Pharmacy Prior Authorization Criteria

April 1, 2024

AmeriHealth Caritas
New Hampshire

Field Name	Field Description
Prior Authorization Group Description	**Medications without Drug or Class Specific Criteria**
Drugs	• Medications without drug or class specific prior authorization criteria • Brand drugs and reference biologics when a therapeutic equivalent generic drug or biosimilar/interchangeable biologic is available ***The Oncology Drugs prior authorization criteria will be applied to oncology drugs without drug or class specific criteria***
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If all of the conditions are met, requests will be approved for up to 12 months (depending on the diagnosis and usual treatment duration), or 6 months if the request is for a non-preferred ADHD medication due to the shortage.
Other Criteria	**<u>Initial Authorization:</u>** **All Requests:** • The drug is requested for an appropriate use (per the references outlined in "Covered Uses" • The dose requested is appropriate for the requested use (per the references outlined in "Covered Uses") • If the request is for a brand drug with a therapeutically equivalent (A-rated) generic drug currently available, documentation of the following: o The provider either verbally or in writing has submitted a medical or member specific reason why the brand name drug is required based on the member's condition or treatment history; **AND** if the member had side effects or a reaction to the generic drug, the provider has completed and submitted an FDA MedWatch form to justify the member's need to avoid this drug. The MedWatch form must be included with the prior authorization request Form FDA 3500 – Voluntary Reporting

	- 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

Revision/ Review Date 12/2023	• 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 **Non-PDL drugs where prior authorization is required without specific criteria:** Patient must meet one of the three following criteria: • 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. **Reauthorization:** • Documentation of provider attestation that demonstrates a clinical benefit • The requested drug is for a medically accepted dose as outlined in Covered Uses **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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 Revision/Review Date 4/2023	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) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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

Revision/Review Date 4/2023	3. Medication is being requested at an appropriate dose per literature **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group	**Oncology Drugs**
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	**All of the following criteria must be met:** • Requested use must be a labeled indication or be supported by NCCN Category 1 or 2A level of evidence. If the request is for an off-label use supported by NCCN as Category 2B recommendation then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g. allergic reaction, contraindication) • Documentation has been provided of the results of all required genetic testing where required per product package insert • Documentation has been provided of the results of all required laboratory values and patient specific information (e.g. weight, ALT/AST, Creatine Kinase, etc.) necessary to ensure the patient has no contraindications to therapy per product package insert • The product is being prescribed at a dose that is within FDA approved/NCCN guidelines. • If the request is for a reference biologic drug with either a biosimilar or interchangeable biologic drug currently available, documentation of one of the following: o The provider has verbally or in writing submitted a member specific reason why the reference biologic is required based on the member’s condition or treatment history; AND if the member had side effects or a reaction to the biosimilar or interchangeable biologic,

Revision/Review 12/2023	the provider has completed and submitted an FDA MedWatch form to justify the member's need to avoid these drugs. The MedWatch form must be included with the prior authorization request o The currently available biosimilar product does not have the same appropriate use (per the references outlined in "Covered Uses") as the reference biologic drug being requested Form FDA 3500 – Voluntary Reporting • **If the request is for abiraterone (Zytiga) 500 mg tablet, a documented medical reason why two tablets of generic abiraterone acetate 250 mg cannot be used** **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

<table>
<tr><th>Field Name</th><th>Field Description</th></tr>
<tr><td>Prior Authorization Group Description</td><td>Prior Authorization Exception Criteria</td></tr>
<tr><td>Covered Uses</td><td>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.</td></tr>
<tr><td>Scope</td><td>Requests for exception to the drug’s prior authorization criteria requirements</td></tr>
<tr><td>Coverage Duration</td><td>12 months</td></tr>
<tr><td>Criteria</td><td>The provider either verbally or in writing has submitted a medical or member specific reason why prior authorization criteria all or in part is not applicable to the member.
Medical and/or member specific reasons may include but are not limited to:
Uniqueness of the member’s condition or other physical characteristics of the member’s condition.
Psychiatric, intellectual, physical, cultural, and/or linguistic characteristics of the member which may inhibit the provider from obtaining all necessary prior authorization criteria requirements.
Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.</td></tr>
<tr><td>Revision/Review Date:</td><td>10/2023</td></tr>
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Field Name	Field Description
Prior Authorization Group Description	**Quantity Limit Exception Criteria**
Covered Uses	All medically accepted indications. Medically accepted indications are defined using the following compendia resources: the Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), American Hospital Formulary Service Drug Information (AHFS-DI), and DRUGDEX Information System. The reviewer may also reference disease state specific standard of care guidelines.
Scope	Requests for formulary drugs exceeding the health plan’s published quantity limits
Criteria	• The provider has submitted a medical reason why the plan’s quantity limit will be inadequate based on the member’s condition and treatment history. **AND one of the following:** o The member has a documented treatment failure with the drug prescribed at the health plan’s quantity limit AND the dose requested is supported by the Medical Compendia or current treatment guidelines. o The member requires a dose within prescribing guidelines that exceeds the plan’s quantity limit. **Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.**
Coverage Duration	12 Months
Revision/Review Date	10/2023

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 non-formulary drugs: • Exceeding the Food and Drug Administration (FDA) or compendia max dose recommendations • Exceeding the FDA dosing or compendia administration frequency recommendations • Exceeding the FDA or compendia duration of therapy recommendations • Duplication of therapy error at Point of Service (POS) • Age Restriction error at POS • Day Supply Limit error at POS • Concurrent Use error at POS • Drug Drug Interaction error at POS
Criteria	**Exceeding the Food and Drug Administration (FDA) or compendia maximum dose, administration frequency or duration of therapy recommendations.** • The member must have a documented treatment failure with the drug at the maximum dose based on patient age/weight, administration frequency, or duration of therapy per FDA or compendia. AND • The provider must submit a medical reason why the maximum dose, administration frequency or duration of therapy needs to be exceeded based on the member's condition or treatment history. **Duplication of therapy** <u>Transition from one agent to another</u> • If a provider has outlined a plan to transition a member to a similar drug or provided a dose titration schedule, the requested drug is approved for one month*. <u>Concurrent Therapy with two similar agents</u>

	- The provider must submit a medical reason why treatment with more than one drug in the same class is required based on the member’s condition and treatment history. OR - The provider must submit disease state specific standard of care guidelines supporting concurrent therapy. **Age Restriction** - The provider must submit a medical reason why the drug is needed for a member whose age is outside of the plan’s minimum or maximum age limit. AND - The indication and dose requested is supported by the Medical Compendia or current treatment guidelines. **Day Supply Limit** - An additional fill exceeding the day supply limit is needed based on a dose increase or is needed to achieve a total daily dose OR - The provider must submit a medical reason why an additional fill is needed outside of the plan’s day supply limit. AND - The indication and dose requested is supported by the FDA, Medical Compendia or current treatment guidelines. **Concurrent Use/Drug-Drug Interaction** - The provider must submit a medical reason why treatment with both drugs is necessary for the member - 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: - If the request is for concurrent medication-assisted treatment (MAT) agent and a benzodiazepine - 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: • Required step therapy drug(s) would be ineffective, or; • Required step therapy drug(s) have the potential to cause harm or deterioration of the member's condition, or; • The requested drug would be superior to the required prerequisite trial(s) with preferred drug(s). **Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.**
Coverage Duration	12 Months
Revision/Review Date:	10/2023

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	Preferred (Step 1): 5-HT3 RA: ondansetron (Zofran) oral tablet, orally disintegrating tablet (ODT), oral solution, IV solution, injection (IV/SQ) solution or granisetron (Kytril) oral tablet, IV solution NK1 RA: aprepitant (Emend) oral capsule, fosaprepitant (Emend) IV emulsion Preferred (Step 2): 5-HT3 RA: palonosetron (Aloxi) IV solution Non-Preferred: Sustol (granisetron ER) SQ injection, Sancuso (granisetron ER) transdermal patch, Zuplenz (ondansetron) oral film, dolasetron (Anzemet) oral tablet, Cinvanti (aprepitant) IV emulsion, Emend (aprepitant) oral suspension, Varubi (rolapitant) oral capsule, Akynzeo (palonosetron/netupitant) oral capsule, IV solution Any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	None
Required Medical Information	See "Other Criteria"
Age Restrictions	None
Prescriber Restrictions	Prescribed by, 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	• The medication is being requested for a Food and Drug Administration (FDA) approved indication or a medical condition that is supported by the medical compendium, the National Comprehensive Cancer Network (NCCN), and/or American Society of Clinical Oncology (ASCO) standard of care guidelines for antiemetic therapy.

Revision/Review Date
12/2023
	• The requested dosing of the 5-HT3 RA and/or NK1 RA is within FDA approved, NCCN/ASCO or other medical compendia standard of care guidelines
	• Patients meeting one of the following criteria may receive the generic 5-HT3 RA palonosetron hydrochloride without prior trial and failure of ondansetron/granisetron
	  o Adult patients receiving an antineoplastic agent with HIGH or MODERATE emetic risk per the NCCN Practice Guidelines
	  o Pediatric patients receiving an antineoplastic agent with HIGH emetic risk per the NCCN Practice Guidelines who are unable to receive dexamethasone
	• For all other patients, if the medication request is for any 5-HT3 RA other than ondansetron, granisetron, or an NK1-RA other than aprepitant oral capsule or fosaprepitant IV emulsion:
	  o The patient has a documented treatment failure after receiving an adequate trial of a preferred 5-HT3 RA and a preferred NK1 RA and/or has a documented medical reason (intolerance, hypersensitivity, contraindication, etc.) for not utilizing these medications to treat their medical condition.
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Prior Authorization Group Description	**Adakveo (crizanlizumab-tmca)**
Drugs	Adakveo (crizanlizumab-tmca)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	Member must be 16 years of age or older
Prescriber Restrictions	Prescriber must be a hematologist or sickle cell specialist
Coverage Duration	If the criteria are met, requests may be approved for 12 months.

Other Criteria
 	
Revision/Review Date: 7/2023
	Initial Authorization:
	• Member has a confirmed diagnosis of sickle cell disease
	• Documentation was provided that the member has had 2 or more pain crises in the last 12 months
	• Documentation was provided that the member has been taking hydroxyurea at the maximum tolerated dose and has been compliant within the last 6 months (or a medical reason was provided why the patient is unable to use hydroxyurea)
	• Documentation of the member’s current weight
	• Request is for an FDA-approved dose
	
	Reauthorization:
	• Documentation has been submitted that the member has demonstrated or maintained ONE of the following changes from baseline:
	    o Reduction in pain crises
	    o Increased time between crises
	    o Decrease in days hospitalized
	• Documentation of the member’s current weight
	• Request is for an FDA-approved dose
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

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

Other Criteria	**Initial Authorization:**
	• Member must have documentation of baseline low density lipoprotein cholesterol (LDL-C)
	• One of the following:
	  o Member has a diagnosis of heterozygous familial hypercholesterolemia (FH)
	  o Member has a diagnosis of hyperlipidemia and atherosclerotic cardiovascular disease (ASCVD) as evidenced by a fasting LDL-C $\geq$ 70 mg/dL and a history of least one of the following:
	    ▪ Myocardial infarction or acute coronary syndrome,
	    ▪ Stroke or transient ischemic attack,
	    ▪ Coronary artery disease with stable angina,
	    ▪ Coronary or other arterial revascularization,
	    ▪ Peripheral vascular disease, or
	    ▪ Aortic aneurysm
	    ▪ Clinically significant congenital heart disease (CHD) diagnosed by invasive or non-invasive testing (such as coronary angiography, stress test using treadmill, stress echocardiography, or nuclear imaging)

Revision/Review Date 7/2023	• Member has tried and failed a high-intensity statin (i.e. atorvastatin 40-80 mg, rosuvastatin 20-40 mg) at maximum tolerated dose for 3 months via claim history or chart notes OR documentation has been provided that the member is not able to tolerate a statin.
	• Member has tried and failed ezetimibe at a maximum tolerated dose or documentation has been provided that the patient is not able to tolerate ezetimibe.
	• Member will continue on maximum tolerated statin dose while receiving Nexletol/Nexlizet or documentation has been provided that the member is not able to tolerate a statin.
	• Documentation was provided indicating provider has counseled member on smoking cessation and following a "heart healthy diet".
	
	Reauthorization:
	• Documentation provided that the member has obtained clinical benefit from medication (e.g. LDL-C lowering from baseline)
	• One of the following:
	    o Member will continue on maximum tolerated statin and ezetimibe dose while receiving Nexletol or documentation has been provided that the member is not able to tolerate a statin and/or ezetimibe.
	    o Member will continue on maximum tolerated statin dose while receiving Nexlizet, or documentation has been provided that the member is not able to tolerate a statin
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

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

Other Criteria	**<u>Initial Authorization:</u>**
	• Member has confirmed diagnosis of Cushing's Disease
	• Pituitary surgery is not an option or has not been curative
	• Provider attests baseline electrocardiogram (ECG) has been obtained and hypokalemia and/or hypomagnesemia has been corrected prior to initiating therapy if present
	• The medication is being prescribed at a dose that is consistent with FDA-approved package labeling, nationally recognized compendia or peer-reviewed literature
	• Documented baseline urinary free cortisol (UFC) test ≥ 1.3upper limit of normal (ULN)
	  o UFC Normal Range = 3.5-45 mcg/24 hrs (9.66-124.2 nmol/24 hrs)
	• Member has had a documented trial and failure of one of the following:
	  o ketoconazole
	  o Metopirone (metyrapone)
	  o Lysodren (mitotane)
	  o cabergoline
	  o Signifor/Signifor LAR (pasireotide)
	  o etomidate
	OR
	Member has a documented medical reason (e.g. contraindication, intolerance, hypersensitivity) as to why these medications cannot be used

Revision/Review Date: 1/2023	**<u>Reauthorization:</u>** • Member has responded to therapy as defined by a documented urinary free cortisol (UFC) test ≤ the upper limit of normal (ULN) • The medication is being prescribed at a dose that is consistent with FDA-approved package labeling, nationally recognized compendia **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	Adrenal Enzyme Inhibitors for Cushing's Syndrome
Drugs	Recorlev (levoketoconazole)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Patients with a non-endogenous source of hypercortisolism, such as exogenous source of glucocorticoids or therapeutic use of ACTH. • Patient has a diagnosis of pituitary or adrenal carcinoma
Required Medical Information	See "Other Criteria"
Age Restrictions	Per FDA approved package insert
Prescriber Restrictions	Prescriber must be an endocrinologist or in consultation with an endocrinologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 4/2023	**Initial Authorization:** • 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 $\geq$ 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. **Re-Authorization:** • 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 **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Adrenergic, alpha-receptor-blocking agent**
Drug(s)	Phenoxybenzamine (Dibenzyline)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or specialist in the management of pheochromocytoma.
Coverage Duration	If the conditions are met, the request will be approved for up to a 14-day duration for perioperative management or up to a 6 month duration for non-surgical initial requests. For continuation of therapy, the request will be approved for 12 months. Medical Director/clinical reviewer for medical necessity review.
Other Criteria Revision/Review Date: 1/2023	**Initial Authorization:** • Diagnosis of pheochromocytoma • Documented use for either perioperative management or long term use when surgery is contraindicated • Documented trial and failure, intolerance, or contraindication to doxazosin • Medication is prescribed at an FDA approved dose **Re-Authorization** • Documented long term use when surgery is contraindicated • Documentation or provider attestation that demonstrates a clinical benefit • Medication is prescribed at an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Aduhelm (aducanumab)**
Drugs	Aduhelm (aducanumab) *****Initial authorizations and reauthorizations must be approved by a Medical Director*****
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Patients with moderate to severe Alzheimer's Disease (AD) Patients with neurodegenerative disease caused by a condition other than AD
Required Medical Information	See "Other Criteria"
Age Restrictions	None
Prescriber Restrictions	Prescriber must be prescribed by, or in consultation with, a specialist in neurology or gerontology
Coverage Duration	For initial authorization: the request will be approved in accordance with the FDA-indicated titration schedule for up to 6 months For reauthorization: if all of the conditions are met, the request will be approved for 6 months.

Other Criteria	**<u>Initial Authorization</u>**
	• Diagnosis of mild cognitive impairment (MCI) caused by AD or mild AD as evidenced by at least one of the following:
	  o Clinical Dementia Rating Global (CDR-G) score of 0.5 (very mild dementia)
	  o Repeatable Battery for Assessment of Neuropsychological Status (RBANS) delayed memory index (DMI) score ≤ 85 (low average)
	  o Mini-Mental State Examination (MMSE) score ≥ 24 (questionably significant impairment)
	• The request is for an FDA approved dose
	• Documentation of BOTH of the following:
	  o Recent, within past year, positive results for the presence of beta-amyloid plaques on a positron emission tomography (PET) scan or cerebrospinal fluid testing
	  o Recent, within past year, baseline Magnetic Resonance Imaging (MRI) scan
	• Not currently using blood thinners (except aspirin)

	- No recent (past 1 year) history of stroke or transient ischemic attack (TIA)
	
	<u>Reauthorization</u>
	- The request is for an FDA approved dose
	- Provider attestation of safety monitoring and management of amyloid related imaging abnormalities (ARIA) and intracerebral hemorrhage, as recommended per the manufacturer's prescribing information.
	- Patient continues to have a diagnosis of mild cognitive impairment (MCI) caused by AD or mild AD consistent with Stage 3 or Stage 4 Alzheimer's disease as evidenced by at least one of the following:
	    o CDR-G score of 0.5 (very mild dementia)
	    o RBANS DMI score ≤ 85 (low average)
	    o MMSE score of 24-30
	- Not currently using blood thinners (except aspirin)
	- No recent (past 1 year) history of stroke or TIA
	- Recent, within past year, positive results for the presence of beta-amyloid plaques on a positron emission tomography (PET) scan
	
	If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.

Revision/Review Date: 7/2023	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Agents for Atopic Dermatitis**
Drugs	**Preferred:** Dupixent (dupilumab) Elidel (pimecrolimus) Eucrisa (crisaborole) pimecrolimus (Elidel) Protopic (tacrolimus) tacrolimus (Protopic) **Non-Preferred:** Adbry (tralokinumab) Cibinqo (abrocitinib) Opzelura (ruxolitinib) Rinvoq (abrocitinib)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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, or allergist
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	**<u>Initial Authorization</u>** **For pimecrolimus:** o Diagnosis of <u>mild to moderate</u> atopic dermatitis (AD) o For mild AD: trial and failure of one formulary medium to high potency topical corticosteroid o For moderate AD: Trial and failure of one formulary medium to high potency topical corticosteroid AND topical tacrolimus **For tacrolimus:** o Diagnosis of <u>moderate to severe</u> AD o Trial and failure of one formulary medium to high potency topical corticosteroid

	For Eucrisa:
	o Diagnosis of <u>mild to moderate</u> AD
	o Trial and failure of one formulary medium to high potency topical corticosteroid
	o Trial and failure of topical tacrolimus or pimecrolimus (for members less than 2 years of age requesting Eucrisa, trial of topical tacrolimus of pimecrolimus is not required)
	
	For Dupixent :
	o Diagnosis of <u>moderate to severe</u> AD
	o For <u>moderate</u> AD: Trial and failure, or contraindication/intolerance to TWO of the following:
	    o One formulary medium to high potency topical corticosteroid
	    o Topical tacrolimus or pimecrolimus (for members less than 2 years of age requesting Dupixent, trial of topical tacrolimus or pimecrolimus is not required)
	    o Eucrisa (crisaborole)
	o For <u>severe</u> AD: Trial and failure of, or contraindication/intolerance to, ALL of the following:
	    o One formulary topical medium to high potency topical corticosteroid
	    o Topical tacrolimus (for members less than 2 years of age requesting Dupixent, trial of topical tacrolimus is not required)
	For Adbry:
	o Diagnosis of <u>moderate to severe</u> AD
	o For <u>moderate</u> AD: Trial and failure, or contraindication/intolerance to ALL of the following:
	    o One formulary medium to high potency topical corticosteroid
	    o Topical tacrolimus or pimecrolimus
	    o Eucrisa (crisaborole)
	o For <u>severe</u> AD: Trial and failure of, or contraindication/intolerance to, ALL of the following:
	    o One formulary topical medium to high potency topical corticosteroid
	    o Topical tacrolimus
	
	<u>For Opzelura:</u>
	o Diagnosis of mild to moderate AD
	o Member must have 3% to 20% of body surface are (BSA) atopic dermatitis involvement (excluding scalp)
	o Trial and failure, or contraindication/intolerance to, ALL of the following:
	    o One formulary medium to high potency topical corticosteroid
	    o Topical tacrolimus or pimecrolimus
	    o Eucrisa (crisaborole)

Revisio 7/2023	**<u>**A MAXIMUM of ONE 60 g TUBE of OPZELURA MAY BE APPROVED PER WEEK**</u>**
	
	<u>For Rinvoq or Cibinqo:</u>
	• Diagnosis of refractory, moderate to severe, AD
	• For moderate AD: Trial and failure of, or contraindication to, ALL of the following:
	    o One formulary topical medium to high potency topical corticosteroid
	    o Topical tacrolimus or pimecrolimus
	    o Eucrisa (crisaborole)
	• For severe AD: Trial and failure of, or contraindication to ALL of the following:
	    o One formulary medium to high potency topical corticosteroid
	    o Topical tacrolimus
	• Trial and failure of, intolerance to, or contraindication to another systemic drug product
	
	<u>Reauthorization:</u>
	o Prescriber attests that the member has experienced improvement in symptoms (e.g. significant clearing of the skin, reduction in itching)
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

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

Revision/Review Date: 12/2023	calcineurin inhibitors, mycophenolate mofetil, ibrutinib, ruxolitinib), one of which must be a systemic corticosteroid, or documentation is provided as to why a systemic corticosteroid cannot be used
	    o The drug is prescribed at an FDA-approved dose
	• Orencia
	    o Orencia is being requested for prophylaxis against acute graft versus host disease
	    o Member will be undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor
	    o Member will be receiving Orencia in combination with a calcineurin inhibitor (e.g., tacrolimus, cyclosporine) and methotrexate
	    o Member will be receiving antiviral prophylactic treatment for Epstein-Barr virus reactivation and will continue for 6 months following HSCT
	    o Attestation provider has considered prophylactic antivirals for cytomegalovirus (CMV) infection/reactivation during treatment and for 6 months following HSCT
	    o The drug is prescribed at an FDA-approved dose
	
	Re-Authorization:
	• Documentation is provided that the member has achieved a clinical benefit from medication (e.g. symptom improvement, reduction in corticosteroid dose)
	• The drug is prescribed at an FDA-approved dose
	
	If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

S!Field Name	Field Description
Prior Authorization Group Description	**Agents for Homozygous Familial Hypercholesterolemia (HoFH)**
Drugs	**Preferred:** Evkeeza (evinacumab-dgnb) **Non-Preferred:** Juxtapid (lomitapide) ****Please refer to the "Proprotein Convertase Subtilisin/kexin 9 (PCSK9) Inhibitors" policy for requests for medications in that class****
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by cardiologist or specialist in treatment of lipid disorders.
Coverage Duration	If all of the above conditions are met, the initial request will be approved for up to a 6 month duration, and the reauthorization request will be approved for a 12 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

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

Revision/Review Date 1/2023	• 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. • Patient has tried and failed ezetimibe at a maximal tolerated dose or a medical reason was provided why the member is not able to use ezetimibe • Member has documented trial and failure with PCSK9 inhibitor for at least 3 months, or a medical reason has been provided, why member is unable to use a PCSK9 inhibitor indicated for HoFH to manage their condition. • Documentation was provided indicating provider has counseled member on smoking cessation and following a “heart healthy diet”. • Documentation was provided of current LDL level • If the request is for Juxtapid the member has had documented trial and failure with Evkeeza for at least 6 month or a medical reason has been provided why the member is unable to use Evkeeza **Reauthorization:** • Documentation submitted indicates that the member has obtained clinical benefit from the medication including repeat fasting lipid panel lab report, and the member has achieved or maintained a LDL reduction from the levels immediately prior to initiation of treatment with Juxtapid. • The patient’s claim history shows consistent therapy (monthly fills). **Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

<table>
<tr><td>Prior Authorization Group Description</td><td>Agents for Thrombocytopenia</td></tr>
<tr><td>Drugs</td><td><u>Preferred Thrombocytopenia Agent(s)</u>:
• Promacta (eltrombopag)
• Doptelet (avatrombopag)

<u>Non-Preferred Thrombocytopenia Agent(s)</u>:
• Nplate (romiplostim)
• Mulpleta (lusutrombopag)
• Tavalisse (fostamatinib)</td></tr>
<tr><td>Covered Uses</td><td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td></tr>
<tr><td>Exclusion Criteria</td><td>N/A</td></tr>
<tr><td>Required Medical Information</td><td>See “other criteria”</td></tr>
<tr><td>Age Restrictions</td><td>For Doptelet, Mulpleta, and Tavalisse, member must be 18 years or older
ITP: For Promacta and Nplate, member must be 1 year or older.
Severe aplastic anemia: For Promacta, member must be 2 years or older.</td></tr>
<tr><td>Prescriber Restrictions</td><td>Prescriber must be a hematologist</td></tr>
<tr><td>Coverage Duration</td><td>If the criteria are met, the requests for Promacta, 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.</td></tr>
<tr><td>Other Criteria</td><td>Chronic immune (idiopathic) thrombocytopenia (ITP):
• Platelet count < 30,000 cells/microL
• Documented trial and failure, or intolerance, contraindication, to ONE of the following:
  o Glucocorticoids
  o Intravenous immune globulin (IVIG)
  o Rituximab
  o splenectomy
• If the request is for Doptelet, Nplate or Tavalisse, the member has a documented trial and failure, intolerance, or contraindication to Promacta

Severe aplastic anemia (Promacta only):
• Promacta is being prescribed in conjunction with at least one immunosuppressive agent OR there is a documented trial and</td></tr>
</table>

Revision/Review Date 4/2023	failure, intolerance, or contraindication to at least one immunosuppressive agent • Platelet count < 20,000 cells/microL OR platelet cout < 30,000 cells/microL with bleeding OR reticulocyte count < 20,000 cells/microL OR absolute neutrophil count < 500 cells/microL **Thrombocytopenia in patients with Hepatitis C infection** (Promacta only): • Diagnosis of chronic hepatitis C • Platelet count < 50,000 cells/microL • Documented treatment with interferon-based therapy AND patient's degree of thrombocytopenia prevents the initiation or limits the ability to maintain interferon-based therapy **Thrombocytopenia associated with chronic liver disease in _adult_ patients requiring elective surgery** (Doptelet and Mulpleta only): • Patient has a diagnosis of chronic liver disease and is scheduled to undergo a procedure • Platelet count < 50,000 cells/microL • For Mulpleta, approve if there is documentation of trial and failure, intolerance, or contraindication to use Doptelet **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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

Revision/Review Date 1/2023	documented medical reason (intolerance, hypersensitivity, contraindication, treatment failure, etc.) for not using Prolastin-C to treat their medical condition **Reauthorization:** • Documentation of the member's current weight • Documentation was submitted indicating member is a non-smoker or an ex-smoker (e.g. smoking cessation treatment) • Documentation was submitted indicating the member has clinically benefited from therapy (i.e. stable lung function, improved PFTs, alpha-1 antitrypsin serum level maintained above 11 micromol/L [approximately 57 mg/dL using or 80 mg/dL by radial immunodiffusion], improved quality of life) • The Alpha-1 Proteinase Inhibitor (human) is being prescribed at an FDA approved dosage **Clinical reviewer/Medical Director must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

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	**<u>Initial Authorization:</u>** • 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 **<u>Re-authorization:</u>** • 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
Revision/Review Date 1/2023	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**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 prescribers who specialize in the treatment of lymphoma.
Coverage Duration	If all the criteria are met, the initial request will be approved for a one – time infusion per lifetime.

Other Criteria	**Initial authorization:**
	• Patient must not have received prior anti-CD19 CAR-T therapy.
	• Patient will be screened for HBV, HCV, and HIV in accordance with clinical guidelines.
	• Patient does not have an active infection or inflammatory disorder.
	• Patient has a life expectancy >12 weeks.
	• Patient will not receive live virus vaccines for at least 6 weeks prior to the start of lymphodepleting chemotherapy and until immune recovery following treatment.
	
	Leukemia
	
	B-cell precursor Acute Lymphoblastic Leukemia (ALL):
	• If the request is for Kymriah
	    o Patient is 25 years of age or younger
	    o ALL that is refractory or in second or later relapse
	• If the request is for Tecartus
	    o Patient is 18 years of age or older
	    o ALL that is relapsed or refractory
	
	Non-Hodgkin's Lymphoma (NHL)
	
	Mantle Cell Lymphoma (MCL):
	• If the request is for Tecartus:
	    o Patient is 18 years of age or older

Revision/Review Date: 12/2023	- Patient has relapsed/refractory disease defined as failure of BOTH the following lines of therapy:
	    ▪ Chemoimmunotherapy such as an anti-CD20 monoclonal antibody (e.g. Rituxan) + any chemotherapeutic agent
	    ▪ Bruton Tyrosine Kinase (BTK) Inhibitor (e.g. Calquence, Imbruvica, Brukinsa)
	
	Other forms of NHL:
	• If the request is for Breyanzi (lisocabtagene maraleucel), Kymriah (tisagenlecleucel), Yescarta (axicabtagene ciloleucel)
	  o Use is supported by a labeled indication or NCCN guidelines
	  o Patient is 18 years of age or older
	  o For Breyanzi: One of the following:
	    ▪ Patient is refractory to first-line chemoimmunotherapy or relapses within 12 months of first-line chemoimmunotherapy
	    ▪ Patient is refractory to first-line chemoimmunotherapy or relapses 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
	  o For Kymriah: Patient has relapsed/refractory disease defined as failure of two or more lines of systemic therapy
	  o For Yescarta: Patient refractory to first-line chemoimmunotherapy or relapses within 12 months of first-line chemoimmunotherapy OR has failed two or more lines of systemic therapy
	
	<u>Re-authorization</u>:
	• Treatment exceeding 1 dose per lifetime will not be authorized.
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Prior Authorization Group Description	**Anti-FGF23 Monoclonal Antibodies**
Drugs	Crysvita (burosumab) SQ solution, or any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: The Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	See Other Criteria
Required Medical Information	See Other Criteria
Age Restrictions	X-linked hypophosphatemia (XLH): 6 months of age or older Tumor-induced osteomalacia (TIO): 2 years of age and older
Prescriber Restrictions	Prescribed by, or in consultation with, an endocrinologist, nephrologist, molecular geneticist, or other specialist experienced in the treatment of metabolic bone disorders
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months and reauthorization requests will be approved for 12 months.

Other Criteria	<u>**Initial Authorization:**</u>
	
	For X-linked hypophosphatemia (XLH):
	• Diagnosis of XLH
	• Dosing is appropriate as per labeling or is supported by compendia or standard of care guidelines
	• Labs, as follows:
	    o Serum phosphorus below normal for patient age
	    o eGFR > 30 mL/min/1.73 m2 or CrCl ≥ 30 mL/min
	• Patient will not use concurrent oral phosphate and/or active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol)
	• Additionally, for adults:
	    o Clinical signs and symptoms of XLH (e.g. bone/joint pain, fractures, osteomalacia, osteoarthritis, ensethopathies, spinal stenosis impaired mobility, presence or history of lower limb deformities, etc.)
	    o Trial and failure of, or contraindication to, combination therapy with oral phosphate and active vitamin D (calcitriol) for a minimum of 8 weeks
	
	For tumor-induced osteomalacia (TIO):
	• Diagnosis of FGF23-related hypophosphatemia in TIO
	• Dosing is appropriate as per labeling or is supported by compendia or standard of care guidelines

Revision/Review Date: 12/2023	- The tumor(s) is/are not amenable to surgical excision or cannot be located - Labs, as follows: - 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) **<u>Re-authorization:</u>** **For XLH or TIO:** - Documented effectiveness as evidenced by at least one of the following: - 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 **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-Fungal Medications
Drugs	**Preferred:** ciclopirox solution 8% solution itraconazole 100 mg capsule, solution luliconazole 1% cream oxiconazole 1% cream tavaborole 5% solution terbinafine 250 mg tablet **Non-Preferred:** Jublia (efinaconazole) Kerydin (tavaborole) Luzu (luliconazole) Oxistat (oxiconazole) Sporanox (itraconazole)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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	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; itraconazole (Sporanox), luliconazole (Luzu), oxiconazole (Oxistat), terbinafine: up to 3 months
Other Criteria	**For all requests:** • 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 **Additional Requirements for Onychomycosis:** • Onychomycosis confirmed by a positive KOH stain, positive PAS

Date: 1/2023	stain, or a positive fungal culture, and experiencing pain that limits normal activity. • If the request is for a topical agent, the member has failed either oral terbinafine, oral itraconazole, or oral fluconazole **<u>Additional Requirements for luliconazole (Luzu) & oxiconazole (Oxistat):</u>** • 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 **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	**Anti-Parkinson's Agents for OFF Episodes**
Drugs	Preferred: Ongentys (opicapone), Xadago (safinamide) Non-preferred: Nourianz (istradefylline), Inbrija (levodopa) inhalation, Apokyn (apomorphine), Kynmobi (apomorphine) or any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: The Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	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	**<u>Initial Authorization:</u>**
	• Diagnosis of Parkinson's disease
	• Patient is currently taking and will continue to take carbidopa/levodopa
	• Patient is experiencing symptom fluctuations or off episodes while taking carbidopa/levodopa where attempts have been made to adjust the carbidopa/levodopa dose and/or formulation in order to manage symptoms without success
	• Documented trial and failure (or contraindication) to **at least two** of the following adjunctive medication classes:
	    o COMT-inhibitors (e.g., entacapone)
	    o Dopamine agonists (e.g., ropinirole, pramipexole)
	    o MAO-B inhibitors (e.g., rasagiline, selegiline)
	• Dosing is appropriate as per labeling or is supported by compendia or standard of care guidelines
	• If the request is for Inbrija, patient does not have asthma, COPD, or other chronic underlying lung disease
	• If the request is for Nourianz, Inbrija, Apokyn, Kynmobi or any other newly marketed agent, patient must also have a documented trial and failure or intolerance to Ongentys and Xadago.
	<u>Re-authorization:</u>
	• Documentation of positive clinical response

Revision/Review Date 1/2023	• Dosing is appropriate as per labeling or is supported by compendia or standard of care guidelines **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

<u>Antifibrotic Respiratory Tract Agents</u>

<u>Drugs:</u>
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.

<u>INITIAL CRITERIA:</u>
<u>For all requests:</u>
- 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

<u>If the request is for Idiopathic Pulmonary Fibrosis (IPF):</u>
- Confirmed diagnosis of IPF
- Pulmonary function test indicate patient has Forced Vital Capacity (%FVC) ≥ 50% within 30 days of request

<u>If the request is for Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) *(Ofev only)*:</u>
- Confirmed diagnosis of SSc-ILD
- FVC ≥ 40% within 30 days of request
- Trial and failure of mycophenolate mofetil (MMF), cyclophosphamide or azathioprine.

<u>If the request is for Chronic Fibrosing Intersitial Lung Diseases (ILDs) with a progressive phenotype *(Ofev only)*:</u>
- Diagnosis of chronic fibrosing ILD (such as connective tissue disease [CTD]-associated ILD, chronic fibrosing hypersensitivity pneumonitis [HP], idiopathic non-specific interstitial pneumonia [iNSIP], unclassifiable idiopathic interstitial pneumonia [IIP]) of a progressive phenotype
- Recent (12 month) history of treatment with at least one medication to treat ILD (e.g., corticosteroid, azathioprine, MMF, n-acetylcysteine (NAC), rituximab, cyclophosphamide, cyclosporine, or tacrolimus).
- FVC ≥ 45% predicted within 30 days of request

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

<u>REAUTHORIZATION CRITERIA:</u>

- 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: 7/2023

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

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

Revision/Review Date 4/2023	• 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 **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	**Atovaquone Suspension**
Drugs	Atovaquone (Mepron) suspension
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 6 month duration.
Other Criteria Revision/Review Date 4/2023	<u>Treatment/Prevention of *Pneumocystis jirovecii* pneumonia</u> • Diagnosis of mild to moderate *Pneumocystis jirovecii* pneumonia (PCP) or diagnosis with the need to prevent PCP infection • Documented trial and failure with therapeutic doses or intolerance to trimethoprim- sulfamethoxazole (TMP-SMX). • Documented trial and failure with therapeutic doses or intolerance to dapsone. <u>Treatment/Prevention of *Toxoplasma gondii* encephalitis in patients with HIV</u>: • Diagnosis of *Toxoplasma gondii* encephalitis or documentation of supporting diagnosis for prophylaxis • Documented trial and failure with therapeutic doses or intolerance to trimethoprim- sulfamethoxazole (TMP-SMX). **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**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	**<u>Initial Authorization</u>**
	• Member has a diagnosis of relapsed or refractory multiple myeloma (RRMM)
	• Member must have received at least 4 prior lines of therapy, which must include ALL of the following:
	  o An immunomodulatory agent (e.g. lenalidomide, pomalidomide, thalidomide)
	  o A proteasome inhibitor (e.g. bortezomib, carfilzomib, ixazomib)
	  o An anti-CD38 monoclonal antibody (e.g. daratumumab, isatuximab)
	• Member does not have an active infection
	• Member will be screened for cytomegalovirus (CMV), hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines
	• Member will not receive live virus vaccines for at least 6 weeks prior to the start of lymphodepleting chemotherapy and until immune recovery following treatment
	• Member has not previously received a BCMA CAR-T therapy
	
	<u>Re-authorization:</u>
	• Treatment exceeding 1 dose per lifetime will not be authorized.

Revision/Review Date 12/2023	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**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	**<u>Initial Authorization</u>**: • <u>Active systemic lupus erythematosus (SLE)</u> o Provider attestation that the patient is positive for autoantibodies (or antinuclear antibodies or anti–double-stranded DNA [anti-dsDNA] antibodies) o The member has tried and failed both of the following (or contraindication/inability to use these medications): ▪ Hydroxychloroquine ▪ One other immunosuppressant [e.g., methotrexate, azathioprine, calcineurin inhibitors or mycophenolate] • <u>Active lupus nephritis</u> o Provider attestation of diagnosis confirmed by kidney biopsy o The member has tried and failed, or has a medical reason for not using, both of the following ▪ Cyclophosphamide or tacrolimus ▪ Mycophenolate • Provider states the member will not be receiving concomitant therapy with the following: o B-cell targeted therapy including (but not limited to) rituximab o Interferon receptor antagonist, type 1 including (but not limited to) Saphnelo (anifrolumab) • Dosing is appropriate per labeling **<u>Criteria for Reauthorization</u>**: • Documentation or provider attestation of positive clinical response as indicated by one of the following: o Fewer flares that required steroid treatment

Revision/Review Date: 1/2023	- 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	Prescriber must be an allergist or otolaryngologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy the request will be approved for 6 months.
Other Criteria	****Xolair: For asthma and urticaria, please refer to the “Xolair for Asthma and Urticaria” policy**** ****Dupixent: For atopic dermatitis, please refer to the “Agents for Atopic Dermatitis” policy; For asthma, please refer to the “Pulmonary Biologics for Asthma and Eosinophilic Conditions” policy**** ****Nucala: For asthma or other eosinophilic conditions, please refer to the “Pulmonary Biologics for Asthma and Eosinophilic Conditions” policy**** **<u>Initial Authorization:</u>** • Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) • Medication is being prescribed at an FDA approved dosage • Documentation of ONE of the following: o Trial and failure, or medical reason for not using, all of the following therapies: ▪ Intranasal saline irrigation/spray ▪ an intranasal corticosteroid ▪ a systemic corticosteroid ▪ montelukast o Prior surgery for nasal polyps

Revision/Review Date 4/2023	• Patient is currently using an intranasal corticosteroid, will be prescribed at an intranasal corticosteroid, or has a documented medical reason for not using an intranasal corticosteroid **<u>Re-authorization:</u>** • Medication is prescribed at an FDA-approved dosage • Member will continue to use an intranasal corticosteroid, or has a medical reason for not using an intranasal corticosteroid • Documentation has been provided that demonstrates a clinical benefit (e.g. improvements in symptom severity, nasal polyp score [NPS], sino-nasal outcome test-22 [SNOT-22], nasal congestion score [NCS], nasal obstruction symptom visual analogue scale [VAS]) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Blincyto**
Drugs	Blincyto (blinatumomab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restriction	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist/hematologist
Coverage Duration	The request will be approved for up to a 12 month duration.
Other Criteria Revision/Review Date 12/2023	**Initial Authorization:** • Patient has a diagnosis of one of the following forms of Acute Lymphoblastic Leukemia (ALL): a) Relapsed CD19-positive B-cell precursor ALL b) Refractory CD19-positive B-cell precursor ALL c) CD19-positive B-cell precursor ALL in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1% • Provider attests to monitor patient for Cytokine Release Syndrome (CRS) and neurological toxicities **Reauthorization:** • 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 ***For CD19-positive B-cell precursor ALL with MRD, reauthorization is not allowed*** **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Botulinum Toxins A&B**
Drugs	**Preferred Agents for FDA approved indications:** IncobotulinumtoxinA (Xeomin) AbobotulinumtoxinA (Dysport) **Non-preferred Agents:** OnabotulinumtoxinA (Botox) RimabotulinumtoxinB (Myobloc) DaxibotulinumtoxinA (Daxxify) Or any newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	According to package insert
Prescriber Restrictions	None
Coverage Duration	If all of the conditions are met, the request will be approved for 12 month duration.

Other Criteria	****The use of these medications for cosmetic purposes is NOT a covered benefit under the Medical Assistance program****
	
	For Initial Approval:
	
	• The drug is being used for a medically accepted indication and dose as outlined in Covered Uses
	• The member has tried and failed standard first line therapy for their disease state and/or has a documented medical reason (intolerance, hypersensitivity, contraindication, etc) for not using first line therapy
	• If the diagnosis is **Chronic Migraines** (≥15 days per month with headache lasting 4 hours a day or longer), the member has tried and failed, or has a medical reason for not using one drug from two of the following categories for at least 4 weeks each at a minimum effective dose:
	  o Beta blockers (e.g. propranolol, timolol, etc.)
	  o Amitriptyline or venlafaxine

Revision/Review Date 10/2023	o 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,** o Documentation is provided that the member has had sialorrhea lasting at least 3 months o The member has tried and failed, or has a medical reason for not using, an anticholinergic medication (e.g. glycopyrrolate, hyoscyamine, benztropine) • If the request is for a non-preferred agent, the member tried and failed a preferred agent if appropriate for the requested indication **For Reauthorization:** • Documentation of provider attestation that demonstrates a clinical benefit • The requested drug is for a medically accepted dose as outlined in Covered Uses **Physician/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Brineura (cerliponase alfa)**
Drugs	Brineura (cerliponase alfa)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert, and/or per the National Comprehensive Cancer Network (NCCN)
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	Member must be 3 years of age or older
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	If the criteria are met, the request will be approved for 6 months.

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

Revision/Review Date: 7/2023	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Buprenorphine/Naloxone and Buprenorphine (Oral) Criteria**
Drugs	**Preferred:** buprenorphine (Subutex) buprenorphine/naloxone* (Suboxone) **Preferred buprenorphine/naloxone products for doses of 24 mg/day or less do NOT require a prior approval (PA)* Zubsolv (buprenorphine/naloxone) **Non-Preferred:** Suboxone (buprenorphine/naloxone)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the 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	**All requests:** 1. Diagnosis of opiate use disorder 2. Attestation that the New Hampshire Prescription Drug Monitoring (PDMP) has been reviewed within the last 60 days **Buprenorphine Single Agent Products:** 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) **Non-Preferred Products:** 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

Revision/Review Date 7/2023	**Concurrent Use/ Drug-Drug Interaction:** 5. The provider must submit a medical reason why treatment with both drugs is necessary for the member 6. The increased risk for side effects when taking the drugs together has been discussed with the member 7. Medications must be prescribed by the same provider for the following scenarios: a. If the request is for concurrent medication-assisted treatment (MAT) agent and a benzodiazepine b. 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) **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	**Calcitonin Gene-Related Peptide Inhibitors for Acute Migraine Treatment**
Drugs	**Preferred: Ubrelvy (ubrogepant)** **Non-Preferred: Nurtec ODT (rimegepant)** (if the request is for migraine prevention please refer to the Calcitonin Gene-Related Peptide (CGRP) Antagonists for Headache Prevention criteria); **Zavzpret (zavegepant)**; Or any newly marketed CGRP for acute migraine treatment
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	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	**<u>Initial Authorization:</u>** 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) Ubrelvy **<u>Criteria for Re-Authorization:</u>** • Documentation of improvement in migraine pain and symptom(s) (e.g., photophobia, nausea, phonophobia) **Nurtec ODT QL of 8 units per month.** **Ubrelvy QL of 16 units per month** **Zavzpret QL of 8 units per month** **<u>Criteria for exceeding the quantity limit</u> (note all of the above criteria must also be met)**

Revision/Review Date: 7/2023	• Documented trial and failure (or a medical justification for not using e.g. hypersensitivity, baseline bradycardia or hypotension, adverse events experienced from previous trial, etc.) with at least one drug from two categories below for at least 4 weeks EACH, at minimum effective doses: o Beta-adrenergic blockers o Topiramate or divalproex ER or DR o Amitriptyline or venlafaxine o Frovatriptan, zolmitriptan or naratriptan (for menstrual migraine prophylaxis) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Calcitonin Gene-Related Peptide (CGRP) Antagonists for Headache Prevention**
Drugs	**Preferred**: Ajovy (fremanezumab) Emgality (galcanezumab) 120 mg **Non-Preferred:** Aimovig (erenumab) Emgality (galcanezumab) 100 mg Vyepti (eptinezumab) Nurtec ODT (rimegepant) – if the request is for acute treatment of migraine, please refer to the Acute Migraine Treatments criteria Qulipta (atogepant) any newly marketed drug in the class
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Request for indication of **chronic** cluster headaches
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	If the criteria are met, the request will be approved for 6 months. Reauthorization may be approved for 6 months.
Other Criteria	**<u>Criteria for Initial Authorization:</u>** **<u>Cluster Headache:</u>** • 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 **<u>Migraine Headache Prophylaxis:</u>** • Diagnosis of episodic migraine as evidenced by number of headache days per month (4 to 14 migraine days per month) or chronic migraine

Revision/Review Date: 7/2023	(≥ 15 headache days per month with ≥ 8 migraine days per month) despite use of abortive therapy (e.g. triptan or NSAIDs) • 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: 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. **<u>Criteria for Re-Authorization:</u>** **Episodic Cluster Headache:** • Documented reduction in the frequency of headaches (clinical benefit) **Migraine:** • Documented clinical benefit as evidenced by one of the following: o Reduction of ≥50% in the number of headache days per month relative to pre-treatment baseline (clinical benefit) o Improvement in member's Migraine Disability Assessment (MIDAS), Migraine Physical Function Impact diary (MFPDI), or Headache Impact Test (HIT-6) score **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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

Other Criteria	**<u>Initial Authorization:</u>**
	• Diagnosis of symptomatic New York Heart Association (NYHA) class II or III obstructive hypertrophic cardiomyopathy (oHCM)
	• Patient has a left ventricular ejection fraction (LVEF) ≥55%
	• Patient has a peak left ventricular outflow tract (LVOT) gradient ≥ 50 mmHg at rest or with provocation
	• Trial and failure or contraindication to ALL of the following:
	    o Beta blockers (i.e. metoprolol, propranolol, atenolol)
	    o Non-dihydropyridine calcium channel blockers (i.e. verapamil, diltiazem)
	• Prescriber attests that patient is not diagnosed with a disorder that causes cardiac hypertrophy that mimics oHCM (i.e., Fabry disease, amyloidosis, or Noonan syndrome with LV hypertrophy)
	• Prescriber attests that patient is not using moderate to strong CYP2C19 or CYP3A4 inhibitors or inducers
	• Medication is prescribed at an FDA approved dose
	
	<u>Re-Authorization:</u>
	• Documentation of clinical benefit as evidenced by an improvement 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%

Date: 7/2023	• Medication is prescribed at an FDA approved dose **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	**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 Revision/Review Date 1/2023	**Initial Authorization**: • Member has had a trial and failure, or intolerance to, cyclobenzaprine or a nonsteroidal anti-inflammatory drug (NSAID) in the last 90 days; **AND** • If the member has previously received a carisoprodol containing drug within the past 90 days, then the provider attests the member has been screened for, and demonstrates no signs of, carisoprodol abuse **Re-Authorization**: • Documentation has been provided that states the member has been screened for, and demonstrates no signs of, carisoprodol abuse **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Chelating Agents**
Drugs	• **Chemet (succimer)** capsule, *up to a 19 day supply, pays at point of sale* • **Deferasirox (Exjade)** Tablet for Oral Suspension • **Deferasirox (Jadenu)** Tablet, Granule Pack • **Deferiprone (Ferriprox)** Tablet • **Ferriprox (Deferiprone)** solution • **Ferriprox (Twice a Day) (Deferiprone)** tablet • **Deferoxamine Mesylate (Desferal)** Vial • **Penicillamine (Cuprimine, Depen, D-penamine)** capsule, tablet • **Radiogardase (Prussian blue)** capsule • **Trientine (Syprine)** capsule • **Cuvrior (trientine tetrahydrochloride)** tablet • **Galzin (Zinc acetate)** capsule • **Bal in Oil (Dimercaprol)** Ampule • **Pentetate calcium trisodium** ampule • **Pentetate zinc trisdoium** 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	**Requests for deferasirox (Exjade, Jadenu) only:** **Chronic iron overload due to blood transfusions:** For Pediatric Population**:**

- 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 > 300mcg/L at least one month apart - If the request is for deferasirox oral granules in packet member has had a documented trial and failure of deferasirox dispersible tablets or medical reason why deferasirox dispersible tablets cannot be used - The medication requested is being prescribed at an FDA approved dose **<u>Requests for Ferriprox (deferiprone) only:</u>** **<u>Transfusion Iron overload due to thalassemia syndrome, sickle cell disease, or other anemias</u>** - Patient must be ≥ 3 years old for oral solution OR ≥ 8 years old for tablets - Diagnosis of thalassemia syndrome, sickle cell disease, or other anemia - Patient receiving blood transfusions on a regular basis/participating in blood transfusion program - Serum Ferritin concentration is consistently > 1000 mcg/L. If the serum ferritin levels fall consistently below 500 mcg/L, Ferriprox must be discontinued - Documentation patient is unable to use deferoxamine (Desferal) parenterally - Documented trial and failure of deferasirox (Exjade, Jadenu) or medical reason why deferasirox cannot be used - If the request is for deferiprone 1,000 mg tablet there is a documented medical reason why deferiprone 500 mg tablet - If the request is for Ferriprox Twice a Day there is a documented medical reason why deferiprone 500 mg tablet and Ferriprox 1,000 mg tablet cannot be used - The medication requested is being prescribed at an FDA approved dose **<u>Requests for Wilson’s Disease:</u>** **Cuvrior (trientene tetrahydrochloride) only**: - Diagnosis of Wilson’s disease - Patient is de-coppered

Revision/Review Date 7/2023	• Patient is tolerant to penicillamine and will discontinue penicillamine before starting therapy with Cuvrior • The medication requested is being prescribed at an FDA approved dose **Trientene (Syprine) only:** • Diagnosis of Wilson's disease • Documented trial and failure, intolerance, or contraindication to penicillamine • The medication requested is being prescribed at an FDA approved dose **<u>Requests for all other drugs and indications:</u>** • The drug is requested for an appropriate use (per the references outlined in "Covered Uses") • The dose requested is appropriate for the requested use (per the references outlined in "Covered Uses") **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

<table>
<tr><td>Prior Authorization Group Description</td><td>Cholbam</td></tr>
<tr><td>Drugs</td><td>Cholbam (cholic acid)</td></tr>
<tr><td>Covered Uses</td><td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td></tr>
<tr><td>Exclusion Criteria</td><td>N/A</td></tr>
<tr><td>Required Medical Information</td><td>See “other criteria”</td></tr>
<tr><td>Age Restrictions</td><td>According to package insert</td></tr>
<tr><td>Prescriber Restrictions</td><td>MD is a gastroenterologist OR hepatologist</td></tr>
<tr><td>Coverage Duration</td><td>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.</td></tr>
<tr><td>Other Criteria</td><td><u>Initial authorization:</u>

Patient has a confirmed diagnosis of:

Bile acid synthesis disorder due to single enzyme defect (SEDs)

OR

Peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients that exhibit manifestations of liver disease, steatorrhea or complications from decreased fat soluble vitamin absorption

Current labs (within 30 days of request) have been submitted for the following:

ALT/AST
GGT (serum gamma glutamyltransferase)
ALP (Alkaline phosphatase)
Bilirubin
INR

<u>Re-authorization:</u>

Documentation has been submitted indicating clinical benefit/ liver function has improved since beginning treatment
For reauthorization after the first 3 months of treatment, lab results must show an improvement in liver function and there must be no evidence of biliary obstruction or cholestasis
Current labs (within 30 days of request) have been submitted for the following:

ALT/AST

</td></tr>
</table>

Revision/Review Date 10/2023	- GGT (serum gamma glutamyltransferase) - ALP (Alkaline phosphatase) - Bilirubin - INR **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Chronic Dry Eye Agents**
Drugs	<u>**FORMULARY STATUS**</u> Preferred, Pays at Point-of-Sale **ARTIFICIAL TEARS (Glycerin-Peg) 1 %-0.3 % Eye Drops** **POLYVINYL ALCOHOL 1.4 % Eye drops** **HYPROMELLOSE 0.3% Eye Drops** **REFRESH TEARS 0.5 % Eye Drops** <u>**FORMULARY STATUS**</u> Preferred, Requires Step Therapy with one prior step **CYCLOSPORINE 0.05% (RESTASIS) EYE DROPS** **RESTASIS EYE DROPS** **XIIDRA 5% EYE DROPS** **Note: Patient must meet criteria #1 & #2 for approval of the PA request.** <u>**FORMULARY STATUS**</u> Non-Preferred, Prior Authorization Required **CEQUA 0.09% EYE DROPS** **MIEBO EYE DROPS** **TYRVAYA NASAL SPRAY** **Note: Patient must meet criteria #1, #2 & #3 for approval of the PA request.**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 7/2023	<u>**Initial Authorization:**</u> 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

Field Name	Field Description
Prior Authorization Group Description	**Colchicine**
Drugs	**<u>Formulary Status:</u>** Preferred, requires step therapy Colchicine (Colcrys) tablets Colchicine (Mitigare) capsules **<u>Formulary Status:</u>** Non-preferred, requires prior authorization Gloperba (colchicine) solution
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 4/2023	• Presumed or documented diagnosis of gout • Documented trial and failure or intolerance with a preferred NSAID/COX-2 inhibitor, preferred oral corticosteroid, allopurinol, probenecid, or probenecid/colchicine for a minimum of one week of therapy in the previous 3 months • If the request if Gloperba there is a documented medical reason why colchicine tablets or capsules cannot be used **Note: Colchicine tablets and capsules may be approved as a first line agent if the request is for a diagnosis of Familial Mediterranean Fever or Pericarditis** **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Complement Inhibitors**
Drugs	Soliris (eculizumab), Ultomiris (ravulizumab), Empaveli (pegcetacoplan), Syfovre (pegcetacoplan injection) , Izervay (avacincaptad pegol injection)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a hematologist, nephrologist, neurologist, oncologist, ophthalmologist, or other appropriate specialist.
Coverage Duration	If the criteria are met, the criteria will be approved as follows: For Soliris (eculizumab), Ultomiris (ravulizumab), and Empaveli (pegcetacoplan): initial request will be approved for up to 3 month duration; reauthorization requests will be approved for up to 6 months. For Syfovre (pegcetacoplan injections): initial and reauthorization requests will be approved for up to 12 months. For Izervay (avacincaptad pegol injection): initial request will be approved for up to 12 month duration with no reauthorization

Other Criteria	**<u>Initial Authorization:</u>**
	• The request is age appropriate according to FDA approved package labeling or nationally recognized compendia; **AND**
	• 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 Soliris (eculizumab), Ultomiris (ravulizumab), and Empaveli (pegcetacoplan)
	    o Documentation of vaccination against meningococcal disease or a documented medical reason why the patient cannot receive vaccination or vaccination needs to be delayed; **AND**
	    o Antimicrobial prophylaxis with oral antibiotics (penicillin, or macrolides if penicillin-allergic) for two weeks will be administered if the meningococcal vaccine is administered less than two weeks before

	starting therapy or a documented medical reason why the patient cannot receive oral antibiotic prophylaxis. **Paroxysmal Nocturnal Hemoglobinuria (PNH):** • Documentation of diagnosis by high sensitivity flow cytometry • Hemoglobin (Hgb) < 10.5 g/dL • If the request is for Empaveli (pegcetacoplan), documented trial and failure of, contraindication to, or medical reason for not using 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 $\geq$ 2.5 and $\leq$ 17.5 mm^2 with at least 1 lesion $\geq$ 1.25 mm^2 **<u>Re-Authorization:</u>** • Re-authorization may be considered for all agents included in these criteria with the exception of Izervay (avacincaptad pegol injection), which is only indicated for a 12 month duration • Provider has submitted documentation of clinical response to therapy (e.g., reduction in disease severity, improvement in quality of life scores, 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

Revision/Review Date 10/2023	recognized compendia in accordance with the patient's diagnosis, age, and concomitant medical condition; **AND** • If the request is for aHUS/Complement Mediated HUS o Documentation of confirmed diagnosis as evidenced by complement genotyping and complement antibodies **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Continuous Glucose Monitors**
Drugs	Preferred: Freestyle Libre 14 Day, Freestyle Libre 2, FreeStyle Libre 3, Dexcom G6, Dexcom G7 Non-Preferred: Eversense (Sensor, Transmitter, and Reader components) And any newly marketed product in this class **This policy does not apply to continuous glucose monitor/insulin pump combination products reviewed and/or covered by the Medical Benefit including, but not limited to, the MiniMed. Requests for these products are referred to the plan’s Utilization Management team for Review**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Diabetes not treated with insulin with exception for compelling indication
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 Revision/Review Date 10/2023	• 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 **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Corlanor**
Drugs	Corlanor (ivabradine)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Pregnancy
Required Medical Information	See "Other Criteria"
Age Restrictions	See "Other Criteria"
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist
Coverage Duration	If all of the conditions are met, the request will be approved for 12 month duration.
Other Criteria	**Heart Failure in Adult Patients:** 1. Member is aged 18 years or older 2. Member has a diagnosis of stable symptomatic chronic heart failure (NYHA functional class II-IV) with a left ventricular ejection fraction ≤ 35% 3. Member is in sinus rhythm with a resting heart rate ≥ 70 beats per minute (bpm) 4. Member is currently being prescribed, or documentation has been provided that the member is not able to tolerate, an evidence based beta-blocker (i.e., bisoprolol, carvedilol, metoprolol succinate) at maximally tolerated dose **Heart Failure in Pediatric Patients:** 1. Member is aged 6 months to less than 18 years of age 2. Member has stable heart failure (NYHA/Ross functional class II-IV) due to dilated cardiomyopathy and a left ventricular ejection fraction ≤ 45% 3. Member is in sinus rhythm with an elevated resting heart rate
Revision/Review Date 1/2023	**Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**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	**<u>Infantile Spasms (West Syndrome):</u>** • 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) **<u>Multiple Sclerosis:</u>** • 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 **<u>All Other FDA Approved Conditions and Indications:</u>** • Documented trial and failure of an IV corticosteroid AND an oral corticosteroid, or documented medical reason for why the patient cannot use these therapies for treatment • Documentation was provided that ALL other standard therapies have been used to treat the member's condition as described in the medical compendium (Micromedex, AHFS, Drug Points, and package insert) as defined in the Social Security Act and/or per recognized standard of care guidelines OR there is a documented medical reason (i.e.

Revision/Review Date 7/2023	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 Revision/Review Date 7/2023	Prevention of spontaneous preterm delivery: • Patient has singleton pregnancy and prior preterm birth or short cervix Secondary Amenorrhea: • Patient has a diagnosis of secondary amenorrhea • Patient has tried and failed, or has contraindication or intolerance to, oral progestin therapy (e.g. medroxyprogesterone acetate, norethindrone acetate tablets, micronized progesterone) • If the request is for Crinone 8% gel the patient has tried and failed, or has a contraindication or intolerance to, Crinone 4% gel **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Cystic Fibrosis transmembrane conductance regulator (CFTR) Modulators**
Drug(s)	Kalydeco, Kalydeco Granules (ivacaftor), Orkambi, Orkambi Granules (lumacaftor/ivacaftor), Symdeko (tezacaftor/ivacaftor), Trikafta (elexacaftor/tezacaftor/ivacaftor), or any newly marketed CFTR modulator to treat cystic fibrosis
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	See "Other Criteria"
Required Medical Information	See "Other Criteria"
Age Restrictions	See "Other Criteria"
Prescriber Restrictions	Prescriber is pulmonologist or specializes in the treatment of cystic fibrosis
Coverage Duration	If all of the conditions are met the initial request will be 6 months. Reauthorization requests will be 12 months.
Other Criteria Review/Revision Date 1/2023	<u>Initial criteria:</u> • Documentation provided includes a copy of the FDA-cleared cystic fibrosis (CF) mutation test OR documentation from the National Cystic Fibrosis Registry (e.g. screen shot) with member's genetic mutations • The request is for an FDA approved indication for the member's genotype and within dosing guidelines • The request is appropriate for member (e.g. age/weight) based on FDA-approved package labeling, peer reviewed medical literature and nationally-recognized compendia. <u>Reauthorization:</u> • Based on prescriber's assessment, patient continues to benefit from therapy • The request is within FDA dosing guidelines **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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
 	
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	<u>ENDOMETRIOSIS</u>
	o Diagnosis of endometriosis
	o One of the following:
	    o Documented trial and failure or medical reason for not using an analgesic pain reliever (e.g., NSAIDs, COX-2 inhibitors) taken in combination with a hormonal contraceptive (e.g. estrogen/progestin, progestin only)
	    o Documented trial and failure of a gonadotropin-releasing hormone (GnRH) agonists or a GNRH antagonist.
	o Prescribing physician is a gynecologist.
	
	<u>HEREDITARY ANGIOEDEMA:</u>
	o Diagnosis of hereditary angioedema.
	o Prescriber is an immunologist, allergist, rheumatologist, or hematologist
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	**Daraprim**
Drugs	**pyrimethamine (Daraprim)**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Patients with documented megaloblastic anemia due to folate deficiency.
Required Medical Information	See “Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be an appropriate specialist or documentation has been provided that prescriber has consulted with an appropriate specialist (i.e. infectious disease, OB/GYN).
Coverage Duration	If all of the conditions are met, congenital toxoplasmosis requests will be approved for 12 months, and all other requests will be approved for 3 months-at a time.
Other Criteria Revision/Review Date 10/2023	**Congenital Toxoplasmosis** • Diagnosis of congenital toxoplasmosis **Acquired Toxoplasmosis** • Diagnosis of acquired toxoplasmosis • Prescribed in combination with leucovorin and either a sulfonamide or clindamycin **Patients with Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS)** • Diagnosis of Toxoplasmosis OR • Both of the following: o Medication is being prescribed for one of the following: ▪ Toxoplasmosis prophylaxis ▪ Cystoisosporiasis ▪ Pneumocystis jiroveci pneumonia prophylaxis/treatment o Documented medical reason why (e.g. intolerance, hypersensitivity, contraindication) sulfamethoxazole/trimethoprim cannot be used **Hematopoietic Cell Transplantation Recipients** • Medication prescribed for Toxoplasmosis prophylaxis • Documentation of medical reason why sulfamethoxazole/trimethorprim cannot be used **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	Daybue (trofinetide)
Drugs	Daybue (trofinetide)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	If all the criteria are met, the initial request will be approved for 3 months. For continuation of therapy, the request will be approved for 6 months.

Other Criteria
 	
Revision/Review Date 7/2023
	Initial Authorization:
	• Medication is prescribed at an FDA approved dose
	• Diagnosis of classic or typical Rett Syndrome (RTT)
	• Documentation or attestation of mutation of the MECP2 gene
	• Documentation of patient weight
	• Documentation or provider attestation of all the following:
	    o RTT Clinical Severity Scale rating of 10–36
	    o Clinical Global Impression–Severity (CGI-S) score of ≥4
	    o Baseline Rett Syndrome Behavior Questionnaire (RSBQ) score
	Re-Authorization:
	• Documentation or provider attestation of positive clinical response (i.e., decrease from baseline in RSBQ score, decrease in Clinical Global Impression–Improvement (CGI-I, etc.)
	• Medication is prescribed at an FDA approved dose
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

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

Other Criteria
 	
Revision/Review Date 12/2023
	<u>Initial Authorization:</u>
	• Metastatic castrate resistant (hormone-refractory) prostate cancer (mCRPC) (consistent with medical chart history)
	    o Evidenced by soft tissue and/or bony metastases
	    o Patient does NOT have
	        ▪ M0CRPC (defined as CRPC whose only evidence of disseminated disease is an elevated serum PSA) is not authorized
	        ▪ Visceral metastases (e.g. liver, lung, adrenal, peritoneal, brain)
	• Patient is not currently being treated with systemic immunosuppressants (e.g. chemotherapy, corticosteroids) or, if the patient is being treated with immunosuppressants, the prescriber has provided a valid medical reason for combination therapy
	• Eastern Cooperative Oncology Group (ECOG) score 0-1
	• Serum testosterone <50 ng/dL (e.g. castration levels of testosterone)
	• Predicted survival of at least six months
	<u>Reauthorization:</u>
	• Treatment exceeding 3 doses per lifetime will not be authorized
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	**Dificid (fidaxomicin)**
Drugs	Dificid (fidaxomicin)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, an infectious disease specialist or gastroenterologist
Coverage Duration	If the criteria are met, the request will be approved for up to a 10-day duration.
Other Criteria Revision/Review Date: 7/2023	**<u>Authorization for initial Clostridium difficile infection:</u>** 1. Documentation provided for intolerance or medical reason why patient is unable to use oral vancomycin 2. Dose requested follows FDA labeling **<u>Authorization for recurrent Clostridium difficile infection:</u>** 1. Documentation provided that patient has tried oral vancomycin for management of Clostridium difficile infection 2. Dose requested follows FDA labeling **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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

Other Criteria	**<u>Initial Authorization</u>:**
	• Member has a molecularly confirmed diagnosis of a long-chain fatty acid oxidation disorder (LC-FAOD)
	• Documentation of at least two of the following:
	    o Disease specific elevation of acylcarnitines on a newborn blood spot or in plasma
	    o Low enzyme activity in cultured fibroblasts
	    o One or more known pathogenic mutations in either the *CPT2, ACADVL, HADHA, or HADHB* gene
	• 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
	
	<u>Re-Authorization:</u>
	• 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
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Revision/Review Date: 1/2023	

Field Name	Field Description
Prior Authorization Group Description	**Drugs for Chronic Bowel Disorders/GI Motility**
Drug(s)	**<u>Preferred, PA Required</u>**: alosetron (Lotronex) Amitiza (lubiprostone) Linzess (linaclotide) lubiprostone (Amitiza) Movantik (naloxegol) **<u>Non-Preferred, PA Required:</u>** Ibsrela (tenapanor) Lotronex (alosetron) Motegrity (prucalopride) Relistor (methylnaltrexone) Symproic (naldemedine) Trulance (plecanatide) Viberzi (eluxadoline) Or any newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	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	**<u>Criteria for Initial Authorization</u>**: 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 (bulk-forming, 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 **<u>Criteria for Reauthorization</u>**:

	1. Documentation that the member has experienced treatment efficacy.
Review/Revision Date: 7/2023	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Emflaza**
Drugs	**Emflaza (deflazacort)**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	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 approval will be for a 12 month duration.
Other Criteria	**<u>Initial Authorization:</u>** • Confirmed diagnosis of Duchenne Muscular Dystrophy (documented mutation of dystrophin gene, genetic sequencing indicating mutations attributed to Duchene Muscular Dystrophy, OR muscle biopsy indicating absence of dystrophin protein), and copies of testing were submitted with request • Patient has onset of weakness before 5 years of age, and serum creatinine kinase activity of at least 10 times the upper limit of normal (ULN) at some stage in their illness • Prescriber attests patient has had a baseline eye examination • Prescriber attests patient has had a baseline bone mineral density (BMD) screening completed • Patient is or will be taking adequate calcium and vitamin D supplementation if dietary intake is less than recommended for age according to Institute of Medicine Guidelines • Patient has trial and failure with prednisone administered at a dose no lower than 0.75 mg/kg per day or 10 mg/kg per week for at least 12 months • Documented medical reason why prednisone cannot be continued, and Emflaza would be medically necessary and not have the same side effect as the preferred agents • The request is for an FDA approved dose

Revision/Review Date 1/2023	**<u>Reauthorization:</u>** • Physician attests that the patient’s muscle strength has stabilized or improved since starting treatment • Patient’s claim history shows consistent therapy (monthly fills) • Physician attests patient has had repeat eye and BMD screenings as appropriate • The request is for an FDA approved dose **Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

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 Revision/Review Date 10/2023	Initial: • Member has diagnosis of sickle cell disease • Documentation was provided that the patient had 2 or more crises in the last 12 months • Documentation was provided the member has been on hydroxyurea at the maximum tolerated dose and was compliant within the last 6 months (or a medical reason was provided why patient is unable to use hydroxyurea) • Request is for an FDA approved dose Reauthorization: • Prescriber attests member had reduction in number of sickle cell crises • Request is for an FDA approved dose **Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

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

Other Criteria
 	
Date: 1/2023
	<u>Initial Authorization:</u>
	• Medication is prescribed at an FDA approved dose
	• Member has a diagnosis of ASMD confirmed by one of the following:
	    o Deficiency in acid sphingomyelinase (ASM) enzyme activity (as measured by peripheral blood leukocytes, cultured skin fibroblasts, or dried blood spots)
	    o Sphingomyelin phosphodiesterase-1 (SMPD1) gene mutation
	• Member has a clinical presentation consistent with ASMD type B or type A/B
	• Documentation of members height and weight
	• Documentation of baseline ALT and AST within 1 month prior to initiation of treatment
	
	<u>Re-Authorization:</u>
	• Documentation or provider attestation of positive clinical response (i.e. improvement in splenomegaly, hepatomegaly, pulmonary function, etc.)
	• Medication is prescribed at an FDA approved dose
	
	If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

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

Revision/Review Date: 7/2023	**<u>Re-Authorization:</u>** • Documentation that member has experienced an improvement in symptoms from baseline including but not limited to: decreased pain, decreased gastrointestinal manifestations, decrease in proteinuria, stabilization of increase in eGFR, reduction of left ventricular hypertrophy (LVH) on echocardiogram, or improved myocardial function, or has remained asymptomatic • Member must not be using concurrently with Galafold (migalastat) • Documentation of the member's current weight • Request is for an FDA-approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Erythropoiesis-Stimulating Agents (ESAs)**
Drugs	**Preferred:** Aranesp (darbepoetin alfa-polysorbate 80) Retacrit (epoetin alfa-epbx) **Non-preferred:** Epogen (epoetin alfa) Mircera (methoxy peg-epoetin beta) Procrit (epoetin alfa)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If criteria are met, the request will be approved for up to 1 month if the member is deficient in iron, vitamin B12, folate, or in the persurgical setting, and up to 3 months for all other requests.
Other Criteria	**Existing ESA users who are NEW to the plan:** • Documentation of current dose • Drug is being prescribed for an FDA-approved indication at an FDA-approved dose or is otherwise supported by the compendia or standard-of-care guidelines • The members HgB is within the following indication specific range: o Anemia of CKD: ≤ 11 g/dL o Anemia related to cancer: ≤ 12 g/dL o Zidovudine related anemia in members with HIV: HgB ≤ 12 g/dL o Ribavirin-induced anemia: HgB ≤ 12g/dL **Initial Authorization for all requests:** • Drug is being prescribed for an FDA-approved indication at an FDA-approved dose or is otherwise supported by the compendia or standard-of-care guidelines • All submitted lab results have been drawn within 30 days of the request • The following lab results must be submitted: o Hemoglobin (HgB) o Hematocrit (HCT)

- The following lab results must be submitted and demonstrate normal values, otherwise, the member MUST be receiving, or is beginning therapy, to correct the deficiency:
    - 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.

Revision/Review Date: 12/2023	• The following lab results must be submitted:
	    o Hemoglobin (HgB)
	• The following lab results must be submitted and demonstrate normal values, otherwise, the member <u>MUST</u> be receiving, or is beginning therapy, to correct the deficiency:
	    o Serum ferritin level (> 100ng/mL)
	    o Transferrin saturation (TSAT) (> 20%)
	    o Vitamin B12 level (> 223pg/mL)
	    o Folate level (> 3.1 ng/mL)
	• The members HgB is within the following indication specific range:
	    o Anemia of CKD: ≤ 11 g/dL
	    o Anemia related to cancer: ≤ 12 g/dL
	    o Zidovudine related anemia in members with HIV: HgB ≤ 12 g/dL
	    o Ribavirin-induced anemia: HgB ≤ 12g/dL
	
	For requests that fall outside of these parameters, or if the criteria are not met, the request will be referred to a Medical Director/clinical reviewer for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	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: 7/2023	• Medication is prescribed at an FDA approved dose • Diagnosis of at least 1 recurrent episode of CDI (≥2 total CDI episodes) • Current episode of CDI must be controlled (<3 unformed/loose stools/day for 2 consecutive days) • Positive stool test for C. difficile within 30 days before prior authorization request • Administration will occur 24–72 hours following completion of antibiotic course for CDI treatment • For Vowst only: attestation patient will bowel cleanse using magnesium citrate or polyethylene glycol electrolyte solution the day before the first dose of Vowst *Rebyota and Vowst are limited to 1 treatment course* **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	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	• 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 Date: 4/2023	**Initial Authorization:** • 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 **Re-Authorization:** • 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 **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Galafold**
Drugs	Galafold (migalastat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	Members should be greater than or equal to 18 years of age
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, cardiologist, nephrologist or specialist experienced in the treatment of Fabry disease
Coverage Duration	Initial Authorization: If the criteria are met, the request will be approved for a 6-month duration. Reauthorization: If the criteria are met, the request will be approved for a 12-month duration.
Other Criteria	<u>**Initial Authorization**</u>: • 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 <u>**Re-Authorization:**</u> • Documentation that member has experienced an improvement in symptoms from baseline including but not limited to: decreased pain, decreased gastrointestinal manifestations, decrease in proteinuria, stabilization of increase in eGFR, reduction of left ventricular hypertrophy (LVH) on echocardiogram, or improved myocardial function • 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	**Agents to Treat Gaucher's Disease**
Drugs	Cerdelga (eliglustat), Cerezyme (imiglucerase), Vpriv (velaglucerase alfa), Elelyso (taliglucerase alfa), miglustat (Zavesca)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	None
Required Medical Information	See "Other Criteria"
Age Restrictions	Per package insert
Prescriber Restrictions	Prescriber is a specialist in treatment of Gaucher's Disease (e.g. endocrinologist, hematologist or geneticist), or is in consultation with a specialist
Coverage Duration	If all of the conditions are met, the request will be approved with 6-month duration.
Other Criteria	**<u>Initial Authorization:</u>** <u>Cerezyme, Vpriv, Elelyso, or miglustat initial authorization:</u> • Patient has a confirmed diagnosis of Gaucher's disease, type 1 (GD1) • Request is for an FDA approved dose <u>Cerdelga initial authorization:</u> • Patient has a confirmed diagnosis of Gaucher's disease, type 1 (GD1) and is a CYP2D6 extensive metabolizer (EM), intermediate metabolizer (IM) or poor metabolizer (PM), as detected by an FDA-approved test. • Patient is not concomitantly taking Class IA (e.g. quinidine, procainamide) or Class III antiarrhythmic (e.g. amiodarone, sotalol). • For EMs or IMs, patient is not concomitantly taking a moderate or strong CYP2D6 inhibitor (e.g. fluoxetine, bupropion) WITH a moderate or strong CYP3A inhibitor (fluconazole, ketoconazole). • For IMs and PMs, patient is not concomitantly taking a strong CYP3A inhibitor. • Patient has no pre-existing cardiac disease or long QT syndrome. • For EM's, patient does not have moderate or severe hepatic impairment • For IM's or PMs, patient does not have any degree of hepatic impairment.

Revision/Review Date 4/2023	**<u>Re-Authorization criteria for all agents:</u>** • Documentation has been provided that patient has obtained clinical benefit from medication (e.g. increased platelet count, improvement in anemia, PFT's, improvement in radiographic scans, improved quality of life) • Request is for an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Generalized Pustular Psoriasis (GPP) Agents**
Drugs	Spevigo (spesolimab-abzo)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	≥ 18 years
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist or geneticist
Coverage Duration	If all of the criteria are met, the request will be approved for up to 2 doses. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.

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

Field Name	Field Description
Prior Authorization Group Description	**Glycopyrrolate (oral)**
Drugs	**Formulary Status**: Formulary; Pays at point-of-sale glycopyrrolate 1, 2 mg tablet **Formulary Status:** Requires prior authorization Glycopyrrolate (Cuvposa) 1 mg/5 mL oral solution Glycopyrrolate (Glycate) 1.5 mg tablet Dartisla ODT (glycopyrrolate) 1.7 mg orally disintegrating tablet
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	Per package insert
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month.
Other Criteria	Requests for glycopyrrolate (Cuvposa) 1 mg/5 mL oral solution: • Documented diagnosis of chronic severe drooling **AND** • Documented neurological condition associated with problem drooling (e.g., cereberal palsy) **AND** • Member has tried and failed non-pharmacologic approaches to treatment (e.g., correction of situational factors, treatment of dental malocclusion and caries, orthodontic appliances, swallowing therapy, biofeedback and automatic cueing, positive and negative reinforcement) **AND** • Drug is being prescribed at FDA approved dose Requests for Dartisla ODT or glycopyrrolate 1.5 mg tablet: • Documented diagnosis of peptic ulcer disease **AND** • Glycopyrrolate will be used as an adjunct to other therapies **AND**

Revision/Review Date 1/2023	• Member has tried and failed glycopyrrolate 1 mg or 2 mg tablets or has a medical reason (e.g. intolerance, hypersensitivity, contraindication, etc.) for not using glycopyrrolate 1 mg and 2 mg tablets **AND** • Drug is being prescribed at and FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Gonadotropin Releasing Hormone Agonists (GNRH)** **If diagnosis is Gender Dysphoria, use Medications without Drug or Class Specific Criteria** **If diagnosis is cancer, use Oncology Criteria**
Drug(s)	**Preferred GNRH Agonist(s) for their respective indications:** 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) **Non-Preferred GNRH Agonist(s):** Supprelin LA (histrelin acetate), Triptodur (triptorelin pamoate), and any newly marketed GnRH agonist**.**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per the National Comprehensive Cancer Network (NCCN), the American Society of Clinical Oncology (ASCO), the American College of Obstetricians and Gynecologists (ACOG), or the American Academy of Pediatrics (AAP) standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert if not detailed in “Other Criteria”
Prescriber Restrictions	Prescriber must be a specialist in the field to treat the member’s condition.
Coverage Duration	If all of the conditions are met, the request will be approved for up to 12 months if diagnosis is central precocious puberty, and up to 3-6 months as indicated below for other indications as recommended per FDA approved indications and/or as defined by the medical compendium or standard of care guidelines.
Other Criteria	<u>**INITIAL AUTHORIZATION for ALL REQUESTS:**</u> • 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. <u>AND the member meets the following for the respective diagnosis:</u>

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 0.3mlU/ml (where IU- International units)] in a child with precocious puberty, then a diagnosis of CPP can be made without proceeding to a GnRH stimulation test*.
- Brain magnetic resonance imaging (MRI) has been performed for all boys with CPP and for girls with onset of secondary sexual characteristics before the age of six years of age to rule out a tumor.

Endometriosis

- For all therapies except Lupron, Lupron Depot, or Lupron Depot-Ped, member is ≥ 18 years of age
- Member has a confirmed diagnosis (e.g. laparoscopy, etc.)
- Documented trial and failure or medical reason for not using an analgesic pain reliever (e.g., NSAIDs, COX-2 inhibitors) taken in combination with combined estrogen progestin oral contraceptive pills (OCPs):
    - 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:

Review Date 12/2023	• 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. <u>AND meets the following per diagnosis:</u> <u>Central precocious puberty (CPP)</u> • 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 <u>Endometriosis</u> • 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. <u>Fibroids</u> • The patient has not received cumulative doses of the GnRH agonist greater than 6 months of therapy **NOTE: Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

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

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

Revision Date 1/2023	*IGF-1 levels are highly age and gender specific. In the event the form provides a value and not the corresponding reference range, refer to published reference ranges for interpretation. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

HEPATITIS C TREATMENT

Preferred	Non-Preferred
Direct Acting Antiviral Products	
• ledipsavir-sofosbuvir (Harvoni) • Mavyret • sofosbuvir-velpatasvir (Epclusa)	• Epclusa • Harvoni, Harvoni Pellet Pack • Sovaldi, Sovaldi Pellet Pack • Viekira Pak • Vosevi • Zepatier
Pegylated Interferon Alpha Products	
• Pegasys syringe/vial	
Ribavirin Products	
• 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

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

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

Treatment Experienced		Duration	
Failed Regimen	Treatment Options	No Cirrhosis	Compensated Cirrhosis (Child-Pugh A)
Sofosbuvir-based (Sovaldi, Harvoni, and Epclusa) and Zepatier	Vosevi	12 weeks	12 weeks
	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.

[β]Genotype 3: If the patient has compensated cirrhosis, weight-based ribavirin is recommended.

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

[μ]May be extended to 24 weeks in difficult cases (e.g. genotype 3 with cirrhosis) or failure following Sovaldi plus Epclusa

<table>
<tr><th colspan="2"><u>Unique patient populations (e.g. Decompensated Cirrhosis, Post-Transplant, etc. not addressed in previous tables)</u></th></tr>
<tr><td>Decompensated Cirrhosis (Child-Pugh B or C)</td><td rowspan="4">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.</td></tr>
<tr><td>Post-Transplant</td></tr>
<tr><td>Hepatocellular Carcinoma</td></tr>
<tr><td>Pediatrics</td></tr>
</table>

Revision/Review Date: 10/2023

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

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

Other Criteria	**Initial Requests:**
	• Documentation submitted indicates the medication is being prescribed at FDA approved dose.
	• The patient is not taking ACE inhibitors or estrogen containing oral contraceptives/hormone replacement therapy
	• Diagnosis of one of the following**:**
	    o HAE with deficient or dysfunctional C1INH (e.g. type I, type II, or acquired C1NH deficiency
	    o HAE with normal C1INH:
	        ▪ If known origin, documentation of results of confirmatory genetic test (e.g. mutations in gene for factor XII, angiopoietin-1, plasminogen, kininogen-1)

        - 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)

<u>Renewal Criteria:</u>

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:

- 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

Revision/Review Date: 4/2023	• If the request is for Takhzyro and the patient has been well controlled (e.g. attack free) for 6 months or more while receiving Takhzyro the patient will be receiving 300 mg every four weeks, or a medical reason has been provided why continued therapy with 300 mg every two weeks is necessary • The patient is receiving no other medications for prophylaxis **NOTE: Medical Director/Clinical Reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary**

Field Name	Field Description
Prior Authorization Group Description	**Hormone Replacement Therapy** (estrogen-only oral and vaginal products)
Drugs	**<u>FORMULARY STATUS</u>** Preferred, Pays at Point-of-Sale **Estradiol** (Estrace) oral tablet **Estradiol** (Estrace) vaginal cream **Estradiol** (Vagifem) vaginal tablet **<u>FORMULARY STATUS</u>** Preferred, Requires Step Therapy **Premarin** (estrogens, conjugated) oral tablet **Premarin** (estrogens, conjugated) vaginal cream **Menest** (estrogens, esterified) oral tablet
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 10/2023	**<u>For all requests:</u>** • The request is for an FDA approved indication. **<u>Initial authorization for Premarin and Menest oral tablet</u>** • 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 **<u>Initial authorization for Premarin vaginal cream</u>** • Documented trial and failure or intolerance with estradiol vaginal cream OR estradiol vaginal tablet **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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

Other Criteria
 	
Date: 4/2023
	<u>Initial Authorization:</u>
	• Medication is prescribed at an FDA approved dose
	• If request is for preterm birth, do not approve
	• Request is for one of the following indications:
	  o Amenorrhea or abnormal uterine bleeding due to hormonal imbalance
	  o Production of secretory endometrium and desquamation
	  o Test for endogenous estrogen production
	  o Advanced uterine adenocarcinoma
	
	<u>Re-Authorization:</u>
	• Documentation or provider attestation of clinical benefit
	• Medication is prescribed at an FDA approved dose
	
	If all the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	**Ileal bile acid transporter 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	**Initial Authorization:**
	
	Progressive Familial Intrahepatic Cholestasis (Bylvay ONLY)
	• Diagnosis of progressive familial intrahepatic cholestasis (PFIC) type 1, 2, or 3 with genetic confirmation
	• Documentation that patient does not have an *ABCB11* variant that results in non-functional or complete absence of bile salt export pump protein (BSEP-3)
	• Documented history of moderate to very severe pruritus
	• Documentation of patient’s weight
	• Prescriber attests to monitor liver function tests and fat soluble vitamin (FSV) levels during treatment
	• Baseline serum bile acid level is provided
	• Documentation of trial and failure OR contraindication to at least ONE of the following:
	  o Ursodiol
	  o Cholestyramine or colesevelam
	• The prescribed dose is within FDA approved dosing guidelines
	
	Alagille Syndrome (Livmarli ONLY)
	• Diagnosis of Alagille syndrome (ALGS)
	• 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:
	  o Ursodiol

Revision/Review Date: 7/2023	- 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 **<u>Reauthorization:</u>** • Documentation of clinical benefit indicating each of the following: - 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 **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	**Immune Globulins**
Drugs	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 ****Gamunex-C is the preferred product for the indications of primary immunodeficiency, chronic idiopathic thrombocytopenic purpura, and chronic inflammatory demyelinating polyneuropathy****
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	See “other criteria”
Coverage Duration	If the criteria are met the request will be approved for a 3 month duration unless otherwise specified in the diagnosis specific “Other Criteria” section below.
Other Criteria	**<u>All Requests:</u>** • Documentation of diagnosis confirmed by a specialist • Member has tried and failed, or has a documented medical

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

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

	• Either patient's IgG level is < 400mg/dL or
	• If patient's IgG level is ≥ 400 mg/dL than significant deficiency of humoral immunity as evidenced by ONE of the following:
	  o Inability to produce an adequate immunologic response to specific antigens.
	  o History of recurrent bacterial infections despite prophylactic antibiotics
	• Dose does not exceed 400mg/kg/dose every 2-4 weeks
	
	• If criteria is met, approve for 3 months.
	
	<u>Multifocal motor neuropathy (MMN)</u>:
	• Duration of symptoms has been at least 1 month with disability.
	• Nerve conduction studies were completed to rule out other possible conditions, and confirms the diagnosis of MMN.
	• Dose does not exceed 2g/kg/month administered over 2 to 5 days.
	
	• If criteria is met, approve for up to 5 days for 3 months.
	
	<u>Chronic inflammatory demyelinating polyneuropathy (CIDP)</u>:
	• 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.
	  o 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
	
	<u>Guillain-Barre syndrome</u>:

	- 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. **<u>Myasthenia Gravis:</u>** - <u>Acute:</u> - 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 - <u>Chronic:</u> - 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 **<u>Dermatomyositis (DM):</u>** - 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

Revision/Review Date 10/2023	- rituximab. - Member has severe, life-threatening weakness or dysphagia • For a diagnosis of cutaneous DM (i.e. amyopathic DM, hypomyopathic DM): - Member has tried and failed, or has a documented medical reason for not using all of the following: MTX and mycophenolate mofetil. • Dose does not exceed 2 g/kg administered over 2-5 days every 4 weeks. • If criteria is met, approve for up to 3 months. If criteria is met, the request will be approved for the duration listed above. If the criteria is not met, the request is referred to a Medical Director/Clinical reviewer for medical necessity review. **Medical Director/Clinical Reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary**

Field Name	Field Description
Prior Authorization Group Description	Immunosuppressants for Lupus Nephritis
Drugs	Lupkynis (voclosporin)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Member must be 18 years of age or older
Prescriber Restrictions	Prescriber must be rheumatologist, nephrologist or other specialist in the treatment of autoimmune disorders
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Revision/Review Date 4/2023	**Initial Authorization** • Member must have a diagnosis of systemic lupus erythematosus (SLE) with a kidney biopsy indicating a histologic diagnosis of lupus nephritis (LN) Class III, IV, or V • Documentation that the member has a baseline eGFR > 45 mL/min/1.73m^2 • Documentation of the member’s urine protein/creatinine ratio (UPCR) is provided • Member is concurrently being treated with background immunosuppressive therapy, or has a medical reason for not using background immunosuppressive therapy • Member is NOT concurrently being treated with cyclophosphamide • Medication is prescribed at an FDA approved dose **Reauthorization** • Documentation of improvement in renal function (i.e. reduction in UPCR or no confirmed decrease from baseline eGFR ≥ 20%) • Medication is prescribed at an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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

Other Criteria
 	
Revision/Review Date 7/2023
	<u>Initial Authorization</u>
	• Member has a diagnosis of one of the following
	    o Growth hormone (GH) gene deletion with the development of neutralizing antibodies to GH
	    o Severe primary insulin-like growth factor-1 (IGF-1) deficiency as defined as:
	        ▪ Height and basal IGF-1 standard deviation scores ≤ -3.0
	        ▪ Normal or elevated GH levels
	• Member does not have a closed epiphyses
	• Member does not have known or suspected malignancies
	• Request is for an FDA-approved dose
	
	<u>Reauthorization</u>
	• Growth velocity must be ≥ 2 cm in the past year
	• Member does not have a closed epiphyses
	• Member does not have known or suspected malignancies
	• Request is for an FDA-approved dose
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

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

	consistent with claims history, or has a documented medical reason (intolerance, hypersensitivity, contraindication, renal insufficiency, etc.) for not utilizing one of these agents to manage their medical condition • If the request is for Prolia (denosumab) for prostate cancer, approve.
Revision/Review 12/2023	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Injectable/Infusible Bone-Modifying Agents for Osteoporosis and Paget's Disease**
Drugs	Pamidronate, ibandronate (Boniva), Prolia (denosumab), zoledronic acid (Reclast), Forteo (teriparatide), 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	**<u>For all Requests</u>**: • The medication is FDA-approved for indication and is being requested at an FDA approved dose <u>If the diagnosis is postmenopausal or male osteoporosis</u>: • If the request is for male osteoporosis or high risk postmenopausal osteoporosis with no prior fractures the member has a documented (consistent with pharmacy claims) adequate trial of an oral bisphosphonate or has a medical reason (e.g. intolerance, hypersensitivity, contraindication, etc.) for not using an oral bisphosphonate • If the request is for very high risk postmenopausal osteoporosis or postmenopausal osteoporosis with prior fractures a documented trial and failure of an oral bisphosphonate will not be required. o Very high risk is defined as having one or more of the following:

	▪ History of fracture in the past 12 months ▪ Multiple fractures ▪ Fractures while on drugs causing skeletal harm (e.g. long-term glucocorticoids) ▪ Very low T scores (< -3.0) ▪ High risk for falls ▪ History of injurious falls ▪ Very high fracture probability as determined by fracture risk assessment tool (FRAX) (e.g. major osteoporosis fracture >30%, hip fracture > 4.5%) • Documentation was submitted indicating the member is a postmenopausal woman or a male member over 50 years of age and one of the following: o A bone mineral density (BMD) value consistent with osteoporosis (T-scores equal to or less than –2.5) o Has had an osteoporotic fracture o A T-score between -1 and -2.5 at the femoral neck or spine and a 10 year hip fracture probability >3% or a 10 year major osteoporosis-related fracture probability >20% (based on the US-adapted WHO absolute fracture risk model) • If request is for Forteo (teriparatide), teriparatide (biosimilar), Tymlos (abaloparatide), or Evenity (romosozumab) one of the following applies to member: o 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 o Has SEVERE osteoporosis (T-Score -3.5 or below, or T-Score of -2.5 or below plus a fragility fracture) • If request is for Forteo or teriparatide (biosimilar), a medical reason why member is unable to use Tymlos (abaloparatide) or Evenity (romosozumab) if appropriate based on diagnosis o Requests for brand Forteo (teriparatide) also require a medical reason why member is unable to use teriparatide (biosimilar) • If the request is for Evenity (romosozumab), the member does not have a history of heart attack or stroke within the preceding year <u>If the diagnosis is Paget's disease</u>: • 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

Revision/Review Date: 1/2023	• Documentation (within 60 days of request) was submitted including member's serum alkaline phosphatase level of ≥ two times the upper limit of normal AND the member is symptomatic OR there is documentation of active disease
	
	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
	• Documentation that the member is currently utilizing oral glucocorticoid therapy for a minimum of 3 months and that the dosage of the oral glucocorticoid therapy is equivalent to a dose greater than 5 mg of prednisone daily
	• Member is 40 years of age or older
	• Member has a moderate to high risk of fracture based on ONE of the following:
	    o History of osteoporotic fracture
	    o BMD less than or equal to -2.5 at the hip or spine
	    o FRAX 10-year risk for major osteoporotic fracture greater than or equal to10% (with glucocorticoid adjustment)
	    o FRAX 10-year risk for hip fracture greater than 1%
	• If the request is for teriparatide (biosimilar), Forteo (teriparatide), 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
	    o Requests for brand Forteo (teriparatide) also require a medical reason why member is unable to use teriparatide (biosimilar)
	
	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	**<u>Initial Authorization:</u>**
	
	Tepezza is approved when all of the following are met:
	• Dosing does not exceed dosing guidelines as outlined in the package insert
	• Patient has a confirmed diagnosis of Graves’ disease
	• Documentation of moderate-severe thyroid eye disease as evidenced by one or more of the following:
	    o Lid retraction of >2mm
	    o Moderate or severe soft-tissue involvement
	    o Proptosis ≥3mm above normal values for race and sex
	    o Periodic or constant diplopia
	• Patient must be euthyroid or thyroxine and free triiodothyronine levels are less than 50% above or below normal limits (submit laboratory results with request)
	• Patients of reproductive potential: attestation the patient is not pregnant, and appropriate contraception methods will be used before, during, and 6 months after the last infusion
	• Patient has had a trial and therapy failure of, or contraindication to:
	    o For active disease: oral or IV glucocorticoids
	    o For chronic/inactive disease: rehabilitative surgery

Revision/Review Date 7/2023	**Re-authorization:** • Retreatment or renewal requests beyond a total of 24 weeks of treatment (8 total infusions) will not be allowed. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Insulin Pumps**
Drugs	Omnipod Dash Intro Kit, Omnipod Dash Pods, Omnipod 5 G6 Intro Kit, Omnipod 5 G6 Pods, OmniPod GO **This policy does not apply to pumps reviewed and/or covered by the Medical Benefit including, but not limited to V-Go 24-hour disposable system and t:slim X2, and continuous glucose monitor/insulin pumps such as MiniMed. Requests for these products are referred to the plan's Utilization Management team for review.**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	None
Required Medical Information	See "Other Criteria"
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist, a certified diabetes care and education specialist (CDCES), or an obstetrician/gynecologist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.

Other Criteria	**<u>Initial Authorization</u>**
	• Diagnosis – diabetes
	• One of the following
	    o Type 1 diabetes or other insulin-deficient forms of diabetes (e.g. cystic-fibrosis related diabetes)
	    o Treatment with multiple daily doses (≥ 3) of insulin
	    o Pregnancy
	    o Continuation of therapy for patient new to plan
	    o For OmniPod GO: trial and failure of a long-acting insulin or a medical reason why long-acting insulin cannot be used (adherence, etc.)
	
	<u>Reauthorization</u>
	• One of the following:
	    o Type 1 diabetes or other insulin-deficient form of diabetes

Revision/Review Date 10/2023	o Continued use of multiple daily injections (≥ 3) of insulin o Initial approval was based on continuation of therapy for patient new to plan. o For OmniPod GO: continuous use of approved insulin compatible with device • Continuation of therapy based on a diagnosis of pregnancy alone is not eligible for reauthorization **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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

Other Criteria
 	
Revision/Review Date 10/2023
	<u>Initial Authorization</u>
	o Diagnosis of nonsegmental vitiligo
	o Documentation of depigmented lesions including measurements and locations is provided
	o Prescriber attests that the total body vitiligo area (facial and nonfacial) being treated does not exceed 10% BSA
	o Trial and failure of, or intolerance to, ALL of the following:
	    o Topical corticosteroids
	    o Topical calcineurin inhibitors
	    o Targeted phototherapy
	o Prescriber attests that the member will not concomitantly use therapeutic biologics, other Janus kinase inhibitors, potent immunosuppressants, or phototherapy for repigmentation purposes
	o Request is for an FDA-approved dose
	
	<u>A MAXIMUM OF ONE 60 GRAM TUBE OF OPZELURA PER WEEK OR ONE 100 GRAM TUBE EVERY TWO WEEKS MAY BE APPROVED**</u>**
	
	<u>Reauthorization</u>
	o Prescriber attests that the member has experienced a clinical benefit (e.g. reduction in size or quantity of or stabilization of existing depigmented lesions; absence of new depigmented lesions)
	o Request is for an FDA-approved dose
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

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

Other Criteria	**<u>Initial Authorization:</u>**
	• 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:
	    o Serum ferritin level (> 100ng/mL)
	    o Transferrin saturation (TSAT) (> 20%)
	• Provider attests that member has no history of myocardial infarction, cerebrovascular event, or acute coronary syndrome in the past 3 months
	• Member will not be receiving concurrent treatment with an ESA
	• Request is for an FDA-approved dose
	• All submitted lab results have been drawn within 30 days of the request
	
	<u>Reauthorization:</u>
	• All submitted lab results have been drawn within 30 days of the reauthorization request.

Revision/Review Date: 04/2023	• Member has a documented increase in hemoglobin from baseline
	• The following lab results must be submitted and demonstrate normal values, otherwise, the member MUST be receiving, or is beginning therapy, to correct the deficiency:
	    o Serum ferritin level (> 100ng/mL)
	    o Transferrin saturation (TSAT) (> 20%)
	• Member will not be receiving concurrent treatment with an ESA
	• Request is for an FDA-approved dose
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary

Field Name	Field Description
Prior Authorization Group Description	Joenja
Drugs	Joenja (leniolisib)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Per prescribing information.
Prescriber Restrictions	Prescriber must be an immunologist, hematologist, medical geneticist, or other prescriber who specializes in the treatment of genetic or immunologic disorders.
Coverage Duration	If the criteria are met, requests will be approved with up to a 6-month duration. Thereafter, reauthorization requests will be approved with up to a 12-month duration.
Other Criteria Revision/Review Date 7/2023	**Initial Authorization:** • Documentation of APDS/PASLI-associated PIK3CD/PIK3R1 mutation, confirmed by genetic testing. • Documentation of nodal and/or extranodal lymphoproliferation, history of repeated oto-sino-pulmonary infections and/or organ dysfunction (e.g., lung, liver) • Prescriber attests that the member is not currently taking immunosuppressive medication • Prescriber attests that female patients have been advised of the potential risk to a fetus, will use effective contraception and have had a negative pregnancy test prior to initiation of treatment • Medication is being prescribed at an FDA approved dose **Reauthorization:** • Documentation has been submitted indicating member has experienced a clinical benefit from treatment (e.g., decreased lymph node size, increase in percentage of naïve B cells) • Prescriber attests that female patients will use effective contraception and have had a negative pregnancy test • Medication is being prescribed at an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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

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

Last review: 4/2023	• The medication is being prescribed at an FDA approved dosage. **NOTE: Clinical reviewer/Medical Director must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group	**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	Specialist experienced in treating Phenylketonuria (PKU)
Coverage Duration	**<u>Initial:</u>** If the criterion is met, the request will be approved for a duration of 1 month; if the above conditions are not met, the request will be referred to a clinical reviewer for medical necessity review. **<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; if the above conditions are not met, the request will be referred to a clinical reviewer/Medical Director for medical necessity review.
Other Criteria	**INITIAL AUTHORIZATION:** • Documentation of a confirmed diagnosis of Phenylketonuria (PKU) • Documentation of the patient's baseline blood Phe level~~.~~ (within 30 days of the request) • Documentation or prescriber attestation that the patient is currently utilizing a Phe-restricted diet • Documentation of the patient's current weight. • The medication is being prescribed at an FDA approved dosage **PA CRITERIA FOR REAUTHORIZATION:** *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.* • Documentation of the patient's current weight. • Documentation of updated blood Phe level results showing reduction in Phe level from baseline.

	◦ Bisphosphonate (in the setting of abnormal uptake on bone scan) **Re-authorization:** • Patient has demonstrated clinical benefit.
Revision/Review Date 4/2023	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Lamzede**
Drugs	Lamzede (velmanase alfa-tycv)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	"See Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a specialist in the treatment of alpha-mannosidosis or other lysosomal storage disorders
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months
Other Criteria	**Initial Authorization** • Diagnosis of alpha-mannosidosis as confirmed by one of the following: o Deficiency in alpha-mannosidase enzyme levels or activity in blood leukocytes o DNA testing • Prescriber attests that medication will only be used to treat non-central nervous system manifestations of alpha-mannosidosis • Patient's weight • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines **Reauthorization** • Patient has demonstrated a clinical response (i.e., reduction in serum oligosaccaride concentrations, stabilization or improvement in 3-minute stair climbing test [3MSCT], 6-minute walking test [6-MWT], forced vital capacity [FVC], etc.) • Prescriber attests that medication will only be used to treat non-central nervous system manifestations of alpha-mannosidosis • Prescriber attests patient can walk without support • Patient's weight • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**
Revision/Review Date 4/2023	

Field Name	Field Description
Prior Authorization Group Description	**Lantidra (donislecel)**
Drugs	Lantidra (donislecel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed or consulted by an endocrinologist
Coverage Duration	If all criteria are met, the request will be approved for one infusion. A member may only receive a maximum of 3 infusions per lifetime as there is no data regarding the efficacy or safety for treatment with more than 3 infusions.

Other Criteria	**<u>Initial Authorization</u>**
	
	• Documentation of Type 1 Diabetes diagnosis for more than 5 years
	• Documentation of blood glycated hemoglobin (HbA1c) above target goal
	• Documentation of intensive insulin management efforts (i.e., adjusting insulin regimen to multiple daily injections, frequently monitoring blood glucose levels daily, the use of devices such as a continuous glucose monitor, etc.)
	• Member has at least one of the following, despite intensive insulin management efforts:
	    o Inability to sense hypoglycemia until the blood glucose falls to less than 54 mg/dL
	    o At least 1 or more episodes of severe hypoglycemia (blood glucose below 50 mg/dL) in the past 3 years
	• Provider must confirm the following:
	    o Blood glycosylated hemoglobin (HbA1c) is not higher than 12%
	    o Member has an insulin requirement of no more than 0.7 International Units (IU)/kilogram/day
	    o Member has a Body Mass Index (BMI) less than 27 kg/m^2
	• Provider attests that member will be receiving concomitant immunosuppression therapy
	• Drug is being requested at an FDA-approved dose

	• Member's weight **<u>Reauthorization</u>** • Member has not achieved independence from exogenous insulin within one year of infusion OR member has lost independence from exogenous insulin within one year after a previous infusion • Provider attests that member will be receiving concomitant immunosuppression therapy • Drug is being requested at an FDA-approved dose • Member's weight
Revision/Review Date: 10/2023	**Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Leqembi (lecanemab-irmb)**
Drugs	Leqembi (lecanemab-irmb) *****Initial authorizations and reauthorizations must be approved by a Medical Director*****
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Patients with moderate to severe Alzheimer's Disease (AD) Patients with neurodegenerative disease caused by a condition other than AD
Required Medical Information	See "Other Criteria"
Age Restrictions	age 50-90 years
Prescriber Restrictions	Prescriber must be prescribed by, or in consultation with, a specialist in neurology or gerontology
Coverage Duration	For initial authorization: the request will be approved in accordance with the FDA-indicated titration schedule for up to 6 months For reauthorization: if all of the conditions are met, the request will be approved for 6 months.

Other Criteria	**<u>Initial Authorization</u>**
	• Diagnosis of mild cognitive impairment (MCI) caused by AD or mild AD consistent with Stage 3 or Stage 4 Alzheimer's disease as evidenced by at least one of the following:
	    o Clinical Dementia Rating Global (CDR-G) score of 0.5-1.0 and a Memory Box score of 0.5 or greater
	    o Mini-Mental State Examination (MMSE) score ≥ 22 and ≤ 30
	    o Wechsler Memory Scale IV-Logical Memory (subscale) II (WMS-IV LMII) score at least 1 standard deviation below age-adjusted mean
	• The request is for an FDA approved dose
	• Documentation of BOTH of the following:
	    o Recent, within past year, positive results for the presence of beta-amyloid plaques on a positron emission tomography (PET) scan or cerebrospinal fluid testing
	    o Recent, within past year, baseline Magnetic Resonance Imaging (MRI) scan

Revision/Review Date: 07/2023	• Physician has assessed baseline disease severity utilizing an objective measure/tool (i.e., Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog-14], Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory-Mild Cognitive Impairment version [ADCS-ADL-MCI], Clinical Dementia Rating Sum of Boxes [CDR-SB], etc.)
	• No recent (past 1 year) history of stroke, seizures or transient ischemic attack (TIA), or findings on neuroimaging that indicate an increased risk for intracerebral hemorrhage.
	
	<u>Reauthorization</u>
	• The request is for an FDA approved dose
	• Patient continues to have a diagnosis of mild cognitive impairment (MCI) caused by AD or mild AD consistent with Stage 3 or Stage 4 Alzheimer's disease as evidenced by at least one of the following:
	    o CDR-G score of 0.5-1.0 and a Memory Box score of 0.5 or greater
	    o MMSE score of 22-30
	    o Wechsler Memory Scale IV-Logical Memory (subscale) II (WMS-IV LMII) score at least 1 standard deviation below age-adjusted mean
	• Provider attestation of safety monitoring and management of amyloid related imaging abnormalities (ARIA) and intracerebral hemorrhage, as recommended per the manufacturer's prescribing information.
	• Documentation that member has experienced clinical benefit from the medication (such as: stabilization or decreased rate of decline in symptoms from baseline on CDR-SB, ADAS-Cog14, or ADCS MCI-ADL scales)
	• No recent (past 1 year) history of stroke, seizures, or TIA
	
	If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	**Lidocaine Topical Patch**
Drugs	Lidocaine 5% topical patch (Lidoderm) Ztlido 1.8% topical patch (lidocaine)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	Age 18 and older
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 6 month duration; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria Revision/Review Date 4/2023	<u>**Initial Authorization**</u> • Diagnosis of postherpetic neuralgia • If the request is for Ztlido there has been a documented trail and failure or intolerance to lidocaine 5% patch (Lidoderm) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**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 Revision/Review Date 4/2023	**The Patient meets one of the two following criteria:** • 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. **AND** • 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. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Medications for Management of Obesity**
Drugs	Xenical/orlistat benzphetamine diethylpropion, diethylpropion ER phendimetrazine, phendimetrazine ER phentermine (Adipex-P) Lomaira (phentermine)Saxenda (liraglutide) Wegovy (semaglutide) Imcivree (setmelanotide) Any newly-approved medication indicated for obesity or weight management *Note: Alli, Contrave, Qsymia are not a covered benefit*
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	Age appropriate per labeling
Prescriber Restrictions	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	**<u>Initial Authorization:</u>** • Requested dose is appropriate per labeling • Documentation of current weight and body mass index (BMI) • BMI must be one of the following: 1. BMI of 27 - 29.9 kg/m^2 with one of the following weight-related comorbidities: coronary artery disease, diabetes, hypertension, dyslipidemia, or obstructive sleep apnea 2. BMI of 30 kg/m^2 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: trial and failure or medical reason for not using 2 of the following: 1. orlistat 2. Saxenda 3. Wegovy • For Lomaira: trial and failure or medical reason for not using

Revision/Review Date: 10/2023	generic phentermine • For Imcivree, the patient meets one of the following: 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: ▪ 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 **<u>Re-Authorization:</u>** • 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) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Medications for Use in ADHD Treatment for Members 21 and Older**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Preferred drugs will pay for members 20 and younger; PA required for members 21 and older
Prescriber Restrictions	N/A
Coverage Duration	If 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.
Other Criteria Revision/Review Date: 4/2023	**Initial Authorization (for members who are new starts to ADHD therapy):** • Prescriber attests that the Diagnostic and Statistical Manual of Mental Disorders V (DSM-5) criteria for diagnosis of ADHD in adults has been met • Behavioral modification techniques have been tried prior to medication being prescribed **AND** **Criteria for ALL requests including renewal requests:** • Appropriate dose of medication based on age and indication. • The patient is not on another stimulant with the same duration of action (i.e., short-acting or long-acting) simultaneously. • If the request is for a non-preferred medication, documented trial and failure or intolerance to two preferred medications used to treat the documented diagnosis (12 month approval); OR If the request is for a non-preferred medication, and 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 (6 month approval). **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Mucopolysaccharidosis II (Hunter Syndrome) Agents**
Drugs	**Elaprase (idursulfase)**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	“See Other Criteria”
Age Restrictions	Patient is ≥ 16 months of age
Prescriber Restrictions	Prescribed by or in consultation with a specialist in genetics or metabolic disorders
Coverage Duration	Initial Authorization: 6 months Reauthorization: 12 months
Other Criteria Revision/Review Date 7/2023	**Initial Authorization** • Diagnosis of Mucopolysaccharidosis II as confirmed by one of the following: o Enzyme assay demonstrating a deficiency of iduronate 2-sulfatase activity o Genetic testing • Patient’s weight • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines **Reauthorization** • Patient has demonstrated a beneficial response (i.e., stabilization or improvement in 6-minute walk test [6-MWT], forced vital capacity [FVC]), urinary glycosaminoglycan (GAG) levels, liver volume, spleen volume, etc.) • Patient’s weight • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Mucopolysaccharidosis VI (Maroteaux-Lamy Syndrome) Agents**
Drugs	**Naglazyme (galsulfase)**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	"See Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months Renewal: 12 months
Other Criteria	**Initial Authorization** • Diagnosis of Mucopolysaccharidosis VI as confirmed by one of the following: o Enzyme assay demonstrating a deficiency in N-acetygalactosamine 4-sulfatase (arylsulfatase B) enzyme activity o DNA testing • Patient's weight • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines **Reauthorization** • Patient has demonstrated a beneficial response (i.e., stabilization or improvement in 12-minute walk test [12-MWT], 3-minute stair climb test, urinary glycosaminoglycan (GAG) levels, etc.) • Patient's weight • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines
Revision/Review Date 1/2023	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Multaq**
Drugs	**Multaq (dronedarone)**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Pregnancy
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	Request must be from a cardiologist or electrophysiologist.
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 4/2023	• Diagnosis of paroxysmal or persistent arterial fibrillation (AF) or atrial flutter (AFL) with a recent episode. • Must not have NYHA Class IV heart failure or symptomatic heart failure with recent decompensation requiring hospitalization or referral to a specialized heart failure clinic • Must have AF that can be cardioverted into normal sinus rhythm, or is currently in sinus rhythm • Prescriber attests women of childbearing potential have been counseled regarding appropriate contraceptives **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Myasthenia Gravis Agents**
Drugs	Rystiggo (rozanolixizumab), Soliris (eculizumab), Ultomiris (ravulizumab),Vyvgart (efgartigimod), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the 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	**<u>Initial Authorization:</u>**
	• Diagnosis of generalized myasthenia gravis (gMG)
	• Patient has a positive serological test for one of the following:
	  o Anti-AChR antibodies
	  o Anti-muscle-specific tyrosine kinase (MuSK) antibodies (Rystiggo only)
	• Patient has a Myasthenia Gravis Foundation of America (MGFA) clinical classification of class II, III or IV
	• Patient has tried and failed, or has contraindication, to one of the following:
	  o 2 or more conventional therapies (i.e. acetylcholinesterase inhibitors, corticosteroids, non-steroidal immunosuppressive therapies)
	  o Failed at least 1 conventional therapy and required chronic plasmapheresis or plasma exchange or intravenous immunoglobulin
	• Medication is prescribed at an FDA approved dose
	• Patient is not using agents covered by this policy concurrently (i.e. no concurrent use of Vyvgart, Vyvgart Hytrulo, Rystiggo, Soliris, or Ultomiris)
	• For Vyvgart Hytrulo, patient has tried and failed, or has contraindication, to Vyvgart
	• Requests for Soliris (eculizumab) and Ultomiris (ravulizxumab) will

Revision/Review Date: 10/2023	also require all of the following: o Patient has tried and failed, or has contraindication, to Vyvgart, Vyvgart Hytrulo, or Rystiggo. o Documentation of vaccination against meningococcal disease or a documented medical reason why the patient cannot receive vaccination or vaccination needs to be delayed o Antimicrobial prophylaxis with oral antibiotics (penicillin, or macrolides if penicillin-allergic) for two weeks will be administered if the meningococcal vaccine is administered less than two weeks before starting therapy or a documented medical reason why the patient cannot receive oral antibiotic prophylaxis **Re-Authorization:** • Provider has submitted documentation of clinical response to therapy (e.g., reduction in disease severity, improvement in quality of life scores, MG-ADL scores, etc). • Medication is prescribed at an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	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: 4/2023	**<u>Initial Authorization:</u>** • Member has a diagnosis of achondroplasia as confirmed via genetic testing • Prescriber attests patient has open epiphyses • Documentation is provided of baseline recent (within the past 6 months) growth velocity $\geq$1.5 cm/year • Medication is prescribed at an FDA approved dose **<u>Re-Authorization:</u>** • Documentation of positive clinical response to therapy (as demonstrated by improvement over baseline in annualized growth velocity) • Prescriber attests patient has open epiphyses • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**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	**<u>Initial Authorization:</u>** <u>For rituximab (Rituxan, Truxima, Riabni, or Ruxience):</u> • 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 <u>For Enspryng:</u> • Member has a diagnosis of anti-aquaporin-4 (AQP4) antibody **positive** NMOSD • Provider attests to completion of the following assessments prior to the first dose of Enspryng as outlined in the prescribing information: o Hepatitis B virus screening o Tuberculosis screening o Liver transaminase screening

    - 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

<u>For Uplizna:</u>

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

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

<u>For Soliris:</u>

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

Revision/Review Date 10/2023	• 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):
	    o Rituximab (Rituxan, Truxima, Riabni, or Ruxience), azathioprine, or mycophenolate mofetil
	    o Enspryng
	    o Uplizna
	• Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines
	
	Reauthorization:
	• Documentation that the prescriber has evaluated the member and recommends continuation of therapy (clinical benefit)
	• Request is for an FDA approved/medically accepted dose
	
	Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	**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	**Initial Authorization:** • Diagnosis of primary biliary cholangitis (PBC) with confirmation of diagnosis by the following tests: 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: a) Serum ALP b) Total bilirubin **Reauthorization:** • Provider attests that the patient has not developed complete biliary obstruction, decompensated cirrhosis (e.g., Child-Pugh Class B or C), or compensated cirrhosis (Child-Pugh Class A) with evidence of portal hypertension • Submission of lab tests confirming each of the following: ○ A decrease in ALP of ≥ 15% from baseline ○ ALP is less than 1.67 times the upper limit normal (ULN);

	defined as 118 U/L for females and 124 U/L for males ◦ Total bilirubin ≤ ULN defined as 1.1 mg/dL for females and 1.5 mg/dL for males
Revision/Review Date 1/2023	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Opioid Containing Products**
Drugs	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	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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	Patient must be age appropriate per package insert
Prescriber Restrictions	Pain Specialist, Oncologist, Hospice Physician, Hematologist, Surgeon, or attestation that the requesting prescriber is working in consultation with or has consulted with one of the above specialty types. If the prescriber is not one of the above specialties and is unable to consult with one of the above specialties, provider has attested that an attempt has been made to refer and/or transition patient to one of the above specialties.
Coverage Duration	If the criteria are met, the request will be approved for up to six months duration. Requests for members with cancer, sickle cell disease, hospice, or end-of-life patients may be approved for up to 12 months.
Other Criteria	*****Hospice, end-of-life, cancer, and sickle cell patients are exempt from prior authorization. Please automatically authorize for up to 12 months***** **Initial Authorization for Opioid Containing Products:** 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 short-acting 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).

	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

Revision/Review Date 4/2023	why and has discussed risks of using opioids and benzodiazepines concurrently and has outlined plan for tapering if appropriate. 3. Member is not taking concurrent muscle relaxants, 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 **Requests for Opioid Containing Cough/Cold Products** 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. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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

	Quetiapine Extended Release (Seroquel XR) ≥ 10 years old Risperidone (Risperdal) ≥ 5 years old Rexulti (brexpiprazole) ≥ 13 years old Saphris (asenapine) ≥ 10 years old Secuado (asenapine) ≥ 18 years old Vraylar (cariprazine) ≥ 18 years old Ziprasidone (Geodon) ≥ 18 years old
Prescriber Restrictions	Prescription is written by, or in consultation with, a Pediatric Neurologist, Child and Adolescent Psychiatrist, Child Development Pediatrician
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 10/2023	**For members below the FDA approved minimum age:** • Documentation of severe behavioral problems related to psychotic or neuro-developmental disorders (such as, but not limited to: autism, intellectual disability, bipolar disorder, tic disorder, or schizophrenia); **AND** • Documentation of a trial of non-pharmacologic therapies (e.g., behavioral, or cognitive); **AND** • If the request is for a non-preferred antipsychotic there has been a documented trial and failure or intolerance of 1 preferred antipsychotic for requested diagnosis **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Oxbryta (voxelotor)**
Drugs	Preferred: Oxbryta (voxelotor) 500 mg tablets Oxbryta (voxelotor) 300 mg tablets NDC 72786-0102-03 Oxbryta (voxelotor) tablets for suspension NDC 72786-0111-03 Non-Preferred: Oxbryta (voxelotor) 300 mg tablets NDC 72786-0102-02 Oxbryta (voxelotor) tablets for suspension NDC 72786-0111-02
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the 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 6-month duration. Reauthorization requests may be approved for 12 months. If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.

Other Criteria	**Initial Authorization:**
	• Member has a confirmed diagnosis of sickle cell disease
	• Baseline labs have been submitted for the following:
	    o Hemoglobin (Hb)
	    o Indirect bilirubin
	    o Reticulocytes
	• 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

Revision/Review Date: 1/2023	• 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 72786-0102-03 • Request is for an FDA-approved dose **Reauthorization:** • Documentation of ONE of the following: o Hb increase from baseline (at 6 months from initiation) OR maintenance of such Hb increase (at 12-month intervals thereafter) o Documentation of a reduced number of vaso-occlusive/pain crises since Oxbryta was started o Improvement from baseline in hemolytic markers (i.e. decrease in indirect bilirubin, decrease in percentage of reticulocytes) **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	**Oxlumo (lumasiran)**
Drugs	Oxlumo (lumasiran)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a nephrologist, urologist, hepatologist, endocrinologist or 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	**<u>Initial Authorization</u>**
	• Diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by one of the following:
	    o Genetic testing confirming at least one mutation at the AGXT gene
	    o Liver biopsy demonstrating absent or significantly reduced AGT activity
	• Metabolic testing demonstrating one of the following:
	    o Increased urinary oxalate excretion (≥ 0.5 mmol/1.73 m^3 per day[45 mg/1.73 m^3 per day])
	    o Increased urinary oxalate:creatinine ratio relative to normative values for age
	    o Increased plasma oxalate level (≥ 20 µmol/L)
	• Member is concurrently using pyridoxine or has tried and failed previous pyridoxine therapy for at least 3 months, or has a medical reason for not using pyridoxine
	• Member has no history of liver transplant
	• Medication is prescribed at an FDA approved dose
	
	<u>Reauthorization</u>
	• Members previously using pyridoxine will continue to use pyridoxine, or have a medical reason for not using pyridoxine

Revision/Review Date 1/2023	• Documentation has been provided that demonstrates a clinical benefit (e.g. symptomatic improvement, reduction in urinary or plasma oxalate levels from baseline) • Medication is prescribed at an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	**Field Description**
Prior Authorization Group Description	**Palynziq**
Drugs	Palynziq (pegvaliase-pqpz)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	None
Required Medical Information	See "other criteria"
Age Restrictions	None
Prescriber Restrictions	Specialist experienced in the treatment of phenylketonuria (PKU).
Coverage Duration	Initial Authorizations: 12 months Dose Increases (to 40 mg or 60 mg daily): 16 weeks Reauthorization: 12 months
Other Criteria	**<u>INITIAL AUTHORIZATION:</u>** • 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. **<u>DOSE INCREASES:</u>** • 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:

Revision/Review Date: 4/2023	- o For requests for a dose of 40 mg per day, the patient has been on 20 mg once daily continuously for at least 24 weeks and has not achieved adequate control - o For requests for a dose of 60 mg per day, the patient has been on 40 mg once daily continuously for at least 16 weeks and has not achieved adequate control - The medication is being prescribed at an FDA approved dose (maximum of 60 mg once daily). **<u>REAUTHORIZATION:</u>** - Documentation of recent blood Phe level results (within the previous 90 days); **AND** - The medication is being prescribed at an FDA approved dose; **AND** - Member has achieved a reduction in blood phenylalanine concentration from pre-treatment baseline. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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

Revision/Review Date 4/2023	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**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	Patient is 18 years of age or older
Prescriber Restrictions	Prescriber is a cardiologist or nephrologist or in consultation with one of these specialties
Coverage Duration	If the criteria are met, the request will be approved with up to a 3 month duration for initial requests and up to 6 months for renewal requests.
Other Criteria Revision/Review Date 4/2023	**<u>Initial Authorization</u>** • Diagnosis of hyperkalemia • Documentation patient has been counseled to follow a low potassium diet • Where clinically appropriate, documentation of medications known to cause hyperkalemia (e.g. angiotensin-converting enzyme inhibitor, angiotensin II receptor blocker, aldosterone antagonist, NSAIDs) have been discontinued or decreased to lowest effective dose • 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 **<u>Re-Authorization</u>** • Documentation that demonstrates member is receiving clinical benefit from treatment (e.g. potassium level returned to normal or significant decrease from baseline). **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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

Revision/Review Date 4/2023	• Trial and failure of one formulary alternative (i.e. gabapentin, amitriptyline) • Request is for pregabalin capsule or solution **Fibromyalgia**: • Documented diagnosis of fibromyalgia. o Trial and failure of one formulary alternatives (i.e. gabapentin, duloxetine, amitriptyline) • Request is for pregabalin capsule or solution **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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

Revision/Review Date 4/2023	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**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	Prescriber must be cardiologist or specialist in treatment of lipid disorders
Coverage Duration	If the criteria are met, the initial request will be approved for up to a 3 month duration, and the reauthorization request will be approved for up to a 12 month duration; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	<u>**Initial Authorization**</u> **For All Requests:** • Request is appropriate for member (e.g. age) as indicated in package labeling or standard of care guidelines • Patient has tried and failed atorvastatin 40mg-80mg or rosuvastatin 20-40mg (consistently for 3 months via claim history or chart notes). If patient is not able to tolerate atorvastatin or rosuvastatin, documentation was provided that patient is taking another statin at the highest tolerated dose, or a medical reason was provided why the member is not able to use these therapies. • If prescriber indicates member is "statin intolerant", documentation was provided including description of the side effects, duration of therapy, "wash out", re-trial, and then change of agents. • Documentation was provided indicating provider has counseled member on smoking cessation and following a "heart healthy diet". • If the request is for a non-preferred agent, documentation was provided of trial and failure, or a medical reason has been provided, why member is unable to use the preferred agent to manage their condition. AND the member meets the following for the respective diagnosis: <u>Familial Hypercholesterolemia (FH):</u>

	• Member has a diagnosis of familial hypercholesterolemia as evidenced by one of the following:
	    o Documentation provided including two fasting lipid panel lab reports with abnormal low density lipoprotein (LDL) levels ≥190 for FH in adults or ≥160 for FH in children.
	    o Results of positive genetic testing for an LDL-C-raising gene defect (LDL receptor, apoB, or PCSK9)
	• Additionally, if the diagnosis is heterozygous FH (HeFH), both of the following:
	    o Patient has tried and failed ezetimibe at a maximal tolerated dose or documentation has been provided that the patient is not able to tolerate ezetimibe.
	    o LDL remains ≥100 mg/dL despite maximally tolerated LDL-lowering therapy
	
	<u>Hyperlipidemia (Primary OR Secondary Atherosclerotic Cardiovascular Disease [ASCVD] Prevention)</u>
	• If the diagnosis is primary severe hyperlipidemia (i.e. LDL ≥190 mg/dL)
	    o LDL remains ≥ 100 mg/dL despite maximally tolerated LDL-lowering therapy
	• If the diagnosis is secondary ASCVD prevention
	    o Patient has tried and failed ezetimibe at a maximal tolerated dose or documentation has been provided that the patient is not able to tolerate ezetimibe.
	    o LDL remains ≥ 55 mg/dL or non-HDL (i.e. total cholesterol minus HDL) ≥ 85 mg/dL despite maximally tolerated LDL-lowering therapy
	    o And ONE of the following:
	        ▪ Documented history of multiple major ASCVD events (acute coronary syndrome within past 12 months, history of myocardial infarction, history of ischemic stroke, symptomatic peripheral artery disease)
	        ▪ Documented history of 1 major ASCVD event (acute coronary syndrome within past 12 months, history of myocardial infarction, history of ischemic stroke, symptomatic peripheral artery disease) AND multiple high-risk conditions (age ≥ 65 years, history of coronary artery bypass graft or percutaneous coronary intervention, diabetes mellitus, hypertension, chronic kidney disease, current smoker, or congestive heart failure)
	
	<u>**Reauthorization for all indications:**</u>

Revision/Review Date 4/2023	• Documentation submitted indicates that the member has obtained clinical benefit from the medication including repeat fasting lipid panel lab report and the member has had a reduction in LDL from baseline • The patient's claim history shows consistent therapy (i.e. monthly fills) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Pulmonary Biologics for Asthma and Eosinophilic Conditions**
Drugs	Nucala (mepolizumab), Fasenra (benralizumab), Cinqair (reslizumab), Dupixent (dupilumab), Tezspire (tezepelumab) or any newly marketed agents
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• When being used for relief of acute bronchospasm or status asthmaticus • When used in combination with another monoclonal antibody for the treatment of 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	<u>**Initial Authorization:**</u>
	
	<u>Asthma:</u>
	• Confirmed diagnosis of one of the following:
	    o Nucala, Fasenra, and Cinqair: Severe Eosinophilic Asthma
	    o Dupixent: Moderate-to-Severe eosinophilic asthma
	    o Tezspire: Severe Asthma
	• Documentation has been provided of blood eosinophil count within ONE of the following ranges:
	    o Nucala and Dupixent: ≥ 150 cells/mcL (within 6 weeks of request) OR ≥ 300 cells/mcL (within the past 12 months)
	    o Fasenra: ≥ 150 cells/mcL (within the past 12 months)
	    o Cinqair: ≥ 400 cells/mcL (within the past 12 months)
	    o Tezspire: No baseline blood eosinophil counts are required
	• The member has a documented baseline FEV_1 < 80% of predicted with evidence of reversibility by bronchodilator response.
	    o Tezspire ONLY: If age is < 18 years, the member has a documented baseline FEV_1 < 90% of predicted with evidence of reversibility by bronchodilator response
	• Documentation has been provided indicating that that the member

	continues to experience significant symptoms while compliant on a maximally tolerated inhaled corticosteroid with long-acting beta2 agonist (ICS/LABA) AND long-acting muscarinic antagonist (LAMA) (or a documented medical reason must be provided why the member is unable to use these therapies) and ONE of the following: o Nucala: ≥ 2 exacerbations in the past 12 months o Fasenra: ≥ 1 exacerbation in the past 12 months o Cinqair: ≥ 1 exacerbation in the past 12 months requiring systemic corticosteroids o Dupixent: ≥ 1 exacerbation in the past 12 months requiring systemic corticosteroids or hospitalization o Tezspire: ≥ 2 exacerbations requiring systemic corticosteroids OR ≥ 1 exacerbation in the past 12 months requiring hospitalization • The prescribed dose is within FDA approved dosing guidelines • For requests for agents other than Fasenra and Dupixent, the member has a trial and failure or medical reason why Fasenra, Dupixent, 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 FEV_1 < 80% of predicted with evidence of reversibility by bronchodilator response. • Documentation has been provided indicating patient still is having significant symptoms with ≥ 1 exacerbations in the previous 12 months requiring additional medical treatment, (emergency room visits, hospital admissions) while compliant on a high-dose inhaled corticosteroid with a long-acting B_2 agonist (ICS/LABA) AND a long-acting muscarinic antagonist (LAMA). If the patient has not utilized these therapies, a documented medical reason must be provided why patient is unable to do so. • The prescribed dose is within FDA approved dosing guidelines 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 <u>Prurigo Nodularis (PN) (*Dupixent only*):</u> • Confirmed diagnosis of PN lasting for at least three months prior to request • Member has a Worst-itch Numeric Rating Scale (WI-NRS) score of 7 or higher indicating severe or very severe itching • Member has at least 20 PN lesions in total • Documented trial and failure, intolerance, or contraindication to at least two of the following for a minimum of two weeks: o One medium to super-high potency topical corticosteroid o One topical calcineurin inhibitor o UVB phototherapy or psoralen plus UVA phototherapy • The prescribed dose is within FDA approved dosing guidelines <u>Eosinophilic granulomatosis with polyangiitis (EGPA) (*Nucala only*):</u> • Confirmed diagnosis of EGPA and eosinophilic asthma lasting for ≥6 months • Member has a history of relapsing disease defined as at least one EGPA relapse requiring additional corticosteroids or immunosuppressant or hospitalization within the past 2 years OR member has a history of refractory disease defined as failure to attain remission in the prior 6 months following induction treatment with standard therapy • Member must be on a stable dose of oral corticosteroids for at least 4 weeks prior to request • Member has a blood eosinophil count ≥1,000 cells/mcL OR > 10% of total leukocyte count • Documented trial and failure, intolerance, or contraindication to cyclophosphamide, azathioprine, methotrexate, rituximab, OR mycophenolate mofetil • The prescribed dose is within FDA approved dosing guidelines <u>Hypereosinophilic Syndrome (HES) (*Nucala only*):</u> • Confirmed diagnosis of FIP1 like 1-platelet derived growth factor receptor alpha (FIP1L1-PDGFRA)-negative HES lasting for ≥6 months without an identifiable non-hematologic secondary cause • Member has a history of two or more HES flares (worsening of HES-related symptoms necessitating therapy escalation or ≥2 courses of rescue oral corticosteroids) within the past 12 months • Member has a blood eosinophil count ≥1,000 cells/mcL • Documented trial and failure, intolerance, or contraindication to oral corticosteroids AND at least one second-line agent (e.g.

Revision/Review Date 7/2023	hydroxyurea, interferon, imatinib, methotrexate, cyclophosphamide, cyclosporine, azathioprine) (member must be on stable dose of at least one agent for at least 4 weeks prior to request) **<u>Re-Authorization:</u>** 1. Documentation submitted indicates the member has clinically benefited from the medication (e.g. Asthma: improved FEV_1, reduced exacerbations; HES: symptomatic improvement, reduced oral corticosteroid dose; EGPA: reduction in relapse frequency or severity, disease remission, symptomatic improvement, reduced oral corticosteroid dose); EoE: histological remission, improvement in DSQ scores; PN: improvement in WI-NRS score, symptomatic improvement) 2. The prescribed dose is within FDA approved dosing guidelines **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

<table>
<tr><th>Field Name</th><th>Field Description</th></tr>
<tr><td>Prior Authorization Group Description</td><td>Pyruvate Kinase Activators</td></tr>
<tr><td>Drugs</td><td>Pyrukynd (mitapivat)</td></tr>
<tr><td>Covered Uses</td><td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td></tr>
<tr><td>Exclusion Criteria</td><td>N/A</td></tr>
<tr><td>Required Medical Information</td><td>See “Other Criteria”</td></tr>
<tr><td>Age Restrictions</td><td>Age ≥18 years</td></tr>
<tr><td>Prescriber Restrictions</td><td>Prescribed by or in consultation with a hematologist</td></tr>
<tr><td>Coverage Duration</td><td>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</td></tr>
<tr><td>Other Criteria</td><td><u>Initial Authorization:</u>

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 non-missense variants of the PKLR gene, without the presence of another missense variant in the PKLR gene
Documentation of ONE of the following:

The member does not regularly require blood transfusions (defined as requiring <u>less than or equal to</u> 3 red blood cell (RBC) transfusions in the past 52 weeks and no transfusions in the past 3 months) AND hemoglobin (Hb) level ≤ 10 g/dL
The member has required more than or equal to 6 RBC transfusions in the past 12 months

Documentation of the number of transfusions and the number of red blood cell (RBC) units transfused

</td></tr>
</table>

Revision/Review Date: 7/2023	• Prescriber attests that the member does not have moderate or severe hepatic dysfunction • Prescriber attests that the member has not had a splenectomy in the past 12 months • Prescriber attests that the member does not have a history of a prior bone marrow or stem cell transplant • The member is not concurrently using hematopoietic-stimulating agents (e.g. Procrit or Retacrit) • Prescriber attests the member is taking at least 0.8mg of folic acid daily **Reauthorization:** • The prescribed dose is within FDA approved dosing guidelines • For the first reauthorization, documentation of benefit: increase in Hb ≥1.5 g/dL over baseline OR a reduction in transfusions, defined as ≥33% reduction in the number of red blood cell (RBC) units transfused over baseline • For subsequent reauthorizations: documentation of benefit: stabilization in Hb levels OR a sustained reduction in transfusions • If the reauthorization criteria are not met, may authorize up to 14 days of a Pyrukynd Taper Pack to allow for tapering. To reduce the risk of acute hemolysis, abrupt discontinuation of Pyrukynd should be avoided. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	Qalsody (tofersen)
Drugs	Qalsody (tofersen)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	See “Other Criteria”
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, neuromuscular specialist, or physician specializing in the treatment of amyotrophic lateral sclerosis (ALS)
Coverage Duration	If all the criteria are met, initial and renewal requests will be approved for 6 months
Other Criteria Review/Revision Date: 7/2023	**<u>Initial Authorization:</u>** • Diagnosis of ALS • Documentation of genetic test confirming a mutation in the superoxide dismutase 1 (SOD1) gene • Member is not dependent on invasive ventilation or tracheostomy • Documentation of slow vital capacity (SVC) ≥ 50% • Medication is prescribed at an FDA approved dose **<u>Re-Authorization:</u>** • Documentation or provider attestation of positive clinical response (e.g., reduction in the mean concentration of neurofilament light [NfL] chains in the plasma, reduction in concentration of SOD1 in cerebrospinal fluid (CSF), or improvement in the Revised ALS Functional Rating Scale (ALSFRS-R) total score) • Member is not dependent on invasive ventilation or tracheostomy • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Radicava**
Drugs	Radicava, Radivaca ORS (edaravone) and any other newly marketed agent *** riluzole (Rilutek) is Preferred and does not require prior authorization***
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	If the criteria are met, requests will be approved for up to 6 month duration
Other Criteria Revision/Review Date 4/2023	**Initial Authorization:** • Member must have a diagnosis of ALS • Member must have a documented baseline evaluation of functionality using the revised ALS functional rating scale (ALSFRS-R) score ≥ 2 • Member’s disease duration is 2 years or less • Member has a baseline forced vital capacity (FVC) of ≥ 80% • Member has been on riluzole (Rilutek), is beginning therapy as an adjunct to treatment with Radicava, or provider has provided a medical reason why patient is unable to use riluzole • Dose is within FDA approved limits **Reauthorization:** • Member is not ventilator-dependent • Provider documents clinical stabilization in symptoms (e.g. stabilization of ALSFRS-R score) • Dose is within FDA approved limits **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	Relyvrio (sodium phenylbutyrate and taurursodiol)
Drugs	Relyvrio (sodium phenylbutyrate and taurursodiol)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	See “Other Criteria”
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, neuromuscular specialist, or physician specializing in the treatment of amyotrophic lateral sclerosis (ALS)
Coverage Duration	If all the criteria are met, initial and renewal requests will be approved for 6 months
Other Criteria Review/Revision Date: 1/2023	**<u>Initial Authorization:</u>** • Medication is prescribed at an FDA approved dose • Diagnosis of ALS with onset of symptoms within the previous 18 months • Member is not dependent on invasive ventilation or tracheostomy • Documentation of slow vital capacity (SVC) > 60% **<u>Re-Authorization:</u>** • Documentation or provider attestation of positive clinical response (such as improvement in the Revised ALS Functional Rating Scale (ALSFRS-R) total score) • Member is not dependent on invasive ventilation or tracheostomy • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Retinoids (Dermatologic)**
Drugs	**<u>FORMULARY STATUS</u>** Requires Prior Authorization, Generically Available Agents Preferred: • **Claravis (isotretinoin)** • **Myorisan (isotretinoin)** • **Zenatane (isotretinoin)** • **Amnesteem (isotretinoin)** • **Isotretinoin** **<u>FORMULARY STATUS</u>** Requires Prior Authorization, Non-Preferred: • **Absorica (isotretinoin)** • **Absorica LD (isotretinoin)** • **Or any newly marketed oral retinoid product**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 6 month duration.
Other Criteria	**<u>Initial Authorization</u>** • 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 **<u>Re-Authorization</u>**

Revision/Review Date 10/2023	• Prescriber attests the member has experienced clinical benefit from therapy (e.g. perceived improvement of acne) and continued treatment with, or retreatment with, isotretinoin is necessary **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**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 Revision/Review Date 1/2023	**<u>Initial Authorization:</u>** 1. Diagnosis of ocular hypertension or open-angle glaucoma 2. Documented trial and failure of a prostaglandin inhibitor or beta-adrenergic antagonist 3. Member is using in conjunction with another medication for glaucoma (Rhopressa only) 4. Member has not had: a. Previous glaucoma intraocular surgery or glaucoma laser provider in the affected eye; OR b. Ocular surgery or laser treatment within three months prior to initiation 5. Member does not currently have any of the following: a. Ocular infection b. Inflammation c. Blepharitis d. Conjunctivitis e. Ocular disease **<u>Re-authorization:</u>** 1. Member must continue to meet above criteria 2. Member has demonstrated efficacy (e.g. reduction in intraocular pressure) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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:

NEUORMYELITIS OPTICA SPECTRUM DISORDER (NMOSD):

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

RHEUMATOID ARTHRITIS:

Initial Authorization

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

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

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

Reauthorization

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

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

PEMPHIGUS VULGARIS

Initial Authorization

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

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

Reauthorization

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

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

ONCOLOGY INDICATIONS

Initial Authorization:

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

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

Reauthorization

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

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

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

Initial Authorization:

- The medication is being recommended and prescribed by a rheumatologist or nephrologist.
- The patient is 2 years of age or older and has a documented clinical diagnosis of GPA (Wegener's Granulomatosis), eosinophilic granulomatosis with polyangiitis (EGPA), or MPA AND the prescriber indicates whether there is severe or non-severe disease.
- For non-severe disease, 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 of three months (including dates, doses) of glucocorticoid (i.e. prednisone) AND methotrexate or documentation includes a medical reason (intolerance, hypersensitivity, etc.) why patient is not able to use these therapies to manage their medical condition.
- For severe disease, a trial of glucocorticoid and methotrexate is not required
- 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) 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.

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: 12/2023

Field Name	Field Description
Prior Authorization Group Description	**Scopolamine Patch**
Drugs	Scopolamine Patch (Transderm-Scop)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved for the treatment of motion sickness and post-operative nausea and vomiting for a one (1) month duration and for the treatment of sialorrhea for a 12 month duration.
Other Criteria Revision/Review Date: 7/2023	**<u>Initial Authorization:</u>** <u>Motion Sickness and Post-Operative Nausea and Vomiting:</u> • Diagnosis of nausea and vomiting associated with motion sickness or nausea and vomiting associated with recovery from anesthesia and/or opiate analgesia and surgery. AND • Documented trial and failure at therapeutic doses of, intolerance to, or contraindication to two of the following: meclizine, diphenhydramine and dimenhydrinate. <u>Sialorrhea</u> • Documented trial and failure at therapeutic doses, intolerance or contraindication to glycopyrrolate. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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

	• The prescriber has provided documentation of clinical benefit/response to Serostim. • Request is for FDA approved or medically accepted dosing
Revision/Review Date: 7/2023	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	Skyclarys (omaveloxolone)
Drugs	Skyclarys (omaveloxolone)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Per FDA-approved prescribing information
Prescriber Restrictions	Prescriber must be a neurologist or in consultation with a neurologist or specialist with expertise in treating patients with Friedreich's Ataxia.
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Revision/Review Date 7/2023	**Initial Authorization:** • Diagnosis of Friedreich's Ataxia, confirmed via genetic testing (must submit documentation) • Modified FARS score ≥20 and ≤80 • Medication is prescribed at an FDA approved dose **Re-Authorization:** • Documentation or provider attestation of positive clinical response to Skyclarys therapy (i.e. improvement in symptoms, slowing of disease progression, etc.) • Medication is prescribed at an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Sleep Disorder Therapy**
Drugs	**Formulary status**: Preferred, Prior Authorization Required • modafinil (Provigil) tablets • armodafinil (Nuvigil) tablets **Formulary status**: Non-preferred, Prior Authorization Required • Sunosi (solriamfetol) tablets • Wakix (pitolisant) tablets • Sodium oxybate solution • Xyrem (sodium oxybate) solution • Xywav (calcium, magnesium, potassium, and sodium oxybates) • Lumryz (sodium oxybate) 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	Wakix: severe hepatic impairment (Child-Pugh class C) Sodium oxybate (Xyrem/Xyway/Lumryz): Succinic semialdehyde dehydrogenase deficiency
Required Medical Information	See “Other Criteria”
Age Restrictions	Per FDA approved prescribing information.
Prescriber Restrictions	Prescribed by or in consultation with a sleep specialist, neurologist, or other specialist in the treatment of the member’s diagnosis (does not apply for diagnosis of shift-work disorder)
Coverage Duration	If the criteria are met, requests for modafinil, armodafinil, Sunosi, and Wakix will be approved with up to a 12 month duration. Requests for sodium oxybate products will be approved with up to a 3 month duration.
Other Criteria	**<u>For all requests:</u>** • Medication is being prescribed at an FDA approved dose **<u>Modafinil/armodafinil initial authorization:</u>** • For a diagnosis of obstructive sleep apnea (OSA) documentation that the member has been compliant with or is unable to use positive airway pressure [continuous positive airway pressure (CPAP), bilevel positive airway pressure (BPAP), or automatic positive airway pressure (APAP)]. **<u>Sunosi initial authorization</u>** • Documented trial and failure of modafinil or armodafinil or a documented medical reason for not utilizing these medications. • For members with OSA: o Documentation that the member has been compliant with or is unable to use positive airway pressure (CPAP, BPAP, or APAP) **<u>Wakix initial authorization:</u>**

Revision/Review Date 10/2023	• For a diagnosis of narcolepsy without cataplexy: documented trial and failure of (or medical reason for not using), BOTH of the following:
	  o Modafinil or armodafinil
	  o Sunosi (solriamfetol)
	• For a diagnosis of narcolepsy with cataplexy: documented trial and failure of, or medical reason for not using, the following:
	  o Dextroamphetamine
	
	<u>Sodium Oxybate (Xyrem/Xywav/Lumryz) initial authorization</u>
	• Medication is not being taken concurrently with sedative hypnotics
	• For a diagnosis of narcolepsy without cataplexy:
	  o Documented trial and failure of, or a medical reason for not using, ALL of the following:
	    ▪ Either modafinil or armodafinil
	    ▪ Sunosi (solriamfetol)
	    ▪ Wakix (pitolisant)
	  o For Xyrem, Xywav, or Lumryz: documented trial and failure of, or medical reason for not using generic sodium oxybate.
	• For a diagnosis of narcolepsy with cataplexy:
	  o Documented trial and failure of each of, or medical reason for not using BOTH of the following:
	    ▪ Dextroamphetamine
	    ▪ Wakix (pitolisant)
	  o For Xyrem, Xywav, or Lumryz: documented trial and failure of, or medical reason for not using generic sodium oxybate.
	• For a diagnosis of idiopathic hypersomnia (Xywav only):
	  o Patient has a documented trial and failure of, or medical contraindication to, the following:
	    ▪ Modafinil or armodafinil
	
	<u>Reauthorization:</u>
	• Documentation has been submitted indicating member has experienced a clinical benefit from treatment (e.g. improvement on Epworth Sleepiness Score, reduction in frequency of cataplexy attacks)
	• For a diagnosis of obstructive sleep apnea (OSA) documentation that the member continues to be compliant with or is unable to use positive airway pressure (CPAP, BPAP, or APAP)
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary

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

	submitted with request [e.g. CHOP Infant Test of Neuromuscular Disorders (CHOP-INTEND) or Hammersmith Infant Neurological Examination (HINE) for Type 1 or Hammersmith Functional Motor Scale Expanded Scores (HFMSE) for Type II and Type III, or 6 minute walk test in subjects able to walk] • The request is for an FDA approved dose **Reauthorization** • 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
Revision/Review Date 1/2023	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	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	**<u>Initial Authorization</u>** <u>For all FDA approved indications (including FDA-approved oncology related uses)</u> • 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. <u>For Acromegaly</u> • Patient has had an inadequate response to, or medical reason why, surgical treatment cannot be used.

Revision/Review Date 12/2023	- 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:** - 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:** - 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:** - 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. For Cushing's Disease (pasireotide products only) - Patient must have had inadequate response, or medical reason why surgical treatment cannot be used **Reauthorization** - 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.) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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

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

Revision/Review Date 10/2023	<u>Oralair</u>: • Diagnosis has been confirmed by positive skin, or in vitro, testing to Sweet Vernal, Orchard, Rye, Timothy, Kentucky Blue Grass, or cross reactive, pollen <u>Ragwitek</u>: • Diagnosis has been confirmed by positive skin, or in vitro, testing to Short Ragweed pollen **<u>Reauthorization:</u>** <u>For all requests</u>: • Member has experienced a reduction in symptoms associated with allergic rhinitis **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	**Field Description**
Prior Authorization Group Description	**Synagis (palivizumab)**
Drugs	Synagis (palivizumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	A maximum of 5 doses may be approved within the Respiratory Syncytial Virus (RSV) season. Requests for additional doses will be reviewed on a case-by case basis based on CDC surveillance reports, state/local health department recommendations, and other current medical literature.

Other Criteria	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:
	• Born at less than 29 weeks, 0 days gestation
	• Born at less than 32 weeks, 0 days gestation AND had chronic lung disease of prematurity defined as greater than 21% oxygen for at least 28 days after birth
	• Born at any gestational age with hemodynamically significant heart disease including:
	    o Cyanotic heart disease in consultation with a pediatric cardiologist
	    o Acyanotic Heart disease with one of the following:
	        ▪ On heart failure medication and expected to require cardiac surgical procedure
	        ▪ Moderate to severe pulmonary hypertension
	• Cystic fibrosis with clinical evidence of chronic lung disease (CLD) and/or nutritional compromise in the first year of life
	• Born at any gestational age with pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the lower airway
	
	Infants less than 2 years of age at the onset of the RSV season (which typically starts November 1st, but may vary seasonally) **AND** have one of the following indications:
	• Born at less than 32 weeks, 0 days AND had a diagnosis of chronic lung disease of prematurity at birth as defined above

	AND had continued need for one of the following respiratory interventions in the 6 months preceding RSV season: Chronic steroids, chronic diuretics, supplemental oxygen • Cystic fibrosis with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) or weight for length less than the 10th percentile • Born at any gestational age and will be profoundly immunocompromised during the RSV season, including: o Solid organ or hematopoietic stem cell transplant recipient o Chemotherapy recipient • Born at any gestational age and receiving a cardiac transplant
Revision/Review Date: 7/2023	**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	**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.
Other Criteria Revision/Review Date: 4/2023	• Diagnosis of primary immunoglobulin A nephropathy (IgAN) • Prescriber attests member is at risk of rapid disease progression • Member has an estimated glomerular filtration rate (eGFR) ≥35 mL/min/1.73 m^2 and proteinuria (defined as either ≥1 g/day or urine protein/creatinine ratio [UPCR] ≥0.8 g/g) • Member is on an ACE inhibitor or ARB at a maximally tolerated dose OR there is a medical reason that they cannot be on one • Medication is prescribed at an FDA approved dose ***Reauthorization requests will not be allowed as the safety and efficacy of subsequent courses of Tarpeyo have not been established*** **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

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

	the upper limit of normal and bilirubin >2 times the upper limit of normal) • Prescriber attestation that patient has no active HBV infection • The prescribed dose is within FDA approved dosing guidelines
Revision/Review Date: 1/2023	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	Topical mTOR Kinase Inhibitors
Drugs	Hyftor (sirolimus topical gel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	Member concomitantly taking an oral mTOR inhibitor
Required Medical Information	See “Other Criteria”
Age Restrictions	Member must be 6 years or older
Prescriber Restrictions	Prescriber must be a dermatologist, medical geneticist, neurologist, or other prescriber who specializes in the treatment of genetic or dermatologic disorders.
Coverage Duration	If the criteria are met, requests will be approved with up to a 3 month duration. Thereafter, reauthorization requests will be approved with up to a 6 month duration.
Other Criteria Revision/Review Date 4/2023	**Initial Authorization:** • Member has a confirmed diagnosis of tuberous sclerosis complex (TSC) • Member has at least 3 facial angiofibromas measuring 2 mm or larger in diameter • Documentation of a comprehensive dermatologic evaluation has been provided • Prescriber attests that the member is not a candidate for laser therapy or surgery • Medication is being prescribed at an FDA approved dose **Reauthorization:** • Documentation has been provided indicating that the member has experienced a clinical benefit from treatment (e.g. improvement in size and color of angiofibromas) • Documentation of a comprehensive dermatologic evaluation has been provided • Prescriber attests that the member is not a candidate for laser therapy or surgery • Medication is being prescribed at an FDA approved dose

Field Name	Field Description
Prior Authorization Group Description	**Toremifene (Fareston)**
Drugs	**<u>FORMULARY STATUS</u>** Formulary, Pays at Point-of-Sale **TAMOXIFEN TABLETS 10MG AND 20MG** **<u>FORMULARY STATUS</u>** Requires Step Therapy with one prior step **TOREMIFENE (FARESTON) 60MG TABLET** **Note: Patient must meet criteria #1 & #2 for approval of the PA request.**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 12/2023	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 **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	**Transthyretin-mediated Amyloidosis Agents**
Drugs	**<u>Preferred</u>:** Polyneurpathy – Onpattro (patisiran), Amvuttra (vutrisiran) Cardiomyopathy – Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis) **<u>Non-preferred</u>**: Polyneuropathy – Tegsedi (inoterson) Or any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Patient must be 18 years of age or older
Prescriber Restrictions	Prescriber must be neurologist, cardiologist, or specialist in the treatment of amyloidosis
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy the request will be approved for 6 months.
Other Criteria	**<u>Initial Authorization</u>**: • 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 or Vyndamax • If the request is for Onpattro, Amvuttra, or Tegsedi, patient has diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis as evidenced by: o Documented transthyretin variant by genotyping o One of the following: ▪ Patient has baseline polyneuropathy disability (PND) score ≤ IIIb ▪ Patient has a baseline FAP Stage 1 or 2 ▪ Patient has baseline neuropathy impairment (NIS) score ≥ 5 and ≤ 130 o Patient has clinical signs/symptoms of neuropathy o For Tegsedi, patient has contraindication to/or previous trial and failure of use of Onpattro or Amvuttra • If the request is for Vyndaqel or Vyndamax, patient has diagnosis of cardiomyopathy of wild-type or hereditary

Revision/Review Date:1/2023	transthyretin-mediated amyloidosis as evidenced by all of the following: o Documented transthyretin variant by genotyping or wild-type amyloidosis o Documented amyloid deposit by biopsy or positive technetium 99m pyrophosphate (Tc 99m PYP) cardiac imaging o Patient has New York Heart Association (NYHA) functional class I, II, or III heart failure symptoms. **Re-authorization (for continuing and new patients to the plan)** : • Patient's regimen does not exceed FDA-approved dose/frequency for the agent • Patient has not undergone a liver or heart transplant • Patient is not taking any of these agents concurrently: Tegsedi, Onpattro, Amvuttra, Vyndaqel or Vyndamax) • Documented positive clinical response to therapy from baseline (stabilization/slowing of disease progression, improved neurological impairment, motor functions, improved NIS score, stabilization/reduced rate of decline in 6 minute walk test, etc.) • If the request is for Vyndaqel/Vyndamax o Patient has continued NYHA functional class I, II, or III heart failure symptoms **Continuation of Therapy/Grandfathering Provision:** Members with history (within the past 90 days) of a non-formulary product are not required to try a formulary agent prior to receiving the non-formulary product. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

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

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

	adjustments must be made AND the prescriber must provide a medical justification as to why therapy should be continued. • The request is for an FDA approved dose
Revision/Review Date 4/2023	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Type I Interferon (IFN) Receptor Antagonist**
Drugs	Saphnelo (anifrolumab-fnia)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Severe active central nervous system lupus • Active lupus nephritis
Required Medical Information	See "Other Criteria"
Age Restrictions	≥ 18 years
Prescriber Restrictions	Prescriber must be a rheumatologist or in consultation with a rheumatologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Date: 10/2023	**Initial Authorization:** • Diagnosis of active moderate to severe systemic lupus erythematosus (SLE) • Member has tried all of the following (or there is a medical reason they cannot use these therapies) before Saphnelo: o Hydroxychloroquine + Glucocorticoids o One other immunosuppressant (i.e., methotrexate, azathioprine, calcineurin inhibitors, or mycophenolate) o Benlysta (belimumab), if member has autoantibody-positive SLE • Prescriber attests member will not be using Saphnelo concurrently with Benlysta • Medication is prescribed at an FDA approved dose **Re-Authorization:** • Documentation or provider attestation of positive clinical response (i.e., reduction in signs and symptoms of SLE, fewer flares, reduced oral corticosteroid use, etc.) • Prescriber attests member will not be using Saphnelo concurrently with Benlysta • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

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

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

Field Name	Field Description
Prior Authorization Group Description	**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
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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.

Other Criteria	**<u>Initial Authorization:</u>**
	• 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:
	    o Organic nitrates (i.e. nitroglycerin, isosorbide, etc.)
	    o Guanylate Cyclase (GC) stimulators (Adempas)
	    o HIV protease inhibitors (i.e. ritonavir, darunavir, etc.) – sildenafil only
	• If the provider is requesting drug is to be used in combination with another PAH agent, ONE of the following:
	    o A PDE-5 inhibitor and an ERA are requested as the combination therapy
	    o Documentation is provided as to why patient is unable to be treated with existing therapy. (e.g. worsening of the symptoms of dyspnea or fatigue, decline in functional class by at least one class or in 6-minute walk test (6MWD) by greater than 30 minutes)
	• The medication is prescribed at a dose that is within FDA approved guidelines
	
	<u>Re-authorization:</u>
	• Documentation has been submitted indicating the clinical benefit of therapy (e.g. improvement in functional class, improvement in 6-minute walk test, exercise capacity, or hemodynamics).

Revision/Review Date 7/2023	• The medication is being prescribed at a dose that is within FDA approved guidelines. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Veopoz (pozelimab-bbfg)**
Drugs	Veopoz (pozelimab-bbfg)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Patients with unresolved Neisseria meningitidis infection • Concurrent use of another complement inhibitor (i.e. Soliris)
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must have experience in treating complement related disorders (i.e., gastroenterologist, immunologist, cardiologist, etc.)
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 10/2023	**Initial Authorization:** • Medication is prescribed at an FDA approved dose • Diagnosis of CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease • Documentation of hypoalbuminemia (serum albumin <3.5 g/dL) • Documentation of patient weight **Re-Authorization:** • Documentation or provider attestation of positive clinical response (i.e. symptom improvement, normalization of labs such as serum albumin (3.5-5.5 g/dL) and IgG concentrations, reduced hospitalizations and severe adverse events, increased quality of life, etc.) • Documentation of patient weight • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Verquvo**
Drugs	Verquvo (vericiguat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Pregnancy
Required Medical Information	See “Other Criteria”
Age Restrictions	Patient must be 18 years or older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist
Coverage Duration	If all of the conditions are met, the request will be approved for 12 month duration.
Other Criteria Revision/Review Date 7/2023	1. Medication is prescribed at an FDA approved dose 2. The medication is being used for the treatment of symptomatic chronic heart failure with reduced ejection fraction (less than 45%) 3. Documentation that the patient has had a previous hospitalization for heart failure or has required outpatient IV diuretics 4. Member is currently being prescribed the following treatment regimens, or documentation has been provided that the member is not able to tolerate or has a contraindication to any of these agents: a. Angiotensin-converting enzyme (ACE) inhibitor OR angiotensin receptor blocker (ARB) OR angiotensin receptor/neprilysin inhibitor b. Mineralocorticoid receptor antagonist (e.g. spironolactone) c. Evidence based beta-blocker (i.e., bisoprolol, carvedilol, metoprolol succinate) d. Farxiga or Jardiance 5. Patient is not concomitantly using a phosphodiesterase-5 (PDE-5) enzyme inhibitor (e.g. sildenafil) 6. Negative pregnancy test (for females of reproductive age; as indicated) within 30 days of request 7. Prescriber attests to discussing with females of reproductive potential the need to use effective forms of contraception during treatment and for one month after stopping treatment **Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors
Drugs	Austedo/Austedo XR (deutetrabenazine) Ingrezza (valbenazine) tetrabenazine (Xenazine) Any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Concurrent use of monoamine oxidase inhibitors (MAOIs)
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by, or in consultation with, a neurologist or psychiatrist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.

Other Criteria	**<u>Initial Authorization:</u>**
	• Dose is within FDA-approved limits
	• Prescriber attests patient will not be receiving treatment with any other VMAT2 inhibitor
	For approval for use in Tardive Dyskinesia (TD):
	• Member must have clinical diagnosis of tardive dyskinesia that has persisted for the last 90 days, with documented baseline evaluation (e.g., Abnormal Involuntary Movement Scale (AIMS), the Tardive Dyskinesia Rating Scale (TDRS), etc.)
	• For members on antipsychotics, the antipsychotic dose(s) must have been stable for a continuous 90 day period at some point prior to the request
	• Prescriber has attempted at least ONE of the following strategies to manage the patient’s condition, or has provided a clinical reason why NONE of the following are possible:
	    o Reducing the dose of the drug responsible for causing dyskinesia
	    o Discontinuing the drug responsible for causing dyskinesia
	    o For members on first generation antipsychotics, switching to a second generation antipsychotic
	    o Trial of benzodiazepines
	• For Austedo requests:

Revision/Review Date: 10/2023	◦ Prescriber attests patient has no signs of hepatic impairment ◦ For patients at risk for QT prolongation, prescriber attests a baseline ECG has been obtained • For Ingrezza requests: ◦ Must be dosed at one capsule per day **For approval for use in chorea associated with Huntington's Disease (HD):** • Patient must have diagnosis of moderate to severe Huntington's with chorea, with documented baseline Total Maximal Chorea (TMC) score provided • For Austedo requests: ◦ Prescriber attests patient has no signs of hepatic impairment ◦ For patients at risk for QT prolongation, prescriber attests a baseline ECG has been obtained • For Ingrezza requests: ◦ Must be dosed at one capsule per day **Re-Authorization:** • Documentation or provider attestation of positive clinical response (e.g., improvement from baseline in average scores on the previously submitted symptom rating scale, decrease in symptoms, etc.) • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Vijoice**
Drugs	Vijoice (alpelisib)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	≥ 2 years
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, dermatologist, vascular surgeon, hematologist/oncologist, or other specialist in the treatment of PIK3CA-Related Overgrowth Spectrum (PROS)
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.

Other Criteria	**<u>Initial Authorization:</u>**
	• 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:
	    o At least a 20% reduction in the sum of measurable target lesion volume (1 to 3 lesions, via central review of imaging scans)
	    o None of the individual target lesions have ≥ 20% increase from baseline
	    o Absence of progression of non-target lesions
	    o Absence of any new lesions
	• Prescriber attests the patient does not have any serious adverse events or unacceptable toxicity
	• Medication is prescribed at an FDA approved dose

Date: 07/2023	**If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Vimizim (elosulfase alfa)**
Drugs	Vimizim (elosulfase alfa)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	Patient must be 5 years of age or older.
Prescriber Restrictions	Prescriber is, or is collaborating with another provider who is, a specialist in the treatment of Morquio A syndrome or other lysosomal storage disorders.
Coverage Duration	6 months

Other Criteria	**<u>Initial Authorization (new to therapy):</u>**
	• Patient has confirmed diagnosis of mucopolysaccharidosis IVA (MPS IVA, or Morquio A syndrome) via one of the following:
	    o Genetic testing
	    o Analysis of N-Acetylgalactosamine 6-sulfatase (GALNS) activity in leukocytes or fibroblasts
	• Dosage does not exceed 2 mg/kg once a week.
	• 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.
	
	<u>Re-Authorization:</u>
	• Dosage does not exceed 2 mg/kg once a week.
	• Patient shows signs of improvement from baseline in a 6-minute walk test (must submit results with request)
	
	<u>Re-authorization for members new to the plan previously treated with Vimizim:</u>
	• Patient has confirmed genetic diagnosis of mucopolysaccharidosis IVA (MPS IVA, or Morquio A syndrome) via one of the following:
	    o Genetic testing
	    o Analysis of N-Acetylgalactosamine 6-sulfatase (GALNS) activity in leukocytes or fibroblasts
	• Dosage does not exceed 2 mg/kg once a week.
	• Patient must have completed a 6-minute walk test for baseline evaluation, and patient shows signs of improvement from baseline in a recent 6-minute walk test (must submit both results with request).
	• If a baseline 6-minute walk test was not completed prior to initiation of Vimizim therapy, then:

Revision/Review Date 7/2023	- 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. **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 Revision/Review Date 7/2023	**<u>Initial Authorization</u>**: 1. Voriconazole is being used to treat invasive aspergillosis or a serious fungal infection caused by Scedosporium apiospermum and Fusarium species **OR** 2. Voriconazole is being used to treat esophageal candidiasis, candidemia (nonneutropenics), or disseminated candidiasis of the skin, abdomen, kidney, bladder wall or wounds; **AND** o Documented trial and failure with a formulary treatment option (i.e. fluconazole or nystatin) or documented medical reason (e.g., recent discharge from hospital on oral voriconazole, intolerance, hypersensitivity, contraindication) for not using a formulary treatment option for relevant indications **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Vuity**
Drugs	Vuity (pilocarpine HCl ophthalmic solution)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	≥ 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 Revision/Review Date: 7/2023	**Initial Authorization:** • Diagnosis of presbyopia • Trial and failure or contraindication to corrective lenses (i.e., eye glasses, contact lenses) • Member does not have glaucoma or ocular hypertension • Medication is prescribed at an FDA approved dose **Re-Authorization:** • Documentation or provider attestation of positive clinical response • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Vyjuvek (beremagene geperpavec-svdt)**
Drugs	Vyjuvek (beremagene geperpavec-svdt)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Other forms of epidermolysis bullosa, such as epidermolysis bullosa simplex, junctional epidermolysis bullosa, kindler epidermolysis bullosa
Required Medical Information	See “Other Criteria”
Age Restrictions	Per prescribing information
Prescriber Restrictions	Prescriber must be a dermatologist, geneticist, or specialist experienced in the treatment of dystrophic epidermolysis bullosa.
Coverage Duration	If all of the criteria are met, the initial request will be approved for three (3) months. Subsequent requests will be approved for six (6) months.
Other Criteria	**Initial Authorization:** • Patient has a diagnosis of dystrophic epidermolysis bullosa, with confirmed mutation(s) in the COL7A1 gene via genetic testing. • Documentation is provided that wound(s) to be treated are clean with adequate granulation tissue, excellent vascularization, and do not appear infected • Documentation is provided that there is no evidence of, or history of squamous cell carcinoma in the wound(s) to be treated • Medication is prescribed at an FDA approved dose, and maximum weekly dispensable amount is not exceeded **Re-Authorization:** • Documentation or provider attestation of positive clinical response (i.e. improvement in wound appearance, wound closure, healing, etc.) • Documentation indicating need for continued treatment is needed (either to partially healed wounds or to other wound sites) • Documentation is provided that wound(s) to be treated are clean with adequate granulation tissue, excellent vascularization, and do not appear infected • Documentation is provided that there is no evidence of, or history of squamous cell carcinoma in the wound(s) to be treated • Medication is prescribed at an FDA approved dose, and maximum weekly dispensing amount is not exceeded.

Date: 10/2023	**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	**White Blood Cell Stimulators**
Drugs	**FORMULARY STATUS** **Short-Acting G-CSFs:** **Neupogen** (filgrastim) syringe – PREFERRED AGENT **Granix** (TBO-filgrastim) **Neupogen** (filgrastim) vial **Nivestym** (filgrastim-aafi) **Releuko** (filgrastim-ayow) **Zarxio** (filgrastim-sndz) Or any newly market agent **Long-Acting G-CSFs:** **Nyvepria** (pegfilgrastim-apgf) – PREFERRED AGENT **Fulphila** (pegfilgrastim-jmdb) **Fylnetra** (pegfilgrastim-pbbk) **Neulasta** (pegfilgrastim) **Neulasta Onpro** (pegfilgrastim) **Rolvedon** (eflapegrastim-xnst) **Stimufend** (pegfilgrastim-fpgk) **Udenyca** (pegfilgrastim-cbqv) **Ziextenzo** (pegfilgrastim-bmez) Or any newly market agent **Additional Agents:** **Mozobil** (Plerixafor) **Leukine** (Sargramostim) Or any newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USPDI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	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	**Initial Authorization:**

Revision/Review Date: 12/2023	• The drug is being used for an appropriate indication at an appropriate dose per "Covered Uses". • ***For ALL requests for treatment or prophylaxis of febrile neutropenia:*** Documentation of the patient's absolute neutrophil count (ANC) within the last 30 day has been provided. **<u>Short-Acting G-CSFs:</u>** • ***For all requests for non-preferred agents:*** The patient has a documented treatment failure {i.e. failure to reach and/or maintain target ANC, prolonged febrile neutropenia, unplanned hospitalization or infection requiring prolonged anti-infective use} with an adequate trial (including dates, doses of therapy) of Neupogen syringe or has another documented medical reason (intolerance, hypersensitivity, stem cell collection, etc.) for not using Neupogen syringe to treat their medical condition. **<u>Long-Acting G-CSFs:</u>** • ***For all requests for non-preferred agents:*** The patient has a documented treatment failure (i.e. failure to reach and/or maintain target ANC, prolonged febrile neutropenia 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 **<u>Additional Agents:</u>** • ***For Leukine requests***: Documentation is submitted of the patient's current diagnosis, current body weight, body surface area (within 30 days of the request). • ***For Mozobil requests:*** Documentation is submitted of the patient's current diagnosis, current body weight, and that the patient is using Mozobil in combination with a granulocyte-colony stimulating factor (G-CSF) agent (e.g. Neupogen, Zarxio, Nivestym) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary**.

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

Revision/Review 7/2023	• Patient has the diagnosis of moderate to severe IBS-D • Patient has tried and failed or has a contraindication or intolerance to one formulary tricyclic antidepressant **Re-Authorization (Hepatic Encephalopathy and IBS-D only)**: • Documentation indicating the member has clinically benefited from therapy. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

<table>
<tr><th>Field Name</th><th>Field Description</th></tr>
<tr><td>Prior Authorization Group Description</td><td>Xolair for Asthma and Urticaria</td></tr>
<tr><td>Drugs</td><td>Xolair (omalizumab)</td></tr>
<tr><td>Covered Uses</td><td>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</td></tr>
<tr><td>Exclusion Criteria</td><td>Use of Xolair concomitantly with another pulmonary biologic (e.g. Fasenra, Nucala, Cinqair, Dupixent, Tezspire)</td></tr>
<tr><td>Required Medical Information</td><td>See “Other Criteria”</td></tr>
<tr><td>Age Restrictions</td><td>Asthma: ≥ 6 years
Chronic idiopathic urticaria: ≥ 12 years</td></tr>
<tr><td>Prescriber Restrictions</td><td>Prescribed by, or in consultation with, an allergist/immunologist, pulmonologist, or dermatologist</td></tr>
<tr><td>Coverage Duration</td><td>If all of the conditions are met, the request will be approved for up to a 4 month duration for initial requests and up to a 6 month duration for renewal requests.</td></tr>
<tr><td>Other Criteria</td><td>**For nasal polyposis, please refer to the “Biologic Agents for Nasal Polyposis” policy**

<u>Initial Authorization:</u>

<u>Asthma:</u>

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:

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:

Asthma Control Questionnaire (ACQ) consistently > 1.5 or Asthma Control Test (ACT)

</td></tr>
</table>

    - < 20
    - Daytime asthma symptoms more than twice per week
    - Use of an inhaled short acting B-2 agonist to relieve asthma symptoms more than twice per week (not including use prior to exercise)
    - Limited physical activity due to asthma symptoms
    - Nighttime awakening due to asthma symptoms
- Member has a positive immediate response on RAST test and/or skin prick test to at least 1 common allergen (e.g. dermatophagoides farinae, dermatop hagoides pteronyssinus, dog, cat, or cockroach) that is an asthma trigger (copy of results required).
- Pre-treatment serum IgE levels must be greater than or equal to 30 IU/mL

Chronic Idiopathic Urticaria:

- 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

Re-Authorization:

- 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)

Review/Revision Date: 10/2023	**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	**Zulresso (brexanolone)**
Drugs	Zulresso (brexanolone)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the 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 15 years of age or older
Prescriber Restrictions	Prescriber must be a psychiatrist or an obstetrician-gynecologist
Coverage Duration	If all the criteria are met, the initial request will be approved for a one – time infusion per postpartum period. Continuation after the initial infusion is not indicated for this medication.
Other Criteria Revision/Review Date 10/2023	**Initial Authorization:** • Diagnosis of moderate to severe postpartum depression (PPD) confirmed by a rating scale such as Montgomery-Åsberg Depression Rating Scale (MADRS) or the Hamilton Rating Scale for Depression (HAM-D) with a score of ≥ 20 • Patient is ≤ 12 months postpartum with onset of a major depressive episode between the third trimester and 4 weeks after delivery • Healthcare facility and patient must be enrolled in the Zulresso REMS program prior to initiation of medication • Patient’s weight has been provided and dosing is consistent with FDA approved labeling **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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-adaz, adalimumab-adbm, adalimumab-fjkp, Enbrel, Humira, infliximab (generic Remicade), Otezla, Taltz, Xeljanz tablets

Non-Preferred:
Actemra/ACTPen, Amjevita, Arcalyst, Avsola, Cibinqo, Cimzia, Cosentyx, Cyltezo, Entyvio, Hadlima, Hulio, Hyrimoz, Idacio, Ilaris, Ilumya, Inflectra, Kevzara, Kineret, Olumiant, Orencia, Remicade, Renflexis, Rinvoq, Siliq, Simponi/Aria, Skyrizi, Sotyktu, Spevigo, Stelara, Tremfya, Xeljanz solution, Xeljanz XR, Yuflyma, Yusimry

***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 Remicade®, Avsola®, Inflectra®, and Renflexis® requests only)
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.

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New Hampshire

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