



Next Generation Pharmacy Benefits

AmeriHealth Caritas New Hampshire Prior Authorization Criteria

Updated 4/14/2022



Pharmacy Prior Authorization Criteria

Field Name	Field Description
Prior Authorization Group Description	Non-Preferred/Prior Authorization Required Medications Criteria ***Please Note: If the request is for a non-formulary brand with an A-rated generic, refer to Brand Name Medication Criteria***
Drugs	<ul style="list-style-type: none"> Non-preferred drugs on the state preferred drug list (PDL) without drug or class specific criteria Drugs not defined on the state PDL without drug or class specific criteria Drugs requiring prior authorization without drug or class specific criteria
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criterion is met, the request will be approved for up to a 12 month duration (depending on the diagnosis and usual treatment duration). If criterion is not met, the request will be referred to a Clinician for medical necessity review.
Other Criteria	<p><u>For all requests:</u></p> <ul style="list-style-type: none"> Appropriate diagnosis/indication Appropriate dose of medication based on age (i.e. pediatric and elderly populations) and indication. <p><u>Non-Preferred drugs on the state PDL</u> Patient must meet one of the following criteria:</p> <ul style="list-style-type: none"> Documentation that patient has a trial and failure of the required number of preferred products listed for the drug class: https://www.dhhs.nh.gov/ombp/pharmacy/documents/preferred.pdf If a specific number is not outlined for the class, a trial and failure of all preferred products in the class must be documented. 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

<p>Revision/Review Date 5/2021</p>	<ul style="list-style-type: none"> • 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 • Documentation that patient has an age-specific indication that requires a non- preferred PDL drug and member age/indication for request has been provided • Documentation that patient has a medical co-morbidity or other medical complication that precludes the use of a preferred drug • Documentation that patient has clinically unacceptable risk with a change in therapy to a preferred drug and risks have been provided <p><u>Non-Preferred drugs not defined on the state PDL or Drugs where prior authorization is required without specific criteria</u></p> <p>Patient must meet one of the following criteria:</p> <ul style="list-style-type: none"> • Documented trial and failure or intolerance with up to two formulary drugs used to treat the documented diagnosis. For medications where there is only one formulary agent, only that agent must have been ineffective or not tolerated. • No other formulary drug has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia. • All other formulary drugs are contraindicated based on the patient's diagnosis, other medical conditions, or other medication therapy. <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
--	--

Field Name	Field Description
Prior Authorization Group Description	Brand Drug and Non-Specialty Reference Biologics
Drugs	<p>Oral and injectable brand drugs and reference biologics when a therapeutic equivalent generic drug or biosimilar/interchangeable biologic is available</p> <p>*** The Oncology Drugs prior authorization criteria will be applied to oncology drugs without drug or class specific criteria***</p> <p>*** The Specialty Drugs prior authorization criteria will be applied to specialty drugs without drug or class specific criteria***</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If all of the conditions are met, requests will be approved for up to 12 months. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria	<p>Brand Drug:</p> <ul style="list-style-type: none"> The provider either verbally or in writing has submitted a medical or member specific reason why the brand name drug is required based on the member’s condition or treatment history; AND If the member had side effects or a reaction to the generic drug, the provider has completed and submitted an FDA MedWatch form to justify the member’s need to avoid these drugs. The MedWatch form must be included with the prior authorization request <p>Form FDA 3500 – Voluntary Reporting</p> <p>Reference Biologic:</p> <ul style="list-style-type: none"> The provider has either verbally or in writing submitted a member specific reason why the reference biologic is required based on the member’s condition or treatment history; AND if the member had side effects or a reaction to the biosimilar or interchangeable biologic, the provider has

<p>Revision/Review Date 10/2021</p>	<p>completed and submitted an FDA MedWatch form to justify the member's need to avoid these drugs. The MedWatch form must be included with the prior authorization request</p> <p>OR</p> <ul style="list-style-type: none"> • The currently available biosimilar product does not have the same appropriate use (per the references outlined in "Covered Uses") as the reference biologic drug being requested <p>Form FDA 3500 – Voluntary Reporting</p> <p>Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>
---	---

Field Name	Field Description
Prior Authorization Group Description	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). If criterion is not met, the request will be referred to a Clinician for medical necessity review.
Other Criteria	Provider has submitted a diagnosis that is FDA approved or referenced in disease state specific standard of care guidelines for the requested drug. (Please see covered uses section for appropriate sources)
Revision/Review Date 5/2021	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; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	<p>All of the following criteria must be met:</p> <ul style="list-style-type: none"> • Requested use must be a labeled indication or be supported by NCCN Category 1 or 2A level of evidence. If the request is for an off-label use supported by NCCN as Category 2B recommendation then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g. allergic reaction, contraindication); AND • Documentation has been provided of the results of all required genetic testing where required per drug package insert; AND • 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 drug package insert; AND • The medication is being prescribed at a dose that is within FDA approved/NCCN guidelines. • If the request is for a reference biologic drug with either a biosimilar or interchangeable biologic drug currently available, documentation of one of the following: <ul style="list-style-type: none"> ○ The provider has verbally or in writing submitted a member specific reason why the reference biologic is required based on the member’s condition or treatment

<p>Revision/Review 10/2021</p>	<p>history; AND if the member had side effects or a reaction to the biosimilar or interchangeable biologic, the provider has completed and submitted an FDA MedWatch form to justify the member's need to avoid these drugs. The MedWatch form must be included with the prior authorization request</p> <ul style="list-style-type: none"> ○ The currently available biosimilar product does not have the same appropriate use (per the references outlined in "Covered Uses") as the reference biologic drug being requested <p><u>Form FDA 3500 – Voluntary Reporting</u></p> <ul style="list-style-type: none"> • If the request is for abiraterone (Zytiga) 500 mg tablet, a documented medical reason why two tablets of generic abiraterone acetate 250 mg cannot be used <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>
------------------------------------	--

Field Name	Field Description
Prior Authorization Group Description	Prior Authorization Exception Criteria
Covered Uses	All medically accepted indications. Medically accepted indications are defined using the following compendia resources: the Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), American Hospital Formulary Service Drug Information (AHFS-DI), and DRUGDEX Information System. The reviewer may also reference disease state specific standard of care guidelines.
Scope	Requests for exception to the drug's prior authorization criteria requirements
Criteria	<ul style="list-style-type: none"> • The provider either verbally or in writing has submitted a medical or member specific reason why prior authorization criteria all or in part is not applicable to the member. <ul style="list-style-type: none"> ○ Medical and/or member specific reasons may include but are not limited to: <ul style="list-style-type: none"> ▪ Uniqueness of the member's condition or other physical characteristics of the member's condition. ▪ Psychiatric, intellectual, physical, cultural, and/or linguistic characteristics of the member which may inhibit the provider from obtaining all necessary prior authorization criteria requirements. <p>Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Coverage Duration	12 months
Revision/Review Date:	10/2021

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 drugs exceeding the health plan's published quantity limits
Criteria	<ul style="list-style-type: none"> • The provider has submitted a medical reason why the plan's quantity limit will be inadequate based on the member's condition and treatment history. <p>AND one of the following:</p> <ul style="list-style-type: none"> ○ The member has a documented treatment failure with the drug prescribed at the health plan's quantity limit AND the dose requested is supported by the Medical Compendia or current treatment guidelines. <p>OR</p> <ul style="list-style-type: none"> ○ The member requires a dose within prescribing guidelines that exceeds the plan's quantity limit. <p>Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Coverage Duration	12 Months
Revision/Review Date	10/2021

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: <ul style="list-style-type: none"> Exceeding the Food and Drug Administration (FDA) or compendia max dose recommendations Exceeding the FDA dosing or compendia administration frequency recommendations Exceeding the FDA or compendia duration of therapy recommendations Duplication of therapy error at Point of Service (POS) Age Restriction error at POS Day Supply Limit at POS Concurrent Use error at POS Drug Drug Interaction error at POS
Criteria	<p>Exceeding the Food and Drug Administration (FDA) or compendia maximum dose, administration frequency or duration of therapy recommendations.</p> <ul style="list-style-type: none"> The member must have a documented treatment failure with the drug at the maximum dose based on patient age/weight, administration frequency, or duration of therapy per FDA or compendia. <p>AND</p> <ul style="list-style-type: none"> The provider must submit a medical reason why the maximum dose, administration frequency or duration of therapy needs to be exceeded based on the member's condition or treatment history. <p>Duplication of therapy</p> <p><u>Transition from one agent to another</u></p> <ul style="list-style-type: none"> If a provider has outlined a plan to transition a member to a similar drug or provided a dose titration schedule, the requested drug is approved for one month*. <p><u>Concurrent Therapy with two similar agents</u></p>

- The provider must submit a medical reason why treatment with more than one drug in the same class is required based on the member's condition and treatment history.

OR

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

Age Restriction

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

AND

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

Day Supply Limit

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

OR

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

AND

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

Concurrent Use/Drug-Drug Interaction:

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

	Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.
Coverage Duration	*One month approval for Duplication of therapy when transitioning from one agent to another, or for Concurrent Use with a MAT agent and opioid. All Other Scenarios: 12 months
Revision/Review Date: 10/2021	

Field Name	Field Description
Prior Authorization Group Description	Specialty Drugs
Drugs	<p>Oral and injectable specialty drugs without drug or class specific prior authorization criteria</p> <p>*** The Oncology Drugs prior authorization criteria will be applied to oncology drugs without drug or class specific criteria***</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If all of the conditions are met, requests will be approved for up to 6 months. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria	<ul style="list-style-type: none"> • The drug is requested for an appropriate use (per the references outlined in “Covered Uses” • The dose requested is appropriate for the requested use (per the references outlined in “Covered Uses”) • If the request is for a non-formulary/non-preferred drug, documentation has been provided that the member has tried and failed two formulary/preferred drugs appropriate for the requested use (per the references outlined in “Covered Uses” or has a medical reason why these drug(s) cannot be used (e.g. intolerance, contraindication) • If the request is for a reference biologic drug with either a biosimilar or interchangeable biologic drug currently available, documentation of one of the following: <ul style="list-style-type: none"> ○ The provider has verbally or in writing submitted a member specific reason why the reference biologic is required based on the member’s condition or treatment history; AND if the member had side effects or a reaction to the biosimilar or interchangeable biologic, the provider has completed and submitted an FDA MedWatch form to justify the member’s need to avoid these drug. The MedWatch form must be included with the prior authorization ○ The currently available biosimilar product does not have the same appropriate use (per the references

Revision/Review Date 10/2021	<p>outlined in “Covered Uses”) as the reference biologic drug being requested</p> <p>Form FDA 3500 – Voluntary Reporting</p> <p>Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>
---------------------------------	--

Field Name	Field Description
Prior Authorization Group Description	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	<p>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:</p> <ul style="list-style-type: none"> • Required step therapy drug(s) would be ineffective, or; • Required step therapy drug(s) have the potential to cause harm or deterioration of the member's condition, or; • The requested drug would be superior to the required prerequisite trial(s) with preferred drug(s). <p>Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Coverage Duration	12 Months
Revision/Review Date:	10/2021

Field Name	Field Description
Prior Authorization Group Description	5-Hydroxytryptamine-3 Serotonin Receptor Antagonists (5-HT3 RA), Substance P/Neurokinin 1 Receptor Antagonists (NK1 RA), and Combination Agents
Drugs	<p><u>Preferred (1st line):</u></p> <p>5-HT3 RA: ondansetron (Zofran) oral tablet, orally disintegrating tablet (ODT), oral solution, IV solution, injection (IV/SQ) solution or granisetron (Kytril) oral tablet, IV solution</p> <p>NK1 RA: aprepitant (Emend) oral capsule, Emend (fosaprepitant) IV emulsion</p> <p><u>Preferred (2nd Line):</u></p> <p>5-HT3 RA palonosetron (Aloxi) 0.25 mg/2 mL IV solution</p> <p><u>Non-Preferred:</u></p> <p>Sustol (granisetron ER) SQ injection, Sancuso (granisetron ER) transdermal patch, Zuplenz (ondansetron) oral film, dolasetron (Anzemet) oral tablet, palonosetron (Aloxi) 0.25 mg/5 mL IV solution, Cinvanti (aprepitant) IV emulsion, Varubi (rolapitant) oral capsule, IV emulsion, Akynzeo (palonosetron/netupitant) oral capsule, IV solution</p> <p>Any other newly marketed agent</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	None
Required Medical Information	See “Other Criteria”
Age Restrictions	None
Prescriber Restrictions	Prescribed by a specialist in the field to treat the patient’s respective medical condition
Coverage Duration	If all of the conditions are met, the request will be approved for up to 6 months or as long as recommended by the medical compendium and/or per the NCCN/ASCO standard of care guidelines.
Other Criteria	<ul style="list-style-type: none"> The medication is being requested for a Food and Drug Administration (FDA) approved indication or a medical condition that is supported by the medical compendium, the National Comprehensive Cancer Network (NCCN), and/or American Society of Clinical Oncology (ASCO) standard of

<p>Revision/Review Date 10/2021</p>	<p>care guidelines for antiemetic therapy.</p> <ul style="list-style-type: none"> • The requested dosing of the 5-HT3 RA and/or NK1 RA is within FDA approved, NCCN/ASCO or other medical compendia standard of care guidelines • Patients meeting one of the following criteria may receive the generic 5-HT3 RA palonosetron hydrochloride without prior trial and failure of ondansetron/granisetron <ul style="list-style-type: none"> ○ Adult patients receiving an antineoplastic agent with HIGH or MODERATE emetic risk per the NCCN Practice Guidelines ○ Pediatric patients receiving an antineoplastic agent with HIGH emetic risk per the NCCN Practice Guidelines who are unable to receive dexamethasone • For all other patients, if the medication request is for any 5-HT3 RA other than ondansetron, granisetron, or palonosetron, or an NK1-RA other than aprepitant (Emend) or Emend (fosaprepitant): <ul style="list-style-type: none"> ○ The patient has a documented treatment failure after receiving an adequate trial of a preferred 5-HT3 RA and a preferred NK1 RA and/or has a documented medical reason (intolerance, hypersensitivity, contraindication, etc.) for not utilizing these medications to treat their medical condition. <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
---	---

Field Name	Field Description
Prior Authorization Group Description	Acthar
Drugs	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; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	<p><u>Infantile Spasms (West Syndrome):</u></p> <ul style="list-style-type: none"> • Patient is < 2 years of age • The medication is being prescribed by a neurologist. • Documentation of the patient’s current weight (in kg) and height/length (in cm) or body surface area (BSA) <p><u>Multiple Sclerosis:</u></p> <ul style="list-style-type: none"> • Documentation was submitted that patient is having 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 <p><u>All Other FDA Approved Conditions and Indications:</u></p> <ul style="list-style-type: none"> • Documented trial and failure of an IV corticosteroid AND an oral corticosteroid, or documented medical reason for why the patient cannot use these therapies for treatment <p>AND</p> <ul style="list-style-type: none"> • Documentation was provided that ALL other standard therapies have been used to treat the member’s condition as described in the medical compendium (Micromedex, AHFS, Drug Points, and package insert) as defined in the Social Security Act and/or per recognized standard of care guidelines OR there is a documented medical reason (i.e. medical intolerance, treatment failure, etc.) for why all other

<p>Revision/Review Date 7/2021</p>	<p>standard therapies could not be used to treat the member's condition.</p> <p>AND</p> <ul style="list-style-type: none"> • Prescriber is a specialist in the condition they are treating. <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
--	---

Prior Authorization Group Description	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, the initial request may be approved for up to a 6-month duration. Reauthorization requests may be approved for 12 months.
Other Criteria	<p>Initial Authorization:</p> <ul style="list-style-type: none"> • Member has a confirmed diagnosis of sickle cell disease • Documentation was provided that the member has had 2 or more pain crises in the last 12 months • Documentation was provided that the member has been taking hydroxyurea at the maximum tolerated dose and has been compliant within the last 6 months (or a medical reason was provided why the patient is unable to use hydroxyurea) • Documentation of the member’s current weight • Request is for an FDA-approved dose <p>Reauthorization:</p> <ul style="list-style-type: none"> • Documentation has been submitted that the member has demonstrated or maintained ONE of the following changes from baseline: <ul style="list-style-type: none"> ○ Reduction in pain crises ○ Increased time between crises ○ Decrease in days hospitalized • Documentation of the member’s current weight • Request is for an FDA-approved dose <p>If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.</p>
Revision/Review Date: 7/2021	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. If all of the criteria are not met, the request is referred to a clinical reviewer for medical necessity review.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> Member must have documentation of baseline low density lipoprotein cholesterol (LDL-C) One of the following: <ul style="list-style-type: none"> Member has a diagnosis of heterozygous familial hypercholesterolemia (FH) Member has a diagnosis of hyperlipidemia and atherosclerotic cardiovascular disease (ASCVD) as evidenced by a fasting LDL-C ≥ 70 mg/dL and a history of least one of the following: <ul style="list-style-type: none"> 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 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.

<p>Revision/Review Date 7/2021</p>	<ul style="list-style-type: none"> • 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 or documentation has been provided that the member is not able to tolerate a statin. • Documentation was provided indicating provider has counseled member on smoking cessation and following a “heart healthy diet”. <p><u>Reauthorization:</u></p> <ul style="list-style-type: none"> • Documentation provided that the member has obtained clinical benefit from medication (e.g. LDL-C lowering from baseline) • One of the following: <ul style="list-style-type: none"> ○ 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. ○ 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 <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
--	--

Field Name	Field Description
Prior Authorization Group Description	Adrenal Enzyme Inhibitors for Cushing's Disease
Drugs	Isturisa (osilodrostat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be ≥ 18 years of age
Prescriber Restrictions	Prescribed by, or in consultation with, an endocrinologist or other specialist in the treatment of metabolic disorders
Coverage Duration	<p>Initial Authorization: If the criteria are met, the request will be approved for a 6-month duration.</p> <p>Reauthorization: If the criteria are met, the request will be approved for a 12-month duration.</p>
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Member has confirmed diagnosis of Cushing's Disease • Pituitary surgery is not an option or has not been curative • Provider attests baseline electrocardiogram (ECG) has been obtained and hypokalemia and/or hypomagnesemia has been corrected prior to initiating therapy if present • The medication is being prescribed at a dose that is consistent with FDA-approved package labeling, nationally recognized compendia or peer-reviewed literature • Documented baseline urinary free cortisol (UFC) test ≥ 1.5 upper limit of normal (ULN) <ul style="list-style-type: none"> ○ UFC Normal Range = 3.5-45 mcg/24 hrs (9.66-124.2 nmol/24 hrs) • Member has had a documented trial and failure of one of the following: <ul style="list-style-type: none"> ○ ketoconazole ○ Metopirone (metyrapone) ○ Lysodren (mitotane) ○ cabergoline ○ Signifor/Signifor LAR (pasireotide) ○ etomidate <p>OR</p> <ul style="list-style-type: none"> • Member has a documented medical reason (e.g. contraindication, intolerance, hypersensitivity) as to why these medications cannot be used

<p>Revision/Review Date: 2/2021</p>	<p><u>Reauthorization:</u></p> <ul style="list-style-type: none"> • Member has responded to therapy as defined by a documented urinary free cortisol (UFC) test \leq the upper limit of normal (ULN) • The medication is being prescribed at a dose that is consistent with FDA-approved package labeling, nationally recognized compendia <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
---	--

Field Name	Field Description
Prior Authorization Group Description	Agents for Atopic Dermatitis
Drugs	<p>Preferred: Elidel (pimecrolimus) Eucrisa (crisaborole) pimecrolimus (Elidel) Protopic (tacrolimus) tacrolimus (Protopic)</p> <p>Non-Preferred: Dupixent (dupilumab)</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	Protopic 0.1%: age 16 years and older Protopic 0.03%: age 2 years and older Elidel: age 2 years and older Eucrisa: age 3 months and older Dupixent: age 6 years and older
Prescriber Restrictions	For Dupixent requests: Provider must be a pediatrician, dermatologist, or allergist
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	<p><u>Initial Authorization</u></p> <p>For pimecrolimus:</p> <ul style="list-style-type: none"> ○ Diagnosis of <u>mild to moderate</u> atopic dermatitis in non-immunocompromised patients in whom the use of other topical prescription treatments is not advisable or in patients who have failed to respond adequately or are intolerant to a formulary topical medium to high potency corticosteroids. AND ○ For moderate atopic dermatitis: Trial and failure of topical tacrolimus <p>For tacrolimus:</p> <ul style="list-style-type: none"> ○ Diagnosis of <u>moderate to severe</u> atopic dermatitis in non-immunocompromised patients in whom the use of other topical prescription treatments is not advisable or in patients who have

<p>Revision/Review Date 1/2022</p>	<p>failed to respond adequately or are intolerant to a formulary topical medium to high potency corticosteroids</p> <p>For Eucrisa:</p> <ul style="list-style-type: none"> ○ Diagnosis of <u>mild to moderate</u> atopic dermatitis AND ○ Trial and failure of a formulary topical corticosteroid AND ○ Trial and failure of topical tacrolimus or pimecrolimus <p>For Dupixent:</p> <ul style="list-style-type: none"> ○ Diagnosis of <u>moderate to severe</u> atopic dermatitis AND <ul style="list-style-type: none"> ○ For <u>moderate</u> atopic dermatitis: Trial and failure of each of the following: <ul style="list-style-type: none"> ▪ Formulary topical medium to high potency corticosteroid AND ▪ topical tacrolimus or pimecrolimus AND ▪ Eucrisa (crisaborole) OR ○ For <u>severe</u> atopic dermatitis: Trial and failure of each of the following: <ul style="list-style-type: none"> ▪ Formulary topical medium to high potency corticosteroid AND ▪ Topical tacrolimus <p><u>Reauthorization:</u></p> <ul style="list-style-type: none"> ○ Patient experienced improvement (e.g. skin clear or almost clear, little or no itch) <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
--	--

Field Name	Field Description
Prior Authorization Group Description	Agents for Gender Dysphoria
Drugs	Anti-androgens, progestins, GnRH agonists, estrogens, testosterone **See table that follows**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	“see other criteria”
Age Restrictions	Requests for members under the age of 12 must be sent to the Medical Director for review.
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist, mental health professional, or prescriber trained in transgender health care
Coverage Duration	If all of the conditions are met, requests will be approved for a 12 months. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria	<ul style="list-style-type: none"> • Documented diagnosis of gender dysphoria • If significant medical or mental health concerns are present, they must be reasonably well-controlled OR are being managed concurrently with gender dysphoria treatment. • If request is for a non-preferred agent, documentation of a medical reason (e.g. intolerance, hypersensitivity, contraindication) was submitted with request why the member is not able to use two preferred alternatives • If the member is under 12 years of age, the request must be sent to the Medical Director for clinical review. • Dosing is within the recommended range
Revision/Review Date 7/2021	Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

***Recommended dosing next page/table

<i>Hormone regimens in adult transsexual persons</i>	
<i>Estrogen</i>	
Oral: estradiol (17 β -estradiol valerate)	2 to 6 mg/day
Transdermal: estradiol patch	0.025-0.2mg/24 hours, changed once or twice weekly depending on product
Parenteral: estradiol valerate	5 to 30mgIM every two weeks
estradiol cypionate	2 to 10mg IM every week
<i>Antiandrogens</i>	
Oral: spironolactone	100 to 400mg/daily
<i>GnRH agonists</i>	
Leuprolide	3.75 IM depot monthly OR 11.25 mg IM depot every 3 months
<i>Testosterone</i>	
Parenteral: testosterone enanthate or cypionate	50 to 100mg IM every week OR 100mg to 200mg IM every two weeks
Transdermal: testosterone gel 1%	2.5 to 10 grams of gel per day (equivalent to 25 to 100mg/day testosterone)
Androderm patch	2 to 6mg/day

- Dose of estrogen should be adjusted according to serum 17 β -estradiol levels (i.e., 100 to 200 pg/mL) and effect. Lower doses of estradiol are generally sufficient for feminization goals when combined with an anti-androgen, GnRH agonist, or after gonadectomy. Anti-androgen therapy is discontinued after gonadectomy. Synthetic estrogens, e.g. ethinyl estradiol, are not recommended due to elevated risk of thromboembolic disease, cardiovascular mortality and inability to regulate dose by measurement of serum levels.
- Doses of testosterone should be adjusted according to serum testosterone levels (i.e., normal male range 320 to 1000 ng/dL) and effect. Time to onset of effect of parenteral preparations may be less than with transdermal preparations.

Prior Authorization Group Description	Agents for Thrombocytopenia
Drugs	<p><u>Preferred Thrombocytopenia Agent(s):</u></p> <ul style="list-style-type: none"> • Promacta (eltrombopag) • Doptelet (avatrombopag) <p><u>Non-Preferred Thrombocytopenia Agent(s):</u></p> <ul style="list-style-type: none"> • Nplate (romiplostim) • Mulpleta (lusutrombopag) • Tavalisse (fostamatinib)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	For Doptelet, Mulpleta, and Tavalisse, member must be 18 years or older ITP: For Promacta and Nplate, member must be 1 year or older. Severe aplastic anemia: For Promacta, member must be 2 years or older.
Prescriber Restrictions	Prescriber must be a hematologist
Coverage Duration	If the criteria are met, the 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. If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	<p>Chronic immune (idiopathic) thrombocytopenia (ITP):</p> <ul style="list-style-type: none"> • Platelet count < 30,000 cells/microL • Documented trial and failure, or intolerance, contraindication, to ONE of the following: <ul style="list-style-type: none"> ○ Glucocorticoids ○ Intravenous immune globulin (IVIG) ○ Rituximab ○ splenectomy • If the request is for Doptelet, Nplate or Tavalisse, the member has a documented trial and failure, intolerance, or contraindication to Promacta <p>Severe aplastic anemia (Promacta only):</p> <ul style="list-style-type: none"> • Promacta is being prescribed in conjunction with at least one

<p>Revision/Review Date 5/2021</p>	<p>immunosuppressive agent OR there is a documented trial and failure, intolerance, or contraindication to at least one immunosuppressive agent; AND</p> <ul style="list-style-type: none"> • Platelet count < 20,000 cells/microL OR platelet count < 30,000 cells/microL with bleeding OR reticulocyte count < 20,000 cells/microL OR absolute neutrophil count < 500 cells/microL <p>Thrombocytopenia in patients with Hepatitis C infection (Promacta only):</p> <ul style="list-style-type: none"> • Diagnosis of chronic hepatitis C; AND • Platelet count < 50,000 cells/microL, AND • Documented treatment with interferon-based therapy AND patient's degree of thrombocytopenia prevents the initiation or limits the ability to maintain interferon-based therapy <p>Thrombocytopenia associated with chronic liver disease in <u>adult</u> patients requiring elective surgery (Doptelet and Mulpleta only):</p> <ul style="list-style-type: none"> • Patient has a diagnosis of chronic liver disease and is scheduled to undergo a procedure; AND • Platelet count < 50,000 cells/microL; AND • For Mulpleta, approve if there is documentation of trial and failure, intolerance, or contraindication to use Doptelet <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
--	--

Field Name	Field Description
Prior Authorization Group Description	Alpha-1 Proteinase Inhibitors (Human)
Drugs	<p><u>Preferred:</u> Prolastin-C</p> <p><u>Non-Preferred:</u> Aralast NP Glassia Zemaira Or any other newly marketed agent</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or specialist in the treatment of AAT
Coverage Duration	The request will be approved for up to a 12 month duration; if all of the above criteria are not met, the request is referred to a Medical Director for medical necessity review.
Other Criteria	<p>Initial Authorization:</p> <ul style="list-style-type: none"> • Documented diagnosis of a congenital deficiency of alpha-1 antitrypsin (AAT) (serum AAT level < 11 micromol/L or 80mg/dl). • 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 [FEV₁] in the range of 35%-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 documented medical reason (intolerance, hypersensitivity, contraindication, treatment failure, etc.) for not using Prolastin-C to treat their medical condition <p>Reauthorization:</p> <ul style="list-style-type: none"> • Documentation of the member's current weight • Documentation was submitted indicating the member has clinically benefited from therapy (i.e. stable lung function, improved PFTs, alpha-1 antitrypsin

Revision/Review Date 2/2021	<p>serum level maintained above 11 micromol/L or 80 mg/dL, improved quality of life)</p> <ul style="list-style-type: none">• The Alpha-1 Proteinase Inhibitor (human) is being prescribed at an FDA approved dosage <p>Clinical reviewer/Medical Director must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>
--------------------------------	--

Prior Authorization Group Description	Amifampridine
Drugs	Firdapse (amifampridine), Ruzurgi (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 18 years age or older for Firdapse, and members must be 6 years of age or older for Ruzurgi
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. If all of the above criteria are not met, the request is referred to a Clinical Reviewer for medical necessity review.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) based on at least one electrodiagnostic study (i.e., repetitive nerve stimulation, nerve conduction studies, electromyography) OR anti-P/Q-type voltage-gated calcium channel antibody testing • Member has been screened for small cell lung cancer (SCLC) and/or other malignancies • Member does not have a history of seizures • Medication is being prescribed at an FDA approved dose or is supported by compendia or standard of care guidelines <p><u>Re-authorization:</u></p> <ul style="list-style-type: none"> • Medication is prescribed at an FDA-approved dose or is supported by compendia or standard of care guidelines • Documentation provided that prescriber has evaluated the member and recommends continuation of therapy
Revision/Review Date 2/2021	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	Amyotrophic lateral sclerosis (ALS agents)
Drugs	Radicava (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; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	<p>Initial:</p> <ul style="list-style-type: none"> • Patient must have a documented baseline evaluation of functionality using the revised ALS functional rating scale (ALSFRS-R) score ≥ 2 • Patient’s disease duration is 2 years or less • Patient has a baseline forced vital capacity (FVC) of $\geq 80\%$ • Patient has been on riluzole (Rilutek), is beginning therapy as an adjunct to treatment with Radicava, or provider has provided a medical reason why patient is unable to use riluzole • Dose is within FDA approved limits <p>Reauthorization:</p> <ul style="list-style-type: none"> • Patient is not ventilator dependent • Provider documents clinical stabilization in symptoms (e.g. stabilization of ALSFRS-R score) • Dose is within FDA approved limits <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 5/2021	

Prior Authorization Group Description	Anti-amyloid Monoclonal Antibodies
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 other than AD
Required Medical Information	See "Other Criteria"
Age Restrictions	None
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	For initial authorization: the request will be approved in accordance with the FDA-indicated titration schedule for up to 6 months For reauthorization: if all of the conditions are met, the request will be approved for 6 months.
Other Criteria	<p><u>Initial Authorization</u></p> <ul style="list-style-type: none"> • Diagnosis of mild cognitive impairment (MCI) caused by AD or mild AD • The request is for an FDA approved dose • Documentation of BOTH of the following: <ul style="list-style-type: none"> ○ Recent, within past year, positive results for the presence of beta-amyloid plaques on a positron emission tomography (PET) scan ○ Recent, within past year, baseline Magnetic Resonance Imaging (MRI) scan • Clinical Dementia Rating Global (CDR-G) score of 0.5 (very mild dementia) • Repeatable Battery for Assessment of Neuropsychological Status (RBANS) delayed memory index (DMI) score ≤ 85 (low average) • Mini-Mental State Examination (MMSE) score ≥ 24 (questionably significant impairment) • Patient is not taking any chronic medications that can substantially contribute to cognitive impairment (i.e. strong anticholinergics such as first-generation antihistamines,

<p>Revision/Review Date: 12/2021</p>	<p>tricyclic antidepressants; benzodiazepines; antipsychotics; barbiturates; skeletal muscle relaxants; see Beer's List)</p> <ul style="list-style-type: none"> • Not currently using blood thinners (except aspirin) • No recent (past 1 year) history of stroke or transient ischemic attack (TIA) <p><u>Reauthorization</u></p> <ul style="list-style-type: none"> • The request is for an FDA approved dose • Before the 7th and 13th doses, documentation (i.e. chart notes, test results) of repeat MRI scan to monitor for amyloid related imaging abnormalities (ARIA) including the following: <ul style="list-style-type: none"> ○ Type of ARIA (-edema [E] or hemosiderin deposition [H]), if any ○ Severity of ARIA (mild, moderate, severe), if any ○ If severe ARIA-H, approval of continued therapy is contingent upon repeat MRI demonstrating radiographic stabilization • CDR-G score of 0.5 (very mild dementia) • RBANS DMI score \leq 85 (low average) • MMSE score of 24-30 • Patient is not taking any medications that can substantially contribute to cognitive impairment (i.e. strong anticholinergics such as first-generation antihistamines, tricyclic antidepressants; benzodiazepines; antipsychotics; barbiturates; skeletal muscle relaxants; see Beer's List) • 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 <p>If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.</p> <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
--	---

Field Name	Field Description
Prior Authorization Group Description	Anti-CD19 CAR-T Immunotherapies
Drugs	Kymriah (tisagenlecleucel), Yescarta (axicabtagene ciloleucel), Tecartus (brexucabtagene autoleucel), Brevanzi (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	<p><u>Initial authorization:</u></p> <ul style="list-style-type: none"> • Patient must not have received prior anti-CD19 CAR-T therapy. • Patient will be screened for HBV, HCV, and HIV in accordance with clinical guidelines. • Patient does not have an active infection or inflammatory disorder. • Patient has a life expectancy >12 weeks. • Patient will not receive live virus vaccines for at least 6 weeks prior to the start of lymphodepleting chemotherapy and until immune recovery following treatment. <p><u>Leukemia</u></p> <p>B-cell precursor Acute Lymphoblastic Leukemia (ALL):</p> <ul style="list-style-type: none"> • If the request is for Kymriah <ul style="list-style-type: none"> ○ Patient is 25 years of age or younger ○ ALL that is refractory or in second or later relapse <p><u>Non-Hodgkin’s Lymphoma (NHL)</u></p> <p>Mantle Cell Lymphoma (MCL):</p> <ul style="list-style-type: none"> • If the request is for Tecartus: <ul style="list-style-type: none"> ○ Patient is 18 years of age or older ○ Patient has relapsed/refractory disease defined as failure of BOTH the following lines of therapy:

<p>Revision/Review Date: 5/2021</p>	<ul style="list-style-type: none"> ▪ Chemoimmunotherapy such as an anti-CD20 monoclonal antibody (e.g. Rituxan) + any chemotherapeutic agent ▪ Bruton Tyrosine Kinase (BTK) Inhibitor (e.g. Calquence, Imbruvica, Brukinsa) <p>Other forms of NHL:</p> <ul style="list-style-type: none"> • If the request is for Breyanzi (lisocabtagene maraleucel), Kymriah (tisagenlecleucel), Yescarta (axicabtagene ciloleucel) <ul style="list-style-type: none"> ○ Use is supported by a labeled indication or NCCN guidelines ○ Patient is 18 years of age or older ○ Patient has relapsed/refractory disease defined as failure of two or more lines of systemic therapy <p><u>Re-authorization:</u></p> <ul style="list-style-type: none"> • Treatment exceeding 1 dose per lifetime will not be authorized. <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
---	---

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. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review
Other Criteria	<p><u>Initial Authorization:</u></p> <p>For X-linked hypophosphatemia (XLH):</p> <ul style="list-style-type: none"> • Diagnosis of XLH • Dosing is appropriate as per labeling or is supported by compendia or standard of care guidelines • Labs, as follows: <ul style="list-style-type: none"> ○ Serum phosphorus below normal for patient age ○ eGFR > 30 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: <ul style="list-style-type: none"> ○ Clinical signs and symptoms of XLH (e.g. bone/joint pain, fractures, osteomalacia, osteoarthritis, enthesopathies, spinal stenosis impaired mobility, presence or history of lower limb deformities, etc.) ○ Trial and failure of, or contraindication to, combination therapy with oral phosphate and active vitamin D (calcitriol) for a minimum of 8 weeks <p>For tumor-induced osteomalacia (TIO):</p> <ul style="list-style-type: none"> • Diagnosis of FGF23-related hypophosphatemia in TIO

<p>Revision/Review Date: 7/2021</p>	<ul style="list-style-type: none"> • Dosing is appropriate as per labeling or is supported by compendia or standard of care guidelines • The tumor(s) is/are not amenable to surgical excision or cannot be located • Labs, as follows: <ul style="list-style-type: none"> ○ Serum phosphorus below normal for patient age ○ eGFR > 30 mL/min/1.73 m² or CrCl ≥ 30 mL/min • Patient will not use concurrent oral phosphate and/or active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol) <p><u>Re-authorization:</u></p> <p>For XLH or TIO:</p> <ul style="list-style-type: none"> • Documented effectiveness as evidenced by <ul style="list-style-type: none"> ○ Serum phosphorus within normal limits for patient age OR ○ Clinical improvement (e.g. improved rickets, improved bone histomorphometry, increased growth velocity, increased mobility, decrease in bone fractures, improved fracture healing, reduction in bone-related pain) • 25-hydroxyvitamin D level and, if abnormally low, documented supplementation with cholecalciferol or ergocalciferol • Patient is not concurrently using oral phosphate and/or active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol) • Dosing continues to be appropriate as per labeling or is supported by compendia or standard of care guidelines <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
---	---

Antifibrotic Respiratory Tract Agents

Drugs:

Preferred: Ofev (nintedanib esylate)

Non-Preferred: Esbriet (pirfenidone)

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

INITIAL CRITERIA:

For all requests:

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

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

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

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

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

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

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

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

REAUTHORIZATION CRITERIA:

- Prescriber is a pulmonologist or lung transplant specialist

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

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

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

Revision/Review Date: 1/2022

Field Name	Field Description
Prior Authorization Group Description	Anti-Parkinson's Agents for OFF Episodes
Drugs	Nourianz (istradefylline), Inbrija (levodopa) inhalation, Apokyn (apomorphine), Kynmobi (apomorphine), Xadago (safinamide), and Ongentys (opicapone), or any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: The Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescriber is a neurologist or is working in consultation with a neurologist
Coverage Duration	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. If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of Parkinson's disease • Patient is currently taking and will continue to take carbidopa/levodopa • Patient is experiencing symptom fluctuations or off episodes while taking carbidopa/levodopa where attempts have been made to adjust the carbidopa/levodopa dose and/or formulation in order to manage symptoms without success • Documented trial and failure (or contraindication) to at least two of the following adjunctive medication classes: <ul style="list-style-type: none"> ○ COMT-inhibitors (e.g., entacapone) ○ Dopamine agonists (e.g., ropinirole, pramipexole) ○ MAO-B inhibitors (e.g., rasagiline, selegiline, safinamide) • 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.

Revision/Review Date 2/2021	<p><u>Re-authorization:</u></p> <ul style="list-style-type: none">• Documentation of positive clinical response• Dosing is appropriate as per labeling or is supported by compendia or standard of care guidelines <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
--------------------------------	--

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 \leq 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. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> Member has a diagnosis of Duchenne muscular dystrophy (DMD) and lab test was submitted confirming the mutation of dystrophin gene amenable to ONE of the following: <ul style="list-style-type: none"> Exon 51 skipping for Exondys 51 Exon 53 skipping for Vyondys 53 or Viltepso Exon 45 skipping for Amondys 45 Member is ambulatory Baseline dystrophin levels AND results of motor function tests are provided [e.g. 6-Minute Walk Test (6MWT), Time to Stand Test (TTSTAND), Time to Run/Walk Test (TTRW), North Star Ambulatory Assessment (NSAA), Time to Climb 4 Steps Test (TTCLIMB)] Member has stable pulmonary and cardiac function ONE of the following applies: <ul style="list-style-type: none"> Member has been on a stable dose of corticosteroids for at least 3 months for Viltepso Member has been on a stable dose of corticosteroids for at least 6 months for Vyondys 53, Exondys 51, or Amondys 45 Attestation of renal function monitoring is provided with request The request is for an FDA approved dose

<p>Revision/Review Date 5/2021</p>	<p><u>Reauthorization</u></p> <ul style="list-style-type: none"> • Documentation is provided that the member had an increase in dystrophin levels from baseline • Documentation is provided that the member had the expected clinical response (e.g. provider statement that the therapy has reduced the rate of further decline in function as demonstrated by 6MWT, TTSTAND, TTRW, NSAA, or TTCLIMB) • Member is ambulatory • Attestation of renal function monitoring is provided with request • The request is for an FDA approved dose <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
--	---

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; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	<p><u>Treatment/Prevention of <i>Pneumocystis jirovecii</i> pneumonia</u></p> <ul style="list-style-type: none"> • Diagnosis of mild to moderate <i>Pneumocystis jirovecii</i> pneumonia (PCP) or diagnosis with the need to prevent PCP infection. <p>AND</p> <ul style="list-style-type: none"> • Documented trial and failure with therapeutic doses or intolerance to trimethoprim- sulfamethoxazole (TMP-SMX). <p>AND</p> <ul style="list-style-type: none"> • Documented trial and failure with therapeutic doses or intolerance to dapsone. <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 5/2021	

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)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Member must be 18 years or older
Prescriber Restrictions	Prescriber must be a hematologist, an oncologist, or other appropriate specialist
Coverage Duration	If all the criteria are met, the initial request will be approved for a one – time infusion per lifetime.
Other Criteria	<p><u>Initial Authorization</u></p> <ul style="list-style-type: none"> • Member has a diagnosis of relapsed or refractory multiple myeloma (RRMM) • Member must have received at least 4 prior lines of therapy, which must include ALL of the following: <ul style="list-style-type: none"> ○ An immunomodulatory agent (e.g. lenalidomide, pomalidomide, thalidomide) ○ A proteasome inhibitor (e.g. bortezomib, carfilzomib, ixazomib) ○ An anti-CD38 monoclonal antibody (e.g. daratumumab, isatuximab) • 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 <p><u>Re-authorization:</u></p> <ul style="list-style-type: none"> • Treatment exceeding 1 dose per lifetime will not be authorized. <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 05/2021	

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	Prescriber must be a rheumatologist or in consultation with a rheumatologist
Coverage Duration	If all the criteria are met initial authorization requests may be approved for up to 6 months. Reauthorization requests may be approved for up to 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • <u>Active systemic lupus erythematosus (SLE)</u> <ul style="list-style-type: none"> ○ Provider attestation that the patient is positive for autoantibodies (or antinuclear antibodies or anti–double-stranded DNA [anti-dsDNA] antibodies) ○ The member has tried and failed both of the following (or contraindication/inability to use these medications): <ul style="list-style-type: none"> ▪ Hydroxychloroquine ▪ One other immunosuppressant [methotrexate, azathioprine, or mycophenolate] • <u>Active lupus nephritis</u> <ul style="list-style-type: none"> ○ Provider attestation of diagnosis confirmed by kidney biopsy ○ The member has tried and failed, or has a medical reason for not using, both of the following <ul style="list-style-type: none"> ▪ Cyclophosphamide or tacrolimus ▪ Mycophenolate • Provider states the member will not be receiving concomitant B-cell targeted therapy including (but not limited to) rituximab • Dosing is appropriate per labeling <p><u>Criteria for Reauthorization:</u></p> <ul style="list-style-type: none"> • Documentation or provider attestation of positive clinical response such as <ul style="list-style-type: none"> ○ Fewer flares that required steroid treatment ○ 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

Revision/Review Date: 2/2021	<ul style="list-style-type: none">○ Sustained improvement in laboratory measures of lupus activity● Dosing is appropriate per labeling <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
---------------------------------	---

Field Name	Field Description
Prior Authorization Group Description	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. If all of the above criteria are not met, the request is referred to a Clinical Reviewer for medical necessity review.
Other Criteria	<p>**Xolair: For asthma and urticaria, please refer to the “Xolair for Asthma and Urticaria” policy**</p> <p>**Dupixent: For atopic dermatitis, please refer to the “Agents for Atopic Dermatitis” policy; For asthma, please refer to the “Interleukin Receptor Antagonists for Eosinophilic Conditions” policy**</p> <p>**Nucala: For asthma or other eosinophilic conditions, please refer to the “Interleukin Receptor Antagonists for Eosinophilic Conditions” policy**</p> <p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) • Medication is being prescribed at an FDA approved dosage • 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 • Documentation of ONE of the following: <ul style="list-style-type: none"> ○ Trial and failure, or medical reason for not using, all of the following therapies: <ul style="list-style-type: none"> ▪ an intranasal corticosteroids ▪ a systemic corticosteroid

<p>Revision/Review Date 10/2021</p>	<ul style="list-style-type: none"> ▪ montelukast ○ Prior surgery for nasal polyps <p><u>Re-authorization:</u></p> <ul style="list-style-type: none"> • Medication is prescribed at an FDA-approved dosage • Member will continue to use an intranasal corticosteroid, or has a medical reason for not using an intranasal corticosteroid • Documentation has been provided that demonstrates a clinical benefit (e.g. improvements in symptom severity, nasal polyp score [NPS], sino-nasal outcome test-22 [SNOT-22], nasal congestion score [NCS], nasal obstruction symptom visual analogue scale [VAS]) <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
---	---

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	Prescriber must be an oncologist/hematologist
Coverage Duration	The request will be approved for up to a 12 month duration; if all of the above criteria are not met, the request is referred to a Medical Director for medical necessity review.
Other Criteria	<p>Initial Authorization:</p> <ul style="list-style-type: none"> • Patient has a diagnosis of one of the following forms of Acute Lymphoblastic Leukemia (ALL): <ul style="list-style-type: none"> a) Relapsed B-cell precursor ALL b) Refractory B-cell precursor ALL c) B-cell precursor ALL in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1 • Provider attests to monitor patient for Cytokine Release Syndrome (CRS) and neurological toxicities <p>Reauthorization:</p> <ul style="list-style-type: none"> • Patient has a diagnosis of relapsed or refractory B-cell precursor ALL and has not exceeded 9 total cycles of Blincyto therapy • Provider attests to treatment response or stabilization of disease • Prescriber attests to monitor patient for Cytokine Release Syndrome (CRS) and neurological toxicities <p>***For B-cell precursor ALL with MRD, reauthorization is not allowed***</p>
Revision/Review Date 2/2021	<p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>

Field Name	Field Description
Prior Authorization Group Description	Botulinum Toxins A&B
Drugs	<p>Preferred Agents for FDA approved indications: IncobotulinumtoxinA (Xeomin) AbobotulinumtoxinA (Dysport)</p> <p>Non-preferred Agents: OnabotulinumtoxinA (Botox) RimabotulinumtoxinB (Myobloc) Or any newly marketed agent</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	According to package insert
Prescriber Restrictions	None
Coverage Duration	If all of the conditions are met, the request will be approved for 12 month duration. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria	<p>**The use of these medications for cosmetic purposes is NOT a covered benefit under the Medical Assistance program**</p> <p>For Approval:</p> <ul style="list-style-type: none"> • The drug is being used for a medically accepted indication and dose as outlined Covered Uses • The member has tried and failed standard first line therapy for their disease state and/or has a documented medical reason (intolerance, hypersensitivity, contraindication, etc) for not using first line therapy • If the diagnosis is Chronic Migraines (≥ 15 days per month with headache lasting 4 hours a day or longer), the member has tried and failed, or has a medical reason for not using one drug from two of the following categories for at least 4 weeks each at a minimum effective dose: <ul style="list-style-type: none"> ○ Beta blockers (e.g. propranolol, timolol, etc.) ○ Amitriptyline or venlafaxine ○ Topiramate, divalproex ER or DR, or valproic acid • If the diagnosis is Overactive Bladder, the patient has tried and failed 2 formulary drugs (e.g. oxybutynin)

<p>Revision/Review Date 2/2021</p>	<ul style="list-style-type: none"> • If the diagnosis is Hyperhidrosis, the member has tried and failed a prescription strength antiperspirant (e.g. 20% aluminum chloride hexahydrate) • If the diagnosis is Chronic Sialorrhea, <ul style="list-style-type: none"> ○ Documentation is provided that the member has had sialorrhea lasting at least 3 months ○ The member has tried and failed, or has a medical reason for not using, an anticholinergic medication (e.g. glycopyrrolate, hyoscyamine, benztropine) • If the request is for a non-preferred agent, the member tried and failed a preferred agent if appropriate for the requested indication <p>Physician/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
--	---

Field Name	Field Description
Prior Authorization Group Description	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	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Documentation of confirmed diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2) with one of the following: <ul style="list-style-type: none"> ○ Lab results demonstrating deficient TPP1 enzyme activity ○ Identification of causative mutations in the TPP1/CLN2 gene • Prescribed dose is consistent with FDA-approved labeling • Documentation of baseline CLN2 Clinical Rating Scale motor +language score. Baseline CLN2 score must be > 0. <p><u>Re-authorization:</u></p> <ul style="list-style-type: none"> • Prescribed dose is consistent with FDA-approved labeling • Documentation of CLN2 Clinical Rating Scale motor +language score has remained > 0
Revision/Review Date: 7/2021	Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Buprenorphine/Naloxone and Buprenorphine (Oral) Criteria

Medication

Brand Name	Generic Name	Dosage Strengths
Bunavail®	buprenorphine/naloxone	2.1 mg/0.3 mg, 4.2 mg/0.7 mg, 6.3 mg/1 mg
Suboxone®	buprenorphine/naloxone	2 mg/0.5 mg, 8 mg/2 mg (SL tablet and film)
generic	buprenorphine	2 mg, 8 mg
Zubsolv®	buprenorphine/naloxone	0.7/0.18 mg, 1.4/0.36 mg, 2.9/0.71 mg, 5.7/1.4 mg, 8.6/2.1 mg, 11.4/2.9 mg sublingual tablets

Preferred buprenorphine/naloxone products for doses of 24 mg/day or less do not require a prior approval (PA).

Criteria for Approval

Buprenorphine/Naloxone Products for Doses Above 24 mg/Day:

1. Diagnosis of opiate use disorder; AND
2. Prescribed by a qualified physician with Substance Abuse and Mental Health Services Administration Waiver; AND
3. Patient is receiving substance use disorder counseling; AND
4. A substance use disorder assessment has been performed; AND
5. Patient is ≥ 16 years of age; AND
6. Attestation that the New Hampshire Prescription Drug Monitoring Program (PDMP) has been reviewed within the last 60 days.

Buprenorphine Single Agent Products:

1. Diagnosis of opiate use disorder; AND
2. Prescribed by a qualified physician with Substance Abuse and Mental Health Services Administration Waiver; AND
3. Patient is receiving substance use disorder counseling; AND
4. A substance use disorder assessment has been performed; AND

5. Patient is ≥ 16 years of age; AND
6. Attestation that the New Hampshire Prescription Drug Monitoring Program (PDMP) has been reviewed within the last 60 days; AND
7. Patient is pregnant or lactating OR there is documentation of allergic reaction to buprenorphine/naloxone combination product (please provide type of reaction and date)

Criteria for Denial

1. Criteria for approval not met
2. Use for Pain Management
3. Patient is on concurrent opioid medication
4. Patient is on concurrent Methadone Treatment

Length of Authorization: 12 months

- Non-Preferred drugs on the Preferred Drug List (PDL) require additional Prior Approval (PA).

Dispensing Limits: 24 mg/day

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
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Member is 18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 3 months. For continuation of therapy the request will be approved for 6 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ol style="list-style-type: none"> 1. Diagnosis of migraine headache 2. Requested dose is within FDA approved dosing guidelines 3. Documented trial and failure of (or medical justification for not using) two preferred triptan products 4. If request is for Nurtec ODT, the member must also have documentation of a trial and failure of (or medical justification for not using) Ubrelvy <p><u>Criteria for Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation of improvement in pain and symptom (s) (e.g., photophobia, nausea, phonophobia) <p>Nurtec ODT QL of 8 units per month. Ubrelvy QL of 10 units per month</p> <p><u>Criteria for exceeding the quantity limit</u> (note all of the above criteria must also be met)</p> <ul style="list-style-type: none"> • Documented trial and failure (or a medical justification for not using e.g. hypersensitivity, baseline bradycardia or hypotension, adverse events experienced from previous trial,

<p>Revision/Review Date: 1/2022</p>	<p>etc.) with at least one drug from two categories below for at least 4 weeks EACH, at minimum effective doses:</p> <ul style="list-style-type: none"> o Beta-adrenergic blockers o Topiramate or divalproex ER or DR o Amitriptyline or venlafaxine o Frovatriptan, zolmitriptan or naratriptan (for menstrual migraine prophylaxis) <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
---	--

Field Name	Field Description
Prior Authorization Group Description	Calcitonin Gene-Related Peptide (CGRP) Antagonists for Headache Prevention
Drugs	<p><u>Preferred:</u></p> <p>Emgality 120 mg (galcanezumab) Ajoovy (fremanezumab)</p> <p><u>Non-Preferred:</u></p> <p>Aimovig (erenumab) Emgality 100 mg (galcanezumab) Vyepti (eptinezumab) Nurtec ODT (rimegepant) – if the request is for acute treatment of migraine please refer to the Acute Migraine Treatments criteria</p> <p>and any newly marketed drug in the class</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Request for indication of chronic cluster headaches
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	If the criteria are met, the initial authorization request will be approved for 6 months. Reauthorization may be approved for 6 months.
Other Criteria	<p><u>Criteria for Initial Authorization:</u></p> <p>Cluster Headache:</p> <ul style="list-style-type: none"> • Request for Emgality (galcanezumab) for diagnosis of episodic cluster headache • If the request is for any other CGRP, do not approve; not indicated • Requested dose is within FDA approved dosing guidelines • Documented trial and failure with (or a medical justification for not using) verapamil for at least 4 weeks, at minimum effective doses <p>Migraine Headache Prophylaxis:</p>

<p>Revision/Review Date: 1/2022</p>	<ul style="list-style-type: none"> • Diagnosis of migraine headache. Patient must have at least 4 migraine days per month or one or more severe migraines lasting for greater than 12 hours despite use of abortive therapy (e.g. triptan or NSAIDs) • 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 • Requested dose is within FDA approved dosing guidelines • Documented trial and failure (or a medical justification for not using e.g. hypersensitivity, baseline bradycardia or hypotension, adverse events experienced from previous trial, etc.) with at least one drug from two categories below for at least 4 weeks EACH, at minimum effective doses: <ul style="list-style-type: none"> ○ Beta-adrenergic blockers ○ Topiramate or divalproex ER or DR ○ Amitriptyline or venlafaxine ○ Frovatriptan, zolmitriptan or naratriptan (for menstrual migraine prophylaxis) • If the medication request is for a non-preferred CGRP Antagonist the patient has a documented medical reason (intolerance, hypersensitivity, contraindication, treatment failure etc.) for not using Emgality or Ajovy to treat their medical condition. <p><u>Criteria for Re-Authorization:</u></p> <p>Episodic Cluster Headache:</p> <ul style="list-style-type: none"> • Documented reduction in the frequency of headaches (clinical benefit) <p>Migraine:</p> <ul style="list-style-type: none"> • Documented clinical benefit as evidenced by one of the following: • Reduction in the number of headache days per month relative to pre-treatment baseline • Improvement in member's Migraine Disability Assessment (MIDAS), Migraine Physical Function Impact diary (MFPDI), or Headache Impact Test (HIT-6) score <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>
---	---

Field Name	Field Description
Prior Authorization Group Description	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 days supply and requests for carisoprodol-aspirin will be approved for a single fill for a maximum of 168 tablets for a 21 day supply; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • 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 <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation has been provided that states the member has been screened for, and demonstrates no signs of, carisoprodol abuse <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 5/2021	

Field Name	Field Description
Prior Authorization Group Description	Chelating Agents
Drugs	<p><u>FORMULARY STATUS</u> Formulary, pays at point-of-sale</p> <ul style="list-style-type: none"> • Chemet (succimer) capsule, <i>up to a 19 day supply</i> <p><u>FORMULARY STATUS</u> Non-preferred (PA Required)</p> <ul style="list-style-type: none"> • deferasirox (Exjade) Tablet for Oral Suspension • deferasirox (Jadenu) Tablet, Granule Pack • deferiprone (Ferriprox) 500 mg Tablet • Ferriprox (deferiprone) 1,000 mg Tablet, solution • Ferriprox (Twice a Day) (deferiprone) Tablet • deferoxamine Mesylate (Desferal) Vial • penicillamine (Cuprimine, Depen, D-penaminate) capsule • Radiogardase (Prussian blue) capsule • Trientine (Spyrine) capsule • Galzin (zinc acetate) capsule • Bal in Oil (Dimercaprol) Ampule • pentetate calcium trisodium ampule • pentetate zinc trisodium ampule • calcium disodium versenate (edetate calcium disodium) ampule
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	See “other criteria”
Prescriber Restrictions	N/A
Coverage Duration	If the above conditions are met, the request will be approved with a 6 month duration; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	<p><u>Requests for deferasirox (Exjade, Jadenu) only:</u></p> <p>Chronic iron overload due to blood transfusions:</p> <p><u>For Pediatric Population:</u></p>

- Patient must be ≥ 2 years old and < 21 years old
AND
- Diagnosis of chronic iron overload due to blood transfusions
AND
- Patient receiving blood transfusions on a regular basis/participating in blood transfusion program
AND
- 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
AND
- The medication requested is being prescribed at an FDA approved dose

For Adult Population:

- Patient must be > 21 years old
AND
- Diagnosis of chronic iron overload due to blood transfusions
AND
- Patient receiving blood transfusions on a regular basis/participating in blood transfusion program
AND
- 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
AND
- Documented patient is unable to use deferoxamine (Desferal) parenterally
AND
- 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
AND
- Diagnosis of thalassemia syndrome
AND
- Liver iron content (LIC) by liver biopsy of ≥ 5 mg Fe/g dry weight
AND
- ≥ 2 measurements of serum ferritin levels > 300 mcg/L at least one month apart
AND

Revision/Review
Date 7/2021

- The medication requested is being prescribed at an FDA approved dose

Requests for Ferriprox (deferiprone) only:

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

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

Requests for all other drugs and indications:

- The drug is requested for an appropriate use (per the references outlined in “Covered Uses”)
- The dose requested is appropriate for the requested use (per the references outlined in “Covered Uses”)

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

Prior Authorization Group Description	Cholbam
Drugs	Cholbam (cholic acid)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	MD is a gastroenterologist OR hepatologist
Coverage Duration	If all of the conditions are met, the request will be approved for a 3 month duration for the first year of therapy, and then for a 6 month duration after one year of treatment. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria	<p><u>Initial authorization:</u></p> <ul style="list-style-type: none"> • Patient has a confirmed diagnosis of: <ul style="list-style-type: none"> ➤ Bile acid synthesis disorder due to single enzyme defect (SEDs) OR ➤ Peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients that exhibit manifestations of liver disease, steatorrhea or complications from decreased fat soluble vitamin absorption • Current labs (within 30 days of request) have been submitted for the following: <ul style="list-style-type: none"> ➤ ALT/AST ➤ GGT (serum gamma glutamyltransferase) ➤ ALP (Alkaline phosphatase) ➤ Bilirubin ➤ INR <p><u>Re-authorization:</u></p> <ul style="list-style-type: none"> • Documentation has been submitted indicating clinical benefit/ liver function has improved since beginning treatment • For reauthorization after the first 3 months of treatment, lab results must show an improvement in liver function and there must be no evidence of biliary obstruction or cholestasis • Current labs (within 30 days of request) have been submitted for the following:

<p>Revision/Review Date 10/20201</p>	<ul style="list-style-type: none"> ➤ ALT/AST ➤ GGT (serum gamma glutamyltransferase) ➤ ALP (Alkaline phosphatase) ➤ Bilirubin ➤ INR <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
--	--

Field Name	Field Description
Prior Authorization Group Description	Chronic Dry Eye Agents
Drugs	<p><u>FORMULARY STATUS</u> Preferred, Pays at Point-of-Sale ARTIFICIAL TEARS (Glycerin-Peg) 1 %-0.3 % Eye Drops POLYVINYL ALCOHOL 1.4 % Eye drops HYPROMELLOSE 0.3% Eye Drops REFRESH TEARS 0.5 % Eye Drops</p> <p><u>FORMULARY STATUS</u> Preferred, Requires Step Therapy with one prior step XIIDRA 5% EYE DROPS RESTASIS 0.05% EYE DROPS Note: Patient must meet criteria #1 & #2 for approval of the PA request.</p> <p><u>FORMULARY STATUS</u> Non-Preferred, Prior Authorization Required CEQUA 0.09% EYE DROPS Note: Patient must meet criteria #1 & #3 for approval of the PA request.</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration for; 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>
Revision/Review Date 1/2022	<ol style="list-style-type: none"> 1. Presumed or documented diagnosis of chronic dry eye 2. Documented trial and failure or intolerance with a preferred artificial tears product for a minimum of 3 weeks within past 60 days 3. Documented trial and failure or intolerance with both Restasis and Xiidra

Field Name	Field Description
Prior Authorization Group Description	Colchicine
Drugs	Colchicine (Colcris) tablets Colchicine (Mitigare) 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	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	<p><u>Initial Authorization</u></p> <ul style="list-style-type: none"> • 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 <p>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</p>
Revision/Review Date 5/2021	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)
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, or other appropriate specialist.
Coverage Duration	If the criteria are met, the initial request will be approved for up to 3 month duration; reauthorization requests will be approved for up to 6 months. If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • 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 • Documentation of vaccination against meningococcal disease or a documented medical reason why the patient cannot receive vaccination or vaccination needs to be delayed; AND • 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. <p>Paroxysmal Nocturnal Hemoglobinuria (PNH):</p> <ul style="list-style-type: none"> • Documentation of diagnosis by high sensitivity flow cytometry • Hemoglobin (Hgb) < 10.5 g/dL

- 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):

- The request is for Soliris (eculizumab)
- Patient has a positive serologic test for anti-AChR antibodies; **AND**
- Patient has a Myasthenia Gravis Foundation of America (MGFA) clinical classification of class II, III or IV at initiation of therapy; **AND**
- Patient has a Myasthenia Gravis-specific Activities of Daily Living scale (MG-ADL) total score ≥ 6 at initiation of therapy; **AND**
- One of the following:
 - Failed treatment over a total of 1 year or more with 2 or more immunosuppressive therapies (ISTs) either in combination or as monotherapy; **OR**
 - Failed at least 1 IST and required chronic plasmapheresis or plasma exchange or intravenous immunoglobulin; **OR**
 - Has a documented history of contraindications or intolerance to ISTs

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

Re-Authorization:

- 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); **AND**
- The request is for an FDA approved dose; **AND**
- If the request is for aHUS/Complement Mediated HUS

Revision/Review Date: 7/2021	<ul style="list-style-type: none">○ Documentation of confirmed diagnosis as evidenced by complement genotyping and complement antibodies <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
---------------------------------	--

Field Name	Field Description
Prior Authorization Group Description	Continuous Glucose Monitors
Drugs	<p>Preferred: Freestyle Libre, Freestyle Libre 2 Non-Preferred: Dexcom G6, Eversense (Sensor, Transmitter, and Reader components) And any newly marketed product in this class</p> <p>This policy does not apply to continuous glucose monitor/insulin pump combination products reviewed and/or covered by the Medical Benefit including, but not limited to, the MiniMed. Requests for these products are referred to the plan's Utilization Management team for Review</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Diabetes not treated with insulin
Required Medical Information	See "Other Criteria"
Age Restrictions	Patient must be age appropriate per prescribing information (PI)
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	<p>If all of the criteria are met, the request will be approved for 12 months.</p> <p>If the criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
Other Criteria	<p><u>Initial Authorization</u></p> <ul style="list-style-type: none"> • Diagnosis – diabetes • One of the following <ul style="list-style-type: none"> ○ Child or adolescent with type 1 diabetes ○ Treatment with insulin via a compatible infusion pump ○ Treatment with multiple daily doses of insulin requiring glucose testing 3 or more times per day and one of the following <ul style="list-style-type: none"> ▪ Persistently inadequate glycemic control defined as EITHER: HbA1C \geq 7% on multiple consecutive readings with one being within the last 3 months OR frequent bouts of hypoglycemia

<p>Revision/Review Date 10/2021</p>	<ul style="list-style-type: none"> ▪ Hypoglycemia unawareness • 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 and requesting non-preferred sensors/transmitters only, trial of preferred sensors/transmitters first are not required <p><u>Reauthorization</u></p> <ul style="list-style-type: none"> • One of the following: <ul style="list-style-type: none"> ○ Child or adolescent with type 1 diabetes – Approve ○ Documentation of positive clinical response (i.e. improved HbA1C or reduced frequency of severe hypoglycemia episodes) <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
---	---

Field Name	Field Description
Prior Authorization Group Description	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. If the criteria are not met, the request will be referred to a clinician for medical necessity review.
Other Criteria	<p><u>Initial Authorization:</u></p> <p><u>Prevention of spontaneous preterm delivery:</u></p> <ul style="list-style-type: none"> • Patient has singleton pregnancy and prior preterm birth or short cervix <p><u>Secondary Amenorrhea:</u></p> <ul style="list-style-type: none"> • Patient has a diagnosis of secondary amenorrhea • Patient has tried and failed, or has contraindication or intolerance to, oral progestin therapy (e.g. medroxyprogesterone acetate, norethindrone acetate tablets, micronized progesterone) • If the request is for Crinone 8% gel the patient has tried and failed, or has a contraindication or intolerance to, Crinone 4% gel
Revision/Review Date 7/2021	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. If all of the criteria are not met, the request is referred to a Medical director/clinical reviewer for medical necessity review.
Other Criteria	<p><u>Initial criteria:</u></p> <ul style="list-style-type: none"> • Documentation provided includes a copy of the FDA-cleared cystic fibrosis (CF) mutation test OR documentation from the National Cystic Fibrosis Registry (e.g. screen shot) with member’s genetic mutations • The request is for an FDA approved indication for the member’s genotype and within dosing guidelines • The request is appropriate for member (e.g. age/weight) based on FDA-approved package labeling, peer reviewed medical literature and nationally-recognized compendia. <p><u>Reauthorization:</u></p> <ul style="list-style-type: none"> • Based on prescriber’s assessment, patient continues to benefit from therapy • The request is within FDA dosing guidelines
Review/Revision Date 2/2021	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	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 with a 6 month duration for generic medication; if the criteria are not met, the request will be referred to a Medical Director for medical necessity review.
Other Criteria	<p><u>ENDOMETRIOSIS</u></p> <ul style="list-style-type: none"> ○ Diagnosis of endometriosis ○ One of the following: <ul style="list-style-type: none"> ○ Documented trial and failure or medical reason for not using an analgesic pain reliever (e.g., NSAIDs, COX-2 inhibitors) taken in combination with a hormonal contraceptive (e.g. estrogen/progestin, progestin only) ○ Documented trial and failure of a gonadotropin-releasing hormone (GnRH) agonist or a GNRH antagonist. ○ Prescribing physician is a gynecologist.
Revision/Review Date 10/2021	<p><u>HEREDITARY ANGIOEDEMA:</u></p> <ul style="list-style-type: none"> ○ Diagnosis of hereditary angioedema. ○ Prescriber is an immunologist, allergist, rheumatologist, or hematologist <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>

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. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria	<p>Congenital Toxoplasmosis</p> <ul style="list-style-type: none"> • Diagnosis of congenital toxoplasmosis <p>Acquired Toxoplasmosis</p> <ul style="list-style-type: none"> • Diagnosis of acquired toxoplasmosis • Prescribed in combination with leucovorin and either a sulfonamide or clindamycin <p>Patients with Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS)</p> <ul style="list-style-type: none"> • Diagnosis of Toxoplasmosis OR • Both of the following: <ul style="list-style-type: none"> ○ Medication is being prescribed for one of the following: <ul style="list-style-type: none"> ▪ Toxoplasmosis prophylaxis ▪ Cystoisosporiasis ▪ Pneumocystis jiroveci pneumonia prophylaxis/treatment ○ Documented medical reason why (e.g. intolerance, hypersensitivity, contraindication) sulfamethoxazole/trimethoprim cannot be used
Revision/Review Date 10/2021	<p>Hematopoietic Cell Transplantation Recipients</p> <ul style="list-style-type: none"> • Medication prescribed for Toxoplasmosis prophylaxis • Documentation of medical reason why sulfamethoxazole/trimethoprim cannot be used <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>

Field Name	Field Description
Prior Authorization Group Description	Dendritic Cell Tumor Peptide Immunotherapy
Drugs	Provenge (sipuleucel-T)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Small cell/neuroendocrine prostate cancer
Required Medical Information	See "Other Criteria"
Age Restrictions	See "Other Criteria"
Prescriber Restrictions	Prescriber must be an oncologist or urologist
Coverage Duration	3 doses per lifetime
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> Metastatic castrate resistant (hormone-refractory) prostate cancer (mCRPC) (consistent with medical chart history) <ul style="list-style-type: none"> Evidenced by soft tissue and/or bony metastases Patient does NOT have <ul style="list-style-type: none"> M0CRPC (defined as CRPC whose only evidence of disseminated disease is an elevated serum PSA) is not authorized Visceral metastases (e.g. liver, lung, adrenal, peritoneal, brain) Patient is not currently being treated with systemic immunosuppressants (e.g. chemotherapy, corticosteroids) or, if the patient is being treated with immunosuppressants, the prescriber has provided a valid medical reason for combination therapy Eastern Cooperative Oncology Group (ECOG) score 0-1 Serum testosterone <50 ng/dL (e.g. castration levels of testosterone) Predicted survival of at least six months <p><u>Reauthorization:</u></p> <ul style="list-style-type: none"> Treatment exceeding 3 doses per lifetime will not be authorized <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 2/2021	

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
Coverage Duration	If the criteria are met, the request will be approved for up to a 10-day duration.
Other Criteria	<p><u>Authorization for initial Clostridium difficile infection:</u></p> <ol style="list-style-type: none"> 1. Documentation provided for intolerance or medical reason why patient is unable to use oral vancomycin 2. Dose requested follows FDA labeling <p><u>Authorization for recurrent Clostridium difficile infection:</u></p> <ol style="list-style-type: none"> 1. Documentation provided that patient has tried oral vancomycin for management of Clostridium difficile infection 2. Dose requested follows FDA labeling
Revision/Review Date: 7/2021	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	Drugs for Chronic Bowel Disorders/GI Motility
Drug(s)	<p><u>Preferred, PA Required:</u> alosetron (Lotronex) Lotronex (alosetron) Linzess (linaclotide) lubiprostone (Amitiza) Amitiza (lubiprostone) Movantik (naloxegol)</p> <p><u>Non-Preferred, PA Required:</u> Motegrity (prucalopride) Relistor (methylnaltrexone) Symproic (naldemedine) Trulance (plecanatide) Viberzi (eluxadoline) Zelnorm (tegaserod) Or any newly marketed agent</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Age 18 or older
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the request will be approved for 6 months.
Other Criteria	<p><u>Criteria for Initial Authorization:</u></p> <ol style="list-style-type: none"> 1. Approved FDA indication and dose 2. For request for diagnosis involving chronic constipation patient has tried and failed 2 different laxatives from 2 different classes (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 <p><u>Criteria for Reauthorization:</u></p>

Review/Revision Date: 1/2022	<ol style="list-style-type: none">1. Documentation that the member has experienced treatment efficacy. <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>
---------------------------------	---

Field Name	Field Description
Prior Authorization Group Description	Emergency Use Authorization (EUA) Drugs/Products for COVID-19
Drugs	Any drug/product approved by EUA for COVID-19
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Emergency Use Authorization for the drug/product in question, and the Drug Package Insert (PPI).
Exclusion Criteria	See “Other Criteria”
Required Medical Information	See “Other Criteria”
Age Restrictions	As outlined within current FDA Emergency Use Authorization (EUA) guidelines
Prescriber Restrictions	N/A
Coverage Duration	As outlined within current FDA Emergency Use Authorization (EUA) guidelines
Other Criteria	<p>Emergency Use Authorization for COVID-19 related drugs/products (all must apply):</p> <ul style="list-style-type: none"> • The requested drug/product has a currently active Emergency Use Authorization as issued by the U.S. Food and Drug Administration. • Use of the requested drug/product is consistent with the current terms and conditions of the emergency use authorization (such as appropriate age/weight, disease severity, concurrent use with other medications or medical interventions, etc.). • Attestation that the requested drug/product was purchased by the entity seeking payment (not provided at no charge or reimbursed by the U.S. government).
Revision/Review Date 10/2021	<p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>

Field Name	Field Description
Prior Authorization Group Description	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. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> Confirmed diagnosis of Duchenne Muscular Dystrophy (documented mutation of dystrophin gene, genetic sequencing indicating mutations attributed to Duchenne Muscular Dystrophy, OR muscle biopsy indicating absence of dystrophin protein), and copies of testing were submitted with request Patient has onset of weakness before 5 years of age, and serum 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 <p><u>Reauthorization:</u></p>

<p>Revision/Review Date 2/2021</p>	<ul style="list-style-type: none"> • 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 <p>Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>
--	---

Field Name	Field Description
Prior Authorization Group Description	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. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria	<p>Initial:</p> <ul style="list-style-type: none"> • Member has diagnosis of sickle cell disease • Documentation was provided that the patient had 2 or more crises in the last 12 months • Documentation was provided the member has been on hydroxyurea at the maximum tolerated dose and was compliant within the last 6 months (or a medical reason was provided why patient is unable to use hydroxyurea) • Request is for an FDA approved dose <p>Reauthorization:</p> <ul style="list-style-type: none"> • Prescriber attests member had reduction in number of sickle cell crises • Request is for an FDA approved dose
Revision/Review Date 10/2021	Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Prior Authorization Group Description	Erythropoiesis-Stimulating Agents (ESAs)
Drugs	<p>Preferred: Epogen (epoetin alfa) Retacrit (epoetin alfa-epbx)</p> <p>Non-preferred: Aranesp (darbepoetin alfa-polysorbate 80) Mircera (methoxy peg-epoetin beta) Procrit (epoetin alfa)</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If criteria are met, the request will be approved for up to 1 month if the member is deficient in iron, vitamin B12, folate, or in the presurgical setting, and up to 3 months for all other requests.
Other Criteria	<p><u>Existing ESA users who are NEW to the plan:</u></p> <ul style="list-style-type: none"> • Documentation of current dose • Drug is being prescribed for an FDA-approved indication at an FDA-approved dose or is otherwise supported by the compendia or standard-of-care guidelines • The members HgB is within the following indication specific range: <ul style="list-style-type: none"> ○ Anemia of CKD: ≤ 11 g/dL ○ Anemia related to cancer: ≤ 12 g/dL ○ Zidovudine related anemia in members with HIV: HgB ≤ 12 g/dL ○ Ribavirin-induced anemia: HgB ≤ 12g/dL <p><u>Initial Authorization for all requests:</u></p> <ul style="list-style-type: none"> • Drug is being prescribed for an FDA-approved indication at an FDA-approved dose or is otherwise supported by the compendia or standard-of-care guidelines • All submitted lab results have been drawn withdrawn 30 days of the request • The following lab results must be submitted: <ul style="list-style-type: none"> ○ Hemoglobin (HgB) ○ Hematocrit (HCT)

- The following lab results must be submitted and demonstrate normal values, otherwise, the member **MUST** be receiving, or is beginning therapy, to correct the deficiency:
 - Serum ferritin level (> 100ng/mL)
 - Transferrin saturation (TSAT) (> 20%)
 - Vitamin B12 level (> 223pg/mL)
 - Folate level (> 3.1 ng/mL)
- For requests for non-preferred ESAs, documentation must be provided as to why preferred products are not medically appropriate for the member.

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 be 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.
- The following lab results must be submitted:

<p>Revision/Review Date: 5/2021</p>	<ul style="list-style-type: none"> ○ 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: <ul style="list-style-type: none"> ○ Serum ferritin level (> 100ng/mL) ○ Transferrin saturation (TSAT) (> 20%) ○ Vitamin B12 level (> 223pg/mL) ○ Folate level (> 3.1 ng/mL) • The members HgB is within the following indication specific range: <ul style="list-style-type: none"> ○ Anemia of CKD: ≤ 11 g/dL ○ Anemia related to cancer: ≤ 12 g/dL ○ Zidovudine related anemia in members with HIV: HgB ≤ 12 g/dL ○ Ribavirin-induced anemia: HgB ≤ 12g/dL <p>For requests that fall outside of these parameters, or if the criteria are not met, the request will be referred to a Medical Director/clinical reviewer for medical necessity review.</p>
---	---

Field Name	Field Description
Prior Authorization Group Description	Fabrazyme
Drugs	Fabrazyme (agalsidase beta)
Covered Uses	Medically accepted indications are defined using the following 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 2 years of age
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, cardiologist, nephrologist or specialist experienced in the treatment of Fabry disease
Coverage Duration	Initial Authorization: If the criteria are met, the request will be approved for a 6-month duration. Reauthorization: If the criteria are met, the request will be approved for a 12-month duration.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> Male members must have a documented diagnosis of Fabry disease confirmed by one of the following: <ol style="list-style-type: none"> An undetectable (<3%) alpha galactosidase A (alpha-Gal-A) activity level OR A deficient (3-35%) alpha-Gal- activity level AND a documented detection of pathogenic mutations in the galactosidase alpha (<i>GLA</i>) gene by molecular genetic testing Female members must have a documented diagnosis of Fabry disease confirmed by detection of pathogenic mutations in the <i>GLA</i> gene by molecular genetic testing AND evidence of clinical manifestation of the disease (e.g. kidney, neurologic, cardiovascular, gastrointestinal) Member must not be using concurrently with Galafold (migalastat) Documentation of the member’s current weight Request is for an FDA-approved dose <p><u>Re-Authorization:</u></p>

<p>Revision/Review Date: 10/2021</p>	<ul style="list-style-type: none"> • Documentation that member has experienced an improvement in symptoms from baseline including but not limited to: decreased pain, decreased gastrointestinal manifestations, decrease in proteinuria, stabilization of increase in eGFR, reduction of left ventricular hypertrophy (LVH) on echocardiogram, or improved myocardial function, or has remained asymptomatic • Member must not be using concurrently with Galafold (migalastat) • Documentation of the member's current weight • Request is for an FDA-approved dose <p>If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.</p> <p>Physician/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
--	--

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

.

Field Name	Field Description
Prior Authorization Group Description	Fintepla (fenfluramine)
Drugs	Fintepla (fenfluramine)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Member must be ≥ 2 years of age
Prescriber Restrictions	Prescriber must be neurologist or specialist in treatment of seizure disorder
Coverage Duration	If the criteria are met, the request will be approved for a 6 month duration
Other Criteria	<p>Initial Authorization</p> <ul style="list-style-type: none"> • Diagnosis of Dravet syndrome • Documented trial and failure or intolerance of at least two of the following within the member’s lifetime: clobazam, valproate, topiramate, levetiracetam, stiripentol, or Epidiolex (cannabidiol) • Member is currently taking a stable dose of at least one other antiepileptic medication • Member’s weight • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines <p>Reauthorization</p> <ul style="list-style-type: none"> • Documentation has been provided that demonstrates reduction or stabilization of seizure frequency • Member’s weight • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines
Revision/Review Date 10/2021	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Galafold
Drugs	Galafold (migalastat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	Members should be greater than or equal to 18 years of age
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, cardiologist, nephrologist or specialist experienced in the treatment of Fabry disease
Coverage Duration	Initial Authorization: If the criteria are met, the request will be approved for a 6-month duration. Reauthorization: If the criteria are met, the request will be approved for a 12-month duration.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Member has a documented diagnosis of Fabry disease • Documentation member has an amenable galactosidase alpha (GLA) gene variant based on in vitro assay data • Member will not be using Galafold concurrently with enzyme replacement therapy (e.g., Fabrazyme) • Documented baseline eGFR ≥ 30 mL/min • Request is for an FDA-approved dose <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation that member has experienced an improvement in symptoms from baseline including but not limited to: decreased pain, decreased gastrointestinal manifestations, decrease in proteinuria, stabilization of increase in eGFR, reduction of left ventricular hypertrophy (LVH) on echocardiogram, or improved myocardial function • Member must not be using concurrently with other enzyme replacement therapy (e.g., Fabrazyme) • Documented eGFR ≥ 30 mL/min • Request is for an FDA-approved dose

<p>Revision/Review Date: 10/2021</p>	<p>If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.</p> <p>Physician/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
--	--

Field Name	Field Description
Prior Authorization Group Description	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	Cerdelga, miglustat: 18 years of age or older Elelyso: 4 years of age or older Cerezyme, Vpriv; N/A
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. If all of the criteria are not met, the request is referred to a clinical reviewer for medical necessity review.
Other Criteria	<p><u>Initial Authorization:</u> <u>Cerezyme, Vpriv, Elelyso, or miglustat initial authorization:</u></p> <ul style="list-style-type: none"> • Patient has a confirmed diagnosis of Gaucher's disease, type 1 (GD1) • Request is for an FDA approved dose <p><u>Cerdelga initial authorization:</u></p> <ul style="list-style-type: none"> • Patient is 18 years of age or older. • 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.

<p>Revision/Review Date 5/2021</p>	<ul style="list-style-type: none"> • For EM's, patient does not have moderate or severe hepatic impairment • For IM's or PMs, patient does not have any degree of hepatic impairment. <p><u>Re-Authorization criteria for all agents:</u></p> <ul style="list-style-type: none"> • Documentation has been provided that patient has obtained clinical benefit from medication (e.g. increased platelet count, improvement in anemia, PFT's, improvement in radiographic scans, improved quality of life) • Request is for an FDA approved dose <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
--	---

Field Name	Field Description
Prior Authorization Group Description	Glycopyrrolate (oral)
Drugs	<p><u>Formulary Status:</u> Formulary; Pays at point-of-sale glycopyrrolate 1, 2 mg tablet</p> <p><u>Formulary Status:</u> Requires prior authorization Cuvposa (glycopyrrolate) 1 mg/5 mL oral solution glycopyrrolate (Glycate) 1.5 mg tablet</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	Cuvposa – Age 3 to 16 years glycopyrrolate – Age 12 years or older
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month. If the criteria are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria	<p><u>Requests for Cuvposa (glycopyrrolate) 1 mg/5 mL oral solution:</u></p> <ul style="list-style-type: none"> • Documented diagnosis of chronic severe drooling AND • Documented neurological condition associated with problem drooling (e.g., cerebral palsy) AND • Member has tried and failed non-pharmacologic approaches to treatment (e.g., correction of situational factors, treatment of dental malocclusion and caries, orthodontic appliances, swallowing therapy, biofeedback and automatic cueing, positive and negative reinforcement) AND • Drug is being prescribed at FDA approved dose <p><u>Requests for glycopyrrolate 1.5 mg tablet:</u></p> <ul style="list-style-type: none"> • Documented diagnosis of peptic ulcer disease AND • Glycopyrrolate will be used as an adjunct to other therapies AND • Member has tried and failed glycopyrrolate 1 mg or 2 mg

<p>Revision/Review Date 2/2021</p>	<p>tablets or has a medical reason (e.g. intolerance, hypersensitivity, contraindication, etc.) for not using glycopyrrolate 1 mg and 2 mg tablets AND</p> <ul style="list-style-type: none"> • Member has tried and failed propantheline or has a medical reason (e.g. intolerance, hypersensitivity, contraindication, etc.) for not using propantheline AND • Drug is being prescribed at and FDA approved dose <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
--	--

Field Name	Field Description
Prior Authorization Group Description	Gonadotropin Releasing Hormone Agonists (GNRH) **IF DIAGNOSIS IS GENDER DYSPHORIA, USE GENDER DYSPHORIA CRITERIA**
Drug(s)	<p>Preferred GNRH Agonist(s) for their respective indications: Eligard (leuprolide acetate), Fensolvi (leuprolide acetate), leuprolide acetate, Lupron Depot (leuprolide acetate), Lupron Depot-Ped (leuprolide acetate), Synarel (nafarelin acetate), Vantas (histrelin acetate), Zoladex (goserelin acetate)</p> <p>Non-Preferred GNRH Agonist(s): Lupaneta Pack (leuprolide acetate/norethindrone acetate), Supprelin LA (histrelin acetate), Trelstar (triptorelin pamoate), Triptodur (triptorelin pamoate), and any newly marketed GnRH agonist.</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), 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 cancer or 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. If the conditions are not met, the request will be sent to a Medical Director/Clinical Reviewer for medical necessity review.
Other Criteria	<p><u>INITIAL AUTHORIZATION for ALL REQUESTS:</u></p> <ul style="list-style-type: none"> • The medication is being prescribed for an FDA approved/standard of care guideline indication and within FDA approved/standard of care dosing guidelines. • If the request is for a non-preferred medication, the member has a documented treatment failure with 2 indicated preferred drugs (if applicable) or has a documented medical reason (intolerance, hypersensitivity, contraindication, etc.) why they are not able to use preferred drugs if appropriate for the requested indication

AND the member meets the following for the respective diagnosis:

Central precocious puberty (CPP)

- Onset of secondary sexual characteristics occurred when member was aged less than 8 years for females or aged less than 9 years for males
- Diagnosis is confirmed by a pubertal response to a GnRH stimulation test and/or measurement of gonadotropins (FSH/LH), and bone age advanced beyond chronological age.
 - Patients with low or intermediate basal levels of LH should have a GnRH stimulation test to clarify the diagnosis.
 - *If basal levels of LH are markedly elevated [e.g. more than 0.3mIU/ml (where IU- International units)] in a child with precocious puberty, then a diagnosis of CPP can be made without proceeding to a GnRH stimulation test.*
- Brain magnetic resonance imaging (MRI) has been performed for all boys with CPP and for girls with onset of secondary sexual characteristics before the age of six years of age to rule out a tumor.

Endometriosis

- For all therapies except Lupron, Lupron Depot, or Lupron 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)

- 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

<p>Review Date 1/2022</p>	<p><u>Oncology Diagnosis</u></p> <ul style="list-style-type: none"> • The drug is being requested for an indication that is supported by NCCN Category 1 or 2A level of evidence. If the request is for a Category 2B recommendation then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g. allergic reaction, contraindication) • The medication is being prescribed at a dose that is within FDA approved/NCCN guidelines. <p><u>REAUTHORIZATION for all requests:</u></p> <ul style="list-style-type: none"> • The medication is being prescribed for an FDA approved indication and within FDA approved dosing guidelines. • Documentation was provided supporting continued treatment (e.g. patient still has symptoms), and medication is being continued as recommended in package insert or standard of care guidelines. <p><u>AND meets the following per diagnosis:</u></p> <p><u>Central precocious puberty (CPP)</u></p> <ul style="list-style-type: none"> • If the medication reauthorization is for central precocious puberty, the child is male and < 12 years or female and < 11 years of age OR a documented medical reason to continue treatment was provided with request, and includes current height and bone age <p><u>Endometriosis</u></p> <ul style="list-style-type: none"> • Provider has evaluated patient for osteoporosis (e.g. Dexascan), and patient is receiving “add back” hormonal therapy (norethindrone acetate 5 mg daily alone or with conjugated estrogen therapy) or an oral bisphosphonate AND calcium and vitamin D supplementation. • The patient has not received cumulative doses of the GnRH agonist greater than 12 months of therapy. <p><u>Fibroids</u></p> <ul style="list-style-type: none"> • The patient has not received cumulative doses of the GnRH agonist greater than 6 months of therapy <p>NOTE: Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>
-------------------------------	--

Field Name	Field Description
Prior Authorization Group Description	Gonadotropin Releasing Hormone Antagonist Combination Products
Drugs	Myfembree (relugolix, estradiol, and norethindrone acetate)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	<ul style="list-style-type: none"> • Pregnancy • History of osteoporosis • History of hepatic impairment
Required Medical Information	See “Other Criteria”
Age Restrictions	Member must be ≥ 18 years of age
Prescriber Restrictions	Prescriber is an OB/GYN
Coverage Duration	<p>If the criteria are met, the request will be approved for (a maximum treatment duration of):</p> <ul style="list-style-type: none"> • Initial Authorization: 6 months • Subsequent Authorizations: 12 months • Eligible maximum lifetime treatment duration: 24 months
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Patient is premenopausal and has a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) • Documented trial and failure or medical reason for not using estrogen-progestin contraceptive therapy as a first line agent • If one of the following drugs has been tried previously, a trial of estrogen-progestin contraceptive therapy is not required: <ul style="list-style-type: none"> ○ gonadotropin-releasing hormone (GnRH) agonists, ○ progestin-releasing intrauterine device ○ tranexamic acid • Request is for an FDA-approved dose • If the request is from Myfembree, there is a documented trial and failure of Oriahnn, or medical reason why Oriahnn cannot be used <p><u>Reauthorization:</u></p> <ul style="list-style-type: none"> • Patient’s eligible maximum lifetime treatment duration has not been exceeded (see Coverage Duration above) • Request is for an FDA-approved dose • Prescriber indicates patient has reduced menstrual bleeding from baseline <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary</p>

Revision/Review Date: 1/2022	
---------------------------------	--

HEPATITIS C TREATMENT

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

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.

Exceptions: BRAND EPCLUSA 200 mg/50 mg can be approved in children between 17 and 30 kg and BRAND HARVONI 45 mg/200 mg can be approved in children between 17 and 35 kg without a documented medical reason for not using their respective generic high-strength tablets.

Initial requests must meet ALL of the following requirements:

1. Diagnosis of chronic hepatitis C virus (HCV)
 - 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/or liver transplant
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 complete Hepatitis B immunization series OR Hepatitis B screening (sAB, sAG, and cAB)
 - Quantitative HBV DNA results if positive for hepatitis B sAg
 - If there is detectable HBV DNA, a treatment plan for Hepatitis B consistent with AASLD recommendations
 - If negative for Hepatitis B sAb, a hepatitis B immunization plan or counseling to

receive the hepatitis B immunization series

6. Provider attests that they have documented HIV screening (HIV Ag/Ab) and if confirmed positive by HIV-1/HIV-2 differentiation immunoassay:
 - Is being treated for HIV; OR
 - 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:
 - Genotype (and subtype if provided) must be provided for:
 - Patients who are not going to receive Mavyret or generic Epclusa
 - Generic Epclusa in treatment naïve patients with compensated cirrhosis
 - Patients who do not qualify for simplified treatment (treatment-experienced, have or had decompensated cirrhosis (Child-Pugh B and C), have ESRD, are HIV positive, have current HBV infection (positive for HbsAg), are pregnant, have known or suspected hepatocellular carcinoma, or have had a liver transplant)
 - Has documentation of AASLD-recommended resistance-associated substitution (RAS) testing for:
 - Zepatier requests: all members with genotype 1a
 - Harvoni requests: treatment-experienced members with genotype 1a
 - Epclusa requests: treatment naïve members with cirrhosis and treatment experienced members without cirrhosis with genotype 3

TREATMENT SUMMARY

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

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

Treatment Naïve Recommended Treatments			
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 Y94H RAS to qualify for treatment

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

Treatment Experienced			
Failed Regimen	Treatment Options	Duration	
		No Cirrhosis	Compensated Cirrhosis (Child-Pugh A)
Sofosbuvir-based (Sovaldi, Harvoni, and Epclusa) and Zepatier	Vosevi	12 weeks	12 weeks
	Mavyret*	16 weeks	16 weeks
Mavyret	Epclusa 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 ^u	16 weeks ^u
	Vosevi plus ribavirin	24 weeks	24 weeks

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

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

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

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

Review/Revision Date: 10/2021

Prior Authorization Group Description	Treatment of Hereditary Angioedema (HAE)
Drugs	<p><u>Preferred:</u> Berinert (C1 esterase inhibitor, human) Haegarda (C1 esterase inhibitor, human) Ruconest (C1 esterase inhibitor, recombinant) icatibant (Firazyr)</p> <p><u>Non-preferred:</u> Cinryze (C1 esterase inhibitor, human) Kalbitor (ecallantide) Takhzyro (lanadelumab-flyo) Orladeyo (berotralstat)</p> <p>For danazol requests, refer to the “Danazol” policy</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be an immunologist, allergist, rheumatologist, or hematologist
Coverage Duration	<p>If criteria are met, the request will be approved as follows:</p> <ul style="list-style-type: none"> • Acute treatment: 1 + 5 refills • Pre procedural prophylaxis: 1 treatment • Long-term prophylaxis: Initially 6 months, reauthorization 12 months <p>If the below conditions are not met, the request will be referred to a Medical Director/clinical reviewer for medical necessity review.</p>
Other Criteria	<p><u>Initial Requests:</u></p> <ul style="list-style-type: none"> • Documentation submitted indicates the medication is being prescribed at FDA approved dose. • The patient is not taking ACE inhibitors or estrogen containing oral contraceptives/hormone replacement therapy • Diagnosis: <ul style="list-style-type: none"> ○ HAE with deficient or dysfunctional C1INH (e.g. type I, type II, or acquired C1INH deficiency) ○ HAE with normal C1INH: <ul style="list-style-type: none"> ▪ If known origin, documentation of results of confirmatory genetic test (e.g. mutations in gene for factor XII, angiopoietin-1, plasminogen, kininogen-1)

	<ul style="list-style-type: none"> ▪ If unknown origin (U-HAE), documentation of a prolonged trial of high-dose non-sedating antihistamines <ul style="list-style-type: none"> • For acute treatment: <ul style="list-style-type: none"> ○ 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 <p>For prophylaxis:</p> <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> ○ 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 <ul style="list-style-type: none"> ○ 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) <p><u>Renewal Criteria:</u></p> <p>For acute treatment:</p> <ul style="list-style-type: none"> • 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. <p>For prophylaxis:</p> <ul style="list-style-type: none"> • Documentation was submitted that the patient has clinically benefited from prophylactic therapy as demonstrated by a reduced number of attacks • The medication is being prescribed at an FDA approved dose • If the request is for Takhzyro and the patient has been well controlled (e.g. attack free) for 6 months or more while receiving
--	--

<p>Revision/Review Date: 5/2021</p>	<p>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</p> <ul style="list-style-type: none"> • The patient is receiving no other medications for prophylaxis <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p> <p>NOTE: Medical Director/Clinical Reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary</p>
---	--

Field Name	Field Description
Prior Authorization Group Description	Hormone Replacement Therapy (estrogen-only oral and vaginal products)
Drugs	<p><u>FORMULARY STATUS</u> Preferred, Pays at Point-of-Sale</p> <p>Estradiol (Estrace) oral tablet Estradiol (Estrace) vaginal cream Estradiol (Vagifem) vaginal tablet</p> <p><u>FORMULARY STATUS</u> Preferred, Requires Step Therapy</p> <p>Premarin (estrogens, conjugated) oral tablet Premarin (estrogens, conjugated) vaginal cream Menest (estrogens, esterified) oral tablet</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration for; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	<p><u>For all requests:</u></p> <ul style="list-style-type: none"> The request is for an FDA approved indication. <p><u>Initial authorization for Premarin and Menest oral tablet</u></p> <ul style="list-style-type: none"> Documented trial and failure or intolerance with estradiol oral tablet If the request is for the treatment of moderate to severe symptoms of vulvar and vaginal atrophy or atrophic vaginitis due to menopause, must also have documented trial and failure or intolerance with estradiol vaginal cream OR estradiol vaginal tablet <p><u>Initial authorization for Premarin vaginal cream</u></p> <ul style="list-style-type: none"> Documented trial and failure or intolerance with estradiol vaginal cream OR estradiol vaginal tablet <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 10/2021	

Human Growth Hormones Criteria

Pharmacology

Somatropin (rDNA Origin) is a polypeptide hormone of recombinant DNA origin. The amino acid sequence of these products is identical to that of human growth hormone of pituitary origin.

Human growth hormone (hGH) is a 191-amino acid polypeptide hormone secreted by the anterior pituitary gland. It has important metabolic effects, including stimulation of protein synthesis and cellular uptake of amino acids.

Indications

Drug	GHD (ped)	PWS	Turner Syndrome	CKD	SGA	GHD (adult)	ISS	SHOX	SBS	HIV wasting or cachexia	Other
Genotropin®	X	X	X		X	X	X				
Humatrope®	X		X		X	X	X	X			Hypopituitarism (Adults)
Norditropin®	X	X	X		X	X	X				Noonan Syndrome
Nutropin AQ®	X		X	X		X	X				CKD up to the time of renal transplantation. (Pediatric)
Omnitrope®	X	X	X		X	X					
Saizen®	X					X					
Serostim®										X	
Zomacton™	X		X		X	X	X	X			
Zorbtive®									X		

GHD = growth hormone deficiency; PWS = Prader-Willi Syndrome; CKD = Chronic kidney disease; SGA = small gestational age; ISS = idiopathic short stature; SHOX = short stature homeobox gene; SBS = short bowel syndrome.

Medications

Brand Name	Generic Name	Dosage Strengths
Genotropin®	somatropin	5, 12 mg cartridge, 0.2, 0.4, 0.6, 0.8, 1, 1.2, 1.4, 1.6, 1.8, 2 mg syringe device

Humatrope®	somatropin	5 mg vial, 6, 12, 24 mg cartridge kits
Norditropin®	somatropin	5, 10, 15, 30 mg prefilled pen
Nutropin AQ®	somatropin	5, 10, 20 mg NuSpin prefilled cartridge 10 mg/2 ml, 20 mg/2 ml pen cartridge
Omnitrope®	somatropin	5.8 mg vial, 5 mg/1.5 ml, 10 mg/1.5 ml cartridge
Saizen®	somatropin	5 mg, 8.8 mg vial, 8.8 mg cartridge
Serostim®	somatropin	5, 6 mg single dose vial, 4 mg multi dose vial
Zomacton™ (name change from Tev-Tropin)	somatropin	5, 10 mg vial
Zorbtive®	somatropin	8.8 mg vial

Criteria for Approval

Pediatrics (18 and Under)

1. Prescriber is an endocrinologist or nephrologist or one has been consulted on this case; AND
 2. MRI of the brain has been performed (to document absence of a brain tumor); AND
 3. ONE of the following diagnoses:
 - a. Patient has a diagnosis of growth hormone deficiency; AND
 - i. Patient's height is more than 2 SD below average for the population mean height for age and sex, and a height velocity measured over one year to be 1 SD below the mean for chronological age; or for children over two years of age, a decrease in height SD of more than 0.5 over one year; AND
 - ii. Other causes of poor growth have been ruled out, including hypothyroidism, chronic illness, malnutrition, malabsorption, and genetic syndrome; AND
 - iii. Growth hormone response of less than 10 ng/ml to at least two provocative stimuli of growth hormone release: insulin, levodopa, L-Arginine, clonidine, or glucagons; OR
 - b. Patient has a diagnosis of Noonan Syndrome, short stature homeobox gene, Turner Syndrome, Prader-Willi Syndrome, or chronic kidney disease (Nutropin AQ only) AND meets auxological criteria for short stature – height more than two standard deviations below normal for age; OR
-

- c. Patient has a diagnosis of small for gestational age (including Russell-Silver variant) AND height is more than 2.25 standard deviations below normal for age and sex AND failure to catch up in growth by two years of age; OR
- d. Patient is newborn with hypoglycemia and a diagnosis of hypopituitarism or panhypopituitarism.

Adults (Over 18)

- 1. Prescriber is an endocrinologist; AND
- 2. ALL of the following diagnoses and conditions have been met:
 - a. Patient has a diagnosis of growth hormone deficiency; AND
 - b. The etiology for patient's diagnosis of growth hormone deficiency is Adult Onset Growth Hormone Deficiency (AO-GHD), alone or with multiple hormone deficiencies, such as hypopituitarism as a result of hypothalamic or pituitary disease, radiation therapy, surgery or trauma; AND
 - c. GHD has been confirmed by growth hormone stimulation tests and rule-out of other hormonal deficiency as follows: growth hormone response of fewer than five nanograms per mL to at least two provocative stimuli of growth hormone release: insulin, levodopa, L-Arginine, clonidine, or glucagon when measured by polyclonal antibody (RIA) or fewer than 2.5 nanograms per mL when measured by monoclonal antibody (IRMA); AND
 - d. Rule-out other hormonal deficiencies (thyroid, cortisol, or sex steroids)
 - i. Stimulation testing would not produce a clinical response such as in a diagnosis of panhypopituitarism as defined by the absence of all anterior pituitary hormones: Luteinizing Hormone (LH), Follicle Stimulating Hormone (FSH), Thyroid Stimulating Hormone (TSH), Adrenocorticotrophic Hormone (ACTH) and Growth Hormone (GH); OR
 - e. Patient has a diagnosis of AIDS Wasting or cachexia (for Serostim only); AND
 - i. Patient has a documented failure, intolerance, or contraindication to appetite stimulants and/or other anabolic agents (both Megace® and Marinol®); OR
 - f. Patient has a diagnosis of short bowel syndrome (Zorbative® only).

Criteria for Denial

- 1. Failure to meet criteria for authorization; OR
 - 2. Constitutional delay of growth and development; OR
 - 3. Skeletal dysplasias; OR
 - 4. Osteogenesis imperfecta; OR
 - 5. Down syndrome and other syndromes associated with short stature and malignant diathesis (Fanconi syndrome and Bloom syndrome); OR
-

6. Continuation of growth hormone treatment once epiphyses are closed; OR
7. The following diagnoses for which GH cannot be the primary treatment:
 - a. Obesity; OR
 - b. Osteoporosis; OR
 - c. Muscular dystrophy; OR
 - d. Infertility; OR
 - e. Increased athletic performance; OR
 - f. Somatopause.

Length of Authorization

Pediatrics: One year.

1. Reauthorization is contingent upon response as shown by growth curve chart. Patient must demonstrate improved/normalized growth velocity. Growth velocity has increased by at least 2 cm in the first year and is greater than 2.5 cm per year and that epiphyses are not fused.

Adults: One year.

1. Reauthorization is contingent upon prescriber affirmation of positive response to therapy (e.g., improved body composition, reduced body fat, and increased lean body mass).

Adults/Serostim: Three months initial; then one year.

1. Reauthorization is contingent upon improvement in lean body mass or weight measurements.
-

Field Name	Field Description
Prior Authorization Group Description	Ileal bile acid transporter inhibitor (IBAT)
Drugs	Bylvay (odevixibat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	3 months and older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist or hepatologist
Coverage Duration	If the conditions are met, the request will be approved for a 6 month duration for initial requests and a 12 month duration for renewal requests. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of progressive familial intrahepatic cholestasis (PFIC) type 1, 2, or 3 with genetic confirmation • Documentation that patient does not have an <i>ABCB11</i> variant that results in non-functional or complete absence of bile salt export pump protein (BSEP-3) • Documented history of significant pruritus • Documentation of patient’s weight • Prescriber attests to monitor liver function tests and fat soluble vitamin (FSV) levels during treatment • Baseline serum bile acid level • Documentation of trial and failure OR contraindication to at least ONE of the following: <ul style="list-style-type: none"> ○ Ursodiol ○ Cholestyramine • The prescribed dose is within FDA approved dosing guidelines <p><u>Reauthorization:</u></p> <ul style="list-style-type: none"> • Documentation submitted indicates the member has had BOTH of the following: <ul style="list-style-type: none"> ○ An improvement in pruritus (e.g. improved observed scratching, decreased sleep

<p>Revision/Review Date: 10/2021</p>	<p>disturbances/nighttime awakenings due to scratching, etc.)</p> <ul style="list-style-type: none"> ○ Reduction in serum bile acid level from baseline • Documentation of patient's weight • Prescriber attests to monitor liver function tests and FSV levels during treatment • Prescriber attests that patient has had no evidence of hepatic decompensation (e.g. variceal hemorrhage, ascites, hepatic encephalopathy, portal hypertension, etc.) • The prescribed dose is within FDA approved dosing guidelines <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
--	---

Field Name	Field Description
Prior Authorization Group Description	Immune Globulins
Drugs	<p>Gamunex-C (IV or SQ) (Immune Globulin) – <i>Preferred for all applicable indications</i></p> <p>Bivigam (IV) (Immune Globulin)</p> <p>Cuvitru (SQ) (Immune Globulin)</p> <p>Flebogamma (IV) (Immune Globulin)</p> <p>Gamastan (IM) (Immune Globulin)</p> <p>Gamastan SD (IM) (Immune Globulin)</p> <p>Gammagard liquid (IV or SQ) (Immune Globulin)</p> <p>Gammagard SD (IV) (Immune Globulin)</p> <p>Gammaked (IV or SQ) (Immune Globulin)</p> <p>Gammaplex (IV) (Immune Globulin)</p> <p>Hizentra (SQ) (Immune Globulin)</p> <p>Octagam (IV) (Immune Globulin)</p> <p>Privigen (IV) (Immune Globulin)</p> <p>Asceniv (IV) (Immune Globulin-slra)</p> <p>Cutaquig (SQ) (Immune Globulin-hipp)</p> <p>Panzyga (IV) (Immune Globulin-ifas)</p> <p>Hyqvia (SQ) (Immune Globulin Human/Recombinant Human Hyaluronidase)</p> <p>Xembify (SQ) (Immune Globulin-klhw)</p> <p>Or any newly marketed immune globulin</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	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	<p><u>All Requests:</u></p> <ul style="list-style-type: none"> • Diagnosis has been confirmed by a specialist • Member has tried and failed, or has a documented medical reason for not using, all other standard of care therapies as defined per recognized guidelines • Member’s height and weight are provided • Dosing will be calculated using ideal body weight (IBW),

unless ONE of the following:

- If the member's actual weight is less than their IBW, then dosing will be calculated using their actual weight
- If the member's body mass index (BMI) is ≥ 30 kg/m² 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:
 - Inability to produce an adequate immunologic response to specific antigens.
 - History of recurrent infections despite prophylactic antibiotics
- Dose is consistent with FDA approved package labeling, nationally recognized compendia, or peer-reviewed literature
- If the request is for any medication other than Gamunex-C, the member has tried and failed, or has a documented medical reason for not using, Gamunex-C
- If criteria is met, approve for 6 months.

*Primary Immunodeficiency includes, but is not limited to, the following: Congenital agammaglobulinemia.

Hypogammaglobulinemia (Common Variable Immunodeficiency, CVID), Severe combined immunodeficiency (SCID), Wiskott-Aldrich syndrome, X-linked agammaglobulinemia or Bruton's agammaglobulinemia, Hypergammaglobulinemia, X-linked Hyper IgM syndrome

Idiopathic Thrombocytopenic Purpura, acute and chronic:

- Acute:
 - Patient has active bleeding, requires an urgent invasive procedure, is deferring splenectomy, has platelet counts $< 20,000/\mu\text{l}$ and is at risk for intracerebral hemorrhage or has life threatening bleeding, or has an inadequate increase in platelets from corticosteroids or is unable to tolerate corticosteroids
 - Dose does not exceed 1g/kg daily for up to 2 days, or 400mg/kg daily for 5 days

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

Kawasaki disease:

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

Chronic B-cell lymphocytic leukemia:

- The patient has history of severe bacterial infections
- Dose does not exceed 500mg/kg every 3-4 weeks
- If criteria is met, approve for 3 months.

Bone marrow transplantation:

- Patient's IgG level is < 400mg/dL
- Dose does not exceed 500mg/kg/wk for the first 100 days post- transplant
- Dose does not exceed 500 mg/kg every 3-4 weeks 100 days after transplant
- If criteria is met, approve for 3 months.

Pediatric HIV:

- Patient is < 13 years of age
- Either patient's IgG level is < 400mg/dL or
- If patient's IgG level is \geq 400 mg/dL than significant deficiency of humoral immunity as evidenced by ONE of the following:
 - Inability to produce an adequate immunologic response to specific antigens.
 - History of recurrent bacterial infections despite

prophylactic antibiotics

- Dose does not exceed 400mg/kg/dose every 14 days
- If criteria is met, approve for 3 months.

Multifocal motor neuropathy (MMN):

- Duration of symptoms has been at least 1 month with disability.
- Nerve conduction studies were completed to rule out other possible conditions, and confirms the diagnosis of MMN.
- Dose does not exceed 2g/kg/month administered over 2 to 5 days.
- If criteria is met, approve for up to 5 days for 3 months.

Chronic inflammatory demyelinating polyneuropathy (CIDP):

- Duration of symptoms has been at least 2 months with disability.
- Nerve conduction studies or a nerve biopsy were completed in order to rule out other possible conditions, and confirms the diagnosis of CIDP.
- Patient has tried and failed, or has a documented medical reason for not using, corticosteroids.
 - If the patient has severe and fulminant CIDP a trial of corticosteroids is not required
- Dose is consistent with FDA approved package labeling, nationally recognized compendia, or peer-reviewed literature
- If the request is for any medication other than Gamunex-C, the member has tried and failed, or has a documented medical reason for not using, Gamunex-C
- If criteria is met, approve for up to 5 days for 3 months

Guillain-Barre syndrome:

- Patient has severe disease with the inability to walk without aid
- Onset of symptoms within the last 4 weeks
- Dose does not exceed 2g/kg administered over 2-5 days
- If criteria is met, approve for up to 5 days.

Myasthenia Gravis:

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

Dermatomyositis (DM):

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

<p>Revision/Review Date 10/2021</p>	<ul style="list-style-type: none"> ○ Member has tried and failed, or has a documented medical reason for not using all of the following: MTX and mycophenolate mofetil. ● Dose does not exceed 2 g/kg administered over 2-5 days every 4 weeks. ● If criteria is met, approve for up to 3 months. <p>If criteria is met, the request will be approved for the duration listed above. If the criteria is not met, the request is referred to a Medical Director/Clinical reviewer for medical necessity review.</p> <p><u>Medical Director/Clinical Reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary</u></p>
---	---

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. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria	<p><u>Initial Authorization</u></p> <ul style="list-style-type: none"> • Member must have a diagnosis of systemic lupus erythematosus (SLE) with a kidney biopsy indicating a histologic diagnosis of lupus nephritis (LN) Class III, IV, or V • Documentation that the member has a baseline eGFR > 45 mL/min/1.73m² • Documentation of the member's urine protein/creatinine ratio (UPCR) is provided • Member is concurrently being treated with background immunosuppressive therapy, or has a medical reason for not using background immunosuppressive therapy • Member is NOT concurrently being treated with cyclophosphamide • Medication is prescribed at an FDA approved dose <p><u>Reauthorization</u></p> <ul style="list-style-type: none"> • Documentation of improvement in renal function (i.e. reduction in UPCR or no confirmed decrease from baseline eGFR ≥ 20%) • Medication is prescribed at an FDA approved dose <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 05/2021	

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. If all of the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	<p><u>Initial Authorization</u></p> <ul style="list-style-type: none"> • Member has a diagnosis of one of the following <ul style="list-style-type: none"> ○ Growth hormone (GH) gene deletion with the development of neutralizing antibodies to GH ○ Severe primary insulin-like growth factor-1 (IGF-1) deficiency as defined as: <ul style="list-style-type: none"> ▪ Height and basal IGF-1 standard deviation scores ≤ -3.0 ▪ Normal or elevated GH levels • Member does not have a closed epiphyses • Member does not have known or suspected malignancies • Request is for an FDA-approved dose <p><u>Reauthorization</u></p> <ul style="list-style-type: none"> • Growth velocity must be ≥ 2 cm in the past year • Member does not have a closed epiphyses • Member does not have known or suspected malignancies • Request is for an FDA-approved dose
Revision/Review Date 7/2021	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Inhaled Insulin Criteria

Indication

Afrezza®, an insulin inhalation powder, is a rapid-acting, orally inhaled insulin indicated to improve glycemic control in adults with Type 1 or Type 2 diabetes mellitus (T1DM, T2DM). Insulin inhalation powder must be used with a long-acting insulin in patients with T1DM. It is not recommended for the treatment of diabetic ketoacidosis (DKA). Insulin inhalation powder should not be used in patients who smoke or who have recently stopped smoking, as safety and efficacy has not been established in this population. Afrezza® consists of Technosphere® insulin inhalation powder and the breath-powered Gen 2 inhaler.

Medications

Brand Name	Generic Name	Dosage Strengths
Afrezza®	Insulin human inhalation powder	4 units, 8 units, 12 units single use cartridges

Criteria for Authorization

1. Patient is ≥ 18 years of age; AND
2. Patient is a non-smoker or has stopped smoking for more than six months prior to starting Afrezza®; AND
3. A diagnosis of Type 1 diabetes; AND
 - a. Patient has history of treatment failure with fast-acting SC insulin; AND
 - b. Patient is on concurrent use of a long-acting insulin; OR
4. Diagnosis of Type 2 diabetes; AND
 - a. Failure to attain adequate glycemic control on maximum tolerated doses of combination therapy of sulfonylureas, metformin, and TZDs; AND
 - b. Patient has HgA1C $> 7\%$; AND
 - c. Patient has history of treatment failure with fast-acting SC insulin.

Criteria for Denial

1. Failure to meet criteria for authorization.
2. Patient has chronic lung disease such as COPD, asthma, or emphysema.

3. FEV1 < 80%.
4. Patient is a smoker or has stopped smoking within the last six months.
5. No concurrent long-acting insulin (Type 1 diabetes only).
6. Hypersensitivity to regular human insulin.

Initial approval period: Six months

Second approval: Six months; second FEV1 measurement required. DENY if there is a decrease > 20% in FEV1 compared to baseline.

Continued approval: One year; annual FEV1 measurement required. DENY if there is a decrease > 20% in FEV1 compared to baseline.

Field Name	Field Description
Prior Authorization Group Description	Insulin Pumps
Drugs	<p>Omnipod Dash, insulin delivery pods only (Notes: The Omnipod Dash PDM (Personal Diabetes Manager) is provided direct by Insulet and should not be requested by the prescriber/billed to the plan.)</p> <p>This policy does not apply to pumps reviewed and/or covered by the Medical Benefit including, but not limited to V-Go 24-hour disposable system and t:slim X2, and continuous glucose monitor/insulin pumps such as MiniMed. Requests for these products are referred to the plan's Utilization Management team for review.</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months. If the criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.
Other Criteria	<p><u>Initial Authorization</u></p> <ul style="list-style-type: none"> • Diagnosis – diabetes • One of the following <ul style="list-style-type: none"> ○ ≤ 18 years with type 1 diabetes or other insulin-deficient forms of diabetes (i.e. cystic-fibrosis related diabetes) ○ Continuation of therapy for patient new to plan ○ Treatment with multiple daily doses (≥ 3) of insulin and one of the following <ul style="list-style-type: none"> ▪ Persistently inadequate glycemic control (i.e. HbA1C ≥ 7% on multiple consecutive readings with one being within the last 3 months, frequent bouts of hypoglycemia,

<p>Revision/Review Date 10/2021</p>	<p>overt microvascular complications)</p> <ul style="list-style-type: none"> ▪ History of acutely dangerous symptoms (i.e. severe glycemic excursions; brittle diabetes; nocturnal hypoglycemia; hypoglycemia unawareness, ketosis) ▪ Other difficult to manage symptoms/scenarios (i.e. “dawn” phenomenon; extreme insulin sensitivity; very low insulin requirements) ▪ Pregnancy <p><u>Reauthorization</u></p> <ul style="list-style-type: none"> • One of the following: <ul style="list-style-type: none"> ○ Child or adolescent with type 1 diabetes or other insulin-deficient form of diabetes ○ Documentation of positive clinical response (i.e. improved HbA1C; reduced frequency of severe hypoglycemia episodes; target time in range [TIR] > 70% or time below range < 4%) with 1st reauthorization ○ Initial approval was based on continuation of therapy for patient new to plan. • Continuation of therapy based on a diagnosis of pregnancy alone is not eligible for reauthorization <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
---	---

Field Name	Field Description
Prior Authorization Group	Injectable/Infusible Bone-Modifying Agents for Oncology Indications
Drugs	<p>Preferred Bone-Modifying Agent(s): Pamidronate disodium (Aredia), Zoledronic Acid (Zometa)</p> <p>Non-preferred Bone-Modifying Agent(s): Xgeva, Prolia (denosumab)</p>
Covered Uses	The request is for an FDA approved indication or for a medically accepted indications as defined or as supported by the medical compendium (Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI) , Drug Package Insert) as defined in the Social Security Act 1927, or per the National Comprehensive Cancer Network (NCCN), the American Society of Clinical Oncology (ASCO), or the National Institutes of Health (NIH) Consensus Panel standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber is an oncologist
Coverage Duration	6 months
Other Criteria	<ul style="list-style-type: none"> • The request is for an approved/accepted indication at an approved dose • Documentation has been provided that the patient is being treated with calcium and vitamin D, unless contraindicated (e.g. history of recurrent renal stones) • If the request is for, Xgeva (denosumab) for any of the indications below, the patient has a documented trial and failure of generic pamidronate (Aredia) OR zoledronic acid (Zometa) that is consistent with claims history, or has a documented medical reason (intolerance, hypersensitivity, contraindication, renal insufficiency, etc) for not utilizing one of these agents to manage their medical condition <ul style="list-style-type: none"> ○ Bone metastases from solid tumors ○ Hypercalcemia of malignancy ○ Multiple myeloma osteolytic lesions • If the request is for Xgeva (denosumab) for treating Giant cell tumor of bone, documentation has been submitted that the tumor is unresectable, that surgical resection is likely to result in morbidity (e.g. denosumab therapy is being used to aide in the possibility of resection with tumor shrinkage), or that disease has recurred.

<p>Revision/Review 5/2021</p>	<ul style="list-style-type: none"> • If the request is 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. <p>If these conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.</p> <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
-----------------------------------	---

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	<p>If all of the conditions are met, requests will be approved for a 1 year.</p> <p>*** TERIPARATIDE/FORTEO/TYMLOS REQUESTS WILL ONLY BE APPROVED FOR A TOTAL DURATION OF 24 MONTHS***</p> <p>***EVENITY WILL ONLY BE APPROVED FOR A TOTAL DURATION OF 12 MONTHS***</p> <p>If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.</p>
Other Criteria	<p><u>For all Requests:</u></p> <ul style="list-style-type: none"> • The member has a documented (consistent with pharmacy claims) adequate trial of an oral bisphosphonate or has a medical reason (e.g. intolerance, hypersensitivity, contraindication, etc.) for not using an oral bisphosphonate • The member is taking calcium and vitamin D • The medication is FDA-approved for indication and is being requested at an FDA approved dose <p><u>If the diagnosis is postmenopausal or male osteoporosis:</u></p> <ul style="list-style-type: none"> • If the request is for male osteoporosis or high risk postmenopausal osteoporosis with no prior fractures the member has a documented (consistent with pharmacy claims) adequate trial of an oral bisphosphonate or has a medical

	<p>reason (e.g. intolerance, hypersensitivity, contraindication, etc.) for not using an oral bisphosphonate</p> <ul style="list-style-type: none"> • If the request is for very high risk postmenopausal osteoporosis or postmenopausal osteoporosis with prior fractures a documented trial and failure of an oral bisphosphonate will not be required. <ul style="list-style-type: none"> ○ Very high risk is defined as having one or more of the following: <ul style="list-style-type: none"> ▪ History of fracture in the past 12 months ▪ Multiple fractures ▪ Fractures while on drugs causing skeletal harm (e.g. long-term glucocorticoids) ▪ Very low T scores (< -3.0) ▪ High risk for falls ▪ History of injurious falls ▪ Very high fracture probability as determined by fracture risk assessment tool (FRAX) (e.g. major osteoporosis fracture $>30\%$, hip fracture $> 4.5\%$) • Documentation was submitted indicating the member is a postmenopausal woman or a male member over 50 years of age and one of the following: <ul style="list-style-type: none"> ○ A bone mineral density (BMD) value consistent with osteoporosis (T-scores equal to or less than -2.5) ○ Has had an osteoporotic fracture ○ A T-score between -1 and -2.5 at the femoral neck or spine and a 10 year hip fracture probability $>3\%$ or a 10 year major osteoporosis-related fracture probability $>20\%$ (based on the US-adapted WHO absolute fracture risk model) • If request is for Forteo (teriparatide), teriparatide (biosimilar), Tymlos (abaloparatide), or Evenity (romosozumab) one of the following applies to member: <ul style="list-style-type: none"> ○ Documented trial and failure of Prolia (denosumab) AND EITHER ibandronate (Boniva) injection OR zoledronic acid (Reclast) or has a medical reason (e.g. intolerance, contraindication, etc.) why these therapies are not suitable to be used ○ Has SEVERE osteoporosis (T-Score -3.5 or below, or T-Score of -2.5 or below plus a fragility fracture) • If request is for Forteo or teriparatide (biosimilar), a medical reason why member is unable to use Tymlos (abaloparatide) or Evenity (romosozumab) if appropriate based on diagnosis <ul style="list-style-type: none"> ○ Requests for brand Forteo (teriparatide) also require a medical reason why member is unable to use teriparatide (biosimilar)
--	--

<p>Revision/Review Date: 5/2021</p>	<p>If the request is for Evenity (romosozumab), the member does not have a history of heart attack or stroke within the preceding year</p> <p><u>If the diagnosis is Paget's disease:</u></p> <ul style="list-style-type: none"> • The member has a documented (consistent with pharmacy claims) adequate trial of an oral bisphosphonate or has a medical reason (e.g. intolerance, hypersensitivity, contraindication, etc.) for not using an oral bisphosphonate • Documentation (within 60 days of request) was submitted including member's serum alkaline phosphatase level of \geq two times the upper limit of normal AND the member is symptomatic OR there is documentation of active disease <p><u>If the diagnosis is glucocorticoid-induced osteoporosis:</u></p> <ul style="list-style-type: none"> • The member has a documented (consistent with pharmacy claims) adequate trial of an oral bisphosphonate or has a medical reason (e.g. intolerance, hypersensitivity, 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: <ul style="list-style-type: none"> ○ History of osteoporotic fracture ○ BMD less than or equal to -2.5 at the hip or spine ○ FRAX 10-year risk for major osteoporotic fracture greater than or equal to 10% (with glucocorticoid adjustment) ○ FRAX 10-year risk for hip fracture greater than 1% • 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 <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>
---	--

Field Name	Field Description
Prior Authorization Group Description	Insulin-Like Growth Factor-1 Receptor (Igf-1r) Antagonists For Thyroid Eye Disease
Drugs	Tepezza (teprotumumab-trbw)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Member must be 18 years age or older
Prescriber Restrictions	Prescriber must be an ophthalmologist, endocrinologist, or specialist with expertise in the treatment of Grave’s disease with thyroid eye disease.
Coverage Duration	If all of the criteria are met, the request will be approved for up to 24 weeks of treatment (8 total infusions). Retreatment requests will not be allowed beyond the 8 dose limit.
Other Criteria	<p><u>Initial Authorization:</u></p> <p>Tepezza is approved when all of the following are met:</p> <ul style="list-style-type: none"> • Dosing does not exceed dosing guidelines as outlined in the package insert • Patient has a confirmed diagnosis of Graves’ disease • Documentation of active moderate-severe thyroid eye disease as evidenced by one or more of the following: <ul style="list-style-type: none"> ○ Lid retraction of >2mm ○ Moderate or severe soft-tissue involvement ○ Proptosis \geq3mm above normal values for race and sex ○ Periodic or constant diplopia • Patients Clinical Activity Score must be \geq4 (must be submitted with request) • 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, oral or IV glucocorticoids to treat their

<p>Revision/Review Date 5/2021</p>	<p>condition</p> <p><u>Re-authorization:</u></p> <ul style="list-style-type: none"> • Retreatment or renewal requests beyond a total of 24 weeks of treatment (8 total infusions) will not be allowed. <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
--	--

Field Name	Field Description
Prior Authorization Group Description	Interleukin Receptor Antagonists for Eosinophilic Conditions
Drugs	Nucala (mepolizumab), Fasenra (benralizumab), Cinqair (reslizumab), Dupixent (dupilumab), or any newly marketed agents
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	<ul style="list-style-type: none"> When being used for relief of acute bronchospasm or status asthmaticus, or for the treatment of other eosinophilic conditions. When used in combination with another monoclonal antibody for the treatment of asthma
Required Medical Information	See “other criteria”
Age Restrictions	Per Package Insert
Prescriber Restrictions	Prescriber must be an allergist, pulmonologist, immunologist, rheumatologist, other provider who specializes in the treatment of 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. If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	<p><u>Initial Authorization:</u></p> <p><u>Severe Asthma in Patients with Eosinophilic Phenotype:</u></p> <ul style="list-style-type: none"> Confirmed diagnosis of eosinophilic asthma Documentation has been provided (within the last year of the date of the request) of an eosinophil count ≥ 150 cells/mcL for Dupixent and Fasenra, ≥ 150 cells/mcL at screening (within 6 weeks of request) or ≥ 300 cells/mcL within the past 12 months for Nucala, or ≥ 400 cells/mcL for Cinqair requests. 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 ≥ 2 exacerbations in the previous 12 months requiring additional medical treatment for Nucala OR with ≥ 1 exacerbation for Dupixent Fasenra, and Cinqair (emergency room visits, hospital admissions) while compliant on a maximally tolerated inhaled corticosteroid with a long-acting B₂ agonist (ICS/LABA) AND a long-acting muscarinic antagonist (LAMA). If the patient has not utilized these therapies, a documented medical reason must be provided why patient is unable to do so. The prescribed dose is within FDA approved dosing guidelines

Oral Corticosteroid Dependent Asthma: (*Dupixent only*)

- Confirmed diagnosis of oral corticosteroid (OCS) dependent asthma with at least 5 mg oral prednisone or equivalent per day for at least 4 weeks within the last 3 months
- The patient has a documented baseline FEV₁ < 80% of predicted with evidence of reversibility by bronchodilator response.
- Documentation has been provided indicating patient still is having significant symptoms with ≥ 1 exacerbations in the previous 12 months requiring additional medical treatment, (emergency room visits, hospital admissions) while compliant on a high-dose inhaled corticosteroid with a long-acting B₂ agonist. 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 granulomatosis with polyangiitis (EGPA) (*Nucala only*):

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

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

- Confirmed diagnosis of FIP1 like 1-platelet derived growth factor receptor alpha (FIP1L1-PDGFRα)-negative HES lasting for ≥6 months without an identifiable non-hematologic secondary cause
- Member has a history of two or more HES flares (worsening of HES-related symptoms necessitating therapy escalation or ≥2 courses of rescue oral corticosteroids) within the past 12 months
- Member has a blood eosinophil count ≥1,000 cells/mcL
- Documented trial and failure, intolerance, or contraindication to oral corticosteroids AND at least one second-line agent (e.g. hydroxyurea, interferon, imatinib, methotrexate, cyclophosphamide,

<p>Revision/Review Date 10/2021</p>	<p>cyclosporine, azathioprine) (member must be on stable dose of at least one agent for at least 4 weeks prior to request)</p> <p><u>Re-Authorization:</u></p> <ol style="list-style-type: none"> 1. Documentation submitted indicates the member has clinically benefited from the medication (e.g. Asthma: improved FEV₁, reduced exacerbations; HES: symptomatic improvement, reduced oral corticosteroid dose; EGPA: reduction in relapse frequency or severity, disease remission, symptomatic improvement, reduced oral corticosteroid dose) 2. The prescribed dose is within FDA approved dosing guidelines <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>
---	---

Field Name	Field Description
Prior Authorization Group Description	<u>Juxtapid</u>
Drugs	Juxtapid (lomitapide)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the 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	<p>Initial Authorization:</p> <ul style="list-style-type: none"> • Documentation of a diagnosis of homozygous familial hypercholesterolemia (HoFH) via either: <ul style="list-style-type: none"> ○ Genetic confirmation of two mutant alleles at the LDL receptor, ApoB, PCSK9 or ARH adaptor protein gene locus; OR ○ A clinical diagnosis of HoFH which includes: untreated LDL-C >500 mg/dL (>13 mmol/L) or treated LDL-C ≥300 mg/dL (>8 mmol/L), AND <ul style="list-style-type: none"> ▪ Cutaneous or tendon xanthoma before age 10 years, OR ▪ Elevated LDL-C levels consistent with heterozygous FH in both parents. • Patient has tried and failed atorvastatin 40mg-80mg or rosuvastatin 20-40mg (consistently for 3 months via claim history or chart notes). If patient is not able to tolerate atorvastatin or rosuvastatin, documentation was provided that patient is taking another statin at the highest tolerated dose, or a medical reason was provided why the member is not able to use these therapies. • If prescriber indicates member is “statin intolerant”, documentation was provided including description of the side effects, duration of therapy, “wash out”, re-trial, and then change of agents.

<p>Revision/Review Date 2/2021</p>	<ul style="list-style-type: none"> • 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 • 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 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 <p>Reauthorization:</p> <ul style="list-style-type: none"> • Documentation submitted indicates that the member has obtained clinical benefit from the medication including repeat fasting lipid panel lab report, and the member has achieved or maintained a LDL reduction from the levels immediately prior to initiation of treatment with Juxtapid. • The patient’s claim history shows consistent therapy (monthly fills). <p>Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>
--	--

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	<p><u>Depression</u></p> <p>Initial Authorization:</p> <ul style="list-style-type: none"> • 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). <p>Re-authorization:</p> <ul style="list-style-type: none"> • Documentation was submitted indicating the member has clinically benefited from therapy. <p><u>CRPS</u></p> <p>Initial Authorization:</p> <ul style="list-style-type: none"> • Diagnosis of CRPS (may also be termed reflex sympathetic dystrophy, algodystrophy, causalgia, Sudeck atrophy, transient osteoporosis, and acute atrophy of bone) • Patient has tried and failed at least 8 weeks treatment with or continues to receive physical therapy (PT) and/or occupational therapy (OT). • Patient has tried and failed at least two of the following: <ul style="list-style-type: none"> ○ NSAIDs ○ Anticonvulsants (e.g. gabapentin, pregabalin) ○ Antidepressants (e.g. SNRIs, TCAs)

<p>Revision/Review Date 5/2021</p>	<ul style="list-style-type: none"> ○ Bisphosphonate (in the setting of abnormal uptake on bone scan) <p>Re-authorization:</p> <ul style="list-style-type: none"> ● Patient has demonstrated clinical benefit. <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
--	--

Field Name	Field Description
Prior Authorization Group	Kuvan
Drug(s)	sapropterin (Kuvan)
Covered Uses	*Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI) , and the Drug Package Insert).
Exclusion Criteria	None
Required Medical Information	See “Other Criteria”
Age Restrictions	None
Prescriber Restrictions	Specialist experienced in treating PKU
Coverage Duration	<p><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.</p> <p><u>Reauthorization:</u> If the criteria is met, the request will be approved for a duration of 1 month for patients who require a dose increase to 20 mg/kg/day due to non-responsiveness and for all other patients the request will be approved for a duration of 3 months; if the above conditions are not met, the request will be referred to a clinical reviewer/Medical Director for medical necessity review.</p>
Other Criteria	<p>INITIAL AUTHORIZATION:</p> <ul style="list-style-type: none"> • Documentation of a confirmed diagnosis of Phenylketonuria (PKU) • Documentation of the patient’s baseline blood Phe level- (within 30 days of the request) • Documentation consistent with order forms OR receipts (within 30 days of request) that the patient is currently utilizing a Phe-restricted diet • Documentation of the patient’s current weight. • The medication is being prescribed at an FDA approved dosage <p>PA CRITERIA FOR REAUTHORIZATION: <i>Patients that were dosed at 20mg/kg/day and did not have a decrease in Phe level of at least 30% from baseline, are considered NON RESPONDERS and NO ADDITIONAL TREATMENT will be authorized.</i></p> <ul style="list-style-type: none"> • Documentation of the patient’s current weight. • Documentation of at least two separate blood Phe level results after initiation of therapy (within 30 days of request).

Last review: 5/2021	<ul style="list-style-type: none">• The medication is being prescribed at an FDA approved dosage. <p>NOTE: Clinical reviewer/Medical Director must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>
---------------------	--

Long-Acting Opioid Analgesic Criteria

Medications

Brand Names	Generic Names	Available Dosages	Abuse-Deterrent Formulation
Belbuca™	buprenorphine buccal	75, 150, 300, 450, 600, 750, and 900 mcg buccal film	No
Butrans®	buprenorphine transdermal	5, 7.5, 10, 15, 20 mcg/hr patches	No
Duragesic®	fentanyl transdermal	12, 25, 37.5, 50, 62.5, 75, 87.5, 100 mcg/hr patches	No
Hysingla® ER	hydrocodone ER	20, 30, 40, 60, 80, 120 mg tablets	Yes
Zohydro® ER	hydrocodone ER	10, 15, 20, 30, 40, 50 mg capsules	No
Exalgo®	hydromorphone ER	8, 12, 16, 32 mg tablets	No
MS Contin®	morphine sulfate CR	15, 30, 60, 100, 200 mg tablets	No
Arymo ER™	morphine sulfate extended-release	15 mg, 30 mg, and 60 mg tablets	Yes
Kadian®	morphine sulfate ER	10, 20, 30, 40, 50, 60, 80, 100, 200 mg capsules	No
Avinza®	morphine sulfate extended-release (generic available only)	30, 45, 60, 75, 90, 120 mg capsule	No
Morphabond™ ER	morphine sulfate extended-release	15 mg, 30 mg, 60 mg, and 100 mg tablets	Yes

Brand Names	Generic Names	Available Dosages	Abuse-Deterrent Formulation
Embeda®	morphine sulfate ER/naltrexone	20/0.8, 30/1.2, 50/2, 60/2.4, 80/3.2, 100/4 mg capsules	Yes
OxyContin®	oxycodone CR	10, 15, 20, 30, 40, 60, 80 mg tablets	Yes
Xtampza ER™	oxycodone extended-release	9 mg, 13.5 mg, 18 mg, 27 mg, and 36 mg capsules	Yes
Opana® ER	oxymorphone ER	5, 7.5, 10, 15, 20, 30, 40 mg biconcave tablets	No
Nucynta® ER	tapentadol ER	50, 100, 150, 200, 250 mg tablets	No
ConZip®	tramadol ER	100, 150 (generic only), 200, 300 mg capsules	No
Ultram® ER, Ryzolt®	tramadol ER	100, 200, 300 mg tablets	No

Criteria for Approval

Hospice patients and end-of-life patients are exempt from prior authorization.

1. Pain associated with cancer; OR
 2. Pain associated with acute sickle cell disease (quantity limit: 10-day supply); OR
 3. Patient is ≥ 18 years old who requires management of moderate to severe pain with a continuous around-the-clock analgesic for at least 10 days; AND
 4. Failure on two other opioids for pain treatment for which the requested long-acting opioid is indicated; AND
 5. Attestation that the New Hampshire Prescription Drug Monitoring Program (PDMP) has been reviewed within the last 60 days; AND
 6. Confirmation that patient has a written pain agreement; AND
 7. Confirmation that the patient will be prescribed concurrent naloxone.
-

Criteria for Denial

1. Criteria for approval not met; OR
2. Dosage greater than three times a day; OR
3. Concurrent long-acting opioid (two or more); OR
4. High starting dose without a prior history of opiate tolerance.

Length of Approval

Initial: Three months

Renewal: Six months

Non-preferred drugs on the Preferred Drug List (PDL) require additional Prior Authorization (PA).

Dispensing Limits: 34-day supply. In accordance with New Hampshire State Law (RSA 318-B: 9 IV).

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	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; 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> <ul style="list-style-type: none"> • Diagnosis of postherpetic neuralgia AND • Documented trial and failure (maximum tolerated dose) or intolerance to one of the following medications: <ul style="list-style-type: none"> ○ Amitriptyline, Nortriptyline, or Gabapentin AND • If the request is for Ztlido there has been a documented trail and failure or intolerance to lidocaine 5% patch (Lidoderm)
Revision/Review Date 5/2021	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; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	<p>The Patient meets one of the two following criteria:</p> <ul style="list-style-type: none"> • Documented history of treatment with linezolid IV (continuation of therapy, IV to PO conversion). • Documented trial and failure, or intolerance, to 1 preferred antibiotic to which the organism is susceptible. <p>AND</p> <ul style="list-style-type: none"> • Requests for linezolid oral suspension require a documented trial and failure of linezolid oral tablets or a medical reason (e.g. intolerance, hypersensitivity, contraindication) why linezolid oral tablets cannot be used.
Revision/Review Date 5/2021	<p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>

Prior Authorization Group Description	Medications for Management of Obesity
Drugs	Alli, Xenical (orlistat) benzphetamine diethylpropion, diethylpropion ER phendimetrazine, phendimetrazine ER phentermine (Adipex-P) Lomaira (phentermine) Contrave (naltrexone/bupropion) Qsymia (phentermine/topiramate) Saxenda (liraglutide) Wegovy (semaglutide) Imcivree (setmelanotide) Any newly-approved medication indicated for obesity or weight management
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	Age appropriate per labeling
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved for 6 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Requested dose is appropriate per labeling • Documentation of current weight and body mass index (BMI) • BMI must be one of the following: <ul style="list-style-type: none"> ○ BMI of 27 - 29.9 kg/m² with one of the following weight-related comorbidities: coronary artery disease, diabetes, hypertension, dyslipidemia, or obstructive sleep apnea ○ BMI of 30 kg/m² or more • Documentation of failure of comprehensive lifestyle modifications (reduced-calorie diet and increased physical activity) for at least 6 months • Documentation that drug therapy will be administered in conjunction with lifestyle modifications • For Xenical: trial and failure or medical reason for not using Alli • For Lomaira: trial and failure or medical reason for not using generic phentermine • For Qsymia: trial and failure or medical reason for not using all of the following: <ul style="list-style-type: none"> ○ Alli

<p>Revision/Review Date: 10/2021</p>	<ul style="list-style-type: none"> ○ phentermine and topiramate as separate ingredients • For Contrave: trial and failure or medical reason for not using all of the following: <ul style="list-style-type: none"> ○ Alli ○ Qsymia • For Saxenda and Wegovy, documentation of one of the following: Trial and failure of, or medical reason for not using, orlistat and Contrave <ul style="list-style-type: none"> ○ Diagnosis of diabetes and consistent utilization of Victoza or Ozempic over the previous 6 months • For Imcivree, all of the following apply: <ul style="list-style-type: none"> ○ Documentation of obesity related to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency ○ Documentation of genetic testing confirming variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (cases with variants classified as benign or likely benign may not be approved) <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation of at least 5% reduction in body weight compared with baseline AND • If a weight-related comorbidity was previously noted, an objective improvement is documented (e.g. reduction in blood pressure, cholesterol, hemoglobin A1c, etc) <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
--	--

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. If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	<p>Initial Authorization (for members who are new starts to stimulant therapy):</p> <ul style="list-style-type: none"> • 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 <p>AND</p> <p>Criteria for ALL requests including renewal requests:</p> <ul style="list-style-type: none"> • 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. <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date: 5/2021	

Methadone (Pain Management Only) Criteria

Indication

Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Medications

Brand Name	Generic Name	Dosage Strengths
Methadone®, Diskets®, Dolophine®, Westadone®	methadone	Concentrate, oral: 10 mg/ml; Solution, oral: 10 mg/5 ml; 5 mg/ml; Tablet, oral: 5 mg, 10 mg, 40 mg; Tablet for suspension, oral: 40 mg (only for detoxification)

Criteria for Authorization

Hospice, cancer, and end-of-life patients are exempt from prior authorization.

1. Patient is ≥ 18 years of age; AND
2. Patient has a diagnosis of chronic pain; AND
3. Attestation that non-opioid treatment has been maximized or is contraindicated; AND
4. Patient has documented failure on two other opioids with same FDA indication for pain management; AND
5. Attestation that the New Hampshire Prescription Drug Monitoring Program (PDMP) has been reviewed within the last 60 days; AND
6. Attestation that the prescriber has reviewed with the patient the risks associated with continuing high-dose opioids; AND
7. Confirmation that patient has a written pain agreement; AND
8. Attestation that the prescriber has discussed with the patient to attempt to taper the dose slowly at an individualized pace; AND
9. Attestation that the prescriber is monitoring the patient to mitigate overdose risk; AND
10. Confirmation that the patient will be prescribed concurrent naloxone.

Criteria for Denial

1. Failure to meet criteria for authorization; OR

2. History of severe asthma or other lung disease; OR
3. Concurrent long-acting opioid; OR
4. Concurrent benzodiazepine, sedative hypnotics, or barbiturates.

Initial approval period: Six months

Continued approval: Six months, provided there is documentation that patient continues to be assessed for pain control

Dispensing Limits: 150 mg/day

Morphine Milligram Equivalent Criteria

Criteria for Approval

Hospice, cancer, end-of-life patients and sickle cell are exempt from prior authorization.

If ≥ 100 Morphine Milligram Equivalent (MME) requested:

1. Patient is ≥ 18 years of age; AND
2. Patient has a diagnosis of chronic pain; AND
3. Attestation that non-opioid treatment has been maximized or is contraindicated; AND
4. Patient has documented failure or adequate trial of opioid at a lower MME dose; AND
5. Attestation that the New Hampshire Prescription Drug Monitoring Program (PDMP) has been reviewed within the last 60 days; AND
 - a. The prescription is written by a pain specialist; OR
 - b. The prescriber consulted with a pain specialist; OR
 - c. The prescription is written by a prescriber specializing in the same organ system as the primary pain diagnosis; AND
6. Attestation that the prescriber has reviewed with the patient the risks associated with continuing high-dose opioids; AND
7. Confirmation that patient has a written pain agreement; AND
8. Attestation that the prescriber has discussed with the patient to attempt to taper the dose slowly at an individualized pace; AND
9. Attestation that the prescriber is monitoring the patient to mitigate overdose risk; AND
10. Confirmation that the patient will be prescribed concurrent naloxone.

Criteria for Denial

1. Failure to meet criteria for authorization; OR
2. History of severe asthma or other lung disease; OR
3. Concurrent benzodiazepine, sedative hypnotics, or barbiturates.

Initial approval period: Six months

Continued approval: Six months, provided there is documentation that patient continues to be assessed for pain control.

Field Name	Field Description
Prior Authorization Group Description	Mucopolysaccharidosis II (Hunter Syndrome) Agents
Drugs	Elaprase (idursulfase)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	“See Other Criteria”
Age Restrictions	Patient is \geq 16 months of age
Prescriber Restrictions	Prescribed by or in consultation with a specialist in genetics or metabolic disorders
Coverage Duration	Initial Authorization: 6 months Reauthorization: 12 months
Other Criteria	<p>Initial Authorization</p> <ul style="list-style-type: none"> • Diagnosis of Mucopolysaccharidosis II as confirmed by one of the following: <ul style="list-style-type: none"> ○ Enzyme assay demonstrating a deficiency of iduronate 2-sulfatase activity ○ Genetic testing • Patient’s weight • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines <p>Reauthorization</p> <ul style="list-style-type: none"> • Patient has demonstrated a beneficial response (i.e., stabilization or improvement in 6-minute walk test [6-MWT], forced vital capacity [FVC]), urinary glycosaminoglycan (GAG) levels, liver volume, spleen volume, etc.) • Patient’s weight • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 7/2021	

Field Name	Field Description
Prior Authorization Group Description	Mucopolysaccharidosis VI (Maroteaux-Lamy Syndrome) Agents
Drugs	Naglazyme (galsulfase)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	“See Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months Renewal: 12 months
Other Criteria	<p>Initial Authorization</p> <ul style="list-style-type: none"> • Diagnosis of Mucopolysaccharidosis VI as confirmed by one of the following: <ul style="list-style-type: none"> ○ Enzyme assay demonstrating a deficiency in N-acetylgalactosamine 4-sulfatase (arylsulfatase B) enzyme activity ○ DNA testing • Patient’s weight • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines <p>Reauthorization</p> <ul style="list-style-type: none"> • Patient has demonstrated a beneficial response (i.e., stabilization or improvement in 12-minute walk test [12-MWT], 3-minute stair climb test, urinary glycosaminoglycan (GAG) levels, etc.) • Patient’s weight • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines
Revision/Review Date 2/2021	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 (dronedaron)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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; if the criteria are not met, the request will be referred to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria	<ul style="list-style-type: none"> • 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
Revision/Review Date 5/2021	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	Natpara
Drugs	Natpara (parathyroid hormone)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Members with hypoparathyroidism caused by calcium-sensing receptor mutations or in members with acute postsurgical hypoparathyroidism, or those who are at increased risk for osteosarcoma (e.g. Paget's disease or unexplained elevations of alkaline phosphatase, open epiphyses, predisposing hereditary disorders, prior history of external beam or implant radiation therapy involving the skeleton)
Required Medical Information	See "other criteria"
Age Restrictions	Member is 18 years of age or older
Prescriber Restrictions	Prescriber must be an endocrinologist
Coverage Duration	If all of the conditions are met, the initial request will be approved for a 6 month duration, and the reauthorization request will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Documentation has been submitted that the patient has a diagnosis of chronic hypoparathyroidism who cannot maintain stable serum and urinary calcium levels with calcium and vitamin D • Documentation has been submitted (with dates of therapy) that the patient has had an adequate trial with calcium and vitamin D • Documentation has been submitted that the patient will take Natpara in combination with calcium and vitamin D • Patient is NOT currently taking alendronate • Current labs (within 60 days of request) have been submitted for the following: <ul style="list-style-type: none"> ➤ Serum calcium (must be above 7.5mg/dL to start therapy) ➤ Vitamin D level (must be greater than or equal to 20 ng/mL to start therapy). <p><u>Reauthorization:</u></p>

Revision/Review Date 2/2021	<ul style="list-style-type: none">• Documentation has been submitted that the patient will continue to take Natpara in combination with calcium and vitamin D• Prescriber attests member has responded to therapy (e.g., reduction in oral calcium dose, reduction in vitamin D dose, stable total serum calcium levels within normal range) <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
--------------------------------	---

Field Name	Field Description
Prior Authorization Group Description	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. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria	<p><u>Initial Authorization:</u></p> <p><u>For rituximab (Rituxan, Truxima, Riabni, or Ruxience):</u></p> <ul style="list-style-type: none"> • Member has a diagnosis of NMOSD • Documentation indicating that the patient has been screened for HBV (hepatitis B virus) prior to initiation of treatment • Dosing is supported by compendia or standard of care guidelines • If the request is for any medication other than Ruxience (rituximab-pvvr) or Riabni (rituximab-arrrx), there is a documented trial and failure of Ruxience or Riabni, or medical reason why (e.g. intolerance, hypersensitivity, contraindication) they cannot be used <p><u>For Enspryng:</u></p> <ul style="list-style-type: none"> • Member has a diagnosis of anti-aquaporin-4 (AQP4) antibody positive NMOSD • Provider attests to completion of the following assessments prior to the first dose of Enspryng as outlined in the prescribing information: <ul style="list-style-type: none"> ○ Hepatitis B virus screening ○ Tuberculosis screening

	<ul style="list-style-type: none"> ○ 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 or medical contraindication to rituximab (Rituxan, Truxima, Riabni, or Ruxience), azathioprine, or mycophenolate mofetil • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines <p>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</p> <p><u>For Uplizna:</u></p> <ul style="list-style-type: none"> • Member has a diagnosis of anti-aquaporin-4 (AQP4) antibody positive NMOSD • Provider attests to completion of appropriate assessments prior to the first dose of Uplizna as outlined in the prescribing information: <ul style="list-style-type: none"> ○ 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 or medical contraindication to rituximab (Rituxan, Truxima, Riabni, or Ruxience), azathioprine, or mycophenolate mofetil • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines <p>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</p> <p><u>For Soliris:</u></p> <ul style="list-style-type: none"> • Member has a diagnosis of anti-aquaporin-4 (AQP4) antibody positive NMOSD • Documentation of vaccination against meningococcal disease or a documented medical reason why the patient cannot receive vaccination or vaccination needs to be delayed
--	---

Revision/Review Date
10/2021

- 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 or medical contraindication to (one from each bullet below):
 - Rituximab (Rituxan, Truxima, Riabni, or Ruxience), azathioprine, or mycophenolate mofetil
 - Enspryng
 - Uplizna
- Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines

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	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 10mg once daily for up to a 12 month duration for reauthorization; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review. ***If member has moderate or severe hepatic impairment, 5mg once weekly will be approved for initial and 5mg twice weekly or 10mg twice weekly will be approved for reauthorization.***
Other Criteria	<p>Initial Authorization:</p> <ul style="list-style-type: none"> • Diagnosis of primary biliary cholangitis (PBC) with confirmation of diagnosis by the following tests: <ul style="list-style-type: none"> a) Positive antimitochondrial antibody test b) Elevated serum alkaline phosphatase (ALP) level • Ocaliva is being requested in addition to ursodeoxycholic acid (UDCA) due to patient having an inadequate response to UDCA monotherapy for at least 1 year, OR member has a documented medical reason (e.g. contraindication, intolerance, hypersensitivity) why UDCA cannot be used and is taking Ocaliva as monotherapy • If patient has moderate or severe hepatic impairment, requested dose is for 5 mg once weekly • Prescriber attests the patient does not have complete biliary obstruction • Submission of the following test results within 30 days of request: <ul style="list-style-type: none"> a) Serum ALP b) Total bilirubin <p>Reauthorization:</p> <ul style="list-style-type: none"> • Provider attests that the patient has not developed complete biliary obstruction

<p>Revision/Review Date 2/2021</p>	<ul style="list-style-type: none"> • Submission of lab tests confirming each of the following: <ul style="list-style-type: none"> ○ A decrease in ALP of $\geq 15\%$ from baseline ○ ALP is less than 1.67 times the upper limit normal (ULN); defined as 118 U/L for females and 124 U/L for males ○ Total bilirubin \leq ULN defined as 1.1 mg/dL for females and 1.5 mg/dL for males • If patient has moderate or severe hepatic impairment, requested dose is for 5 mg twice weekly or 10 mg twice weekly. <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
--	--

Field Name	Field Description
Prior Authorization Group Description	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). If criterion is not met, the request will be referred to a Clinician for medical necessity review.
Other Criteria	<p><u>Authorization:</u></p> <ol style="list-style-type: none"> 1. One of the following: <ol style="list-style-type: none"> a. Patient has had a documented trial and or intolerance with up to two preferred medications used to treat the documented diagnosis, or for medications where there is only one preferred agent, only that agent must have been ineffective or not tolerated. b. No other formulary medication has a medically accepted use for the patient’s specific diagnosis as referenced in the medical compendia <p>AND</p> 2. One of the following: <ol style="list-style-type: none"> a. Medication is being requested for an accepted 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 <p>AND</p>

Revision/Review Date 5/2021	<p>3. Medication is being requested at an appropriate dose per literature</p> <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
--------------------------------	---

Anti-Fungal Medication for Onychomycosis Criteria

Indications

Brand Names	Generic Names	Treatment
	ciclopirox	As part of a comprehensive management program for the topical treatment in immunocompetent patients with mild to moderate onychomycosis of fingernails and toenails without lunula involvement due to <i>Trichophyton rubrum</i> .
Jublia	efinaconazole	Treatment of onychomycosis of the toenail due to <i>Trichophyton rubrum</i> and <i>Trichophyton mentagrophytes</i> .
Kerydin	tavaborole	Treatment of onychomycosis of the toenail due to <i>Trichophyton rubrum</i> and <i>Trichophyton mentagrophytes</i> .
Luzu	luliconazole	Treatment of interdigital tinea pedis, tinea cruris, and tinea corporis caused by <i>Trichophyton rubrum</i> and <i>Epidermophyton floccosum</i> in patients \geq two years old for Tinea corporis and patients \geq 12 years old for Tinea cruris and Tinea pedis.
Onmel	itraconazole	Treatment of onychomycosis of the toenail caused by <i>Trichophyton rubrum</i> or <i>Trichophyton mentagrophytes</i> .
Oxistat	oxiconazole	Treatment of tinea pedis (can be used for both interdigital and plantar), tinea cruris, tinea corporis, and tinea versicolor (cream only).
Pedipak	ciclopirox/urea	Topical treatment in immunocompetent patients with mild to moderate onychomycosis of fingernails and toenails due to <i>Trichophyton rubrum</i> .
Sporanox	itraconazole	<p>Treatment of the following fungal infections in normal, predisposed, and immunocompromised patients:</p> <ul style="list-style-type: none"> ▪ Cutaneous infections due to tinea corporis, tinea cruris, tinea pedis, and pityriasis versicolor when oral therapy is considered appropriate ▪ Onychomycosis of the toenail and fingernail caused by dermatophytes (tinea unguium) ▪ Invasive and noninvasive pulmonary aspergillosis ▪ Oral and oral/esophageal candidiasis

		<ul style="list-style-type: none"> ▪ Cutaneous and lymphatic sporotrichosis ▪ Paracoccidioidomycosis ▪ Chromomycosis ▪ Blastomycosis
	terbinafine	Treatment of onychomycosis of the toenail and fingernail caused by dermatophytes (tinea unguium) only.

Medications

Brand Names	Generic Names	Dosage Strength	Dosage Form	Administration
Ciclodan	ciclopirox	8%	Topical solution	Fingernails & toenails: once daily application
CNL-8	ciclopirox	8%	Topical solution	Fingernails & toenails: once daily application
Jublia	efinaconazole	10%	Topical solution	Toenails: once daily application for 48 weeks
Kerydin	tavaborole	5%	Topical solution	Toenails: once daily application for 48 weeks
Lamisil	terbinafine	250 mg	Tablet	<ul style="list-style-type: none"> ▪ Fingernail: 250 mg/day for 6 weeks ▪ Toenail: 250 mg/day for 12 weeks
Luzu	Luliconazole	1%	Topical cream	<ul style="list-style-type: none"> ▪ Fingernails: once daily application for 2 weeks ▪ Toenails: once daily application for 1 week
Onmel	itraconazole	200 mg	Tablet	Toenail: 200 mg/day for 12 weeks
Oxistat	oxiconazole	1%	Cream/lotion	
Pedipak	ciclopirox/urea	8%/20%	8% nail lacquer topical solution (co-packaged with 20% urea cream)	<ul style="list-style-type: none"> ▪ Lacquer: once daily for 48 weeks ▪ Cream: twice daily
Pediprox 4 Nail Kit	ciclopirox	8%	Topical solution	
Penlac Nail Lacquer	ciclopirox	8%	Topical solution	

Sporanox	itraconazole	100 mg 100 mg/10mL	Capsule Oral Solution	<ul style="list-style-type: none"> ▪ Fingernails: Pulse therapy; two one-week courses of 200 mg BID x 7 days (28 caps) ▪ Toenails: Pulse therapy; two one-week courses of 200 mg BID x 7 days (28 caps)
Terbinex	terbinafine	250 mg tablet with nail lacquer	Tablet	<ul style="list-style-type: none"> ▪ Fingernail: 250 mg/day for 6 weeks ▪ Toenail: 250 mg/day for 12 weeks

Criteria for Approval

- Prior authorization (PA) will be granted if a patient meets the following conditions:
 - terbinafine, Onmel® (itraconazole), Luzu® (luliconazole), Jublia® (efinaconazole), Kerydin® (tavaborole), Pedipak® (ciclopirox/urea):

 - Onychomycosis confirmed by a positive KOH stain, positive PAS stain, or a positive fungal culture, and experiencing pain that limits normal activity.
 - Sporanox (itraconazole):
 - Approval will be granted for onychomycosis confirmed by a positive KOH stain, positive PAS stain, or a positive fungal culture and any of the following:
 - Patient is experiencing pain which limits normal activity; OR
 - Patient has an iatrogenically-induced or disease-associated immunosuppression; OR
 - Patient has diabetes; OR
 - Patient has significant peripheral vascular compromise.
 - Approval will be granted for treatment of other fungal infections listed in the above indications.
 - Ciclopirox topical solution:
 - Approval will be granted for onychomycosis confirmed by a positive KOH stain, positive PAS stain, or a positive fungal culture and patient is experiencing pain that limits normal activity.
 - Approval will be granted only if the patient has failed an adequate treatment of both oral terbinafine and Sporanox or has a contraindication for use of these agents.
 - Non-preferred drugs on the Preferred Drug List (PDL) require additional prior authorization (PA).
-

Criteria for Denial

1. Prior approval will be denied if the criteria for approval are not met.
2. Prior approval will be denied for cosmetic use.

Length of Approval:

Brand Names	Generic Names	Length of Approval
	ciclopirox	<ul style="list-style-type: none">▪ Initial: 3 months▪ Follow-up: 3 months (up to 1 year)
Jublia	efinaconazole	<ul style="list-style-type: none">▪ Toenail: 48 weeks
Kerydin	tavaborole	<ul style="list-style-type: none">▪ Toenail: 48 weeks
Luzu	luliconazole	<ul style="list-style-type: none">▪ Fingernail: 2 weeks▪ Toenail: 1 week
Onmel	itraconazole	<ul style="list-style-type: none">▪ Toenail: 12 weeks
Pedipak	ciclopirox/urea	<ul style="list-style-type: none">▪ Fingernail/toenail: 48 weeks
Sporanox	itraconazole	<ul style="list-style-type: none">▪ Fingernail: 8 weeks▪ Toenail: 12 weeks
	terbinafine	<ul style="list-style-type: none">▪ Fingernail: 6 weeks▪ Toenail: 12 weeks

Prior Authorization Group Description	Oxbryta (voxelotor)
Drugs	Oxbryta (voxelotor) tablets
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	Member must be 12 years of age or older
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	<p>Initial Authorization:</p> <ul style="list-style-type: none"> • Member has a confirmed diagnosis of sickle cell disease • Baseline labs have been submitted for the following: <ul style="list-style-type: none"> ○ Hemoglobin (Hb) ○ Indirect bilirubin ○ Reticulocytes • 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 between 5.5 and 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) • Request is for an FDA-approved dose <p>Reauthorization:</p> <ul style="list-style-type: none"> • Documentation of ONE of the following: <ul style="list-style-type: none"> ○ Hb increase from baseline (at 6 months from initiation) OR maintenance of such Hb increase (at 12-month intervals thereafter) ○ Documentation of a reduced number of vaso-occlusive/pain crises since Oxbryta was started • Documentation of ONE of the following: <ul style="list-style-type: none"> ○ Decrease in indirect bilirubin from baseline ○ Decrease in percentage of reticulocytes from baseline

Revision/Review Date: 7/2021	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	<p><u>Initial Authorization</u></p> <ul style="list-style-type: none"> • Diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by at least one mutation at the AGXT gene and a urinary oxalate excretion exceeding 0.5 mmol/1.73m² per day • 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 is concurrently using oral potassium citrate, or has a medical reason for not using oral potassium citrate (e.g. impaired renal function) • Prescriber attests that the member has attempted to increase fluid intake • Member has no history of liver or kidney transplant • Medication is prescribed at an FDA approved dose <p><u>Reauthorization</u></p> <ul style="list-style-type: none"> • Members previously using pyridoxine and oral potassium citrate will continue to use these medications, or have a medical reason for not using them • Prescriber attests that the member continues to maintain increased fluid intake
Revision/Review Date 5/2021	

	<ul style="list-style-type: none">• Documentation has been provided that demonstrates a clinical benefit (e.g. symptomatic improvement, reduction in urinary oxalate excretion)• Medication is prescribed at an FDA approved dose <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
--	--

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	<p><u>INITIAL AUTHORIZATION:</u></p> <ul style="list-style-type: none"> • Documentation of a confirmed diagnosis of Phenylketonuria (PKU); AND • Documentation the member’s blood Phe level is greater than 600 micromol/L(include lab results; must be within the past 90 days); AND • Documentation consistent with order forms OR receipts that the member is currently utilizing 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) AND • Member is currently receiving sapropterin (Kuvan) and has had inadequate response to therapy OR has a contraindication to sapropterin therapy OR was a non-responder to sapropterin therapy (defined as members who were dosed at 20mg/kg/day and did not have a decrease in Phe level of at least 30% from baseline) AND • The medication is being prescribed at a dose no greater than the FDA approved maximum initial dose of 20 mg SQ once daily. <p><u>DOSE INCREASES:</u></p> <ul style="list-style-type: none"> • Documentation of recent blood Phe level results (within the past 90 days). • Confirmation Phe control has not been achieved after

<p>Revision/Review Date: 5/2021</p>	<p>adequate timeframe on the current dosing regimen:</p> <ul style="list-style-type: none"> ○ For requests for a dose of 40 mg per day, the patient has been on 20 mg once daily continuously for at least 24 weeks and has not achieved adequate control ○ For requests for a dose of 60 mg per day, the patient has been on 40 mg once daily continuously for at least 16 weeks and has not achieved adequate control <ul style="list-style-type: none"> • • The medication is being prescribed at an FDA approved dose (maximum of 60 mg once daily). <p><u>REAUTHORIZATION:</u></p> <ul style="list-style-type: none"> • Documentation of recent blood Phe level results (within the previous 90 days); AND • The medication is being prescribed at an FDA approved dose; AND • Member has achieved a clinical response of at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration less than or equal to 600 micromol/L. <p><u>NOTE:</u> Members who have not achieved a response (at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration less than or equal to 600 micromol/L) after 16 weeks of continuous treatment with the maximum dosage of 60 mg once daily will be considered NON RESPONDERS and continued treatment will NOT be authorized.</p> <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
---	--

Field Name	Field Description
Prior Authorization Group Description	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	<p><u>Initial Authorization:</u> Palforzia is approved when all of the following criteria are met:</p> <ul style="list-style-type: none"> • Patient has a confirmed diagnosis of peanut allergy • For patients starting initial dose escalation (new to therapy) <ul style="list-style-type: none"> ○ Patient has not had severe or life-threatening anaphylaxis within the previous 60 days • Patient will follow a peanut-avoidant diet • Patient has been prescribed and has acquired (as demonstrated by pharmacy claims or documentation) injectable epinephrine • No history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease • Patient does not have uncontrolled asthma <p><u>Criteria for Re-Authorization:</u> Palforzia is approved for re-authorization when all of the following criteria are met</p> <ul style="list-style-type: none"> • Patient will follow a peanut-avoidant diet • Patient is able to tolerate at least the 3 mg dose daily • Patient is able to comply with the daily dosing requirements • Patient does not have recurrent asthma exacerbations or persistent loss of asthma control • Patient has been prescribed and has acquired (as demonstrated by pharmacy claims or documentation) injectable epinephrine

Revision/Review Date 5/2021	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; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	<p><u>Initial Authorization</u></p> <ul style="list-style-type: none"> • Diagnosis of hyperkalemia • Documentation patient follows a low potassium diet • Where clinically appropriate, documentation of medications known to cause hyperkalemia (e.g. angiotensin-converting enzyme inhibitor, angiotensin II receptor blocker, aldosterone antagonist, NSAIDs) have been discontinued or decreased to lowest effective dose • If the request is for a non-preferred drug, member has a documented treatment failure with a preferred drug or has a documented medical reason (intolerance, hypersensitivity, contraindication, etc.) why they are not able to use a preferred drug
Revision/Review Date 5/2021	<p><u>Re-Authorization</u></p> <ul style="list-style-type: none"> • Documentation that demonstrates member is receiving clinical benefit from treatment (e.g. potassium level returned to normal or significant decrease from baseline). <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>

Field Name	Field Description
Prior Authorization Group Description	Pregabalin
Drugs	Pregabalin (Lyrica) capsule and oral solution & Lyrica CR (pregabalin) extended-release tablets
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	<p><u>Initial Authorization:</u></p> <p><u>Partial-Onset Seizures:</u></p> <ul style="list-style-type: none"> • Documented diagnosis of partial-onset seizures. • Request is for pregabalin capsule or solution <p><u>Postherpetic Neuralgia:</u></p> <ul style="list-style-type: none"> • Documented diagnosis of postherpetic neuralgia. • Documented trial and failure of two formulary alternatives (gabapentin, amitriptyline, nortriptyline) • If the request is for Lyrica CR there is a documented trial and failure of, or intolerance to, generic pregabalin capsule <p><u>Neuropathic Pain Associated with Diabetic Peripheral Neuropathy:</u></p> <ul style="list-style-type: none"> • Documented diagnosis of pain associated with diabetic peripheral neuropathy. • Documented trial and failure of one formulary alternative (i.e. gabapentin, duloxetine) • If the request is for Lyrica CR there is a documented trial and failure of, or intolerance to, generic pregabalin capsule <p><u>Neuropathic Pain Associated with Spinal Cord Injury:</u></p> <ul style="list-style-type: none"> • Documented diagnosis of neuropathic pain associated with spinal cord injury

<p>Revision/Review Date 5/2021</p>	<ul style="list-style-type: none"> • Trial and failure of one formulary alternative (i.e. gabapentin, amitriptyline) • Request is for pregabalin capsule or solution <p><u>Fibromyalgia:</u></p> <ul style="list-style-type: none"> • Documented diagnosis of fibromyalgia. <ul style="list-style-type: none"> ○ Trial and failure of two formulary alternatives (i.e. gabapentin, duloxetine, amitriptyline) • Request is for pregabalin capsule or solution <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
--	--

Field Name	Field Description
Prior Authorization Group Description	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	<p>*Gamifant will only be approved for members who have not yet received HSCT and will be discontinued at the initiation of HSCT*</p> <p>Initial Authorization</p> <ul style="list-style-type: none"> • Member has a diagnosis of Primary HLH • Member does NOT have a diagnosis of Secondary HLH due to a proven rheumatic or neoplastic disease or an infection • Prescriber attests that member has not achieved a satisfactory response to or is intolerant to conventional HLH therapy (e.g. etoposide, dexamethasone) or has recurrent disease • Prescriber attests that the member is a candidate for hematopoietic stem cell transplant (HSCT) • Member has been screened for latent tuberculosis infection • Member has or will receive prophylactic pre-medications (e.g. antivirals, antibiotics, antifungals) for Herpes Zoster, <i>Pneumocystis jirovecii</i>, and other fungal infections • Dosing is consistent with FDA approved labeling <p>Reauthorization</p> <ul style="list-style-type: none"> • Member continues to meet initial authorization criteria • Member is receiving prophylactic pre-medications (e.g. antivirals, antibiotics, antifungals) for Herpes Zoster, <i>Pneumocystis jirovecii</i>, and other fungal infections • HSCT has not yet been initiated for member

Revision/Review Date 5/2021	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) Inhibitors
Drugs	<u>Preferred:</u> Repatha (evolocumab) <u>Non-preferred:</u> Praluent (alirocumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the 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 cardiologist or specialist in treatment of lipid disorders
Coverage Duration	If the criteria are met, the initial request will be approved for up to a 3 month duration, and the reauthorization request will be approved for up to a 12 month duration; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	<p><u>Initial Authorization</u></p> <p><u>Diagnosis of Familial Hypercholesterolemia (FH):</u></p> <ul style="list-style-type: none"> • Member has a diagnosis of familial hypercholesterolemia as evidenced by documentation provided including two fasting lipid panel lab reports with abnormal low density lipoprotein (LDL) levels ≥ 190 for Familial Hypercholesterolemia (FH) in adults or ≥ 160 for FH in children. • 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. • 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. • Documentation was provided indicating provider has counseled member on smoking cessation and following a “heart healthy diet”.

- If the request is for Praluent, documentation was provided of trial and failure, or a medical reason has been provided, why member is unable to use Repatha to manage their condition.

Diagnosis of Primary Hyperlipidemia OR Secondary Hyperlipidemia with Atherosclerotic Cardiovascular Disease:

- Request is appropriate for member (e.g. age) as indicated in package labeling or standard of care guidelines
- Documentation was provided that one of the following applies:
 - 1) Member has atherosclerotic cardiovascular disease (ASCVD)
 - 2) Member has elevations of LDL-C >190 mg/dL
 - 3) Member has diabetes and is age 40-75 years old
 - 4) Member does not have diabetes, is age 40-75 years old, and has a 10 year ASCVD risk of 7.5% or greater
- 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.
- 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.
- Documentation was provided indicating provider has counseled member on smoking cessation and following a “heart healthy diet”.
- One of the following applies:
 - Documentation was provided including two fasting lipid panel lab reports within the last 12 months with abnormal LDL levels at or above 70 mg/dL or non-HDL cholesterol (total cholesterol minus HDL) remains at or above 100 mg/dL despite maximally tolerated statin and ezetimibe AND additional documentation for one of the following:
 - Patient has a history of a recent acute coronary syndrome (within the past 12 months)
 - Patient has a history of stable or unstable coronary artery disease
 - Patient has a history of ischemic stroke or transient ischemic attack
 - Patient has a history of peripheral arterial disease
 - Documentation was provided including two fasting lipid panel

<p>Revision/Review Date 2/2021</p>	<p>lab reports within the last 12 months with abnormal low density lipoprotein (LDL) levels at or above 100 mg/dL despite maximally tolerated statin and ezetimibe AND additional documentation for one of the following:</p> <ul style="list-style-type: none"> ▪ Age \geq 65 years ▪ Diabetes ▪ Chronic kidney disease stages 3, 4, and 5 ▪ Hypertension ▪ Recurrent atherosclerotic CVD event or need for revascularization while on a statin ▪ Polyvascular disease ▪ Congestive heart failure <ul style="list-style-type: none"> ● If the request is for Praluent, documentation was provided of trial and failure, or a medical reason has been provided, why member is unable to use Repatha to manage their condition. <p><u>Reauthorization for all indications:</u></p> <ul style="list-style-type: none"> ● Documentation submitted indicates that the member has obtained clinical benefit from the medication including repeat fasting lipid panel lab report, and the member has had at least a 50% reduction in LDL OR a maintained reduction of 50% decrease of LDL from baseline prior to treatment. ● The patient's claim history shows consistent therapy (i.e. monthly fills) <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
--	---

Field Name	Field Description
Prior Authorization Group Description	Retinoids (Dermatologic)
Drugs	<p><u>FORMULARY STATUS</u> Requires Prior Authorization, Generically Available Agents Preferred:</p> <ul style="list-style-type: none"> • Claravis (isotretinoin) • Myorisan (isotretinoin) • Zenatane (isotretinoin) • Amnesteem (isotretinoin) • Isotretinoin <p><u>FORMULARY STATUS</u> Requires Prior Authorization, Non-Preferred:</p> <ul style="list-style-type: none"> • Absorica (isotretinoin) • Absorica LD (isotretinoin) • Or any newly marketed oral retinoid product
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 6 month duration; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	<p><u>Initial Authorization</u></p> <ul style="list-style-type: none"> • Diagnosis of moderate to severe recalcitrant nodular acne AND • Documented treatment with a therapeutic trial and failure or intolerance to one or more first line topical therapies (e.g. topical antibiotics or topical retinoids) IN COMBINATION WITH one or more first line oral therapies (e.g. doxycycline, tetracycline, or minocycline) for at least 4 weeks (28 days) of therapy of each drug in the previous 180 days. • If the request is for a non-preferred drug, documentation has been provided that the member has tried and failed two preferred drugs or has a medical reason why these drugs cannot be used

Revision/Review Date 10/2021	<p><u>Re-Authorization</u></p> <ul style="list-style-type: none">• Prescriber attests the member has experienced clinical benefit from therapy (e.g. perceived improvement of acne) and continued treatment with, or retreatment with, isotretinoin is necessary <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
---------------------------------	---

Field Name	Field Description
Prior Authorization Group Description	Rho-associated, coiled-coil containing protein kinase (ROCK) inhibitors for chronic graft versus host disease
Drugs	Rezurock (belumosudil)
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	≥ 12 years
Prescriber Restrictions	Prescriber must be a hematologist, oncologist, or other specialist in the treatment of hematopoietic cell transplants
Coverage Duration	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. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Member has a diagnosis of chronic graft versus-host disease • Member has tried and failed at least two lines of systemic immunosuppressive therapy (e.g. corticosteroids, calcineurin inhibitors, mycophenolate mofetil, ibrutinib, ruxolitinib), one of which must be a systemic corticosteroid, or documentation is provided as to why a systemic corticosteroid cannot be used • The drug is prescribed at an FDA-approved dose <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation is provided that the member has achieved a clinical benefit from medication (e.g. symptom improvement, reduction in corticosteroid dose) • The drug is prescribed at an FDA-approved dose
Revision/Review Date: 10/2021	<p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>

Rho Kinase Inhibitor Criteria

Medications

Brand Names	Generic Names	Dosage
Rhopressa™	netarsudil	0.02% (0.2 mg/mL) 2.5 mL vial
Rocklatan™	netarsudil/latanoprost	0.02%/0.005% 2.5ml vial

Indication

Rhopressa™ (netarsudil) is indicated to reduce intraocular pressure (IOP) in patients with ocular hypertension (OHT) or open-angle glaucoma (OAG).

Rocklatan™ (netarsudil/latanoprost) is indicated to indicated for the reduction of elevated IOP in patients with open-angle glaucoma or ocular hypertension.

Criteria for Approval

1. Patient must be ≥ 18 years old; AND
2. Have a diagnosis of ocular hypertension or open-angle glaucoma; AND
3. Have had an adequate trial and failure of a prostaglandin inhibitor or beta-adrenergic antagonist AND
4. Is to be used in conjunction with another medication for glaucoma (Rhopressa™ only); AND
5. Patient must NOT have had:
 - a. Previous glaucoma intraocular surgery or glaucoma laser procedure in the affected eye; OR
 - b. Ocular surgery or laser treatment within three months prior to initiation; AND
6. Not currently have:
 - a. Ocular infection; OR
 - b. Inflammation; OR
 - c. Blepharitis; OR
 - d. Conjunctivitis; OR
 - e. Ocular Disease.

Approval period: One year

Renewal Criteria:

1. Patient must continue to meet above criteria; AND
2. Have demonstrated efficacy (e.g., reduction in IOP).

Renewal approval period: One year

Criteria for Denial

Failure to meet criteria for approval.

Rituximab

Drugs:

Rituxan (rituximab)

Rituxan Hycela (rituximab/hyaluronidase human, recombinant)

Truxima (rituximab-abbs)

Ruxience (rituximab-pvvr)

Riabni (rituximab-arrx)

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

NEUROMYELITIS OPTICA SPECTRUM DISORDER (NMOSD):

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

RHEUMATOID ARTHRITIS:

Initial Authorization

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

documented trial and failure of Truxima (rituximab-abbs), or medical reason why (e.g. intolerance, hypersensitivity, contraindication) Truxima (rituximab-abbs) cannot be used.

If all of the above conditions are met, the request will be approved for up to a 1 month duration; 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.
- 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 PCP 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 PCP prophylaxis
- Rituximab is being prescribed at an FDA approved dose/frequency

If all of the above conditions are met, the request will be approved for up to a 1 year duration; if all 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 the 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) there is a documented trial and failure of Ruxience (rituximab-pvvr), or medical reason why (e.g. intolerance, hypersensitivity, contraindication) Ruxience (rituximab-pvvr) cannot be used.
- If the request is for Rituxan Hycela (rituximab/hyaluronidase human, recombinant), 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) or MPA.
- 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 glucocorticoid AND cyclophosphamide (Cytoxan) documentation includes a medical reason (intolerance, hypersensitivity, etc.) why patient is not able to use these therapies to manage their medical condition.
- 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) 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:

- 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
- Rituxan is being prescribed at an FDA approved dose.

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

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.
- Exclusion Criteria: Diagnosis of Dermatomyositis, polymyositis, dermatopolymyositis
- The medication is prescribed at a medically accepted dose per the medical compendia as defined above.
- The medication is recommended and prescribed a specialist in the field to treat the member's respective medical condition.
- Documentation indicating that the patient has been screened for HBV prior to initiation of treatment.
- Documentation was submitted indicating that the member has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trial (including dates, doses of medications) of ALL first

line medical therapies as recommended by the medical compendia and standard care guidelines and/or has another documented medical reason (e.g. intolerance, contraindications, etc.) for not receiving or trying all first line medical treatment(s).

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

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

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

Re-authorization:

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

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

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

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

Revision/Review Date: 7/2021

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; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	<p><u>Initial Authorization:</u></p> <p><u>Motion Sickness and Post-Operative Nausea and Vomiting:</u></p> <ul style="list-style-type: none"> • Diagnosis of nausea and vomiting associated with motion sickness or nausea and vomiting associated with recovery from anesthesia and/or opiate analgesia and surgery. <p>AND</p> <ul style="list-style-type: none"> • Documented trial and failure at therapeutic doses of, intolerance to, or contraindication to two of the following: meclizine, diphenhydramine and dimenhydrinate. <p><u>Sialorrhea</u></p> <ul style="list-style-type: none"> • Documented trial and failure at therapeutic doses, intolerance or contraindication to glycopyrrolate.
Revision/Review Date: 7/2021	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	<p>Formulary status: Preferred, Prior Authorization Required</p> <ul style="list-style-type: none"> • modafinil (Provigil) tablets • armodafinil (Nuvigil) tablets <p>Formulary status: Non-preferred, Prior Authorization Required</p> <ul style="list-style-type: none"> • Sunosi (solriamfetol) tablets • Wakix (pitolisant) tablets • Xyrem (sodium oxybate) solution • Xywav (calcium, magnesium, potassium, and sodium oxybates)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	See “Other Criteria”
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 Xyrem and Xywav will be approved with up to a 3 month duration. If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	<p><u>For all requests:</u></p> <ul style="list-style-type: none"> • Appropriate diagnosis/indication for requested medication • Medication is being prescribed at an FDA approved dose <p><u>Modafinil/armodafinil initial authorization:</u></p> <ul style="list-style-type: none"> • For a diagnosis of obstructive sleep apnea (OSA) documentation that the member has been compliant with or is unable to use positive airway pressure [continuous positive airway pressure (CPAP), bilevel positive airway pressure (BPAP), or automatic positive airway pressure (APAP)]. <p><u>Sunosi initial authorization</u></p> <ul style="list-style-type: none"> • Documented trial and failure of modafinil or armodafinil or a documented medical reason for not utilizing these medications. • For members with OSA: <ul style="list-style-type: none"> ○ Documentation that the member has been compliant with or is unable to use positive airway pressure (CPAP, BPAP, or APAP) <p><u>Wakix initial authorization:</u></p>

<p>Revision/Review Date 10/2021</p>	<ul style="list-style-type: none"> • For a diagnosis of narcolepsy without cataplexy: documented trial and failure of (or medical reason for not using), each of the following: <ul style="list-style-type: none"> ○ Either modafinil or armodafinil <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> ○ Sunosi (solriamfetol) • For a diagnosis of narcolepsy with cataplexy: documented trial and failure of, or medical reason for not using, the following: <ul style="list-style-type: none"> ○ Dextroamphetamine <p><u>Xyrem/Xywav initial authorization</u></p> <ul style="list-style-type: none"> • Medication is not being taken concurrently with sedative hypnotics • If member has a history of substance abuse, documentation has been provided that prescriber has referred the member for substance abuse disorder treatment. • For a diagnosis of narcolepsy without cataplexy: <ul style="list-style-type: none"> ○ Documented trial and failure of, or a medical reason for not using, each of the following: <ul style="list-style-type: none"> ▪ Either modafinil or armodafinil <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> ▪ Sunosi (solriamfetol) <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> ▪ Wakix (pitolisant) • For a diagnosis of narcolepsy with cataplexy: <ul style="list-style-type: none"> ○ Documented trial and failure of each of, or medical reason for not using each of the following: <ul style="list-style-type: none"> ▪ Dextroamphetamine <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> ▪ Wakix (pitolisant) • For a diagnosis of idiopathic hypersomnia (Xywav only): <ul style="list-style-type: none"> ○ Patient has a documented trial and failure of, or medical contraindication to, the following: <ul style="list-style-type: none"> ▪ modafinil or armodafinil <p><u>Reauthorization:</u></p> <ul style="list-style-type: none"> • Documentation has been submitted indicating member has experienced a clinical benefit from treatment (e.g. improvement on Epworth Sleepiness Score) • For members with cataplexy: Documentation has been provided that there has been a reduction in frequency of cataplexy attacks. <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary</p>
---	--

Field Name	Field Description
Prior Authorization Group Description	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	Patient has previously received treatment with Zolgensma
Required Medical Information	For Evrysdi: Patient's body weight
Age Restrictions	For Evrysdi: 2 months of age and older For Spinraza: N/A
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	<p>For Evrysdi: If all of the conditions are met, the request will be approved for 6 months for initial approval, followed by 12 months for reauthorization requests.</p> <p>For Spinraza: If all of the conditions are met, the request will be approved for 6 months for 5 doses (4 loading doses and 1st maintenance dose) for initial approval, and 12 months for 3 additional maintenance doses for reauthorization requests.</p> <p>If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.</p>
Other Criteria	<p><u>Initial approval</u></p> <ul style="list-style-type: none"> • Member has a confirmed diagnosis of SMA types I, II or III and the molecular genetic test with mutation analysis was submitted that is positive for the genetic deletion of the exon 7 of the survival motor neuron (SMN1) • 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 • 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

<p>Revision/Review Date 10/2021</p>	<p>(HFMSE) for Type II and Type III, or 6 minute walk test in subjects able to walk]</p> <ul style="list-style-type: none"> • The request is for an FDA approved dose • Patient has not previously received treatment with Zolgensma <p><u>Reauthorization</u></p> <ul style="list-style-type: none"> • Documentation of clinical response was submitted with request (e.g. improvement in motor function/motor milestone achievement scores using CHOP-INTEND or HFMSE, 6 minute walk test or HINE improvement in more categories of motor milestones than worsening, patient remains permanent ventilation free if no prior ventilator support) • The request is for an FDA approved dose <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
---	--

Field Name	Field Description
Prior Authorization Group Description	Somatostatin Analogs
Drugs	Lanreotide (Somatuline Depot) Octreotide (Sandostatin, Sandostatin LAR, Bynfezia, Mycapssa) Pasireotide (Signifor, Signifor LAR)
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. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria	<p><u>Initial Authorization</u></p> <p><u>For all FDA approved indications (including FDA-approved oncology related uses)</u></p> <ul style="list-style-type: none"> Medication requested is for an FDA approved indication and dose If the provider is requesting therapy with more than one somatostatin analog, 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. Additionally for Bynfezia: <ul style="list-style-type: none"> Clinical justification is provided as to why patient cannot use immediate-release octreotide <p><u>For Acromegaly</u></p> <ul style="list-style-type: none"> Patient must have had inadequate response to, or medical contraindication to one of the following: <ul style="list-style-type: none"> surgical treatment radiation therapy trial of a dopamine agonist (ex. bromocriptine mesylate, cabergoline) at a therapeutically appropriate dose

<p>Revision/Review Date 05/2021</p>	<ul style="list-style-type: none"> • Additionally for Mycapssa: <ul style="list-style-type: none"> ○ Patient has showed clinical response to and tolerates treatment with octreotide or lanreotide therapy ○ Clinical justification is provided as to why patient cannot continue use of injectable somatostatin analog therapy • Additionally for Bynfezia: <ul style="list-style-type: none"> ○ Clinical justification is provided as to why patient cannot use immediate-release octreotide <p><u>For Cushing's Disease (pasireotide products only)</u></p> <ul style="list-style-type: none"> • Patient must have had inadequate response or medical contraindication to surgical treatment <p><u>Reauthorization</u></p> <ul style="list-style-type: none"> • Medication requested is for an FDA approved indication and dose • Documentation has been provided that demonstrates a clinical benefit (e.g. improvement in laboratory values, improvement or stabilization of clinical signs/symptoms, etc.) <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
---	---

Field Name	Field Description
Prior Authorization Group Description	Sublingual Allergenic Extracts
Drugs	Grastek (timothy grass pollen allergen extract) Odactra (house dust mite allergen extract) Oralair (sweet vernal/orchard/rye/timothy/Kentucky blue grass mixed pollen allergenic extract) Ragwitek (Short ragweed pollen allergenic extract)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to Package Insert
Prescriber Restrictions	Prescriber is an allergist or immunologist
Coverage Duration	If all of the conditions are met, the request will be approved for a 12 month duration.
Other Criteria	<p><u>Initial authorization:</u></p> <p><u>For all requests:</u></p> <ul style="list-style-type: none"> • Requested allergenic extract is being used to treat allergic rhinitis • Member has had a documented trial and failure of, or intolerance to, an intranasal corticosteroid (e.g. fluticasone) used in combination with at least one of the following: <ul style="list-style-type: none"> ○ Oral antihistamine (e.g. cetirizine) ○ Intranasal antihistamine (e.g. azelastine) ○ Oral leukotriene receptor antagonist (montelukast) • Patient has been prescribed (as demonstrated by pharmacy claims or documentation) injectable epinephrine <p><u>Grastek:</u></p> <ul style="list-style-type: none"> • Diagnosis has been confirmed by positive skin or in vitro testing to Timothy Grass, or cross reactive, pollen <p><u>Odactra:</u></p> <ul style="list-style-type: none"> • Diagnosis has been confirmed by either positive skin test to house dust mite allergen extract OR positive in vitro testing for IgE antibodies to <i>Dermatophagoides farinae</i> or <i>Dermatophagoides pteronyssinus</i>

<p>Revision/Review Date 10/2021</p>	<p><u>Oralair:</u></p> <ul style="list-style-type: none"> • Diagnosis has been confirmed by positive skin, or in vitro, testing to Sweet Vernal, Orchard, Rye, Timothy, Kentucky Blue Grass, or cross reactive, pollen <p><u>Ragwitek:</u></p> <ul style="list-style-type: none"> • Diagnosis has been confirmed by positive skin, or in vitro, testing to Short Ragweed pollen <p><u>Reauthorization:</u></p> <p><u>For all requests:</u></p> <ul style="list-style-type: none"> • Member has experienced a reduction in symptoms associated with allergic rhinitis <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
---	--

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 8 doses may be approved within the Respiratory Syncytial Virus (RSV) season
Other Criteria	<p><u>Infants less than 1 year of age at the onset of the respiratory syncytial virus (RSV) season (which typically starts November 1st, but may vary seasonally) AND have one of the following indications:</u></p> <ul style="list-style-type: none"> • Born at less than 29 weeks, 0 days gestation • Born at less than 32 weeks, 0 days gestation AND had chronic lung disease of prematurity defined as greater than 21% oxygen for at least 28 days after birth • Born at any gestational age with hemodynamically significant heart disease including: <ul style="list-style-type: none"> ○ Cyanotic heart disease in consultation with a pediatric cardiologist ○ Acyanotic Heart disease with one of the following: <ul style="list-style-type: none"> ▪ On heart failure medication and expected to require cardiac surgical procedure ▪ Moderate to severe pulmonary hypertension • Cystic fibrosis with clinical evidence of chronic lung disease (CLD) and/or nutritional compromise in the first year of life • Born at any gestational age with pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the lower airway <p><u>Infants less than 2 years of age at the onset of the RSV season (which typically starts November 1st, but may vary seasonally) AND have one of the following indications:</u></p> <ul style="list-style-type: none"> • Born at less than 32 weeks, 0 days AND had a diagnosis of chronic lung disease of prematurity at birth as defined above AND had continued need for one of the following respiratory interventions in the 6 months preceding RSV season: Chronic steroids, chronic diuretics, supplemental oxygen

<p>Revision/Review Date: 1/2022</p>	<ul style="list-style-type: none"> • Cystic fibrosis with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) or weight for length less than the 10th percentile • Born at any gestational age and will be profoundly immunocompromised during the RSV season, including: <ul style="list-style-type: none"> ○ Solid organ or hematopoietic stem cell transplant recipient ○ Chemotherapy recipient • Born at any gestational age and receiving a cardiac transplant <p>Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
---	---

Systemic Immunomodulator Criteria

Medications

Brand Names	Generic Names	Dosage Strength	Dosage Form
Actemra	tocilizumab	80 mg/4 mL, 200 mg/10 mL, 400 mg/20 mL	single-use vial, prefilled syringe
Arava	leflunomide	10 mg, 20 mg, 100 mg	capsules
Arcalyst	rilonacept	220 mg	single-use vial
Cimzia	certolizumab	200 mg	powder for SC injection, syringe kits, starter kits
Cosentyx	secukinumab	150 mg/mL, 150 mg, 75 mg/0.5 mL	single-use Sensoready® pen, single-use prefilled syringe, Single-use vial (HCP admin only)
Enbrel/Mini	etanercept	25mg, 50 mg/mL; Mini 50 mg/mL	SC prefilled syringe, autoinjector, multiuse vials
Entyvio	vedolizumab	300 mg/20 mL	single-use vial
Humira	adalimumab	10 mg/0.2 mL, 20 mg/0.4 mL, 40 mg/0.8 mL	SC syringe, single-use pens, starter packages
Ilaris	canakinumab	180 mg reconstituted to 150 mg/mL	single-use vial
Ilumya	tildrakizumab-asmn	100 mg/1 mL	subcutaneous solution
Inflectra (biosimilar to Remicade)	infliximab-dyyb	100 mg/20 mL	intravenous infusion single-dose vial
Kevzara	sarilumab	150 mg/1.14 mL, 200 mg/1.14 mL	single-dose pre-filled syringe
Kineret	anakinra	100 mg/0.67 mL	SC prefilled syringe
Orencia	abatacept	250 mg	powder for injection, single-dose vial, prefilled syringe, prefilled autoinjector
Olumiant	baricitinib	2 mg	tablet
Otezla	apremilast	30 mg, two starter packs	tablet
Remicade	infliximab	100 mg/20 mL	single-use vial

Renflexis (biosimilar to Remicade)	infliximab-abda	100 mg/20 mL	intravenous infusion single-dose vial
Siliq	brodalumab	210 mg/1.5 mL	single-dose pre-filled syringe
Simponi/ Simponi Aria	golimumab	50 mg/0.5 mL, 50 mg/4 mL	single-dose prefilled syringe, SmartJect autoinjector, IV solution
Skyrizi	risankizumab-rzaa	75 mg/0.83 mL, 150 mg/mL	Subcutaneous solution
Stelara	ustekinumab	45 mg/0.5 mL, 90 mg/1 mL	single-use vial, prefilled syringe
Taltz	ixekizumab	80 mg/mL	prefilled syringe, prefilled auto-injector
Tremfya	guselkumab	100 mg/mL	single-dose prefilled syringe single-dose One-Press patient-controlled injector
Xeljanz/XR	tofacitinib	5 mg tablet, 11 mg tablet (XR)	tablet, ER tablet

Indications

Brand Names	Generic Names	Indications
Actemra	tocilizumab	<ul style="list-style-type: none"> ✦ Reduction in signs and symptoms of active Rheumatoid Arthritis (RA) in adult patients ✦ Juvenile Idiopathic Arthritis (JIA) in patients ≥2 years old (previously listed as Juvenile Rheumatoid Arthritis [JRA]) ✦ Systemic onset juvenile chronic arthritis in patients ≥2 years old
Arava	leflunomide	<ul style="list-style-type: none"> ✦ Reduction in signs and symptoms of active RA in adult patients
Arcalyst	rilonacept	<ul style="list-style-type: none"> ✦ Cryopyrin-Associated Periodic Syndromes (CAPS) in patients ≥12 years old
Cimzia	certolizumab	<ul style="list-style-type: none"> ✦ Ankylosing spondylitis in patients ≥18 years old ✦ Moderately to severely active Crohn's Disease in adult patients ✦ Moderately to severely active RA in combination with methotrexate in patients ≥18 years old ✦ Psoriatic arthritis in patients ≥18 years old ✦ Moderate to severe plaque psoriasis in patients ≥18 years old ✦ Non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation in patients ≥18 years old
Cosentyx	secukinumab	<ul style="list-style-type: none"> ✦ Moderate to severe plaque psoriasis in patients ≥18 years old ✦ Ankylosing spondylitis in patients ≥18 years old ✦ Psoriatic arthritis in patients ≥18 years old
Enbrel/Mini	etanercept	<ul style="list-style-type: none"> ✦ Moderately to severely active RA in patients ≥18 years old ✦ Moderate to severe JIA in patients ≥2 years old (previously listed as JRA) ✦ Psoriatic arthritis in patients ≥18 years old

		<ul style="list-style-type: none"> ✦ Ankylosing spondylitis in patients ≥18 years old ✦ Moderate to severe chronic plaque psoriasis in patients ≥4 years old
Entyvio	vedolizumab	<ul style="list-style-type: none"> ✦ Moderately to severely active Crohn's disease in adult patients
Humira	adalimumab	<ul style="list-style-type: none"> ✦ Reduction in signs and symptoms of active RA in adult patients ✦ Moderate to severe chronic plaque psoriasis in patients ≥18 years old ✦ JIA in patients ≥2 years old (previously listed as JRA) ✦ Psoriatic arthritis in patients ≥18 years old ✦ Ankylosing spondylitis in patients ≥18 years old ✦ Moderately to severely active Crohn's disease in patients ≥6 years old ✦ Moderately to severely active ulcerative colitis in patients ≥18 years old ✦ Hidradenitis Suppurativa in patients ≥12 years old ✦ Uveitis in patients ≥2 years old
Ilaris	canakinumab	<ul style="list-style-type: none"> ✦ JIA in patients ≥2 years old (previously listed as JRA) ✦ CAPS in patients ≥4 years old, including: <ul style="list-style-type: none"> – Familial Cold Autoinflammatory Syndrome (FCAS) – Muckle-Wells Syndrome (MWS) – Tumor Necrosis Factor Receptor-Associated Periodic Syndrome (TRAPS) in adult and pediatric patients – Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) in adult and pediatric patients – Familial Mediterranean Fever (FMF) in adult and pediatric patients
Ilumya	tildrakizumab-asmn	<ul style="list-style-type: none"> ✦ Moderate to severe plaque psoriasis in patients ≥18 years old
Inflectra (biosimilar to Remicade)	infliximab-dyyb	<ul style="list-style-type: none"> ✦ Ankylosing spondylitis in patients ≥18 years old ✦ Fistulizing Crohn's disease in patients ≥18 years old ✦ Moderately to severely Crohn's disease in patients ≥6 years old ✦ Chronic severe Plaque psoriasis in patients ≥18 years old ✦ PsA in patients ≥18 years old ✦ Moderately to severely RA in patients ≥18 years old in combination with methotrexate ✦ Moderately to severely ulcerative colitis in patients ≥6 years old
Kevzara	sarilumab	<ul style="list-style-type: none"> ✦ Moderately to severely active RA with or without methotrexate in adults who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs)
Kineret	anakinra	<ul style="list-style-type: none"> ✦ Moderately to severely active RA in patients ≥18 years old ✦ Chronic infantile neurological, cutaneous, and articular syndrome
Orencia	abatacept	<ul style="list-style-type: none"> ✦ Moderately to severely active RA in patients ≥18 years old ✦ JIA in patients ≥2 years old (previously listed as JRA) ✦ Adult Psoriatic Arthritis (PsA)
Olumiant	baricitinib	<ul style="list-style-type: none"> ✦ Moderately to severely active RA in patients ≥18 years old
Otezla	apremilast	<ul style="list-style-type: none"> ✦ PsA in patients ≥18 years old ✦ Plaque psoriasis in patients ≥18 years old ✦ Oral ulcers associated with Behçet's disease in patients ≥18 years old

Remicade	infliximab	<ul style="list-style-type: none"> ✦ Moderately to severely active RA in patients ≥ 18 years old in combination with methotrexate ✦ PsA in patients ≥ 18 years old ✦ Ankylosing spondylitis in patients ≥18 years old ✦ Chronic severe plaque psoriasis in patients ≥18 years old ✦ Moderately to severely active Crohn's disease in patients ≥6 years old ✦ Fistulizing Crohn's disease in patients ≥18 years old ✦ Moderately to severely active ulcerative colitis in patients ≥6 years old
Renflexis (biosimilar to Remicade)	infliximab-abda	<ul style="list-style-type: none"> ✦ Ankylosing spondylitis in patients ≥18 years old ✦ Fistulizing Crohn's disease in patients ≥18 years old ✦ Moderately to severely Crohn's disease in patients ≥6 years old ✦ Chronic severe plaque psoriasis in patients ≥18 years old ✦ PsA in patients ≥18 years old ✦ Moderately to severely RA in patients ≥18 years old in combination with methotrexate ✦ Moderately to severely ulcerative colitis in patients ≥6 years old
Siliq	brodalumab	<ul style="list-style-type: none"> ✦ Moderate to severe plaque psoriasis in adult patients
Simponi/ Simponi Aria	golimumab	<ul style="list-style-type: none"> ✦ Moderately to severely active RA in adults, in combination with methotrexate ✦ Active PsA in adults, alone or in combination with methotrexate ✦ Active Ankylosing Spondylitis (AS) in adults ✦ Moderately to severely active ulcerative colitis in patients ≥18 years old
Skyrizi	risankizumab-rzaa	<ul style="list-style-type: none"> ✦ Moderate to severe plaque psoriasis in patients ≥18 years old
Stelara	ustekinumab	<ul style="list-style-type: none"> ✦ Moderate to severe plaque psoriasis in patients ≥12 years old ✦ Psoriatic arthritis in patients ≥18 years old ✦ Moderately to severely active Crohn's disease in patients ≥18 years old who have: <ul style="list-style-type: none"> – Failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker; or – Failed or were intolerant to treatment with one or more TNF blockers
Taltz	ixekizumab	<ul style="list-style-type: none"> ✦ Moderate to severe plaque psoriasis in patients ≥18 years old
Tremfya	Guselkumab	<ul style="list-style-type: none"> ✦ Moderate to severe plaque psoriasis in patients ≥18 years old
Xeljanz/XR	tofacitinib	<ul style="list-style-type: none"> ✦ Moderately to severely active RA in adults alone or in combination with methotrexate or other DMARDS ✦ Psoriatic arthritis in patients ≥18 years old ✦ Moderate to severe ulcerative colitis in patients ≥18 years old

Criteria for Approval

Prior authorization will only be granted for the approved FDA indications listed above 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 an 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) (all of the following must be met):
 - 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 (all of 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:
 - a. Must have a previous failure on a topical psoriasis agent
6. Psoriatic Arthritis:
 - a. Trial and failure required with methotrexate first or in combination with methotrexate if appropriate
7. Rheumatoid Arthritis:
 - a. Trial and failure of, contraindication, or adverse reaction to methotrexate and at least one other DMARD (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 Rx 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® request 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 (PA).

Field Name	Field Description
Prior Authorization Group Description	Toremifene (Fareston)
Drugs	<p><u>FORMULARY STATUS</u> Formulary, Pays at Point-of-Sale TAMOXIFEN TABLETS 10MG AND 20MG</p> <p><u>FORMULARY STATUS</u> Requires Step Therapy with one prior step TOREMIFENE (FARESTON) 60MG TABLET</p> <p>Note: Patient must meet criteria #1 & #2 for approval of the PA request.</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to 12 month duration for; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	<ol style="list-style-type: none"> 1. Diagnosis of metastatic breast cancer in postmenopausal female patient 2. Documented trial and failure or intolerance with tamoxifen 10 or 20 mg tablet for a minimum of 3 weeks <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 7/2021	

Field Name	Field Description
Prior Authorization Group Description	Transthyretin-mediated Amyloidosis Agents
Drugs	<p><u>Preferred:</u> Polyneuropathy – Onpattro (patisiran) Cardiomyopathy – Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis)</p> <p><u>Non-preferred:</u> Polyneuropathy – Tegsedi (inoterson) Or any other newly marketed agent</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Patient must be 18 years of age or older
Prescriber Restrictions	Prescriber must be neurologist, cardiologist, or specialist in the treatment of amyloidosis
Coverage Duration	<p>If all of the criteria are met, the initial request will be approved for 6 months.</p> <p>For continuation of therapy the request will be approved for 6 months.</p> <p>If all of the criteria are not met, the request is referred to a Clinical Reviewer for medical necessity review.</p>
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Regimen does not exceed FDA-approved dose/frequency • Patient has not undergone a liver or heart transplant • Patient is not taking any of these agents concurrently: Tegsedi, Onpattro, diflunisal, or tafamidis (Vyndaqel/Vyndamax) • If the request is for Onpattro or Tegsedi, patient has diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis as evidenced by: <ul style="list-style-type: none"> ○ Documented transthyretin variant by genotyping ○ Documented amyloid deposit by biopsy ○ One of the following: <ul style="list-style-type: none"> ▪ Patient has baseline polyneuropathy disability (PND) score \leq IIIb ▪ Patient has a baseline FAP Stage 1 or 2 ▪ Patient has baseline neuropathy impairment (NIS) score \geq 10 and \leq 130 ○ Patient has clinical signs/symptoms of neuropathy

<p>Revision/Review Date: 2/2021</p>	<ul style="list-style-type: none"> ○ For Tegsedi, patient has contraindication to/or previous trial and failure of use of Onpattro ● If the request is for Vyndaqel or Vyndamax, patient has diagnosis of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis as evidenced by: <ul style="list-style-type: none"> ○ Documented transthyretin variant by genotyping or wild-type amyloidosis ○ Documented amyloid deposit by biopsy or positive technetium 99m pyrophosphate (Tc 99m PYP) cardiac imaging ○ Patient has New York Heart Association (NYHA) functional class I, II, or III heart failure symptoms. <p><u>Re-authorization (for continuing and new patients to the plan) :</u></p> <ul style="list-style-type: none"> ● Patient's regimen does not exceed FDA-approved dose/frequency for the agent ● Patient has not undergone a liver or heart transplant ● Patient is not taking any of these agents concurrently: Tegsedi, Onpattro, diflunisal, or tafimidis (Vyndaqel/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 Onpattro or Tegsedi, one of the following: <ul style="list-style-type: none"> ○ Patient has a continued PND score \leq IIIb ○ Patient has a continued FAP Stage 1 or 2 ● If the request is for Vyndaqel/Vyndamax <ul style="list-style-type: none"> ○ Patient has continued NYHA functional class I, II, or III heart failure symptoms <p><u>Continuation of Therapy/Grandfathering Provision:</u> Members with history (within the past 90 days) of a non-formulary product are not required to try a formulary agent prior to receiving the non-formulary product.</p> <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>
---	--

Field Name	Field Description
Prior Authorization Group Description	Type I Interferon (IFN) Receptor Antagonist
Drugs	Saphnelo (anifrolumab-fnia)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	<ul style="list-style-type: none"> • Severe active central nervous system lupus • Active lupus nephritis
Required Medical Information	See "Other Criteria"
Age Restrictions	≥ 18 years
Prescriber Restrictions	Prescriber must be a rheumatologist or in consultation with a rheumatologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of active moderate to severe systemic lupus erythematosus (SLE) • Member has tried all of the following (or there is a medical reason they cannot use these therapies) before Saphnelo: <ul style="list-style-type: none"> ○ Hydroxychloroquine + Glucocorticoids ○ One other immunosuppressant (i.e., methotrexate, azathioprine, calcineurin inhibitors, or mycophenolate) ○ Benlysta (belimumab), if member has autoantibody-positive SLE • Prescriber attests member will not be using Saphnelo concurrently with Benlysta • Medication is prescribed at an FDA approved dose <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation or provider attestation of positive clinical response (i.e., reduction in signs and symptoms of SLE, fewer flares, reduced oral corticosteroid use, etc.) • Prescriber attests member will not be using Saphnelo concurrently with Benlysta • Medication is prescribed at an FDA approved dose <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
Date: 10/2021	

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 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. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of pulmonary arterial hypertension (PAH) • For oral suspension ONLY, is unable to take oral tablets • Patient has NO recent history with use of the following medications: <ul style="list-style-type: none"> ○ Organic nitrates (i.e. nitroglycerin, isosorbide, etc.) ○ Guanylate Cyclase (GC) stimulators (Adempas) ○ HIV protease inhibitors (i.e. ritonavir, darunavir, etc.) – sildenafil only • If the provider is requesting drug is to be used in combination with another PAH agent, ONE of the following: <ul style="list-style-type: none"> ○ Ambrisentan and tadalafil are requested as the combination therapy ○ 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 <p><u>Re-authorization:</u></p>

Revision/Review Date 7/2021	<ul style="list-style-type: none">• 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).• The medication is being prescribed at a dose that is within FDA approved guidelines. <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>
-----------------------------------	--

Field Name	Field Description
Prior Authorization Group Description	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. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria	<ol style="list-style-type: none"> 1. Medication is prescribed at an FDA approved dose 2. The medication is being used for the treatment of symptomatic chronic heart failure with reduced ejection fraction (less than 45%) 3. Documentation that the patient has had a previous hospitalization for heart failure or has required outpatient IV diuretics 4. Member is currently being prescribed, or will be prescribed, at least one of the following treatment regimens, or documentation has been provided that the member is not able to tolerate these agents: <ol style="list-style-type: none"> a. Angiotensin-converting enzyme (ACE) inhibitor OR angiotensin receptor blocker (ARB) OR angiotensin receptor/neprilysin inhibitor b. Mineralocorticoid receptor antagonist (e.g. spironolactone) c. Beta-blocker 5. Documented trial and failure, intolerance, or contraindication to either Entresto or Farxiga 6. Patient is not concomitantly using a long-acting nitrate (e.g. isosorbide mononitrate, transdermal nitroglycerin) or a phosphodiesterase-5 (PDE-5) enzyme inhibitor (e.g. sildenafil) 7. Negative pregnancy test (for females of reproductive age; as indicated) within 30 days of request 8. 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

Revision/Review Date 7/2021	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 for Huntington's Disease
Drugs	tetrabenazine (Xenazine) Austedo (deutetrabenazine) – if the indication is Tardive Dyskinesia please refer to the Tardive Dyskinesia criteria or any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	<ul style="list-style-type: none"> Hepatic impairment Concurrent use of monoamine oxidase inhibitors (MAOIs), reserpine, or Ingrezza (valbenazine)
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	If the criteria are met, the request will be approved for up to 12 month duration; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> Patient must have diagnosis of moderate to severe Huntington's with chorea, with documented baseline Total Maximal Chorea (TMC) score provided If the request is for Austedo, the patient has a documented medical reason (e.g., treatment failure, intolerance, hypersensitivity, contraindication) for not using tetrabenazine Prescriber attests that patient has had a baseline electrocardiogram (EKG) and is aware of the possible risk of QT prolongation Documentation was provided that shows the patient has no signs of hepatic impairment as defined by one or more of the following: <ul style="list-style-type: none"> AST or ALT > 2.5x upper limit normal (ULN) ALP or TBil > 2 times ULN Prothrombin time > 4 seconds prolonged Positive Hepatitis B surface antigen (HBsAg) Patient will not be receiving tetrabenazine and Austedo concurrently Dose is within FDA approved limits <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> Prescriber attests that the member has received clinical benefit from therapy Dose is within FDA approved limits

Revision/Review Date: 7/2021	Physician/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.
---------------------------------	---

Prior Authorization Group Description	Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors for Tardive Dyskinesia
Drugs	Ingrezza (valbenazine) Austedo (deutetrabenazine) – if the indication is Huntington’s Disease, please refer to the Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors for Huntington’s Disease criteria Any other newly marketed agent
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	Concurrent use of monoamine oxidase inhibitors (MAOIs)
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a psychiatrist or neurologist.
Coverage Duration	If the criteria are met, the request will be approved for up to 6 months duration and renewal requests will 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: <ul style="list-style-type: none"> Member must have clinical diagnosis of tardive dyskinesia that has persisted for the last 90 days with documented baseline evaluation using a scoring tool such as: Abnormal Involuntary Movement Scale (AIMS), Extrapyramidal Symptom Rating Scale (ESRI), Schooler and Kane’s Research Diagnoses for Tardive Dyskinesia (RD-TD), the Tardive Dyskinesia Rating Scale (TDRS), the Dyskinesia Identification System-Condensed User Scale (DISCUS), or the Texas Research Institute of Mental Sciences Dyskinesia Rating Scale (TRIMS) For members on antipsychotics, the antipsychotic dose(s) must have been stable for a continuous 90 day period at some point prior to the request Prescriber has attempted at least one of the following strategies to manage the patient’s condition, or has provided a clinical reason why one of the following is not possible: <ul style="list-style-type: none"> Reducing the dose of the drug responsible for causing dyskinesia Discontinuing the drug responsible for causing dyskinesia For members on first generation antipsychotics, switching to a second generation antipsychotic Trial of tetrabenazine or benzodiazepines

<p>Revision/Review Date: 10/2021</p>	<ul style="list-style-type: none"> • Patient will not be receiving treatment with any other vesicular monoamine transporter 2 (VMAT2) inhibitor • Dose is within FDA approved limits • For Ingrezza (valbenazine) requests: <ul style="list-style-type: none"> ○ Ingrezza (valbenazine) will be dosed one capsule once daily • For Austedo requests: <ul style="list-style-type: none"> ○ Prescriber attests patient has no signs of hepatic impairment ○ For patients at risk for QT prolongation, prescriber attests a baseline ECG has been obtained <p>Reauthorization:</p> <ul style="list-style-type: none"> • Documentation was provided that demonstrates stabilization or improvement in average score on the previously-submitted symptom rating scale • Patient will not be receiving treatment with any other vesicular monoamine transporter 2 (VMAT2) inhibitor • Dose is within FDA approved limits <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
--	---

Field Name	Field Description
Prior Authorization Group Description	Vimizim (elosulfase alfa)
Drugs	Vimizim (elosulfase alfa)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	Patient must be 5 years of age or older.
Prescriber Restrictions	Prescriber is, or is collaborating with another provider who is, a specialist in the treatment of Morquio A syndrome or other lysosomal storage disorders.
Coverage Duration	6 months
Other Criteria	<p><u>Initial Authorization (new to therapy):</u></p> <ul style="list-style-type: none"> • Patient has confirmed diagnosis of mucopolysaccharidosis IVA (MPS IVA, or Morquio A syndrome) via one of the following: <ul style="list-style-type: none"> ○ Genetic testing ○ Analysis of N-Acetylgalactosamine 6-sulfatase (GALNS) activity in leukocytes or fibroblasts • 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. <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • 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) <p><u>Re-authorization for members new to the plan previously treated with Vimizim:</u></p> <ul style="list-style-type: none"> • Patient has confirmed genetic diagnosis of mucopolysaccharidosis IVA (MPS IVA, or Morquio A syndrome) via one of the following: <ul style="list-style-type: none"> ○ Genetic testing ○ Analysis of N-Acetylgalactosamine 6-sulfatase (GALNS) activity in leukocytes or fibroblasts • 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:

<p>Revision/Review Date 7/2021</p>	<ul style="list-style-type: none"> ○ A current test must be completed and patient must be able to walk a minimum of 30 meters (must submit results with request). ○ Continued authorizations for Vimizim for patients without a completed baseline 6-minute walk test evaluation prior to initiation of therapy must continue to be able to walk a minimum of 30 meters in subsequent evaluations. ○ If patient is established on Vimizim therapy prior to enrollment on the plan, but is not able to walk a minimum of 30 meters, then medical justification is required as to how the patient continues to receive benefit from Vimizim therapy. <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
--	---

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; if the above conditions are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	<p><u>Initial Authorization:</u></p> <ol style="list-style-type: none"> 1. Voriconazole is being used to treat invasive aspergillosis or a serious fungal infection caused by <i>Scedosporium apiospermum</i> and <i>Fusarium</i> species <p>OR</p> <ol style="list-style-type: none"> 2. Voriconazole is being used to treat esophageal candidiasis, candidemia (nonneutropenics), or disseminated candidiasis of the skin, abdomen, kidney, bladder wall or wounds; AND <ul style="list-style-type: none"> o Documented trial and failure with a formulary treatment option (i.e. fluconazole or nystatin) or documented medical reason (e.g., recent discharge from hospital on oral voriconazole, intolerance, hypersensitivity, contraindication) for not using a formulary treatment option for relevant indications
Revision/Review Date 7/2021	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	White Blood Cell Stimulators
Drugs	<p><u>FORMULARY STATUS</u></p> <p><u>Short-Acting G-CSFs:</u> Nivestym (filgrastim-aafi) – PREFERRED AGENT Zarxio (filgrastim-sndz) – PREFERRED AGENT Granix (TBO-filgrastim) Neupogen (filgrastim) Or any newly market agent</p> <p><u>Long-Acting G-CSFs:</u> Ziextenzo (pegfilgrastim-bmez) – PREFERRED AGENT Nyvepria (pegfilgrastim-apgf) Fulphila (pegfilgrastim-jmdb) Udenyca (pegfilgrastim-cbqv) Neulasta (pegfilgrastim) Neulasta Onpro (pegfilgrastim) Or any newly market agent</p> <p><u>Additional Agents:</u> Mozobil (Plerixafor) Leukine (Sargramostim) Or any newly marketed agent</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USPDI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a hematologist, an oncologist, or an infection disease specialist
Coverage Duration	Initial authorization requests for all indications will be approved for 12 weeks. Reauthorization requests for all indications, with the exception of chronic neutropenia, will be approved for 12 weeks. Reauthorization requests for chronic neutropenia will be approved for 24 weeks.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> <i>For ALL requests for treatment or prophylaxis of febrile neutropenia:</i> Documentation of the patient’s absolute neutrophil count (ANC) within the last 30 day has been provided.

<p>Revision/Review Date: 7/2021</p>	<p><u>Short-Acting G-CSFs:</u></p> <ul style="list-style-type: none"> • <i>For all requests for non-preferred agents:</i> The patient has a documented treatment failure {i.e. failure to reach and/or maintain target ANC, prolonged febrile neutropenia, unplanned hospitalization or infection requiring prolonged anti-infective use} with an adequate trial (including dates, doses of therapy) of both Zarxio AND Nivestym or has another documented medical reason (intolerance, hypersensitivity, stem cell collection, etc.) for not using Zarxio AND Nivestym to treat their medical condition. <p><u>Long-Acting G-CSFs:</u></p> <ul style="list-style-type: none"> • <i>For Fulphila, Udenyca, or Nyvepria requests:</i> The patient has a documented treatment failure (i.e. failure to reach and/or maintain target ANC, prolonged febrile neutropenia or infection requiring prolonged anti-infection use) with the use of Ziextenzo, or has a documented medical reason (intolerance, hypersensitivity, stem cell collection, etc.) for not using Ziextenzo • <i>For Neulasta or Neulasta Onpro requests:</i> The patient has a documented treatment failure (i.e. failure to reach and/or maintain target ANC, prolonged febrile neutropenia or infection requiring prolonged anti-infection use) with the use of Ziextenzo AND either Fulphila, Udenyca, or Nyvepria or has a documented medical reason (intolerance, hypersensitivity, stem cell collection, etc.) for not using these therapies <p><u>Additional Agents:</u></p> <ul style="list-style-type: none"> • <i>For Leukine requests:</i> Documentation is submitted of the patient's current diagnosis, current body weight, body surface area and absolute neutrophil count (within 30 days of the request). • <i>For Mozobil requests:</i> 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. Zarxio, Nivestym) <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
---	---

Field Name	Field Description
Prior Authorization Group Description	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> <ul style="list-style-type: none"> • Patient has the diagnosis of hepatic encephalopathy • Patient will be using lactulose concurrently or has a medical reason for being unable to use lactulose <u>Traveler’s Diarrhea Treatment</u> <ul style="list-style-type: none"> • Patient has the diagnosis of traveler’s diarrhea • Patient has tried and failed therapy with one formulary antibiotic or has a medical reason for not trying a formulary antibiotic (e.g., levofloxacin, azithromycin, sulfamethoxazole-trimethoprim) <u>Irritable Bowel Syndrome with diarrhea (IBS-D)</u>

<p>Revision/Review 7/2021</p>	<ul style="list-style-type: none"> • 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 <p><u>Re-Authorization (Hepatic Encephalopathy and IBS-D only):</u></p> <ul style="list-style-type: none"> • Documentation indicating the member has clinically benefited from therapy. <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
-----------------------------------	--

Field Name	Field Description
Prior Authorization Group Description	Xolair for Asthma and Urticaria
Drugs	Xolair (omalizumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	Use of Xolair concomitantly with another pulmonary biologic (e.g. Fasenra, Nucala, Cinqair, Dupixent)
Required Medical Information	See “Other Criteria”
Age Restrictions	Asthma: ≥ 6 years Chronic idiopathic urticaria: ≥ 12 years
Prescriber Restrictions	Prescribed by, or in consultation with, an allergist/immunologist, pulmonologist, or dermatologist
Coverage Duration	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. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria	<p>**For nasal polyposis, please refer to the “Biologic Agents for Nasal Polyposis” policy**</p> <p><u>Initial Authorization:</u></p> <p><u>Asthma:</u></p> <ul style="list-style-type: none"> • Member has at least a 6 month history of moderate to severe asthma • The drug is being prescribed at an approved dose according to member’s weight and IgE level • Member is taking maximally tolerated ICS/LABA combination in addition to a LAMA (e.g. tiotropium) for at least 3 months, or there is a documented medical reason why the member is unable to take these medications • Member’s asthma is uncontrolled as defined by having one of the following: <ul style="list-style-type: none"> ○ Frequent severe exacerbations requiring two or more bursts of systemic glucocorticoids (more than three days each) in the previous year ○ History of serious exacerbation: at least one hospitalization, intensive care unit stay, or mechanical ventilation in the previous year ○ Airflow limitation defined as a forced expiratory volume in 1 second (FEV1) less than 80% of predicted ○ Poor symptom control including at least THREE of the following: <ul style="list-style-type: none"> ▪ Asthma Control Questionnaire (ACQ)

<p>Review/Revision Date: 10/2021</p>	<p>consistently > 1.5 or Asthma Control Test (ACT) < 20</p> <ul style="list-style-type: none"> ▪ Daytime asthma symptoms more than twice per week ▪ Use of an inhaled short acting B-2 agonist to relieve asthma symptoms more than twice per week (not including use prior to exercise) ▪ Limited physical activity due to asthma symptoms ▪ Nighttime awakening due to asthma symptoms <ul style="list-style-type: none"> • Member has a positive immediate response on RAST test and/or skin prick test to at least 1 common allergen (e.g. dermatophagoides farinae, dermatophagoides 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 30IU/mL <p><u>Chronic Idiopathic Urticaria:</u></p> <ul style="list-style-type: none"> • The drug is prescribed at an approved dose • Member has at least a 6 week history of urticaria • Member requires oral corticosteroids to control symptoms • The patient remains symptomatic despite a minimum two week trial (or has medical reason for not utilizing) of two preferred second generation H1 antihistamines at the maximum tolerated dose <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • The drug is indicated for the member's age and is being prescribed at an approved dose • Prescriber has re-evaluated member and recommends continuation of therapy • The member has significantly benefited from medication (e.g. decrease exacerbations, reduction in use of oral steroids) <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
--	--

Field Name	Field Description
Prior Authorization Group Description	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 18 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. If all the above criteria are not met, the request must be referred to a Clinical Reviewer for a medical necessity review.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • 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
Revision/Review Date 10/2021	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.