



Pharmacy Prior Authorization Criteria

3/26/2025


AmeriHealth Caritas[™]
New Hampshire

Field Name	Field Description
Prior Authorization Group Description	Medications without Drug or Class Specific Criteria
Drugs	<ul style="list-style-type: none"> • Medications without drug or class specific prior authorization criteria • Brand drugs and reference biologics when a therapeutic equivalent generic drug or biosimilar/interchangeable biologic is available <p>***The Oncology Drugs prior authorization criteria will be applied to oncology drugs without drug or class specific criteria***</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If all of the conditions are met, requests will be approved for up to 12 months (depending on the diagnosis and usual treatment duration), or 6 months if the request is for a non-preferred ADHD medication due to the shortage.
Other Criteria	<p><u>Initial Authorization:</u></p> <p>All Requests:</p> <ul style="list-style-type: none"> • The drug is requested for an appropriate use (per the references outlined in “Covered Uses” • The dose requested is appropriate for the requested use (per the references outlined in “Covered Uses”) • If the request is for a brand drug with a therapeutically equivalent (A-rated) generic drug currently available, documentation of the following: <ul style="list-style-type: none"> ○ The provider either verbally or in writing has submitted a medical or member specific reason why the brand name drug is required based on the member’s condition or treatment history; AND if the member had side effects or a reaction to the generic drug, the provider has completed and submitted an FDA MedWatch form to justify the member’s need to avoid this drug. The MedWatch form must be included with the prior authorization request <p style="text-align: center;">Form FDA 3500 – Voluntary Reporting</p>

- 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:
 - The prescriber has verbally or in writing submitted a medical or member specific reason why the reference biologic is required based on the member’s condition or treatment history; **AND** if the member had side effects or a reaction to two (if available) biosimilar or interchangeable biologics, the provider has completed and submitted an FDA MedWatch form to justify the member’s need to avoid these drugs. The MedWatch form must be included with the prior authorization
 - The currently available biosimilar product(s) does not have the same appropriate use (per the references outlined in “Covered Uses”) as the reference biologic drug being requested

[Form FDA 3500 – Voluntary Reporting](#)

Non-Preferred drugs on the state PDL:

Patient must meet one of the following criteria:

- Documentation that patient has a trial and failure of the required number of preferred products listed for the drug class:
[NH Medicaid PDL](#)
If a specific number is not outlined for the class, a trial and failure of all preferred products in the class must be documented. For non-preferred ADHD medications where the member has not tried/failed two preferred medications due to the ongoing shortage of preferred medications, a trial with preferred agents is not required, and approval will be for 6 months.
- Documentation that patient has an allergy to all preferred drugs within the same class on the PDL and description of the reaction has been provided
- Documentation that patient has a contraindication to or drug-to-drug interaction with all preferred drugs within the same class on the PDL and description of the reaction or contraindication has been provided
- Documentation that patient has a history of unacceptable or toxic side effects to all preferred drugs within the same class on the PDL and clinical information is provided describing effects
- Documentation that patient has an indication that is unique to a non-preferred drug and is supported by peer-reviewed literature or unique federal FDA-approved indication

<p>Revision/ Review Date 12/2023</p>	<ul style="list-style-type: none"> • Documentation that patient has an age-specific indication that requires a non- preferred PDL drug and member age/indication for request has been provided • Documentation that patient has a medical co-morbidity or other medical complication that precludes the use of a preferred drug • Documentation that patient has clinically unacceptable risk with a change in therapy to a preferred drug and risks have been provided <p>Non-PDL drugs where prior authorization is required without specific criteria: Patient must meet one of the three following criteria:</p> <ul style="list-style-type: none"> • Documented trial and failure or intolerance with up to two alternative preferred medications appropriate for the requested use (per the references outlined in “Covered Uses” or has a medical reason why these drug(s) cannot be used [e.g. intolerance, contraindication]). For medications where there is only one preferred agent, only that agent must have been ineffective or not tolerated. • No other preferred medication has a medically accepted use for the patient’s specific diagnosis as referenced in the medical compendia. • All other preferred medications are contraindicated based on the patient’s diagnosis, other medical conditions, or other medication therapy. <p><u>Reauthorization:</u></p> <ul style="list-style-type: none"> • Documentation of provider attestation that demonstrates a clinical benefit • The requested drug is for a medically accepted dose as outlined in Covered Uses <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Diagnosis Code Requirement
Drugs	Formulary/preferred medications that will pay at point of sale if the required ICD-10 code is submitted at the pharmacy
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.

Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criterion is met, the request will be approved for up to a 12 month duration (depending on the diagnosis and usual treatment duration).
Other Criteria	Provider has submitted a diagnosis that is FDA approved or referenced in disease state specific standard of care guidelines for the requested drug. (Please see covered uses section for appropriate sources)
Revision/Review Date 4/2024	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Off-Label Uses Criteria
Drugs	Medications with off-label uses
Covered Uses	Off-label uses: Medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer LexiDrugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criterion is met, the request will be approved for up to a 12 month duration (depending on the diagnosis and usual treatment duration).

<p>Other Criteria</p>	<p><u>Authorization:</u> the</p> <ol style="list-style-type: none"> 1. One of following: <ol style="list-style-type: none"> a. Patient has had a documented trial and or intolerance with up to two preferred medications used to treat the documented diagnosis, or for medications where there is only one preferred agent, only that agent must have been ineffective or not tolerated. b. No other formulary medication has a medically accepted use for the patient’s specific diagnosis as referenced in the medical compendia <p>AND</p> 2. One of the following: <ol style="list-style-type: none"> a. Medication is being requested for an accepted offlabel use and is listed in the standard clinical decision support resources (as noted in Covered Uses section above) b. Requested use can be supported by at least two published peer reviewed clinical studies <p>AND</p>
<p>Revision/Review Date 4/2024</p>	<ol style="list-style-type: none"> 3. Medication is being requested at an appropriate dose per literature <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>

Field Name	Field Description
Prior Authorization Group	Oncology Drugs
Drugs	Oral and Injectable Oncology Medications (specialty or non-specialty) without medication specific criteria when requested for an oncology diagnosis
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI) , and the Drug Package Insert, and/or per the National Comprehensive Cancer Network (NCCN)
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescriber is an oncologist, or specialist in type of cancer being treated
Coverage Duration	If the criteria are met, the request will be approved for up to 6 month duration.
Other Criteria	<p>All of the following criteria must be met:</p> <ul style="list-style-type: none"> • Requested use must be a labeled indication or be supported by NCCN Category 1 or 2A level of evidence. If the request is for an off-label use supported by NCCN as Category 2B recommendation then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g. allergic reaction, contraindication) • Documentation has been provided of the results of all required genetic testing where required per product package insert • Documentation has been provided of the results of all required laboratory values and patient specific information (e.g. weight, ALT/AST, Creatine Kinase, etc.) necessary to ensure the patient has no contraindications to therapy per product package insert • The product is being prescribed at a dose that is within FDA approved/NCCN guidelines. • If the request is for a reference biologic drug with either a biosimilar or interchangeable biologic drug currently available, documentation of one of the following: <ul style="list-style-type: none"> ○ 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,

<p>Revision/Review 12/2023</p>	<p>the provider has completed and submitted an FDA MedWatch form to justify the member’s need to avoid these drugs. The MedWatch form must be included with the prior authorization request</p> <ul style="list-style-type: none">○ 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 <p>Form FDA 3500 – Voluntary Reporting</p> <ul style="list-style-type: none">• If the request is for abiraterone (Zytiga) 500 mg tablet, a documented medical reason why two tablets of generic abiraterone acetate 250 mg cannot be used <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>

Field Name	Field Description
Prior Authorization Group Description	Prior Authorization Exception Criteria
Covered Uses	All medically accepted indications. Medically accepted indications are defined using the following compendia resources: the Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), American Hospital Formulary Service Drug Information (AHFS-DI), and DRUGDEX Information System. The reviewer may also reference disease state specific standard of care guidelines.
Scope	Requests for exception to the drug's prior authorization criteria requirements
Coverage Duration	12 months
Criteria	<ul style="list-style-type: none"> • 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. <ul style="list-style-type: none"> ○ Medical and/or member specific reasons may include but are not limited to: <ul style="list-style-type: none"> ▪ Uniqueness of the member's condition or other physical characteristics of the member's condition. ▪ Psychiatric, intellectual, physical, cultural, and/or linguistic characteristics of the member which may inhibit the provider from obtaining all necessary prior authorization criteria requirements. <p>Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date:	10/2023

Field Name	Field Description
Prior Authorization Group Description	Quantity Limit Exception Criteria
Covered Uses	All medically accepted indications. Medically accepted indications are defined using the following compendia resources: the Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), American Hospital Formulary Service Drug Information (AHFS-DI), and DRUGDEX Information System. The reviewer may also reference disease state specific standard of care guidelines.
Scope	Requests for formulary drugs exceeding the health plan's published quantity limits

Criteria	<ul style="list-style-type: none"> • 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. <p>AND one of the following:</p> <ul style="list-style-type: none"> ○ 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. ○ The member requires a dose within prescribing guidelines that exceeds the plan’s quantity limit. <p>Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Coverage Duration	12 Months
Revision/Review Date	10/2023

Field Name	Field Description
Prior Authorization Group Description	Safety Edit Exception Criteria
Covered Uses	All medically accepted indications. Medically accepted indications are defined using the following compendia resources: the Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), American Hospital Formulary Service Drug Information (AHFS-DI), and DRUGDEX Information System. The reviewer may also reference disease state specific standard of care guidelines.
Scope	Requests for formulary drugs and for previously approved nonformulary drugs: <ul style="list-style-type: none"> • Exceeding the Food and Drug Administration (FDA) or compendia max dose recommendations • Exceeding the FDA dosing or compendia administration frequency recommendations • Exceeding the FDA or compendia duration of therapy recommendations • Duplication of therapy error at Point of Service (POS) • Age Restriction error at POS • Day Supply Limit error at POS • Concurrent Use error at POS • Drug Drug Interaction error at POS

Criteria	<p>Exceeding the Food and Drug Administration (FDA) or compendia maximum dose, administration frequency or duration of therapy recommendations.</p> <ul style="list-style-type: none">• 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. <p>AND</p> <ul style="list-style-type: none">• 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. <p>Duplication of therapy</p> <p><u>Transition from one agent to another</u></p> <ul style="list-style-type: none">• 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*. <p><u>Concurrent Therapy with two similar agents</u></p>
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- The provider must submit a medical reason why treatment with more than one drug in the same class is required based on the member's condition and treatment history.

OR

- The provider must submit disease state specific standard of care guidelines supporting concurrent therapy.

Age Restriction

- The provider must submit a medical reason why the drug is needed for a member whose age is outside of the plan's minimum or maximum age limit.

AND

- The indication and dose requested is supported by the Medical Compendia or current treatment guidelines.

Day Supply Limit

- An additional fill exceeding the day supply limit is needed based on a dose increase or is needed to achieve a total daily dose

OR

- The provider must submit a medical reason why an additional fill is needed outside of the plan's day supply limit.

AND

- The indication and dose requested is supported by the FDA, Medical Compendia or current treatment guidelines.

Concurrent Use/Drug-Drug Interaction

- The provider must submit a medical reason why treatment with both drugs is necessary for the member
- The increased risk for side effects when taking the drugs together has been discussed with the member
- Medications must be prescribed by the same provider for the following scenarios:
 1. If the request is for concurrent medication-assisted treatment (MAT) agent and a benzodiazepine
 2. If the request is for concurrent use with a MAT agent and an opioid*

	Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.
Coverage Duration	*One month approval for Duplication of therapy when transitioning from one agent to another, Day Supply Limit due to a dose increase, or for Concurrent Use with a MAT agent and opioid. All Other Scenarios: 12 months
Revision/Review Date: 10/2023	

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
Criteria	Requests for drugs on the plan's formulary with a step therapy restriction which do not meet step therapy requirements will be considered when the provider verbally or in writing has submitted a medical reason why: <ul style="list-style-type: none"> • Required step therapy drug(s) would be ineffective, or; • Required step therapy drug(s) have the potential to cause harm or deterioration of the member's condition, or; • The requested drug would be superior to the required prerequisite trial(s) with preferred drug(s). <p>Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Coverage Duration	12 Months
Revision/Review Date:	10/2023

Field Name	Field Description
Prior Authorization Group Description	5-Hydroxytryptamine-3 Serotonin Receptor Antagonists (5-HT3 RA), Substance P/Neurokinin 1 Receptor Antagonists (NK1 RA), and Combination Agents

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

<p>Revision/Review Date 12/2023</p>	<ul style="list-style-type: none">• The requested dosing of the 5-HT3 RA and/or NK1 RA is within FDA approved, NCCN/ASCO or other medical compendia standard of care guidelines• Patients meeting one of the following criteria may receive the generic 5-HT3 RA palonosetron hydrochloride without prior trial and failure of ondansetron/granisetrone<ul style="list-style-type: none">○ Adult patients receiving an antineoplastic agent with HIGH or MODERATE emetic risk per the NCCN Practice Guidelines○ Pediatric patients receiving an antineoplastic agent with HIGH emetic risk per the NCCN Practice Guidelines who are unable to receive dexamethasone• For all other patients, if the medication request is for any 5-HT3 RA other than ondansetron, granisetron, or an NK1-RA other than aprepitant oral capsule or fosaprepitant IV emulsion:<ul style="list-style-type: none">○ The patient has a documented treatment failure after receiving an adequate trial of a preferred 5-HT3 RA and a preferred NK1 RA and/or has a documented medical reason (intolerance, hypersensitivity, contraindication, etc.) for not utilizing these medications to treat their medical condition. <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Adakveo (crizanlizumab-tmca)
Drugs	Adakveo (crizanlizumab-tmca)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	Member must be 16 years of age or older
Prescriber Restrictions	Prescriber must be a hematologist or sickle cell specialist
Coverage Duration	If the criteria are met, requests may be approved for 12 months.
Other Criteria	<p>Initial Authorization:</p> <ul style="list-style-type: none"> • 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 <p>Reauthorization:</p> <ul style="list-style-type: none"> • Documentation has been submitted that the member has demonstrated or maintained ONE of the following changes from baseline: <ul style="list-style-type: none"> ○ Reduction in pain crises ○ ○ Increased time between crises ○ ○ Decrease in days hospitalized • Documentation of the member’s current weight • Request is for an FDA-approved dose <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date: 7/2024	

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

<p>Other Criteria</p>	<p><u>Initial Authorization: All Requests</u></p> <ul style="list-style-type: none"> • Member must have documentation of baseline low density lipoprotein cholesterol (LDL-C) • Member has tried and failed a high-intensity statin (i.e. atorvastatin 40-80 mg, rosuvastatin 20-40 mg) at maximum tolerated dose for 3 months via claim history or chart notes OR documentation has been provided that the member is not able to tolerate a statin. • Documentation was provided indicating provider has counseled member on smoking cessation and following a “heart healthy diet”. <p>For Hyperlipidemia • One of the following:</p> <ul style="list-style-type: none"> ○ Member has a diagnosis of heterozygous familial hypercholesterolemia (FH) ○ Member has a diagnosis of primary hyperlipidemia • Member has tried and failed ezetimibe at a maximum tolerated dose or documentation has been provided that the patient is not able to tolerate ezetimibe.
<p>Revision/Review Date 7/2024</p>	<p>For Cardiovascular Risk Reduction</p> <ul style="list-style-type: none"> • Member has established cardiovascular disease (documented history of coronary artery disease, symptomatic peripheral arterial disease, and or cerebrovascular atherosclerotic disease) • Member does not have established cardiovascular disease but is considered high risk (one of the following): <ul style="list-style-type: none"> ○ Diabetes mellitus (type 1 or type 2) in females over 65 years of age or males over 60 years of age ○ A Reynolds Risk score > 30% or a SCORE Risk score > 7.5% over 10 years ○ A coronary artery calcium score >400 Agatston units at any time in the past. • Member has a fasting LDL-C \geq 70 mg/dL <p><u>Reauthorization:</u></p> <ul style="list-style-type: none"> • Documentation provided that the member has obtained clinical benefit from medication (e.g. LDL-C lowering from baseline) <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>

Field Name	Field Description
Prior Authorization Group Description	Adrenal Enzyme Inhibitors for Cushing’s Disease
Drugs	Isturisa (osilodrostat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Member must be ≥ 18 years of age
Prescriber Restrictions	Prescribed by, or in consultation with, an endocrinologist or other specialist in the treatment of metabolic disorders
Coverage Duration	<p>Initial Authorization: If the criteria are met, the request will be approved for a 6-month duration.</p> <p>Reauthorization: If the criteria are met, the request will be approved for a 12-month duration.</p>
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • 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 compendia or peer-reviewed literature with FDA- Documented baseline urinary free cortisol (UFC) test \geq approved package labeling, nationally recognized • 1.3upper limit of normal (ULN) \circ UFC Normal Range = 3.5-45 mcg/24 hrs (9.66-124.2 nmol/24 hrs) • Member has had a documented trial and failure of one of the following: <ul style="list-style-type: none"> \circ ketoconazole \circ Metopirone (metyrapone) \circ Lysodren (mitotane) \circ cabergoline \circ Signifor/Signifor LAR (pasireotide) \circ etomidate <p>OR</p> <p>Member has a documented medical reason (e.g. contraindication, intolerance, hypersensitivity) as to why these medications cannot be used</p>

<p>Revision/Review Date: 2/2024</p>	<p><u>Reauthorization:</u></p> <ul style="list-style-type: none">• Member has responded to therapy as defined by a documented urinary free cortisol (UFC) test \leq 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 <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>

Field Name	Field Description
Prior Authorization Group Description	Adrenal Enzyme Inhibitors for Cushing’s Syndrome
Drugs	Recorlev (levoketoconazole)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	<ul style="list-style-type: none"> • Patients with a non-endogenous source of hypercortisolism, such as exogenous source of glucocorticoids or therapeutic use of ACTH. • Patient has a diagnosis of pituitary or adrenal carcinoma
Required Medical Information	See “Other Criteria”
Age Restrictions	Per FDA approved package insert
Prescriber Restrictions	Prescriber must be an endocrinologist or in consultation with an endocrinologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Patient has a diagnosis of endogenous Cushing’s syndrome. • Patient is not a candidate for surgery, surgery is not an option, or prior surgery has not been curative. • Documented baseline urinary free cortisol (UFC) test ≥ 1.5 times ULN (within the past 30 days). • Patient has tried and failed, or has a medical reason for not using, ketoconazole. • Medication is prescribed at an FDA approved dose. <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation or provider attestation of positive clinical response (i.e. decrease in urinary free cortisol from baseline.) • Medication is prescribed at an FDA approved dose <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
Revision/Review Date: 4/2024	

Field Name	Field Description
Prior Authorization Group Description	Adrenergic, alpha-receptor-blocking agent
Drug(s)	Phenoxybenzamine (Dibenzyline)

Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or specialist in the management of pheochromocytoma.
Coverage Duration	If the conditions are met, the request will be approved for up to a 14-day duration for perioperative management or up to a 6 month duration for non-surgical initial requests. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of pheochromocytoma • Documented use for either perioperative management or long term use when surgery is contraindicated • Documented trial and failure, intolerance, or contraindication to doxazosin • Medication is prescribed at an FDA approved dose <p><u>Re-Authorization</u></p> <ul style="list-style-type: none"> • Documented long term use when surgery is contraindicated • Documentation or provider attestation that demonstrates a clinical benefit • Medication is prescribed at an FDA approved dose
Revision/Review Date: 2/2024	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Adzynma
Drugs	Adzynma (ADAMTS13, recombinant-krhn)

Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist, oncologist, intensive care specialist, or specialist in the treatment of rare genetic hematologic diseases
Coverage Duration	<p><u>On-demand therapy</u>: If all criteria are met, the request will be approved for 1 month.</p> <p><u>Prophylactic therapy</u>: If all criteria are met, the initial request will be approved for 6 months. Reauthorization requests will be approved for 12 months.</p>
Other Criteria	<p><u>Initial Authorization</u></p> <ul style="list-style-type: none"> • Diagnosis of congenital thrombotic thrombocytopenic purpura (cTTP) as confirmed by BOTH of the following: <ul style="list-style-type: none"> ○ Molecular genetic testing ○ ADAMTS13 activity <10% • Prescriber attestation that member has not been diagnosed with any other TTP-like disorder (i.e., microangiopathic hemolytic anemia, immune-mediated thrombotic thrombocytopenic purpura [iTTP]) • If request is for prophylactic therapy, member must also have a history of at least one documented TTP event • Member’s weight • Request is for an FDA-approved dose <p><u>Reauthorization</u></p> <ul style="list-style-type: none"> • Documentation of positive clinical response to therapy (i.e., improvement in acute and subacute TTP events, platelet counts, microangiopathic hemolytic anemia episodes, or clinical symptoms) • Member’s weight • Request is for an FDA-approved dose
Revision/Review Date: 4/2024	Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Agents for Atopic Dermatitis
Drugs	<p>Preferred: Adbry (tralokinumab) Dupixent (dupilumab) Elidel (pimecrolimus) Eucrisa (crisaborole) pimecrolimus (Elidel) Rinvoq (abrocitinib) tacrolimus (Protopic)</p> <p>Non-Preferred: Cibinqo (abrocitinib) Opzelura (ruxolitinib)</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Tacrolimus (Protopic), pimecrolimus (Elidel), and Opzelura (ruxolitinib): Immunocompromised members
Required Medical Information	See “other criteria”
Age Restrictions	Per package insert
Prescriber Restrictions	Adbry, Cibinqo, Dupixent, Opzelura, and Rinvoq requests: Provider must be a pediatrician, dermatologist, immunologist, or allergist (or one has been consulted)
Coverage Duration	For Opzelura: If the criteria are met, the request will be approved with up to an 8 week duration and all reauthorization requests will be approved for up to a 6 month duration. For all others: If the criteria are met, the request will be approved with up to a 6 month duration.
Other Criteria	<p><u>Initial Authorization</u></p> <p>For pimecrolimus:</p> <ul style="list-style-type: none"> ○ Diagnosis of <u>mild to moderate</u> atopic dermatitis (AD) ○ For mild AD: trial and failure of one formulary medium to high potency topical corticosteroid ○ For moderate AD: Trial and failure of one formulary medium to high potency topical corticosteroid AND topical tacrolimus <p>For tacrolimus: Diagnosis of <u>moderate to severe</u> AD</p>

- Trial and failure of one formulary medium to high potency topical corticosteroid

For Eucrisa:

- Diagnosis of mild to moderate AD
- Trial and failure of one formulary medium to high potency topical corticosteroid
- Trial and failure of topical tacrolimus or pimecrolimus (for members less than 2 years of age requesting Eucrisa, trial of topical tacrolimus or pimecrolimus is not required)

For Dupixent and Adbry:

- Diagnosis of moderate to severe AD ○ For moderate AD: Trial and failure, or contraindication/intolerance to TWO of the following:
 - One formulary medium to high potency topical corticosteroid
 - Topical tacrolimus or pimecrolimus (for members less than 2 years of age requesting Dupixent, trial of topical tacrolimus or pimecrolimus is not required)
- Eucrisa (crisaborole) ○ For severe AD: Trial and failure of, or contraindication/intolerance to, ALL of the following:
 - One formulary topical medium to high potency topical corticosteroid
 - Topical tacrolimus (for members less than 2 years of age requesting Dupixent, trial of topical tacrolimus is not required)

For Rinvoq:

- Diagnosis of refractory, moderate to severe, AD
- For moderate AD: Trial and failure of, or contraindication to, TWO of the following:
 - One formulary topical medium to high potency topical corticosteroid
 - Topical tacrolimus or pimecrolimus ○ Eucrisa (crisaborole)
- For severe AD: Trial and failure of, or contraindication to ALL of the following:
 - One formulary medium to high potency topical corticosteroid
 - Topical tacrolimus
- Trial and failure of, intolerance to, or contraindication to another systemic drug product

For Opzelura:

<p>Revision/Review Date 9/2024</p>	<ul style="list-style-type: none"> ○ Diagnosis of mild to moderate AD ○ Member must have 3% to 20% of body surface are (BSA) atopic dermatitis involvement (excluding scalp) ○ Trial and failure, or contraindication/intolerance to, ALL of the following: ○ One formulary medium to high potency topical corticosteroid ○ Topical tacrolimus or pimecrolimus ○ Eucrisa (crisaborole) <p><u>**A MAXIMUM of ONE 60 g TUBE of OPZELURA MAY BE APPROVED PER WEEK**</u></p> <p>For Cibinqo:</p> <ul style="list-style-type: none"> • Diagnosis of refractory, moderate to severe, AD • For moderate AD: Trial and failure of, or contraindication to, ALL of the following: <ul style="list-style-type: none"> ○ One formulary topical medium to high potency topical corticosteroid ○ Topical tacrolimus or pimecrolimus ○ Eucrisa (crisaborole) • For severe AD: Trial and failure of, or contraindication to ALL of the following: <ul style="list-style-type: none"> ○ One formulary medium to high potency topical corticosteroid ○ Topical tacrolimus • Trial and failure of, intolerance to, or contraindication to another systemic drug product <p><u>Reauthorization:</u></p> <ul style="list-style-type: none"> ○ Prescriber attests that the member has experienced improvement in symptoms (e.g. significant clearing of the skin, reduction in itching) <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Agents for Graft versus Host Disease

Drugs	Rezurock (belumosudil), Imbruvica (ibrutinib), Jakafi (ruxolitinib phosphate), Orenzia (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	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with 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. Orenzia: If all of the conditions are met, the request will be approved for 1 month duration (4 total infusions)
Other Criteria	<p><u>**For oncological indications, please refer to the “Oncology Agents” policy**</u></p> <p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Imbruvica <ul style="list-style-type: none"> ○ Member has a diagnosis of chronic graft versus host disease <ul style="list-style-type: none"> ○ Member has tried and failed or cannot use a systemic corticosteroid or documentation is provided as to why a systemic corticosteroid cannot be used ○ The drug is prescribed at an FDA-approved dose • Jakafi <ul style="list-style-type: none"> ○ Member has a diagnosis of acute graft versus host disease or a diagnosis of chronic graft versus host disease <ul style="list-style-type: none"> ○ Member has tried and failed or cannot use a systemic corticosteroid or documentation is provided as to why a systemic corticosteroid cannot be used ○ The drug is prescribed at an FDA-approved dose • Rezurock <ul style="list-style-type: none"> ○ Member has a diagnosis of chronic graft versus-host disease <ul style="list-style-type: none"> ○ Member has tried and failed at least two lines of systemic immunosuppressive therapy (e.g. corticosteroids, calcineurin inhibitors, mycophenolate mofetil, ibrutinib,

<p>Revision/Review Date: 4/2024</p>	<p>ruxolitinib), one of which must be a systemic corticosteroid, or documentation is provided as to why a systemic corticosteroid cannot be used</p> <ul style="list-style-type: none"> ○ The drug is prescribed at an FDA-approved dose <ul style="list-style-type: none"> • Orenzia ○ Orenzia is being requested for prophylaxis against acute graft versus host disease <ul style="list-style-type: none"> ○ Member will be undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allelemismatched unrelated donor ○ Member will be receiving Orenzia 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 <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • 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 <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
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Field Name	Field Description
Prior Authorization Group Description	Agents for Homozygous Familial Hypercholesterolemia (HoFH)
Drugs	<p>Preferred: Evkeeza (evinacumab-dgnb) Non-Preferred: Juxtapid (lomitapide)</p> <p>**Please refer to the “Proprotein Convertase Subtilisin/kexin 9 (PCSK9) Inhibitors” policy for requests for medications in that class**</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A

Required Medical Information	N/A
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by cardiologist or specialist in treatment of lipid disorders.
Coverage Duration	If all of the above conditions are met, the initial request will be approved for up to a 6 month duration, and the reauthorization request will be approved for a 12 month duration.
Other Criteria	<p>Initial Authorization:</p> <ul style="list-style-type: none"> • Documentation of a diagnosis of homozygous familial hypercholesterolemia (HoFH) via either: <ul style="list-style-type: none"> ○ Genetic confirmation of two mutant alleles at the LDL receptor, ApoB, PCSK9 or ARH adaptor protein gene locus; OR ○ 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 <ul style="list-style-type: none"> ▪ Cutaneous or tendon xanthoma before age 10 years, OR ▪ Elevated LDL-C levels consistent with heterozygous FH in both parents. • Patient has tried and failed atorvastatin 40mg-80mg or rosuvastatin 20-40mg (consistently for 3 months via claim history or chart notes). If patient is not able to tolerate atorvastatin or rosuvastatin, documentation was provided that patient is taking another statin at the highest tolerated dose, or a medical reason was provided why the member is not able to use these therapies. • If prescriber indicates member is “statin intolerant”, documentation was provided including description of the side

<p>Revision/Review Date 2/2024</p>	<p>effects, duration of therapy, “wash out”, re-trial, and then change of agents.</p> <ul style="list-style-type: none"> • Patient has tried and failed ezetimibe at a maximal tolerated dose or a medical reason was provided why the member is not able to use ezetimibe • Member has documented trial and failure with PCSK9 inhibitor for at least 3 months, or a medical reason has been provided, why member is unable to use a PCSK9 inhibitor indicated for HoFH to manage their condition. • Documentation was provided indicating provider has counseled member on smoking cessation and following a “heart healthy diet”. • Documentation was provided of current LDL level • If the request is for Juxtapid the member has had documented trial and failure with Evkeeza for at least 6 month or a medical reason has been provided why the member is unable to use Evkeeza <p>Reauthorization:</p> <ul style="list-style-type: none"> • Documentation submitted indicates that the member has obtained clinical benefit from the medication including repeat fasting lipid panel lab report, and the member has achieved or maintained a LDL reduction from the levels immediately prior to initiation of treatment with Juxtapid or Evkeeza. • The patient’s claim history shows consistent therapy (monthly fills). <p>Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Agents for the Treatment of Postpartum Depression
Drugs	Zulresso (brexanalone) Zurzuvae (zuranolone)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”

Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a psychiatrist or an obstetrician-gynecologist.
Coverage Duration	If all of the criteria are met, the initial request will be approved for a one-time administration of Zulresso or one 14-day course of Zurzuvae per postpartum period. Reauthorization will not be permitted.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Prescriber attestation of severe postpartum depression (PPD) diagnosis and submission of validated screening tool result(s) (e.g. Edinburgh Postnatal Depression Scale, Hamilton Depression Rating Scale) that requires quick onset where the patient cannot wait 4-6 weeks for the standard of care antidepressants to take effect • Patient is ≤ 6 months postpartum with a major depressive episode without psychosis that began no earlier than the third trimester and no later than the first 4 weeks after delivery • For requests for Zurzuvae: <ul style="list-style-type: none"> ○ Attestation that the provider warned the patient not to drive for at least 12 hours after each dose. • For requests for Zulresso: <ul style="list-style-type: none"> ○ Healthcare facility and patient must be enrolled in the Zulresso REMS program prior to initiation of medication ○ Patient's weight has been provided • Medication is prescribed at an FDA approved dose
Revision/Review Date: 2/2024	<p><u>Renewal Authorization:</u></p> <ul style="list-style-type: none"> • Renewals will not be authorized <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>

Prior Authorization Group Description	Agents for Thrombocytopenia
Drugs	<p><u>Preferred Thrombocytopenia Agent(s):</u></p> <ul style="list-style-type: none"> • Promacta (eltrombopag) • Doptelet (avatrombopag) <p><u>Non-Preferred Thrombocytopenia Agent(s):</u></p> <ul style="list-style-type: none"> • Alvaiz (eltrombopag) • Nplate (romiplostim) • Mulpleta (lusutrombopag) • Tavalisse (fostamatinib)

Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	Per package insert
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	If the criteria are met, the requests for Promacta, Alvaiz, Nplate, and Tavalisse will be approved for 12 months. Mulpleta will be approved for a maximum of 7 days. Doptelet will be approved for 12 months if the request is for ITP or for a maximum of 5 days if the request is for thrombocytopenia associated with chronic liver disease in adult patients requiring elective surgery.
Other Criteria	<p>Chronic immune (idiopathic) thrombocytopenia (ITP):</p> <ul style="list-style-type: none"> • Platelet count < 30,000 cells/microL • Documented trial and failure, or intolerance, contraindication, to ONE of the following: <ul style="list-style-type: none"> • Glucocorticoids • Intravenous immune globulin (IVIG) • Rituximab • splenectomy • If the request is for Alvaiz, Doptelet, Nplate or Tavalisse, the member has a documented trial and failure, intolerance, or contraindication to Promacta <p>Severe aplastic anemia (Promacta and Alvaiz only):</p> <ul style="list-style-type: none"> • Promacta is being prescribed in conjunction with at least one immunosuppressive agent OR there is a documented trial and failure, intolerance, or contraindication to at least one immunosuppressive agent

<p>Revision/Review Date 4/2024</p>	<ul style="list-style-type: none"> • Platelet count < 20,000 cells/microL OR platelet count < 30,000 cells/microL with bleeding OR reticulocyte count < 20,000 cells/microL OR absolute neutrophil count < 500 cells/microL • If the request is for Alvaiz, the member has a documented trial and failure, intolerance, or contraindication to Promacta <p>Thrombocytopenia in patients with Hepatitis C infection (Promacta and Alvaiz only):</p> <ul style="list-style-type: none"> • Diagnosis of chronic hepatitis C • Platelet count < 50,000 cells/microL • Documented treatment with interferon-based therapy AND patient's degree of thrombocytopenia prevents the initiation or limits the ability to maintain interferon-based therapy • If the request is for Alvaiz, the member has a documented trial and failure, intolerance, or contraindication to Promacta <p>Thrombocytopenia associated with chronic liver disease in <u>adult</u> patients requiring elective surgery (Doptelet and Mulpleta only):</p> <ul style="list-style-type: none"> • Patient has a diagnosis of chronic liver disease and is scheduled to undergo a procedure • Platelet count < 50,000 cells/microL • For Mulpleta, approve if there is documentation of trial and failure, intolerance, or contraindication to use Doptelet <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Agents to Treat Gaucher's Disease
Drugs	Cerdelga (eliglustat), Cerezyme (imiglucerase), Vpriv (velaglucerase alfa), Elelyso (taliglucerase alfa), miglustat (Zavesca)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	None

Required Medical Information	See “Other Criteria”
Age Restrictions	Per package insert
Prescriber Restrictions	Prescriber is a specialist in treatment of Gaucher’s Disease (e.g. endocrinologist, hematologist or geneticist), or is in consultation with a specialist
Coverage Duration	If all of the conditions are met, the request will be approved with 6month duration.
Other Criteria	<p><u>Initial Authorization:</u></p> <p><u>Cerezyme, Vpriv, Elelyso, or miglustat initial authorization:</u></p> <ul style="list-style-type: none"> • Patient has a confirmed diagnosis of Gaucher’s disease, type 1 (GD1) • Request is for an FDA approved dose <p><u>Cerdelga initial authorization:</u></p> <ul style="list-style-type: none"> • Patient has a confirmed diagnosis of Gaucher’s disease, type 1 (GD1) and is a CYP2D6 extensive metabolizer (EM), intermediate metabolizer (IM) or poor metabolizer (PM), as detected by an FDA-approved test. • Patient is not concomitantly taking Class IA (e.g. quinidine, procainamide) or Class III antiarrhythmic (e.g. amiodarone, sotalol). • For EMs or IMs, patient is not concomitantly taking a moderate or strong CYP2D6 inhibitor (e.g. fluoxetine, bupropion) WITH a moderate or strong CYP3A inhibitor (fluconazole, ketoconazole). • For IMs and PMs, patient is not concomitantly taking a strong CYP3A inhibitor. • Patient has no pre-existing cardiac disease or long QT syndrome. • For EM’s, patient does not have moderate or severe hepatic impairment • For IM’s or PMs, patient does not have any degree of hepatic impairment.

<p>Revision/Review Date 4/2024</p>	<p><u>Re-Authorization criteria for all agents:</u></p> <ul style="list-style-type: none">• Documentation has been provided that patient has obtained clinical benefit from medication (e.g. increased platelet count, improvement in anemia, PFT's, improvement in radiographic scans, improved quality of life)• Request is for an FDA approved dose <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Alpha-1 Proteinase Inhibitors (Human)
Drugs	<p><u>Preferred:</u> Prolastin-C</p> <p><u>Non-Preferred:</u> Aralast NP Glassia Zemaira Or any other newly marketed agent</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or specialist in the treatment of AAT
Coverage Duration	The request will be approved for up to a 12 month duration.
Other Criteria	<p>Initial Authorization:</p> <ul style="list-style-type: none"> • Documented diagnosis of a congenital deficiency of alpha-1 antitrypsin (AAT) (serum AAT level < 11 micromol/L [approximately 57 mg/dL using nephelometry or 80mg/dl by radial immunodiffusion]). • Documentation was submitted indicating the member has undergone genetic testing for AAT deficiency and is classified as phenotype PiZZ, PiSZ, PiZ(null) or Pi(null)(null) [NOTE: phenotypes PiMZ or PiMS are not candidates for treatment with Alpha1-Proteinase Inhibitors] • Documentation was submitted (member’s pulmonary function test results) indicating airflow obstruction by spirometry (forced expiratory volume in 1 second [FE_{V1}] ≤ 65% of predicted), or provider has documented additional medical information demonstrating medical necessity • Documentation was submitted indicating member is a non-smoker or an ex-smoker (eg. smoking cessation treatment) • Documentation of the member’s current weight • The Alpha-1 Proteinase Inhibitor (human) is being prescribed at an FDA approved dosage • If the medication request is for an Alpha1-Proteinase Inhibitor (human) product other than Prolastin-C, the patient has a

<p>Revision/Review Date 2/2024</p>	<p>documented medical reason (intolerance, hypersensitivity, contraindication, treatment failure, etc.) for not using Prolastin-C to treat their medical condition</p> <p>Reauthorization:</p> <ul style="list-style-type: none">• Documentation of the member's current weight• Documentation was submitted indicating member is a non-smoker or an ex-smoker (e.g. smoking cessation treatment)• Documentation was submitted indicating the member has clinically benefited from therapy (i.e. stable lung function, improved PFTs, alpha-1 antitrypsin serum level maintained above 11 micromol/L [approximately 57 mg/dL using or 80 mg/dL by radial immunodiffusion], improved quality of life)• The Alpha-1 Proteinase Inhibitor (human) is being prescribed at an FDA approved dosage <p>Clinical reviewer/Medical Director must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>
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Prior Authorization Group Description	Amifampridine
Drugs	Firdapse (amifampridine)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Patients must be 6 years age or older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a neuromuscular specialist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy the request will be approved for 6 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) based on at least one electrodiagnostic study (i.e., repetitive nerve stimulation, nerve conduction studies, electromyography) OR anti-P/Q-type voltage-gated calcium channel antibody testing • Member has been screened for small cell lung cancer (SCLC) and/or other malignancies • Member does not have a history of seizures • Medication is being prescribed at an FDA approved dose or is supported by compendia or standard of care guidelines <p><u>Re-authorization:</u></p> <ul style="list-style-type: none"> • Medication is prescribed at an FDA-approved dose or is supported by compendia or standard of care guidelines • Documentation provided that prescriber has evaluated the member and recommends continuation of therapy <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 2/2024	

Field Name	Field Description
Prior Authorization Group Description	Amtagvi (lifileucel)

Drugs	Amtagvi (lifileucel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	<ul style="list-style-type: none"> • Uncontrolled brain metastases • Melanoma of uveal or ocular origin • Systemic steroid therapy for any reason
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be an oncologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for a one-time treatment.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of unresectable or metastatic melanoma (Stage IIIc or Stage IV) • Member must have progressed through at least one prior systemic therapy including a PD-1/PD-L1 blocking antibody and, if BRAF V600 mutation–positive, a BRAF inhibitor or BRAF inhibitor in combination with a MEK inhibitor • Member must have at least one resectable lesion (or aggregate of lesions resected) of a minimum 1.5 cm in diameter post-resection • Eastern Cooperative Oncology Group (ECOG) score of 0 or 1 • Medication is prescribed at an FDA approved dose <p>The safety and effectiveness of repeat administration of Amtagvi has not been evaluated and will not be approved.</p>
Revision/Review Date: 4/2024	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Anti-CD19 CAR-T Immunotherapies
Drugs	Kymriah (tisagenlecleucel), Yescarta (axicabtagene ciloleucel), Tecartus (brexucabtagene autoleucel), Breyanzi (lisocabtagene maraleucel)

Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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	<p><u>Initial authorization:</u></p> <ul style="list-style-type: none"> • 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. • Use is supported by a labeled indication or NCCN guidelines <p><u>Leukemia</u></p> <p>B-cell precursor Acute Lymphoblastic Leukemia (ALL):</p> <ul style="list-style-type: none"> • If the request is for Kymriah <ul style="list-style-type: none"> ○ Patient is 25 years of age or younger ○ ALL that is refractory or in second or later relapse • If the request is for Tecartus <ul style="list-style-type: none"> ○ Patient is 18 years of age or older ○ ALL that is relapsed or refractory <p>Chronic Lymphocytic Leukemia (CLL):</p> <ul style="list-style-type: none"> • If the request is for Breyanzi <ul style="list-style-type: none"> ○ Patient is 18 years of age or older

- Patient has relapsed/refractory disease defined as failure of two or more lines of therapy, including a Bruton tyrosine kinase (BTK) inhibitor AND a B-cell lymphoma 2 (BCL-2) inhibitor

Non-Hodgkin's Lymphoma (NHL)

Follicular Lymphoma (FL):

- If the request is for Breyanzi, Kymriah, or Yescarta: ○ Patient is 18 years of age or older
 - Patient has relapsed/refractory disease defined as failure of two or more lines of systemic therapy

Large B-cell Lymphoma (LBCL), Diffuse Large B-cell Lymphoma (DLBCL) not otherwise specified, primary mediastinal high grade B-cell lymphoma, follicular lymphoma grade 3B, and DLBCL arising from follicular lymphoma:

- If the request is for Breyanzi, Kymriah, or Yescarta ○ Patient is 18 years of age or older ○ 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 therapy
- For Kymriah: Patient has relapsed/refractory disease defined as failure of two or more lines of systemic therapy
- For Yescarta ONE of the following:
 - Patient is refractory to first-line chemoimmunotherapy or relapses within 12 months of first-line chemoimmunotherapy or
 - Patient has failed two or more lines of systemic therapy

Mantle Cell Lymphoma (MCL):

- If the request is for Tecartus:
 - Patient is 18 years of age or older

<p>Revision/Review Date: 7/2024</p>	<ul style="list-style-type: none">○ Patient has relapsed/refractory disease defined as failure of BOTH the following lines of therapy:<ul style="list-style-type: none">▪ Chemoimmunotherapy such as an anti-CD20 monoclonal antibody (e.g. Rituxan) + any chemotherapeutic agent▪ Bruton Tyrosine Kinase (BTK) Inhibitor (e.g. Calquence, Imbruvica, Brukinsa) <p>Small Lymphocytic Lymphoma (SLL):</p> <ul style="list-style-type: none">• If the request is for Breyanzi<ul style="list-style-type: none">○ Patient is 18 years of age or older○ Patient has received at least 2 prior lines of therapy including, a Bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor <p><u>Re-authorization:</u></p> <ul style="list-style-type: none">• Treatment exceeding 1 dose per lifetime will not be authorized. <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Prior Authorization Group Description	Anti-FGF23 Monoclonal Antibodies
Drugs	Crysvita (burosumab) SQ solution, or any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: The Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	See Other Criteria
Required Medical Information	See Other Criteria
Age Restrictions	X-linked hypophosphatemia (XLH): 6 months of age or older Tumor-induced osteomalacia (TIO): 2 years of age and older
Prescriber Restrictions	Prescribed by, or in consultation with, an endocrinologist, nephrologist, molecular geneticist, or other specialist experienced in the treatment of metabolic bone disorders
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months and reauthorization requests will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <p>For X-linked hypophosphatemia (XLH):</p> <ul style="list-style-type: none"> • Diagnosis of XLH • Dosing is appropriate as per labeling or is supported by compendia or standard of care guidelines • Labs, as follows: <ul style="list-style-type: none"> ○ Serum phosphorus below normal for patient age ○ $eGFR > 30 \text{ mL/min/1.73 m}^2$ or $CrCl \geq 30 \text{ mL/min}$ • Patient will not use concurrent oral phosphate and/or active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol) • Additionally, for adults: <ul style="list-style-type: none"> ○ Clinical signs and symptoms of XLH (e.g. bone/joint pain, fractures, osteomalacia, osteoarthritis, ensethopathies, spinal stenosis impaired mobility, presence or history of lower limb deformities, etc.) ○ Trial and failure of, or contraindication to, combination therapy with oral phosphate and active vitamin D (calcitriol) for a minimum of 8 weeks <p>For tumor-induced osteomalacia (TIO):</p> <ul style="list-style-type: none"> • Diagnosis of FGF23-related hypophosphatemia in TIO • Dosing is appropriate as per labeling or is supported by compendia or standard of care guidelines

<p>Revision/Review Date: 7/2024</p>	<ul style="list-style-type: none"> • The tumor(s) is/are not amenable to surgical excision or cannot be located • Labs, as follows: <ul style="list-style-type: none"> ○ Serum phosphorus below normal for patient age ○ eGFR > 30 mL/min/1.73 m² or CrCl ≥ 30 mL/min • Patient will not use concurrent oral phosphate and/or active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol) <p><u>Re-authorization:</u></p> <p>For XLH or TIO:</p> <ul style="list-style-type: none"> • Documented effectiveness as evidenced by at least one of the following: <ul style="list-style-type: none"> ○ Serum phosphorus within normal limits for patient age ○ Clinical improvement (e.g. improved rickets, improved bone histomorphometry, increased growth velocity, increased mobility, decrease in bone fractures, improved fracture healing, reduction in bone-related pain) • 25-hydroxyvitamin D level and, if abnormally low, documented supplementation with cholecalciferol or ergocalciferol • Patient is not concurrently using oral phosphate and/or active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol) • Dosing continues to be appropriate as per labeling or is supported by compendia or standard of care guidelines <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Anti-Fungal Medications

Drugs	<p><u>Preferred:</u> ciclopirox solution 8% solution itraconazole 100 mg capsule, solution luliconazole 1% cream oxiconazole 1% cream tavaborole 5% solution terbinafine 250 mg tablet</p> <p><u>Non-Preferred:</u> Jublia (efinaconazole) Kerydin (tavaborole) Luzu (luliconazole) Oxistat (oxiconazole) Sporanox (itraconazole)</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Cosmetic use
Required Medical Information	See “Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	<p>If all the criteria are met, the request will be approved for the following length of time: ciclopirox, Jublia (efinaconazole), tavaborole (Kerydin): up to 48 weeks;</p> <p>itraconazole (Sporanox), luliconazole (Luzu), oxiconazole (Oxistat), terbinafine: up to 3 months</p>
Other Criteria	<p><u>For all requests:</u></p> <ul style="list-style-type: none"> • The medication is being prescribed for an FDA approved/standard of care guidelines indication and dose • If the request is for a non-preferred medication, a trial and failure of 2 preferred products are required or member has a documented medical reason (intolerance, hypersensitivity, contraindication, etc.) why they are not able to use preferred drugs <p><u>Additional Requirements for Onychomycosis:</u></p> <ul style="list-style-type: none"> • Onychomycosis confirmed by a positive KOH stain, positive PAS

Date: 2/2024	<p>stain, or a positive fungal culture, and experiencing pain that limits normal activity.</p> <ul style="list-style-type: none">• If the request is for a topical agent, the member has failed either oral terbinafine, oral itraconazole, or oral fluconazole <p><u>Additional Requirements for luliconazole (Luzu) & oxiconazole (Oxistat):</u></p> <ul style="list-style-type: none">• The member has had an adequate trial and failure (at least 2 weeks within the last 60 days) of topical ciclopirox, clotrimazole, econazole, ketoconazole, miconazole, nystatin, terbinafine, or tolnaftate, or has a documented intolerance to those topical treatments <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
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Field Name	Field Description
Prior Authorization Group Description	Anti-Parkinson's Agents for OFF Episodes
Drugs	Preferred: Ongentys (opicapone), Xadago (safinamide) Non-preferred: Nourianz (istradefylline), Inbrija (levodopa) inhalation, apomorphine (Apokyn), 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	If the criteria are met, the initial requests will be approved for up to a 6 month duration and reauthorization requests will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ○ COMT-inhibitors (e.g., entacapone) ○ Dopamine agonists (e.g., ropinirole, pramipexole) ○ 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, apomorphine (Apokyn), or any other newly marketed agent, patient must also have a documented trial and failure or intolerance to Ongentys and Xadago. <p><u>Re-authorization:</u></p> <ul style="list-style-type: none"> • Documentation of positive clinical response

	<ul style="list-style-type: none">• Dosing is appropriate as per labeling or is supported by compendia or standard of care guidelines
Revision/Review Date 2/2024	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Antifibrotic Respiratory Tract Agents

Drugs:

Preferred: Ofev (nintedanib esylate), pirfenidone Non-Preferred: Esbriet (pirfenidone)

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

INITIAL CRITERIA:

For all requests:

- Patient is 18 years of age or older
- Prescriber is a pulmonologist or lung transplant specialist
- Provider attests that they have reviewed the patient's other medications, and have addressed all potential drug interactions
- Documentation has been provided that the patient does not smoke
- If the request is for a non-preferred drug, patient must have a documented trial and failure or intolerance to one preferred drug

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

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

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

Confirmed diagnosis of SSc-ILD

- FVC \geq 40% within 30 days of request
- Trial and failure of mycophenolate mofetil (MMF), cyclophosphamide or azathioprine.

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

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

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

REAUTHORIZATION CRITERIA:

- Prescriber is a pulmonologist or lung transplant specialist

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

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

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

Revision/Review Date: 7/2024

Field Name	Field Description
Prior Authorization Group Description	Antisense Oligonucleotides for Duchenne Muscular Dystrophy
Drugs	Exondys 51 (eteplirsen), Vyondys 53 (golodirsen), Viltepso (viltolarsen), Amondys 45 (casimersen)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Concomitant use with another antisense oligonucleotide
Required Medical Information	See “Other Criteria”
Age Restrictions	Age ≤ 20 years
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or provider who specializes in the treatment of DMD
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months and reauthorization requests will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Member has a diagnosis of Duchenne muscular dystrophy (DMD) and lab test was submitted confirming the mutation of dystrophin gene amenable to ONE of the following: <ul style="list-style-type: none"> ○ Exon 51 skipping for Exondys 51 ○ Exon 53 skipping for Vyondys 53 or Viltepso ○ Exon 45 skipping for Amondys 45 • Member is ambulatory • Baseline dystrophin levels AND results of motor function tests are provided [e.g. 6-Minute Walk Test (6MWT), Time to Stand Test (TTSTAND), Time to Run/Walk Test (TTRW), North Star Ambulatory Assessment (NSAA), Time to Climb 4 Steps Test (TTCLIMB)] • Member has stable pulmonary and cardiac function • ONE of the following applies: <ul style="list-style-type: none"> ○ Member has been on a stable dose of corticosteroids for at least 3 months for Viltepso ○ Member has been on a stable dose of corticosteroids for at least 6 months for Vyondys 53, Exondys 51, or Amondys 45 • Attestation of renal function monitoring is provided with request • The request is for an FDA approved dose <p><u>Reauthorization</u></p>

<p>Revision/Review Date 4/2024</p>	<ul style="list-style-type: none">• Documentation is provided that the member had an increase in dystrophin levels from baseline• Documentation is provided that the member had the expected clinical response (e.g. provider statement that the therapy has reduced the rate of further decline in function as demonstrated by 6MWT, TTSTAND, TTRW, NSAA, or TTCLIMB)• Member is ambulatory• Attestation of renal function monitoring is provided with request • The request is for an FDA approved dose <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Atovaquone Suspension
Drugs	Atovaquone (Mepron) suspension
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 6 month duration.
Other Criteria	<p><u>Treatment/Prevention of <i>Pneumocystis jirovecii</i> pneumonia</u></p> <ul style="list-style-type: none"> • Diagnosis of mild to moderate <i>Pneumocystis jirovecii</i> pneumonia (PCP) or diagnosis with the need to prevent PCP infection • Documented trial and failure with therapeutic doses or intolerance to trimethoprim- sulfamethoxazole (TMP-SMX). • Documented trial and failure with therapeutic doses or intolerance to dapsone. <p><u>Treatment/Prevention of <i>Toxoplasma gondii</i> encephalitis in patients with HIV:</u></p> <ul style="list-style-type: none"> • Diagnosis of <i>Toxoplasma gondii</i> encephalitis or documentation of supporting diagnosis for prophylaxis • Documented trial and failure with therapeutic doses or intolerance to trimethoprim- sulfamethoxazole (TMP-SMX). <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date	4/2024

Field Name	Field Description
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Prior 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	<p><u>Initial Authorization</u></p> <ul style="list-style-type: none"> • Member has a diagnosis of relapsed or refractory multiple myeloma (RRMM) • For Abecma, member must have also received at least 2 prior lines of therapy including: <ul style="list-style-type: none"> ○ An immunomodulatory agent (e.g. lenalidomide, pomalidomide, thalidomide) ○ A proteasome inhibitor (e.g. bortezomib, carfilzomib, ixazomib) ○ An anti-CD38 monoclonal antibody (e.g. daratumumab, isatuximab) • For Carvykti, member must also be refractory to lenalidomide AND have received at least 1 prior line of therapy including: <ul style="list-style-type: none"> ○ An immunomodulatory agent (e.g. lenalidomide, pomalidomide, thalidomide) ○ A proteasome inhibitor (e.g. bortezomib, carfilzomib, ixazomib) • Member does not have an active infection or inflammatory disorder • 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 <p><u>Re-authorization:</u></p>

Revision/Review
Date: 7/2024

- 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.

Field Name	Field Description
Prior Authorization Group Description	Benlysta (belimumab)
Drugs	Benlysta (belimumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	Severe active central nervous system lupus
Required Medical Information	See “other criteria”
Age Restrictions	Must be at least 5 years of age
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist or nephrologist
Coverage Duration	If all the criteria are met initial authorization requests may be approved for up to 6 months. Reauthorization requests may be approved for up to 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • <u>Active systemic lupus erythematosus (SLE)</u> ○ Provider attestation that the patient is positive for autoantibodies (or antinuclear antibodies or anti–doublestranded DNA [anti-dsDNA] antibodies) <ul style="list-style-type: none"> ○ The member has tried and failed both of the following (or contraindication/inability to use these medications): <ul style="list-style-type: none"> ▪ Hydroxychloroquine ▪ One other immunosuppressant [e.g., methotrexate, azathioprine, calcineurin inhibitors or mycophenolate] • <u>Active lupus nephritis</u> ○ Provider attestation of diagnosis confirmed by kidney biopsy ○ The member has tried and failed, or has a medical reason for not using, both of the following <ul style="list-style-type: none"> ▪ Cyclophosphamide or tacrolimus ▪ Mycophenolate • Provider states the member will not be receiving concomitant therapy with the following: <ul style="list-style-type: none"> ○ B-cell targeted therapy including (but not limited to) rituximab ○ Interferon receptor antagonist, type 1 including (but not limited to) Saphnelo (anifrolumab) • Dosing is appropriate per labeling <p><u>Criteria for Reauthorization:</u></p> <ul style="list-style-type: none"> • Documentation or provider attestation of positive clinical response as indicated by one of the following: <ul style="list-style-type: none"> Fewer flares that required steroid treatment

Revision/Review
Date: 2/2024

- Lower average daily oral prednisone dose
 - Improved daily function either as measured through a validated functional scale or through improved daily performance documented at clinic visits
 - Sustained improvement in laboratory measures of lupus activity
- Dosing is appropriate per labeling

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

Field Name	Field Description
Prior Authorization Group Description	Biologic Agents for Nasal Polyposis
Drugs	Dupixent (dupilumab), Xolair (omalizumab), Nucala (mepolizumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Use of Dupixent, Xolair, or Nucala concomitantly or with another pulmonary biologic (e.g. Fasenra, Cinqair)
Required Medical Information	See “Other Criteria”
Age Restrictions	Patients must be 18 years age or older
Prescriber Restrictions	Prescribed by or in consultation with an allergist or otolaryngologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy the request will be approved for 6 months.
Other Criteria	<p>**Xolair: For asthma and urticaria, please refer to the “Xolair for Asthma, Urticaria, and IgE-Mediated Food Allergy” policy**</p> <p>**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**</p> <p>**Nucala: For asthma or other eosinophilic conditions, please refer to the “Pulmonary Biologics for Asthma and Eosinophilic Conditions” policy**</p> <p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) <ul style="list-style-type: none"> • Medication is being prescribed at an FDA approved dosage • Documentation of ONE of the following: <ul style="list-style-type: none"> ○ Trial and failure, or medical reason for not using, all of the following therapies: <ul style="list-style-type: none"> ▪ an intranasal corticosteroid ▪ a systemic corticosteroid ○ Prior surgery for nasal polyps • Patient is currently using an intranasal corticosteroid, will be prescribed at an intranasal corticosteroid, or has a documented medical reason for not using an intranasal corticosteroid

<p>Revision/Review Date 4/2024</p>	<p><u>Re-authorization:</u></p> <ul style="list-style-type: none">• Medication is prescribed at an FDA-approved dosage• Member will continue to use an intranasal corticosteroid, or has a medical reason for not using an intranasal corticosteroid• Documentation has been provided that demonstrates a clinical benefit (e.g. improvements in symptom severity, nasal polyp score [NPS], sino-nasal outcome test-22 [SNOT-22], nasal congestion score [NCS], nasal obstruction symptom visual analogue scale [VAS]) <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Blincyto
Drugs	Blincyto (blinatumomab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restriction	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist/hematologist
Coverage Duration	The request will be approved for up to a 12 month duration.
Other Criteria	<p>Initial Authorization:</p> <ul style="list-style-type: none"> • Patient has a diagnosis of one of the following forms of Acute Lymphoblastic Leukemia (ALL): <ul style="list-style-type: none"> a) Relapsed CD19-positive B-cell precursor ALL b) Refractory CD19-positive B-cell precursor ALL c) CD19-positive B-cell precursor ALL in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1% • Provider attests to monitor patient for Cytokine Release Syndrome (CRS) and neurological toxicities <p>Reauthorization:</p> <ul style="list-style-type: none"> • Patient has a diagnosis of relapsed or refractory CD19-positive B-cell precursor ALL and has not exceeded 9 total cycles of Blincyto therapy • Provider attests to treatment response or stabilization of disease • Prescriber attests to monitor patient for Cytokine Release Syndrome (CRS) and neurological toxicities <p>***For CD19-positive B-cell precursor ALL with MRD, reauthorization is not allowed***</p> <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date	4/2024

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

<p>Revision/Review Date 10/2023</p>	<ul style="list-style-type: none"> ○ Topiramate, divalproex ER or DR, or valproic acid • If the diagnosis is Overactive Bladder, the member has tried and failed 2 formulary drugs (e.g. oxybutynin) • If the diagnosis is Hyperhidrosis, the member has tried and failed a prescription strength antiperspirant (e.g. 20% aluminum chloride hexahydrate) • If the diagnosis is Chronic Sialorrhea, <ul style="list-style-type: none"> ○ Documentation is provided that the member has had sialorrhea lasting at least 3 months ○ 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 <p>For Reauthorization:</p> <ul style="list-style-type: none"> • Documentation of provider attestation that demonstrates a clinical benefit • The requested drug is for a medically accepted dose as outlined in Covered Uses <p>Physician/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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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 12 months.
<p data-bbox="224 1079 444 1115">Other Criteria</p> <p data-bbox="224 1696 444 1766">Revision/Review Date: 7/2024</p>	<p data-bbox="493 1079 781 1115"><u>Initial Authorization:</u></p> <ul data-bbox="537 1121 1409 1461" style="list-style-type: none"> <li data-bbox="537 1121 1409 1346">• Documentation of confirmed diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2) with one of the following: <ul data-bbox="634 1192 1409 1346" style="list-style-type: none"> <li data-bbox="634 1192 1409 1262">○ Lab results demonstrating deficient TPP1 enzyme activity <li data-bbox="634 1268 1409 1346">○ Identification of causative mutations in the TPP1/CLN2 gene <li data-bbox="537 1352 1409 1461">• Documentation of baseline CLN2 Clinical Rating Scale motor +language score. Baseline CLN2 score must be > 0. • Medication is prescribed at an FDA approved dose <p data-bbox="493 1503 732 1539"><u>Re-authorization:</u></p> <ul data-bbox="537 1545 1409 1654" style="list-style-type: none"> <li data-bbox="537 1545 1409 1614">• Documentation of CLN2 Clinical Rating Scale motor +language score has remained > 0 <li data-bbox="537 1621 1409 1654">• Medication is prescribed at an FDA approved dose <p data-bbox="493 1717 1386 1829">Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>

Field Name	Field Description
Prior Authorization Group Description	Buprenorphine/Naloxone and Buprenorphine (Oral) Criteria
Drugs	<p>Preferred: buprenorphine (Subutex) buprenorphine/naloxone* (Suboxone) <i>*Preferred buprenorphine/naloxone products for doses of 24 mg/day or less do NOT require a prior approval (PA)</i> Zubsolv (buprenorphine/naloxone)</p> <p>Non-Preferred: Suboxone (buprenorphine/naloxone)</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the 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, the request will be approved for 12 months.
Other Criteria	<p>All requests:</p> <ol style="list-style-type: none"> 1. Diagnosis of opiate use disorder 2. Attestation that the New Hampshire Prescription Drug Monitoring (PDMP) has been reviewed within the last 60 days <p>Buprenorphine Single Agent Products:</p> <ol style="list-style-type: none"> 3. Patient is pregnant or lactating OR there is documentation of allergic reaction to buprenorphine/naloxone combination product (please provide type of reaction and date) <p>Non-Preferred Products:</p> <ol style="list-style-type: none"> 4. The member has a documented treatment failure with 1 preferred drug or has a documented medical reason (intolerance, hypersensitivity, contraindication, etc.) why they are not able to use preferred drugs <p>Concurrent Use/ Drug-Drug Interaction:</p>

Revision/Review Date 4/2024	<ol style="list-style-type: none">5. The provider must submit a medical reason why treatment with both drugs is necessary for the member6. The increased risk for side effects when taking the drugs together has been discussed with the member7. Medications must be prescribed by the same provider for the following scenarios:<ol style="list-style-type: none">a. If the request is for concurrent medication-assisted treatment (MAT) agent and a benzodiazepineb. If the request is for concurrent use with a MAT agent and an opioid, medications must be prescribed by the same provider (One month approval only) <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>

Field Name	Field Description
Prior Authorization Group Description	Calcitonin Gene-Related Peptide Antagonists for Acute Migraine Treatment
Drugs	<p>Preferred: Ubrelvy (ubrogepant) Nurtec ODT (rimegepant) – If the request is for migraine prevention please refer to the Calcitonin Gene-Related Peptide (CGRP) Antagonists for Headache Prevention criteria</p> <p>Non-Preferred: Zavzpret (zavegepant); Or any newly marketed CGRP for acute migraine treatment</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the 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	<p><u>Initial Authorization:</u></p> <ol style="list-style-type: none"> 1. Diagnosis of migraine headache 2. Requested dose is within FDA approved dosing guidelines 3. Documented trial and failure of (or medical justification for not using) two triptan products 4. If the request is for a non-preferred agent, the member must also have documentation of a trial and failure of (or medical justification for not using) a preferred agent <p><u>Criteria for Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation of improvement in migraine pain and symptom(s) (e.g., photophobia, nausea, phonophobia) <p>Nurtec ODT QL of 8 units per month. Ubrelvy QL of 16 units per month Zavzpret QL of 8 units per month</p>

<p>Revision/Review Date: 9/2024</p>	<p><u>Criteria for exceeding the quantity limit (note all of the above criteria must also be met)</u></p> <ul style="list-style-type: none">• 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:<ul style="list-style-type: none">o Beta-adrenergic blockers o Topiramate or divalproex ER or DR o Amitriptyline or venlafaxineo Frovatriptan, zolmitriptan or naratriptan (for menstrual migraine prophylaxis) <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Prior Authorization Group Description	Calcitonin Gene-Related Peptide (CGRP) Antagonists for Headache Prevention
Drugs	<p>Preferred: Ajoovy (fremanezumab) Emgality (galcanezumab) 120 mg Nurtec ODT (rimegepant) – if the request is for acute treatment of migraine, please refer to the Acute Migraine Treatments criteria Qulipta (atogepant)</p> <p>Non-Preferred: Aimovig (erenumab) Emgality (galcanezumab) 100 mg Vyepiti (eptinezumab) any newly marketed drug in the class</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Request for indication of chronic cluster headaches
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	If the criteria are met, the request will be approved for 6 months. Reauthorization may be approved for 6 months.
Other Criteria	<p><u>Criteria for Initial Authorization:</u></p> <p><u>Cluster Headache:</u></p> <ul style="list-style-type: none"> • Request for Emgality (galcanezumab) for diagnosis of episodic cluster headache • If the request is for any other CGRP, do not approve; not indicated • Requested dose is within FDA approved dosing guidelines • Documented trial and failure (or a medical justification for not using) with verapamil for at least 4 weeks, at minimum effective doses <p><u>Migraine Headache Prophylaxis:</u></p> <ul style="list-style-type: none"> • Diagnosis of episodic migraine as evidenced by number of headache days per month (4 to 14 migraine days per month) or

<p>Revision/Review Date: 9/2024</p>	<p>chronic migraine (≥ 15 headache days per month with ≥ 8 migraine days per month) despite use of abortive therapy (e.g. triptan or NSAIDs)</p> <ul style="list-style-type: none"> • Requested dose is within FDA approved dosing guidelines • Documentation of the number of headache days per month • Documentation of members Migraine Disability Assessment (MIDAS), Migraine Physical Function Impact diary (MFPDI), or Headache Impact Test (HIT-6) score • 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: <ol style="list-style-type: none"> 1. Beta-adrenergic blockers 2. Topiramate or divalproex ER or DR 3. Amitriptyline or venlafaxine 4. Frovatriptan, zolmitriptan or naratriptan (for menstrual migraine prophylaxis) • If the request is for a non-preferred CGRP antagonist, the patient has a documented medical reason (intolerance, hypersensitivity, contraindication, treatment failure etc) for not using a preferred CGRP antagonist for migraine prophylaxis. <p><u>Criteria for Re-Authorization:</u></p> <p>Episodic Cluster Headache:</p> <ul style="list-style-type: none"> • Documented reduction in the frequency of headaches (clinical benefit) <p>Migraine:</p> <ul style="list-style-type: none"> • Documented clinical benefit as evidenced by one of the following: <ul style="list-style-type: none"> ○ Reduction of $\geq 50\%$ in the number of headache days per month relative to pre-treatment baseline (clinical benefit) ○ Improvement in member’s Migraine Disability Assessment (MIDAS), Migraine Physical Function Impact diary (MFPDI), or Headache Impact Test (HIT6) score <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
<p>Field Name</p>	<p>Field Description</p>
<p>Prior Authorization Group Description</p>	<p>Camzyos</p>

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	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ○ Beta blockers (i.e. metoprolol, propranolol, atenolol) ○ 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 <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation of clinical benefit as evidenced by an improvement in oHCM symptoms (i.e., improvement in shortness of breath, LVOT, peak oxygen consumption, etc.) from baseline OR improvement or no worsening of NYHA functional class from baseline • Patient has a left ventricular ejection fraction (LVEF) ≥50% • Medication is prescribed at an FDA approved dose
Revision/Review Date: 7/2024	If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	Carisoprodol
Drugs	Carisoprodol (Soma) Carisoprodol-Aspirin (Soma Compound)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Member 16 years of age or older.
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the requests for carisoprodol will be approved for a single fill for a maximum of 84 tablets for a 21 day supply and requests for carisoprodol-aspirin will be approved for a single fill for a maximum of 168 tablets for a 21 day supply.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Member has had a trial and failure, or intolerance to, cyclobenzaprine, tizanidine, baclofen, or a nonsteroidal antiinflammatory drug (NSAID) in the last 90 days; AND • If the member has previously received a carisoprodol containing drug within the past 90 days, then the provider attests the member has been screened for, and demonstrates no signs of, carisoprodol abuse <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation has been provided that states the member has been screened for, and demonstrates no signs of, carisoprodol abuse <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 2/2024	

Field Name	Field Description
Prior Authorization Group Description	Chelating Agents
Drugs	<ul style="list-style-type: none"> • Chemet (succimer) capsule, <i>up to a 19 day supply, pays at point of sale</i> • Deferasirox (Exjade) Tablet for Oral Suspension • Deferasirox (Jadenu) Tablet, Granule Pack • Deferiprone (Ferriprox) Tablet • Ferriprox (Deferiprone) solution • Ferriprox (Twice a Day) (Deferiprone) tablet • Deferoxamine Mesylate (Desferal) Vial • Penicillamine (Cuprimine, Depen, D-penammine) capsule, tablet • Radiogardase (Prussian blue) capsule • Trientine (Syprine) capsule • Cuvrior (trientine tetrahydrochloride) tablet • Galzin (Zinc acetate) capsule • Bal in Oil (Dimercaprol) Ampule • Pentetate calcium trisodium ampule • Pentetate zinc trisodium ampule • Calcium Disodium Versenate (edetate calcium disodium) ampule
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	See “other criteria”
Prescriber Restrictions	N/A
Coverage Duration	If the above conditions are met, the request will be approved with a 6 month duration.

Other Criteria	<p><u>Requests for deferasirox (Exjade, Jadenu) only:</u></p> <p>Chronic iron overload due to blood transfusions:</p> <p><u>For Pediatric Population:</u></p>
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- Patient must be ≥ 2 years old and < 21 years old
- Diagnosis of chronic iron overload due to blood transfusions
- Patient receiving blood transfusions on a regular basis/participating in blood transfusion program
- Serum Ferritin concentration is consistently > 1000 mcg/L. If the serum ferritin levels fall consistently below 500 mcg/L, deferasirox (Exjade, Jadenu) must be discontinued
- If the request is for deferasirox oral granules in packet member has had a documented trial and failure of deferasirox dispersible tablets or medical reason why deferasirox dispersible tablets cannot be used
- The medication requested is being prescribed at an FDA approved dose

For Adult Population:

- Patient must be ≥ 21 years old
- Diagnosis of chronic iron overload due to blood transfusions
- Patient receiving blood transfusions on a regular basis/participating in blood transfusion program
- Serum Ferritin concentration is consistently > 1000 mcg/L. If the serum ferritin levels fall consistently below 500 mcg/L, deferasirox (Exjade, Jadenu) must be discontinued
- Documented patient is unable to use deferoxamine (Desferal) parenterally
- If the request is for deferasirox oral granules in packet member has had a documented trial and failure of deferasirox dispersible tablets or medical reason why deferasirox dispersible tablets cannot be used
- The medication requested is being prescribed at an FDA approved dose

Chronic iron overload in non-transfusion dependent thalassemia Syndromes:

- Patient must be ≥ 10 years old
- Diagnosis of thalassemia syndrome
- Liver iron content (LIC) by liver biopsy of ≥ 5 mg Fe/g dry weight

- ≥ 2 measurements of serum ferritin levels $> 300\text{mcg/L}$ at least one month apart
- If the request is for deferasirox oral granules in packet member has had a documented trial and failure of deferasirox dispersible tablets or medical reason why deferasirox dispersible tablets cannot be used
- The medication requested is being prescribed at an FDA approved dose

Requests for Ferriprox (deferiprone) only:

Transfusion Iron overload due to thalassemia syndrome, sickle cell disease, or other anemias

- Patient must be ≥ 3 years old for oral solution OR ≥ 8 years old for tablets
- Diagnosis of thalassemia syndrome, sickle cell disease, or other anemia
- Patient receiving blood transfusions on a regular basis/participating in blood transfusion program
- Serum Ferritin concentration is consistently $> 1000\text{ mcg/L}$. If the serum ferritin levels fall consistently below 500 mcg/L , Ferriprox must be discontinued
- Documentation patient is unable to use deferoxamine (Desferal) parenterally
- Documented trial and failure of deferasirox (Exjade, Jadenu) or medical reason why deferasirox cannot be used
- If the request is for deferiprone 1,000 mg tablet there is a documented medical reason why deferiprone 500 mg tablet cannot be used
- If the request is for Ferriprox Twice a Day there is a documented medical reason why deferiprone 500 mg tablet and deferiprone 1,000 mg tablet cannot be used
- The medication requested is being prescribed at an FDA approved dose

Requests for Wilson's Disease:

Cuvrior (trientene tetrahydrochloride) only:

- Laboratory confirmed diagnosis of Wilson's disease supported by at least one appropriate diagnostic test (e.g., slit lamp

<p>Revision/Review Date 7/2024</p>	<p>examination, 24-urinary copper excretion, serum ceruloplasmin, serum copper concentration, liver biopsy, genetic testing, brain imaging, etc.)</p> <ul style="list-style-type: none"> • Patient is de-coppered • Patient is tolerant to penicillamine and will discontinue penicillamine before starting therapy with Cuvrior • The medication requested is being prescribed at an FDA approved dose <p>Trientine (Syprine) only:</p> <ul style="list-style-type: none"> • Laboratory confirmed diagnosis of Wilson’s disease supported by at least one appropriate diagnostic test (e.g., slit lamp examination, 24-urinary copper excretion, serum ceruloplasmin, serum copper concentration, liver biopsy, genetic testing, brain imaging, etc.) • Documented trial and failure, intolerance, or contraindication to penicillamine • The medication requested is being prescribed at an FDA approved dose <p><u>Requests for all other drugs and indications:</u></p> <ul style="list-style-type: none"> • 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”) <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Prior Authorization Group Description	Cholbam
Drugs	Cholbam (cholic acid)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert

<p>Prescriber Restrictions</p>	<p>MD is a gastroenterologist OR hepatologist</p>
<p>Coverage Duration</p>	<p>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.</p>
<p>Other Criteria</p>	<p><u>Initial authorization:</u></p> <ul style="list-style-type: none"> • Patient has a confirmed diagnosis of: <ul style="list-style-type: none"> ➤ Bile acid synthesis disorder due to single enzyme defect (SEDs) OR ➤ Peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients that exhibit manifestations of liver disease, steatorrhea or complications from decreased fat soluble vitamin absorption <ul style="list-style-type: none"> • Current labs (within 30 days of request) have been submitted for the following: <ul style="list-style-type: none"> ➤ ALT/AST ➤ GGT (serum gamma glutamyltransferase) ➤ ALP (Alkaline phosphatase) ➤ Bilirubin ➤ INR <p><u>Re-authorization:</u></p> <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ➤ ALT/AST
<p>Revision/Review Date 10/2023</p>	<ul style="list-style-type: none"> ➤ GGT (serum gamma glutamyltransferase) ➤ ALP (Alkaline phosphatase) ➤ Bilirubin ➤ INR <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>

Field Name	Field Description
Prior Authorization Group Description	Chronic Dry Eye Agents
Drugs	<p><u>FORMULARY STATUS</u> Preferred, Pays at Point-of-Sale ARTIFICIAL TEARS (Glycerin-Peg) 1 %-0.3 % Eye Drops POLYVINYL ALCOHOL 1.4 % Eye drops HYPROMELLOSE 0.3% Eye Drops REFRESH TEARS 0.5 % Eye Drops</p> <p><u>FORMULARY STATUS</u> Preferred, Requires Step Therapy with one prior step CYCLOSPORINE 0.05% (RESTASIS) EYE DROPS RESTASIS 0.05% EYE DROPS XIIDRA 5% EYE DROPS Note: Patient must meet criteria #1 & #2 for approval of the PA request.</p> <p><u>FORMULARY STATUS</u> Non-Preferred, Prior Authorization Required CEQUA 0.09% EYE DROPS MIEBO EYE DROPS TYRVAYA NASAL SPRAY VEVYE 0.1% EYE DROPS Note: Patient must meet criteria #1, #2 & #3 for approval of the PA request.</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration.

Other Criteria	<p><u>Initial Authorization:</u></p> <ol style="list-style-type: none"> 1. Presumed or documented diagnosis of chronic dry eye 2. Documented trial and failure or intolerance with a preferred artificial tears product for a minimum of 3 weeks within past 60 days 3. Documented trial and failure or intolerance with both cyclosporine 0.05% (Restasis) and Xiidra
Revision/Review Date 7/2024	
Field Name	Field Description
Prior Authorization Group Description	Colchicine
Drugs	<p><u>Formulary Status:</u> Preferred, requires step therapy Colchicine (Colcrys) tablets</p> <p><u>Formulary Status:</u> Non-preferred, requires prior authorization Colchicine (Mitigare) capsules Gloperba (colchicine) solution</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration.

<p>Coverage Duration</p>	<p>If the criteria are met, the criteria will be approved as follows:</p> <p>Initial Requests</p> <ul style="list-style-type: none"> • 3 months: Soliris (eculizumab), Ultomiris (ravulizumab), Empaveli (pegcetacoplan), Voydeya (danicopan) • 6 months: Fabhalta (iptacopan) • 12 months: Syfovre (pegcetacoplan), Izervay (avacincaptad pegol) <p>Reauthorization</p> <ul style="list-style-type: none"> • 6 months: Soliris (eculizumab), Ultomiris (ravulizumab), Empaveli (pegcetacoplan), Voydeya (danicopan) • 12 months: Syfovre (pegcetacoplan), Fabhalta (iptacopan) <p>No Reauthorization</p> <p>Izervay (avacincaptad pegol)</p>
<p>Other Criteria</p>	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • The request is for a dose that is FDA approved or in nationally recognized compendia in accordance with the patient’s diagnosis, age and concomitant medical conditions; AND • For Fabhalta (iptacopan), Soliris (eculizumab), Ultomiris (ravulizumab), Empaveli (pegcetacoplan), and Voydeya (danicopan) <ul style="list-style-type: none"> ○ Documentation patient complies with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria. <p>Paroxysmal Nocturnal Hemoglobinuria (PNH):</p> <ul style="list-style-type: none"> • Documentation of diagnosis by high sensitivity flow cytometry

- Hemoglobin (Hgb) < 10.5 g/dL for Empaveli (pegcetacoplan), or Hgb < 10 g/dL for Fabhalta (iptacopan)
- For Voydeya (danicopan):
 - Member has been receiving Soliris (eculizumab) or Ultomiris (ravulizumab) therapy for at least 6 months
 - Member has clinically evident extravascular hemolysis [defined as anemia (Hgb ≤9.5 gram/deciliter) with absolute reticulocyte count ≥120 x 10⁹/liter] despite treatment with Soliris (eculizumab) or Ultomiris (ravulizumab)
 - Voydeya (danicopan) will be used as add-on therapy to Soliris (eculizumab) or Ultomiris (ravulizumab)

Generalized Myasthenia Gravis (gMG):

- Refer to the “Myasthenia Gravis Agents” policy

Neuromyelitis Optica Spectrum Disorder (NMOSD)

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

Atypical Hemolytic Uremic Syndrome (aHUS)/Complement-Mediated HUS)

- Documentation of confirmed diagnosis as evidenced by complement genotyping and complement antibodies; **OR**
- Provider attestation treatment is being used empirically and delay in therapy will lead to unacceptable risk to the patient

Geographic Atrophy (GA):

- Diagnosis of GA secondary to age-related macular degeneration (AMD)
- Absence of choroidal neovascularization (CNV) in treated eye
- Best-corrected visual acuity (BCVA) of 24 letters (approximately 20/320) or better using Early Treatment Diabetic Retinopathy Study (ETDRS)
- GA lesion size ≥ 2.5 and ≤ 17.5 mm² with at least 1 lesion ≥ 1.25 mm²

Re-Authorization:

- Re-authorization may be considered for all agents included in these criteria with the exception of Izervay (avacincaptad pegol injection), which is only indicated for a 12 month duration
- Provider has submitted documentation of clinical response to therapy (e.g., reduction in disease severity, improvement in quality of life scores, increase in Hgb, reduced need for blood transfusions, slowing of growth rate of GA lesions, etc.); **AND**
- The request is for a dose that is FDA approved or in nationally

<p>Revision/Review Date 7/2024</p>	<p>recognized compendia in accordance with the patient's diagnosis, age, and concomitant medical condition; AND</p> <ul style="list-style-type: none">• If the request is for aHUS/Complement Mediated HUS ○ Documentation of confirmed diagnosis as evidenced by complement genotyping and complement antibodies <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Continuous Glucose Monitors
Drugs	<p><u>Preferred</u>: Freestyle Libre 14 Day, Freestyle Libre 2, FreeStyle Libre 3, Dexcom G6, Dexcom G7</p> <p><u>Non-Preferred</u>: Eversense (Sensor, Transmitter, and Reader components) And any newly marketed product in this class</p> <p>This policy does not apply to continuous glucose monitor/insulin pump combination products reviewed and/or covered by the Medical Benefit including, but not limited to, the MiniMed. Requests for these products are referred to the plan’s Utilization Management team for Review</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Patient must be age appropriate per prescribing information (PI)
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Other Criteria	<ul style="list-style-type: none"> • Diagnosis – diabetes • Treatment with insulin or other compelling indication • If the request is for a non-preferred product, trial and failure of or medical reason why patient cannot use a preferred product. • If member is continuing use of a non-preferred CGM, trial of a preferred CGM first is not required <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 7/2024	

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	<p>Heart Failure in Adult Patients:</p> <ol style="list-style-type: none"> 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 $\leq 35\%$ 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 <p>Heart Failure in Pediatric Patients:</p> <ol style="list-style-type: none"> 1. Member is aged 6 months to less than 18 years of age 2. Member has stable heart failure (NYHA/Ross functional class IIIIV) due to dilated cardiomyopathy and a left ventricular ejection fraction $\leq 45\%$ 3. Member is in sinus rhythm with an elevated resting heart rate <p>Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>
Revision/Review Date 2/2024	

Field Name	Field Description
Prior Authorization Group Description	Corticosteroids for Duchenne Muscular Dystrophy (DMD)
Drugs	Agamree (vamorolone) 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	Patient must be 2 years of age or older
Prescriber Restrictions	Prescribed by a neurologist, provider who specializes in the treatment of DMD, or in consultation with a neurologist of provider who specialized in the treatment of DMD
Coverage Duration	If all of the conditions are met, the initial request will be approved for a 6 month duration. For reauthorization, the request will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> Confirmed diagnosis of Duchenne Muscular Dystrophy (such as documented mutation of dystrophin gene, genetic sequencing indicating mutations attributed to Duchene Muscular Dystrophy, muscle biopsy indicating absence of dystrophin protein, etc.), and copies of testing were submitted with request Trial and failure with prednisone, and documented medical reason why prednisone cannot be continued The request is for an FDA approved dose <p><u>Reauthorization:</u></p> <ul style="list-style-type: none"> Documentation or attestation of clinical benefit (such as improved muscle strength, muscle function, or overall symptom improvement) The request is for an FDA approved dose <p>Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>
Revision/Review Date	2/2024

Field Name	Field Description
Prior Authorization Group Description	Corticotropin
Drugs	<u>Preferred:</u> Cortrophin (corticotropin) <u>Non-Preferred:</u> Acthar (corticotropin)

Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	See “other criteria”
Prescriber Restrictions	See “other criteria”
Coverage Duration	If the criteria are met, the request will be approved for up to a 1 month duration.
Other Criteria	<p><u>Infantile Spasms (West Syndrome):</u></p> <ul style="list-style-type: none"> • 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) <p><u>Multiple Sclerosis:</u></p> <ul style="list-style-type: none"> • Documentation was submitted that patient is having an acute attack, with neurologic symptoms and increased disability or impairments in vision, strength or cerebellar function, and has failed therapy with intravenous (IV) methylprednisolone, or a medical reason has been submitted why patient is unable to use IV methylprednisolone. • The medication is being prescribed by a neurologist • If the request is for a non-preferred product, trial and failure of, contraindication to, or medical reason for not using the preferred product <p><u>All Other FDA Approved Conditions and Indications:</u></p> <ul style="list-style-type: none"> • Documented trial and failure of an IV corticosteroid AND an oral corticosteroid, or documented medical reason for why the patient cannot use these therapies for treatment

Revision/Review
Date 7/2024

- Documentation was provided that ALL other standard therapies have been used to treat the member's condition as described in the medical compendium (Micromedex, AHFS, Drug Points, and package insert) as defined in the Social Security Act and/or per recognized standard of care guidelines OR there is a documented medical reason (i.e. medical intolerance, treatment failure, etc.) for why all other standard therapies could not be used to treat the member's condition.
- Prescriber is a specialist in the condition they are treating.
- If the request is for a non-preferred product, trial and failure of, contraindication to, or medical reason for not using the preferred product

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

Field Name	Field Description
Prior Authorization Group Description	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	Diagnosis or treatment of infertility
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved for 30 single use applicators per 30 days until the end of pregnancy if the diagnosis is the prevention of spontaneous preterm delivery (singleton pregnancy and prior preterm birth or short cervix), or for up to 6 single use applicators if the diagnosis is secondary amenorrhea.
Other Criteria	<p><u>Prevention of spontaneous preterm delivery:</u></p> <ul style="list-style-type: none"> • Patient has singleton pregnancy and prior preterm birth or short cervix <p><u>Secondary Amenorrhea:</u></p> <ul style="list-style-type: none"> • Patient has a diagnosis of secondary amenorrhea • Patient has tried and failed, or has contraindication or intolerance to, oral progestin therapy (e.g. medroxyprogesterone acetate, norethindrone acetate tablets, micronized progesterone) • If the request is for Crinone 8% gel the patient has tried and failed, or has a contraindication or intolerance to, Crinone 4% gel <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 7/2024	

Prior Authorization Group Description	Cystic Fibrosis transmembrane conductance regulator (CFTR) Modulators
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Drug(s)	Kalydeco, Kalydeco Granules (ivacaftor), Orkambi, Orkambi Granules (lumacaftor/ivacaftor), Symdeko (tezacaftor/ivacaftor), Trikafta (elixacaftor/tezacaftor/ivacaftor), or any newly marketed CFTR modulator to treat cystic fibrosis
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	See “Other Criteria”
Required Medical Information	See “Other Criteria”
Age Restrictions	See “Other Criteria”
Prescriber Restrictions	Prescriber is pulmonologist or specializes in the treatment of cystic fibrosis
Coverage Duration	If all of the conditions are met the initial request will be 6 months. Reauthorization requests will be 12 months.
Other Criteria	<p><u>Initial criteria:</u></p> <ul style="list-style-type: none"> • 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. <p><u>Reauthorization:</u></p> <ul style="list-style-type: none"> • Based on prescriber’s assessment, patient continues to benefit from therapy • The request is within FDA dosing guidelines <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Review/Revision Date 2/2024	

Field Name	Field Description
Prior Authorization Group Description	Danazol
Drugs	Danazol capsules

Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Pregnancy
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	See “other criteria”
Coverage Duration	If the criteria are met, the request will be approved with a 6 month duration for generic medication.
Other Criteria	<p><u>ENDOMETRIOSIS</u></p> <ul style="list-style-type: none"> ○ Diagnosis of endometriosis ○ One of the following: <ul style="list-style-type: none"> ○ Documented trial and failure or medical reason for not using an analgesic pain reliever (e.g., NSAIDs, COX-2 inhibitors) taken in combination with a hormonal contraceptive (e.g. estrogen/progestin, progestin only) ○ Documented trial and failure of a gonadotropinreleasing hormone (GnRH) agonists or a GNRH antagonist. ○ Prescribing physician is a gynecologist. <p><u>HEREDITARY ANGIOEDEMA:</u></p> <ul style="list-style-type: none"> ○ Diagnosis of hereditary angioedema. <ul style="list-style-type: none"> ○ Prescriber is an immunologist, allergist, rheumatologist, or hematologist <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 10/2023	

Field Name	Field Description
Prior Authorization Group Description	Daraprim
Drugs	pyrimethamine (Daraprim)

Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Patients with documented megaloblastic anemia due to folate deficiency.
Required Medical Information	See “Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be an appropriate specialist or documentation has been provided that prescriber has consulted with an appropriate specialist (i.e. infectious disease, OB/GYN).
Coverage Duration	If all of the conditions are met, congenital toxoplasmosis requests will be approved for 12 months, and all other requests will be approved for 3 months-at a time.
Other Criteria	<p>Congenital Toxoplasmosis</p> <ul style="list-style-type: none"> • Diagnosis of congenital toxoplasmosis <p>Acquired Toxoplasmosis</p> <ul style="list-style-type: none"> • Diagnosis of acquired toxoplasmosis • Prescribed in combination with leucovorin and either a sulfonamide or clindamycin <p>Patients with Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS)</p> <ul style="list-style-type: none"> • Diagnosis of Toxoplasmosis OR • Both of the following: <ul style="list-style-type: none"> ○ Medication is being prescribed for one of the following: Toxoplasmosis prophylaxis <ul style="list-style-type: none"> ▪ Cystoisosporiasis ▪ Pneumocystis jiroveci pneumonia prophylaxis/treatment ○ Documented medical reason why (e.g. intolerance, hypersensitivity, contraindication) <p>sulfamethoxazole/trimethoprim cannot be used</p> <p>Hematopoietic Cell Transplantation Recipients</p> <ul style="list-style-type: none"> • Medication prescribed for Toxoplasmosis prophylaxis • Documentation of medical reason why sulfamethoxazole/trimethoprim cannot be used
Revision/Review Date 10/2023	

	<p align="center">Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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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	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ○ RTT Clinical Severity Scale rating of 10–36 ○ Clinical Global Impression–Severity (CGI-S) score of ≥ 4 ○ Baseline Rett Syndrome Behavior Questionnaire (RSBQ) score <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • 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
Revision/Review Date 7/2024	<p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>

Field Name	Field Description
Prior Authorization Group Description	Dendritic Cell Tumor Peptide Immunotherapy
Drugs	Provenge (sipuleucel-T)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Small cell/neuroendocrine prostate cancer
Required Medical Information	See “Other Criteria”

Age Restrictions	See “Other Criteria”
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	If all the criteria are met, the request will be approved for 3 doses per lifetime
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Metastatic castrate resistant (hormone-refractory) prostate cancer (mCRPC) (consistent with medical chart history) <ul style="list-style-type: none"> ○ Evidenced by soft tissue and/or bony metastases ○ Patient does NOT have <ul style="list-style-type: none"> ▪ M0CRPC (defined as CRPC whose only evidence of disseminated disease is an elevated serum PSA) is not authorized ▪ Visceral metastases (e.g. liver, lung, adrenal, peritoneal, brain) • Patient is not currently being treated with systemic immunosuppressants (e.g. chemotherapy, corticosteroids) or, if the patient is being treated with immunosuppressants, the prescriber has provided a valid medical reason for combination therapy • Eastern Cooperative Oncology Group (ECOG) score 0-1 • Serum testosterone <50 ng/dL (e.g. castration levels of testosterone) • Predicted survival of at least six months <u>Reauthorization:</u> • Treatment exceeding 3 doses per lifetime will not be authorized <p>Revision/Review Date 4/2024</p> <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>

Field Name	Field Description
Prior Authorization Group Description	Desmopressin nasal spray
Drugs	Desmopressin 1.5 mg/mL nasal spray
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	≥ 11 months

Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria	<p><u>Initial Authorization</u> One of the following:</p> <ul style="list-style-type: none"> • Diagnosis of Hemophilia A with Factor VIII coagulant activity levels greater than 5%. • Hemophilia A carrier • Diagnosis of mild to moderate Type 1 (classic) von Willebrand’s disease with Factor VIII coagulant activity levels greater than 5%. • Diagnosis of mild to moderate Type 2A, 2M, or 2N von Willebrand’s disease and documentation of a desmopressin trial and response <ul style="list-style-type: none"> ○ A single unit of desmopressin nasal spray will be approved for a desmopressin trial <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 8/2024	

Field Name	Field Description
Prior Authorization Group Description	Dificid (fidaxomicin)
Drugs	Dificid (fidaxomicin)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, an infectious disease specialist or gastroenterologist
Coverage Duration	If the criteria are met, the request will be approved for up to a 10-day duration.

Other Criteria	<p><u>Authorization for initial Clostridium difficile infection:</u></p> <ol style="list-style-type: none"> 1. Documentation provided for intolerance or medical reason why patient is unable to use oral vancomycin 2. Dose requested follows FDA labeling <p><u>Authorization for recurrent Clostridium difficile infection:</u></p> <ol style="list-style-type: none"> 1. Documentation provided that patient has tried oral vancomycin for management of Clostridium difficile infection 2. Dose requested follows FDA labeling
Revision/Review Date: 7/2024	<p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>

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

Coverage Duration	Initial: 6 months Renewal: 12 months
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Member has a molecularly confirmed diagnosis of a long-chain fatty acid oxidation disorder (LC-FAOD) • Documentation of at least two of the following: <ul style="list-style-type: none"> ○ Disease specific elevation of acylcarnitines on a newborn blood spot or in plasma ○ Low enzyme activity in cultured fibroblasts One or more known pathogenic mutations in either the <i>CPT2</i>, [○] <i>ACADVL</i>, <i>HADHA</i>, or <i>HADHB</i> gene • Member will not be receiving any other medium-chain triglyceride products while taking Dojolvi • Documentation of member's daily caloric intake (DCI) • Dose is within FDA-indicated limits and does not exceed 35% of DCI <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation submitted indicating the member has experienced a clinical benefit (e.g. increased left ventricular ejection fraction, reduced left ventricular wall mass, reduced maximum heart rate, decreased incidence of rhabdomyolysis) • Documentation of member's DCI • Dose is within FDA-indicated limits and does not exceed 35% of DCI <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date: 2/2024	

Field Name	Field Description
Prior Authorization Group Description	Drugs for Chronic Bowel Disorders/GI Motility

Drug(s)	<p><u>Preferred, PA Required:</u> alosetron (Lotronex) Amitiza (lubiprostone) Linzess (linaclotide) lubiprostone (Amitiza) Movantik (naloxegol) Trulance (plecanatide)</p> <p><u>Non-Preferred, PA Required:</u> Ibsrela (tenapanor) Lotronex (alosetron) Motegrity (prucalopride) Relistor (methylnaltrexone) Symproic (naldemedine) Viberzi (eluxadoline) Or any newly marketed agent</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the 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	Linzess: functional constipation in pediatric patients 6 to 17 years All other indications/drugs: Age 18 or older
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the request will be approved for 6 months.
Other Criteria	<p><u>Criteria for Initial Authorization:</u></p> <ol style="list-style-type: none"> 1. Approved FDA indication and dose 2. For request for diagnosis involving chronic constipation patient has tried and failed 2 different laxatives from 2 different classes (bulkforming, osmotic, stimulant) 3. If the request is for a non-preferred drug, the member has a documented treatment failure with 2 indicated preferred drugs or has a documented medical reason (intolerance, hypersensitivity, contraindication, etc.) why they are not able to use preferred drugs if appropriate for the requested indication

<p>Review/Revision Date: 9/2024</p>	<p><u>Criteria for Reauthorization:</u></p> <p>1. Documentation that the member has experienced treatment efficacy.</p> <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Duvyzat
Drugs	Duvyzat (givinostat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or provider who specializes in the treatment of Duchenne Muscular Dystrophy (DMD)
Coverage Duration	If all the criteria are met, the initial request will be approved for 12 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> Medication is prescribed at an FDA approved dose according to body weight Genetically confirmed diagnosis of DMD and copies of testing were submitted with request Patient has been stable on baseline corticosteroids for at least 6 months Patient is ambulatory Patient's platelet count is $\geq 150 \times 10^9/L$ <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> Documentation or provider attestation of positive clinical response (such as improved muscle function, muscle strength, or disease stabilization) Patient is on concurrent corticosteroid treatment Patient is ambulatory Medication is prescribed at an FDA approved dose according to body weight <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
Review/Revision Date: 7/2024	

Field Name	Field Description
Prior Authorization Group Description	Elevidys
Drugs	Elevidys (delandistrogene moxeparvovec-rokl)

Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	<ul style="list-style-type: none"> 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 or in consultation with a 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 onetime treatment.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> Medication is prescribed at an FDA approved dose Documentation of weight Genetically confirmed diagnosis of DMD and copies of testing were submitted with request Patient has been on a stable dose of corticosteroids for at least 3 months Attestation patient has anti-recombinant adeno-associated virus serotype rh74 (anti-AAVrh74) total binding antibody titers of less than 1:400 Attestation prescriber has assessed the patient’s liver function, platelet counts, and troponin-I before treatment <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
Revision/Review Date: 7/2024	

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	According to package insert
Prescriber Restrictions	Prescriber must be a hematologist or sickle cell specialist
Coverage Duration	If all of the conditions are met, requests will be approved for a 12 months.
Other Criteria	Initial: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • Prescriber attests member had reduction in number of sickle cell crises • Request is for an FDA approved dose <p>Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>
Revision/Review Date 10/2023	

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

Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Medication is prescribed at an FDA approved dose • Member has a diagnosis of ASMD confirmed by one of the following: <ul style="list-style-type: none"> ○ Deficiency in acid sphingomyelinase (ASM) enzyme activity (as measured by peripheral blood leukocytes, cultured skin fibroblasts, or dried blood spots) ○ Sphingomyelin phosphodiesterase-1 (SMPD1) gene mutation • Member has a clinical presentation consistent with ASMD type B or type A/B • Documentation of members height and weight • Documentation of baseline ALT and AST within 1 month prior to initiation of treatment <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation or provider attestation of positive clinical response (i.e. improvement in splenomegaly, hepatomegaly, pulmonary function, etc.) • Medication is prescribed at an FDA approved dose <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
Date: 2/2024	

Field Name	Field Description
Prior Authorization Group Description	Enzyme Replacement Therapies for Fabry Disease
Drugs	Fabrazyme (agalsidase beta) Elfabrio (peguniigalsidase alfa)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to the FDA approved prescribing information
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, cardiologist, nephrologist or specialist experienced in the treatment of Fabry disease

Coverage Duration	<p>Initial Authorization: If the criteria are met, the request will be approved for a 6-month duration.</p> <p>Reauthorization: If the criteria are met, the request will be approved for a 12-month duration.</p>
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Male members must have a documented diagnosis of Fabry disease confirmed by <u>one</u> of the following: <ol style="list-style-type: none"> 1. An undetectable (<1%) alpha galactosidase A (alpha-Gal-A) activity level OR 2. A deficient alpha-Gal- activity level AND a documented detection of pathogenic mutations in the galactosidase alpha (<i>GLA</i>) gene by molecular genetic testing • Female members must have a documented diagnosis of Fabry disease confirmed by detection of pathogenic mutations in the <i>GLA</i> 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 <p><u>Re-Authorization:</u></p>

<p>Revision/Review Date: 7/2024</p>	<ul style="list-style-type: none"> • 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 <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Eohilia
Drugs	Eohilia (budesonide)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, allergist, immunologist, or other provider who specializes in the treatment of eosinophilic esophagitis (EoE)
Coverage Duration	If all criteria are met, the request will be approved for 3 months ***Reauthorization requests for maintenance therapy will not be approved as Eohilia has not been shown to be safe and effective for the treatment of EoE for longer than 12 weeks. Requests for subsequent courses for induction therapy will be handled on a case-by-case basis***
Other Criteria	<ul style="list-style-type: none"> • Diagnosis of EoE as confirmed by esophageal biopsy indicating ≥ 15 eosinophils per high-power field (eos/hpf) • Member must have experienced dysphagia for at least 4 days over a 2-week period • Documented trial and failure, intolerance, or contraindication to one proton pump inhibitor (PPI) at a maximally tolerated dose for a minimum of 8 weeks • Documented trial and failure, intolerance, or contraindication to an inhaled corticosteroid that can be swallowed (i.e., fluticasone, ciclesonide, mometasone, etc.) • Request is for an FDA-approved dose <p>Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date: 4/2024	

Field Name	Field Description
Prior Authorization Group Description	Epidermolysis Bullosa Agents

Drugs	Vyjuvek (beremagene geperpavec-svdt), Filsuvez (birch triterpenes)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	<ul style="list-style-type: none"> • Other forms of epidermolysis bullosa, such as epidermolysis bullosa simplex, kindler epidermolysis bullosa • Concurrent use of Vyjuvek and Filsuvez
Required Medical Information	See “Other Criteria”
Age Restrictions	Per prescribing information
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist, geneticist, or specialist experienced in the treatment of epidermolysis bullosa.
Coverage Duration	If all of the criteria are met, the initial request will be approved for two (2) months. Subsequent requests will be approved for six (6) months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Patient has a diagnosis of dystrophic or junctional epidermolysis bullosa, with genetic mutation(s) confirmed via genetic testing. • Requested product is FDA approved for the patient’s epidermolysis bullosa subtype • Documentation is provided that wound(s) to be treated are clean with adequate granulation tissue, excellent vascularization, and do not appear infected • Documentation is provided that there is no evidence of, or history of squamous cell carcinoma in the wound(s) to be treated • Medication is prescribed at an FDA approved dose, and maximum dispensable amount is not exceeded <ul style="list-style-type: none"> ○ Vyjuvek: Requests exceeding more than one vial per week will not be approved. ○ Filsuvez: documentation of size of treatment area(s) and frequency of dressing changes is required. One tube of Filsuvez covers up to 250 cm² surface area. Requests exceeding a quantity sufficient to cover the treatment area more than once daily will not be approved. <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation or provider attestation of positive clinical response (i.e. improvement in wound appearance, wound closure, healing, etc.)

Revision/Review
Date: 4/2024

- Documentation indicating need for continued treatment is needed (either to partially healed wounds or to other wound sites)
- Documentation is provided that wound(s) to be treated are clean with adequate granulation tissue, excellent vascularization, and do not appear infected
- Documentation is provided that there is no evidence of, or history of squamous cell carcinoma in the wound(s) to be treated
- Medication is prescribed at an FDA approved dose, and maximum dispensable amount is not exceeded.
 - Vyjuvek: Requests exceeding more than one vial per week will not be approved.
 - Filsuvez: documentation of size of treatment area(s) and frequency of dressing changes is required. One tube of Filsuvez covers up to 250 cm² surface area. Requests exceeding a quantity sufficient to cover the treatment area more than once daily 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.

Prior Authorization Group Description	Erythropoiesis-Stimulating Agents (ESAs)
Drugs	<p>Preferred: Aranesp (darbepoetin alfa-polysorbate 80) Retacrit (epoetin alfa-epbx)</p> <p>Non-preferred: Epogen (epoetin alfa) Mircera (methoxy peg-epoetin beta) Procrit (epoetin alfa)</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If criteria are met, the request will be approved for up to 1 month if the member is deficient in iron, vitamin B12, folate, or in the persurgical setting, and up to 3 months for all other requests.
Other Criteria	<p><u>Existing ESA users who are NEW to the plan:</u></p> <ul style="list-style-type: none"> • Documentation of current dose • Drug is being prescribed for an FDA-approved indication at an FDA-approved dose or is otherwise supported by the compendia or standard-of-care guidelines • The members HgB is within the following indication specific range: <ul style="list-style-type: none"> ○ Anemia of CKD: ≤ 11 g/dL ○ Anemia related to cancer: ≤ 12 g/dL ○ Zidovudine related anemia in members with HIV: HgB ≤ 12 g/dL ○ Ribavirin-induced anemia: HgB ≤ 12g/dL <p><u>Initial Authorization for all requests:</u></p> <ul style="list-style-type: none"> • Drug is being prescribed for an FDA-approved indication at an FDA-approved dose or is otherwise supported by the compendia or standard-of-care guidelines • All submitted lab results have been drawn within 30 days of the request • The following lab results must be submitted: <ul style="list-style-type: none"> ○ Hemoglobin (HgB) ○ 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:
 - Serum ferritin level (> 100ng/mL)
 - Transferrin saturation (TSAT) (> 20%)
 - Vitamin B12 level (> 223pg/mL)
 - Folate level (> 3.1 ng/mL)
- If the request is for a non-preferred ESA the member has tried and failed a preferred ESA or has a documented medical reason (e.g., intolerance, hypersensitivity, contraindication) why the preferred ESAs cannot be used.

Requests for anemia of CKD:

- HgB < 10 g/dL

Requests for anemia related to chemotherapy in cancer patients:

- The member must have a documented cancer diagnosis for which they will be receiving myelosuppressive therapy for palliative treatment for at least two additional months (members receiving myelosuppressive therapy with curative intent should not receive ESAs) **AND** documented symptomatic anemia with HgB < 10 g/dL **OR**
- The member has symptomatic anemia related to myelodysplastic syndrome **AND** documented serum erythropoietin level ≤ 500 mU/mL

Requests for zidovudine-related anemia in HIV:

- The member is currently receiving highly active antiretroviral therapy (HAART) **AND** has a documented serum erythropoietin level ≤ 500 mU/mL

Requests for ribavirin-induced anemia:

- Member is currently receiving ribavirin and a documented attempt to reduce dose has been made
- Hgb < 12 g/dL

Requests for members undergoing surgery to reduce the need for allogenic blood transfusion:

- Perioperative HgB < 13g/dL and > 10 g/dL.
- The member is scheduled for an elective, non-cardiac, nonvascular surgery.

Reauthorization:

- All submitted lab results have been drawn within 30 days of the reauthorization request.

<p>Revision/Review Date: 12/2023</p>	<ul style="list-style-type: none"> • The following lab results must be submitted: <ul style="list-style-type: none"> ○ Hemoglobin (Hgb) • The following lab results must be submitted and demonstrate normal values, otherwise, the member MUST be receiving, or is beginning therapy, to correct the deficiency: <ul style="list-style-type: none"> ○ Serum ferritin level (> 100ng/mL) ○ Transferrin saturation (TSAT) (> 20%) ○ Vitamin B12 level (> 223pg/mL) ○ Folate level (> 3.1 ng/mL) • The members Hgb is within the following indication specific range: <ul style="list-style-type: none"> ○ Anemia of CKD: ≤ 11 g/dL ○ Anemia related to cancer: ≤ 12 g/dL ○ Zidovudine related anemia in members with HIV: Hgb ≤ 12 g/dL ○ Ribavirin-induced anemia: Hgb ≤ 12g/dL <p>For requests that fall outside of these parameters, or if the criteria are not met, the request will be referred to a Medical Director/clinical reviewer for medical necessity review.</p>
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Field Name	Field Description
Prior Authorization Group Description	Fecal Microbiota
Drugs	Rebyota (fecal microbiota, live-jslm) Vowst (fecal micromiota spores, live-brpk)

Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Treatment of Clostridioides difficile infection (CDI)
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If all the criteria are met, the request will be approved for 1 treatment course
Other Criteria Date: 7/2024	<ul style="list-style-type: none"> • Medication is prescribed at an FDA approved dose • Diagnosis of at least 1 recurrent episode of CDI (≥ 2 total CDI episodes) • Current episode of CDI must be controlled (< 3 unformed/loose stools/day for 2 consecutive days) • Positive stool test for C. difficile within 30 days before prior authorization request • Administration will occur 24–72 hours following completion of antibiotic course for CDI treatment • For Vowst only: attestation patient will bowel cleanse using magnesium citrate or polyethylene glycol electrolyte solution the day before the first dose of Vowst <p>*Rebyota and Vowst are limited to 1 treatment course*</p> <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>

Field Name	Field Description
Prior Authorization Group Description	Filspari (sparsentan)
Drugs	Filspari (sparsentan)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.

Exclusion Criteria	<ul style="list-style-type: none"> • Pregnancy • Coadministration with renin-angiotensin-aldosterone system (RAAS) inhibitors, endothelin receptor antagonists, or aliskiren
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a nephrologist or in consultation with a nephrologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 9 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Medication is prescribed at an FDA approved dose • Diagnosis of primary immunoglobulin A nephropathy (IgAN) verified by biopsy • Total urine protein ≥ 1.0 g/day • eGFR ≥ 30 mL/min/1.73 m² • Trial and failure with a maximized stable dose of ACE inhibitor or ARB <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation of positive clinical response as evidenced by a decrease in urine protein-to-creatinine ratio (UPCR) • Medication is prescribed at an FDA approved dose <p>Date: 4/2024</p> <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>

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	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Member has a documented diagnosis of Fabry disease • Documentation member has an amenable galactosidase alpha (GLA) gene variant based on in vitro assay data • Member will not be using Galafold concurrently with enzyme replacement therapy (e.g., Fabrazyme) • Documented baseline eGFR ≥ 30 mL/min • Request is for an FDA-approved dose <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation that member has experienced an improvement in symptoms from baseline including but not limited to: decreased pain, decreased gastrointestinal manifestations, decrease in proteinuria, stabilization of increase in eGFR, reduction of left ventricular hypertrophy (LVH) on echocardiogram, or improved myocardial function • Member must not be using concurrently with other enzyme replacement therapy (e.g., Fabrazyme) • Documented eGFR ≥ 30 mL/min • Request is for an FDA-approved dose

Revision/Review Date:
10/2023

If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.

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

Field Name	Field Description
Prior Authorization Group Description	Gene Therapy for Hemophilia B
Drugs	Hemgenix (etranacogene dezaparvovec), Beqvez (fidanacogene elaparvovec-dzkt)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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 treatment with Hemgenix or Beqvez
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 onetime treatment for one gene therapy agent for Hemophilia B.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of Hemophilia B (congenital Factor IX deficiency) with ONE of the following: <ul style="list-style-type: none"> ○ Currently using Factor IX prophylaxis therapy ○ Has current or historical life-threatening hemorrhage ○ Has repeated, serious spontaneous bleeding episodes • Documentation that patient has $\leq 2\%$ of normal circulating Factor IX) • Prescriber attests they have performed liver health assessments • Documented Factor IX inhibitor titer test showing the patient is negative for Factor IX inhibitors • For Beqvez: Patient does not have neutralizing antibodies to adenoassociated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test • Patient’s weight • Medication is prescribed at an FDA approved dose <p>The safety and effectiveness of repeat administration of Hemgenix or Beqvez have not been evaluated and will not be approved.</p> <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Date: 7/2024	

Field Name	Field Description
Prior Authorization Group Description	Gene Therapy for Regular Red Blood Cell (RBC) Transfusion Dependent Beta-Thalassemia
Drugs	Casgevy (exagamglogene autotemcel), 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	Repeat use of same gene therapy agent Trial of a different gene therapy agent after another has been used
Required Medical Information	See "Other Criteria"
Age Restrictions	Per FDA approved prescribing information
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 for one gene therapy agent.
Other Criteria Revision/Review Date: 8/2024	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Medication is prescribed at an FDA approved dose • Member has a diagnosis of transfusion dependent betathalassemia • Member requires regular RBC transfusions defined as ONE of the following: <ul style="list-style-type: none"> ○ History of ≥ 100 mL/kg/year of packed red blood cell (pRBCs) in the past 2 years ○ History of ≥ 8 transfusions of pRBCs per year in the past 2 years • Patient has not had a prior HSCT or gene therapy treatment • If the request is for Zynteglo, a medical reason must be submitted why the patient is unable to use Casgevy • Negative pregnancy test (if applicable) <p>The safety and effectiveness of repeat administration of Casgevy or Zynteglo have not been evaluated and will not be approved.</p>

Field Name	Field Description
Prior Authorization Group Description	Gene Therapy for Sickle Cell Disease
Drugs	Casgevy (exagamglogene autotemcel), Lyfgenia (lovotibeglogene 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	Repeat use of same gene therapy agent Trial of a different gene therapy agent after another has been used
Required Medical Information	See "Other Criteria"
Age Restrictions	Per FDA approved prescribing information
Prescriber Restrictions	Prescriber must be a hematologist or specialist in the treatment of sickle cell disease
Coverage Duration	If all the criteria are met, the initial request will be approved for a one-time treatment for one gene therapy agent . If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Medication is prescribed at an FDA approved dose • Member has a diagnosis of sickle cell disease • Member has experienced at least 2 severe vaso-occlusive crises/events per year in the past 2 years defined as either: <ul style="list-style-type: none"> ○ VOE requiring a hospitalization or multiple visits to an emergency department/urgent care over 72 hours and receiving intravenous medications at each visit ○ priapism lasting > 2 hours and requiring a visit to a medical facility ○ acute chest syndrome ○ splenic sequestration ○ hepatic sequestration • 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)

	<ul style="list-style-type: none">• Documentation was provided that the member had a trial and failure of, or a medical reason was provided why the patient is unable to trial two of the following agents
Revision/Review Date: 1/2024	<ul style="list-style-type: none">○ Endari ○Adakveo ○Oxbryta• Prescriber attests pregnancy has been ruled out prior to initiation of treatment (if applicable)• Patient has not had a prior HSCT or gene therapy treatment• If the request is for Lyfgenia, a medical reason must be submitted why the patient is unable to use Casgevy. <p>The safety and effectiveness of repeat administration of Casgevy or Lyfgenia have not been evaluated and will not be approved.</p>

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

<p>Other Criteria</p>	<p><u>Initial Authorization</u></p> <ul style="list-style-type: none"> • Diagnosis of generalized pustular psoriasis (GPP) • If request is for an acute GPP flare (IV vial), member must be experiencing an acute flare of GPP of moderate to severe intensity as defined by having all of the following: <ul style="list-style-type: none"> ○ 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 request is for maintenance treatment of GPP (SQ syringe), member must have all of the following: <ul style="list-style-type: none"> ○ History of at least two GPP flares in the past year of moderate to severe intensity ○ GPPPGA score of 0 or 1 ○ Documented trial and failure, intolerance, or contraindication to TWO of the following: oral retinoids, methotrexate, and cyclosporine • Medication is prescribed at an FDA approved dose
<p>Date: 7/2024</p>	<p><u>Reauthorization</u></p> <ul style="list-style-type: none"> • If request is for an acute GPP flare (IV vial), member must have achieved a clinical response, defined as achieving a GPPPGA score of 0 or 1, to previous treatment but is now experiencing a new flare • If request is for maintenance treatment of GPP (SQ syringe), member must have documentation of positive clinical response to therapy (i.e. reduction in GPP flares) • Medication is prescribed at an FDA approved dose <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>

Field Name	Field Description
Prior Authorization Group Description	Glucagon-Like Peptide-1 (GLP-1) Agonists and Combinations Step Therapy
Drugs	<p><u>Preferred:</u> Byetta (exenatide) Ozempic (semaglutide) Trulicity (dulaglutide) Victoza (liraglutide)</p> <p><u>Non-Preferred:</u> Bydureon BCise (exenatide) Mounjaro (tirzepatide) Rybelsus (semaglutide) Soliqua (insulin glargine/lixisenatide) SymlinPen (pramlintide) Xultophy (insulin degludec/liraglutide)</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved for 12 months
Other Criteria	<ol style="list-style-type: none"> 1. Diagnosis of diabetes mellitus, type II. 2. One of the following: <ol style="list-style-type: none"> a. Documented trial and failure or intolerance with metformin at the maximally tolerated dose for a minimum of 3 months. b. If the request is for Ozempic, Trulicity, or Victoza the member has established atherosclerotic cardiovascular disease (ASCVD) or is at high risk for ASCVD. 3. If the request is for a non-preferred medication, a trial and failure of 2 preferred products are required, or member has a documented medical reason (intolerance, hypersensitivity, contraindication, etc.) why they are not able to use preferred drugs.
Revision/Review Date 3/2024	

Field Name	Field Description
Prior Authorization Group Description	Glycopyrrolate (oral)
Drugs	<p><u>Formulary Status:</u> Formulary; Pays at point-of-sale glycopyrrolate 1, 2 mg tablet</p> <p><u>Formulary Status:</u> Requires prior authorization Glycopyrrolate (Cuvposa) 1 mg/5 mL oral solution Glycopyrrolate (Glycate) 1.5 mg tablet</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	Per package insert
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month.
Other Criteria	<p><u>Requests for glycopyrrolate (Cuvposa) 1 mg/5 mL oral solution:</u></p> <ul style="list-style-type: none"> • Documented diagnosis of chronic severe drooling AND • Documented neurological condition associated with problem drooling (e.g., cerebral palsy) AND • Member has tried and failed non-pharmacologic approaches to treatment (e.g., correction of situational factors, treatment of dental malocclusion and caries, orthodontic appliances, swallowing therapy, biofeedback and automatic cueing, positive and negative reinforcement) AND • Drug is being prescribed at FDA approved dose <p><u>Requests for glycopyrrolate 1.5 mg tablet:</u></p> <ul style="list-style-type: none"> • Documented diagnosis of peptic ulcer disease AND • Glycopyrrolate will be used as an adjunct to other therapies AND • Member has tried and failed glycopyrrolate 1 mg or 2 mg tablets or has a medical reason (e.g. intolerance,

<p>Revision/Review Date 2/2024</p>	<p>hypersensitivity, contraindication, etc.) for not using glycopyrrolate 1 mg and 2 mg tablets AND</p> <ul style="list-style-type: none">• Drug is being prescribed at and FDA approved dose <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	<p>Gonadotropin Releasing Hormone Agonists (GNRH)</p> <p>**If diagnosis is Gender Dysphoria, use Medications without Drug or Class Specific Criteria**</p> <p>**If diagnosis is cancer, use Oncology Criteria**</p>
Drug(s)	<p>Preferred GNRH Agonist(s) for their respective indications: Camcevi (leuprolide mesylate), Eligard (leuprolide acetate), Fensolvi (leuprolide acetate), leuprolide acetate, Lupron Depot (leuprolide acetate), Lupron Depot-Ped (leuprolide acetate), Synarel (nafarelin acetate), Trelstar (triptorelin pamoate), Vantas (histrelin acetate)</p> <p>Non-Preferred GNRH Agonist(s): Supprelin LA (histrelin acetate), Triptodur (triptorelin pamoate), and any newly marketed GnRH agonist.</p>
Covered Uses	<p>Medically accepted indications are defined using the following sources: the Food and Drug 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.</p>
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert if not detailed in "Other Criteria"
Prescriber Restrictions	Prescriber must be a specialist in the field to treat the member's condition.
Coverage Duration	If all of the conditions are met, the request will be approved for up to 12 months if diagnosis is central precocious puberty, and up to 3-6 months as indicated below for other indications as recommended per FDA approved indications and/or as defined by the medical compendium or standard of care guidelines.

Other Criteria	<p><u>INITIAL AUTHORIZATION for ALL REQUESTS:</u></p> <ul style="list-style-type: none">• The medication is being prescribed for an FDA approved/standard of care guideline indication and within FDA approved/standard of care dosing guidelines.• If the request is for a non-preferred medication, the member has a documented treatment failure with 2 indicated preferred drugs (if applicable) or has a documented medical reason (intolerance, hypersensitivity, contraindication, etc.) why they are not able to use preferred drugs if appropriate for the requested indication. <p><u>AND the member meets the following for the respective diagnosis:</u></p>
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Central precocious puberty (CPP)

- Onset of secondary sexual characteristics occurred when member was aged less than 8 years for females or aged less than 9 years for males
- Diagnosis is confirmed by a pubertal response to a GnRH stimulation test and/or measurement of gonadotropins (FSH/LH), and bone age advanced beyond chronological age.
 - 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 0.3mIU/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.

Endometriosis

- For all therapies except Lupron, Lupron Depot, or Lupron DepotPed, member is ≥ 18 years of age
- Member has a confirmed diagnosis (e.g. laparoscopy, etc.)
- Documented trial and failure or medical reason for not using an analgesic pain reliever (e.g., NSAIDs, COX-2 inhibitors) taken in combination with combined estrogen progestin oral contraceptive pills (OCPs):
 - If one of the following drugs has been tried previously, a trial of OCPs is not required: progestins, Orilissa (elagolix), danazol, or aromatase inhibitors (e.g. anastrozole, letrozole)
- Approval is 6 months

Uterine leiomyomas (Fibroids)

- Member has a confirmed diagnosis (e.g. pelvic examination, etc.)
- Approval is 3 months

Endometrial thinning

- Member has a confirmed diagnosis (e.g. pelvic examination, etc.)
- Documentation indicates patient is scheduled for endometrial ablation for dysfunctional uterine bleeding.
- Approval is 3 months

REAUTHORIZATION for all requests:

<p>Review Date 12/2023</p>	<ul style="list-style-type: none"> • The medication is being prescribed for an FDA approved indication and within FDA approved dosing guidelines. • Documentation was provided supporting continued treatment (e.g. patient still has symptoms), and medication is being continued as recommended in package insert or standard of care guidelines. <p><u>AND meets the following per diagnosis:</u></p> <p><u>Central precocious puberty (CPP)</u></p> <ul style="list-style-type: none"> • 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 <p><u>Endometriosis</u></p> <ul style="list-style-type: none"> • Provider has evaluated patient for osteoporosis (e.g. Dexascan), and patient is receiving “add back” hormonal therapy (norethindrone acetate 5 mg daily alone or with conjugated estrogen therapy) or an oral bisphosphonate AND calcium and vitamin D supplementation. • The patient has not received cumulative doses of the GnRH agonist greater than 12 months of therapy. <p><u>Fibroids</u></p> <ul style="list-style-type: none"> • The patient has not received cumulative doses of the GnRH agonist greater than 6 months of therapy <p>NOTE: Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group	Growth Hormone (GH) for Growth Failure or GH Deficiency
Drug(s)	<p>Preferred: Genotropin (somatropin) cartridge/MiniQuick Norditropin (somatropin) FlexPro Sogroya (somapacitan)</p> <p>Non-preferred: Humatrope (somatropin), Ngenla (somatrogon), Nutropin (somatropin) AQ NuSpin, Omnitrope (somatropin), Saizen (somatropin), Saizenprep (somatropin), Skytrofa (lonapegsomatropin-tcgd), Zomacton (somatropin), and any newly marketed growth hormone agent</p>

Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Treatment of idiopathic short stature (ISS)-not a covered benefit and will not be approved
Required Medical Information	See other criteria
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or specialist in stated diagnosis
Coverage Duration	If all of the conditions are met, the initial request will be approved for 12 months. If all of the above criteria are not met, the request is referred to a Clinical Reviewer/Medical Director for medical necessity review.
Other Criteria	<p><u>Initial Authorization</u></p> <ul style="list-style-type: none"> • If diagnosis is for growth failure associated with chronic kidney disease (CKD), documentation that: either pretreatment height is < -1.88 standard deviations (SD) below the mean for age or a height velocity-for-age < 3rd percentile that persists beyond 3 months AND epiphyses are open • If diagnosis is for growth failure associated with Prader-Willi Syndrome, Noonan Syndrome, Turner’s Syndrome, or short stature homeobox-containing gene (SHOX) mutation, or other underlying genetic cause, documentation of confirmatory genetic test • If diagnosis is adult-onset GH deficiency (AO-GHD), documentation of one of the following: <ul style="list-style-type: none"> ○ Insulin Growth Factor (IGF-1) deficiency (< -2 SD below reference range for age and gender)* and

- multiple (≥ 3) pituitary hormone deficiencies (MPHD)
- Evidence of genetic defects affecting the hypothalamic pituitary axes (HPA)
- Evidence of hypothalamic pituitary structural brain defects
- Positive results of GH stimulatory test (e.g. insulin tolerance test [ITT], glucagon, or macimorelin)
- If diagnosis is childhood-onset GH deficiency (CO-GHD)
 - And patient is currently pediatric, all of the following
 - IGF-1 and insulin-like growth factor binding protein-3 (IGFBP-3) deficiency (< 0 SD below reference range for age and gender)* with prescriber attestation of growth failure; AND
 - Provider attests that MRI or CT has been completed to exclude possibility of a pituitary tumor; AND
 - Provider attests that member's epiphyses are open
 - And patient is currently adult, one of the following
 - If diagnosis is idiopathic isolated GHD, documentation was provided that indicates GH therapy is still medically necessary (IGF-1 retesting during the transition period after a minimum 1 month of therapy discontinuation reveals continued GH deficiency)
 - Diagnosis is GHD associated with MPHD, genetic defect affecting the HPA axes, or patient with hypothalamic pituitary structural brain defect
- If the request is for a non-preferred product, member had a trial and failure of 2 preferred products or the provider submitted a documented medical reason (i.e. intolerance) why it is medically necessary to use another agent.

Reauthorization

- Documentation of diagnosis (Note: ISS is not a covered benefit)
- Documented IGF-1 levels do not exceed upper limit of normal (ULN) (> 2 SD above reference range for age and gender)*, or if the IGF-1 levels exceed ULN, the dose has been reduced
- In CO-GHD, growth response (as demonstrated by length/height and calculated height velocity within previous 6 months).

*IGF-1 levels are highly age and gender specific. In the event the form provides a value and not the corresponding reference range,

<p>Revision Date 9/2024</p>	<p>refer to published reference ranges for interpretation.</p> <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>
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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. If the provider states that the requested medication is for a chronic or longterm condition for which the medication may be necessary for the life of the patient, the request will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization:</u> Documentation submitted indicates the following:</p> <ul style="list-style-type: none"> • The patient’s weight • Dose is within FDA-indicated limits • Severe hemophilia A AND one of the following <ul style="list-style-type: none"> ○ Member has tried Factor VIII products and is not wellmanaged due to limited venous access (attestation must be submitted from prescriber) <ul style="list-style-type: none"> ○ Request is for routine prophylaxis in patients with a diagnosis of severe hemophilia A WITH Factor VIII inhibitors and history of spontaneous or traumatic bleeding episode ○ Request is for routine prophylaxis in patients with a diagnosis of severe hemophilia A WITHOUT Factor VIII inhibitors and patient requires management with Factor VIII products at a total weekly dose of >100 U/kg (attestation must be submitted by prescriber) <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation submitted indicating the member has experienced a clinical benefit from the medication (e.g. reduction in bleeding episodes, improved quality of life) • The patient’s weight • Dose is within FDA-indicated limits
Revision/Review Date: 8/2024	

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	Hemophilia Factor VIII Replacement Products for Hemophilia A
Drugs	<p><u>Preferred:</u> Novoeight (antihemophilic factor, recombinant)</p> <p><u>Non-preferred:</u> Advate, Afstyla, Kogenate FS, Kovaltry, Nuwiq, Recombinate, Xyntha/Solofuse (antihemophilic factor, recombinant); Adynovate, Esperoct, Jivi (antihemophilic factor, recombinant, pegylated); Alphanate, Humate P, Wilate (antihemophilic factor/Von Willebrand factor complex); Eloctate (antihemophilic factor, recombinant, Fc fusion protein); Altuviio (antihemophilic factor, recombinant, Fc-VWF-XTEN fusion protein); Obizur (antihemophilic factor, recombinant, porcine sequence); Hemofil M, Koate (antihemophilic factor, human); And any newly marketed factor VIII replacement product</p>

Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the 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 1 month.
Other Criteria	<ul style="list-style-type: none"> • Patient has a diagnosis of Hemophilia A • The drug is being used for an FDA-approved indication at an FDA approved dose or the indication/dose are otherwise supported by treatment guidelines. • If the request is for any Factor VIII replacement product other than Novoeight, the member has a trial and failure or has a medical reason for not utilizing Novoeight, if appropriate based on the member’s diagnosis
Revision/Review Date 8/2024	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

HEPATITIS C TREATMENT

<u>Preferred</u>	<u>Non-Preferred</u>
Direct Acting Antiviral Products	
<ul style="list-style-type: none"> • ledipasvir-sofosbuvir (Harvoni) • Mavyret • sofosbuvir-velpatasvir (Epclusa) 	<ul style="list-style-type: none"> • Epclusa • Harvoni, Harvoni Pellet Pack • Sovaldi, Sovaldi Pellet Pack • Viekira Pak • Vosevi • Zepatier
Pegylated Interferon Alpha Products	
<ul style="list-style-type: none"> • Pegasys syringe/vial 	
Ribavirin Products	
<ul style="list-style-type: none"> • Ribavirin 	

Treatment naïve patients (1-year lookback) are exempt from prior authorization when a preferred drug that is FDA (Food and Drug Administration)-approved for treatment naïve patients is prescribed.

Where applicable and appropriate: A trial and failure of 1 Preferred product is required prior to Non-Preferred product from the same class if indicated, or a documented medical reason has been provided (intolerance, hypersensitivity, contraindication, etc.) why the member is not able to use the preferred products.

Initial requests must meet ALL of the following requirements:

1. Diagnosis of chronic hepatitis C virus (HCV)
 - a. Document if additional diagnosis of cirrhosis
2. Patient is ≥3 years old or otherwise specified by package insert
3. Drug must be prescribed by, or in consultation with, a specialist in hepatology/gastroenterology/infectious disease/HIV/liver transplant, or the prescriber must have completed continuing medical education on the treatment of hepatitis C
4. Request must be for an appropriate FDA approved/AASLD guideline recommended indication, at an approved dose and duration, and for appropriate member (e.g. age/weight)
5. Provider attests that patient has documentation of all the following:
 - a. A complete Hepatitis B immunization series OR Hepatitis B screening (sAB, sAG, and cAB)
 - b. Quantitative HBV DNA results if positive for hepatitis B sAg
 - c. If there is detectable HBV DNA, a treatment plan for Hepatitis B consistent with AASLD recommendations
 - d. If negative for Hepatitis B sAb, a hepatitis B immunization plan or counseling to receive the hepatitis B immunization series
6. Provider attests that they have documented HIV screening (HIV Ag/Ab), and if confirmed positive by HIV-1/HIV-2 differentiation immunoassay, then one of the following:
 - a. Is being treated for HIV; OR
 - b. Is not being treated for HIV and the medical record documents the rationale for not being treated
7. Provider attests that all potential drug interactions with concomitant medications have been addressed (including discontinuation of the interacting drug, dose reduction, or counseling of the member of the risks associated with the use of both medications).
8. Provider attests if member is actively abusing alcohol or IV drugs, or has a history of abuse that they have counseled member regarding the risks of alcohol or IV drug abuse, and an offer of referral for substance abuse disorder treatment has been made.
9. The following lab testing is required before treatment in the following cases:
 - a. Genotype (and subtype if provided) must be provided for:
 - i. Patients who are not going to receive Mavyret or generic Epclusa

- ii. Patients who do not qualify for simplified treatment (treatment experienced, have or had decompensated cirrhosis (Child-Pugh B and C), have ESRD, are HIV positive, have current HBV infection (positive for HbsAg), are pregnant, have known or suspected hepatocellular carcinoma, or have had a liver transplant)
- b. Has documentation of AASLD-recommended resistance-associated substitution (RAS) testing for:
 - i. Zepatier requests: all members with genotype 1a
 - ii. Harvoni requests: treatment-experienced members with genotype 1a
 - iii. Epclusa requests: treatment naïve members with cirrhosis and treatment experienced members without cirrhosis with genotype 3

TREATMENT SUMMARY

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

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

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

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

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

Treatment Experienced		Duration	
Failed Regimen	Treatment Options	No Cirrhosis	Compensated Cirrhosis (Child-Pugh A)
	Vosevi	12 weeks	12 weeks

Sofosbuvir-based (Sovaldi, Harvoni, and Epclusa) and Zepatier	Mavyret*	16 weeks	16 weeks ^β
Mavyret	Mavyret plus Sovaldi and ribavirin	16 weeks	16 weeks
	Vosevi	12 weeks	12 weeks [^]
Multiple including Vosevi or Sovaldi plus Mavyret	Mavyret plus Sovaldi and ribavirin	16 weeks ^μ	16 weeks ^μ
	Vosevi plus ribavirin	24 weeks ^μ	24 weeks

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

^βGenotype 3: If the patient has compensated cirrhosis, weight-based ribavirin is recommended.

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

^μMay be extended to 24 weeks in difficult cases (e.g. genotype 3 with cirrhosis) or failure following Sovaldi plus Epclusa

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

Revision/Review Date: 10/2023

Field Name	Field Description
Prior Authorization Group Description	Hormone Replacement Therapy (estrogen-only oral and vaginal products)
Drugs	<p><u>FORMULARY STATUS</u> Preferred, Pays at Point-of-Sale</p> <p>Estradiol (Estrace) oral tablet Estradiol (Estrace) vaginal cream Estradiol (Vagifem) vaginal tablet</p> <p><u>FORMULARY STATUS</u> Preferred, Requires Step Therapy</p> <p>Premarin (estrogens, conjugated) oral tablet Premarin (estrogens, conjugated) vaginal cream Menest (estrogens, esterified) oral tablet</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria	<p><u>For all requests:</u></p> <ul style="list-style-type: none"> The request is for an FDA approved indication. <p><u>Initial authorization for Premarin and Menest oral tablet</u></p> <ul style="list-style-type: none"> Documented trial and failure or intolerance with estradiol oral tablet If the request is for the treatment of moderate to severe symptoms of vulvar and vaginal atrophy or atrophic vaginitis due to menopause, must also have documented trial and failure or intolerance with estradiol vaginal cream OR estradiol vaginal tablet <p><u>Initial authorization for Premarin vaginal cream</u></p> <ul style="list-style-type: none"> Documented trial and failure or intolerance with estradiol vaginal cream OR estradiol vaginal tablet <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 10/2023	

Field Name	Field Description
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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	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ○ Amenorrhea or abnormal uterine bleeding due to hormonal imbalance ○ Production of secretory endometrium and desquamation ○ Test for endogenous estrogen production ○ Advanced uterine adenocarcinoma <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation or provider attestation of clinical benefit • Medication is prescribed at an FDA approved dose <p>If all the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
Revision/Review Date: 4/2024	

Field Name	Field Description
Prior Authorization Group Description	Ileal bile acid transporter inhibitor (IBAT)
Drugs	Bylvay (odevixibat), Livmarli (maralixibat)

Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	Per prescribing information
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist or hepatologist
Coverage Duration	If the conditions are met, the request will be approved for a 6 month duration for initial requests and a 12 month duration for renewal requests.
Other Criteria	<p><u>Initial Authorization:</u></p> <p>Progressive Familial Intrahepatic Cholestasis</p> <ul style="list-style-type: none"> • Diagnosis of progressive familial intrahepatic cholestasis (PFIC) <ul style="list-style-type: none"> ○ For Bylvy: PFIC type 1 or 2 with confirmed biallelic mutations via genetic testing ○ For Livmarli: PFIC type 1, 2, 3, 4, or 6, with confirmed biallelic mutations via genetic testing • Documentation that patient does not have an <i>ABCB11</i> variant that results in non-functional or complete absence of bile salt export pump protein • Documented history of moderate to very severe pruritus • Documentation of patient’s weight • Prescriber attests to monitor liver function tests and fat soluble vitamin (FSV) levels during treatment • Baseline serum bile acid level is provided • Documentation of trial and failure OR contraindication to at least ONE of the following: <ul style="list-style-type: none"> ○ Ursodiol ○ Cholestyramine or colesevelam • The prescribed dose is within FDA approved dosing guidelines <p>Alagille Syndrome</p> <ul style="list-style-type: none"> • Diagnosis of Alagille syndrome (ALGS)

<p>Revision/Review Date: 7/2024</p>	<ul style="list-style-type: none"> • Documented history of moderate to very severe pruritus • Documentation of trial and failure OR medical reason why the member is unable to use all of the following: <ul style="list-style-type: none"> ○ Ursodiol ○ Cholestyramine or colesevelam ○ Rifampin • Prescriber attests that the member has cholestasis • Baseline serum bile acid level is provided • Documentation of patient’s weight • Prescriber attests to monitor liver function tests and fat soluble vitamin (FSV) levels during treatment • The prescribed dose is within FDA approved dosing guidelines <p><u>Reauthorization:</u></p> <ul style="list-style-type: none"> • Documentation of clinical benefit indicating each of the following: <ul style="list-style-type: none"> ○ An improvement in pruritus (e.g. improved observed scratching, decreased sleep disturbances/nighttime awakenings due to scratching, etc.) ○ 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 <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Immune Globulins

Drugs	<p>Gamunex-C (IV or SQ) (Immune Globulin) 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 Globulin-klhw) Or any newly marketed immune globulin</p> <p>**Gamunex-C is the preferred product for the indications of primary immunodeficiency, chronic idiopathic thrombocytopenic purpura, and chronic inflammatory demyelinating polyneuropathy**</p>
Covered Uses	<p>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</p>
Exclusion Criteria	<p>N/A</p>
Required Medical Information	<p>See “other criteria”</p>
Age Restrictions	<p>According to package insert</p>
Prescriber Restrictions	<p>See “other criteria”</p>
Coverage Duration	<p>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.</p>
Other Criteria	<p><u>All Requests:</u></p> <ul style="list-style-type: none"> • 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:
 - If the member's actual weight is less than their IBW, then dosing will be calculated using their actual weight
 - If the member's body mass index (BMI) is ≥ 30 OR if their actual weight is greater than 20% kg/m of their IBW, then dosing will be calculated using adjusted body weight (adjBW)

Primary Immunodeficiency*:

- Patient's IgG level is provided and below normal for requested indication
- 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 is met, approve for 6 months.

*Primary Immunodeficiency includes, but is not limited to, the following: Congenital agammaglobulinemia, hypogammaglobulinemia (Common Variable Immunodeficiency, CVID), severe combined immunodeficiency (SCID), WiskottAldrich 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, requires an urgent invasive procedure, is deferring splenectomy, has platelet counts $< 20,000/\text{ul}$ and is at risk for intracerebral hemorrhage or has life threatening bleeding, or has an inadequate increase in platelets from

corticosteroids or is unable to tolerate corticosteroids

- Dose does not exceed 1g/kg daily for up to 2 days, or 400mg/kg daily for 5 days

- **Chronic:** ○ Duration of illness is greater than 12 months ○ Member has documented trial and failure of corticosteroids and splenectomy, or has a documented medical reason why they are not able to use corticosteroids or member is at high risk for post-splenectomy sepsis.
 - Dose does not exceed 1g/kg daily for up to 2 days, or 400mg/kg daily for 5 days
- If the request is for any medication other than Gamunex-C, the member has tried and failed, or has a documented medical reason for not using, Gamunex-C
- If criteria is met, approve for up to 5 days.

Kawasaki disease:

- Immunoglobulin is being given with high dose aspirin unless contraindicated
- Requested dose does not exceed a single 2g/kg dose
- If criteria is met, approve for 1 dose

Chronic B-cell lymphocytic leukemia:

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

Bone marrow transplantation:

- The patient has bacteremia or recurrent sinopulmonary infections and their IgG level is < 400mg/dL
- Dose does not exceed 500mg/kg/wk for the first 100 days post- transplant
- Dose does not exceed 500 mg//kg every 3-4 weeks 100 days after transplant
- If criteria is met, approve for 3 months.

Pediatric HIV:

- Patient is < 13 years of age

- Either patient's IgG level is < 400mg/dL or
- If patient's IgG level is \geq 400 mg/dL than significant deficiency of humoral immunity as evidenced by ONE of the following:
 - Inability to produce an adequate immunologic response to specific antigens.
 - History of recurrent bacterial infections despite prophylactic antibiotics
- Dose does not exceed 400mg/kg/dose every 2-4 weeks
- If criteria is met, approve for 3 months.

Multifocal motor neuropathy (MMN):

- Duration of symptoms has been at least 1 month with disability.
- Nerve conduction studies were completed to rule out other possible conditions, and confirms the diagnosis of MMN.
- Dose does not exceed 2g/kg/month administered over 2 to 5 days.
- If criteria is met, approve for up to 5 days 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 tried and failed, or has a documented medical reason for not using, corticosteroids.
 - If the patient has severe and fulminant or pure motor CIDP a trial of corticosteroids is not required
- Dose is consistent with FDA approved package labeling, nationally recognized compendia, or peer-reviewed literature
- If the request is for any medication other than Gamunex-C, the member has tried and failed, or has a documented medical reason for not using, Gamunex-C
- If criteria is 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 2g/kg administered over 2-5 days
- If criteria is met, approve for up to 5 days.

Myasthenia Gravis:

- Acute:
 - Patient has an acute myasthenic exacerbation (i.e. acute episode of respiratory muscle weakness, difficulty swallowing, etc.) or is in preparation for thymoma surgery to prevent myasthenic exacerbation
 - Dose does not exceed 2 g/kg administered over 2-5 days
 - If criteria is met, approve for up to 5 days
- Chronic:
 - Diagnosis of refractory generalized myasthenia gravis
 - Patient has tried and failed, or has a documented medical reason for not using 2 or more immunosuppressive therapies (i.e. corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil)
 - Dose does not exceed 2 g/kg/month administered over 2-5 days
 - If criteria is met, approve for 3 months

Dermatomyositis (DM):

- One of the following:
 - Bohan and Peter score of 3 (i.e. definite DM)
 - Bohan and Peter score of 2 (i.e. probable DM) AND concurring diagnostic evaluation by ≥ 1 specialist (e.g. neurologist, rheumatologist, dermatologist)
- Patient does NOT have any of the following:
 - Cancer (CA) associated myositis defined as myositis within 2 years of CA diagnosis (except basal or squamous cell skin cancer or carcinoma in situ of the cervix that has been excised and cure)
 - Active malignancy
 - Malignancy diagnosed within the previous 5 years
 - Breast CA within the previous 10 years
- For a diagnosis of DM, one of the following:
 - Member has tried and failed, or has a documented medical reason for not using both of the following:
 - methotrexate (MTX) OR azathioprine

<p>Revision/Review Date 10/2023</p>	<ul style="list-style-type: none">▪ rituximab. ○ Member has severe, life-threatening weakness or dysphagia• For a diagnosis of cutaneous DM (i.e. amyopathic DM, hypomyopathic DM):<ul style="list-style-type: none">○ Member has tried and failed, or has a documented medical reason for not using all of the following: MTX and mycophenolate mofetil.• Dose does not exceed 2 g/kg administered over 2-5 days every 4 weeks.• If criteria is met, approve for up to 3 months. <p>If criteria is met, the request will be approved for the duration listed above. If the criteria is not met, the request is referred to a Medical Director/Clinical reviewer for medical necessity review.</p> <p><u>Medical Director/Clinical Reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary</u></p>
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Field Name	Field Description
Prior Authorization Group Description	Immunosuppressants for Lupus Nephritis
Drugs	Lupkynis (voclosporin)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be 18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a 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	<p><u>Initial Authorization</u></p> <ul style="list-style-type: none"> • 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/1.73m² • 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 <p><u>Reauthorization</u></p> <ul style="list-style-type: none"> • 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 <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 4/2024	

Field Name	Field Description
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Prior Authorization Group Description	Increlex
Drugs	Increlex (mecasermin [recombinant human insulin-like growth factor1])
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	≥ 2 years to < 18 years
Prescriber Restrictions	Prescribed by or in consultation with an Endocrinologist or specialist in the treatment of pediatric growth disorders
Coverage Duration	If all of the conditions are met, the request will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization</u></p> <ul style="list-style-type: none"> • Member has a diagnosis of one of the following <ul style="list-style-type: none"> ○ Growth hormone (GH) gene deletion with the development of neutralizing antibodies to GH <ul style="list-style-type: none"> ○ Severe primary insulin-like growth factor-1 (IGF-1) deficiency as defined as: <ul style="list-style-type: none"> ▪ Height and basal IGF-1 standard deviation scores ≤ -3.0 ▪ Normal or elevated GH levels • Member does not have a closed epiphyses • Member does not have known or suspected malignancies • Request is for an FDA-approved dose <p><u>Reauthorization</u></p> <ul style="list-style-type: none"> • Growth velocity must be ≥ 2 cm in the past year • Member does not have a closed epiphyses • Member does not have known or suspected malignancies • Request is for an FDA-approved dose <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 7/2024	

Field Name	Field Description
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Prior Authorization Group	Injectable/Infusible Bone-Modifying Agents for Oncology Indications
Drugs	<p>Preferred Bone-Modifying Agent(s): Pamidronate disodium (Aredia), Zoledronic Acid (Zometa)</p> <p>Non-preferred Bone-Modifying Agent(s): Xgeva, Prolia (denosumab)</p>
Covered Uses	The request is for an FDA approved indication or for a medically accepted indications as defined or as supported by the medical compendium (Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI) , Drug Package Insert) as defined in the Social Security Act 1927, or per the National Comprehensive Cancer Network (NCCN), the American Society of Clinical Oncology (ASCO), or the National Institutes of Health (NIH) Consensus Panel standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber is an oncologist
Coverage Duration	6 months
Other Criteria	<ul style="list-style-type: none"> • The request is for an approved/accepted indication at an approved dose • 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 <ul style="list-style-type: none"> ○ Bone metastases from solid tumors ○ Hypercalcemia of malignancy ○ 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

<p>Revision/Review 2/2024</p>	<p>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</p> <ul style="list-style-type: none">• If the request is for Prolia (denosumab) for prostate cancer, approve. <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Injectable/Infusible Bone-Modifying Agents for Osteoporosis and Paget's Disease
Drugs	Pamidronate, ibandronate (Boniva), Prolia (denosumab), zoledronic acid (Reclast), teriparatide (Forteo), teriparatide (biosimilar), Tymlos (abaloparatide), Evenity (romosozumab-aqqg) or any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	"See other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be an endocrinologist, rheumatologist, orthopedist, or obstetrician/gynecologist
Coverage Duration	If all of the conditions are met, requests will be approved for a 1 year. *** TERIPARATIDE/FORTEO/TYMLOS REQUESTS WILL ONLY BE APPROVED FOR A TOTAL DURATION OF 24 MONTHS*** ***EVENITY WILL ONLY BE APPROVED FOR A TOTAL DURATION OF 12 MONTHS***

Other Criteria	<p><u>For all Requests:</u></p> <ul style="list-style-type: none">• The medication is FDA-approved for indication and is being requested at an FDA approved dose <p><u>If the diagnosis is postmenopausal or male osteoporosis:</u></p> <ul style="list-style-type: none">• If the request is for male osteoporosis or high risk postmenopausal osteoporosis with no prior fractures the member has a documented (consistent with pharmacy claims) adequate trial of an oral bisphosphonate or has a medical reason (e.g. intolerance, hypersensitivity, contraindication, etc.) for not using an oral bisphosphonate• If the request is for very high risk postmenopausal osteoporosis or postmenopausal osteoporosis with prior fractures a documented trial and failure of an oral bisphosphonate will not be required.<ul style="list-style-type: none">○ Very high risk is defined as having one or more of the following:
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	<ul style="list-style-type: none"> ▪ History of fracture in the past 12 months ▪ Multiple fractures ▪ Fractures while on drugs causing skeletal harm (e.g. long-term glucocorticoids) ▪ Very low T scores (< -3.0) ▪ High risk for falls ▪ History of injurious falls ▪ Very high fracture probability as determined by fracture risk assessment tool (FRAX) (e.g. major osteoporosis fracture >30%, hip fracture > 4.5%) <ul style="list-style-type: none"> • Documentation was submitted indicating the member is a postmenopausal woman or a male member over 50 years of age and one of the following: <ul style="list-style-type: none"> ○ A bone mineral density (BMD) value consistent with osteoporosis (T-scores equal to or less than -2.5) ○ Has had an osteoporotic fracture ○ A T-score between -1 and -2.5 at the femoral neck or spine and a 10 year hip fracture probability >3% or a 10 year major osteoporosis-related fracture probability >20% (based on the US-adapted WHO absolute fracture risk model) • If request is for teriparatide (Forteo), teriparatide (biosimilar), Tymlos (abaloparatide), or Evenity (romosozumab) one of the following applies to member: <ul style="list-style-type: none"> ○ Documented trial and failure of Prolia (denosumab) AND EITHER ibandronate (Boniva) injection OR zoledronic acid (Reclast) or has a medical reason (e.g. intolerance, contraindication, etc.) why these therapies are not suitable to be used ○ Has SEVERE osteoporosis (T-Score -3.5 or below, or T-Score of -2.5 or below plus a fragility fracture) • If request is for teriparatide (Forteo) or teriparatide (biosimilar), a medical reason why member is unable to use Tymlos (abaloparatide) or Evenity (romosozumab) if appropriate based on diagnosis • If the request is for Evenity (romosozumab), the member does not have a history of heart attack or stroke within the preceding year <p><u>If the diagnosis is Paget's disease:</u></p> <ul style="list-style-type: none"> • The member has a documented (consistent with pharmacy claims) adequate trial of an oral bisphosphonate or has a medical reason (e.g. intolerance, hypersensitivity,
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contraindication, etc.) for not using an oral bisphosphonate •
Documentation (within 60 days of request) was submitted
including member's serum alkaline phosphatase level of \geq

two times the upper limit of normal AND the member is symptomatic OR there is documentation of active disease

If the diagnosis is glucocorticoid-induced osteoporosis:

- The member has a documented (consistent with pharmacy claims) adequate trial of an oral bisphosphonate or has a medical reason (e.g. intolerance, hypersensitivity, contraindication, etc.) for not using an oral bisphosphonate
- For members ≥ 40 years of age on long-term glucocorticoid therapy:
 - Dosage of the oral glucocorticoid therapy is equivalent to a dose greater than 2.5 mg of prednisone daily
 - Member has a moderate to very high risk of fracture based on ONE of the following:
 - History of osteoporotic fracture
 - BMD less than or equal to -1 at the hip or spine
 - FRAX 10-year risk for major osteoporotic fracture greater than or equal to 10% (with glucocorticoid adjustment)
 - FRAX 10-year risk for hip fracture greater than 1% (with glucocorticoid adjustment)
- For adult members (all ages) receiving HIGH dose glucocorticoid therapy:
 - Member has a moderate to very high risk of fracture based on ONE of the following:
 - History of prior fracture(s)
 - Glucocorticoid dose ≥ 30 mg/day or cumulative ≥ 5 grams/year
 - Continuing glucocorticoid treatment ≥ 7.5 mg/day for ≥ 6 months AND BMD Z score < -3 OR significant BMD loss ($>$ least significant change of DXA)
- If the request is for teriparatide (biosimilar), teriparatide (Forteo), or Tymlos (abaloparatide), the member has a documented trial and failure of zoledronic acid (Reclast) or Prolia (denosumab) or a medical reason (e.g. intolerance, contraindication, etc.) as to why the member is unable to use these medications is provided

Revision/Review Date:
2/2024

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	Insulin-Like Growth Factor-1 Receptor (Igf-1r) Antagonists For Thyroid Eye Disease
Drugs	Tepezza (teprotumumab-trbw)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Member must be 18 years age or older
Prescriber Restrictions	Prescriber must be an ophthalmologist, endocrinologist, or specialist with expertise in the treatment of Grave’s disease with thyroid eye disease.
Coverage Duration	If all of the criteria are met, the request will be approved for up to 24 weeks of treatment (8 total infusions). Retreatment requests will not be allowed beyond the 8 dose limit.
Other Criteria	<p><u>Initial Authorization:</u></p> <p>Tepezza is approved when all of the following are met:</p> <ul style="list-style-type: none"> • Dosing does not exceed dosing guidelines as outlined in the package insert • Patient has a confirmed diagnosis of Graves’ disease • Documentation of moderate-severe thyroid eye disease as evidenced by one or more of the following: <ul style="list-style-type: none"> ○ Lid retraction of >2mm ○ Moderate or severe soft-tissue involvement ○ Proptosis ≥3mm above normal values for race and sex ○ Periodic or constant diplopia • Patient must be euthyroid or thyroxine and free triiodothyronine levels are less than 50% above or below normal limits (submit laboratory results with request) • Patients of reproductive potential: attestation the patient is not pregnant, and appropriate contraception methods will be used before, during, and 6 months after the last infusion • Patient has had a trial and therapy failure of, or contraindication to: <ul style="list-style-type: none"> ○ For active disease: oral or IV glucocorticoids ○ For chronic/inactive disease: rehabilitative surgery

Revision/Review Date 7/2024	<p><u>Re-authorization:</u></p> <ul style="list-style-type: none">• Retreatment or renewal requests beyond a total of 24 weeks of treatment (8 total infusions) will not be allowed. <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Insulin Pumps
Drugs	<p>Omnipod Dash Intro Kit, Omnipod Dash Pods, Omnipod 5 G6 Intro Kit, Omnipod 5 G6 Pods, OmniPod GO</p> <p>This policy does not apply to pumps reviewed and/or covered by the Medical Benefit including, but not limited to V-Go 24-hour disposable system and t:slim X2, and continuous glucose monitor/insulin pumps such as MiniMed. Requests for these products are referred to the plan’s Utilization Management team for review.</p>
Covered Uses	<p>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</p>
Exclusion Criteria	None
Required Medical Information	See “Other Criteria”
Age Restrictions	None
Prescriber Restrictions	<p>Prescribed by or in consultation with an endocrinologist, a certified diabetes care and education specialist (CDCES), or an obstetrician/gynecologist</p>
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization</u></p> <ul style="list-style-type: none"> • Diagnosis – diabetes • One of the following <ul style="list-style-type: none"> ○ Type 1 diabetes or other insulin-deficient forms of diabetes (e.g. cystic-fibrosis related diabetes) ○ Treatment with multiple daily doses (≥ 3) of insulin ○ Pregnancy ○ Continuation of therapy for patient new to plan ○ For OmniPod GO: trial and failure of a long-acting insulin or a medical reason why long-acting insulin cannot be used (adherence, etc.) <p><u>Reauthorization</u></p> <ul style="list-style-type: none"> • One of the following: <ul style="list-style-type: none"> ○ Type 1 diabetes or other insulin-deficient form of diabetes ○ Prescriber attests member has benefited from, and has continued need for, therapy with an insulin pump

<p>Revision/Review Date 2/2024</p>	<ul style="list-style-type: none">○ Initial approval was based on continuation of therapy for patient new to plan.○ For OmniPod GO: continuous use of approved insulin compatible with device• Continuation of therapy based on a diagnosis of pregnancy alone is not eligible for reauthorization <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Janus Kinase Inhibitors for Nonsegmental Vitiligo
Drugs	Opzelura (ruxolitinib)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI)
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	≥ 12 years of age
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist, immunologist, or specialist experienced in treatment of vitiligo
Coverage Duration	If criteria are met, the request will be approved with up to a 6 month duration. All reauthorization requests will be approved up to 12 months in duration.
Other Criteria	<p><u>Initial Authorization</u> ○ Diagnosis of nonsegmental vitiligo</p> <ul style="list-style-type: none"> ○ Documentation of depigmented lesions including measurements and locations is provided ○ Prescriber attests that the total body vitiligo area (facial and nonfacial) being treated does not exceed 10% BSA ○ Trial and failure of, or intolerance to, ALL of the following: ○ Topical corticosteroids ○ Topical calcineurin inhibitors ○ Targeted phototherapy ○ Prescriber attests that the member will not concomitantly use therapeutic biologics, other Janus kinase inhibitors, potent immunosuppressants, or phototherapy for repigmentation purposes ○ Request is for an FDA-approved dose <p><u>**A MAXIMUM OF ONE 60 GRAM TUBE OF OPZELURA PER WEEK OR ONE 100 GRAM TUBE EVERY TWO WEEKS MAY BE APPROVED**</u></p> <p><u>Reauthorization</u> ○ 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)</p> <ul style="list-style-type: none"> ○ Request is for an FDA-approved dose <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 10/2023	

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	Prescribed by or in consultation with a hematologist or nephrologist
Coverage Duration	If all conditions are met, the request will be approved with a 6 month duration.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • 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 <u>MUST</u> be receiving, or is beginning therapy, to correct the deficiency: <ul style="list-style-type: none"> ○ Serum ferritin level (> 100ng/mL) ○ 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 <p><u>Reauthorization:</u></p> <ul style="list-style-type: none"> • All submitted lab results have been drawn within 30 days of the reauthorization request.

<p>Revision/Review Date: 4/2024</p>	<ul style="list-style-type: none">• Member has a documented increase in hemoglobin from baseline• The following lab results must be submitted and demonstrate normal values, otherwise, the member <u>MUST</u> be receiving, or is beginning therapy, to correct the deficiency:<ul style="list-style-type: none">○ Serum ferritin level (> 100ng/mL)○ Transferrin saturation (TSAT) (> 20%)• Member will not be receiving concurrent treatment with an ESA• Request is for an FDA-approved dose <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary</p>
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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.

<p>Other Criteria</p>	<p><u>Depression</u></p> <p>Initial Authorization:</p> <ul style="list-style-type: none"> • Diagnosis of major depressive disorder (MDD) or treatmentresistant depression (TRD) • Documented trial and failure of two preferred oral antidepressants (e.g. SSRIs, SNRIs, TCAs) of at least a minimum effective dose for four (4) weeks or longer OR a medical justification as to why the patient cannot use preferred alternative(s). <p>Re-authorization:</p> <ul style="list-style-type: none"> • Documentation was submitted indicating the member has clinically benefited from therapy. <p><u>CRPS</u></p> <p>Initial Authorization:</p> <ul style="list-style-type: none"> • Diagnosis of CRPS (may also be termed reflex sympathetic dystrophy, algodystrophy, causalgia, Sudeck atrophy, transient osteoporosis, and acute atrophy of bone) • Patient has tried and failed at least 8 weeks treatment with or continues to receive physical therapy (PT) and/or occupational therapy (OT). • Patient has tried and failed at least two of the following: <ul style="list-style-type: none"> ○ NSAIDs ○ Anticonvulsants (e.g. gabapentin, pregabalin) ○ Antidepressants (e.g. SNRIs, TCAs)
<p>Revision/Review Date 4/2024</p>	<ul style="list-style-type: none"> ○ Bisphosphonate (in the setting of abnormal uptake on bone scan) <p>Re-authorization:</p> <ul style="list-style-type: none"> • Patient has demonstrated clinical benefit. <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>

Field Name	Field Description
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	Prescribed by or in consultation with a specialist experienced in treating Phenylketonuria (PKU)
Coverage Duration	<p><u>Initial:</u> If the criterion is met, the request will be approved for a duration of 1 month.</p> <p><u>Reauthorization:</u> If the criteria is met, the request will be approved for a duration of 1 month for patients who require a dose increase to 20 mg/kg/day due to non-responsiveness and for all other patients the request will be approved for a duration of 6 months.</p>

<p>Other Criteria</p>	<p>INITIAL AUTHORIZATION:</p> <ul style="list-style-type: none"> • Documentation of a confirmed diagnosis of Phenylketonuria (PKU) • Documentation of the patient’s baseline blood Phe level- (within 30 days of the request) • Documentation or prescriber attestation that the patient is currently utilizing a Phe-restricted diet • Documentation of the patient’s current weight. • The medication is being prescribed at an FDA approved dosage <p>PA CRITERIA FOR REAUTHORIZATION:</p> <p><i>Patients that were dosed at 20mg/kg/day and did not have a decrease in Phe level of at least 30% from baseline, are considered NON RESPONDERS and NO ADDITIONAL TREATMENT will be authorized.</i></p> <ul style="list-style-type: none"> • Documentation of the patient’s current weight. • Documentation of updated blood Phe level results showing reduction in Phe level from baseline. • The medication is being prescribed at an FDA approved dosage.
<p>Last review: 4/2024</p>	<p>Medical Director/ Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>

Field Name	Field Description
Prior Authorization Group Description	Lamzede
Drugs	Lamzede (velmanase alfa-tycv)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	“See Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a specialist in the treatment of alpha-mannosidosis or other lysosomal storage disorders
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months
Other Criteria	<p>Initial Authorization</p> <ul style="list-style-type: none"> • Diagnosis of alpha-mannosidosis as confirmed by one of the following: <ul style="list-style-type: none"> ○ Deficiency in alpha-mannosidase enzyme levels or activity in blood leukocytes ○ DNA testing • Prescriber attests that medication will only be used to treat noncentral nervous system manifestations of alpha-mannosidosis • Patient’s weight • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines <p>Reauthorization</p> <ul style="list-style-type: none"> • Patient has demonstrated a clinical response (i.e., reduction in serum oligosaccharide concentrations, stabilization or improvement in 3minute stair climbing test [3MSCT], 6-minute walking test [6MWT], forced vital capacity [FVC], etc.) • Prescriber attests that medication will only be used to treat non-central nervous system manifestations of alpha-mannosidosis • Patient’s weight • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 4/2024	

Field Name	Field Description
Prior Authorization Group Description	Lenmeldy
Drugs	Lenmeldy (atidarsagene 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	According to package insert
Prescriber Restrictions	Prescribed by a neurologist or geneticist
Coverage Duration	If all the criteria are met, the initial request will be approved for a onetime treatment.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Member has diagnosis of one of the following metachromatic leukodystrophies (MLD): <ul style="list-style-type: none"> ○ Pre-symptomatic late infantile (PSLI) MLD ○ Pre-symptomatic early juvenile (PSEJ) MLD ○ Early symptomatic early juvenile (ESEJ) MLD • Documentation patient has both of the following: <ul style="list-style-type: none"> ○ Arylsulfatase A (ARSA) activity below the normal range (normal range 31-198 nmol/mg/h) ○ Identification of two disease-causing ARSA alleles • Medication is prescribed at an FDA approved dose <p>The safety and effectiveness of repeat administration of Lenmeldy has not been evaluated and will not be approved.</p> <p>If all the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
Revision/Review Date: 7/2024	

Field Name	Field Description
Prior Authorization Group Description	Leqembi (lecanemab-irmb)
Drugs	Leqembi (lecanemab-irmb)

Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Patients with moderate to severe Alzheimer’s Disease (AD) Patients with neurodegenerative disease caused by a condition other than AD
Required Medical Information	See “Other Criteria”
Age Restrictions	age 50-90 years
Prescriber Restrictions	Prescriber must be prescribed by, or in consultation with, a specialist in neurology or gerontology
Coverage Duration	For initial and reauthorizations: if all of the conditions are met, the request will be approved for 6 months.
Other Criteria	<p><u>Initial Authorization</u></p> <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ○ Clinical Dementia Rating Global (CDR-G) score of 0.5-1.0 and a Memory Box score of 0.5 or greater ○ Mini-Mental State Examination (MMSE) score ≥ 22 and ≤ 30 ○ 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: <ul style="list-style-type: none"> ○ Recent, within past year, positive results for the presence of beta-amyloid plaques on a positron emission tomography (PET) scan or cerebrospinal fluid testing ○ Recent, within past year, baseline Magnetic Resonance Imaging (MRI) scan • Physician has assessed baseline disease severity utilizing an objective measure/tool (i.e., Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog-14], Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory-Mild Cognitive Impairment version [ADCS-ADLMCI], Clinical Dementia Rating Sum of Boxes [CDR-SB], etc.)

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<p>Revision/Review Date: 7/2024</p>	<ul style="list-style-type: none"> • 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. <p><u>Reauthorization</u></p> <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ○ CDR-G score of 0.5-1.0 and a Memory Box score of 0.5 or greater ○ MMSE score of 22-30 ○ 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 <p>If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.</p> <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Lidocaine Topical Patch
Drugs	Lidocaine 5% topical patch (Lidoderm) Ztlido 1.8% topical patch (lidocaine)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A

Required Medical Information	See “other criteria”
Age Restrictions	Age 18 and older
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 6 month duration.
Other Criteria	<p><u>Initial Authorization</u></p> <ul style="list-style-type: none"> • Diagnosis of postherpetic neuralgia • If the request is for Ztlido there has been a documented trail and failure or intolerance to lidocaine 5% patch (Lidoderm) <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 4/2024	

Field Name	Field Description
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 criteria are met, the request will be approved with up to a 1 month duration.

Other Criteria	<p>The Patient meets one of the two following criteria:</p> <ul style="list-style-type: none"> • Documented history of treatment with linezolid IV (continuation of therapy, IV to PO conversion). • Documented trial and failure, or intolerance, to 1 preferred antibiotic to which the organism is susceptible. <p>AND</p> <ul style="list-style-type: none"> • Requests for linezolid oral suspension require a documented trial and failure of linezolid oral tablets or a medical reason (e.g. intolerance, hypersensitivity, contraindication) why linezolid oral tablets cannot be used. <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 4/2024	

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

<p>Other Criteria</p>	<ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> ○ Strong CYP3A4 inhibitors (ex. atazanavir, clarithromycin, darunavir/ritonavir, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, tipranavir/ritonavir) ○ P-glycoprotein inhibitors (ex. cyclosporine, ranolazine) <p>Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>
<p>Revision/Review Date: 2/2024</p>	

<p>Prior Authorization Group Description</p>	<p>Medications for Management of Obesity</p>
<p>Drugs</p>	<p>Xenical/orlistat benzphetamine diethylpropion, diethylpropion ER phendimetrazine, phenidimetrazine ER phentermine (Adipex-P) Lomaira (phentermine)Saxenda (liraglutide) Wegovy (semaglutide) Imcivree (setmelanotide) Zepbound (tirzepatide) Any newly-approved medication indicated for obesity or weight management *Note: Alli, Contrave, Qsymia are not a covered benefit*</p>
<p>Covered Uses</p>	<p>Medically accepted indications are defined using the following 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).</p>
<p>Exclusion Criteria</p>	<p>N/A</p>
<p>Required Medical Information</p>	<p>See “other criteria”</p>

Age Restrictions	Age appropriate per labeling
Prescriber Restrictions	Imcivree: Prescribed by or in consultation with medical geneticist, endocrinologist, or specialist in metabolic disorders N/A for all other agents
Coverage Duration	If the criteria are met, the request will be approved for 6 months, or 12 months for Imcivree for BBS.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Requested dose is appropriate per labeling • Documentation of current weight and body mass index (BMI) • BMI must be one of the following: <ol style="list-style-type: none"> 1. BMI of 27 - 29.9 kg/m² with one of the following weightrelated comorbidities: coronary artery disease, diabetes, hypertension, dyslipidemia, or obstructive sleep apnea 2. BMI of 30 kg/m² or more 3. Pediatric patients must be considered obese per package labeling • Documentation of counseling regarding lifestyle changes and behavioral modification (e.g., health diet and increased physical activity) • For brand Xenical or Zepbound: trial and failure or medical reason for not using 2 of the following: <ol style="list-style-type: none"> 1. orlistat 2. Saxenda 3. Wegovy

<p>Revision/Review Date: 9/2024</p>	<ul style="list-style-type: none"> • For Lomaira: trial and failure or medical reason for not using generic phentermine • For Imcivree, the patient meets one of the following: <ol style="list-style-type: none"> 1. Diagnosis of Bardet-Biedl syndrome (BBS) 2. Obesity is related to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency AND: <ul style="list-style-type: none"> ▪ 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 <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation of at least 5% reduction in body weight compared with baseline or 5% of baseline BMI for patients with continued growth potential AND • If a weight-related comorbidity was previously noted, an objective improvement is documented (e.g. reduction in blood pressure, cholesterol, hemoglobin A1c, etc) <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Prior Authorization Group Description	Medications for Use in ADHD Treatment for Members 21 and Older
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Preferred drugs will pay for members 20 and younger; PA required for members 21 and older
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved for 12 months, or 6 months if the request is for a non-preferred medication due to the shortage.

<p>Prescriber Restrictions</p>	<p>N/A</p>
<p>Coverage Duration</p>	<p>If all of the criteria are met, the initial request for Mifepristone 300 mg, Korlym will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.</p> <p>If all of the criteria are met, Mifepristone 200 mg, Mifeprex will be approved for a one-time treatment.</p>
<p>Other Criteria</p>	<p>Korlym (mifepristone 300 mg)</p> <p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Patient has a diagnosis of type 2 diabetes with hyperglycemia due to hypercortisolism in patient due to endogenous Cushing’s syndrome; AND • Patient is not a candidate for or has failed surgery. <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation or provider attestation of positive clinical response (i.e. etc.) <p>Mifeprex (mifepristone 200 mg)</p> <p><u>Initial Authorization:</u></p> <ol style="list-style-type: none"> 1. Patient has experienced a miscarriage or early pregnancy loss within the first 70 days of gestation; OR 2. Patient is pregnant and within first 70 days of gestation; AND

Date: 3/7/2025	<p>a. The pregnancy is the result of an act of rape or incest, and evidence of the act of rape or incest is provided through signed documentation from a law enforcement agency of the United States, any State or local jurisdiction, or from an agency of the United States or of a State or local government that provides health or medical services or a rural health clinic whose principal function is not the performance of abortions;</p> <p>i. The documentation provided states:</p> <ol style="list-style-type: none"> (1) That the person to whom the drug has been prescribed was reported to have been the victim of an incident of rape or incest; (2) The date on which the incident occurred; (3) The date on which the report was made, which must have been within 60 days of the date on which the incident occurred; (4) The name and address of the victim and the name and address of the person making the report (if different from the victim); and (5) That the report included the signature of the person who reported the incident; OR <p>b. The woman suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition, that would, as certified by a licensed physician, place the woman in danger of death unless an abortion is performed.</p> <p>i. The documentation provided:</p> <ol style="list-style-type: none"> (1) Is signed by a licensed physician; and (2) Contains the name and address of the patient. <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
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Field Name	Field Description
Prior Authorization Group Description	Mucopolysaccharidosis II (Hunter Syndrome) Agents
Drugs	Elaprase (idursulfase)

Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	“See Other Criteria”
Age Restrictions	Patient is \geq 16 months of age
Prescriber Restrictions	Prescribed by or in consultation with a specialist in the management Mucopolysaccharidosis II (geneticist, endocrinologist, neurologist, rheumatologist, etc.)
Coverage Duration	Initial Authorization: 6 months Reauthorization: 12 months
Other Criteria	<p>Initial Authorization</p> <ul style="list-style-type: none"> Diagnosis of Mucopolysaccharidosis II as confirmed by one of the following: <ul style="list-style-type: none"> Enzyme assay demonstrating a deficiency of iduronate 2-sulfatase activity Genetic testing Patient’s weight Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines <p>Reauthorization</p> <ul style="list-style-type: none"> Patient has demonstrated a beneficial response (i.e., stabilization or improvement in 6-minute walk test [6-MWT], forced vital capacity [FVC]), urinary glycosaminoglycan (GAG) levels, liver volume, spleen volume, etc.) Patient’s weight Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 7/2024	

Field Name	Field Description
Prior Authorization Group Description	Mucopolysaccharidosis VI (Maroteaux-Lamy Syndrome) Agents
Drugs	Naglazyme (galsulfase)

Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	“See Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months Renewal: 12 months
Other Criteria	<p>Initial Authorization</p> <ul style="list-style-type: none"> • Diagnosis of Mucopolysaccharidosis VI as confirmed by one of the following: <ul style="list-style-type: none"> ◦ Enzyme assay demonstrating a deficiency in Nacetylgalactosamine 4-sulfatase (arylsulfatase B) enzyme activity ◦ DNA testing • Patient’s weight • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines <p>Reauthorization</p> <ul style="list-style-type: none"> • Patient has demonstrated a beneficial response (i.e., stabilization or improvement in 12-minute walk test [12-MWT], 3-minute stair climb test, urinary glycosaminoglycan (GAG) levels, etc.) • Patient’s weight • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 2/2024	

Field Name	Field Description
Prior Authorization Group Description	Multaq
Drugs	Multaq (dronedarone)

Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Pregnancy
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or electrophysiologist.
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria	<ul style="list-style-type: none"> • Diagnosis of paroxysmal or persistent atrial fibrillation (AF) or atrial flutter (AFL) with a recent episode. • Must not have NYHA Class IV heart failure or symptomatic heart failure with recent decompensation requiring hospitalization or referral to a specialized heart failure clinic • Must have AF that can be cardioverted into normal sinus rhythm, or is currently in sinus rhythm • Prescriber attests women of childbearing potential have been counseled regarding appropriate contraceptives <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>
Revision/Review Date 4/2024	

Field Name	Field Description
Prior Authorization Group Description	Myasthenia Gravis Agents
Drugs	Rystiggo (rozanolixizumab), Soliris (eculizumab), Ultomiris (ravulizumab), Vyvgart (efgartigimod), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase), Zilbrysq (zilucoplan)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the 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	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of generalized myasthenia gravis (gMG) • Patient has a positive serological test for one of the following: <ul style="list-style-type: none"> ○ Anti-AChR antibodies ○ 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: <ul style="list-style-type: none"> ○ Two (2) or more conventional therapies (i.e. acetylcholinesterase inhibitors, corticosteroids, non-steroidal immunosuppressive therapies) ○ 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, Ultomiris, or Zilbrysq) • For Vyvgart Hytrulo, patient has tried and failed, or has contraindication, to Vyvgart • Requests for Soliris (eculizumab) Ultomiris (ravulizumab), and Zilbrysq (zilucoplan) will also require all of the following:

Revision/Review
Date: 4/2024

- Patient has tried and failed, or has contraindication, to Vyvgart, Vyvgart Hytrulo, or Rystiggo.
- Documentation patient complies with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against meningococcal infections in patients receiving a complement inhibitor. ○

Re-Authorization:

- Provider has submitted documentation of clinical response to therapy (e.g., reduction in disease severity, improvement in qualityof-life scores, MG-ADL scores, etc).
- Medication is prescribed at an FDA approved dose.

If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	Natriuretic Peptides for Achondroplasia
Drugs	Voxzogo (vosoritide)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Hypochondroplasia or short stature condition other than achondroplasia
Required Medical Information	See "Other Criteria"
Age Restrictions	According to FDA approved prescribing information
Prescriber Restrictions	Prescribed by, or in consultation with, an endocrinologist, medical geneticist, or other specialist for the treatment of achondroplasia
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 4/2024	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Member has a diagnosis of achondroplasia as confirmed via genetic testing • Prescriber attests patient has open epiphyses • Documentation of baseline growth velocity • Medication is prescribed at an FDA approved dose <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • 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 <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>

Field Name	Field Description
Prior Authorization Group Description	Neuromyelitis Optica Spectrum Disorder (NMOSD) Agents
Drugs	Step 1: Rituximab (Rituxan, Truxima, Riabni, Ruxience), Step 2: Enspryng (satralizumab-mwge) Uplizna (inebilizumab-cdon) Step 3: Soliris (eculizumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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	<p><u>Initial Authorization:</u></p> <p><u>For rituximab (Rituxan, Truxima, Riabni, or Ruxience):</u></p> <ul style="list-style-type: none"> • Member has a diagnosis of NMOSD • Documentation indicating that the patient has been screened for HBV (hepatitis B virus) prior to initiation of treatment • Dosing is supported by compendia or standard of care guidelines • If the request is for any medication other than Ruxience (rituximab-pvvr) or Riabni (rituximab-arrx), there is a documented trial and failure of Ruxience or Riabni, or medical reason why (e.g. intolerance, hypersensitivity, contraindication) they cannot be used <p><u>For Enspryng:</u></p> <ul style="list-style-type: none"> • Member has a diagnosis of anti-aquaporin-4 (AQP4) antibody positive NMOSD • Provider attests to completion of the following assessments prior to the first dose of Enspryng as outlined in the prescribing information: <ul style="list-style-type: none"> ○ Hepatitis B virus screening ○ Tuberculosis screening Liver transaminase screening

○ Patient has not received live or attenuated-live virus vaccines within 4 weeks before the start of Enspryng therapy

- Documented trial and failure of rituximab (Rituxan, Truxima, Riabni, or Ruxience), azathioprine, or mycophenolate mofetil, or medical reason why (e.g., intolerance, hypersensitivity, contraindication) they cannot be used
- Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines

Exceptions:

Requests for drugs in step 2 (Enspryng, Uplizna) may be approved without a trial and failure of rituximab (Rituxan, Truxima, Riabni, Ruxience), azathioprine, or mycophenolate if the member has been using Soliris

For Uplizna:

- Member has a diagnosis of anti-aquaporin-4 (AQP4) antibody **positive** NMOSD
- Provider attests to completion of appropriate assessments prior to the first dose of Uplizna as outlined in the prescribing information:
 - Hepatitis B virus screening
 - Quantitative serum immunoglobulins
 - Tuberculosis screening
 - Patient has not received live or attenuated-live virus vaccines within 4 weeks before the start of Uplizna therapy
- Documented trial and failure of rituximab (Rituxan, Truxima, Riabni, or Ruxience), azathioprine, or mycophenolate mofetil or medical reason why (e.g., intolerance, hypersensitivity, contraindication) they cannot be used
- Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines

Exceptions:

Requests for drugs in step 2 (Enspryng, Uplizna) may be approved without a trial and failure of rituximab (Rituxan, Truxima, Riabni, Ruxience), azathioprine, or mycophenolate if the member has been using Soliris

For Soliris:

- Member has a diagnosis of anti-aquaporin-4 (AQP4) antibody **positive** NMOSD

<p>Revision/Review Date 10/2023</p>	<ul style="list-style-type: none"> • Documentation 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 (penicillin, or macrolides if penicillin-allergic) for two weeks if the meningococcal vaccine is administered < 2 weeks before starting therapy or a documented medical reason why the patient cannot receive oral antibiotic prophylaxis. • Documented trial and failure of, or medical reason why (e.g. intolerance, hypersensitivity, contraindication) why the following cannot be used (one from each bullet below): <ul style="list-style-type: none"> ○ Rituximab (Rituxan, Truxima, Riabni, or Ruxience), azathioprine, or mycophenolate mofetil ○ Enspryng ○ Uplizna • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines <p><u>Reauthorization:</u></p> <ul style="list-style-type: none"> • Documentation that the prescriber has evaluated the member and recommends continuation of therapy (clinical benefit) • Request is for an FDA approved/medically accepted dose <p>Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>
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Field Name	Field Description
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 in consultation with a hepatologist or gastroenterologist

Coverage Duration	If the criteria are met, the request will be approved for 5 mg once daily for a 3 month duration for initial authorization and up to 10 mg once daily for up to a 12 month duration for reauthorization.
Other Criteria	<p>Initial Authorization:</p> <ul style="list-style-type: none"> • Diagnosis of primary biliary cholangitis (PBC) with confirmation of diagnosis by the following tests: <ul style="list-style-type: none"> a) Positive antimitochondrial antibody test b) Elevated serum alkaline phosphatase (ALP) level • Ocaliva is being requested in addition to ursodeoxycholic acid (UDCA) due to patient having an inadequate response to UDCA monotherapy for at least 1 year, OR member has a documented medical reason (e.g., contraindication, intolerance, hypersensitivity) why UDCA cannot be used and is taking Ocaliva as monotherapy • Prescriber attests the patient 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: <ul style="list-style-type: none"> a) Serum ALP b) Total bilirubin <p>Reauthorization:</p> <ul style="list-style-type: none"> • Provider attests that the patient 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 • Submission of lab tests confirming each of the following: <ul style="list-style-type: none"> ○ A decrease in ALP of $\geq 15\%$ from baseline ○ ALP is less than 1.67 times the upper limit normal (ULN);
Revision/Review Date 2/2024	<p>defined as 118 U/L for females and 124 U/L for males</p> <ul style="list-style-type: none"> ○ Total bilirubin \leq ULN defined as 1.1 mg/dL for females and 1.5 mg/dL for males <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>

Field Name	Field Description
Prior Authorization Group Description	Opioid Containing Products
Drugs	<ol style="list-style-type: none"> 1. All opioids greater than 7 days for new starts (defined as no history opioids in previous 60 days) 2. Opioids >100 Morphine Milligram Equivalents (MME) per day. 3. All long acting opioid products regardless of dose or day supply
Covered Uses	<p>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</p>
Exclusion Criteria	See “Other Criteria”
Required Medical Information	See “Other Criteria”
Age Restrictions	Patient must be age appropriate per package insert
Prescriber Restrictions	<p>Pain Specialist, Oncologist, Hospice Physician, Hematologist, Surgeon, or attestation that the requesting prescriber is working in consultation with or has consulted with one of the above specialty types. If the prescriber is not one of the above specialties and is unable to consult with one of the above specialties, provider has attested that an attempt has been made to refer and/or transition patient to one of the above specialties.</p>
Coverage Duration	<p>If the criteria are met, the request will be approved for up to six months duration. Requests for members with cancer, sickle cell disease, hospice, or end-of-life patients may be approved for up to 12 months.</p>

Other Criteria	<p><u>***Hospice, end-of-life, cancer, and sickle cell patients are exempt from prior authorization. Please automatically authorize for up to 12 months***</u></p> <p><u>Initial Authorization for Opioid Containing Products:</u></p> <ol style="list-style-type: none">1. The diagnosis is pain.2. For long-acting products, the diagnosis is chronic pain that requires daily, around the clock, opioid medication AND the provider attests that the member is treatment experienced with a history of a shortacting opioid.3. The prescriber has justified medical necessity for dosing above 100 MME per day (i.e active tapering) and/or for request above day supply limits.4. The patient has tried and failed non-pharmacologic treatment and two non-opioid containing pain medications (ex. acetaminophen, NSAIDs, selected antidepressants, anticonvulsants).
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5. Member is not taking concurrent benzodiazepines. If member is taking benzodiazepines, prescriber has provided documentation as to why and has discussed risks of using opioids and benzodiazepines concurrently and has outlined plan for tapering if appropriate.
6. Member is not taking concurrent muscle relaxants, sedative hypnotics, or barbiturates. If member is taking any of these drugs, prescriber has provided documentation as to why and has discussed risks of using opioids with any of these medications concurrently and has outlined plan for tapering if appropriate.
7. Prescriber attests urine drug screens will be completed every 6 months and if illicit drugs are found, identifying the patient as high risk, the heightened risk of overdose will be explained to the patient.
8. Prescriber attests to discussing with the patient the level of risk for opioid abuse/overdose with the dose/duration prescribed and discussed patient's disease states that may increase risk for adverse effects (i.e. severe asthma or lung disease, sleep apnea, liver/kidney disease, etc.)
9. Prescriber attests to educating patient on naloxone use and has confirmed prescribing naloxone.
10. Prescriber attests to discussing history of substance abuse and the risks associated with opioid overdose/abuse.
11. Prescriber attests that the member has entered into a written pain management agreement
12. Prescriber attests to checking the New Hampshire Prescription Drug Monitoring Program (PDMP) at the time of prescribing
13. If the request is for a non-preferred opioid, patient must meet above criteria and one of the following conditions:
 - a. Documented trial and failure or intolerance with two preferred medications used to treat the documented diagnosis. For medications where there is only one preferred agent, only that agent must have been ineffective or not tolerated.
 - b. No other preferred medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia.
 - c. All other preferred medications are contraindicated based on the patient's diagnosis, other medical conditions, or other medication therapy.

Reauthorization for Opioid Containing Products:

1. Dose requested is titrated down from initial authorization.
 - a. If not, the prescriber has explained medical necessity for continued dosing above 100MME per day and/or above the day supply limit or proposed plan for titration going forward.
 - b. If the requested dose is higher than that which was approved previously than the provider has submitted documentation of patient reassessment and medical justification explaining why the dose must be increased
2. Member is not taking concurrent benzodiazepines. If member is taking benzodiazepines, prescriber has provided documentation as to

<p>Revision/Review Date 4/2024</p>	<p>why and has discussed risks of using opioids and benzodiazepines concurrently and has outlined plan for tapering if appropriate.</p> <ol style="list-style-type: none"> 3. Member is not taking concurrent muscle relaxants, sedative hypnotics, or barbiturates. If member is taking any of these drugs, prescriber has provided documentation as to why and has discussed risks of using opioids with any of these medications concurrently and has outlined plan for tapering if appropriate. 4. Urine drug screen dates have been submitted every 6 months. If illicit drugs are found, prescriber has attested to identifying patient as high risk and explained heightened risk of overdose to patient. If opioids are not found on urine drug screen, prescriber attests to why member needs to continue therapy. 5. Prescriber attests to discussing with the patient the level of risk for opioid abuse/overdose with the dose/duration prescribed and discussed patient's disease states that may increase risk for adverse effects (i.e. severe asthma or lung disease, sleep apnea, liver/kidney disease, etc.) 6. Prescriber has confirmed prescribing naloxone. 7. Prescriber attests to checking the New Hampshire PDMP at the time of prescribing <p><u>Requests for Opioid Containing Cough/Cold Products</u></p> <p>If the request is for an opioid containing cough/cold product, the prescriber has explained medical necessity for use of this product AND attests to checking the New Hampshire PDMP at the time of prescribing AND attests to being aware of all other opioid prescriptions the member is currently taking if applicable. If the product is non-preferred, there is a documented trial and failure or medical reason why member cannot use two preferred agents.</p> <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Oral Atypical Antipsychotics for Members Below the FDA Approved Minimum Age

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

	<p>Quetiapine (Seroquel) ≥ 10 years old Quetiapine Extended Release (Seroquel XR) ≥ 10 years old Risperidone (Risperdal) ≥ 5 years old Rexulti (brexpiprazole) ≥ 13 years old Saphris (asenapine) ≥ 10 years old Secuado (asenapine) ≥ 18 years old Vraylar (cariprazine) ≥ 18 years old Ziprasidone (Geodon) ≥ 18 years old</p>
Prescriber Restrictions	Prescription is written by, or in consultation with, a Pediatric Neurologist, Child and Adolescent Psychiatrist, or a Child Development Pediatrician
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria	<p>For members below the FDA approved minimum age:</p> <ul style="list-style-type: none"> • Documentation of severe behavioral problems related to psychotic or neuro-developmental disorders (such as, but not limited to: autism, intellectual disability, bipolar disorder, tic disorder, or schizophrenia); AND • Documentation of a trial of non-pharmacologic therapies (e.g., behavioral, or cognitive); AND • If the request is for a non-preferred antipsychotic there has been a documented trial and failure or intolerance of 1 preferred antipsychotic for requested diagnosis
Revision/Review Date 4/2024	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	Oxbryta (voxelotor)
Drugs	<p>Preferred: Oxbryta (voxelotor) 500 mg tablets Oxbryta (voxelotor) 300 mg tablets NDC 72786-0102-03 Oxbryta (voxelotor) tablets for suspension NDC 72786-0111-03</p> <p>Non-Preferred: Oxbryta (voxelotor) 300 mg tablets NDC 72786-0102-02 Oxbryta (voxelotor) tablets for suspension NDC 72786-0111-02</p>

Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a hematologist or sickle cell specialist
Coverage Duration	If the criteria are met, the initial request may be approved for up to a 6month duration. Reauthorization requests may be approved for 12 months.
Other Criteria	<p>Initial Authorization:</p> <ul style="list-style-type: none"> • Member has a confirmed diagnosis of sickle cell disease • Baseline labs have been submitted for the following: <ul style="list-style-type: none"> ○ Hemoglobin (Hb) ○ Indirect bilirubin ○ Reticulocytes • If the member is 12 years of age or 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 ≤ 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 a medical reason was provided why the patient is unable to use hydroxyurea) • If the request is for Oxbryta tablets for suspension, or Oxbryta 300 mg tablets, and member is either 12 years of age or older, or less than 12 years of age and weighs 40 kg or more, there is a documented medical reason why Oxbryta 500 mg tablets cannot be used

<p>Revision/Review Date: 2/2024</p>	<ul style="list-style-type: none">• If the request is for Oxbryta tablets for suspension only NDC 72786-0111-03 will be approved• If the request is for Oxbrytra 300 mg tablets only NDC 727860102-03• Request is for an FDA-approved dose <p>Reauthorization:</p> <ul style="list-style-type: none">• Documentation of ONE of the following:<ul style="list-style-type: none">○ 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 vasoocclusive/pain crises since Oxbryta was started○ Improvement from baseline in hemolytic markers (i.e. decrease in indirect bilirubin, decrease in percentage of reticulocytes) <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Palynziq
Drugs	Palynziq (pegvaliase-pqpz)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	None
Required Medical Information	See “other criteria”
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a specialist experienced in the treatment of phenylketonuria (PKU).
Coverage Duration	Initial Authorizations: 12 months Dose Increases (to 40 mg or 60 mg daily): 16 weeks Reauthorization: 12 months

Other Criteria	<p><u>INITIAL AUTHORIZATION:</u></p> <ul style="list-style-type: none">• Documentation of a confirmed diagnosis of Phenylketonuria (PKU); AND• Documentation the member's blood phenylalanine (Phe) level is greater than 600 micromol/L(include lab results; must be within the past 90 days)• Documentation or prescriber attestation that the member has attempted control of PKU through a Phe restricted diet with Phe-free medical products/foods in conjunction with dietician or nutritionist. (Examples include Phenyl-Free [phenylalanine free diet powder], Loplex, Periflex, Phlex-10, PKU 2, PKU 3, XPhe Maxamaid, XPhe Maxamum)• Member has previously received sapropterin (Kuvan) and either had an inadequate response, was a non-responder (defined as members who were dosed at 20 mg/kg/day and did not have a decrease in blood Phe level after 1 month), or has a documented medical reason why sapropterin (Kuvan) cannot be used• The medication is being prescribed at a dose no greater than the FDA approved maximum initial dose of 20 mg SQ once daily. <p><u>DOSE INCREASES:</u></p> <ul style="list-style-type: none">• Documentation of recent blood Phe level results (within the past 90 days).• Confirmation Phe control has not been achieved after adequate timeframe on the current dosing regimen:
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Revision/Review Date: 4/2024	<ul style="list-style-type: none"> ○ For requests for a dose of 40 mg per day, the patient has been on 20 mg once daily continuously for at least 24 weeks and has not achieved adequate control ○ For requests for a dose of 60 mg per day, the patient has been on 40 mg once daily continuously for at least 16 weeks and has not achieved adequate control • The medication is being prescribed at an FDA approved dose (maximum of 60 mg once daily). <p><u>REAUTHORIZATION:</u></p> <ul style="list-style-type: none"> • Documentation of recent blood Phe level results (within the previous 90 days); AND • The medication is being prescribed at an FDA approved dose; AND • Member has achieved a reduction in blood phenylalanine concentration from pre-treatment baseline. <p style="text-align: center;">Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Peanut Allergy Immunotherapy Agents (FDA Approved)
Drugs	Palforzia [Peanut (Arachis hypogaea) Allergen Powder-dnfp] capsule/sachet
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Use of Palforzia concomitantly with Xolair
Required Medical Information	See "Other Criteria"
Age Restrictions	Initiation: Patient is age 4-17 years. Up dosing and maintenance: Patient is age \geq 4 years
Prescriber Restrictions	Prescribed by or in consultation with a specialist in the area of allergy/immunology
Coverage Duration	6 months

<p>Other Criteria</p>	<p><u>Initial Authorization:</u> Palforzia is approved when all of the following criteria are met:</p> <ul style="list-style-type: none"> • Patient has a confirmed diagnosis of peanut allergy • For patients starting initial dose escalation (new to therapy) ○ Patient has not had severe or life-threatening anaphylaxis within the previous 60 days • Patient will follow a peanut-avoidant diet • Patient has been prescribed and has acquired (as demonstrated by pharmacy claims or documentation) injectable epinephrine • No history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease • Patient does not have uncontrolled asthma <p><u>Criteria for Re-Authorization:</u> Palforzia is approved for re-authorization when all of the following criteria are met</p> <ul style="list-style-type: none"> • 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 <p>Medical Director/clinical reviewer must override criteria when, in</p>
<p>Revision/Review Date 4/2024</p>	<p>his/her professional judgement, the requested item is medically necessary.</p>

Field Name	Field Description
Prior Authorization Group Description	Pompe Disease Agents
Drugs	Lumizyme (alglucosidase alfa) Nexviazyme (avalglucosidase alfa-ngpt) injection Pombiliti (cipaglucosidase alfa-atga) + Opfolda (miglustat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	According to FDA approved prescribing information
Prescriber Restrictions	Prescribed by, or in consultation with, a specialist in the treatment of Pompe disease, such as a genetic or metabolic specialist, neurologist, cardiologist, or pediatrician.
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <p>For infantile onset Pompe Disease (Lumizyme only):</p> <ul style="list-style-type: none"> • Patient has a diagnosis of infantile-onset Pompe Disease, confirmed by one of the following: <ul style="list-style-type: none"> ○ Enzyme assay showing a deficiency of acid alphasglucosidase (GAA) activity in the blood, skin, or muscle ○ Genetic testing showing a mutation in the GAA gene • Requested dose is appropriate per prescribing information (documentation of patient weight must be submitted with request) • Requested regimen will not be used in combination with other enzyme replacement therapies <p>For late onset Pompe Disease (Lumizyme, Nexviazyme, or Pombiliti + Opfolda):</p> <ul style="list-style-type: none"> • Patient has a diagnosis of late-onset (non-infantile) Pompe Disease, confirmed by one of the following: <ul style="list-style-type: none"> ○ Enzyme assay showing a deficiency of acid alphasglucosidase (GAA) activity in the blood, skin, or muscle ○ Genetic testing showing a mutation in the GAA gene • Documentation patient has measurable signs or symptoms of Pompe disease • Results of a baseline 6-minute walk test (6MWT) and percentpredicted forced vital capacity (FVC) are provided (not required for patients who are not old enough to walk)

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<p>Revision/Review Date: 2/2024</p>	<ul style="list-style-type: none"> • Requested dose is appropriate per prescribing information (documentation of patient weight must be submitted with request) • Requested regimen will not be used in combination with other enzyme replacement therapies (Exception: Pombiliti + Opfolda are to be used together) • Additionally for Nexviazyme: Patients < 30 kg must provide documentation of a trial and therapy failure of, or a medical reason why Lumizyme may not be used. • Additionally for Pombiliti + Opfolda: Patient must have trial and failure of another enzyme therapy (Lumizyme or Nexviazyme) <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation or provider attestation of positive clinical response to therapy <ul style="list-style-type: none"> ○ Infantile onset: provider attestation of member benefit ○ Late onset: improvement, stabilization, or slowing of progression of percent-predicted FVC and/or 6MWT • Requested dose is appropriate per prescribing information (documentation of patient weight must be submitted with request) • Requested regimen will not be used in combination with other enzyme replacement therapies (Exception: Pombiliti + Opfolda are to be used together) <p style="text-align: center;">Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Potassium-removing agents
Drugs	Preferred: Lokelma (sodium zirconium cyclosilicate) Non-Preferred: Veltassa (patiromer)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber is a cardiologist or nephrologist or in consultation with one of these specialties

Coverage Duration	If the criteria are met, the request will be approved with up to a 3 month duration for initial requests and up to 6 months for renewal requests.
Other Criteria	<p><u>Initial Authorization</u></p> <ul style="list-style-type: none"> • 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 • If the request is for a non-preferred drug, member has a documented treatment failure with a preferred drug or has a documented medical reason (intolerance, hypersensitivity, contraindication, etc.) why they are not able to use a preferred drug
Revision/Review Date 4/2024	<p><u>Re-Authorization</u></p> <ul style="list-style-type: none"> • Documentation that demonstrates member is receiving clinical benefit from treatment (e.g. potassium level returned to normal or significant decrease from baseline). <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>

Field Name	Field Description
Prior Authorization Group Description	Pregabalin
Drugs	Pregabalin (Lyrica) capsule and oral solution & pregabalin ER (Lyrica CR) extended-release tablets
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A

Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	<p><u>Initial Authorization:</u></p> <p><u>Partial-Onset Seizures:</u></p> <ul style="list-style-type: none"> • Documented diagnosis of partial-onset seizures. • Request is for pregabalin capsule or solution <p><u>Postherpetic Neuralgia:</u></p> <ul style="list-style-type: none"> • Documented diagnosis of postherpetic neuralgia. • Documented trial and failure of one formulary alternatives (gabapentin, amitriptyline, nortriptyline) • If the request is for pregabalin ER there is a documented trial and failure of, or intolerance to, generic pregabalin capsule <p><u>Neuropathic Pain Associated with Diabetic Peripheral Neuropathy:</u></p> <ul style="list-style-type: none"> • Documented diagnosis of pain associated with diabetic peripheral neuropathy. • Documented trial and failure of one formulary alternative (i.e. gabapentin, duloxetine) • If the request is for pregabalin ER there is a documented trial and failure of, or intolerance to, generic pregabalin capsule <p><u>Neuropathic Pain Associated with Spinal Cord Injury:</u></p> <ul style="list-style-type: none"> • Documented diagnosis of neuropathic pain associated with spinal cord injury
Revision/Review Date 4/2024	<ul style="list-style-type: none"> • Trial and failure of one formulary alternative (i.e. gabapentin, amitriptyline) • Request is for pregabalin capsule or solution <p><u>Fibromyalgia:</u></p> <ul style="list-style-type: none"> • Documented diagnosis of fibromyalgia. ○ Trial and failure of one formulary alternatives (i.e. gabapentin, duloxetine, amitriptyline) • Request is for pregabalin capsule or solution <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>

Field Name	Field Description
Prior Authorization Group Description	Presbyopia Agents
Drugs	Vuity (pilocarpine HCl ophthalmic solution) Qlosi (pilocarpine HCl ophthalmic solution)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	≥ 18 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	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of presbyopia • Trial and failure or contraindication to corrective lenses (i.e., eye glasses, contact lenses) • Medication is prescribed at an FDA approved dose <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation or provider attestation of positive clinical response • Medication is prescribed at an FDA approved dose <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date: 2/2024	

Field Name	Field Description
Prior Authorization Group Description	Primary Hemophagocytic Lymphohistiocytosis (HLH) Agents
Drugs	Gamifant (emapalumab-lzsg)

Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Members who have undergone hematopoietic stem cell transplantation (HSCT)
Required Medical Information	“See Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a Hematologist, Oncologist, Immunologist, Transplant Specialist, or other specialist experienced in the treatment of immunologic disorders
Coverage Duration	Initial Authorization: 1 month Reauthorization: 3 months
Other Criteria	<p>*Gamifant will only be approved for members who have not yet received HSCT and will be discontinued at the initiation of HSCT*</p> <p>Initial Authorization</p> <ul style="list-style-type: none"> • Member has a diagnosis of Primary HLH • Prescriber attests that member has not achieved a satisfactory response to or is intolerant to conventional HLH therapy (e.g. etoposide, dexamethasone) or has recurrent disease • Prescriber attests that the member is a candidate for hematopoietic stem cell transplant (HSCT) • Member has been screened for latent tuberculosis infection • Member has or will receive prophylactic pre-medications (e.g. antivirals, antibiotics, antifungals) for Herpes Zoster, <i>Pneumocystis jirovecii</i>, and other fungal infections • Dosing is consistent with FDA approved labeling <p>Reauthorization</p> <ul style="list-style-type: none"> • Member continues to meet initial authorization criteria • Member is receiving prophylactic pre-medications (e.g. antivirals, antibiotics, antifungals) for Herpes Zoster, <i>Pneumocystis jirovecii</i>, and other fungal infections
Revision/Review Date 4/2024	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Primary Hyperoxaluria Agents
Drugs	Oxlumo (lumasiran) Rivfloza (nedosiran)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a nephrologist, urologist, hepatologist, endocrinologist or consultation with one of these specialists
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria	<p><u>Initial Authorization</u></p> <ul style="list-style-type: none"> • Diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by one of the following: <ul style="list-style-type: none"> ○ Genetic testing confirming at least one mutation at the AGXT gene ○ Liver biopsy demonstrating absent or significantly reduced AGT activity • Metabolic testing demonstrating one of the following: <ul style="list-style-type: none"> ○ Oxlumo or Rivfloza <ul style="list-style-type: none"> ▪ Increased urinary oxalate excretion (≥ 0.5 mmol/1.73 m²per day[45 mg/1.73 m²per day]) ▪ relative to normative values for age ○ Oxlumo only: Increased plasma oxalate level (≥ 20 μmol/L) ○ Increased urinary oxalate:creatinine ratio • For Rivfloza: member has relatively preserved kidney function (e.g., EGFR ≥ 30 mL/min/1.73 m²) • Member is concurrently using pyridoxine or has tried and failed previous pyridoxine therapy for at least 3 months, or has a medical reason for not using pyridoxine • Member has no history of liver transplant • Medication is prescribed at an FDA approved dose

<p>Revision/Review Date 2/2024</p>	<ul style="list-style-type: none">• Patient is not using Oxlummo and Rivfloza concurrently <p><u>Reauthorization</u></p> <ul style="list-style-type: none">• Members previously using pyridoxine will continue to use pyridoxine, or have a medical reason for not using pyridoxine• Documentation has been provided that demonstrates a clinical benefit (e.g. symptomatic improvement, reduction in urinary or plasma oxalate levels from baseline)• Medication is prescribed at an FDA approved dose• Patient is not using Oxlummo and Rivfloza concurrently <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Proprotein Convertase Subtilisin/kexin 9 (PCSK9) Monoclonal Antibodies (mAbs)
Drugs	<u>Preferred:</u> Repatha (evolocumab), Praluent (alirocumab) <u>Non-preferred:</u> Leqvio (inclisiran), Any newly marketed PCSK9 inhibitor
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	See “Other Criteria”
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or specialist in treatment of lipid disorders
Coverage Duration	If the criteria are met, the initial request will be approved for up to a 3 month duration, and the reauthorization request will be approved for up to a 12 month duration; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.

Other Criteria	<p><u>Initial Authorization For All Requests:</u></p> <ul style="list-style-type: none">• Request is appropriate for member (e.g. age) as indicated in package labeling or standard of care guidelines• Patient has tried and failed atorvastatin 40mg-80mg or rosuvastatin 20-40mg (consistently for 3 months via claim history or chart notes). If patient is not able to tolerate atorvastatin or rosuvastatin, documentation was provided that patient is taking another statin at the highest tolerated dose, or a medical reason was provided why the member is not able to use these therapies.• Patient has tried and failed ezetimibe at a maximal tolerated dose or a medical reason was provided why the member is not able to use this therapy.• If prescriber indicates member is “statin intolerant”, documentation was provided including description of the side effects, duration of therapy, “wash out”, re-trial, and then change of agents.• Documentation was provided indicating provider has counseled member on smoking cessation and following a “heart healthy diet”.• If the request is for a non-preferred agent, documentation was provided of trial and failure, or a medical reason has been provided,
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why member is unable to use the preferred agent to manage their condition.

AND the member meets the following for the respective diagnosis:

Familial Hypercholesterolemia (FH): • Member has a diagnosis of familial hypercholesterolemia as evidenced by one of the following:

- 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.
- Results of positive genetic testing for an LDL-C-raising gene defect (LDL receptor, apoB, or PCSK9)
- LDL remains above goal despite maximally tolerated LDLlowering therapy

Hyperlipidemia (Primary OR Secondary Atherosclerotic Cardiovascular Disease [ASCVD] Prevention)

- If the diagnosis is primary severe hyperlipidemia (i.e. LDL ≥ 190 mg/dL)
 - LDL remains ≥ 100 mg/dL despite maximally tolerated LDLlowering therapy
- If the diagnosis is secondary ASCVD prevention
 - LDL remains ≥ 55 mg/dL or non-HDL (i.e. total cholesterol minus HDL) ≥ 85 mg/dL despite maximally tolerated LDLlowering therapy
 - And ONE of the following:
 - Documented history of multiple major ASCVD events (acute coronary syndrome within past 12 months, history of myocardial infarction, history of ischemic stroke, symptomatic peripheral artery disease)
 - Documented history of 1 major ASCVD event (acute coronary syndrome within past 12 months, history of myocardial infarction, history of ischemic stroke, symptomatic peripheral artery disease) AND multiple high-risk conditions (age ≥ 65 years, history of coronary artery bypass graft or percutaneous coronary intervention, diabetes mellitus, hypertension, chronic kidney disease, current smoker, or congestive heart failure)

Reauthorization for all indications:

- Documentation submitted indicates that the member has obtained clinical benefit from the medication including repeat fasting lipid

<p>Revision/Review Date 4/2024</p>	<p>panel lab report and the member has had a reduction in LDL from baseline</p> <ul style="list-style-type: none">• The patient's claim history shows consistent therapy (i.e. monthly fills) <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Pulmonary Biologics for Asthma and Eosinophilic Conditions
Drugs	Nucala (mepolizumab), Fasentra (benralizumab), Cinqair (reslizumab), Dupixent (dupilumab), Tezspire (tezepelumab) or any newly marketed agents
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	<ul style="list-style-type: none"> • 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 Package Insert
Prescriber Restrictions	Prescriber must be an allergist, pulmonologist, immunologist, rheumatologist, gastroenterologist, or other provider who specializes in the treatment of asthma or eosinophilic conditions, or in consultation with one of these specialists
Coverage Duration	If the above conditions are met, the initial request will be approved with a 4 month duration. All subsequent requests will be approved with a 6 month duration.
Other Criteria	<p><u>Initial Authorization:</u></p> <p><u>Asthma:</u></p> <ul style="list-style-type: none"> • Confirmed diagnosis of one of the following: <ul style="list-style-type: none"> ○ Nucala, Fasentra, and Cinqair: Severe Eosinophilic Asthma ○ Dupixent: Moderate-to-Severe eosinophilic asthma ○ Tezspire: Severe Asthma • Documentation has been provided of blood eosinophil count within ONE of the following ranges: <ul style="list-style-type: none"> ○ Nucala and Dupixent: ≥ 150 cells/mcL (within 6 weeks of request) OR ≥ 300 cells/mcL (within the past 12 months) ○ Fasentra: ≥ 150 cells/mcL (within the past 12 months) ○ Cinqair: ≥ 400 cells/mcL (within the past 12 months) ○ Tezspire: No baseline blood eosinophil counts are required • The member has a documented baseline FEV₁ < 80% of predicted with evidence of reversibility by bronchodilator response.

	<ul style="list-style-type: none">○ 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 that the member
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continues to experience significant symptoms while compliant on a maximally tolerated inhaled corticosteroid with long-acting beta₂ agonist (ICS/LABA) AND long-acting muscarinic antagonist (LAMA) (or a documented medical reason must be provided why the member is unable to use these therapies) and ONE of the following:

- Nucala: ≥ 2 exacerbations in the past 12 months
 - Fasenra: ≥ 1 exacerbation in the past 12 months
 - Cinqair: ≥ 1 exacerbation in the past 12 months requiring systemic corticosteroids
 - Dupixent: ≥ 1 exacerbation in the past 12 months requiring systemic corticosteroids or hospitalization
 - Tezspire: ≥ 2 exacerbations requiring systemic corticosteroids OR ≥ 1 exacerbation in the past 12 months requiring hospitalization
- The prescribed dose is within FDA approved dosing guidelines
 - For requests for agents other than Fasenra, Dupixent, or Nucala, the member has a trial and failure or medical reason why Fasenra, Dupixent, Nucala, or Xolair cannot be used

Oral Corticosteroid Dependent Asthma: (*Dupixent only*)

- Confirmed diagnosis of oral corticosteroid (OCS) dependent asthma with at least 5 mg oral prednisone or equivalent per day for at least 4 weeks within the last 3 months
- The patient has a documented baseline FEV₁ < 80% of predicted with evidence of reversibility by bronchodilator response.
- Documentation has been provided indicating patient still is having significant symptoms with ≥ 1 exacerbations in the previous 12 months requiring additional medical treatment, (emergency room visits, hospital admissions) while compliant on a high-dose inhaled corticosteroid with a long-acting 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

Eosinophilic Esophagitis (EoE) (*Dupixent only*):

- 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

Prurigo Nodularis (PN) (*Dupixent only*):

- 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:
 - One medium to super-high potency topical corticosteroid
 - One topical calcineurin inhibitor
 - UVB phototherapy or psoralen plus UVA phototherapy
- The prescribed dose is within FDA approved dosing guidelines

Eosinophilic granulomatosis with polyangiitis (EGPA) (*Nucala only*):

- Confirmed diagnosis of EGPA and eosinophilic asthma lasting for ≥ 6 months
- Member has a history of relapsing disease defined as at least one EGPA relapse requiring additional corticosteroids or immunosuppressant or hospitalization within the past 2 years OR member has a history of refractory disease defined as failure to attain remission in the prior 6 months following induction treatment with standard therapy
- Member must be on a stable dose of oral corticosteroids for at least 4 weeks prior to request
- Member has a blood eosinophil count $\geq 1,000$ cells/mcL OR $> 10\%$ of total leukocyte count
- Documented trial and failure, intolerance, or contraindication to cyclophosphamide, azathioprine, methotrexate, rituximab, OR mycophenolate mofetil
- The prescribed dose is within FDA approved dosing guidelines

Hypereosinophilic Syndrome (HES) (*Nucala only*):

- Confirmed diagnosis of FIP1 like 1-platelet derived growth factor receptor alpha (FIP1L1-PDGFR α)-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 $\geq 1,000$ cells/mcL

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| | <ul style="list-style-type: none">• Documented trial and failure, intolerance, or contraindication to oral corticosteroids AND at least one second-line agent (e.g. |
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<p>Revision/Review Date 9/2024</p>	<p>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)</p> <p><u>Re-Authorization:</u></p> <ol style="list-style-type: none">1. Documentation submitted indicates the member has clinically benefited 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)2. The prescribed dose is within FDA approved dosing guidelines <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>
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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 \geq 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	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none">• 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 <u>not</u> homozygous for the R479H variant• Documentation that the member <u>does not have</u> two nonmissense variants of the PKLR gene, without the presence of another missense variant in the PKLR gene• Documentation of ONE of the following:<ul style="list-style-type: none">○ The member does not regularly require blood transfusions (defined as requiring <u>less than or equal to 3 red blood cell (RBC) transfusions in the past 52 weeks and no transfusions in the past 3 months</u>) AND hemoglobin (Hb) level ≤ 10 g/dL<ul style="list-style-type: none">○ The member has required more than or equal to 6 RBC transfusions in the past 12 months<ul style="list-style-type: none">▪ Documentation of the number of transfusions and the number of red blood cell (RBC) units transfused
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<p>Revision/Review Date: 7/2024</p>	<ul style="list-style-type: none"> • Prescriber attests that the member does not have moderate or severe hepatic dysfunction • 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 hematopoieticstimulating agents (e.g. Procrit or Retacrit) • Prescriber attests the member is taking at least 0.8mg of folic acid daily <p><u>Reauthorization:</u></p> <ul style="list-style-type: none"> • 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 $\geq 33\%$ 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. <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Qalsody
Drugs	Qalsody (tofersen)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	See "Other Criteria"

Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, neuromuscular specialist, or physician specializing in the treatment of amyotrophic lateral sclerosis (ALS)
Coverage Duration	If all the criteria are met, initial and renewal requests will be approved for 6 months
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • 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) $\geq 50\%$ • Medication is prescribed at an FDA approved dose <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • 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 <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
Review/Revision Date: 7/2024	

Field Name	Field Description
Prior Authorization Group Description	Radicava
Drugs	Radicava, Radivaca ORS (edaravone) and any other newly marketed agent *** riluzole (Rilutek) is Preferred and does not require prior authorization***
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	If the criteria are met, requests will be approved for up to 6 month duration

Other Criteria	<p>Initial Authorization:</p> <ul style="list-style-type: none"> • Member must have a diagnosis of ALS • Member must have a documented baseline evaluation of functionality using the revised ALS functional rating scale (ALSFRS-R) score ≥ 2 • Member's disease duration is 2 years or less • Member has a baseline forced vital capacity (FVC) of $\geq 80\%$ • Member has been on riluzole (Rilutek), is beginning therapy as an adjunct to treatment with Radicava, or provider has provided a medical reason why patient is unable to use riluzole • Dose is within FDA approved limits <p>Reauthorization:</p> <ul style="list-style-type: none"> • Member is not ventilator-dependent • Provider documents clinical stabilization in symptoms (e.g. stabilization of ALSFRS-R score) • Dose is within FDA approved limits <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 4/2024	

Field Name	Field Description
Prior Authorization Group Description	Retinoids (Dermatologic)
Drugs	<p><u>FORMULARY STATUS</u> Requires Prior Authorization, Generically Available Agents Preferred:</p> <ul style="list-style-type: none"> • Claravis (isotretinoin) • Myorisan (isotretinoin) • Zenatane (isotretinoin) • Amnesteem (isotretinoin) • Isotretinoin <p><u>FORMULARY STATUS</u> Requires Prior Authorization, Non-Preferred:</p> <ul style="list-style-type: none"> • Absorica (isotretinoin) • Absorica LD (isotretinoin) • Or any newly marketed oral retinoid product

Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 6 month duration.
Other Criteria	<p><u>Initial Authorization</u></p> <ul style="list-style-type: none"> • Diagnosis of moderate to severe recalcitrant nodular acne AND • Documented treatment with a therapeutic trial and failure or intolerance to one or more first line topical therapies (e.g. topical antibiotics or topical retinoids) IN COMBINATION WITH one or more first line oral therapies (e.g. doxycycline, tetracycline, or minocycline) for at least 4 weeks (28 days) of therapy of each drug in the previous 180 days. • If the request is for a non-preferred drug, documentation has been provided that the member has tried and failed two preferred drugs or has a medical reason why these drugs cannot be used <p><u>Re-Authorization</u></p>
Revision/Review Date 10/2023	<ul style="list-style-type: none"> • Prescriber attests the member has experienced clinical benefit from therapy (e.g. perceived improvement of acne) and continued treatment with, or retreatment with, isotretinoin is necessary <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>

Field Name	Field Description
Prior Authorization Group Description	Rezdiffra
Drugs	Rezdiffra (resmetirom)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	<ul style="list-style-type: none"> • Patients with decompensated cirrhosis • Patient with thyroid disease including: <ul style="list-style-type: none"> ○ active hyperthyroidism ○ untreated hypothyroidism (TSH >7 IU/L with symptoms of HT or >10 IU/L without symptoms)
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a hepatologist, gastroenterologist, or a specialist in the treatment of liver disease.
Coverage Duration	If all of the criteria are met, the initial and reauthorization requests will be approved for up to a 12 month duration
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis • Documentation of stage F2 to F3 fibrosis confirmed by biopsy or a noninvasive test (NIT) • Documentation of Nonalcoholic Fatty Liver Disease (NAFLD) Activity Score (NAS) of ≥ 4 • Prescriber attestation to providing lifestyle counseling on nutrition and exercise • Prescriber attestation that member avoids excess alcohol intake • The drug is being prescribed at an FDA approved dose according to the member’s weight <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • The member has clinically benefited from the medication (e.g. the resolution of steatohepatitis and no worsening of liver fibrosis, or at least one stage improvement in liver fibrosis and no worsening of steatohepatitis) • The member continues to have a fibrosis stage of ≤ 3 • The drug is being prescribed at an FDA approved dose according to the member’s weight <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
Review Date: 4/2024	

Field Name	Field Description
Prior Authorization Group Description	Rho Kinase Inhibitor Criteria
Drugs	Rhopressa (netarsudil) Rocklatan (netarsudil/latanoprost)
Covered Uses	Medically accepted indications are defined using the following sources: The Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the 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 old
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved for up to a 12 month duration.
Other Criteria	<p><u>Initial Authorization:</u></p> <ol style="list-style-type: none"> 1. Diagnosis of ocular hypertension or open-angle glaucoma 2. Documented trial and failure of a prostaglandin inhibitor or beta-adrenergic antagonist 3. Member has not had: <ol style="list-style-type: none"> a. Previous glaucoma intraocular surgery or glaucoma laser procedure in the affected eye; OR b. Ocular surgery or laser treatment within three months prior to initiation 4. Member does not currently have any of the following: <ol style="list-style-type: none"> a. Ocular infection b. Inflammation c. Blepharitis d. Conjunctivitis e. Ocular disease <p><u>Re-authorization:</u></p> <ol style="list-style-type: none"> 1. Member must continue to meet above criteria 2. Member has demonstrated efficacy (e.g. reduction in intraocular pressure) <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 7/2024	

Rituximab

Drugs:

Rituxan (rituximab)

Rituxan Hycela (rituximab/hyaluronidase human, recombinant)

Truxima (rituximab-abbs)

Ruxience (rituximab-pvvr)

Riabni (rituximab-arrx)

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

NEUROMYELITIS OPTICA SPECTRUM DISORDER (NMOSD):

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

RHEUMATOID ARTHRITIS:

Initial Authorization

- The medication is being recommended and prescribed by a rheumatologist.
- The patient is an adult (≥ 18 y/o) and has a documented clinical diagnosis of rheumatoid arthritis.
- The patient has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trial (including dates and doses) of 3 months or more of therapy with one conventional (nonbiologic) DMARD (e.g. methotrexate, leflunomide, sulfasalazine, hydroxychloroquine) or has a documented medical reason (e.g. intolerance, hypersensitivity) for not utilizing any of these therapies to manage their medical condition.
- The patient has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trial (including dates, doses) of 2 preferred biologics indicated for rheumatoid arthritis, or has documented medical reason (intolerance, hypersensitivity, etc.) for not taking the preferred therapies to manage their medical condition.
- Documentation indicating that rituximab is being used concurrently with methotrexate, or a medical reason why methotrexate cannot be used.
- Documentation indicating that the patient has been screened for Hepatitis B Virus (HBV) prior to initiation of treatment.
- Rituximab is being prescribed at an FDA approved dosage.
- If the request is for any medication other than Ruxience (rituximab-pvvr) or Riabni (rituximab-arrx), there is a documented trial and failure of Ruxience or Riabni, or medical reason why (e.g. intolerance, hypersensitivity, contraindication) they cannot be used.

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

Reauthorization

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

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

PEMPHIGUS VULGARIS

Initial Authorization

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

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

Reauthorization

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

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

ONCOLOGY INDICATIONS

Initial Authorization:

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

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

Reauthorization

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

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

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

Initial Authorization:

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

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

Re-authorization:

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

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

DERMATOMYOSITIS (DM) and POLYMYOSITIS (PM)

Initial Authorization:

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

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

Re-authorization:

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

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

OTHER MEDICALLY ACCEPTED INDICATIONS

Initial Authorization:

- The medication is prescribed for a non-FDA approved indication but is considered to be a medically accepted use of the medication per the medical compendia (Micromedex, American Hospital Formulary Service (AHFS), DrugPoints, the Drug Package Insert as defined in the Social Security Act and/or per the American Academy of Pediatrics (AAP) standard of care guidelines and has a Class I or Iia recommendation.
- The medication is prescribed at a medically accepted dose per the medical compendia as defined above.
- The medication is recommended and prescribed a specialist in the field to treat the member's respective medical condition.
- Documentation indicating that the patient has been screened for HBV prior to initiation of treatment.
- Documentation was submitted indicating that the member has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trial (including dates, doses of medications) of ALL first line medical therapies as recommended by the medical compendia and standard care guidelines and/or has another documented medical reason (e.g. intolerance, contraindications, etc.) for not receiving or trying all first line medical treatment(s).
- If the request is for any medication other than Ruxience (rituximab-pvvr), there is a documented trial and failure of Ruxience (rituximab-pvvr), or medical reason why (e.g. intolerance, hypersensitivity, contraindication) Ruxience (rituximab-pvvr) cannot be used.

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

If all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

Re-authorization:

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

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

If all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

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

Revision/Review Date: 7/2024

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	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • 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 <p>The safety and effectiveness of repeat administration of Roctavian has not been evaluated and will not be approved.</p> <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date: 8/2024	

Field Name	Field Description
Prior Authorization Group Description	Scopolamine Patch
Drugs	Scopolamine Patch (Transderm-Scop)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved for the treatment of motion sickness and post-operative nausea and vomiting for a one (1) month duration and for the treatment of sialorrhea for a 12 month duration.

Other Criteria	<p><u>Initial Authorization:</u></p> <p><u>Motion Sickness and Post-Operative Nausea and Vomiting:</u></p> <ul style="list-style-type: none"> • Diagnosis of nausea and vomiting associated with motion sickness or nausea and vomiting associated with recovery from anesthesia and/or opiate analgesia and surgery. <p>AND</p> <ul style="list-style-type: none"> • Documented trial and failure at therapeutic doses of, intolerance to, or contraindication to two of the following: meclizine, diphenhydramine and dimenhydrinate. <p><u>Sialorrhea</u></p> <ul style="list-style-type: none"> • Documented trial and failure at therapeutic doses, intolerance or contraindication to glycopyrrolate. <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date: 7/2024	

Field Name	Field Description
Prior Authorization Group Description	Serostim (somatropin, mammalian derived)
Drugs	Serostim (somatropin, mammalian derived)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be an HIV or infectious disease specialist
Coverage Duration	If all criteria are met, Serostim will be authorized for 12 weeks

Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Patient has been receiving optimal highly active antiretroviral therapy (HAART) for at least three months prior to initiation • Prescriber attests that the patient has been evaluated for other possible causes of wasting/cachexia (e.g. malignancies) or fat redistribution (e.g. diabetes mellitus, lipodystrophy, etc.) • Request is for the FDA approved or medically accepted dosing • Documentation supporting all of the following must be provided: <ul style="list-style-type: none"> ○ Baseline and repeated evaluation every 3 months of patient’s weight (most recent weight measurement must be within the past 3 months) <ul style="list-style-type: none"> ○ BMI and lean body mass measured by X-ray absorptionmetry (DEXA/DXA) were provided with the request ○ Demonstrable weight loss of greater than 10% of the baseline body weight associated with either chronic diarrhea (two or more loose stools per day for greater than or equal to 1 month) or chronic weakness and fever for greater than or equal to 1 month ○ Patient has had an insufficient response to a three month trial of an anabolic steroid such as oxandolone ○ Patient has had an insufficient response to a three month trial of one of the following agents: megestrol acetate, cyproheptadine, or dronabinol <p><u>Re-authorization:</u></p> <ul style="list-style-type: none"> • The patient is receiving concomitant anti-HIV treatment • The prescriber has provided documentation of clinical benefit/response to Serostim. • Request is for FDA approved or medically accepted dosing
Revision/Review Date: 7/2024	<p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>

Field Name	Field Description
Prior Authorization Group Description	Skyclarys
Drugs	Skyclarys (omaveloxolone)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Per FDA-approved prescribing information
Prescriber Restrictions	Prescriber must be a neurologist or in consultation with a neurologist or specialist with expertise in treating patients with Friedreich’s Ataxia.
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of Friedreich’s Ataxia, confirmed via genetic testing (must submit documentation) • Modified FARS score ≥ 20 and ≤ 80 • Medication is prescribed at an FDA approved dose <u>Re-Authorization:</u> • Documentation or provider attestation of positive clinical response to Skyclarys therapy (i.e. improvement in symptoms, slowing of disease progression, etc.) • Medication is prescribed at an FDA approved dose <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 7/2024	

Field Name	Field Description
Prior Authorization Group Description	Skysona
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	<ul style="list-style-type: none"> • 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 onetime treatment.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Member has a diagnosis of early, active cerebral adrenoleukodystrophy (CALD) defined as all of the following: <ul style="list-style-type: none"> ○ 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. <p><u>Re-Authorization:</u> The safety and effectiveness of repeat administration of Skysona have not been evaluated and will not be approved.</p>
Revision/Review Date: 8/2024	

Field Name	Field Description
Prior Authorization Group Description	Sleep Disorder Therapy

<p>Drugs</p>	<p>Formulary status: Preferred, Prior Authorization Required</p> <ul style="list-style-type: none"> • modafinil (Provigil) tablets • armodafinil (Nuvigil) tablets <p>Formulary status: Non-preferred, Prior Authorization Required</p> <ul style="list-style-type: none"> • Sunosi (solriamfetol) tablets • Wakix (pitolisant) tablets • Sodium oxybate solution • Xyrem (sodium oxybate) solution • Xywav (calcium, magnesium, potassium, and sodium oxybates) •
<p>Covered Uses</p>	<p>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</p>
<p>Exclusion Criteria</p>	<p>Wakix: severe hepatic impairment (Child-Pugh class C) Sodium oxybate (Xyrem/Xywav/Lumryz): Succinic semialdehyde dehydrogenase deficiency</p>
<p>Required Medical Information</p>	<p>See “Other Criteria”</p>
<p>Age Restrictions</p>	<p>Per FDA approved prescribing information.</p>
<p>Prescriber Restrictions</p>	<p>Prescribed by or in consultation with a sleep specialist, neurologist, or other specialist in the treatment of the member’s diagnosis (does not apply for diagnosis of shift-work disorder)</p>
<p>Coverage Duration</p>	<p>If the criteria are met, requests for modafinil, armodafinil, Sunosi, and Wakix will be approved with up to a 12 month duration. Requests for sodium oxybate products will be approved with up to a 3 month duration.</p>
<p>Other Criteria</p>	<p><u>For all requests:</u></p> <ul style="list-style-type: none"> • Medication is being prescribed at an FDA approved dose <p><u>Modafinil/armodafinil initial authorization:</u></p> <ul style="list-style-type: none"> • For a diagnosis of obstructive sleep apnea (OSA) documentation that the member has been compliant with or is unable to use positive airway pressure [continuous positive airway pressure (CPAP), bilevel positive airway pressure (BPAP), or automatic positive airway pressure (APAP)]. <p><u>Sunosi initial authorization</u></p> <ul style="list-style-type: none"> • Documented trial and failure of modafinil or armodafinil or a documented medical reason for not utilizing these medications. • For members with OSA: <ul style="list-style-type: none"> ○ Documentation that the member has been compliant with or is unable to use positive airway pressure (CPAP, BPAP, or APAP) <p><u>Wakix initial authorization:</u></p>

- For a diagnosis of narcolepsy without cataplexy: documented trial and failure of (or medical reason for not using), BOTH of the following:
 - Modafinil or armodafinil
 - Sunosi (solriamfetol)
- For a diagnosis of narcolepsy with cataplexy: documented trial and failure of, or medical reason for not using, the following:
 - Dextroamphetamine

Sodium Oxybate (Xyrem/Xywav) initial authorization

- Medication is not being taken concurrently with sedative hypnotics
 - For a diagnosis of narcolepsy without cataplexy:
 - Documented trial and failure of, or a medical reason for not using, ALL of the following:
 - Either modafinil or armodafinil
 - Sunosi (solriamfetol)
 - Wakix (pitolisant)
 - For Xyrem or Xywav: documented trial and failure of, or medical reason for not using generic sodium oxybate.
 - For a diagnosis of narcolepsy with cataplexy:
 - Documented trial and failure of each of, or medical reason for not using BOTH of the following:
 - Dextroamphetamine
 - Wakix (pitolisant)
 - 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):
 - Patient has a documented trial and failure of, or medical contraindication to, the following:
 - Modafinil or armodafinil

Reauthorization:

- Documentation has been submitted indicating member has experienced a clinical benefit from treatment (e.g. improvement on Epworth Sleepiness Score, reduction in frequency of cataplexy attacks)
- For a diagnosis of obstructive sleep apnea (OSA) documentation that the member continues to be compliant with or is unable to use positive airway pressure (CPAP, BPAP, or APAP)

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

Revision/Review
Date: 7/2024

Field Name	Field Description
Prior Authorization Group Description	SMN2 Splicing Modifiers for the Treatment of Spinal Muscular Atrophy (SMA)
Drugs	Evrysdi (risdiplam) Spinraza (nusinersen)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	<ul style="list-style-type: none"> • For Spinraza: patient has previously received treatment with Zolgensma • Concomitant use of Evrysdi and Spinraza
Required Medical Information	For Evrysdi: Patient's body weight
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	<p>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.</p> <p>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.</p> <p>If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.</p>
Other Criteria	<p><u>Initial approval</u></p> <ul style="list-style-type: none"> • 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

<p>Revision/Review Date 2/2024</p>	<p>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]</p> <ul style="list-style-type: none"> • 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 <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Sohonos
Drugs	Sohonos (palovarotene)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	<ul style="list-style-type: none"> • 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	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • 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
Revision/Review Date: 2/2024	<p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • 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 <p>Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>

Field Name	Field Description
Prior Authorization Group Description	Somatostatin Analogs and Growth Hormone Receptor Antagonists
Drugs	Octreotide (Sandostatin) Sandostatin LAR (octreotide) Lanreotide 120 mg/0.5 mL Somatuline Depot (lanreotide) 60 mg/0.2 mL, 90 mg/0.3 mL, 120 mg/0.5mL Mycapssa (octreotide) Signifor (pasireotide) Signifor LAR (pasireotide) Somavert (pegvisomant)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA) Drug Package Insert (PPI). ** Non-FDA approved (i.e. off-label) uses; refer to the “Off-Label Use” policy for non-oncology indications, and the “Oncology Drugs” policy for off-label oncology uses**
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”

Age Restrictions	Per FDA approved package insert
Prescriber Restrictions	Prescriber must be a specialist with appropriate expertise in treating the condition in question (such as an endocrinologist, neurologist/neurosurgeon, oncologist, etc.). Consultation with appropriate specialist for the condition in question is also acceptable.
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization</u></p> <p><u>For all FDA approved indications (including FDA-approved oncology related uses)</u></p> <ul style="list-style-type: none"> • Medication requested is for an FDA approved indication and dose • If the provider is requesting therapy with more than one somatostatin analog or a somatostatin analog and a growth hormone receptor antagonist, then documentation must be submitted as to why patient is unable to be treated with monotherapy, or a medical reason was provided why monotherapy is not appropriate. <p><u>For Acromegaly</u></p> <ul style="list-style-type: none"> • Patient has had an inadequate response to, or medical reason why, surgical treatment cannot be used.

<p>Revision/Review Date 4/2024</p>	<ul style="list-style-type: none"> • If the patient mild disease (e.g. mild signs and symptoms of growth hormone excess, modest elevations in IGF-1) there is a documented trial of a dopamine agonist (e.g. bromocriptine mesylate, cabergoline) at a therapeutically appropriate dose or a documented medical reason why a dopamine agonist cannot be used • Additionally for Mycapssa: <ul style="list-style-type: none"> ○ Patient has showed clinical response to and tolerates treatment with octreotide or lanreotide therapy ○ Clinical justification is provided as to why patient cannot continue use of injectable somatostatin analog therapy • Additionally for Somavert: <ul style="list-style-type: none"> ○ Patient has had an inadequate response to therapy with a somatostatin analog, or has a documented medical reason why a somatostatin analog cannot be used • Additionally for Signifor LAR: <ul style="list-style-type: none"> ○ Patient has had an inadequate response to therapy with either lanreotide (Somatuline Depot) or octreotide (Sandostain, Sandostatin LAR), or has a documented medical reason why these somatostatin analogs cannot be used. <p><u>For Cushing’s Disease (pasireotide products only)</u></p> <ul style="list-style-type: none"> • Patient must have had inadequate response, or medical reason why surgical treatment cannot be used <p><u>Reauthorization</u></p> <ul style="list-style-type: none"> • Medication requested is for an FDA approved indication and dose • Documentation has been provided that demonstrates a clinical benefit (e.g. improvement in laboratory values, improvement or stabilization of clinical signs/symptoms, etc.) <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Sublingual Allergenic Extracts
Drugs	Grastek (timothy grass pollen allergen extract) Odactra (house dust mite allergen extract) Oralair (sweet vernal/orchard/rye/timothy/Kentucky blue grass mixed pollen allergenic extract) Ragwitek (Short ragweed pollen allergenic extract)

Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to Package Insert
Prescriber Restrictions	Prescriber is an allergist or immunologist
Coverage Duration	If all of the conditions are met, the request will be approved for a 12 month duration.
Other Criteria	<p><u>Initial authorization:</u></p> <p><u>For all requests:</u></p> <ul style="list-style-type: none"> • Requested allergenic extract is being used to treat allergic rhinitis with or without conjunctivitis • Member has had a document trial and failure of, or intolerance to, an intranasal corticosteroid (e.g. fluticasone) used in combination with at least one of the following: <ul style="list-style-type: none"> ○ Oral antihistamine (e.g. cetirizine) ○ Intranasal antihistamine (e.g. azelastine) ○ Oral leukotriene receptor antagonist (montelukast) • Patient has been prescribed (as demonstrated by pharmacy claims or documentation) injectable epinephrine <p><u>Grastek:</u></p> <ul style="list-style-type: none"> • Diagnosis has been confirmed by positive skin or in vitro testing to Timothy Grass, or cross reactive, pollen <p><u>Odactra:</u></p> <ul style="list-style-type: none"> • Diagnosis has been confirmed by either positive skin test to house dust mite allergen extract OR positive in vitro testing for IgE antibodies to <i>Dermatophagoides farinae</i> or <i>Dermatophagoides pteronyssinus</i>

<p>Revision/Review Date 10/2023</p>	<p><u>Oralair:</u></p> <ul style="list-style-type: none">• Diagnosis has been confirmed by positive skin, or in vitro, testing to Sweet Vernal, Orchard, Rye, Timothy, Kentucky Blue Grass, or cross reactive, pollen <p><u>Ragwitek:</u></p> <ul style="list-style-type: none">• Diagnosis has been confirmed by positive skin, or in vitro, testing to Short Ragweed pollen <p><u>Reauthorization:</u></p> <p><u>For all requests:</u></p> <ul style="list-style-type: none">• Member has experienced a reduction in symptoms associated with allergic rhinitis <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Synagis (palivizumab)
Drugs	Synagis (palivizumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	A maximum of 5 doses may be approved within the Respiratory Syncytial Virus (RSV) season. Requests for additional doses will be reviewed on a case-by case basis based on CDC surveillance reports, state/local health department recommendations, and other current medical literature.

Other Criteria	<p><u>Must have documented medical reason for not using Beyfortus (niresvimab) AND</u></p> <p><u>Infants less than 1 year of age at the onset of the respiratory syncytial virus (RSV) season (which typically starts November 1st, but may vary seasonally) AND have one of the following indications:</u></p> <ul style="list-style-type: none">• Born at less than 29 weeks, 0 days gestation• Born at less than 32 weeks, 0 days gestation AND had chronic lung disease of prematurity defined as greater than 21% oxygen for at least 28 days after birth• Born at any gestational age with hemodynamically significant heart disease including:<ul style="list-style-type: none">○ Cyanotic heart disease in consultation with a pediatric cardiologist○ Acyanotic Heart disease with one of the following:<ul style="list-style-type: none">▪ On heart failure medication and expected to require cardiac surgical procedure▪ Moderate to severe pulmonary hypertension• Cystic fibrosis with clinical evidence of chronic lung disease (CLD) and/or nutritional compromise in the first year of life• Born at any gestational age with pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the lower airway <p><u>Infants less than 2 years of age at the onset of the RSV season (which typically starts November 1st, but may vary seasonally) AND have one</u></p>
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<p>Revision/Review Date: 7/2024</p>	<p><u>of the following indications:</u></p> <ul style="list-style-type: none"> • Born at less than 32 weeks, 0 days AND had a diagnosis of chronic lung disease of prematurity at birth as defined above AND had continued need for one of the following respiratory interventions in the 6 months preceding RSV season: Chronic steroids, chronic diuretics, supplemental oxygen • Cystic fibrosis with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) or weight for length less than the 10th percentile • Born at any gestational age and will be profoundly immunocompromised during the RSV season, including: <ul style="list-style-type: none"> ○ Solid organ or hematopoietic stem cell transplant recipient ○ Chemotherapy recipient • Born at any gestational age and receiving a cardiac transplant <p>Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Tarpeyo
Drugs	Tarpeyo (budesonide)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist
Coverage Duration	If all of the criteria are met, the request will be approved for 9 months.

<p>Other Criteria</p>	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • 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 <p><u>Reauthorization:</u></p> <ul style="list-style-type: none"> • 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
<p>Revision/Review Date: 2/2024</p>	<p>the upper limit of normal and bilirubin >2 times the upper limit of normal)</p> <ul style="list-style-type: none"> • Prescriber attestation that patient has no active HBV infection • The prescribed dose is within FDA approved dosing guidelines <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>

Field Name	Field Description
Prior Authorization Group Description	Topical mTOR Kinase Inhibitors
Drugs	Hyftor (sirolimus topical gel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	Member concomitantly taking an oral mTOR inhibitor
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be 6 years or older
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist, medical geneticist, neurologist, or other prescriber who specializes in the treatment of genetic or dermatologic disorders.
Coverage Duration	If the criteria are met, requests will be approved with up to a 3 month duration. Thereafter, reauthorization requests will be approved with up to a 6 month duration.
Other Criteria	<p>Initial Authorization:</p> <ul style="list-style-type: none"> • 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 <p>Reauthorization:</p> <ul style="list-style-type: none"> • 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
Revision/Review Date 4/2024	

Field Name	Field Description
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Prior Authorization Group Description	Toremifene (Fareston)
Drugs	<p align="center"><u>FORMULARY STATUS</u> Formulary, Pays at Point-of-Sale TAMOXIFEN TABLETS 10MG AND 20MG</p> <p align="center"><u>FORMULARY STATUS</u> Requires Step Therapy with one prior step TOREMIFENE (FARESTON) 60MG TABLET</p> <p align="center">Note: Patient must meet criteria #1 & #2 for approval of the PA request.</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria	<ol style="list-style-type: none"> 1. Diagnosis of metastatic breast cancer in postmenopausal female patient 2. Documented trial and failure or intolerance with tamoxifen 10 or 20 mg tablet for a minimum of 3 weeks <p align="center">Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 12/2023	

Field Name	Field Description
Prior Authorization Group Description	Transthyretin-mediated Amyloidosis Agents

Drugs	<p><u>Preferred:</u> Polyneuropathy – Onpattro (patisiran), Amvuttra (vutrisiran), Wainua (eplontersen) Cardiomyopathy – Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis)</p> <p><u>Non-preferred:</u> Polyneuropathy – Tegsedi (inoterson) Or any other newly marketed agent</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the 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	Prescribed by or in consultation with a 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	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • 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, Amvuttra, Vyndaqel, Vyndamax, or Wainua <p>If the request is for Onpattro, Amvuttra, Tegsedi, or Wainua:</p> <ul style="list-style-type: none"> • Patient has diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis as evidenced by documented transthyretin variant by genotyping • One of the following: <ul style="list-style-type: none"> ○ Patient has baseline polyneuropathy disability (PND) score \leq IIIb ○ Patient has a baseline FAP Stage 1 or 2 ○ Patient has baseline neuropathy impairment (NIS) score \geq 5 and \leq 130 • Patient has clinical signs/symptoms of neuropathy • For Tegsedi, patient has contraindication to/or previous trial and failure of use of Onpattro, Amvuttra, or Wainua

<p>Revision/Review Date: 4/2024</p>	<p>If the request is for Vyndaqel or Vyndamax:</p> <ul style="list-style-type: none"> • Patient has a confirmed diagnosis of cardiomyopathy of wildtype or hereditary transthyretin-mediated • Documented amyloid deposit by biopsy or positive technetium 99m pyrophosphate (Tc 99m PYP) cardiac imaging • Patient has New York Heart Association (NYHA) functional class I, II, or III heart failure symptoms. <p><u>Re-authorization (for continuing and new patients to the plan) :</u></p> <ul style="list-style-type: none"> • 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, Amvuttra, Vyndaqel, Vyndamax, or Wainua) • 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 ○ Patient has continued NYHA functional class I, II, or III heart failure symptoms <p><u>Continuation of Therapy Provision:</u> Members with history (within the past 90 days) of a non-formulary product are not required to try a formulary agent prior to receiving the non-formulary product.</p> <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>
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<p>Prior Authorization Group Description</p>	<p>Treatment of Hereditary Angioedema (HAE)</p>
<p>Drugs</p>	<p><u>Preferred:</u> Berinert (C1 esterase inhibitor, human) Haegarda (C1 esterase inhibitor, human) Ruconest (C1 esterase inhibitor, recombinant) icatibant (Firazyr)</p> <p><u>Non-preferred:</u> Cinryze (C1 esterase inhibitor, human) Kalbitor (ecallantide) Takhzyro (lanadelumab-flyo) Orladeyo (berotralstat)</p> <p>For danazol requests, refer to the “Danazol” policy</p>

Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with an immunologist, allergist, rheumatologist, or hematologist
Coverage Duration	<p>If criteria are met, the request will be approved as follows:</p> <ul style="list-style-type: none"> • Acute treatment: 1 + 5 refills • Pre procedural prophylaxis: 1 treatment • Long-term prophylaxis: <ul style="list-style-type: none"> ○ Initial: 6 months ○ Reauthorization: 12 months
Other Criteria	<p><u>Initial Requests:</u></p> <ul style="list-style-type: none"> • Documentation submitted indicates the medication is being prescribed at FDA approved dose. • The patient is not taking ACE inhibitors or estrogen containing oral contraceptives/hormone replacement therapy • Diagnosis of one of the following: <ul style="list-style-type: none"> ○ HAE with deficient or dysfunctional C1INH (e.g. type I, type II, or acquired C1NH deficiency ○ HAE with normal C1INH: <ul style="list-style-type: none"> ▪ If known origin, documentation of results of confirmatory genetic test (e.g. mutations in gene for factor XII,

angiopoietin-1, plasminogen, kininogen-1, myoferlin, heparan sulfate-glucosamine 3-O-sulfotransferase 6)

- If unknown origin (U-HAE), documentation of a prolonged trial of high-dose non-sedating antihistamines

For acute treatment:

- The patient is receiving only one agent for the treatment of acute attacks
- If the request is for a non-preferred agent, the member has documented trial and failure of, or intolerance to a preferred agent or medical reason why the member cannot use a preferred agent

For prophylaxis:

- Pre-procedural ○ Documentation that patient will be undergoing a medical, surgical, or dental procedure associated with mechanical impact to the upper aerodigestive tract
- Long-term
 - The patient has a history of at least two severe attacks/month (e.g. with swelling of the face, throat, or GI tract) or at least one laryngeal attack, and chart notes have been submitted indicating the date and severity of attack.
 - The patient is only receiving one medication for long-term prophylaxis
- If the request is for a non-preferred agent ○ And the patient has a C1INH deficiency or dysfunction, documented trial and failure of or medical reason why patient cannot use a preferred agent
 - And the patient has HAE with normal C1INH, documented trial and failure of, or documented medical reason why patient cannot use danazol (note: danazol may require prior authorization)

Renewal Criteria:

For acute treatment:

- Documentation was submitted that the patient has clinically benefited from medication
- The patient is receiving no other medications for acute treatment
- The medication is being prescribed at FDA approved dose.

For prophylaxis:

<p>Revision/Review Date: 4/2024</p>	<ul style="list-style-type: none">• Documentation was submitted that the patient has clinically benefited from prophylactic therapy as demonstrated by a reduced number of attacks• The medication is being prescribed at an FDA approved dose• The patient is receiving no other medications for prophylaxis <p>NOTE: Medical Director/Clinical Reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary</p>
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Field Name	Field Description
Prior Authorization Group Description	Treatments for Plasminogen Deficiency Type 1 (PLD1)
Drugs	Ryplazim (human plasma-derived plasminogen)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist, medical geneticist, or other specialist in the treatment of rare blood or genetic disorders
Coverage Duration	If all of the criteria are met, the initial request will be approved for 12 weeks. Reauthorization requests will be approved for 12 weeks if the member has not had a documented positive response to therapy and for 12 months if the member has had a documented positive response to therapy.

<p>Other Criteria</p>	<p>Initial Authorization</p> <ul style="list-style-type: none"> • Member must have a diagnosis of PLD1 (i.e. hypoplasminogenemia) • Member must have a documented history of lesions or other symptoms consistent with the diagnosis (e.g. ligneous conjunctivitis, oral, respiratory, gastrointestinal, urogenital, integumentary, or central nervous system manifestations) • Member must have baseline plasminogen activity levels $\leq 45\%$ <ul style="list-style-type: none"> ○ If the member received plasminogen supplementation with fresh frozen plasma, prescriber attests that a 7-day washout period was performed before obtaining baseline plasminogen activity levels. • The request is for an FDA approved dose <p>Reauthorization</p> <ul style="list-style-type: none"> • ONE of the following is true: <ul style="list-style-type: none"> ○ Member has a documented positive response to therapy (e.g. reduction in number or size of lesions, no new or recurring lesions) ○ Member has not had a documented positive response to therapy and ONE of the following: <ul style="list-style-type: none"> ▪ If confirmed plasminogen activity levels are $\geq 10\%$ above baseline, then appropriate dosing frequency adjustments must be made.
<p>Revision/Review Date 4/2024</p>	<ul style="list-style-type: none"> ▪ If confirmed plasminogen activity levels are $< 10\%$ above baseline, then appropriate dosing frequency adjustments must be made AND the prescriber must provide a medical justification as to why therapy should be continued. • The request is for an FDA approved dose <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>

Field Name	Field Description
Prior Authorization Group Description	Type I Interferon (IFN) Receptor Antagonist
Drugs	Saphnelo (anifrolumab-fnia)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	<ul style="list-style-type: none"> • 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	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ○ Hydroxychloroquine + Glucocorticoids ○ One other immunosuppressant (i.e., methotrexate, azathioprine, calcineurin inhibitors, or mycophenolate) ○ 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 <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • 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 <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
Date: 10/2023	

Field Name	Field Description
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Prior Authorization Group Description	Tzielid (teplizumab-mzww)
Drugs	Tzielid (teplizumab-mzww)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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 onetime treatment .
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ○ 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) <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
Date: 2/2024	

Field Name	Field Description
Prior Authorization Group Description	Vascular Endothelial Growth Factor (VEGF) Inhibitors for Ophthalmic Conditions

Drugs	<p>Preferred Vascular Endothelial Growth Factor (VEGF) Inhibitor(s):</p> <ul style="list-style-type: none"> • Avastin (bevacizumab) • Byooviz (ranibizumab-eqrn) • Cimerli (ranibizumab-nuna) <p>Non-Preferred Vascular Endothelial Growth Factor (VEGF) Inhibitor(s):</p> <ul style="list-style-type: none"> • Beovu (brolucizumab) • Eylea (aflibercept) • Eylea HD (aflibercept) • Lucentis (ranibizumab) • Susvimo (ranibizumab) • Vabysmo (faricimab) • Any newly marketed agent in this class
Covered Uses	<p>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</p>
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	<p>Approvable for adults 18 years of age and older only</p> <p>Eylea: approvable in pediatric patients for diagnosis of retinopathy of prematurity</p>
Prescriber Restrictions	Ophthalmologist
Coverage Duration	If the above conditions are met, the request will be approved for 12 months.
Other Criteria	<p>Avastin:</p> <ul style="list-style-type: none"> • Request is for compendia supported dosing for an ophthalmic indication <p>Byooviz or Cimerli:</p> <ul style="list-style-type: none"> • Request is for an FDA-approved dosing regimen <p>Non-Preferred VEGF Inhibitor:</p> <ul style="list-style-type: none"> • Request is for an FDA-approved dosing regimen; AND • Documented trial and failure with a preferred VEGF inhibitor for all FDA-approved indications OR a medical justification for

<p>Revision/Review Date 6/2024</p>	<p>not using a preferred VEGF inhibitor (e.g. experienced a severe ADR such as hypersensitivity, arterial thromboembolism, cerebrovascular accident, raised intraocular pressure, retinal detachment).</p> <ul style="list-style-type: none">• Requests for Eylea (aflibercept) may be approved for a diagnosis of retinopathy of prematurity without a trial and failure of a preferred VEGF inhibitor. Patients must have a diagnosis of retinopathy of prematurity in at least one eye with one of the following retinal findings: ○ ROP Zone 1 Stage 1+, 2+, 3 or 3+, or ○ ROP Zone II Stage 2+ or 3+, or ○ AP-ROP (aggressive posterior ROP) <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Vasodilators for Pulmonary Hypertension Phosphodiesterase Type 5 (PDE-5) Inhibitors Only
Drugs	tadalafil (Adcirca) 20 mg tablet Tadliq (tadalafil) oral suspension sildenafil (Revatio) 20 mg tablet, vial, 10 mg/mL oral suspension Liqrev (sildenafil)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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 erectile dysfunction
Required Medical Information	See “other criteria”
Age Restrictions	Patient is ≥ 18 years old
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist
Coverage Duration	If all of the above conditions are met, the request will be approved for a 12 month duration.

<p>Other Criteria</p>	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of pulmonary arterial hypertension (PAH) • For oral suspension ONLY, is unable to take oral tablets • Patient has NO recent history with use of the following medications: <ul style="list-style-type: none"> ○ Organic nitrates (i.e. nitroglycerin, isosorbide, etc.) ○ Guanylate Cyclase (GC) stimulators (Adempas) ○ HIV protease inhibitors (i.e. ritonavir, darunavir, etc.) – sildenafil only • The medication is prescribed at a dose that is within FDA approved guidelines • If the request is for a non-preferred drug, the member has a documented treatment failure with 1 indicated preferred drugs or has a documented medical reason (intolerance, hypersensitivity, contraindication, etc.) why they are not able to use preferred drugs if appropriate for the requested indication <p><u>Re-authorization:</u></p> <ul style="list-style-type: none"> • Documentation has been submitted indicating the clinical benefit of therapy (e.g. improvement in functional class, improvement in 6minute walk test, exercise capacity, or hemodynamics). • The medication is being prescribed at a dose that is within FDA approved guidelines.
<p>Revision/Review Date 7/2024</p>	<p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>

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	<ul style="list-style-type: none"> • 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	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • 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 <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • 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 <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
Revision/Review Date: 10/2023	

Field Name	Field Description
Prior Authorization Group Description	Verquvo
Drugs	Verquvo (vericiguat)

Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Pregnancy
Required Medical Information	See “Other Criteria”
Age Restrictions	Patient must be 18 years or older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist
Coverage Duration	If all of the conditions are met, the request will be approved for 12 month duration.
Other Criteria	<ol style="list-style-type: none"> 1. Medication is prescribed at an FDA approved dose 2. The medication is being used for the treatment of symptomatic chronic heart failure with reduced ejection fraction (less than 45%) 3. Documentation that the patient has had a previous hospitalization for heart failure or has required outpatient IV diuretics 4. Member is currently being prescribed the following treatment regimens, or documentation has been provided that the member is not able to tolerate or has a contraindication to any of these agents: <ol style="list-style-type: none"> a. Angiotensin-converting enzyme (ACE) inhibitor OR angiotensin receptor blocker (ARB) OR angiotensin receptor/neprilysin inhibitor b. Mineralocorticoid receptor antagonist (e.g. spironolactone) c. Evidence based beta-blocker (i.e., bisoprolol, carvedilol, metoprolol succinate) d. Farxiga or Jardiance 5. Patient is not concomitantly using a phosphodiesterase-5 (PDE-5) enzyme inhibitor (e.g. sildenafil) 6. Negative pregnancy test (for females of reproductive age; as indicated) within 30 days of request 7. Prescriber attests to discussing with females of reproductive potential the need to use effective forms of contraception during treatment and for one month after stopping treatment <p>Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>
Revision/Review Date 7/2024	

Field Name	Field Description
Prior Authorization Group Description	Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors

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

<p>Revision/Review Date: 10/2023</p>	<ul style="list-style-type: none"> ○ 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 <p>For approval for use in chorea associated with Huntington’s Disease (HD):</p> <ul style="list-style-type: none"> • Patient must have diagnosis of moderate to severe Huntington’s with chorea, with documented baseline Total Maximal Chorea (TMC) score provided • For Austedo requests: ○ Prescriber attests patient has no signs of hepatic impairment <ul style="list-style-type: none"> ○ For patients at risk for QT prolongation, prescriber attests a baseline ECG has been obtained • For Ingrezza requests: <ul style="list-style-type: none"> ○ Must be dosed at one capsule per day <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation or provider attestation of positive clinical response (e.g., improvement from baseline in average scores on the previously submitted symptom rating scale, decrease in symptoms, etc.) • Medication is prescribed at an FDA approved dose <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
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Field Name	Field Description
Prior Authorization Group Description	Vijoice
Drugs	Vijoice (alpelisib)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	≥ 2 years

Prescriber Restrictions	Prescribed by or in consultation with a geneticist, dermatologist, vascular surgeon, hematologist/oncologist, or other specialist in the treatment of PIK3CA-Related Overgrowth Spectrum (PROS)
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of PROS • Documented evidence of a mutation in the PIK3CA gene • Patient has at least one target lesion identified on imaging • Prescriber attests the patient’s condition is severe or life-threatening and necessitates systemic treatment • Medication is prescribed at an FDA approved dose <u>Re-Authorization:</u> • Documentation of a positive clinical response defined as the patient achieving ALL of the following: <ul style="list-style-type: none"> ○ At least a 20% reduction in the sum of measurable target lesion volume (1 to 3 lesions, via central review of imaging scans) ○ None of the individual target lesions have $\geq 20\%$ increase from baseline ○ Absence of progression of non-target lesions ○ Absence of any new lesions
Revision/Review Date: 7/2024	<ul style="list-style-type: none"> • Prescriber attests the patient does not have any serious adverse events or unacceptable toxicity • Medication is prescribed at an FDA approved dose <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>

Field Name	Field Description
Prior Authorization Group Description	Vimizim (elosulfase alfa)
Drugs	Vimizim (elosulfase alfa)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”

Age Restrictions	Patient must be 5 years of age or older.
Prescriber Restrictions	Prescriber is, or is collaborating with another provider who is, a specialist in the treatment of Morquio A syndrome or other lysosomal storage disorders.
Coverage Duration	6 months
Other Criteria	<p><u>Initial Authorization (new to therapy):</u></p> <ul style="list-style-type: none"> • Patient has confirmed diagnosis of mucopolysaccharidosis IVA (MPS IVA, or Morquio A syndrome) via one of the following: <ul style="list-style-type: none"> ○ Genetic testing ○ Analysis of N-Acetylgalactosamine 6-sulfatase (GALNS) activity in leukocytes or fibroblasts • Documentation of patient weight Patient must have completed a 6-minute walk test for baseline evaluation (must submit results with request) and be able to walk a minimum of 30 meters at baseline. <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Patient shows signs of improvement from baseline in a 6-minute walk test (must submit results with request) <p><u>Re-authorization for members new to the plan previously treated with Vimizim:</u></p> <ul style="list-style-type: none"> • Patient has confirmed genetic diagnosis of mucopolysaccharidosis IVA (MPS IVA, or Morquio A syndrome) via one of the following: <ul style="list-style-type: none"> ○ Genetic testing ○ Analysis of N-Acetylgalactosamine 6-sulfatase (GALNS) activity in leukocytes or fibroblasts • Documentation of patient weight Patient must have completed a 6-minute walk test for baseline evaluation, and patient shows signs of improvement from baseline in a recent 6-minute walk test (must submit both results with request). • If a baseline 6-minute walk test was not completed prior to initiation of Vimizim therapy, then:

<p>Revision/Review Date 7/2024</p>	<ul style="list-style-type: none"> ○ A current test must be completed and patient must be able to walk a minimum of 30 meters (must submit results with request). ○ 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. ○ 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. <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Voquezna

Drugs	Voquezna (vonoprazan), Voquezna Dual Pack (vonoprazan; amoxicillin), Voquezna Triple Pack (vonoprazan; amoxicillin; clarithromycin)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Per package insert
Prescriber Restrictions	Prescribed by, or in consultation with, a gastroenterologist, infectious disease specialist, or other specialist with expertise in the treatment of erosive esophagitis or H. pylori infection
Coverage Duration	<p>If the criteria are met, the request will be approved for up to the following:</p> <p>Healing of erosive esophagitis: Voquezna 20 mg once daily for up to 8 weeks</p> <p>Maintenance of healed erosive esophagitis: Voquezna 10 mg once daily for up to 6 months</p> <p>Treatment of H. pylori infection: 14 days</p> <p>For heartburn associated with non-erosive gastroesophageal reflux disease: Voquezna 10 mg once daily for 4 weeks</p>
Other Criteria	<p>Initiation of Therapy:</p> <p><u>For erosive esophagitis (healing or maintenance of healed erosive esophagitis):</u></p> <ul style="list-style-type: none"> • Patient has a diagnosis of endoscopy-confirmed erosive esophagitis (all grades) • Patient is H. pylori negative • Patient has a trial and failure of treatment with ≥ 8 weeks with two different formulary proton pump inhibitors at optimized dosing (double-dose or twice daily dosing), or a medical reason is provided why this is inappropriate. <p><u>For the treatment of Helicobacter pylori (H. pylori) infection:</u></p>

- Patient has a confirmed H. pylori positive infection, plus one of the following clinical conditions:
 - dyspepsia lasting at least 2 weeks, functional dyspepsia, recent/new diagnosis of peptic ulcer, or a stable dose of long-term NSAID treatment
- Patient has a trial and failure of a generic, guideline recommended, first-line regimen for H. pylori infection such as clarithromycin triple therapy (proton pump inhibitor (PPI) + clarithromycin + amoxicillin or metronidazole) or bismuth quadruple therapy (PPI + bismuth subcitrate or subsalicylate + tetracycline + metronidazole), or a medical reason is provided both would be inappropriate.

For the relief of heartburn associated with non-erosive gastroesophageal reflux disease:

- Patient has a diagnosis of symptomatic gastroesophageal reflux disease (GERD) with heartburn as the predominant symptom
- Patient has a history of heartburn lasting at least 6 months, with symptoms on at least four days per week
- Patient is H. pylori negative, and endoscopy has confirmed patient has no esophageal erosions
- Prescriber attests patient has been educated about lifestyle modifications related to GERD management (i.e. avoidance of trigger foods, weight loss in overweight and obese patients, avoiding meals within 2-3 hours of bedtime, tobacco cessation, etc.)
- Patient has a trial and failure of treatment with ≥ 8 weeks with two different formulary proton pump inhibitors at optimized dosing (double-dose or twice daily dosing), or a medical reason is provided why this is inappropriate.

Renewal Requests:

Use of Voquezna for longer than 8 weeks for healing of erosive esophagitis, longer than 6 months for maintenance of healing in erosive esophagitis, or longer than 4 weeks for heartburn associated with nonerosive gastroesophageal reflux disease will not be approved.

Renewal requests for Voquezna for treatment of H. pylori infection will not be approved.

Revision/Review
Date: 7/2024

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

Field Name	Field Description
Prior Authorization Group Description	Voriconazole (Vfend)
Drugs	Voriconazole (Vfend) tablets, oral suspension
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	2 years of age and older.
Prescriber Restrictions	N/A
Coverage Duration	If the above conditions are met, the request will be approved with up to a 3 month duration depending upon the severity of the infection.
Other Criteria	<p><u>Initial Authorization:</u></p> <ol style="list-style-type: none"> 1. Voriconazole is being used to treat invasive aspergillosis or a serious fungal infection caused by <i>Scedosporium apiospermum</i> and <i>Fusarium</i> species <p>OR</p> <ol style="list-style-type: none"> 2. Voriconazole is being used to treat esophageal candidiasis, candidemia (nonneutropenics), or disseminated candidiasis of the skin, abdomen, kidney, bladder wall or wounds; AND ○ Documented trial and failure with a formulary treatment option (i.e. fluconazole or nystatin) or documented medical reason (e.g., recent discharge from hospital on oral voriconazole, intolerance, hypersensitivity, contraindication) for not using a formulary treatment option for relevant indications <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 7/2024	

Field Name	Field Description
Prior Authorization Group Description	Wegovy in Cardiovascular Disease

Drugs	<p>Wegovy (semaglutide) injection</p> <p>* For requests for Wegovy for a diagnosis of weight reduction and maintenance of weight reduction, please refer to the Medications for the Management of Obesity criteria*</p>
Covered Uses	<p>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</p>
Exclusion Criteria	<ul style="list-style-type: none"> • Dual eligible members receiving Wegovy for the diagnosis of cardiovascular disease prevention must have Wegovy billed under their Medicare Part D carrier • Concurrent use of any glucagon-like-peptide-1 receptor agonist • Personal history of Type 1 or Type 2 diabetes • Personal or family history of medullary thyroid carcinoma • Multiple Endocrine Neoplasia syndrome type 2
Required Medical Information	<p>See “Other Criteria”</p>
Age Restrictions	<p>Aligned with package insert</p>
Prescriber Restrictions	<p>N/A</p>
Coverage Duration	<p>If all of the criteria are met, the initial request will be approved for 6 months. For re-authorizations, the request will be approved for 12 months.</p>
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Medication is prescribed for reducing the risk of adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease. Documentation demonstrates patient has history of one or more of the following: <ul style="list-style-type: none"> ○ Prior myocardial infarction ○ Prior stroke ○ Symptomatic peripheral arterial disease, as evidenced by ≥ 1 of the following: <ul style="list-style-type: none"> ▪ Intermittent claudication with ankle brachial index < 0.85 (at rest) ▪ Peripheral arterial revascularization procedure ▪ Amputation due to atherosclerotic disease • Documentation is provided that patient is overweight or obese, defined as a body mass index (BMI) ≥ 27 kg/m² • Patient is receiving standard of care treatment of CVD, as

<p>Revision/ Review Date: 4/2024</p>	<p>appropriate/indicated, including an antiplatelet agent (ex. aspirin or P2Y12 inhibitor), lipid-lowering drug (ex. statin, otherwise ezetimibe, fibrate, and/or PCSK-9 inhibitor), antihypertensive (ex. beta blocker, ACE-I, ARB)</p> <ul style="list-style-type: none">• Prescriber attests medication therapy is part of a total treatment plan including diet and exercise/activity as appropriate for the patient's ability• Documentation is provided patient's Hb A1c \leq 6.5% <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none">• Patient is receiving standard of care treatment of CVD, as appropriate/indicated, including an antiplatelet agent (ex. aspirin or P2Y12 inhibitor), lipid-lowering drug (ex. statin, otherwise ezetimibe, fibrate, and/or PCSK-9 inhibitor), antihypertensive (ex. beta blocker, ACE-I, ARB)• Patient continues to not have Type 1 or Type 2 diabetes <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
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Field Name	Field Description
Prior Authorization Group Description	White Blood Cell Stimulators
Drugs	<p><u>FORMULARY STATUS</u></p> <p><u>Short-Acting G-CSFs:</u> Neupogen (filgrastim)– PREFERRED AGENT Granix (TBO-filgrastim) Nivestym (filgrastim-aafi) Releuko (filgrastim-ayow) Zarxio (filgrastim-sndz) Or any newly market agent</p> <p><u>Long-Acting G-CSFs:</u> Nyvepria (pegfilgrastim-apgf) – PREFERRED AGENT Fulphila (pegfilgrastim-jmdb) Fylnetra (pegfilgrastim-pbbk) Neulasta (pegfilgrastim) Neulasta Onpro (pegfilgrastim) Rolvedon (eflapgrastim-xnst) Stimufend (pegfilgrastim-fpgk) Udenyca (pegfilgrastim-cbqv) Ziextenzo (pegfilgrastim-bmez) Or any newly market agent</p> <p><u>Additional Agents:</u> Aphexda (motixafortide) Plerixafor (Mozobil) Leukine (Sargramostim) Or any newly marketed agent</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USPDI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, a hematologist, an oncologist, or an infection disease specialist
Coverage Duration	Initial authorization requests for all indications will be approved for 12 weeks. Reauthorization requests for all indications, with the exception of chronic neutropenia, will be approved for 12 weeks. Reauthorization requests for chronic neutropenia will be approved for 24 weeks.
Other Criteria	<u>Initial Authorization:</u>

<p>Revision/Review Date: 9/2024</p>	<ul style="list-style-type: none"> • The drug is being used for an appropriate indication at an appropriate dose per “Covered Uses”. • <i>For ALL requests for treatment or prophylaxis of febrile neutropenia:</i> Documentation of the patient’s absolute neutrophil count (ANC) within the last 30 day has been provided. <p><u>Short-Acting G-CSFs:</u></p> <ul style="list-style-type: none"> • <i>For all requests for non-preferred agents:</i> The patient has a documented treatment failure {i.e. failure to reach and/or maintain target ANC, prolonged febrile neutropenia, unplanned hospitalization or infection requiring prolonged anti-infective use} with an adequate trial (including dates, doses of therapy) of Neupogen or has another documented medical reason (intolerance, hypersensitivity, stem cell collection, etc.) for not using Neupogen to treat their medical condition. <p><u>Long-Acting G-CSFs:</u></p> <ul style="list-style-type: none"> • <i>For all requests for non-preferred agents:</i> The patient has a documented treatment failure (i.e. failure to reach and/or maintain target ANC, prolonged febrile neutropenia or infection requiring prolonged anti-infection use) with the use of Nyvepria, or has a documented medical reason (intolerance, hypersensitivity, stem cell collection, etc.) for not Nyvepria <p><u>Additional Agents:</u></p> <ul style="list-style-type: none"> • <i>For Leukine requests:</i> Documentation is submitted of the patient’s current diagnosis, current body weight, body surface area (within 30 days of the request). • <i>For plerixafor and Aphexda requests:</i> Documentation is submitted of the patient’s current diagnosis, current body weight, and that the patient is using drug in combination with a granulocyte-colony stimulating factor (G-CSF) agent (e.g. Neupogen, Zarxio, Nivestym). Requests for Aphexda must also have a documented treatment failure (i.e. failure to reach and/or maintain target ANC, prolonged febrile neutropenia or infection requiring prolonged antiinfection use) with plerixafor <p style="text-align: center;">Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Xifaxan (rifaximin)
Drugs	Xifaxan (rifaximin)

Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	For Travelers’ Diarrhea Treatment: Patient must be 12 years of age or older For Hepatic Encephalopathy or Irritable Bowel Syndrome with diarrhea (IBS-D): Patient must be 18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Hepatic Encephalopathy: If the criteria are met, for initial authorization, the request will be approved for 6 months. For reauthorization, the request will be approved for 12 months. Travelers diarrhea: If the criteria are met, the request will be approved for a one-time, 3 day regimen Irritable Bowel Syndrome with diarrhea (IBS-D): If the criteria are met, the request will be approved for 14 days. For re-authorization, the request may be approved up to 2 more times for a 14 day duration.
Other Criteria	<u>Initial Authorization:</u> <u>Hepatic Encephalopathy</u> <ul style="list-style-type: none"> • Patient has the diagnosis of hepatic encephalopathy • Patient will be using lactulose concurrently or has a medical reason for being unable to use lactulose <u>Traveler’s Diarrhea Treatment</u> <ul style="list-style-type: none"> • Patient has the diagnosis of traveler’s diarrhea • Patient has tried and failed therapy with one formulary antibiotic or has a medical reason for not trying a formulary antibiotic (e.g., levofloxacin, azithromycin, sulfamethoxazoletrimethoprim) <u>Irritable Bowel Syndrome with diarrhea (IBS-D)</u> <ul style="list-style-type: none"> • Patient has the diagnosis of moderate to severe IBS-D

<p>Revision/Review 7/2024</p>	<ul style="list-style-type: none">• Patient has tried and failed or has a contraindication or intolerance to one formulary tricyclic antidepressant <p><u>Re-Authorization (Hepatic Encephalopathy and IBS-D only):</u></p> <ul style="list-style-type: none">• Documentation indicating the member has clinically benefited from therapy. <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Xolair for Asthma, Urticaria, and IgE-Mediated Food Allergy
Drugs	Xolair (omalizumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	<ul style="list-style-type: none"> • Use of Xolair concomitantly with another pulmonary biologic (e.g. Fasentra, Nucala, Cinqair, Dupixent, Tezspire) • Use of Xolair concomitantly with Palforzia • Use of Xolair for emergency treatment of allergic reactions, including anaphylaxis
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by, or in consultation with, an allergist/immunologist, pulmonologist, or dermatologist
Coverage Duration	If all of the conditions are met, the initial and reauthorization request will be approved for up to a 6 month duration for renewal requests.
Other Criteria	<p>**For nasal polyposis, please refer to the “Biologic Agents for Nasal Polyposis” policy**</p> <p><u>Initial Authorization:</u></p> <p><u>Asthma:</u></p> <ul style="list-style-type: none"> • Member has at least a 6 month history of moderate to severe asthma • The drug is being prescribed at an approved dose according to member’s weight and IgE level • Member is taking maximally tolerated ICS/LABA combination in addition to a LAMA (e.g. tiotropium) for at least 3 months, or there is a documented medical reason why the member is unable to take these medications • Member’s asthma is uncontrolled as defined by having one of the following: <ul style="list-style-type: none"> ○ Frequent severe exacerbations requiring two or more bursts of systemic glucocorticoids (more than three days each) in the previous year ○ History of serious exacerbation: at least one hospitalization, intensive care unit stay, or mechanical ventilation in the previous year ○ Airflow limitation defined as a forced expiratory volume in 1 second (FEV1) less than 80% of predicted ○ Poor symptom control including at least THREE of the following:

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<p>Review/Revision Date: 4/2024</p>	<ul style="list-style-type: none"> ▪ Asthma Control Questionnaire (ACQ) consistently > 1.5 or Asthma Control Test (ACT) < 20 ▪ Daytime asthma symptoms more than twice per week ▪ Use of an inhaled short acting B-2 agonist to relieve asthma symptoms more than twice per week (not including use prior to exercise) ▪ Limited physical activity due to asthma symptoms ▪ Nighttime awakening due to asthma symptoms <ul style="list-style-type: none"> • Member has a positive immediate response on RAST test and/or skin prick test to at least 1 common allergen (e.g. dermatophagoides farinae, dermatop hagoides pteronyssinus, dog, cat, or cockroach) that is an asthma trigger (copy of results required). • Pre-treatment serum IgE levels must be greater than or equal to 30 IU/mL <p><u>Chronic Idiopathic Urticaria:</u></p> <ul style="list-style-type: none"> • The drug is prescribed at an approved dose • Member has at least a 6 week history of urticaria • Member requires oral corticosteroids to control symptoms • The patient remains symptomatic despite a minimum two week trial (or has medical reason for not utilizing) of two preferred second generation H1 antihistamines at the maximum tolerated dose <p><u>IgE-Mediated Food Allergy:</u></p> <ul style="list-style-type: none"> • Diagnosis of IgE-mediated food allergy with documented allergy to one or more of the following foods: <ul style="list-style-type: none"> ○ Peanut, milk, egg, wheat, cashew, hazelnut, or walnut • Attestation Xolair will be used in conjunction with food allergen avoidance • The drug is being prescribed at an FDA approved dose according to the member’s weight and IgE level <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • The drug is being prescribed at an approved dose • The member has experienced a clinical benefit from medication (e.g. decrease exacerbations, reduction in use of oral steroids)
	<p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>

Field Name	Field Description
Prior Authorization Group Description	Xolremdi
Drugs	Xolremdi (mavorixafor)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	12 years of age and older
Prescriber Restrictions	Prescriber must be an immunologist or a hematologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of WHIM (warts, hypogammaglobulinemia, infections and myelokathexis) syndrome confirmed by genotype variant of chemokine receptor 4 (CXCR4) and absolute neutrophil count (ANC) of ≤ 400 cells/μL • Documentation of baseline ANC and absolute lymphocyte count (ALC) • Documentation of member weight • Medication is prescribed at an FDA approved dose <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation or provider attestation of positive clinical response (i.e., improvement from baseline in ANC and/or ALC) • Documentation of member weight • Medication is prescribed at an FDA approved dose <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
Revision/Review Date: 7/2024	

Field Name	Field Description
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	<ul style="list-style-type: none"> • Patient has previously received this medication • Advanced spinal muscular atrophy (SMA) (e.g., complete paralysis of limbs, permanent ventilator-dependence) • Administration to premature neonates before reaching full-term gestational age
Required Medical Information	Patient's body weight
Age Restrictions	Patient must be less than 2 years of age
Prescriber Restrictions	Prescribed by a neurologist
Coverage Duration	Authorization will be placed for 1 dose.
Other Criteria	<p>Patient must meet all of the following criteria:</p> <ul style="list-style-type: none"> • Diagnosis of Spinal Muscular Atrophy (SMA) • Bi-allelic mutations in the survival motor neuron 1 (SMN1) gene • Documentation is provided that the patient has 3 copies or less of the SMN2 gene • Baseline anti-AAV9 antibody titers of $\leq 1:50$ measured using an enzyme-linked immunosorbent assay (ELISA) • Dosing is consistent with FDA approved labeling <p>The safety and effectiveness of repeat administration of Zolgensma have not been evaluated and will not be approved.</p>
Revision/Review Date 8/2024	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Fibromyalgia Criteria

Medications

Brand Name	Generic Name	Dosage Strengths
Savella®	milnacipran	12.5 mg, 25 mg, 50 mg, 100 mg tablets, 4-week titration pack

For requests for pregabalin (Lyrica® and Lyrica® CR) use the Lyrica® criteria

Criteria for Approval

1. Diagnosis of Fibromyalgia; AND
2. Physical Fitness Intervention (e.g., physical therapy, exercise); AND
3. Trial and failure of, or contraindication to, treatment with one of the following two:
 - a. Amitriptyline 50 mg daily; OR
 - b. Cyclobenzaprine 30 mg daily; AND
4. No concurrent therapy of these medications (duloxetine, pregabalin, milnacipran) beyond 30 days.

Criteria for Denial

1. Criteria for approval not met.

Length of Authorization: One year

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Systemic Immunomodulator Criteria

Preferred:

adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-fjkg, adalimumab-ryvk, Enbrel, Humira, infliximab (generic Remicade), Otezla, Rinvoq, Rinvoq LQ, Taltz, Xeljanz tablets

Non-Preferred:

Abrilada, Actemra/ACTPen, Amjevita, Arcalyst, Avsola, Bimzelx, Cibirgo, Cimzia, Cosentyx, Cyltezo, Entyvio, Hadlima, Hulio, Hyrimoz, Idacio, Ilaris, Ilumya, Inflectra, Kevzara, Kineret, Litfulo, Olumiant, Omvoh, Orencia, Remicade, Renflexis, Siliq, Simponi/Aria, Simlandi, Skyrizi, Sotyktu, Spevigo, Stelara,

Tofidence, Tremfya, Tyenne, Velsipity, Xeljanz solution, Xeljanz XR, Yuflyma, Yusimry, Zymfentra And any newly marketed systemic immunomodulator

***For requests for Rinvoq (upadacitinib) for Atopic Dermatitis, use Atopic Dermatitis Criteria.**

Criteria for Approval

Prior authorization will only be granted for approved FDA indications AND must be prescribed by a rheumatologist, gastroenterologist, or dermatologist based on the approved FDA indication.

1. Ankylosing spondylitis:
 - a. Trial and failure required with a nonsteroidal anti-inflammatory drugs (NSAID)
2. Juvenile idiopathic arthritis (JIA) (previously listed as JRA):
 - a. Trial and failure of, contraindication, or adverse reaction to methotrexate
3. Moderately to severely active Crohn's disease (CD):
 - a. Trial and failure of a compliant regimen of oral corticosteroids (moderate to severe CD) unless contraindicated or intravenous corticosteroids (severe and fulminant CD or failure to respond to oral corticosteroids)
4. Moderately to severely active ulcerative colitis (UC) (all the following must be met):
 - a. Trial and failure of a compliant regimen of oral or rectal aminosalicylates (e.g., sulfasalazine or mesalamine) for two consecutive months; AND
 - b. Trial and failure of a compliant regimen of oral corticosteroids (for moderate to severe ulcerative colitis) unless contraindicated, or intravenous corticosteroids (for severe and fulminant ulcerative colitis or failure to respond to oral corticosteroids); AND
 - c. Trial and failure of a compliant regimen of azathioprine or mercaptopurine for three consecutive months
5. Moderate to severe chronic plaque psoriasis (PP):
 - a. Must have a previous failure on a topical psoriasis agent
6. Psoriatic arthritis (PsA):
 - a. Trial and failure required with methotrexate first or in combination with methotrexate if appropriate
7. Rheumatoid arthritis (RA):
 - a. Trial and failure of, contraindication, or adverse reaction to methotrexate and at least one other DMARD (e.g., sulfasalazine, hydroxychloroquine, minocycline) **Length of Approval:**
 1. Initial three months for Crohn's disease or ulcerative colitis
 2. One year for all other indications
 3. One-year renewal dependent upon medical records supporting response to therapy and review of prescription history.

Criteria for Denial

1. Moderate to severe heart failure (New York Heart Association [NYHA] Functional Class III/IV)

2. Live vaccines should not be given concurrently.
3. Presence of active infections
4. Current or recent malignancy
5. Concomitant treatment with azathioprine or 6-mercaptopurine due to increased risk of fatal hepatosplenic T-cell lymphomas (for any TNF-blocker: adalimumab, certrolizumab, etanercept, golimumab, infliximab, and biosimilars)
6. Pregnancy (for Arava request only)
7. Concomitant use with other systemic immunomodulators
8. Concurrent diagnosis of irritable bowel syndrome (for Cosentyx only)

Non-preferred drugs on the Preferred Drug List (PDL) require additional prior authorization.

Updated 1/2025