had a trial of one of the preferred drugs for a duration of at least two 28-day cycles, or the member has a contraindication, intolerance, or clinical reason why the preferred drugs are not appropriate. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Injectable Antiemetics: 5-Hydroxytryptamine-3 (5HT3) Serotonin Receptor Antagonists and Substance P/Neurokinin 1 Receptor Antagonists (NK1 RA)**
Drugs	**Non formulary:** granisetron (Kytril) IV solution ondansetron (Zofran) IV solution, SubQ injection palonosetron (Aloxi) IV solution Sustol (granistron ER SubQ injection) Cinvanti (aprepitant) IV emulsion Varubi (rolapitant) IV emulsion fosaprepitant (Emend) IV emulsion Akynzeo (palonosetron/netupitant) IV solution Any other newly marketed agent
Covered Uses	The request for the medication is for and Food and Drug Administration (FDA) approved indication, and/or is used for a medical condition that is supported by the medical compendium and/or per the National Comprehensive Cancer Network (NCCN) or American Society of Clinical Oncology (ASCO) standard of care guidelines for antiemetic therapy.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by a specialist in a field appropriate for treatment of the patient's respective medical condition.
Coverage Duration	If the conditions are met, the request may be approved for up to 6 months or as long as recommended by medical compendia and/or per NCCN or ASCO standard of care guidelines.
Other Criteria	**Criteria for Approval:** • The medication is being requested for a Food and Drug Administration (FDA) approved indication or a medical condition that is supported by the medical compendia, NCCN, or ASCO standard of care guidelines for antiemetic therapy • Requested dose must be FDA-approved or within NCCN or ASCO guidelines • For requests for injectable ondansetron and granisetron: a trial and failure of (or documented medical reason for not using) oral ondansetron is required • If the request is for a medication other than generic ondansetron or generic granisetron, the member must have a documented trial and failure of (or documented medical reason for not using) all of the following: o Oral ondansetron o Injectable ondansetron or granisetron • Members receiving an antineoplastic agent with HIGH or MODERATE emetic risk per the NCCN practice guidelines may be approved for generic palonosetron without prior trial and failure of ondansetron/granisetron • Pediatric patients treated with high emetic risk antineoplastics who are unable to receive dexamethasone may be approved for generic palonosetron without prior trial and failure of ondansetron/granisetron
Revision/Review Date: 12/2023	**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 Oncology Indications**
Drugs	pamidronate, zoledronic acid (Zometa), Xgeva, Prolia
Covered Uses	The request is for an FDA approved indication or for a medically-accepted indications as defined or as supported by the medical compendia (Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI) , Drug Package Insert) as defined in the Social Security Act 1927, or per the National Comprehensive Cancer Network (NCCN), the American Society of Clinical Oncology (ASCO), or the National Institutes of Health (NIH) Consensus Panel standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be an oncologist
Coverage Duration	If the criteria are met, the request will be approved for 12 months.

Other Criteria
 	
Revision/Review Date: 12/2023
	Criteria for Approval:
	
	• The request is for an approved/accepted indication at an approved dose
	• Documentation was provided that baseline renal function has been evaluated
	• If the request is for, Xgeva (denosumab) for any of the indications below, the patient has a documented trial and failure of generic pamidronate (Aredia) OR zoledronic acid (Zometa) 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) for treating Giant cell tumor of bone, documentation has been submitted that the tumor is unresectable, that surgical resection is likely to result in morbidity (e.g. denosumab therapy is being used to aide in the possibility of resection with tumor shrinkage), or that disease has recurred.
	• If the request if for Prolia (denosumab) for breast cancer, the patient has a documented trial and failure of generic pamidronate (Aredia) OR zoledronic acid (Zometa) 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) 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 Agents for Osteoporosis and Paget's Disease**
Drugs	Preferred: Forteo (teriparatide) Non-preferred: teriparatide (biosimilar), Tymlos (abaloparatide), Prolia (denosumab) or any other newly marketed agent Other non-formulary: pamidronate, ibandronate (Boniva), zoledronic acid (Reclast), Evenity (romosozumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical	"See other criteria"
Age Restrictions	Member is 18 years of age or older
Prescriber Restrictions	For Paget's Disease, prescriber must be an endocrinologist, rheumatologist, orthopedist, or other specialist in the treatment of Paget's disease
Coverage Duration	If all of the conditions are met, requests will be approved for 1 year. ***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	**For all requests:** • Dose is appropriate per labeling or compendia • The member is taking calcium and vitamin D • The member has a documented (consistent with pharmacy claims) adequate trial of an oral bisphosphonate or has a medical reason (e.g. intolerance, hypersensitivity, contraindication, etc.) for not using an oral bisphosphonate If the diagnosis is osteoporosis: • Documentation was submitted indicating member is a postmenopausal woman or a male member over 50 years of age and ONE of the following: o Has a bone mineral density (BMD) value consistent with osteoporosis (T-score equal to or less than –2.5) o Has had an osteoporotic fracture o Has 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 Tymlos or Prolia, a medical reason why member is unable to use Forteo as appropriate based on diagnosis • If request is for teriparatide, Forteo (teriparatide) or Tymlos (abaloparatide) the member has SEVERE osteoporosis (T-Score -3.5 or below, or T- Score of -2.5 or below plus a fracture) • If the request is for Evenity (romosozumab) o Member has SEVERE osteoporosis (T-Score -3.5 or below, or T- Score of -2.5 or below plus a fracture) o Member does not have a history of a heart attack or stroke within the preceding year o A medical reason why member is unable to use all of the following as appropriate based on diagnosis: Forteo teriparatide, zoledronic acid, and Prolia (denosumab) If the diagnosis is Paget's disease: • Documentation of ONE of the following: o Member's serum alkaline phosphatase level of ≥ two times the upper limit of normal (within 60 days of request) o The member is symptomatic o Documentation of biochemically active disease on bone scintigraphy If the diagnosis is glucocorticoid-induced osteoporosis: • Documentation that the member is currently utilizing glucocorticoid therapy for a minimum of 3 months • Documentation that the dosage of the glucocorticoid therapy is greater than 2.5 mg of prednisone daily or its equivalent • Member is 40 years of age or older • Member has a high to very high risk of fracture based on ONE of the following: o History of osteoporotic fracture o BMD less than or equal to -2.5 at the hip or spine o FRAX 10-year probability of hip fracture of > 3 percent o FRAX 10-year risk for combined major osteoporotic fracture greater than 20% percent If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Revision/Review Date: 9/2023	

Prior Authorization Group Description	**Insulin Pumps**
Drugs	Omnipod Dash Intro Kit, Omnipod Dash Pods, Omnipod 5 G6 Intro kit, Omnipod 5 G6 Pods, Omnipod Go pods **This policy does not apply to pumps reviewed and/or covered by the Medical Benefit including, but not limited to, V-Go 24-hour disposable system and continuous pumps such as MiniMed and t:slim X2. Requests for these products are referred to the plan's Utilization Management team for review.**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	None
Required Medical Information	See "Other Criteria"
Age Restrictions	None
Prescriber Restrictions	See "Other Criteria"
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 9/2023	**<u>Initial Authorization</u>** • Diagnosis – diabetes • One of the following o Prescribed by or in consultation with an endocrinologist o Member is assisted by a certified diabetes care and education specialists (CDCESs) • One of the following o Type 1 diabetes or other insulin-deficient forms of diabetes (e.g. cystic-fibrosis related diabetes) o Treatment with multiple daily doses (≥ 3) of insulin **<u>Reauthorization</u>** • One of the following: o Type 1 diabetes or other insulin-deficient form of diabetes o Continued use of multiple daily injections (≥ 3) of insulin o Initial approval was based on continuation of therapy for patient new to plan. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Jesduvroq**
Drugs	Jesduvroq (daprodustat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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 Concomitant use of strong CYP2C8 inhibitors (e.g., gemfibrozil)
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be at least 18 years of age
Prescriber Restrictions	Prescriber must be a hematologist or nephrologist
Coverage Duration	If all conditions are met, the request will be approved with a 6 month duration.

Other Criteria	**Initial Authorization:**
	• Member has a diagnosis of chronic kidney disease (CKD) and has been undergoing dialysis for at least four months
	• Member has a documented hemoglobin between 8.0 and 11.5 g/dL
	• Member has documentation of trial and failure, intolerance, contraindication, or inability to use erythropoietin stimulating agents (ESA)
	• Documentation of the current ESA product (e.g., Procrit, Aranesp, etc.) and dose.
	• The following lab results must be submitted and demonstrate normal values, otherwise, the member MUST be receiving, or is beginning therapy, to correct the deficiency:
	  o Serum ferritin level (> 100ng/mL)
	  o Transferrin saturation (TSAT) (> 20%)
	• Provider attests that member has no history of myocardial infarction, cerebrovascular event, or acute coronary syndrome in the past 3 months
	• Member will not be receiving concurrent treatment with an ESA
	• Request is for an FDA-approved dose
	• All submitted lab results have been drawn within 30 days of the request
	
	Reauthorization:
	• All submitted lab results have been drawn within 30 days of the reauthorization request.
	• Member has a documented increase in hemoglobin from baseline
	• The following lab results must be submitted and demonstrate normal values, otherwise, the member MUST be receiving, or is beginning therapy, to correct the deficiency:
	  o Serum ferritin level (> 100ng/mL)
	  o Transferrin saturation (TSAT) (> 20%)
	• Member will not be receiving concurrent treatment with an ESA
	• Request is for an FDA-approved dose

Revision/Review Date: 06/2023	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary**

Field Name	Field Description
Prior Authorization Group Description	Joenja
Drugs	Joenja (leniolisib)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Per prescribing information.
Prescriber Restrictions	Prescriber must be an immunologist, hematologist, medical geneticist, or other prescriber who specializes in the treatment of genetic or immunologic disorders.
Coverage Duration	If the criteria are met, requests will be approved with up to a 6-month duration. Thereafter, reauthorization requests will be approved with up to a 12-month duration.
Other Criteria Revision/Review Date 9/2023	**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	Janus Kinase Inhibitors for Nonsegmental Vitiligo
Drugs	Opzelura (ruxolitinib)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI)
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	≥ 12 years of age
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist, immunologist, or specialist experienced in treatment of vitiligo
Coverage Duration	If criteria are met, the request will be approved with up to a 6 month duration. All reauthorization requests will be approved up to 12 months in duration.

Other Criteria
 	
Revision/Review Date 12/2023
	Initial Authorization
	o Diagnosis of nonsegmental vitiligo
	o Documentation of depigmented lesions including measurements and locations is provided
	o Prescriber attests that the total body vitiligo area (facial and nonfacial) being treated does not exceed 10% BSA
	o Trial and failure of, or intolerance to, ALL of the following:
	  o Topical corticosteroids
	  o Topical calcineurin inhibitors
	  o Targeted phototherapy
	o Prescriber attests that the member will not concomitantly use therapeutic biologics, other Janus kinase inhibitors, potent immunosuppressants, or phototherapy for repigmentation purposes
	o Request is for an FDA-approved dose
	
	****A MAXIMUM OF ONE 60 GRAM TUBE OF OPZELURA PER WEEK OR ONE 100 GRAM TUBE EVERY TWO WEEKS MAY BE APPROVED****
	
	Reauthorization
	o Prescriber attests that the member has experienced a clinical benefit (e.g. reduction in size or quantity of or stabilization of existing depigmented lesions; absence of new depigmented lesions)
	o 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	**Agents for Homozygous Familial Hypercholesterolemia (HoFH)**
Drugs	Juxtapid (lomitapide) Evkeeza (evinacumab-dgnb) ****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	See "other criteria"
Age Restrictions	According to labeling
Prescriber Restrictions	Prescriber must be a cardiologist or specialist in the treatment of lipid disorders
Coverage Duration	If the criteria are met, initial requests will be approved for up to 6 months. Reauthorization requests will be approved for 12 months.

Other Criteria	**Criteria for 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.
	• Request is for an appropriate dose for member according to labeling
	• Documentation of current LDL level was provided
	• Member has tried and failed atorvastatin 40 - 80 mg or rosuvastatin 20 – 40 mg (consistent therapy 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 tolerate ezetimibe
	• Member has documented trial and failure with a PCSK9 inhibitor for at least 3 months, or a medical reason has been provided why member is unable to use a PCSK9 inhibitor to manage the condition.
	• Documentation was provided indicating prescriber has counseled member on

Revision/Review Date:3/2023	smoking cessation and following a "heart healthy diet". **Criteria for Re-authorization** • Documentation submitted (including repeat fasting lipid panel) indicates that the member has obtained clinical benefit from the medication and the member has achieved or maintained LDL reduction from the levels drawn immediately prior to initiation of treatment with Juxtapid • The member's claim history shows consistent therapy (monthly fills) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group	**Kuvan**
Drug(s)	sapropterin (Kuvan)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert).
Exclusion Criteria	None
Required Medical Information	See "Other Criteria"
Age Restrictions	None
Prescriber Restrictions	Requestor must be affiliated with or have collaborated with a clinic specializing in phenylketonuria.
Coverage Duration	Initial: If the criteria are met, the request will be approved for 2 months. Reauthorization: If the criteria are met, the request will be approved for 3 months.
Other Criteria Revision/Review Date: 03/2023	**INITIAL AUTHORIZATION:** • Documentation of the member's current weight • Documentation of a confirmed diagnosis of phenylketonuria (PKU) • Documentation of the patient'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 patient is currently utilizing a Phe restricted diet • The medication is being prescribed at the FDA-approved dose **CRITERIA FOR REAUTHORIZATION:** • Documentation of the member's current weight • Documentation of one of the following: o Decrease in Phe level from baseline OR o Increase in dietary Phe tolerance or improvement in clinical symptoms • The medication is being prescribed at the maximum FDA-approved dose **NOTE: Clinical reviewer/Medical Director must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**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 or consulted by an endocrinologist
Coverage Duration	If all 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	**Initial Authorization** • 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 **Reauthorization** • Member has not achieved independence from exogenous insulin within one year of infusion OR member has lost independence from 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

Revision/Review Date: 12/2023	• 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) *****Initial authorizations and reauthorizations must be approved by a Medical Director*****
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Patients with moderate to severe Alzheimer's Disease (AD) Patients with neurodegenerative disease caused by a condition other than AD
Required Medical Information	See "Other Criteria"
Age Restrictions	age 50-90 years
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	For initial authorization: the request will be approved in accordance with the FDA-indicated titration schedule for up to 6 months For reauthorization: if all of the conditions are met, the request will be approved for 6 months.
Other Criteria	**<u>Initial Authorization</u>** • Diagnosis of mild cognitive impairment (MCI) caused by AD or mild AD consistent with Stage 3 or Stage 4 Alzheimer's disease as evidenced by at least one of the following: o Clinical Dementia Rating Global (CDR-G) score of 0.5-1.0 and a Memory Box score of 0.5 or greater o Mini-Mental State Examination (MMSE) score ≥ 22 and ≤ 30 o Wechsler Memory Scale IV-Logical Memory (subscale) II (WMS-IV LMII) score at least 1 standard deviation below age-adjusted mean • The request is for an FDA approved dose • Documentation of BOTH of the following: o Recent, within past year, positive results for the presence of beta-amyloid plaques on a positron emission tomography (PET) scan or cerebrospinal fluid testing o Recent, within past year, baseline Magnetic Resonance Imaging (MRI) scan

Revision/Review Date: 9/2023	• 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 • Patient continues to have a diagnosis of mild cognitive impairment (MCI) caused by AD or mild AD consistent with Stage 3 or Stage 4 Alzheimer's disease as evidenced by at least one of the following: o CDR-G score of 0.5-1.0 and a Memory Box score of 0.5 or greater o MMSE score of 22-30 o Wechsler Memory Scale IV-Logical Memory (subscale) II (WMS-IV LMII) score at least 1 standard deviation below age-adjusted mean • Provider attestation of safety monitoring and management of amyloid related imaging abnormalities (ARIA) and intracerebral hemorrhage, as recommended per the manufacturer's prescribing information. • Documentation that member has experienced clinical benefit from the medication (such as: stabilization or decreased rate of decline in symptoms from baseline on CDR-SB, ADAS-Cog14, or ADCS MCI-ADL scales) • No recent (past 1 year) history of stroke, seizures, or TIA **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Lidocaine patch**
Drugs	lidocaine (Lidoderm) 5% patch Ztlido (lidocaine) 1.8% 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	N/A
Age Restrictions	Per package insert
Prescriber Restrictions	N/A
Coverage Duration	If the conditions are met, the request will be approved for 6 months.
Other Criteria Revision/Review Date: 9/2023	The member has a diagnosis of postherpetic neuralgia OR The member has an alternate diagnosis AND Documented trial and failure of (or documented medical reason for not using) ALL of the following: • Non-steroidal anti-inflammatory drug (NSAID) • Tri-cyclic antidepressant • Gabapentin or pregabalin Physician reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Prior Authorization Group Description	**Linezolid (Zyvox)**
Drugs	Linezolid (Zyvox)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the conditions are met, the request will be approved for up to 42 days (6 weeks).
Other Criteria Revision/Review Date: 6/2023	**Criteria for approval:** • Documentation that the infection is susceptible to linezolid AND patient meets **ONE** of following criteria: • Documented history of treatment with linezolid IV (continuation of therapy, IV to PO conversion). • The member has a documented trial and failure of at least one preferred oral antimicrobial drug with susceptibility or medical reason why (e.g. intolerance, hypersensitivity, contraindication) a preferred drug cannot be used. • Requests for linezolid oral suspension require a documented inability to use (e.g., unable to swallow) linezolid oral tablets. • Requests for treatment courses greater than 2 weeks require attestation that CBC will be monitored weekly **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	Lodoco (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	Per FDA approved prescribing information
Prescriber Restrictions	Prescriber must be, or in consultation with a specialist in the treatment of cardiovascular disease, such as a cardiologist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Other Criteria Review/Revision Date: 12/2023	**<u>Initial Authorization:</u>** • Patient has established atherosclerotic disease or multiple risk factors for cardiovascular disease • Patient is currently receiving statin therapy, or documentation has been provided that the member has a medical reason statin therapy is not appropriate • Documentation is provided that guideline directed medical therapies targeted to patient's specific risk factors are being maximized, such as medications targeted at reduction in cholesterol, blood pressure, antiplatelet therapies, and diabetes • Patient does not have pre-existing blood dyscrasias (ex. leukopenia, thrombocytopenia) • Patient does not have renal failure (CrCl less than 15 ml/min) or severe hepatic impairment • Patient is not currently taking medications contraindicated for concurrent use with Lodoco o Strong CYP3A4 inhibitors (ex. atazanavir, clarithromycin, darunavir/ritonavir, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, tipranavir/ritonavir) o P-glycoprotein inhibitors (ex. cyclosporine, ranolazine) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	Luxturna (voretigene neparvovec-rzyl)
Drugs	Luxturna (voretigene neparvovec-rzyl)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Intraocular surgery within the past 6 months
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If all the criteria are met, the request will be approved for a one-time dose per eye.
Other Criteria Date: 12/2023	• Medication is prescribed at an FDA approved dose • Diagnosis of confirmed biallelic RPE65 mutation-associated retinal dystrophy (e.g., Leber congenital amaurosis (LCA), retinitis pigmentosa (RP), early-onset severe retinal dystrophy (EOSRD), etc.) • Member has viable retinal cells as determined by non-invasive means, such as optical coherence tomography (OCT) and/or ophthalmoscopy indicating one or more of the following: o An area of retina within the posterior pole of >100 µm thickness shown on OCT o ≥ 3 disc areas of retina without atrophy or pigmentary degeneration within the posterior pole o Remaining visual field within 30 degrees of fixation as measured by a III4e isopter or equivalent • Member has significant vision loss determined by one of the following: o Visual acuity of 20/60 or worse in both eyes o Visual field less than 20 degrees in any meridian **The safety and effectiveness of repeat administration of Luxturna have not been evaluated and will not be approved.** **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	Mucopolysaccharidosis VII (MPS VII, Sly syndrome)
Drugs	Mepsevii (vestronidase alfa-vjbk)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Central nervous system manifestations of mucopolysaccharidosis VII
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, a geneticist, metabolic specialist, or a physician who specializes in the treatment of lysosomal storage disorders.
Coverage Duration	If all of the criteria are met, the initial request will be approved for 12 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Date: 12/2023	**Initial Authorization:** • Medication is prescribed at an FDA approved dose • Confirmed diagnosis of MPS VII/Sly syndrome based on leukocyte or fibroblast glucuronidase enzyme assay or genetic testing • Documentation of elevated urinary glycosaminoglycan (uGAG) excretion at a minimum of 3-fold over the mean normal for age • Documentation of baseline values for at least ONE of the following: o uGAG o Age-appropriate motor function, visual acuity, and/or 6-minute walk test (6-MWT) o Age-appropriate pulmonary function tests (e.g. predicted forced vital capacity (FVC)) • Prescriber attestation that Mepsevii will be used as monotherapy **Re-Authorization:** • Medication is prescribed at an FDA approved dose • Documentation or provider attestation of positive clinical response (i.e. reduction in urinary excretion of uGAG, improvement in FVC, etc.) • Prescriber attestation that Mepsevii will be used as monotherapy • Prescriber attestation of the absence of severe adverse events **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Prior Authorization Group Description	**Multaq**
Drugs	**Multaq (dronedarone)**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Permanent atrial fibrillation
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescriber is a cardiologist or electrophysiologist
Coverage Duration	If the criteria are met, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 3/2023	Criteria for Approval: • Documented diagnosis of paroxysmal or persistent atrial fibrillation or atrial flutter • Attestation that the patient does not have NYHA Class III or IV heart failure • Attestation that the patient has not had an episode of decompensated heart failure in the last 4 weeks **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	Myasthenia Gravis Agents
Drugs	Vyvgart (efgartigimod), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase), Rystiggo (rozanolixizumab), Soliris (eculizumab), Ultomiris (ravulizumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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 neurologist or rheumatologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	**Initial Authorization:** • Diagnosis of generalized myasthenia gravis (gMG) • Patient has a positive serological test for one of the following: o Anti-AChR antibodies o Anti-muscle-specific tyrosine kinase (MuSK) antibodies (Rystiggo only) • Patient has a Myasthenia Gravis Foundation of America (MGFA) clinical classification of class II, III or IV • Patient has tried and failed, or has contraindication, to one of the following: o Two (2) or more conventional therapies (i.e., acetylcholinesterase inhibitors, corticosteroids, non-steroidal immunosuppressive therapies) o Failed at least 1 conventional therapy and required chronic plasmapheresis or plasma exchange or intravenous immunoglobulin • Medication is prescribed at an FDA approved dose • Patient is not using agents covered by this policy concurrently (i.e., no concurrent use of Vyvgart, Vyvgart Hytrulo, Rystiggo, Soliris, or Ultomiris) • Requests for Soliris (eculizumab) and Ultomiris (ravulizumab) will also require all of the following: o Documentation of vaccination against meningococcal disease or a documented medical reason why the patient cannot receive vaccination or vaccination needs to be delayed o Antimicrobial prophylaxis with oral antibiotics (penicillin, or

Revision/Review Date: 12/2023	macrolides if penicillin-allergic) for two weeks will be administered if the meningococcal vaccine is administered less than two weeks before starting therapy or a documented medical reason why the patient cannot receive oral antibiotic prophylaxis **<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.**

Field Name	Field Description
Prior Authorization Group Description	Nexviazyme (avalglucosidase alfa-ngpt)
Drugs	Nexviazyme (avalglucosidase alfa-ngpt) 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	Diagnosis of infantile onset Pompe disease
Required Medical Information	See "Other Criteria"
Age Restrictions	According to FDA approved prescribing information
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.

Other Criteria
 	
Date: 12/2023
	Initial Authorization:
	• Nexviazyme is prescribed for a diagnosis of 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 is submitted confirming a diagnosis of late-onset (non-infantile) Pompe disease
	• Nexviazyme will not be used in combination with other enzyme replacement therapies (i.e., alglucosidase-alfa)
	
	Re-Authorization:
	• Nexviazyme will not be used in combination with other enzyme replacement therapies (i.e., alglucosidase-alfa)
	
	If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	**Parsabiv**
Drugs	Parsabiv (eteclacetide)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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	N/A
Coverage Duration	If all criteria are met, the request will be approved for a duration of 12 months.
Other Criteria	Initial: • Confirmed diagnosis of secondary hyperparathyroidism with chronic kidney disease (CKD) • Member is on hemodialysis • Documentation that member's corrected calcium is at or above the lower limit of normal • Documentation of trial and failure, contraindication or intolerance to cinacalcet • Member is on stable doses of active vitamin D analogs or calcium supplements or phosphate binders • Member is not receiving Parsabiv in combination with cinacalcet • Request is for an FDA approved dose Reauthorization: • Documentation that member is responding to therapy and experiencing a clinical benefit (i.e., noticeable reduction in PTH levels) • Member is not receiving Parsabiv with cinacalcet • Request is for an FDA approved dose
Revision/Review Date: 12/2023	**Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Pulmonary Biologics for Asthma and Eosinophilic Conditions**
Drugs	Nucala (mepolizumab), Fasenra (benralizumab), Cinqair (reslizumab), Dupixent (dupilumab), Tezspire (tezepelumab) 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	• When being used for relief of acute bronchospasm or status asthmaticus • When used in combination with another monoclonal antibody for the treatment of asthma or eosinophilic conditions
Required Medical Information	See "other criteria"
Age Restrictions	Per prescribing information
Prescriber Restrictions	Prescriber must be an allergist, immunologist, pulmonologist, dermatologist or rheumatologist; or is a provider working in consultation with one of these specialists
Coverage Duration	The initial request will be approved for 6 months. All subsequent requests will be approved for 12 months.
Other Criteria	**Initial Authorization:** Asthma: • Confirmed diagnosis of one of the following: o Nucala, Fasenra, Cinqair: severe eosinophilic asthma o Dupixent: moderate to severe eosinophilic asthma o Tezspire: severe asthma • The prescribed dose is within FDA approved dosing guidelines • Documentation has been provided of blood eosinophil counts within one of the following ranges: o Nucala and Dupixent: ≥150 cells/mcL (within 6 weeks of request) OR ≥300 cells/mcL (within the past 12 months) o Fasenra: ≥150 cells/mcL (within the past 12 months) o Cinqair: ≥ 400 cells/mcL (within the past 12 months) o Tezspire: No baseline eosinophil counts are required • The member has a documented baseline forced expiratory volume in one second (FEV_1) < 80% of predicted with evidence of reversibility by bronchodilator response. • 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 experience significant symptoms while compliant on a maximally-tolerated inhaled corticosteroid with a long-acting $Beta_2$ agonist (ICS/LABA) AND a long-acting muscarinic antagonist (LAMA) (or a documented medical reason must be provided why the member is unable to use these therapies • The member has experienced the one of the following: o Fasenra: ≥ 2 exacerbation in the previous 12 months o Cinqair: ≥1 exacerbation in the past 12 months requiring systemic corticosteroids o Dupixent: ≥1 exacerbation in the past 12 months requiring systemic corticosteroids or hospitalization o Tezspire: ≥2 exacerbations requiring systemic corticosteroids OR ≥1 exacerbation in the past 12 months requiring hospitalization Nucala: ≥ 2 exacerbations in the previous 12 months <u>Oral Corticosteroid Dependent Asthma: (Dupixent only)</u> • Confirmed diagnosis of oral corticosteroid (OCS) dependent asthma with at least 5 mg oral prednisone or equivalent per day for at least 4 weeks within the last 3 months • The member has a documented baseline FEV1 < 80% of predicted with evidence of reversibility by bronchodilator response. • Documentation has been provided indicating patient is still having significant symptoms with ≥ 1 exacerbation 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 patient has not utilized these therapies, a documented medical reason must be provided why patient is unable to do so. • The prescribed dose is within FDA approved dosing guidelines <u>Eosinophilic Esophagitis (EoE) *(Dupixent only):*</u> • Confirmed diagnosis of EoE by endoscopic biopsy indicating ≥15 intraepithelial eosinophils per high-power field (eos/hpf) • Documentation of baseline esophageal intraepithelial eosinophil count and Dysphagia Symptom Questionnaire (DSQ) scores • Member has a history of at least 2 episodes of dysphagia (with intakes of solids) per week in the last 4 weeks • Documented trial and failure, intolerance, or contraindication to one proton pump inhibitor at a maximally tolerated dose for a minimum of 8 weeks • Member has a documented weight greater than or equal to 40 kg • The prescribed dose is within FDA approved dosing guidelines <u>Prurigo Nodularis (PN) (*Dupixent only):*</u> • Confirmed diagnosis of PN lasting for at least three months prior to request • Member has a Worst-itch Numeric Rating Scale (WI-NRS) score of 7 or higher indicating severe or very severe itching • Member has at least 20 PN lesions in total • Documented trial and failure, intolerance, or contraindication to at least two of the following for a minimum of two weeks: o One medium to super-high potency topical corticosteroid

Revision/Review Date: 9/2023	○ One topical calcineurin inhibitor ○ UVB phototherapy or psoralen plus UVA phototherapy • The prescribed dose is within FDA approved dosing guidelines <u>Eosinophilic granulomatosis with polyangiitis (EGPA) (*Nucala only*):</u> • Confirmed diagnosis of EGPA and eosinophilic asthma lasting for ≥ 6 months • Member has a history of relapsing disease defined as at least one EGPA relapse requiring additional corticosteroids or immunosuppressant or hospitalization within the past 2 years OR member has a history of refractory disease defined as failure to attain remission in the prior 6 months following induction treatment with standard therapy • Member must be on a stable dose of oral corticosteroids for at least 4 weeks prior to request • Member has a blood eosinophil count ≥1,000 cells/mcL OR > 10% of total leukocyte count • Documented trial and failure, intolerance, or contraindication to one of the following: cyclophosphamide, rituximab, azathioprine, methotrexate., or mycophenolate mofetil. • The prescribed dose is within FDA approved dosing guidelines <u>Hypereosinophilic Syndrome (HES) (*Nucala only*):</u> • Confirmed diagnosis of FIP1 like 1-platelet derived growth factor receptor alpha-negative HES lasting for ≥6 months without an identifiable non-hematologic secondary cause • Member has a history of two or more HES flares (worsening of HES-related symptoms necessitating therapy escalation or ≥2 courses of rescue oral corticosteroids) within the past 12 months • Member has a blood eosinophil count ≥1,000 cells/mcL • Documented trial and failure, intolerance, or contraindication to oral corticosteroids AND at least one second-line agent (e.g. hydroxyurea, interferon, imatinib, methotrexate, cyclophosphamide, cyclosporine, azathioprine) (member must be on stable dose of at least one agent for at least 4 weeks prior to request) **<u>Re-Authorization:</u>** • Documentation submitted indicates the member has experienced a clinical benefit from the medication (e.g. Asthma: 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) • 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	**Natriuretic Peptides for Achondroplasia**
Drugs	Voxzogo (vosoritide)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Hypochondroplasia or short stature condition other than achondroplasia
Required Medical Information	See "Other Criteria"
Age Restrictions	According to FDA approved prescribing information
Prescriber Restrictions	Prescribed by, or in consultation with, an endocrinologist, medical geneticist, or other specialist for the treatment of achondroplasia
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 3/2023	**Initial Authorization:** • Member has a diagnosis of achondroplasia as confirmed via genetic testing • Prescriber attests patient has open epiphyses: • Documentation is provided of baseline recent (within the past 6 months) growth velocity ≥1.5 cm/year • Medication is prescribed at an FDA approved dose **Re-Authorization:** • Documentation of positive clinical response to therapy (as demonstrated by improvement over baseline in annualized growth velocity) • Prescriber attests patient has open epiphyses • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Prior Authorization Group Description	**Neuromyelitis Optica Spectrum Disorder (NMOSD) Agents**
Drugs	Step 1: Rituximab (Rituxan, Truxima, Ruxience, Riabni) Enspryng (satralizumab-mwge) Uplizna (inebilizumab-cdon) Step 2: Soliris (eculizumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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: Anti-aquaporin-4 (AQP4) antibody **negative** neuromyelitis optica spectrum disorder (NMOSD)
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a specialist who is experienced in the treatment of NMOSD (such as immunologist, neurologist or hematologist)
Coverage Duration	If all of the conditions are met, requests will be approved for 12 months.
Other Criteria	**Initial Authorization:** For rituximab (Rituxan, Truxima, Ruxience, Riabni): • Member has a diagnosis of NMOSD • Documentation indicating that the patient has been screened for hepatitis B virus (HBV) prior to initiation of treatment • Dosing is supported by compendia or standard of care guidelines • If the request is for a rituximab product other than Ruxience (rituximab-pvvr) or Riabni (rituximab-arrx), there is a documented trial and failure of Ruxience (rituximab-pvvr) or Riabni (rituximab-arrx), or a medical reason why (e.g. intolerance, hypersensitivity, contraindication) they cannot be used For Enspryng or Uplizna: • 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 as outlined in the prescribing information: o Hepatitis B virus screening o Tuberculosis screening o Patient has not received live or attenuated-live virus vaccines within 4 weeks before the start of therapy o Liver transaminase screening (Enspryng only) o Quantitative serum immunoglobulins (Uplizna only) • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines For Soliris: • Member has a diagnosis of anti-aquaporin-4 (AQP4) antibody **positive** NMOSD

Revision/Review Date: 12/2023	• Documentation (including date) of vaccination against meningococcal disease or a documented medical reason why the patient cannot receive vaccination or vaccination needs to be delayed • Antimicrobial prophylaxis with oral antibiotics for two weeks if the meningococcal vaccine is administered less than two weeks before starting therapy, or a documented medical reason why the patient cannot receive oral antibiotic prophylaxis • Documented trial and failure or medical reason (e.g., intolerance, hypersensitivity, contraindication) why member cannot use TWO of the following: o Rituximab o Enspryng o Uplizna • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines **<u>Reauthorization:</u>** • Documentation that the prescriber has evaluated the member and recommends continuation of therapy (clinical benefit) • Request is for an FDA approved/medically accepted dose **Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Prior Authorization Group Description	**Ocaliva**
Drugs	Ocaliva (obeticholic acid)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restriction	Member must be 18 years of age or older
Prescriber Restrictions	Prescribed by, or working in consultation with, a hepatologist or gastroenterologist
Coverage Duration	If the criteria are met, the request will be approved for 6 months for initial authorization and for 12 months for reauthorization.

Other Criteria
 	
Revision/Review Date: 03/2023
	Initial Authorization:
	• Diagnosis of primary biliary cholangitis (PBC) with confirmation of diagnosis by two of the following tests:
	  o Positive antimitochondrial antibody test
	  o Elevated serum alkaline phosphatase level
	  o Imaging of the liver and biliary tree
	• Dose is appropriate according to labeling
	• Ocaliva is being added to ursodeoxycholic acid (UDCA) due to inadequate response for at least 1 year; OR member is unable to tolerate or has a contraindication to UDCA and is taking Ocaliva as monotherapy
	• Prescriber attests the member does not have complete biliary obstruction, decompensated cirrhosis (e.g. Child-Pugh Class B or C) or compensated cirrhosis (Child-Pugh Class A) with evidence of portal hypertension
	• Submission of the following test results within 30 days of request:
	  o Serum alkaline phosphatase (ALP)
	  o Total bilirubin
	
	Reauthorization:
	• 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); defined as 118 U/L for females and 124 U/L for males
	  o Total bilirubin ≤ ULN defined as 1.1 mg/dL for females and 1.5 mg/dL for males
	• Prescriber attests that the member has not developed complete biliary obstruction, decompensated cirrhosis (e.g. Child-Pugh Class B or C) or compensated cirrhosis (Child-Pugh Class A) with evidence of portal hypertension
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary

Field Name	Field Description
Prior Authorization Group Description	**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	Patient 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 the criteria are met, the initial request will be approved for a one-time treatment.
Other Criteria Date: 09/2023	****Drug is being requested through the member's medical benefit**** **Initial Authorization:** • Patient has a hematologic malignancy planned for umbilical cord blood transplantation (UCBT) following myeloablative conditioning • Prescriber attests that the patient 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 • Patient has not received a prior allogenic HSCT • Patient 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 Description	**Oncology Drugs/Therapies**
Drugs	Oncology drugs and Oncology Gene Therapies (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), the American Society of Clinical Oncology (ASCO).
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be an oncologist or a specialist in the type of cancer being treated
Coverage Duration	If the criteria are met, the request will be approved for up to 6 months.

Other Criteria	**All of the following criteria must be met:** • Requested use must be a labeled indication or supported by NCCN Category 1 or 2A level of evidence. If the request is for an off-label use supported by NCCN as a Category 2B recommendation then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g. allergic reaction, contraindication) • Documentation has been provided of the results of genetic testing where required per drug package insert • Documentation has been provided of results of all required laboratory values and patient specific information (e.g. weight, ALT/AST, serum creatinine, absolute neutrophil count etc.) necessary to ensure the patient has no contraindications to therapy per drug package insert •The product is being prescribed at a dose that is within labeling and/or NCCN guidelines. • If the request is for a brand name drug, the prescriber must provide a medical reason why the generic cannot be used (when a generic is available). o If the request is for abiraterone 500 mg tablets, prescriber must submit a medical reason why two tablets of generic abiraterone acetate 250 mg cannot be used • 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 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 o The provider has verbally, or in writing, submitted a member-specific reason why the reference biologic product is required based on the member's condition or treatment history; **AND** if the member had side effects or a reaction to the biosimilar or interchangeable biologic, the provider has completed and submitted an FDA MedWatch form to justify the member's need to avoid these drugs. MedWatch form must be included with the prior authorization request. Form FDA 3500 – Voluntary Reporting **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**
Revision/Review Date: 06/2023	

Prior Authorization Group Description	**Opioid-containing Products**
Drugs	Any opioid being filled for a cumulative morphine milligram equivalent (MME) dose of greater than 90 MME per day or any opioid being filled for > 7 days for a member that has not filled an opioid drug in the past 90 days.
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex (DRUGDEX), American Hospital Formulary Service (AHFS), United States 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	N/A
Age Restrictions	Per package insert
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved for up to 6 months.

Other Criteria	***If the member has **cancer**, is on **hospice**, or is a resident of a **long-term care facility**, the criteria below do not apply. Please authorize for up to 12 months (member must meet non-formulary criteria if request is for non-formulary medication)*** Initial authorization for opioid-containing products: 1. The diagnosis is pain. For long-acting products, the diagnosis is chronic pain that requires daily, around the clock, opioid medication. 2. The member has tried and failed non-pharmacologic treatment and two non-opioid containing pain medications (ex. acetaminophen, non-steroidal anti- inflammatory drugs (NSAIDs), select antidepressants, anticonvulsants). 3. The prescriber has justified medical necessity for dosing above 90 MME per day and/or above the day supply limit. 4. Member is not taking a benzodiazepine. If member is taking a benzodiazepine, prescriber has provided documentation as to why and has discussed risks of using opioids and benzodiazepines together. 5. Prescriber attests that urine drug screens will be completed every 6 months and if illicit drugs are found, the member will be identified as high risk and the heightened risk of overdose will be explained to the member. 6. Prescriber attests to checking the Minnesota Prescription Monitoring Program (PMP) for member history. 7. Prescriber attests to discussing with the member the level of risk for opioid abuse/overdose with the dose/duration prescribed. 8. If member has a high-risk condition stated in the CDC guidelines (ex. sleep apnea or other causes of sleep-disordered breathing, renal or hepatic insufficiency, older adults, pregnant women, depression or other mental health conditions, alcohol or other substance use disorders) prescriber attests to discussing heightened risks of opioid use and has educated the member on naloxone use and has considered prescribing naloxone. 9. Prescriber attests that the member has entered into a pain management agreement (members in a facility are exempt from this requirement). 10. If the request is for a non-formulary opioid, member must meet the criteria above AND documented trial and failure or intolerance with at least 2 formulary medications used to treat the diagnosis. Reauthorization for opioid-containing products: 1. The member's dose has been tapered down since the initial authorization. If it has not, the prescriber has explained medical necessity for continued dosing above 90 MME per day and/or above the day supply limit and has provided a proposed plan for tapering the dose down in the future. 2. The provider has submitted documentation of member's response to the requested medication (ex. improvement in pain severity, improvement in ADL's, etc.) 3. Member is not taking concurrent benzodiazepines. If member requires benzodiazepines, prescriber has provided documentation as to why and has discussed risks of using opioids and benzodiazepines together. 4. Urine drug screen has been conducted every 6 months and results have been submitted with the request. If illicit drugs are found, prescriber has explained heightened risk of overdose to member. If opioids are not found on urine drug screen, prescriber has documented why member needs to continue opioid therapy. 5. Prescriber attests to checking the Minnesota Prescription Monitoring Program (PMP) for member history. **If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.**
Revision/Review Date: 6/2023	

Prior Authorization Group Description	**Oral Retinoids**
Drugs	**Formulary (preferred) products (require PA):** • Claravis (isotretinoin) • Myorisan (isotretinoin) • Zenatane (isotretinoin) • Amnesteem (isotretinoin) • Isotretinoin **Non-formulary (non-preferred) products:** • Absorica, Absorica LD (isotretinoin) • Or any newly marketed oral retinoid product
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved for 6 months.
Other Criteria Revision/Review Date: 12/2023	**Initial Authorization** • Diagnosis of moderate to severe recalcitrant nodular acne • Documented treatment with a therapeutic trial and failure, intolerance to, or medical reason for not using, one or more first line topical therapies (e.g. topical antibiotics or topical retinoids) IN COMBINATION WITH one or more first line oral antibiotic therapies (e.g. doxycycline, minocycline, tetracycline, erythromycin) for at least 28 days of therapy in the previous 60 days. • Dose is appropriate for member • If the request is for a brand product, documented trial and failure or intolerance to a generic product is required. • If the request is for a non-preferred drug, documentation has been provided that the member has tried and failed two preferred drugs or has a medical reason why these drugs cannot be used **Reauthorization** • Documentation that the member has experienced clinical benefit from therapy and continue treatment, 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	**Gonadotropin Releasing Hormone Antagonists**
Drugs	Orilissa (elagolix) Oriahnn (elagolix, estradiol, and norethindrone acetate) Myfembree (relugolix, estradiol, and norethindrone acetate)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	• Pregnancy • History of osteoporosis • History of hepatic impairment (Myfembree, Oriahnn), or severe hepatic impairment (Orilissa)
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be 18 years of age or older
Prescriber Restrictions	Prescriber must be an obstetrician/gynecologist
Coverage Duration	If the criteria are met, the request will be approved as outlined below: • Initial Authorization: 6 months • Reauthorization: 6 months • Eligible maximum lifetime treatment duration: 24 months
Other Criteria	<u>Initial Authorization for all requests:</u> • Medication is prescribed at an FDA approved dose • If patient is of childbearing potential, prescriber attests the patient is not currently pregnant • Prescriber attests the patient does not have a history of osteoporosis • Prescriber attests they have reviewed the patient's liver function <u>For a diagnosis of endometriosis associated with moderate to severe pain:</u> • Request is for Orilissa or Myfembree only • Documented trial and failure or medical reason for not using analgesic pain reliever (ex. NSAIDs, COX-2 inhibitors, opioids) taken in combination with combined estrogen-progestin oral contraceptives o If one of the following drugs has been tried previously, a trial of oral contraceptives is not required: progestins (oral, implant, or intrauterine device), gonadotropin-releasing hormone (GnRH) agonists, aromatase inhibitors (e.g. letrozole, anastrozole), or danazol <u>For a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids):</u> • Request is for Oriahnn or Myfembree only • Documented trial and failure or medical reason for not using estrogen-progestin contraceptive therapy • If one of the following drugs has been tried previously, a trial of estrogen-progestin contraceptive therapy is not required: o gonadotropin-releasing hormone (GnRH) agonists, o progestin-releasing intrauterine device o tranexamic acid

Revision/Review Date: 3/2023	Reauthorization: • Maximum lifetime treatment duration based on previous dosing and/or hepatic functioning has not been exceeded • Documentation or provider attestation of positive clinical response (e.g., reduction in pain, reduced heavy menstrual bleeding). • Medication is prescribed at an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Oxbryta (voxelotor)**
Drugs	Oxbryta (voxelotor) 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 FDA-approved prescribing information
Prescriber Restrictions	Prescriber must be a hematologist or sickle cell disease specialist
Coverage Duration	Initial requests may be approved for up to 6 months. Reauthorization requests may be approved for 12 months.
Other Criteria Revision/Review Date: 9/2023	**Initial Authorization:** • Member has a confirmed diagnosis of sickle cell disease • Baseline labs have been submitted for the following: o Hemoglobin (Hb) o Indirect bilirubin o Reticulocytes • For members 12 years of age and older, documentation was provided that the member has had 1 or more vaso-occlusive/pain crises in the last 12 months • Member has a baseline Hb level less than or equal to 10.5 g/dL • Documentation was provided that the member has been taking hydroxyurea at the maximum tolerated dose and was compliant within the last 6 months as evidenced by paid claims or medical records (or a medical reason was provided why the patient is unable to use hydroxyurea) • Request is for an FDA-approved dose **Reauthorization:** o Documentation of ONE of the following: ▪ Hb increase from baseline (at 6 months from initiation) or maintenance of such Hb increase (at 12-month intervals thereafter) ▪ Documentation of a reduced number of vaso-occlusive/pain crises since Oxbryta was started ▪ Improvement from baseline in hemolytic markers (e.g., indirect bilirubin, percent reticulocyte count) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Oxlumo (lumasiran)**
Drugs	Oxlumo (lumasiran)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a nephrologist, urologist, hepatologist, endocrinologist or is working in consultation with one of these specialists
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.

Other Criteria
 	
Revision/Review Date: 3/2023
	<u>Initial Authorization</u>
	• Diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by evidence of elevated urinary oxalate excretion and one of the following:
	  o At least one mutation at the AGXT gene
	  o Liver biopsy
	• Metabolic testing demonstrating one of the following
	  o Increased urinary oxalate excretion (≥ 0.5 mmol/1.73 m3 per day[45 mg/1.73 m3 per day])
	  o Increased urinary oxalate:creatinine ratio relative to normative values for age
	  o Increased plasma oxalate level (≥20 μmol/L)
	• 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
	• Prescriber attests that medical management strategies (high fluid intake, calcium-oxalate crystallization inhibitors such as citrate, magnesium, and pyrophosphate) are being employed as appropriate, or the member has a medical reason for not using these strategies
	• Member has no history of liver transplant
	• Medication is prescribed at an FDA approved dose
	
	<u>Reauthorization</u>
	• Members previously using medical management strategies (e.g.pyridoxine,calcim-oxalate crystallization inhibitors) will continue to use these medications, or have a medical reason for not using them
	• Prescriber attests that the member continues to maintain increased fluid intake
	• Documentation has been provided that demonstrates a clinical benefit (e.g. symptomatic improvement, reduction in urinary or plasma oxalate levels from baseline)
	• Medication is prescribed at an FDA approved dose
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Prior Authorization Group Description	**Palynziq (pegvaliase-pqpz)**
Drugs	Palynziq (pegvaliase-pqpz)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	None
Required Medical Information	See “other criteria”
Age Restrictions	Member must be 16 or older
Prescriber Restrictions	Specialist experienced in the treatment of phenylketonuria (PKU)
Coverage Duration	Initial authorization: 12 months Dose increases (to 40 mg or 60 mg daily): 16 weeks Reauthorization: 12 months

Other Criteria	INITIAL AUTHORIZATION: • Documentation of a confirmed diagnosis of phenylketonuria (PKU) • Documentation the member's blood Phe level is greater than 600 micromol/L(include lab results; must be within the past 90 days) • Documentation consistent with order forms or receipts that the member has attempted control of PKU through a Phe-restricted diet with Phe-free medical products/foods in conjunction with a dietician or nutritionist. (e.g. Phenyl-Free (phenylalanine free diet powder), Loplex, Periflex, Phlex-10, PKU 2, PKU 3, XPhe Maxamaid, XPhe Maxamum,) • Member has trialed therapy with sapropterin (Kuvan) and either had an inadequate response, was a non-responder, or has a medical reason they cannot trial sapropterin (Kuvan). • The medication is being prescribed at a dose no greater than the FDA approved maximum initial dose of 20 mg SQ once daily. AUTHORIZATION FOR DOSE INCREASE: • Documentation of recent blood Phe level results (within the past 90 days) • The medication is being prescribed at an FDA approved dose • Documentation of one of the following: o Member has maintained a dose of 20 mg daily for at least 24 weeks and did not achieve the desired treatment response o Member has maintained a dose of 40 mg daily for at least 16 weeks and did not achieve the desired treatment response REAUTHORIZATION: • Documentation of recent blood Phe level results (within the previous 90 days). • The medication is being prescribed at an FDA approved dose. • Member has achieved a treatment response as demonstrated by one of the following: o At least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline o A blood phenylalanine concentration less than or equal to 600 micromol/L.
Revision/Review Date: 9/2023	Clinical reviewer/Medical Director must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Prior Authorization Group Description	**Proprotein Convertase Subtilisin/kexin 9 (PCSK9) Inhibitors**
Drugs	**PDL Non-Preferred:** • Praluent (alirocumab) • Repatha (evolocumab) • 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	Prescriber must be a cardiologist or specialist in the treatment of lipid disorders.
Coverage Duration	If the conditions are met, the request will be approved for 3 months for initial requests and for up to 12 months for reauthorization requests.
Other Criteria	**<u>Initial Authorization</u>** For all requests: • Request is appropriate for member (e.g. age) as indicated in labeling or standard of care guidelines • Member has tried and failed atorvastatin 40-80 mg or rosuvastatin 20-40 mg (taken consistently for 3 months via claim history or chart notes). If patient is not able to tolerate atorvastatin or rosuvastatin, documentation was provided that patient is taking another statin at the highest tolerated dose, or a medical reason was provided why the member is not able to use these therapies. o If prescriber indicates member is "statin intolerant", documentation was provided including description of the side effects, duration of therapy, "wash out", re-trial, and change of agents. • Member has tried and failed ezetimibe at a maximal tolerated dose OR one of the following: o Patient 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 o Documentation has been provided that the patient is not able to tolerate ezetimibe • Documentation was provided indicating provider has counseled member on smoking cessation and following a "heart healthy diet". <u>Familial Hypercholesterolemia (FH):</u> • Member has a diagnosis of FH as evidenced by one of the following: o Documentation provided including two fasting lipid panel lab reports with abnormal low density lipoprotein (LDL) levels ≥190 for FH in adults or ≥160 for FH in children. o Results of positive genetic testing for an LDL-C–raising gene defect (LDL receptor, apoB, or PCSK9). • Additionally, if the diagnosis is heterozygous FH (HeFH), ALL of the following: o Documentation of LDL ≥ 100 mg/dL within the last 120 days despite

maximally tolerated LDL-lowering therapy

<u>Hyperlipidemia (Primary OR Secondary Atherosclerotic Cardiovascular Disease [ASCVD] Prevention)</u>

- If the diagnosis is primary severe hyperlipidemia (i.e. LDL ≥ 190 mg/dL):
  - Documentation that LDL remains ≥ 100 mg/dL within the last 120 days despite maximally tolerated LDL-lowering therapy

- If the diagnosis is secondary ASCVD prevention
  - The patient is "very high risk" (i.e. a history of multiple major ASCVD ***<u>events</u>*** or 1 major ASCVD event and multiple high-risk ***<u>conditions</u>***, see table below)

Major ASCVD Events	Recent ACS (within past 12 months)
	History of MI (other than recent ACS event above)
	History of ischemic stroke
	Symptomatic PAD
High-risk Conditions	Age ≥ 65 years
	Heterozygous familial hypercholesterolemia
	History of prior CABG or PCI intervention outside the major ASCVD event(s)
	DM
	HTN
	CKD (eGFR 15-59 mL/min/1.73 m2)
	Current smoker
	CHF

ACS – acute coronary syndrome; CABG – coronary artery bypass graft; CHF – congestive heart failure; CKD – chronic kidney disease; DM – diabetes mellitus; HTN – hypertension; MI – myocardial infarction; PAD – peripheral artery disease; PCI – percutaneous coronary intervention

  - Documentation that LDL remains ≥ 55 mg/dL or non-HDL (i.e. total cholesterol minus HDL) ≥ 85 mg/dL within the last 120 days despite maximally tolerated LDL-lowering therapy

Revision/Review Date: 3/2023

<u>Reauthorization for all indications:</u>

- Repeat fasting lipid panel shows reduction in LDL from baseline (prior to starting PCSK9 inhibitor). The patient'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	**Peanut Allergy Immunotherapy Agents (FDA Approved)**
Drugs	Palforzia [Peanut (Arachis hypogaea) Allergen Powder-dnfp] capsule/sachet
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Initiation: Patient is age 4-17 years. Up dosing and maintenance: Patient is age ≥ 4 years
Prescriber Restrictions	Prescriber is a specialist in the area of allergy/immunology
Coverage Duration	6 months
Other Criteria Revision/Review Date: 06/2023	**<u>Initial Authorization:</u>** Palforzia is approved when all of the following criteria are met: • Patient has a confirmed diagnosis of peanut allergy • For patients starting initial dose escalation (new to therapy) ○ Patient has not had a severe or life-threatening anaphylaxis within the previous 60 days • Patient will follow a peanut-avoidant diet • Patient has been prescribed and has acquired (as demonstrated by pharmacy claims or documentation) injectable epinephrine • No history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease • Patient does not have uncontrolled asthma **<u>Criteria for Re-Authorization:</u>** Palforzia is approved for re-authorization when all of the following criteria are met • Patient will follow a peanut-avoidant diet • Patient is able to tolerate at least the 3 mg dose daily • Patient is able to comply with the daily dosing requirements • Patient does not have recurrent asthma exacerbations or persistent loss of asthma control • Patient has been prescribed and has acquired (as demonstrated by pharmacy claims or documentation) injectable epinephrine

Prior Authorization Group Description	**Pediculicides**
Drugs	**<u>Preferred</u>** • Natroba (BRAND) topical suspension • permethrin cream • piperonyl butoxide/pyrethrins shampoo (OTC) **<u>Non-preferred</u>** • lindane shampoo • malathion (Ovide) lotion • ivermectin (Sklice) lotion • spinosad topical suspension • Crotan (crotamiton) lotion • or any newly marketed pediculicide
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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	Appropriate age per package insert
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved for initial treatment course. For reauthorization, a maximum of 2 treatments in a 30 day period will be approved.
Other Criteria Revision/Review Date: 9/2023	**<u>Initial Authorization:</u>** • Diagnosis of pediculosis capitus (head lice and its eggs) or scabies • One of the following: o Documented intolerance or hypersensitivity to two preferred agents o Documented trial and failure of at least two preferred agents within the previous 45 days, but no earlier than 7 days after the original fill; or a reason was provided as to why preferred agents cannot be used **<u>Re - Authorization:</u>** • Natroba can be approved for a second treatment if live lice are present 7 days after the initial treatment. • Malathion (Ovide) can be approved for a second treatment if live lice are present 7-9 days after the initial treatment. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Potassium-removing agents**
Drugs	**Veltassa (patiromer), Lokelma (sodium zirconium cyclosilicate)**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	Patient is 18 years of age or older
Prescriber Restrictions	Prescriber is a cardiologist, nephrologist or transplant specialist or in consultation with one of these specialties
Coverage Duration	If the criteria are met, the request will be approved with up to a 3 month duration for initial requests and up to 6 months for renewal requests
Other Criteria	**Initial Authorization** • Diagnosis of hyperkalemia • Documentation patient has been counseled to follow a low potassium diet • Where clinically appropriate, documentation of medications known to cause hyperkalemia (e.g. angiotensin-converting enzyme inhibitor, angiotensin II receptor blocker, aldosterone antagonist, NSAIDs) have been discontinued or decreased to lowest effective dose **Re-Authorization** • Documentation that demonstrates member is receiving clinical benefit from treatment (e.g. potassium level returned to normal or significant decrease from baseline).
Revision/Review Date 06/2023	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Pulmonary Arterial Hypertension (PAH)**	
Drugs	Preferred: ambrisentan sildenafil tablets sildenafil suspension Tracleer tablets (BRAND)	Non-preferred/Non-Formulary: Adcirca, Alyq (tadalafil) Adempas (roiciguat) bosentan epoprostenol (Flolan,Veletri) Letairis (BRAND) Opsumit (macitentan) Orenitram ER (treprostinil) Revatio (sildenafil) tadalafil Tracleer (bosentan) suspension treprostinil (Remodulin) Tyvaso (treprostinil) Tadliq (tadalafil) Uptravi (selexipag) Ventavis (iloprost) any other newly marketed PAH treatment
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.	
Exclusion Criteria	N/A	
Required Medical Information	"See other criteria"	
Age Restrictions	N/A	
Prescriber Restrictions	Prescriber must be a pulmonologist or cardiologist, or working in consultation with one of these specialists	
Coverage Duration	Orenitram, Tyvaso, Adempas, or Ventavis: 3 months for initial request Uptravi: Request will be approved for the titration pack for 28 days until the highest tolerated dose (maintenance dose) is achieved. Once the member has achieved maintenance dosing, further refills can be approved for a 6 month duration. For all others, if all of the above conditions are met, the initial request will be approved for a 6 month duration. All refill requests will be approved for a 6 month duration.	
Other Criteria	**Initial Authorization:** • Medication is being used within labeled indications and dosing • Documentation of that the member has undergone acute vasoreactivity testing and whether or not the results were favorable. For members with a favorable response to acute vasoreactivity testing, defined as a reduction in mean pulmonary arterial pressure [PAPm] of at least 10 mm Hg to < 40 mm Hg with an increased or unchanged cardiac output), then documentation has been provided that the member's pulmonary hypertension has progressed despite maximal medical treatment with a calcium channel blocker, or documentation has been provided of medical reason why member is not able to use a calcium channel blocker. • For epoprostenol injection, treprostinil injection, or bosentan (Tracleer) requests, documentation of the patient's current weight is required • If a non-preferred drug is being requested, the member has had a trial of at least two preferred chemically unique drugs within the same drug class, or a trial of at least one preferred drug within the same drug class if there are not two chemically unique	

Revision/Review Date: 3/2023	preferred drugs within the same drug class; or documentation was provided as to why the member cannot use preferred drugs • For Orenitram, Tyvaso, Adempas, Ventavis, and Uptravi requests, documentation of current dosing and titration schedule is required. • If the request is for Tyvaso, Ventavis or Uptravi, and the patient has functional class II or III, documentation has been provided that the patient has tried and failed a phosphodiesterase-5 inhibitor (e.g. sildenafil) and an endothelin receptor antagonist (e.g. ambrisentan), or a medical reason has been submitted why the patient is not able to use BOTH of these therapies before starting Tyvaso, Ventavis or Uptravi. • For combination therapy with two or three agents, documentation of adequate trial with monotherapy (or dual therapy if the request is for three agents) or medical reason as to why monotherapy (or dual therapy) is not appropriate (e.g. worsening of the symptoms of dyspnea or fatigue, decline in functional class by at least one class or in 6-minute walk distance (6MWD) by greater than 30 meters) while on therapy. **Re-authorization:** • Documentation has been submitted indicating the clinical benefit of therapy (e.g. improvement in functional class, improvement in 6-minute walk test, exercise capacity, or hemodynamics). • If dosing is being increased, documentation of the medical necessity to increase the dose is provided. • For Orenitram, Tyvaso, Adempas, Ventavis, and Uptravi requests, documentation of current dosing and titration schedule is required. • The medication is being prescribed by a pulmonologist or a cardiologist 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	Prescriber must be an appropriate specialist or documentation has been provided that prescriber has consulted with an appropriate specialist (i.e. infectious disease, OB/GYN).
Coverage Duration	Toxoplasmosis • primary prophylaxis - 3 months at a time. • - 6 weeks. • congenital toxoplasmosis - up to 12 months. • secondary prophylaxis (i.e., chronic maintenance) - 3 months at a time. • in pregnancy - 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 for pyrimethamine should be accompanied by a prescription for leucovorin.**
	
	<u>Toxoplasmosis:</u>
	• Primary Prophylaxis:
	  o A medical reason must be provided as to why the patient is not able to use trimethoprim-sulfamethoxazole or atovaquone
	  o For adults with HIV: documentation of CD4 count < 200 cells/µL
	• Treatment:
	  o Adults and adolescents: must be used in combination with a sulfonamide or clindamycin.
	  o Pediatrics (congenital and acquired): must be used in combination with sulfadiazine
	• Secondary Prophylaxis (i.e., chronic maintenance treatment)in patient **not** initially treated with a pyrimethamine regimen, a medical reason must be provided as to why the patient is not able to continue with an alternative regimen for maintenance.
	• Toxoplasmosis in pregnancy:
	  o PMust be used in combination with sulfadiazine.
	  o Member must have reached at least 18 weeks gestation.
	<u>Cystoisosporiasis:</u>
	• Treatment: a medical reason must be provided as to why the patient is not able to be treated with trimethoprim-sulfamethoxazole
	• Secondary Prophylaxis:
	  o The patient was previously diagnosed with, and completed a treatment regimen for cystoisosporiasis
	  o If patient was not previously treated with a pyrimethamine regimen for the treatment of cystoisosporiasis, a medical reason was provided why the patient is not able to continue the medications used for treatment
	  o 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:
	  o 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 trimethoprim-sulfamethoxazole, dapsone, aerosolized pentamidine, or atovaquone.
	• Secondary Prophylaxis:
	  o For adults with HIV:
	  ▪ The patient was previously diagnosed with, and completed a treatment regimen for pneumocystis pneumonia
	  ▪ If patient was not previously treated with a pyrimethamine regimen, a medical reason was provided why the patient is not able to continue the medications used for treatment.
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Revision/Review Date: 6/2023	

Field Name	Field Description
Prior Authorization Group Description	**Pyruvate Kinase Activators**
Drugs	Pyrukynd (mitapivat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Age ≥18 years
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	If the conditions are met, the request will be approved for a 6-month duration for initial requests and a 6-month duration for renewal requests. **If the conditions are not met: may approve up to 14 days of a Pyrukynd Taper Pack to allow for discontinuation tapering
Other Criteria Revision/Review Date: 9/2023	**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 • Prescriber attests that the member has not had a splenectomy in the past 12 months • Prescriber attests that the member does not have a history of a prior bone marrow or stem cell transplant • The member is not concurrently using hematopoietic-stimulating agents (e.g. Procrit or Retacrit) • Prescriber attests the member is taking at least 0.8mg of folic acid daily

	<u>Reauthorization:</u> • The prescribed dose is within FDA approved dosing guidelines • For the first reauthorization, documentation of benefit: increase in Hb ≥1.5 g/dL over baseline OR a reduction in transfusions, defined as ≥33% reduction in the number of red blood cell (RBC) units transfused over baseline • For subsequent reauthorizations: documentation of benefit: stabilization in Hb levels OR a sustained reduction in transfusions • If the reauthorization criteria are not met, may authorize up to 14 days of a Pyrukynd Taper Pack to allow for tapering. To reduce the risk of acute hemolysis, abrupt discontinuation of Pyrukynd should be avoided. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	Qalsody (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 the criteria are met, initial and renewal requests will be approved for 6 months
Other Criteria Review/Revision Date: 9/2023	****Drug is being requested through the member's medical benefit**** **Initial Authorization:** • Diagnosis of ALS • Documentation of genetic test confirming a mutation in the superoxide dismutase 1 (SOD1) gene • Member is not dependent on invasive ventilation or tracheostomy • Documentation of slow vital capacity (SVC) ≥ 50% • Medication is prescribed at an FDA approved dose **Re-Authorization:** • Documentation or provider attestation of positive clinical response (e.g., reduction in the mean concentration of neurofilament light [NfL] chains in the plasma, reduction in concentration of SOD1 in cerebrospinal fluid (CSF), or improvement in the Revised ALS Functional Rating Scale (ALSFRS-R) total score) • Member is not dependent on invasive ventilation or tracheostomy • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

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	Prescriber must be a hematologist or oncologist
Coverage Duration	Initial requests will be approved for 3 months. Reauthorization requests will be approved for 6 months.

Other Criteria
 	
Revision/Review Date: 12/2023
	Criteria for initial approval:
	• Requested dose is appropriate per labeling
	• The member's weight has been provided with the request
	• The member's most recent hemoglobin level (within the last month) has been provided with the request
	• Diagnosis appropriate per Covered Uses
	• For requests for anemia due to beta thalassemia, documentation of all of the following is required:
	  o Member requires regular RBC transfusions (defined as no transfusion-free period of more than 35 days 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 red blood cell (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 red-cell 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 red blood cell 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
	
	If the above conditions are not met, the request will be referred to a Medical Director for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	Relyvrio (sodium phenylbutyrate and taurursodiol)
Drugs	Relyvrio (sodium phenylbutyrate and taurursodiol)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	See "Other Criteria"
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, neuromuscular specialist, or physician specializing in the treatment of amyotrophic lateral sclerosis (ALS)
Coverage Duration	If all the criteria are met, initial and renewal requests will be approved for 6 months
Other Criteria Revision/Review Date: 6/2023	**Initial Authorization:** • Medication is prescribed at an FDA approved dose • Diagnosis of ALS with onset of symptoms within the previous 18 months • Member is not dependent on invasive ventilation or tracheostomy • Documentation of slow vital capacity (SVC) > 60% **Re-Authorization:** • Documentation or provider attestation of positive clinical response (such as improvement in the Revised ALS Functional Rating Scale (ALSFRS-R) total score) • Member is not dependent on invasive ventilation or tracheostomy • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Prior Authorization Group Description	**Dry Eye Step Therapy**
Drugs	Restasis (cyclosporine) 0.05% multidose Cyclosporine (Restasis) 0.05% ophthalmic emulsion Xiidra (lifitegrast) 5% ophthalmic solution Cequa (cyclosporine) 0.09% 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), or the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Age appropriate per labeling
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved for 12 months.
Step Therapy Criteria Revision/Review Date: 9/2023	Cyclosporine 0.05% ophthalmic emulsion: • Documentation of a trial and failure or intolerance to artificial tears in the last 6 months • New members to the plan who are stable on the requested drug do not require a trial of artificial tears Restasis multidose, Xiidra, Cequa: • Documentation of a trial and failure or intolerance to artificial tears AND cyclosporine ophthalmic emulsion in the last 6 months • New members to the plan who are stable on the requested drug do not require a trial of artificial tears **If all of the criteria are not met, the request will be referred to a Medical Director or clinical reviewer for medical necessity review.**

Prior Authorization Group Description	**Retinoic Acid Derivatives**
Drugs	Preferred Agents: (will pay at POS for members ≤ 30 years of age) • adapalene (Differin) 0.1% gel (Rx) • adapalene (Differin) 0.3% gel • Retin-A (tretinoin) 0.025%, 0.05%, 0.1% cream • Retin-A (tretinoin) 0.01% gel, 0.025% Non-Preferred Agents • adapalene 0.1% cream • adapalene (Differin) 0.1% gel (OTC) • adapalene (Differin) 0.3% gel with pump • Avita (tretinoin) 0.025% cream • Avita (tretinoin) 0.025% gel • tretinoin 0.025%, 0.05%, 0.1% cream • tretinoin microspheres (Retin-A Micro) 0.04%, 0.1% gel • tretinoin microspheres (Retin-A Micro) 0.04%, 0.1% gel with pump • Retin-A Micro 0.06%, 0.08% gel with pump • tretinoin 0.01%, 0.025% gel • tretinoin (Atralin) 0.05% gel • Aklief (trifarotene) 0.005% cream • Fabior (tazarotene) 0.1% foam • adapalene/benzoyl peroxide (Epiduo) 0.1%-2.5% gel with pump • adapalene/benzoyl peroxide (Epiduo Forte) 0.3%-2.5% gel with pump • clindamycin/tretinoin (Ziana) 1.2%-0.025% gel Non-Formulary Agents • adapalene 0.1% lotion • adapalene 0.1% solution • adapalene 0.1% swab • Altreno (tretinoin) 0.05% lotion • Arazlo (tazarotene) 0.045% lotion • tazarotene 0.1% foam • Veltin (clindamycin/tretinoin) 1.2%-0.025% gel • Tazorac (tazarotene) 0.1%, 0.05% cream • Tazorac (tazarotene) 0.1% gel • Differin (adapalene) 0.1% cream • Differin (adapalene) 0.1% gel (OTC) • Differin (adapalene) 0.3% gel, gel with pump • Differin (adapalene) 0.1% lotion • Epiduo Forte (adapalene/benzoyl peroxide) 0.3%-2.5% gel with pump
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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 **cosmetic use,** such as fine wrinkles, mottled hyperpigmentation, or facial skin roughness, are excluded from coverage.
Required Medical Information	See “other criteria”
Age Restrictions	Criteria applies to patients over 30 years of age, preferred agents pay for patients 30 and under

Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved for a maximum of 50 g/30 days for 12 months.
Other Criteria Revision/Review Date: 12/2023	Preferred Agents in members > 30 years of age: • Diagnosis of acne vulgaris or a non-cosmetic, medically-accepted condition Non-Preferred Agents: • Diagnosis of acne vulgaris or non-cosmetic, medically-accepted condition • Documented trial and failure of, or intolerance to, two preferred topical acne medications OR • If the request is for Tazorac for psoriasis, the member has a diagnosis of plaque psoriasis If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.

Prior Authorization Group Description	**Rituximab Agents**
Drugs	Rituxan (rituximab) Rituxan Hycela (rituximab / human hyaluronidase) Truxima (rituximab-abbs) Ruxience (rituximab-pvvr) Riabni (rituximab-arrx)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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 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 "Neuormyelitis 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 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 3 months of more 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 if 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 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 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 dose. If all of the above conditions are met, the request will be approved for up to a 1 year 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 • The member is receiving *P. jirovecii pneumonia* (PCP) prophylaxis (e.g. 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 was provided with the request • Rituximab is being used in combination with a tapering course of glucocorticoids. • Rituximab is being prescribed at an FDA approved dose/frequency. If all of the above conditions are met, the request will be approved for up to a 1 month duration. **Reauthorization:** • Documentation of clinical benefits (e.g. absence of new lesions) with rituximab therapy was provided by a rheumatologist or dermatologist • The member is receiving 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 1 year duration. If all the above criteria are not met, the request will be referred to a Medical Director/clinical reviewer for medical necessity review.

ONCOLOGY INDICATIONS

Initial Authorization

- The medication is being prescribed by an oncologist.
- Requested use must be a labeled indication or supported by NCCN Category 1 or 2A level of evidence. If the request is for an off-label use supported by NCCN as a Category 2B recommendation then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g. allergic reaction, contraindication)
- Documentation indicates that the member has been screened for HBV (hepatitis B virus) 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 apply:
    - 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
    - A medical reason has been submitted as to why the hyaluronidase formulation is required

If all of the above conditions are met, the request will be approved for up to 3 months.

Reauthorization:

- The medication is being 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 3 months.

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

Initial Authorization

- The medication is being prescribed by a rheumatologist or nephrologist.
- The member is 2 years of age or older and has a documented clinical diagnosis GPA (Wegener's Granulomatosis), EGPA, or MPA AND the prescriber indicates whether this is severe or non-severe disease.
- 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 3 months of glucocorticoid (i.e. prednisone) AND methotrexate, OR glucocorticoid AND cyclophosphamide (Cytoxan) OR documentation includes a medical reason

	(intolerance, hypersensitivity, etc.) why member is not able to use these therapies to manage the condition. o For members with severe GPA or MPA, this is not required. • Documentation indicates that rituximab is being used concurrently with glucocorticoids. • Documentation indicates that the member has been screened for HBV prior to initiation of treatment. • Documentation the patient 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 • Rituximab is being prescribed at an FDA-approved dose. • If the patient 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 all of the above conditions are met, the request will be approved for up to a 1 month duration. **Reauthorization:** • The medication is being recommended and prescribed by a rheumatologist or nephrologist. • Documentation the patient will be receiving *P. jirovecii pneumonia* (PCP) prophylaxis (ex. TMP/SMX, dapsone, atovaquone) during treatment or the prescriber has provided a medical reason for not prescribing PCP prophylaxis • Rituximab is being prescribed at an FDA-approved dose. If all of the above conditions are met, the request will be approved for up to a 1 year duration; if all the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review. **DERMATOMYOSITIS (DM) and POLYMYOSITIS (PM)** **Initial Authorization:** • Rituximab is being recommended and prescribed by a neurologist, rheumatologist, or dermatologist. • Patient meets one of the following: 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) • Patient does NOT have cancer associated myositis defined as myositis within 2 years of cancer diagnosis (except basal or squamous cell skin cancer or carcinoma in situ of the cervix that has been excised and cured) • One of the following: o Patient 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

Revision/Review Date: 12/2023	as defined in the Social Security Act and/or per the American Academy of Pediatrics (AAP) standard of care guidelines and has a Class I or IIa recommendation). • If the request is for any medication other than Ruxience (rituximab-pvvr) there is a documented trial and failure of Ruxience (rituximab-pvvr), or medical reason why (e.g. intolerance, hypersensitivity, contraindication) Ruxience (rituximab-pvvr) cannot be used. If all of the above conditions are met, the request will be approved for up to a 1 month duration; **Re-authorization:** • Rituximab is being recommended and prescribed by a neurologist, rheumatologist, or dermatologist. • Documentation was provided indicating that the patient had clinical benefit from receiving rituximab therapy. • Rituximab is prescribed at a medically accepted dose per the medical compendia. If all of the above conditions are met, the request will be approved for up to a 3 month duration; **OTHER MEDICALLY ACCEPTED INDICATIONS:** **Initial Authorization**: • The medication is being prescribed for a non-FDA approved indication considered to be a medically accepted use of the drug per the medical compendia (Micromedex, American Hospital Formulary Service (AHFS), DrugPoints, the Drug Package Insert) as defined in the Social Security Act or the American Academy of Pediatrics (AAP) standard of care guidelines and has a Class I or IIa recommendation. • The medication being is prescribed at a medically accepted dose per the medical compendia as defined above • The medication is prescribed by a specialist in the field to treat the member's respective medical condition. • Documentation indicates 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 all of the above conditions are met, the request will be approved for up to a 3 month duration. **Reauthorization:** • The medication is being prescribed at a medically accepted dose per the medical

	compendia • The medication is 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 experienced a significant clinical benefit from the medication. If all of the above conditions are met, the request will be approved for up to a 3 month duration. **Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	Roctavian
Drugs	Roctavian (valoctocogene roxaparvovec-rvox)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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 gene therapy for Hemophilia A
Required Medical Information	See "Other Criteria"
Age Restrictions	Patient must be 18 years of age and older
Prescriber Restrictions	Prescriber must be a hematologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for a one-time treatment.
Other Criteria Review/Revision Date: 12/2023	**<u>Initial Authorization:</u>** • Diagnosis of severe hemophilia A (congenital factor VIII deficiency with factor VIII activity < 1 IU/dL) • Documentation of a current prophylactic regimen of Factor VIII infusions or bispecific monoclonal antibodies (i.e. Hemlibra) • Documented FDA-approved anti-AAV5 antibody test showing the patient is negative for anti-AAV5 antibodies • Documented Factor VIII inhibitor titer test showing the patient is negative for Factor VIII inhibitors • Prescriber attestation of performed liver health assessments • Patient weight • Medication is prescribed at an FDA approved dose **The safety and effectiveness of repeat administration of Roctavian 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	**Self-administered Disease Modifying Therapies (DMTs) for Multiple Sclerosis (MS)**
Drugs	**Preferred:** Aubagio (teriflunomide) Avonex (interferon beta-1a) Betaseron (interferon beta-1b) Copaxone 20 mg syringe (BRAND) Gilenya (fingolimod) Rebif (interferon-beta 1a) dimethyl fumarate (Tecfidera) **Non-preferred/Non-formulary:** Copaxone 40 mg syringe glatiramer 20 mg and 40 mg syringe Glatopa 20 mg and 40 mg syringe Extavia (interferon beta-1b) Mavenclad (cladribine) Mayzent (siponimod) Plegridy (peginterferon beta-1a) dimethyl fumarate starter pack (Tecfidera) Vumerity (diroximel fumarate) Zeposia (ozanimod) Bafiertam (monomethyl fumarate) Ponvory (ponesimod) Kesimpta (ofatumumab) Tascenso ODT (fingolimod) fingolimod 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	• Primary progressive MS (PPMS) • For Mavenclad: Clinically Isolated Syndrome (CIS)
Required Medical Information	See “Other Criteria”
Age Restrictions	Member must be an appropriate age per prescribing information
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months for all agents except Mavenclad (cladribine). If all of the criteria for Mavenclad (cladribine) are met, the request will be approved for 1 course at a time with a lifetime maximum of 2 yearly treatment courses [1 course = (1 cycle per 30 days) two times].
Other Criteria	**Initial Authorization:** • Documentation of appropriate indication per drug labeling • 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 • If a non-preferred drug is being requested, the member has had a trial of at least two preferred drugs; or documentation was provided as to why the member cannot use preferred drugs • If the request is for Gilenya (fingolimod), Ponvory (ponesimod), Tascenso ODT (fingolimod), fingolimod or Zeposia (ozanimod): Healthcare Provider (HCP)-confirmed history of chickenpox, results of varicella zoster virus (VZV) antibody testing and, if negative, documentation of VZV vaccination

Revision/Review Date: 9/2023	• If the request is for Mayzent (siponimod), documentation of the following is required:
	  o Healthcare Provider (HCP)-confirmed history of chickenpox, results of varicella zoster virus (VZV) antibody testing and, if negative, documentation of VZV vaccination
	  o Results of CYP2C9 genotyping and
	  ▪ patient does not have CYP2C9 *3/*3 (CONTRAINDICATED)
	  ▪ if patient 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
	• If the request is for Kesimpta (ofatumumab), documentation that immunizations are up-to-date.
	• If the request is for Bafiertam (monomethyl fumarate) or Vumerity (diroximel fumarate), the patient has a trial and failure of or documented medical reason for not using dimethyl fumarate (Tecfidera).
	• If the request is for Mavenclad (cladribine), documentation of the following is required:
	  o Patient's current weight
	  o Healthcare Provider (HCP)-confirmed history of chickenpox, results of varicella zoster virus (VZV) antibody testing and, if negative, documentation of VZV vaccination
	
	Criteria for Reauthorization:
	• 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 seen)
	• If the request is for Mavenclad (cladribine)
	  o Patient's current weight is documented
	  o **NO MORE THAN 2 COURSES IN TOTAL WILL BE APPROVED**
	• If the diagnosis is clinically isolated syndrome, documentation was provided that the prescriber has reviewed the risks and benefits of continuing DMT versus stopping
	• If the diagnosis is secondary progressive MS, documentation was provided that the patient continues to have ongoing relapses (or gadolinium-enhanced lesions on MRI activity) AND continues to be ambulatory or has been non-ambulatory for less than 2 years.
	
	<u>Continuation of Therapy:</u>
	Members with history of a non-preferred product (within the past 90 days or the past 12 months for Mavenclad [cladribine]) 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**
Drugs	Serostim (somatropin, mammalian derived)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See other criteria
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be an HIV or infectious disease specialist
Coverage Duration	If all criteria are met, Serostim will be authorized for 12 weeks.
Other Criteria Revision/Review Date: 9/2023	**Initial Authorization:** • Documented diagnosis of HIV wasting or cachexia • Member has been has been receiving optimal highly active antiretroviral therapy (HAART) for at least three months prior to initiation of Serostim • 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.) • Current weight has been submitted (must be within the past 3 months) • Provider attests that member has experienced weight loss of greater than 10% of the member's baseline body weight associated with either chronic diarrhea or chronic weakness and fever for greater than or equal to 1 month • Member has attempted a course of three months or longer with one (or has a contraindication to all) of the following agents: megestrol acetate, cyproheptadine, or dronabinol • Member has attempted a course of three months or longer with an anabolic steroid, such as oxandrolone, or has a contraindication to anabolic steroid therapy • The request is for an FDA approved/medically accepted dose **Reauthorization:** • The member is receiving concomitant HAART therapy • The prescriber has provided documentation of clinical benefit/response to Serostim • The request is for the FDA approved or medically accepted dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Serotonin Receptor Agonists (Triptans)**	
Drugs	Preferred: Relpax tablets (BRAND) rizatriptan tablets (generic) rizatriptan rapidly disintegrating tablets (generic) sumatriptan tablets (generic) Imitrix nasal spray (BRAND) Imitrex kit (BRAND) Imitrex vial (BRAND)	Non-preferred: almotriptan (Axert) Amerge (BRAND) eletriptan tablets naratriptan (Amerge)frovatriptan (Frova) Frova (BRAND) sumatriptan injectable, kit, nasal spray sumatriptan/naproxen Imitrex tablets (BRAND) Maxalt-Mlt Maxalt oral tablet Onzetra Xsail (sumatriptan) Tosymra nasal Treximet Zembrace Symtouch (sumatriptan) zolmitriptan ODT, tablet, nasal spray Zomig (BRAND) nasal, oral, ODT Zecuity
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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	Diagnosis of migraine headaches or cluster headaches	
Age Restrictions	N/A	
Prescriber Restrictions	N/A	
Coverage Duration	If the conditions are met, the request will be approved for 12 months and a quantity not to exceed maximum labeled dosing.	

Other Criteria	Documented trial and failure at therapeutic doses or intolerance to at least TWO preferred agents or documentation was provided as to why preferred agents cannot be used.
Revision/Review Date: 6/2023	**Medical director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary**.

Field Name	Field Description
Prior Authorization Group Description	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	Per FDA-approved prescribing information
Prescriber Restrictions	Prescriber must be a neurologist or in consultation with a neurologist or specialist with expertise in treating patients with Friedreich's Ataxia.
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Revision/Review Date 9/2023	**Initial Authorization:** • Diagnosis of Friedreich's Ataxia, confirmed via genetic testing (must submit documentation) • Modified FARS score ≥20 and ≤80 • Medication is prescribed at an FDA approved dose **Re-Authorization:** • Documentation or provider attestation of positive clinical response to Skyclarys therapy (i.e. improvement in symptoms, slowing of disease progression, etc.) • Medication is prescribed at an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	Skysona (elivaldogene autotemcel)
Drugs	Skysona (elivaldogene autotemcel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Cerebral adrenoleukodystrophy secondary to head trauma • Positive for human immunodeficiency virus type 1 or 2
Required Medical Information	See "Other Criteria"
Age Restrictions	See "Other Criteria"
Prescriber Restrictions	Prescriber must be a specialist in the disease being treated.
Coverage Duration	If all the criteria are met, the initial request will be approved for a one-time treatment.

Other Criteria
 	
Revision/Review Date: 03/2023
	Initial Authorization:
	• Member has a diagnosis of early, active cerebral adrenoleukodystrophy (CALD) defined as all of the following:
	  ○ elevated very long chain fatty acid (VLCFA) levels
	  ○ confirmed mutations in the ABCD1 gene
	  ○ asymptomatic or mildly symptomatic (neurologic function score, NFS ≤ 1)
	  ○ Gadolinium enhancement on brain magnetic resonance imaging (MRI) of demyelinating lesions and Loes scores of 0.5-9
	• Member is a male 4-17 years of age
	• Medication is prescribed at an FDA approved dose
	• Member has not had a prior allogeneic hematopoietic stem-cell transplant (HSCT)
	• Member has no HLA-matched sibling donor for HSCT, or a reason why HSCT with matched sibling donor is not appropriate.
	
	Re-Authorization:
	The safety and effectiveness of repeat administration of Skysona have not been evaluated and will not be approved.

Prior Authorization Group Description	**Sleep Disorder Therapy**
Drugs	**Formulary:** modafinil armodafinil **Non-formulary/Non-preferred:** Sunosi (solriamfetol) Wakix (pitolisant) Xyrem (sodium oxybate) sodium oxybate Xywav (calcium, magnesium, potassium, and sodium oxybates)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Xyrem/Xywav/Sodium Oxybate: Succinic semialdehyde dehydrogenase deficiency
Required Medical Information	See "other criteria"
Age Restrictions	Per FDA approved prescribing information
Prescriber Restrictions	See "other criteria"
Coverage Duration	If the criteria are met, requests for modafinil, armodafinil, Sunosi, and Wakix will be approved for up to 12 months. Requests for Xyrem/Xywav/sodium oxybate will be approved for up to 3 months.
Other Criteria	**Initial criteria for all requests:** • Medication is being prescribed at an FDA approved or medically accepted dose **<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 [e.g. continuous positive airway pressure (CPAP), bilevel positive airway pressure (BPAP), or automatic positive airway pressure (APAP)]. • Diagnosis of cancer-related fatigue, in patients receiving cancer treatment (modafinil only). **<u>Sunosi initial authorization</u>** • Documented trial and failure of, or medical reason for not utilizing, modafinil or armodafinil • Additionally for a diagnosis of OSA, documentation that the member has been compliant with or is unable to use positive airway pressure (CPAP, BPAP, 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

Revision/Review Date: 9/2023	**AND** o Sunosi • For a diagnosis of narcolepsy **with cataplexy**, documented trial and failure of, or medical reason for not utilizing dextroamphetamine **<u>Sodium Oxybate (Xyrem/Xywav) 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 a diagnosis of narcolepsy in members **18 years of age and older without cataplexy**: o Documented trial and failure of, or medical reason for not utilizing ALL the following: ▪ Modafinil or armodafinil ▪ Sunosi ▪ Wakix o For Xyrem or Xywav: documented trial and failure of, or medical reason for not using generic sodium oxybate • For a diagnosis of narcolepsy in members **18 years of age and older with cataplexy**: o Documented trial and failure of, or medical reason for not utilizing, each of the following: ▪ Dextroamphetamine **AND** ▪ Wakix o For Xyrem or Xywav: documented trial and failure of, or medical reason for not using generic sodium oxybate • For a diagnosis of idiopathic hypersomnia (Xywav only): o Documented trial and failure of, or medical reason for not using one of the following: ▪ modafinil ▪ armodafinil **<u>Reauthorization:</u>** • Documentation has been submitted indicating member has experienced a clinical benefit from treatment (e.g. improvement on Epworth Sleepiness Score, reduced 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	Evrysdi (risdiplam) Spinraza (nusinersen)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	• For Spinraza: Patient has previously received treatment with Zolgensma • Concomitant use of Evrysdi and Sprinraza
Required Medical Information	For Evrysdi: Patient's body weight
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	For Evrysdi: If all of the conditions are met, the request will be approved for 6 months for initial approval, followed by 12 months for reauthorization requests. For Spinraza: If all of the conditions are met, the request will be approved for 6 months for 5 doses (4 loading doses and 1st maintenance dose) for initial approval, and 12 months for 3 additional maintenance doses for reauthorization requests.
Other Criteria Revision/Review Date: 12/2023	**<u>Initial approval</u>** • 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] • The request is for an FDA approved dose **<u>Reauthorization</u>** • Documentation of clinical response was submitted with request (e.g. improvement in motor function/motor milestone achievement scores using CHOP-INTEND or HFMSE, 6 minute walk test or HINE improvement in more categories of motor milestones than worsening, patient remains permanent ventilation free if no prior ventilator support) • The request is for an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	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 patients younger than 8 years of age for females and 10 years of age for males
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with an orthopedic specialist or provider who specializes in rare connective tissue diseases
Coverage Duration	If all of the criteria are met, the initial or reauthorization request will be approved for up to 6 months taking into account patient-specific scenarios.
Other Criteria Review/Revision Date: 12/2023	**Initial Authorization:** • Documented diagnosis of fibrodysplasia ossificans progressiva (FOP) • Documented genetic testing of ACVR1 R206H mutation • Attestation that patient is not pregnant and appropriate contraception methods will be used at least 1 month before treatment, during treatment, and 1 month after the last dose (if applicable) • Documentation of weight for patients younger than 14 years old • Medication is prescribed at an FDA approved dose **Re-Authorization:** • Documentation or provider attestation of clinical benefit (i.e., volume reduction of heterotopic ossification) or worsening (i.e., flare-up presence and/or worsening of flare-ups) • Attestation that patient is not pregnant and appropriate contraception methods will be used at least 1 month before treatment, during treatment, and 1 month after the last dose (if applicable) • Documentation of weight for patients younger than 14 years old • Medication is prescribed at an FDA approved dose **Medical Director/clinical reviewer must 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	Not Applicable
Required Medical Information	See "Other Criteria"
Age Restrictions	≥18 years old
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist or hematologist
Coverage Duration	If the conditions are met, the request will be approved for a 6-month duration for initial requests and a 6-month duration for renewal requests.
Other Criteria Revision/Review Date: 3/2023	**<u>Initial Authorization:</u>** • Diagnosis of one of the following subtypes of severe active antineutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis: granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) • Prescriber attestation that Tavneos will be prescribed in combination with corticosteroids AND cyclophosphamide or rituximab, unless there is documented trial and failure, intolerance, inability to use, or contraindication to these therapies • The prescribed dose is within FDA-approved dosing guidelines • Documentation of baseline Birmingham Vasculitis Activity Score (BVAS) score • Prescriber attestation that the patient will have liver function tests before treatment (ALT, AST, alkaline phosphate, and total bilirubin) and every 4 weeks after start of therapy for the first 6 months of treatment • Prescriber attestation that the patient has been screened for and does not have active hepatitis B virus (HBV) infection at baseline **<u>Reauthorization:</u>** • Documentation of remission (BVAS score of 0) OR improvement in BVAS score • Prescriber attestation that patient has no abnormality in liver function tests (abnormality: ALT or AST >3 times the upper limit of normal and bilirubin >2 times the upper limit of normal) • Prescriber attestation that patient has no active HBV infection • The prescribed dose is within FDA approved dosing guidelines **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	Topical mTOR kinase inhibitors
Drugs	Hyftor (sirolimus topical gel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	Member concomitantly taking an oral mTOR inhibitor
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be 6 years or older
Prescriber Restrictions	Prescriber must be a dermatologist, neurologist, medical geneticist or other prescriber who specializes in the treatment of genetic or dermatologic disorders.
Coverage Duration	If the criteria are met, requests will be approved with up to a 3 month duration. Thereafter, reauthorization requests will be approved with up to a 6 month duration.
Other Criteria Revision/Review Date 12/2023	**Initial Authorization:** • Member has a confirmed diagnosis of tuberous sclerosis complex (TSC) • Member has at least 3 facial angiofibromas measuring 2 mm or larger in diameter • Documentation of a comprehensive dermatologic evaluation has been provided • Prescriber attests that the member is not a candidate for laser therapy or surgery • Medication is being prescribed at an FDA approved dose **Reauthorization:** • Documentation has been provided indicating that the member has experienced a clinical benefit from treatment (e.g. improvement in size and color of angiofibromas) • Documentation of a comprehensive dermatologic evaluation has been provided • Prescriber attests that the member is not a candidate for laser therapy or surgery • Medication is being prescribed at an FDA approved dose

Field Name	Field Description
Prior Authorization Group Description	**Transthyretin-mediated Amyloidosis Agents**
Drugs	**Preferred:** Polyneurpathy – Onpattro (patisiran), Amvuttra (vutrisiran) Cardiomyopathy – Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis) **Non-preferred**: Polyneuropathy – Tegsedi (inoterson) Or any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Patient must be 18 years of age or older
Prescriber Restrictions	Prescriber must be neurologist, cardiologist, or specialist in the treatment of amyloidosis
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy the request will be approved for 6 months.
Other Criteria	**Initial Authorization**: • Regimen does not exceed FDA-approved dose/frequency • Patient has not undergone a liver or heart transplant • Patient is not taking any of these agents concurrently: Tegsedi, Onpattro, Vyndaqel, Vyndamax or Amvuttra • If the request is for Onpattro Tegsedi, or Amvuttra patient has diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis as evidenced by: o Documented transthyretin variant by genotyping o One of the following: ▪ Patient has baseline polyneuropathy disability (PND) score ≤ IIIb ▪ Patient has a baseline FAP Stage 1 or 2 ▪ Patient has baseline neuropathy impairment (NIS) score ≥ 5 and ≤ 130 o Patient has clinical signs/symptoms of neuropathy o For Tegsedi, patient has contraindication to/or previous trial and failure of use of Onpattro or Amvuttra

Revision/Review Date: 12/2023	• If the request is for Vyndaqel or Vyndamax, patient has diagnosis of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis as evidenced by all of the following: 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 Patient has New York Heart Association (NYHA) functional class I, II, or III heart failure symptoms. **Re-authorization (for continuing and new patients to the plan)** : • Patient's regimen does not exceed FDA-approved dose/frequency for the agent • Patient has not undergone a liver or heart transplant • Patient is not taking any of these agents concurrently: Tegsedi, Onpattro, Vyndaqel, Vyndamax or Amvuttra • 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 o Patient has continued NYHA functional class I, II, or III heart failure symptoms **Continuation of Therapy Provision:** Members with history (within the past 90 days) of a non-formulary product are not required to try a formulary agent prior to receiving the non-formulary product. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Prior Authorization Group Description	**Transmucosal Immediate-Release Fentanyl (TIRF) Formulations**
Drugs	fentanyl buccal tablet (Fentora) fentanyl lozenge (Actiq) Lazanda (fentanyl) nasal spray Subsys (fentanyl) sublingual spray *This criteria does not pertain to the fentanyl 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	Diagnosis of cancer
Age Restrictions	N/A
Prescriber Restrictions	Prescribing is limited to oncologists, pain management specialists, and hospice providers.
Coverage Duration	If all of the conditions are met, the request will be approved for up to 6 months.
Other Criteria Revision/Review Date: 6/2023	**<u>Criteria for Approval:</u>** • Patient has a diagnosis of cancer • Documentation that the member is opioid-tolerant and member will remain on around-the-clock opioids when taking a TIRF medication. ○ Opioid tolerance is defined as current use of one the following: oral morphine 60 mg/day, transdermal fentanyl 25 mcg/hour, oral oxycodone 30 mg/day, oral hydromorphone 8 mg/day, oral oxymorphone 25 mg/day, oral hydrocodone 60 mg/day, or an equianalgesic dose of another opioid for at least one week. • Member is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrolled nausea/vomiting. **OR** documentation of trial and failure of at least TWO formulary immediate release oral opioids • If the member is being newly initiated on transmucosal fentanyl, the lowest dose of the respective formulation is being prescribed. (Data do not support an equianalgesic dosing of transmucosal fentanyl in relation to other opioids or between different transmucosal formulations). The only exception is for substitutions between a branded TIRF medicine and its generic equivalent. **If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity.**

Field Name	Field Description
Prior Authorization Group Description	Trogarzo (ibalizumab-uiyk)
Drugs	Trogarzo (ibalizumab-uiyk)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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 initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Date: 12/2023	**Initial Authorization:** • Medication is prescribed at an FDA approved dose • Diagnosis of human immunodeficiency virus type 1 (HIV-1) infection • Documented resistance to at least one antiretroviral (ART) medication from each of the three following classes of antiretroviral medications o Protease inhibitor (PI) o Nucleoside reverse transcriptase inhibitor (NRTI) o Non-nucleoside reverse transcriptase inhibitors (NNRTI) • Documentation of current HIV RNA viral load • Member will use Trogarzo in combination with an optimized background regimen containing at least one ART medication **Re-Authorization:** • Documentation or provider attestation of positive clinical response (decrease in viral load or sustained reduction) • Member continues to use requested medication in combination with an optimized background antiviral regimen containing at least one ART medication • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Prior Authorization Group Description	**Type I Interferon (IFN) Receptor Antagonist**
Drugs	Saphnelo (anifrolumab-fnia)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Severe active central nervous system lupus • Active lupus nephritis
Required Medical Information	See "Other Criteria"
Age Restrictions	≥ 18 years
Prescriber Restrictions	Prescriber must be a rheumatologist or in consultation with a rheumatologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 12/2023	**Initial Authorization:** • 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 **Re-Authorization:** • Documentation or provider attestation of positive clinical response (i.e., reduction in signs and symptoms of SLE, fewer flares, reduced oral corticosteroid use, etc.) • Prescriber attests member will not be using Saphnelo concurrently with Benlysta • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

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

Other Criteria
 	
Revision/Review Date: 3/2023
	<u>Initial Authorization:</u>
	• Medication is prescribed at an FDA approved dose
	• Diagnosis of stage 2 type 1 diabetes (T1D) confirmed by presence of at least two of the following autoantibodies:
	  ○ Glutamic acid decarboxylase 65 (GAD) autoantibody
	  ○ Insulin autoantibody (IAA)
	  ○ Insulinoma-associated antigen 2 autoantibody (IA-2A)
	  ○ Zinc transporter 8 autoantibody (ZnT8A)
	  ○ Islet cell autoantibody (ICA)
	• Abnormal glucose on an oral glucose-tolerance test (or alternative glycemic test if an oral glucose-tolerance test is not available)
	
	If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Prior Authorization Group Description	**Verquvo**
Drugs	Verquvo (vericiguat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Pregnancy
Required Medical Information	See "Other Criteria"
Age Restrictions	Patient must be 18 years or older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist
Coverage Duration	If all of the conditions are met, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 9/2023	• 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 patient has had a previous hospitalization for heart failure or has required outpatient IV diuretics • Member is currently being prescribed, or will be prescribed, at least two of the following treatment regimens, or documentation has been provided that the member is not able to tolerate these agents: o Angiotensin-converting enzyme (ACE) inhibitor OR angiotensin receptor blocker (ARB) OR angiotensin receptor/neprilysin inhibitor o Mineralocorticoid receptor antagonist (e.g. spironolactone) o Evidence-based beta-blocker (i.e. bisoprolol, carvedilol, metoprolol succinate) • Documented trial and failure, intolerance, or contraindication to Entresto, Farxiga, or Jardiance • Patient is not concomitantly using a long-acting nitrate (e.g. isosorbide mononitrate, transdermal nitroglycerin) or 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 judgment, 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	Member must be 5 years of age or older
Prescriber Restrictions	Prescriber is, or is collaborating with another provider, who is a specialist in the treatment of Morquio A syndrome or other lysosomal storage disorders.
Coverage Duration	6 months
Other Criteria Revision/Review Date: 9/2023	**Initial Authorization (new to therapy):** • Patient has confirmed diagnosis of mucopolysaccharidosis IVA (MPS IVA or Morquio A syndrome) via one of the following: o Genetic testing o Analysis of N-acetylgalactosamine 6-sulfatase (GALNS) activity in leukocytes or fibroblasts • Medication is prescribed at an FDA approved dose. • Patient must have completed a 6-minute walk test for baseline evaluation (must submit results with request) and be able to walk a minimum of 30 meters at baseline **Re-Authorization:** • Medication is prescribed at an FDA approved dose. • Patient shows signs of improvement from baseline in a 6-minute walk test (must submit results with request) Re-authorization for members new to the plan previously treated with Vimizim: • Patient has confirmed genetic diagnosis of mucopolysaccharidosis IVA (MPS IVA, or Morquio A syndrome) via one of the following: o Genetic testing o Analysis of N-Acetylgalactosamine 6-sulfatase (GALNS) activity in leukocytes or fibroblasts • Medication is prescribed at an FDA approved dose. • Patient must have completed a 6-minute walk test for baseline evaluation (must submit results with request). • If a baseline 6-minute walk test was not completed prior to initiation of Vimizim therapy: o A current test must be completed and patient must be able to walk a minimum of 30 meters (must submit results with request) o Continued authorizations for Vimizim for patients without a completed baseline 6-minute walk test evaluation prior to initiation of therapy must continue to be able to walk a minimum of 30 meters in subsequent evaluations. o If patient is established on Vimizim therapy prior to enrollment on the plan, but is not able to walk a minimum of 30 meters, then medical justification is required as to how the patient continues to receive benefit from Vimizim therapy.

Prior Authorization Group Description	**Vivitrol (naltrexone)**
Drug	Vivitrol (naltrexone) intramuscular 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 receiving opioid analgesics, members with current physiologic opioid dependence, members in acute opioid withdrawal who have failed the naloxone challenge test or have a urine drug screen positive for opioids, or members with acute hepatitis or liver failure.
Required Medical Information	See "other criteria"
Age Restrictions	Member must be 18 years of age or older
Prescriber Restrictions	Prescriber is, or has consulted with, a behavioral health or licensed Drug and Alcohol (D&A) provider
Coverage Duration	If all of the conditions are met, the request will be approved for up to 6 months.
Other Criteria	**<u>Initial Authorization:</u>** • Attestation that the member had an initial evaluation by a drug and alcohol dependence provider to recommend level of care. • Member must have diagnosis of opioid use disorder, following opioid detoxification, OR alcohol use disorder and prescriber attests that member is able to abstain from alcohol in an outpatient setting. • Prescriber attests to referral to or participation in a substance abuse or behavioral health treatment program or behavioral health counseling by a licensed drug and alcohol dependence provider. • Prescriber attests that the member has been screened for depression and risk of suicide. If these conditions are present, documentation is provided that the member has been referred for treatment with a behavioral health provider. • Prescriber attests that the member is free from opioids (including tramadol) before starting therapy, or for alcohol use disorder, the member is not actively drinking alcohol. • Prescriber attests that the member has been counseled on the risk, signs, and symptoms of precipitated withdrawal. • Prescriber attests that the member does not have severe hepatic or renal impairment. **<u>Re - Authorization:</u>** • If member has symptoms of depression or is at risk for suicide, documentation has been provided that the member is being treated by a behavioral health provider. • Prescriber attests that regular drug and alcohol screening is being performed and monitored as appropriate.
Revision/Review Date: 6/2023	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	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	• Patients with unresolved Neisseria meningitidis infection • Concurrent use of another complement inhibitor (i.e., Soliris)
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must have experience in treating complement related disorders (i.e., gastroenterologist, immunologist, cardiologist, etc.)
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 12/2023	**Initial Authorization:** • Medication is prescribed at an FDA approved dose • Diagnosis of CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease • Documentation of hypoalbuminemia (serum albumin <3.5 g/dL) • Documentation of patient weight **Re-Authorization:** • Documentation or provider attestation of positive clinical response (i.e. symptom improvement, normalization of labs such as serum albumin (3.5-5.5 g/dL) and IgG concentrations, reduced hospitalizations and severe adverse events, increased quality of life, etc.) • Documentation of patient weight • Medication is prescribed at an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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

Revision/Review Date: 12/2023	○ For Austedo, Austedo XR requests: ▪ Prescriber attests patient has no signs of hepatic impairment ▪ For patients at risk for QT prolongation, prescriber attests a baseline ECG has been obtained ○ For Ingrezza requests: ▪ Must be dosed at one capsule per day **For approval for use in chorea associated with Huntington's Disease (HD):** • Patient must have diagnosis of moderate to severe Huntington's with chorea, with documented baseline Total Maximal Chorea (TMC) score provided • For VMAT2 inhibitors other than tetrabenazine, member has a documented medical reason (e.g., treatment failure, intolerance, hypersensitivity, contraindication) for not using tetrabenazine AND ○ For Austedo, Austedo XR requests: ▪ Prescriber attests that patient shows no signs of hepatic impairment ▪ Prescriber attests that patient has had a baseline electrocardiogram (EKG) and is aware of the possible risk of QT prolongation ○ 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.) • Patient 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.**

Field Name	Field Description
Prior Authorization Group Description	**Vuity**
Drugs	Vuity (pilocarpine HCl ophthalmic solution)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	≥ 40 years
Prescriber Restrictions	Prescribed by or in consultation with an optometrist or ophthalmologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Date: 9/2023	**Initial Authorization:** • Diagnosis of presbyopia • Trial and failure or contraindication to corrective lenses (i.e., eye glasses, contact lenses) • Member does not have glaucoma or ocular hypertension • Medication is prescribed at an FDA approved dose **Re-Authorization:** • Documentation or provider attestation of positive clinical response • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	Vyjuvek (beremagene geperpavec-svdt)
Drugs	Vyjuvek (beremagene geperpavec-svdt)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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
Required Medical Information	See "Other Criteria"
Age Restrictions	Per prescribing information
Prescriber Restrictions	Prescriber must be a dermatologist, geneticist, or specialist experienced in the treatment of dystrophic epidermolysis bullosa.
Coverage Duration	If all of the criteria are met, the initial request will be approved for three (3) months. Subsequent requests will be approved for six (6) months.
Other Criteria Review/Revision Date: 12/2023	**<u>Initial Authorization:</u>** • Patient has a diagnosis of dystrophic epidermolysis bullosa, with confirmed mutation(s) in the COL7A1 gene via genetic testing. • 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 dispensable amount is not exceeded **<u>Re-Authorization:</u>** • Documentation or provider attestation of positive clinical response (i.e. improvement in wound appearance, wound closure, healing, etc.) • Documentation indicating need for continued treatment is needed (either to partially healed wounds or to other wound sites) • Documentation is provided that wound(s) to be treated are clean with adequate granulation tissue, excellent vascularization, and do not appear infected • Documentation is provided that there is no evidence of, or history of squamous cell carcinoma in the wound(s) to be treated • Medication is prescribed at an FDA approved dose, and maximum weekly dispensing amount is not exceeded. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Weight Loss Drugs**
Drugs	**<u>Preferred</u>** Saxenda (liraglutide) Wegovy (semaglutide) **<u>Non-preferred/Non-formulary</u>** phentermine benzphetamine diephypropion, diethylpropion ER phendimetrazine, phendimetrazine ER Xenical (orlistat) orlistat (Xenical) Lomaira (phentermine) Qsymia (phentermine/topiramate) Imcivree (setmelanotide) Any newly-approved Rx medication indicated for obesity or weight management *Note: OTC medications for weight loss are excluded from coverage*
Covered Uses	Medically accepted indications are defined using the following 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	Age appropriate per labeling
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved for 6 months.
Other Criteria	**<u>Initial Authorization:</u>** • Requested dose is appropriate per labeling • Documentation of current weight and body mass index (BMI) • Adult BMI must be one of the following: o BMI of 27 - 29.9 kg/m^2 with one of the following weight-related comorbidities: coronary artery disease, diabetes, hypertension, dyslipidemia, or obstructive sleep apnea o BMI of 30 kg/m^2 or more • Pediatric patients must be considered obese per package insert • Documentation of failure of comprehensive lifestyle modifications (reduced-calorie diet and increased physical activity) for at least 6 months • If the request is for a non-preferred/non-formulary agent, the member must also have a trial and failure of (or medical reason for not using) two preferred products • Documentation that drug therapy will be administered in conjunction with lifestyle modifications **<u>AND</u>** • For Imcivree, ONE of the following apply: o Documentation of obesity related to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency ▪ Deficiency is documented by an FDA-approved genetic test confirming variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance ▪ POMC, PCSK1, or LEPR variants classified as benign or likely benign will not be approved

Revision/Review Date: 12/2023	o Documentation of obesity due to Bardet-Biedl syndrome (BBS) **<u>Re-Authorization:</u>** • Documentation of at least 5% reduction in body weight compared with baseline • If a weight-related comorbidity was previously noted, an objective improvement is documented (e.g. reduction in blood pressure, cholesterol, hemoglobin A1c, etc) **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	Preferred: Nivestym (filgrastim-aafi) Zarxio (filgrastim-sndz) Ziextenzo (pegfilgrastim-bmez) Non-Preferred/Non-Formulary: Granix (filgrastim-tbo) Neupogen (filgrastim) Nyvepria (pegfilgrastim-apgf) Neulasta (pegfilgrastim) Neulasta Onpro (pegfilgrastim) Fulphila (pegfilgrastim-jmdb) Udenyca (pegfilgrastim-cbqv) Leukine (sargramostim) Mozobil (plerixafor) Fylnetra (pegfilgrastim-pbbk) Rolvedon (eflapegrastim-xnst) Stimufend (pegfilgrastim-fpgk) and any newly approved product
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a hematologist, oncologist, organ transplant specialist, or infectious disease specialist.
Coverage Duration	If the criteria are met, the request will be approved for up to 12 weeks. Re-authorization requests for all indications, with the exception of chronic neutropenia, will be approved for 12 weeks. Reauthorization requests for *chronic neutropenia* may be approved for 24 weeks.
Other Criteria	**Criteria for Approval:** • Drug is being used for an appropriate indication at an appropriate dose per "Covered Uses". • Member's recent (within the last 30 days) ANC (absolute neutrophil count) has been submitted with request • Additional criteria ***for Non-Preferred filgrastim products:*** the member must have a documented treatment failure (e.g. failure to reach and/or maintain target ANC, prolonged febrile neutropenia, or infection requiring prolonged use) with the use of Nivestym or Zarxio and/or has

Revision/Review Date: 3/2023	another documented medical reason (intolerance, hypersensitivity, etc.) for not using Nivestym or Zarxio. • Additional criteria ***for Non-Preferred PEGfilgrastim or eflapegrastim products:*** the member must have a documented treatment failure (e.g. failure to reach and/or maintain target ANC, prolonged febrile neutropenia, unplanned hospitalization, infection requiring prolonged antimicrobial treatment) which is consistent with pharmacy claims data, with an adequate trial (including dates, doses of therapy) of Ziextenzo and/or has another documented medical reason (intolerance, hypersensitivity, dose dense chemotherapy, or stem cell collection, etc.) for not using Ziextenzo to treat the medical condition. o For Neulasta requests, the member must have a documented treatment failure of two biosimilar pegfilgrastim products • Additional criteria ***for Leukine requests:*** Documentation is submitted of the patient's diagnosis, current body weight, and body surface area. • Additional criteria ***for Mozobil requests:*** Documentation is submitted of the patient's diagnosis and current body weight **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	Xenleta (lefamulin)
Drugs	Xenleta (lefamulin)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Patient must be 18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the initial request will be approved for up to one 7-day course.
Other Criteria Date: 12/2023	• Patient has confirmed diagnosis of community-acquired bacterial pneumonia (CABP) caused by a susceptible microorganism, including, but not limited to: o Streptococcus pneumoniae o Staphylococcus aureus (methicillin-susceptible isolates) o Haemophilus influenzae o Legionella pneumophila o Mycoplasma pneumoniae o Chlamydophila pneumoniae • Patient has had a trial and inadequate response or intolerance to at least one alternative antibiotic that the microorganism is susceptible to (i.e. beta-lactams, fluoroquinolones) • Patient does not have known QT prolongation or ventricular arrhythmias including torsades de pointes, and is not receiving drugs that prolong the QT interval such as antiarrhythmic agents • Request is for an FDA-approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Prior Authorization Group Description	**Xifaxan (rifaximin)**
Drugs	Xifaxan (rifaximin) 200 mg tablets (Formulary, QL 9/30 days) Xifaxan (rifaximin) 550 mg tablets (Formulary, PA required)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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	<u>Hepatic encephalopathy:</u> Initial request – approve for 6 months Renewal request – approve for 12 months <u>Irritable bowel syndrome with diarrhea:</u> Initial request – approve for 14 day course of therapy Renewal request – approve for 14 day course of therapy with 1 refill for a 6 month duration

Other Criteria
 	
Revision/Review Date: 9/2023
	<u>Criteria for Initiation of Therapy</u>:
	• Request is for an FDA-approved dose
	• Documentation of one of the following diagnoses is required:
	  o Traveler's Diarrhea:
	  ▪ Prior authorization not required if the request is for a total of nine 200 mg tablets; requests beyond a 3 day duration require medical necessity review
	  o Hepatic encephalopathy:
	  ▪ Treatment failure or inability to use a nonabsorbable disaccharide (e.g. lactulose, lactitol)
	  ▪ If a dose of 400 mg TID is being requested, documentation must be submitted as to why the member cannot use 550 mg BID
	  o Irritable Bowel Syndrome with Diarrhea (IBS-D):
	  ▪ Must have documented moderate to severe IBS with diarrhea AND without constipation
	  ▪ Documented trial and failure of dietary modification (including lactose restricted diet, if lactose-intolerant; exclusion of gas-producing foods; low carbohydrate diet and elimination of fermentable oligo-, di-, and monosaccharides and polyols (FODMAPs).
	  ▪ Documented trial and failure, or medical reason for not using one formulary tricyclic antidepressant
	
	<u>Criteria for continuation of therapy</u>:
	• Hepatic Encephalopathy:
	  o Documented improvement in signs and symptoms/quality of life, reduction in recurrent episodes, etc.
	• Irritable Bowel Syndrome with Diarrhea (IBS-D)
	  o Documented improvement in abdominal pain and reduction in number of days per week with diarrhea
	
	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 and Urticaria**
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	Members actively using Cinqair, Fasenra, Nucala, Dupixent, or Tezspire
Required Medical Information	See "other criteria"
Age Restrictions	Asthma: ≥ 6 years Chronic idiopathic urticaria: ≥ 12 years
Prescriber Restrictions	Prescriber must be an allergist/immunologist, pulmonologist, dermatologist or is working in collaboration with one of these specialists
Coverage Duration	If all of the conditions are met, the request will be approved for 4 months for initial requests. Reauthorization requests will be approved for 6 months.
Other Criteria	****For nasal polyposis, please refer to the "Biologic Agents for Nasal Polyposis" policy**** **Initial Authorization:** For all **continuation of care requests for asthma** for members new to the plan: • Member has at least a 6 month history of moderate to severe asthma • Request is being prescribed at an approved dose For all members who are **newly initiating Xolair for 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 member's weight and IgE level • Member is taking maximal tolerated dose of inhaled corticosteroid/long-acting beta agonist (ICS/LABA) combination WITH add-on therapy of a LAMA (e.g., tiotropium) for a minimum of 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 at least 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 an 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 beta2 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 • The member has a positive documented immediate response on RAST test and/or skin prick test to at least 1 common allergen (e.g. dermatophagoides farinae, dermatop

Revision/Review Date: 3/2023	hagoides pteronyssinus, dog, cat, or cockroach) which is an asthma trigger (copy of results required). • Pre-treatment serum IgE levels must be greater than or equal to 30 IU/mL For all **continuation of care requests for urticaria** for members new to the plan: • Request is being prescribed at an approved dose For all **members who are newly initiating Xolair for urticaria**: • The drug is being prescribed at an FDA approved dose • The member has a documented history of urticaria for at least 6 weeks • The member requires oral corticosteroids to control symptoms • The 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 **Reauthorization criteria for asthma or urticaria:** • Documentation submitted indicates that the member has experienced a clinical benefit from the medication (e.g. decrease in exacerbations, reduction in use of oral steroids) • Request is being prescribed at an approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review**

Field Name	Field Description
Prior Authorization Group Description	Zinplava (bezlotoxumab)
Drugs	Zinplava (bezlotoxumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Patient must be 1 year of age or older
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the initial request will be approved for one single dose only.

Other Criteria
 	
Date: 12.2023
	• Patient has a confirmed diagnosis of *Clostridium difficile* infection (CDI)
	• Patient is currently receiving the standard of care antibacterial drugs for CDI (i.e. metronidazole, vancomycin)
	• Patient is at high risk of CDI recurrence as defined by at least ONE of the following:
	  o Has a history of CDI within the past 6 months
	  o Is 65 years of age and older
	  o Is immunocompromised
	• Medication is prescribed at an FDA approved dose
	
	If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Prior Authorization Group Description	**Zolgensma**
Drugs	Zolgensma (onasemnogene abeparvovec-xioi)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Advanced spinal muscular atrophy (SMA) (i.e. complete paralysis of limbs, permanent ventilator dependence) • Member has previously received this medication • Premature neonates before reaching full-term gestational age
Required Medical Information	Member's weight
Age Restrictions	Member must be less than 2 years of age
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	If the criteria are met, ONE dose may be approved. Reauthorization is not permitted. **The safety and effectiveness of repeat administration of Zolgensma have not been evaluated and will not be approved.**
Other Criteria Revision/Review Date: 6/2023	**<u>Criteria for Authorization:</u>** • Diagnosis of spinal muscular atrophy SMA • Documentation of genetic testing confirming bi-allelic mutations in the survival motor neuron 1 (SMN1) gene • Documentation of genetic testing confirming 3 or fewer copies of SMN2 gene • Prescriber attests to conducting baseline liver function tests and will continue to monitor liver function for at least 3 months after infusion • Baseline anti-AAV9 antibody titer is less than or equal to 1:50 using an enzyme linked immunosorbent assay (ELISA) • Dosing is consistent with FDA approved labeling **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Specialty Drugs for Ulcerative Colitis**
Drugs	**Preferred:** Humira (adalimumab) Xeljanz (tofacitinib) **Non-Preferred:** Avsola (infliximab-axxq) Inflectra (infliximab-dyyb) Renflexis (infliximab-abda) Remicade (infliximab) Simponi (golimumab) Rinvoq (upadacitinib) Entyvio (vedolizumab) Xeljanz (tofacitinib) Xeljanz XR, Xeljanz solution (tofacitinib) Stelara (ustekinumab) Infliximab Zeposia (ozanimod) Or any newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	According to prescribing information
Prescriber Restrictions	Prescribed by, or in consultation with, a gastroenterologist
Coverage Duration	12 months
Other Criteria	**<u>Initial Authorization (new to therapy):</u>** • The member has a diagnosis of ulcerative colitis • The medication is being prescribed at an appropriate (for age and weight) FDA-approved dose • The member has an adequate trial of, or medical reason for not using, at least one conventional therapy (e.g. oral aminosalicylates, azathioprine, 6-mercaptopurine, or oral corticosteroids) consistent with pharmacy claims/medical chart history • If the request is for a non-preferred agent, there must be documentation of an adequate trial of a preferred drug consistent with pharmacy claims/medical chart data. • For requests for Zeposia (ozanimod): Documentation of results of varicella zoster virus (VZV) antibody testing indication previous infection or vaccination. If negative, documentation of VZV vaccination must be provided with the request **<u>Re-Authorization:</u>** • The medication is being prescribed at an appropriate (for age and weight) FDA-approved dose. • The member has been receiving the medication and there is documentation that a clinical benefit was observed.

Revision/Review Date: 9/2023	**<u>Continuation of Therapy:</u>** • Members with history (within the past 90 days) of a non-preferred drug are not required to try a preferred drug or the above mentioned conventional therapies prior to receiving the non-preferred agent. • Members with history (within the past 90 days) of a preferred drug are not required to try the above mentioned conventional therapies prior to receiving the preferred drug 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 Crohn's Disease**
Drugs	<u>Preferred Biologic Agents</u> Humira (adalimumab) <u>Non-Preferred/Non-Formulary Biologic Agents</u> Avsola (infliximab-axxq) Inflectra (infliximab-dyyb) Renflexis (infliximab-abda) Remicade (infliximab) Cimzia (certolizumab) Entyvio (vedolizumab) Stelara (ustekinumab) Tysabri (natalizumab) Infliximab Skyrizi (risankizumab-rzaa) Rinvoq (upadacitinib) Amjevita (adalimumab) Hadlima (adalimumab) Abrilada (adalimumab) Cyltezo (adalimumab) Yusimry (adalimumab) Hulio (adalimumab) Hyrimoz (adalimumab) Idacio (adalimumab) Yuflyma (adalimumab) adalimumab-fkip Or any newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	See "Other Criteria"
Prescriber Restrictions	The medication is being recommended or prescribed by a gastroenterologist
Coverage Duration	If all of the conditions are met, the request will be approved for up to 12 months.

Other Criteria
 	
Revision/Review Date: 12/2023
	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 remission after an adequate trial (consistent with pharmacy claims/medical record data) of a systemic corticosteroid AND traditional immunomodulatory therapy (e.g. sulfasalazine, azathioprine, 6-mercaptopurine, or methotrexate), or the member has a documented medical reason (e.g. allergy, intolerance, contraindication) for not using these therapies to manage the condition
	  o Request is for maintenance of remission achieved with use of biologic therapy
	• The request is for an appropriate dose for member based on age and weight
	• If the request is for a non-preferred agent, there must be documentation of an adequate trial of preferred biologic agent consistent with pharmacy claims/medical chart data, or a medical reason was submitted as to why a preferred agent is not appropriate for the member.
	
	Re-Authorization:
	• The medication is being recommended or prescribed at an FDA-approved dose.
	• The member has been receiving the medication and there is documentation that a clinical benefit was observed.
	• For members who require Humira 40 mg SC weekly, documentation must be submitted indicating that the member was compliant (consistent with pharmacy claims) with receiving at least 16 weeks of continuous Humira therapy every other week prior to the request for weekly dosing of Humira.
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Prior Authorization Group Description	**Specialty Biologic Agents for Non-Systemic Juvenile Idiopathic Arthritis**
Drugs	Preferred Biologic Agents Enbrel (etanercept) Humira (adalimumab) Xeljanz (tofacitinib) Non-Preferred/Non-Formulary Biologic Agents Actemra (tocilizumab) Orencia (abatacept) Simponi Aria (golimumab) Xeljanz XR, Xeljanz solution (tofacitinib) Remicade (infliximab) Inflectra (infliximab-dyyb) Renflexis (infliximab-abda) Avsola (infliximab-axxq) Infliximab Amjevita (adalimumab) Hadlima (adalimumab) Abrilada (adalimumab) Cyltezo (adalimumab) Yusimry (adalimumab) Hulio (adalimumab) Hyrimoz (adalimumab) Idacio (adalimumab) Yuflyma (adalimumab) adalimumab-fkip Or any newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	See “Other Criteria”
Prescriber Restrictions	The medication is being recommended or prescribed by a rheumatologist
Coverage Duration	If all of the conditions are met, the request will be approved for up to 12 months.

Other Criteria	**Criteria for Initial Approval for All Requests:** • The member has a diagnosis of polyarticular juvenile idiopathic arthritis, active non-systemic polyarthritis, sacroiliitis, enthesitis, or uveitis • The medication is being prescribed at an appropriate (for age and weight) FDA-approved dose • If the request is for Xeljanz, the member has an adequate trial of one preferred TNF inhibitor (Humira, Enbrel) or a medical reason has been documented (e.g. allergy, intolerance, contraindication) for not using an these therapies to manage the condition • If the request is for a non-preferred agent, there must be documentation of an adequate trial of a preferred biologic agent consistent with pharmacy claims/medical chart data **Criteria for Polyarticular Juvenile Idiopathic Arthritis:** • The member has had an adequate trial of methotrexate or leflunomide or sulfasalazine consistent with pharmacy claims/medical chart data or a medical reason has been documented (e.g. allergy, intolerance, contraindication) for not using one of these drugs to manage the condition • If the member has involvement of high-risk joints (cervical spine, hip, wrist), positive rheumatoid factor, positive anti-cyclic citrullinated peptide antibodies, joint damage, or is deemed by the prescriber to be at high risk for disabling joint damage, a trial of conventional therapy is not required. **Criteria for Juvenile Idiopathic Arthritis and Sacroiliitis:** • The member has had an adequate trial of a non-steroidal anti-inflammatory drug (NSAID) (e.g. naproxen, indomethacin) consistent with pharmacy claims/medical chart data or a medical reason has been documented (e.g. allergy, intolerance, contraindication) for not using an NSAID to manage the condition **Criteria for Juvenile Idiopathic Arthritis and Enthesitis:** • The member has had an adequate trial of methotrexate or leflunomide or sulfasalazine AND a non-steroidal anti-inflammatory drug (NSAID) (e.g. naproxen, indomethacin) consistent with pharmacy claims/medical chart data or a medical reason has been documented (e.g. allergy, intolerance, contraindication) for not using these therapies to manage the condition OR • When there is documentation of moderate to severe disease severity warranting TNF inhibitor therapy (Humira, Enbrel), trial of a conventional DMARD (e.g. methotrexate) is not required **Criteria for Juvenile Idiopathic Arthritis with Uveitis:** • The member has had an adequate trial of ophthalmic corticosteroids and methotrexate or a medical reason has been documented (e.g. allergy, intolerance, contraindication) for not using these therapies to manage the condition OR • When there is documentation of moderate to severe disease severity warranting TNF inhibitor therapy (Humira, Enbrel), trial of a conventional therapy is not required **CRITERIA FOR RE-AUTHORIZATION:**
Revision/Review Date: 12/2023	• The medication is being recommended or prescribed by a rheumatologist at an FDA-approved dose. • The member has been receiving the medication and there is documentation that a clinical benefit was observed. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Specialty Biologic Agents for FDA (if no indication specific criteria) and NON-FDA Approved Medically-Accepted Indications**
Drugs	**<u>Preferred Biologic Agents</u>** Enbrel (etanercept) Humira (adalimumab) Xeljanz (tofacitinib) **<u>Non-Preferred Biologic Agents</u>** Actemra (tocilizumab) Cimzia (certolizumab) Kineret (anakinra) Kevzara (sarilumab) Orencia (abatacept) Entyvio (vedolizumab) Otezla (apremilast) Cosentyx (secukinumab) Avsola (infliximab-axxq) Remicade (infliximab) Inflectra (infliximab-dyyb) Renflexis (infliximab-abda) Infliximab Adbry (tralokinumab-ldrm) Ilumya (tildrakizumab-asmn) Spevigo (spesolimab-sbzo) Amjevita (adalimumab) Hadlima (adalimumab) Abrilada (adalimumab) Cyltezo (adalimumab) Yusimry (adalimumab) Ilaris (canakinumab) Tremfya (guselkumab) Siliq (brodalumab) Tysabri (natalizumab) Xeljanz XR, Xeljanz solution (tofacitinib) Taltz (ixekizumab) Olumiant (baricitinib) Rinvoq (upadacitinib) Skyrizi (risankizumab) Simponi (golimumab) Stelara (ustekinumab) Arcalyst (rilonacept) Cibinqo (abrocitinib) Sotyktu (deucravacitinib) Hulio (adalimumab) Hyrimoz (adalimumab) Idacio (adalimumab) Yuflyma (adalimumab) adalimumab-fkipor any newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	See “Other Criteria”
Prescriber Restrictions	The medication being prescribed by a specialist in the field to treat the member’s respective medical condition
Coverage Duration	If all of the conditions are met, the request will be approved for 6 months.

Other Criteria Revision/Review Date: 12/2023	**INITIAL CRITERIA FOR APPROVAL:** • The request is for a medically-accepted use per the medical compendia or standard of care guidelines • Dose is appropriate for member (e.g. age/weight) • The member has had an adequate trial of at least 3 first line therapies (when available) as recommended by the medical compendia or standard of care guidelines consistent with pharmacy claims/medical record data, or has a documented medical reason (e.g. allergy, intolerance, contraindication) for not using first line therapy(ies) to manage the condition • If the request is for a non-preferred agent, there must be documentation of an adequate trial of (or medical reason for not using)a preferred biologic agent consistent with pharmacy claims/medical chart data as appropriate based on the diagnosis **CRITERIA FOR RE-AUTHORIZATION:** • The medication is prescribed by a specialist in the field to treat the member's respective medical condition. • The member has been receiving the medication and there is documentation that a clinical benefit was observed. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Specialty Biologic Agents for Psoriasis**
Drugs	<u>Preferred Biologic Agents</u> Enbrel (etanercept) Humira (adalimumab) <u>Non-Preferred/Non-Formulary Biologic Agents</u> Avsola (infliximab-axxq) Inflectra (infliximab-dyyb) Renflexis (infliximab-abda) Remicade (infliximab) Cimzia (certolizumab) Stelara (ustekinumab) Otezla (apremilast) Infliximab Amjevita (adalimumab-atto) Hadlima (adalimumab) Abrilada (adalimumab) Cyltezo (adalimumab) Yusimry (adalimumab) Hulio (adalimumab) Taltz (ixekizumab) Tremfya (guselkumab) Siliq (brodalumab) Ilumya (tildrakizumab-asmn) Skyrizi (risankizumab) Cosentyx (secukinumab) Sotyktu (deucravacitinib) Hyrimoz (adalimumab) Idacio (adalimumab) Yuflyma (adalimumab) adalimumab-fkip Or any newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	See “Other Criteria”
Prescriber Restrictions	The medication is being recommended or prescribed by a dermatologist
Coverage Duration	If all of the conditions are met, the request will be approved for up to 12 months.

Other Criteria Revision/Review Date: 12/2023	**<u>Initial Authorization:</u>** • The member has a diagnosis of plaque psoriasis • The medication is being prescribed at an appropriate (for age and weight) FDA-approved dose • The member has had an adequate trial of, or medical reason for not using, a therapy in 3 of the following categories, at least one of which must be either systemic therapy or phototherapy (consistent with pharmacy claims/medical chart data): o Topical steroids o Topical calcipotriene, calcitriol, or tazarotene o Topical tacrolimus or pimecrolimus o Topical anthralin, coal tar, or salicylic acid o Oral methotrexate or cyclosporine o Oral acitretin o UVB phototherapy or PUVA (oral psoralen or topical methoxsalen plus UVA therapy) • If the request is for a non-preferred agent, there must be documentation of an adequate trial of (or medical reason for not using) a preferred biologic agent consistent with pharmacy claims/medical chart data. **<u>Re-Authorization:</u>** • The medication is being recommended or prescribed by a dermatologist at an FDA-approved dose. • The member has been receiving the medication and documentation there is documentation that a clinical benefit was observed. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Specialty Biologic Agents for Psoriatic Arthritis (PsA)**
Drugs	**Preferred Biologic Agents** Enbrel (etanercept) Humira (adalimumab) Xeljanz (tofacitinib) **Non-Preferred Biologic Agents** Avsola (infliximab-axxq) Remicade (infliximab) Inflectra (infliximab-dyyb) Renflexis (infliximab-abda) Cimzia (certolizumab) Simponi, Simponi Aria (golimumab) Otezla (apremilast) Stelara (ustekinumab) Cosentyx (secukinumab) Orencia (abatacept) Taltz (ixekizumab) Tremfya (guselkumab) Skyrizi (risankizumab) Rinvoq (upadacitinib) Infliximab Amjevita (adalimumab) Hadlima (adalimumab) Abrilada (adalimumab) Cyltezo (adalimumab) Yusimry (adalimumab) Hulio (adalimumab) Hyrimoz (adalimumab) Idacio (adalimumab) Yuflyma (adalimumab) adalimumab-fkip Xeljanz XR, Xeljanz solution (tofacitinib) Or any newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	See “Other Criteria”
Prescriber Restrictions	The medication is being recommended or prescribed by a rheumatologist or a dermatologist
Coverage Duration	If all of the conditions are met, the request will be approved for up to 12 months.
Other Criteria	**INITIAL CRITERIA FOR APPROVAL:** • The member has a diagnosis of psoriatic arthritis • The medication is being prescribed at an appropriate (for age and weight) FDA-approved dose • If there is documentation of severe erosive disease with functional limitation, a preferred biologic agent may be approved • For all other members, documentation of an adequate trial of, or medical reason for not using, at least one non-steroidal anti-inflammatory drug (NSAID) or cyclooxygenase-2 (COX-2) inhibitor and at least one conventional DMARD (e.g. leflunomide, methotrexate or sulfasalazine) consistent with pharmacy claim/medical chart data

Revision/Review Date: 12/2023	○ If the member has axial disease (i.e. involving the sacroiliac joints and spine) or enthesitis (i.e. involving the plantar fascia and Achilles tendon insertion) only a trial of NSAID or COX-2 therapy is required • If the request is for Xeljanz, the member has an adequate trial of one preferred TNF inhibitor (Humira, Enbrel) or a medical reason has been documented (e.g. allergy, intolerance, contraindication) for not using an these therapies to manage the condition • If the request is for a non-preferred agent, there must be documentation of an adequate trial of, or medical reason for not using, a preferred biologic agent consistent with pharmacy claims/medical record data **<u>CRITERIA FOR RE-AUTHORIZATION:</u>** • The medication is being recommended or prescribed by a rheumatologist or dermatologist at an FDA-approved dose. • The member has been receiving the medication and there is documentation that a clinical benefit was observed. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Specialty Biologic Agents for Rheumatoid Arthritis**
Drugs	**Preferred Biologic Agents** Enbrel (etanercept) Humira (adalimumab) Xeljanz (tofacitinib) **Non-Preferred Biologic Agents** Avsola (infliximab-axxq) Inflectra (infliximab-dyyb) Renflexis (infliximab-abda) Remicade (infliximab) Actemra tocilizumab) Cimzia (certolizumab) Kineret (anakinra) Infliximab Amjevita (adalimumab) Hadlima (adalimumab) Abrilada (adalimumab) Cyltezo (adalimumab) Yusimry (adalimumab) Orencia (abatacept) Simponi, Simponi Aria (golimumab) Xeljanz XR, Xeljanz solution (tofacitinib) Kevzara (sarilumab) Olumiant (baricitinib) Rinvoq (upadacitinib) Hulio (adalimumab) Hyrimoz (adalimumab) Idacio (adalimumab) Yuflyma (adalimumab) adalimumab-fkipor any newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	See "Other Criteria"
Prescriber Restrictions	The medication is being recommended or prescribed by a rheumatologist
Coverage Duration	If all of the conditions are met, the request will be approved for up to 12 months.
Other Criteria Revision/Review Date: 12/2023	**INITIAL CRITERIA FOR APPROVAL:** • The member has a diagnosis of rheumatoid arthritis • The medication is being prescribed at an appropriate (for age and weight) FDA-approved dose • The member has had an adequate trial or a documented medical reason for not using at least one non-biologic disease modifying anti-rheumatic drug (DMARD) (e.g. methotrexate, leflunomide, sulfasalazine or hydroxychloroquine), as noted in pharmacy claims/medical record data/chart notes/physician attestation • If the request is for Xeljanz, the member has an adequate trial of one preferred TNF inhibitor (Humira, Enbrel) or a medical reason has been documented (e.g. allergy, intolerance, contraindication) for not using an these therapies to manage the condition • If the request is for a non-preferred agent, there must be documentation of an adequate trial of a preferred biologic agent consistent with pharmacy claims/medical record data. **CRITERIA FOR RE-AUTHORIZATION:** • The medication is being recommended or prescribed by a rheumatologist at an FDA-approved dose. • The member has been receiving the medication and there is documentation that a clinical benefit was observed. • For members who require Humira 40 mg SC weekly, documentation must be submitted indicating that the member was compliant (consistent with pharmacy claims) with receiving at least 16 weeks of continuous Humira therapy every other week AND the member has a medical reason (e.g. intolerance, hypersensitivity, contraindication) for not receiving concomitant methotrexate. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Specialty Biologic Agents for Spondyloarthritis**
Drugs	**<u>Preferred Biologic Agents</u>** Enbrel (etanercept) Humira (adalimumab) Xeljanz (tofacitinib) **<u>Non-Preferred/Non-Formulary Biologic Agents</u>** Avsola (infliximab-axxq) Remicade (infliximab) Inflectra (infliximab-dyyb) Renflexis (infliximab-abda) Cimzia (certolizumab) Simponi, Simponi Aria (golimumab) Cosentyx (secukinumab) Taltz (ixekizumab) Xeljanz XR, Xeljanz solution (tofacitinib) Infliximab Rinvoq (upadacitinib) Amjevita (adalimumab) Hadlima (adalimumab) Abrilada (adalimumab) Cyltezo (adalimumab) Yusimry (adalimumab) Hulio (adalimumab) Hyrimoz (adalimumab) Idacio (adalimumab) Yuflyma (adalimumab) adalimumab-fkip Or any newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	See “Other Criteria”
Prescriber Restrictions	The medication is being recommended or prescribed by a rheumatologist
Coverage Duration	If all of the conditions are met, the request will be approved for up to 12 months.

Other Criteria	**INITIAL CRITERIA FOR APPROVAL:** • The member has a diagnosis of ankylosing spondylitis or non-radiographic axial spondyloarthritis • The medication is being prescribed at a medically-accepted dose appropriate for member's age and weight per compendia • The member has had an adequate trial and failure of, or medical reason for not using, two different drugs from the following classes, each at least for two weeks: o nonsteroidal anti-inflammatory drugs (NSAIDs) o cyclooxegenase-2 (COX-2) inhibitors • For active disease without axial symptoms (prominent peripheral spondyloarthritis) the member has had an adequate trial and failure of, or medical reason for not using, a conventional DMARD (e.g. sulfasalazine, leflunomide, methotrexate) • If the request is for Xeljanz, the member has an adequate trial of one preferred TNF inhibitor (Humira, Enbrel) or a medical reason has been documented (e.g. allergy, intolerance, contraindication) for not using an these therapies to manage the condition • If the request is for a non-preferred agent, there must be documentation of an adequate trial of a preferred biologic agent consistent with pharmacy claims/medical record data, or documentation of a medical reason for not using a preferred drug. **CRITERIA FOR RE-AUTHORIZATION:** • The medication is being prescribed at a medically-accepted dose appropriate for member's age and weight • The member has been receiving the medication and there is documentation that a clinical benefit was observed. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**
Revision/Review Date: 12/2023	

Prior Authorization Group Description	**Specialty Biologic Agents for Systemic Juvenile Idiopathic Arthritis**
Drugs	Drugs: Actemra (tocilizumab) Ilaris (canakinumab) Kineret (anakinra) Orencia (abatacept) Humira (adalimumab) Enbrel (etanercept) Avsola (infliximab-axxq) Remicade (infliximab) Inflectra (infliximab-dyyb) Renflexis (infliximab-abda) Infliximab Amjevita (adalimumab) Hadlima (adalimumab) Abrilada (adalimumab) Cyltezo (adalimumab) Yusimry (adalimumab) Hulio (adalimumab) Hyrimoz (adalimumab) Idacio (adalimumab) Yuflyma (adalimumab) adalimumab-fkip or any newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	See “Other Criteria”
Prescriber Restrictions	The medication is being recommended or prescribed by a rheumatologist
Coverage Duration	If all of the conditions are met, the request will be approved for up to 12 months.

Other Criteria
 	
Revision/Review Date: 12/2023
	<u>INITIAL CRITERIA FOR APPROVAL:</u>
	• The member has a diagnosis of systemic juvenile idiopathic arthritis
	• The medication is being prescribed at an appropriate (for age and weight) FDA-approved or medically appropriate dose
	• One of the following:
	  • The member has had an adequate trial and failure or medical reason for not using one of the following:
	  o Non-steroid anti-inflammatory drug (NSAID)
	  o Systemic glucocorticoid
	  o Leflunomide
	  o Methotrexate
	  o Cyclosporine
	  o Tacrolimus
	  • Member has documented diagnosis of macrophage activation syndrome (MAS)
	
	<u>CRITERIA FOR RE-AUTHORIZATION:</u>
	• The medication is being recommended or prescribed by a rheumatologist at an FDA-approved or medically appropriate dose.
	• The member has been receiving the medication and there is documentation that a clinical benefit was observed.
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.