



Coverage by AmeriHealth First.

KF/AHC/CHC

**PHARMACY PRIOR
AUTHORIZATION CRITERIA**

Effective 03/09/2026

Non-Statewide PDL Policies

Field Name	Field Description
Prior Authorization Group Description	Off-Label Uses Criteria (Non-Statewide PDL drugs/classes)
Drugs	Medications with off-label uses
Covered Uses	Off-label uses: Medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criterion is met, the request will be approved for up to a 12 month duration (depending on the diagnosis and usual treatment duration).
Other Criteria	<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 style="text-align: center;">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 style="text-align: center;">AND</p> 3. Medication is being requested at an appropriate dose per literature
Revision/Review Date	4/2025

	<p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Medications without Drug or Class Specific Criteria (Non-Statewide PDL drugs/classes)
Drugs	<ul style="list-style-type: none"> • Medications without drug or class specific prior authorization criteria, which includes specialty drugs and non-formulary drugs. • Brand drugs and reference biologics when a therapeutic equivalent generic drug or biosimilar/interchangeable biologic is available <p>***The Oncology Drugs prior authorization criteria will be applied to oncology drugs without drug or class specific criteria***</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to covered uses
Prescriber Restrictions	N/A
Coverage Duration	If the criteria is met, the request will be approved for up to a 12 month duration (depending on the diagnosis and usual treatment duration).
Other Criteria	<p><u>Initial Authorization:</u></p> <p>All Requests:</p> <ul style="list-style-type: none"> • The drug is requested for an appropriate use (per the references outlined in “Covered Uses” • The dose requested is appropriate for the requested use (per the references outlined in “Covered Uses”) • Patient meets one of the three following criteria: <ul style="list-style-type: none"> ○ Documented trial and failure or intolerance of two alternative preferred medications appropriate for the requested use (per the references outlined in “Covered Uses” or has a medical reason why these drug(s) cannot be used [e.g. intolerance, contraindication]). For medications where there is only one preferred agent, only that agent must have been ineffective or not tolerated. <ul style="list-style-type: none"> ▪ Non-formulary drug requests require a trial and failure or intolerance to two alternative products that have a less restrictive formulary status than the drug that is being requested. ▪ Specialty drug requests require a trial and failure or intolerance to two alternative products that exists for that disease state that have criteria to address its use. ○ No other preferred medication has a medically accepted use for the patient’s specific diagnosis as referenced in the medical compendia.

- All other preferred medications are contraindicated based on the patient's diagnosis, other medical conditions, or other medication therapy.

Brand drugs with a therapeutically equivalent (A-rated) generic drug currently available:

- The provider either verbally or in writing has submitted a medical or member specific reason why the brand name drug is required based on the member's condition or treatment history; **AND** if the member had side effects or a reaction to the generic drug, the provider has completed and submitted an FDA MedWatch form to justify the member's need to avoid this drug. The MedWatch form must be included with the prior authorization request

[Form FDA 3500 – Voluntary Reporting](#)

Reference biologic drugs with either a biosimilar or interchangeable biologic drug currently available:

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

[Form FDA 3500 – Voluntary Reporting](#)

Reauthorization:

- Documentation of provider attestation that demonstrates a clinical benefit
- The requested drug is for a medically accepted dose as outlined in Covered Uses

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

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Prior Authorization Group Description	Prior Authorization Exception Criteria
Covered Uses	All medically accepted indications. Medically accepted indications are defined using the following compendia resources: the Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), American Hospital Formulary Service Drug Information (AHFS-DI), and DRUGDEX Information System. The reviewer may also reference disease state specific standard of care guidelines.
Scope	Requests for exception to the drug's prior authorization criteria requirements
Coverage Duration	12 months
Criteria	<ul style="list-style-type: none"> • The provider either verbally or in writing has submitted a medical or member specific reason why prior authorization criteria all or in part is not applicable to the member. <ul style="list-style-type: none"> ○ Medical and/or member specific reasons may include but are not limited to: <ul style="list-style-type: none"> ▪ Uniqueness of the member's condition or other physical characteristics of the member's condition. ▪ Psychiatric, intellectual, physical, cultural, and/or linguistic characteristics of the member which may inhibit the provider from obtaining all necessary prior authorization criteria requirements. <p>Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date:	10/2025

Field Name	Field Description
Prior Authorization Group Description	Quantity Limit Exception Criteria
Covered Uses	All medically accepted indications. Medically accepted indications are defined using the following compendia resources: the Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), American Hospital Formulary Service Drug Information (AHFS-DI), and DRUGDEX Information System. The reviewer may also reference disease state specific standard of care guidelines.
Scope	Requests for formulary drugs outside of the PDL 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. • The provider has submitted justification for the approval of doubling (or higher) of the number of tablets/capsules per prescription for a medication that has a higher strength tablet/capsule available, stating why that higher dose tablet/capsule cannot be used (e.g. two lorazepam 0.5mg tablets to equal the dose of lorazepam 1mg, when lorazepam 1mg tablet exists) <p>AND one of the following:</p> <ul style="list-style-type: none"> ○ The member has a documented treatment failure with the drug prescribed at the health plan's quantity limit AND the dose requested is supported by the Medical Compendia or current treatment guidelines. ○ The member requires a dose within prescribing guidelines that exceeds the plan's quantity limit. <p>Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Coverage Duration	12 Months
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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	<p>Requests for formulary drugs and for previously approved non-formulary drugs outside of the scope of the statewide PDL:</p> <ul style="list-style-type: none"> • Exceeding the Food and Drug Administration (FDA) or compendia max dose recommendations • Exceeding the FDA dosing or compendia administration frequency recommendations • Exceeding the FDA or compendia duration of therapy recommendations • Duplication of therapy error at Point of Service (POS) • Age Restriction error at POS • Day Supply Limit error at POS • Concurrent Use error at POS • Drug Drug Interaction error at POS
Criteria	<p>Exceeding the Food and Drug Administration (FDA) or compendia maximum dose, administration frequency or duration of therapy recommendations.</p> <ul style="list-style-type: none"> • The member must have a documented treatment failure with the drug at the maximum dose based on patient age/weight, administration frequency, or duration of therapy per FDA or compendia. <p>AND</p> <ul style="list-style-type: none"> • The provider must submit a medical reason why the maximum dose, administration frequency or duration of therapy needs to be exceeded based on the member's condition or treatment history. <p>Duplication of therapy</p> <p><u>Transition from one agent to another</u></p> <ul style="list-style-type: none"> • If a provider has outlined a plan to transition a member to a similar drug or provided a dose titration schedule, the requested drug is approved for one month*. <p><u>Concurrent Therapy with two similar agents</u></p> <ul style="list-style-type: none"> • 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. <p>OR</p> <ul style="list-style-type: none"> • The provider must submit disease state specific standard of care guidelines supporting concurrent therapy. <p>Age Restriction</p>

<p>Revision/Review Date: 10/2025</p>	<ul style="list-style-type: none"> • 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. <p>AND</p> <ul style="list-style-type: none"> • The indication and dose requested is supported by the Medical Compendia or current treatment guidelines. <p>Day Supply Limit</p> <ul style="list-style-type: none"> • An additional fill exceeding the day supply limit is needed based on a dose increase or is needed to achieve a total daily dose <p>OR</p> <ul style="list-style-type: none"> • The provider must submit a medical reason why an additional fill is needed outside of the plan’s day supply limit. <p>AND</p> <ul style="list-style-type: none"> • The indication and dose requested is supported by the FDA, Medical Compendia or current treatment guidelines. <p>Concurrent Use/Drug-Drug Interaction</p> <ul style="list-style-type: none"> • The provider must submit a medical reason why treatment with both drugs is necessary for the member <p>AND</p> <ul style="list-style-type: none"> • The increased risk for side effects when taking the drugs together has been discussed with the member <p>Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
<p>Coverage Duration</p>	<p>*One month approval for Duplication of therapy when transitioning from one agent to another and Day Supply Limit due to a dose increase. All Other Scenarios: 12 months</p>

Field Name	Field Description
Prior Authorization Group	Oncology Drugs/Therapies
Drugs	Oncology Medications and Oncology Gene Therapies NOT ON THE STATEWIDE PDL (specialty or non-specialty) without productspecific 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	According to package insert or NCCN guidelines
Prescriber Restrictions	Prescribed by or in consultation with an oncologist, or specialist in type of cancer being treated
Coverage Duration	If the criteria are met, the request will be approved for up to 6 month duration.
Other Criteria	<p>All of the following criteria must be met:</p> <ul style="list-style-type: none"> • Requested use must be a labeled indication or be supported by NCCN Category 1 or 2A level of evidence. If the request is for an off-label use supported by NCCN as Category 2B recommendation then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g. allergic reaction, contraindication) • Documentation has been provided of the results of all required genetic testing where required per product package insert • Documentation has been provided of the results of all required laboratory values and patient specific information (e.g. weight, ALT/AST, Creatine Kinase, etc.) necessary to ensure the patient has no contraindications to therapy per product package insert • The product is being prescribed at a dose and duration that is within FDA approved/NCCN guidelines. • If the request is for a reference biologic drug with either a biosimilar or interchangeable biologic drug currently available, documentation of one of the following: <ul style="list-style-type: none"> ○ The provider has verbally or in writing submitted a member specific reason why the reference biologic is required based on the member’s condition or treatment history; AND if the member had side effects or a reaction to the biosimilar or interchangeable biologic, 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 ○ 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 style="text-align: center;"><u>Form FDA 3500 – Voluntary Reporting</u></p> <p style="text-align: center;">Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>

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Field Name	Field Description
Prior Authorization Group Description	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 outside the scope of the statewide PDL 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:	10/2025

Field Name	Field Description
Prior Authorization Group Description	Alpha-1 Proteinase Inhibitors (Human)
Drugs	<p>Preferred: Prolastin-C</p> <p>Non-Preferred: Aralast NP Glassia Zemaira Or any other newly marketed agent</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or specialist in the treatment of AAT
Coverage Duration	The request will be approved for up to a 12 month duration.
Other Criteria	<p>Initial Authorization:</p> <ul style="list-style-type: none"> • Documented diagnosis of a congenital deficiency of alpha-1 antitrypsin (AAT) (serum AAT level < 11 micromol/L [approximately 57 mg/dL using nephelometry or 80mg/dl by radial immunodiffusion]). • Documentation was submitted indicating the member has undergone genetic testing for AAT deficiency and is classified as phenotype PiZZ, PiSZ, PiZ(null) or Pi(null)(null) [NOTE: phenotypes PiMZ or PiMS are not candidates for treatment with Alpha1-Proteinase Inhibitors] • Documentation was submitted (member's pulmonary function test results) indicating airflow obstruction by spirometry (forced expiratory volume in 1 second [FEV₁] ≤ 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 member is a non-smoker or an ex-smoker (e.g. smoking cessation treatment) • Documentation was submitted indicating the member has clinically benefited from therapy (i.e. stable lung function, improved PFTs, alpha-1 antitrypsin

<p>Revision/Review Date 2/2026</p>	<p>serum level maintained above 11 micromol/L [approximately 57 mg/dL using or 80 mg/dL by radial immunodiffusion], 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>
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Field Name	Field Description
Prior Authorization Group Description	Radicava
Drugs	Edaravone (Radicava), Radivaca ORS (edaravone) and any other newly marketed agent *** riluzole (Rilutek) is Preferred and does not require prior authorization***
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	If the criteria are met, requests will be approved for up to 6 month duration
Other Criteria	<p>Initial Authorization:</p> <ul style="list-style-type: none"> • Member must have a diagnosis of ALS • Member must have a documented baseline evaluation of functionality using the revised ALS functional rating scale (ALSFRS-R) score ≥ 2 • Member’s disease duration is 2 years or less • Member has a baseline forced vital capacity (FVC) of $\geq 80\%$ • Member has been on riluzole (Rilutek), is beginning therapy as an adjunct to treatment with Radicava, or provider has provided a medical reason why patient is unable to use riluzole • Dose is within FDA approved limits <p><u>Reauthorization:</u></p> <ul style="list-style-type: none"> • Member is not ventilator-dependent • Provider documents clinical stabilization in symptoms (e.g. stabilization of ALSFRS-R score) • Dose is within FDA approved limits <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Adzynma
Drugs	Adzynma (ADAMTS13, recombinant-krhn)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a hematologist, oncologist, intensive care specialist, or specialist in the treatment of rare genetic hematologic diseases
Coverage Duration	<p><u>On-demand therapy:</u> If all criteria are met, the request will be approved for 1 month.</p> <p><u>Prophylactic therapy:</u> If all criteria are met, the initial request will be approved for 6 months. Reauthorization requests will be approved for 12 months.</p>
Other Criteria	<p><u>Initial Authorization</u></p> <ul style="list-style-type: none"> • Diagnosis of congenital thrombotic thrombocytopenic purpura (cTTP) as confirmed by BOTH of the following: <ul style="list-style-type: none"> ○ Molecular genetic testing ○ ADAMTS13 activity <10% • Prescriber attestation that member has not been diagnosed with any other TTP-like disorder (i.e., microangiopathic hemolytic anemia, immune-mediated thrombotic thrombocytopenic purpura [iTTP]) • If request is for prophylactic therapy, member must also have a history of at least one documented TTP event • Member’s weight • Request is for an FDA-approved dose <p><u>Reauthorization</u></p> <ul style="list-style-type: none"> • Documentation of positive clinical response to therapy (i.e., improvement in acute and subacute TTP events, platelet counts, microangiopathic hemolytic anemia episodes, or clinical symptoms) • Member’s weight • Request is for an FDA-approved dose <p>Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.</p> <p>Revision/Review Date: 4/2025</p>

Field Name	Field Description
Prior Authorization Group Description	Amifampridine
Drugs	Firdapse (amifampridine)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Patients must be 6 years age or older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a neuromuscular specialist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy the request will be approved for 6 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) based on at least one electrodiagnostic study (i.e., repetitive nerve stimulation, nerve conduction studies, electromyography) OR anti-P/Q-type voltage-gated calcium channel antibody testing • Member has been screened for small cell lung cancer (SCLC) and/or other malignancies • Member does not have a history of seizures • Medication is being prescribed at an FDA approved dose or is supported by compendia or standard of care guidelines <p><u>Re-authorization:</u></p> <ul style="list-style-type: none"> • Medication is prescribed at an FDA-approved dose or is supported by compendia or standard of care guidelines • Documentation provided that prescriber has evaluated the member and recommends continuation of therapy <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Amtagvi (lifileucel)
Drugs	Amtagvi (lifileucel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	<ul style="list-style-type: none"> • Uncontrolled brain metastases • Melanoma of uveal or ocular origin • Systemic steroid therapy for any reason
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be an oncologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for a one-time treatment.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of unresectable or metastatic melanoma (Stage IIIc or Stage IV) • Member must have progressed through at least one prior systemic therapy including a PD-1/PD-L1 blocking antibody and, if BRAF V600 mutation–positive, a BRAF inhibitor or BRAF inhibitor in combination with a MEK inhibitor • Member must have at least one resectable lesion (or aggregate of lesions resected) of a minimum 1.5 cm in diameter post-resection • Eastern Cooperative Oncology Group (ECOG) score of 0 or 1 • Medication is prescribed at an FDA approved dose <p>The safety and effectiveness of repeat administration of Amtagvi has not been evaluated and will not be approved.</p>
Revision/Review Date: 4/2025	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Anti-CD19 CAR-T Immunotherapies
Drugs	Kymriah (tisagenlecleucel), Yescarta (axicabtagene ciloleucel), Tecartus (brexucabtagene autoleucel), Breyanzi (lisocabtagene maraleucel), Aucatzyl (obecabtagene autoleucel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Patients with primary central nervous system lymphoma
Required Medical Information	See "Other Criteria"
Age Restrictions	See "Other Criteria"
Prescriber Restrictions	Prescriber must be an oncologist, hematologist or other appropriate specialist .
Coverage Duration	<p>If all the criteria are met, the initial request will be approved for a single treatment regimen per lifetime.</p> <ul style="list-style-type: none"> • Kymriah, Yescarta, Tecartus, Breyanzi :a one-time infusion • Aucatzyl: a split-dose infusion administered on day 1 and day 10 (± 2 days)
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 will not receive live virus vaccines for at least 6 weeks prior to the start of lymphodepleting chemotherapy and until immune recovery following treatment. • Use is supported by a labeled indication or NCCN guidelines <p><u>Leukemia</u></p> <p>B-cell precursor Acute Lymphoblastic Leukemia (ALL):</p> <ul style="list-style-type: none"> • If the request is for Kymriah <ul style="list-style-type: none"> ○ Patient is 25 years of age or younger ○ ALL that is refractory or in second or later relapse • If the request is for Tecartus or Aucatzyl <ul style="list-style-type: none"> ○ Patient is 18 years of age or older ○ ALL that is relapsed or refractory <p>Chronic Lymphocytic Leukemia (CLL):</p> <ul style="list-style-type: none"> • If the request is for Breyanzi <ul style="list-style-type: none"> ○ Patient is 18 years of age or older

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

Non-Hodgkin's Lymphoma (NHL)

Follicular Lymphoma (FL):

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

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

- If the request is for Breyanzi, Kymriah, or Yescarta
 - Patient is 18 years of age or older
 - For Breyanzi ONE of the following:
 - Patient is refractory to first-line chemoimmunotherapy or relapsed within 12 months of first-line chemoimmunotherapy
 - Patient is refractory to first-line chemoimmunotherapy or relapsed after first-line chemoimmunotherapy and is not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age
 - Patient has relapsed or refractory disease after two or more lines of systemic therapy
 - For Kymriah: Patient has relapsed/refractory disease defined as failure of two or more lines of systemic therapy
 - For Yescarta ONE of the following:
 - Patient is refractory to first-line chemoimmunotherapy or relapses within 12 months of first-line chemoimmunotherapy or
 - Patient has failed two or more lines of systemic therapy

Mantle Cell Lymphoma (MCL):

- Patient is 18 years of age or older
- If the request is for Tecartus:
 - Patient has relapsed/refractory disease defined as failure of BOTH the following:
 - Chemoimmunotherapy such as an anti-CD20 monoclonal antibody (e.g. Rituxan) + any chemotherapeutic agent
 - Bruton Tyrosine Kinase (BTK) Inhibitor (e.g. Calquence, Imbruvica, Brukinsa)
- If the request is for Breynazi:
 - Patient has relapsed or refractory disease who have received at least 2 prior lines of systemic therapy, including a BTK inhibitor

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Small Lymphocytic Lymphoma (SLL):

- If the request is for Breyanzi
 - Patient is 18 years of age or older
 - Patient has received at least 2 prior lines of therapy including, a Bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor

Re-authorization:

- Treatment exceeding 1 single treatment regimen per lifetime will not be authorized.
 - Kymriah, Yescarta, Tecartus, Breyanzi :a one-time infusion
 - Aucatzyl: a split-dose infusion administered on day 1 and day 10 (\pm 2 days)

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

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

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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	N/A
Prescriber Restrictions	Prescribed by neurologist or provider who specializes in the treatment of DMD
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months and reauthorization requests will be approved for 12 months.
Other Criteria	<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 • Baseline 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)] • • Attestation of renal function monitoring is provided with request • The request is for an FDA approved dose <p><u>Reauthorization</u></p> <ul style="list-style-type: none"> • Has documentation of annual evaluation, including an assessment of motor function ability • Based on the prescriber's assessment the member continues to have clinical benefit • 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> <p>Revision/Review Date 4/2025</p>

Field Name	Field Description
Prior Authorization Group Description	B-Cell Maturation Antigen (BCMA) Directed Chimeric Antigen Receptor (CAR) T-Cell Therapy
Drugs	Abecma (idecabtagene vicleucel), Carvykti (ciltacabtagene autoleucel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Member must be 18 years or older
Prescriber Restrictions	Prescriber must be a hematologist, an oncologist, or other appropriate specialist
Coverage Duration	If all the criteria are met, the initial request will be approved for a one – time infusion per lifetime.
Other Criteria	<p><u>Initial Authorization</u></p> <ul style="list-style-type: none"> • Member has a diagnosis of relapsed or refractory multiple myeloma (RRMM) • For Abecma, member must have also received at least 2 prior lines of therapy including: <ul style="list-style-type: none"> ○ An immunomodulatory agent (e.g. lenalidomide, pomalidomide, thalidomide) ○ A proteasome inhibitor (e.g. bortezomib, carfilzomib, ixazomib) ○ An anti-CD38 monoclonal antibody (e.g. daratumumab, isatuximab) • For Carvykti, member must also be refractory to lenalidomide AND have received at least 1 prior line of therapy including: <ul style="list-style-type: none"> ○ An immunomodulatory agent (e.g. lenalidomide, pomalidomide, thalidomide) ○ A proteasome inhibitor (e.g. bortezomib, carfilzomib, ixazomib) • Member does not have an active infection or inflammatory disorder • Member will be screened for cytomegalovirus (CMV), hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines • Member will not receive live virus vaccines for at least 6 weeks prior to the start of lymphodepleting chemotherapy and until immune recovery following treatment • Member has not previously received a BCMA CAR-T therapy <p><u>Re-authorization:</u></p> <ul style="list-style-type: none"> • Treatment exceeding 1 dose per lifetime will not be authorized.

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

Field Name	Field Description
Prior Authorization Group Description	Benlysta (belimumab)
Drugs	Benlysta (belimumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	Severe active central nervous system lupus
Required Medical Information	See “other criteria”
Age Restrictions	Must be at least 5 years of age
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist or nephrologist
Coverage Duration	If all the criteria are met initial authorization requests may be approved for up to 6 months. Reauthorization requests may be approved for up to 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • <u>Active systemic lupus erythematosus (SLE)</u> <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 [e.g., methotrexate, azathioprine, calcineurin inhibitors or mycophenolate] • <u>Active lupus nephritis</u> <ul style="list-style-type: none"> ○ Provider attestation of diagnosis confirmed by kidney biopsy • Provider states the member will not be receiving concomitant therapy with the following: <ul style="list-style-type: none"> ○ B-cell targeted therapy including (but not limited to) rituximab ○ Interferon receptor antagonist, type 1 including (but not limited to) Saphnelo (anifrolumab) • Dosing is appropriate per labeling <p><u>Criteria for Reauthorization:</u></p> <ul style="list-style-type: none"> • Documentation or provider attestation of positive clinical response as indicated by one of the following: <ul style="list-style-type: none"> ○ Fewer flares that required steroid treatment ○ Lower average daily oral prednisone dose ○ Improved daily function either as measured through a validated functional scale or through improved daily performance documented at clinic visits ○ Sustained improvement in laboratory measures of lupus activity • Dosing is appropriate per labeling <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Blincyto
Drugs	Blincyto (blinatumomab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restriction	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist/hematologist
Coverage Duration	The request will be approved for up to a 12 month duration.
Other Criteria	<p>Initial Authorization:</p> <ul style="list-style-type: none"> • Patient has a diagnosis of one of the following forms of Acute Lymphoblastic Leukemia (ALL): <ul style="list-style-type: none"> a) Relapsed CD19-positive B-cell precursor ALL b) Refractory CD19-positive B-cell precursor ALL c) CD19-positive B-cell precursor ALL in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1% d) CD19-positive Philadelphia chromosome-negative B-cell precursor ALL in the consolidation phase of multiphase chemotherapy • Provider attests to monitor patient for Cytokine Release Syndrome (CRS) and neurological toxicities <p>Reauthorization:</p> <ul style="list-style-type: none"> • Provider attests to treatment response or stabilization of disease • Prescriber attests to monitor patient for Cytokine Release Syndrome (CRS) and neurological toxicities <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Brinsupri (brensocatib)
Drugs	Brinsupri (brensocatib)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist
Coverage Duration	If all the criteria are met, the initial and reauthorization request will be approved for 12 months
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of bronchiectasis confirmed by chest CT scan • Documentation patient does not have Cystic Fibrosis • At least 1 exacerbation in the past 12 months requiring an antibiotic prescription, urgent care or emergency room visit, or hospitalization • Medication is prescribed at an FDA approved dose <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation or provider attestation of positive clinical response (i.e. decrease in cough, sputum production, exacerbations, etc.) • Medication is prescribed at an FDA approved dose <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
Revision/Review Date: 10/2025	

Field Name	Field Description
Prior Authorization Group Description	Ileal bile acid transporter inhibitor (IBAT)
Drugs	Bylvay (odevixibat), Livmarli (maralixibat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	Per prescribing information
Prescriber Restrictions	N/A
Coverage Duration	If the conditions are met, the request will be approved for a 6 month duration for initial requests and a 12 month duration for renewal requests.
Other Criteria	<p><u>Initial Authorization:</u></p> <p>Progressive Familial Intrahepatic Cholestasis</p> <ul style="list-style-type: none"> • Diagnosis of progressive familial intrahepatic cholestasis (PFIC) <ul style="list-style-type: none"> ○ For Bylvay: PFIC type 1 or 2 with confirmed biallelic mutations via genetic testing ○ For Livmarli: PFIC type 1, 2, 3, 4, or 6, with confirmed biallelic mutations via genetic testing • Documented history of pruritus • Documentation of patient’s weight • Prescriber attests to monitor liver function tests and fat soluble vitamin (FSV) levels during treatment • The prescribed dose is within FDA approved dosing guidelines <p>Alagille Syndrome</p> <ul style="list-style-type: none"> • Diagnosis of Alagille syndrome (ALGS) • Documented history of pruritus • Prescriber attests that the member has cholestasis • Documentation of patient’s weight • Prescriber attests to monitor liver function tests and fat soluble vitamin (FSV) levels during treatment • The prescribed dose is within FDA approved dosing guidelines <p><u>Reauthorization:</u></p> <ul style="list-style-type: none"> • Documentation of clinical benefit indicating each of the following: <ul style="list-style-type: none"> ○ An improvement in pruritus (e.g. improved observed scratching, decreased sleep disturbances/nighttime awakenings due to scratching, etc.) • Documentation of patient’s weight

<p>Revision/Review Date: 7/2025</p>	<ul style="list-style-type: none">• Prescriber attests to monitor liver function tests and FSV levels during treatment• Prescriber attests that patient has had no evidence of hepatic decompensation (e.g. variceal hemorrhage, ascites, hepatic encephalopathy, portal hypertension, etc.)• The prescribed dose is within FDA approved dosing guidelines <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Camzyos
Drugs	Camzyos (mavacamten)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	≥ 18 years
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of symptomatic New York Heart Association (NYHA) class II or III obstructive hypertrophic cardiomyopathy (oHCM) • Patient has a left ventricular ejection fraction (LVEF) ≥55% • Patient has a peak left ventricular outflow tract (LVOT) gradient ≥ 50 mmHg at rest or with provocation. • Trial and failure, contraindication or intolerance to one agent from BOTH of the following: <ul style="list-style-type: none"> ○ Beta blockers (i.e. metoprolol, propranolol, atenolol) ○ Non-dihydropyridine calcium channel blockers (i.e. verapamil, diltiazem) • Prescriber attests that patient is not diagnosed with a disorder that causes cardiac hypertrophy that mimics oHCM (i.e., Fabry disease, amyloidosis, or Noonan syndrome with LV hypertrophy) • Prescriber attests that patient is not using moderate to strong CYP2C19 inducers, strong CYP2C19 inhibitors, or moderate to strong CYP3A4 inducers. • Medication is prescribed at an FDA approved dose <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation of clinical benefit as evidenced by an improvement in oHCM symptoms (i.e., improvement in shortness of breath, LVOT, peak oxygen consumption, etc.) from baseline OR improvement or no worsening of NYHA functional class from baseline • Patient has a left ventricular ejection fraction (LVEF) ≥50% • Medication is prescribed at an FDA approved dose <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>Revision/Review Date: 7/2025</p>

	If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.
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I. Requirements for Prior Authorization of Casgevy (exagamglogene autotemcel)

A. Prescriptions That Require Prior Authorization

All prescriptions for Casgevy (exagamglogene autotemcel) must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Casgevy (exagamglogene autotemcel), the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed Casgevy (exagamglogene autotemcel) for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling; **AND**
2. Is age-appropriate according to FDA-approved package labeling; **AND**
3. Is prescribed a dose and number of treatments that are consistent with FDA-approved package labeling; **AND**
4. Is prescribed Casgevy (exagamglogene autotemcel) by a specialist at an authorized treatment center for Casgevy (exagamglogene autotemcel); **AND**
5. Does not have a contraindication to the prescribed drug; **AND**
6. Is clinically stable for transplantation based on the prescriber's assessment; **AND**
7. **One** of the following:
 - a. For treatment of sickle cell disease, **both** of the following:
 - i. Has sickle cell disease with confirmatory genetic testing
 - ii. **One** of the following:
 - a) Has a history of vaso-occlusive episodes (e.g., pain crises, acute chest syndrome, splenic sequestration, priapism) that required a medical facility visit (e.g., emergency department, hospital)
 - b) Is currently receiving chronic transfusion therapy for recurrent vaso-occlusive episodes
 - b. For treatment of transfusion-dependent β -thalassemia, **both** of the following:
 - i. Has genetic testing confirming diagnosis of β -thalassemia
 - ii. Has a history of at least 100 mL/kg/year or 8 transfusion episodes/year of packed red blood cell transfusions in the prior 2 years.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for Casgevy (exagamglogene autotemcel). If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of Casgevy (exagamglogene autotemcel) will be approved for 18 months.

E. References

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3. Cappellini MD, Farmakis D, Porter J, Taher A, eds. 2021 Guidelines for the Management of Transfusion Dependent Thalassaemia (TDT). 4th ed. Thalassaemia International Federation (TIF). Available at: <https://thalassaemia.org.cy/>. Accessed March 2024.
4. Frangoul H, Altshuler D, Cappellini MD, et al. CRISPR-Cas9 gene editing for sickle cell disease and β -thalassemia. *N Engl J Med*. 2021;384:252-260.
5. Connor RF, Fosmarin AG, Tirnauer JS. What's new in hematology. UpToDate [internet database]. Waltham, MA: UpToDate Inc. Updated February 29, 2024. Accessed March 18, 2024.
6. Fitzjugh C. Investigational therapies for sickle cell disease. UpToDate [internet database]. DeBaun MR, Tirnauer JS, eds. Waltham, MA: UpToDate Inc. Updated December 22, 2023. Accessed March 15, 2024.

Prior Authorization Group Description	Chelating Agents
Drugs	<ul style="list-style-type: none"> • Chemet (succimer) capsule, <i>up to a 19 day supply, pays at point of sale</i> • Deferoxamine Mesylate (Desferal) Vial • Penicillamine (Cuprimine, Depen, D-penammine) capsule, tablet • Radiogardase (Prussian blue) capsule • Trientine (Syprine) capsule • Cuvrior (trientine tetrahydrochloride) tablet • Galzin (Zinc acetate) capsule • Pentetate calcium trisodium ampule • Penetate zinc trisdoium ampule • Calcium Disodium Versenate (edetate calcium disodium) ampule
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	See “other criteria”
Prescriber Restrictions	N/A
Coverage Duration	If the above conditions are met, the request will be approved with a 6 month duration.
Other Criteria	<p><u>Requests for Wilson’s Disease:</u></p> <p>Cuvrior (trientene tetrahydrochloride) only:</p> <ul style="list-style-type: none"> • Laboratory confirmed diagnosis of Wilson’s disease supported by at least one appropriate diagnostic test (e.g., slit lamp examination, 24-urinary copper excretion, serum ceruloplasmin, serum copper concentration, liver biopsy, genetic testing, brain imaging, etc.) • Patient is de-coppered • Patient is tolerant to penicillamine and will discontinue penicillamine before starting therapy with Cuvrior • The medication requested is being prescribed at an FDA approved dose <p>Trientine (Syprine) only:</p>

<p>Revision/Review Date 7/2025</p>	<ul style="list-style-type: none">• Laboratory confirmed diagnosis of Wilson’s disease supported by at least one appropriate diagnostic test (e.g., slit lamp examination, 24-urinary copper excretion, serum ceruloplasmin, serum copper concentration, liver biopsy, genetic testing, brain imaging, etc.)• Documented trial and failure, intolerance, or contraindication to penicillamine• The medication requested is being prescribed at an FDA approved dose <p><u>Requests for all other drugs and indications:</u></p> <ul style="list-style-type: none">• The drug is requested for an appropriate use (per the references outlined in “Covered Uses”)• The dose requested is appropriate for the requested use (per the references outlined in “Covered Uses”) <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Compound Products
Drugs	Compounds over \$250, compounds that include one or more ingredients that are non-formulary/require prior authorization, or compounds that have a safety edit on any ingredient.
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the 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 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>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Clinical rationale for using a compound product instead of an FDA approved product has been provided AND • Peer reviewed medical literature supporting use of compounded product for the indication being requested has been provided AND • For drugs included in the Statewide PDL, requirements from the associated Statewide PDL Prior Authorization Guidelines also apply if they are applicable to the indication being requested.
Revision/Review Date: 2/2026	<p><u>Reauthorization:</u></p> <ul style="list-style-type: none"> • Provider attests that patient has clinical improvement associated with use of compound product <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	Ivabradine
Drugs	Ivabradine (Corlanor)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Pregnancy
Required Medical Information	See “Other Criteria”
Age Restrictions	See “Other Criteria”
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist
Coverage Duration	If all of the conditions are met, the request will be approved for 12 month duration.
Other Criteria	<p>Heart Failure in Adult Patients:</p> <ol style="list-style-type: none"> 1. Member is aged 18 years or older 2. Member has a diagnosis of stable symptomatic chronic heart failure (NYHA functional class II-IV) with a left ventricular ejection fraction $\leq 35\%$ 3. Member is in sinus rhythm with a resting heart rate ≥ 70 beats per minute (bpm) 4. Member is currently being prescribed, or documentation has been provided that the member is not able to tolerate, an evidence based beta-blocker (i.e., bisoprolol, carvedilol, metoprolol succinate) at maximally tolerated dose <p>Heart Failure in Pediatric Patients:</p> <ol style="list-style-type: none"> 1. Member is aged 6 months to less than 18 years of age 2. Member has stable heart failure (NYHA/Ross functional class II-IV) due to dilated cardiomyopathy and a left ventricular ejection fraction $\leq 45\%$ 3. Member is in sinus rhythm with an elevated resting heart rate <p>Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p> <p>Revision/Review Date 2/2026</p>

Field Name	Field Description
Prior Authorization Group Description	Corticotropin
Drugs	Preferred: Cortrophin (corticotropin) Non-Preferred: Acthar (corticotropin)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	<ul style="list-style-type: none"> • N/A
Required Medical Information	See “other criteria”
Age Restrictions	See “other criteria”
Prescriber Restrictions	See “other criteria”
Coverage Duration	If the criteria are met, the request will be approved for up to a 1 month duration.
Other Criteria	<p><u>Infantile Spasms (West Syndrome):</u></p> <ul style="list-style-type: none"> • Patient is < 2 years of age • The medication is being prescribed by a neurologist. • Documentation of the patient’s current weight (in kg) and height/length (in cm) or body surface area (BSA) <p><u>Multiple Sclerosis:</u></p> <ul style="list-style-type: none"> • Documentation was submitted that patient is having an acute attack, with neurologic symptoms and increased disability or impairments in vision, strength or cerebellar function, and has failed therapy with intravenous (IV) methylprednisolone, or a medical reason has been submitted why patient is unable to use IV methylprednisolone. • The medication is being prescribed by a neurologist • If the request is for a non-preferred product, trial and failure of, contraindication to, or medical reason for not using the preferred product <p><u>All Other FDA Approved Conditions and Indications:</u></p> <ul style="list-style-type: none"> • Documented trial and failure of an IV corticosteroid AND an oral corticosteroid, or documented medical reason for why the patient cannot use these therapies for treatment • Documentation was provided that ALL other standard therapies have been used to treat the member’s condition as described in the medical compendium (Micromedex, AHFS, Drug Points, and package insert) as defined in the Social Security Act and/or per recognized standard of care guidelines OR there is a documented medical reason (i.e. medical intolerance, treatment failure, etc.) for why all other standard therapies could not be used to treat the member’s condition. • Prescriber is a specialist in the condition they are treating. • If the request is for a non-preferred product, trial and failure of, contraindication to, or medical reason for not using the preferred product

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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	Crenessity
Drugs	Crenessity (crinecerfont)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	<ul style="list-style-type: none"> • Patients with non-classic congenital adrenal hyperplasia (CAH) • Patients with adrenal insufficiency due to causes other than 21-hydroxylase deficiency
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by, or in consultation with, an endocrinologist or other specialist experienced in managing congenital adrenal hyperplasia
Coverage Duration	If all the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Medically confirmed diagnosis of classic 21-hydroxylase deficiency congenital adrenal hyperplasia (CAH) • Patient is currently on stable regimen of glucocorticoid therapy at a supraphysiological dose (i.e. >13 mg/m²/day in hydrocortisone dose equivalents for adults and >12 mg/m²/day in hydrocortisone dose equivalents for pediatric patients 4-17 years old) • Medication is prescribed at an FDA approved dose according to package insert (patient’s current weight must be provided) • For all adults and pediatric patients weighing ≥55 kg or patients weighing ≥20 kg if CYP3A4 dose adjustment is required: capsule formulation is requested, or documentation is provided that patient is unable to swallow capsule whole • Dosing requests for capsule formulations will employ strategies to minimize the total number of capsules used daily (i.e. “doubling up” on lower strength capsules to achieve a higher dose when the requested dose strength exists will not be authorized). <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation is provided that patient has successfully achieved a reduction in glucocorticoid dosage from baseline. • Medication is prescribed at an FDA approved dose according to package insert (patient’s current weight must be provided) • For all adults and pediatric patients weighing ≥55 kg or patients weighing ≥20 kg if CYP3A4 dose adjustment is required:

Date: 4/2025	<p>capsule formulation is requested, or documentation is provided that patient is unable to swallow capsule whole</p> <ul style="list-style-type: none">• Dosing requests for capsule formulations will employ strategies to minimize the total number of capsules used daily (i.e. “doubling up” on lower strength capsules to achieve a higher dose when the requested dose strength exists will not be authorized). <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
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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), Alyftrek (vanzacaftor/ tezacaftor/ deutivacaftor) or any newly marketed CFTR modulator to treat cystic fibrosis
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	See “Other Criteria”
Required Medical Information	See “Other Criteria”
Age Restrictions	See “Other Criteria”
Prescriber Restrictions	Prescriber is pulmonologist or specializes in the treatment of cystic fibrosis
Coverage Duration	If all of the conditions are met the initial request will be 6 months. Reauthorization requests will be 12 months.
Other Criteria	<p><u>Initial criteria:</u></p> <ul style="list-style-type: none"> • Documentation provided includes a copy of the FDA-cleared cystic fibrosis (CF) mutation test OR documentation from the National Cystic Fibrosis Registry (e.g. screen shot) with member’s genetic mutations • The request is for an FDA approved indication for the member’s genotype and within dosing guidelines • The request is appropriate for member (e.g. age/weight) based on FDA-approved package labeling, peer reviewed medical literature and nationally-recognized compendia. <p><u>Reauthorization:</u></p> <ul style="list-style-type: none"> • Based on prescriber’s assessment, patient continues to benefit from therapy • The request is within FDA dosing guidelines <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Danazol
Drugs	Danazol capsules
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Pregnancy
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	See “other criteria”
Coverage Duration	If the criteria are met, the request will be approved with a 6 month duration for generic medication.
Other Criteria	<p><u>ENDOMETRIOSIS</u></p> <ul style="list-style-type: none"> ○ Diagnosis of endometriosis ○ One of the following: <ul style="list-style-type: none"> ○ Documented trial and failure or medical reason for not using an analgesic pain reliever (e.g., NSAIDs, COX-2 inhibitors) taken in combination with a hormonal contraceptive (e.g. estrogen/progestin, progestin only) ○ Documented trial and failure of a gonadotropin-releasing hormone (GnRH) agonists or a GNRH antagonist. ○ Prescribing physician is a gynecologist. <p><u>HEREDITARY ANGIOEDEMA:</u></p> <ul style="list-style-type: none"> ○ Diagnosis of hereditary angioedema. ○ 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> <p>Revision/Review Date 10/2025</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.
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 <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>Revision/Review Date 10/2025</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	Daybue (trofinetide)
Drugs	Daybue (trofinetide)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or geneticist
Coverage Duration	If all the criteria are met, the initial request will be approved for 3 months. For continuation of therapy, the request will be approved for 6 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Medication is prescribed at an FDA approved dose • Diagnosis of classic or typical Rett Syndrome (RTT) • Documentation or attestation of mutation of the MECP2 gene • Documentation of patient weight • Documentation or provider attestation of all the following: <ul style="list-style-type: none"> ○ Baseline Rett Syndrome Behavior Questionnaire (RSBQ) score <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation or provider attestation of positive clinical response (i.e., decrease from baseline in RSBQ score, decrease in Clinical Global Impression–Improvement (CGI-I, etc.) • Medication is prescribed at an FDA approved dose <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 7/2025	

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 1. Elmiron (N30.11 or N30.10)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criterion is met, the request will be approved for up to a 12 month duration (depending on the diagnosis and usual treatment duration).
Other Criteria Revision/Review Date 4/2025	Provider has submitted a diagnosis that is FDA approved or referenced in disease state specific standard of care guidelines for the requested drug. (Please see covered uses section for appropriate sources) Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item

Field Name	Field Description
Prior Authorization Group Description	Dose Rounding Limit Exception Criteria
Drugs	Bevacizumab products (Avastin, Mvasi, Zirabev, Vegzelma, Alymsys) for oncologic indications
Covered Uses	All medically accepted indications. Medically accepted indications are defined using the following compendia resources: the Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), American Hospital Formulary Service Drug Information (AHFS-DI), and DRUGDEX Information System. The reviewer may also reference disease state specific standard of care guidelines.
Scope	Requests for drugs exceeding the health plan's dose rounding limits. For members 18 years of age and older, the dose will be rounded down to the nearest whole vial size if the rounded dose falls within 10% of the requested dose.
Criteria	<ul style="list-style-type: none"> • If the drug is subject to other criteria, the member must meet criteria for approval. • The provider has submitted justification why the dose-rounding will be inadequate based on the member's condition and treatment history. Exceptions may include but are not limited to: <ul style="list-style-type: none"> ○ Member previously demonstrated a suboptimal or partial response to therapy at a rounded dose ○ Rounded dose is unavailable due to manufacturer supply/shortage issues ○ Provider has a documented medical reason why dose rounding is inappropriate for the member <p style="text-align: center;">Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Coverage Duration	6 months
Revision/Review Date	2/2025

Field Name	Field Description
Prior Authorization Group Description	Duvyzat
Drugs	Duvyzat (givinostat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or provider who specializes in the treatment of Duchenne Muscular Dystrophy (DMD)
Coverage Duration	If all the criteria are met, the initial request will be approved for 12 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Medication is prescribed at an FDA approved dose according to body weight • Genetically confirmed diagnosis of DMD and copies of testing were submitted with request • Patient has been stable on baseline corticosteroids for at least 6 months unless contraindicated or intolerant • Patient's platelet count is $\geq 150 \times 10^9/L$ <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation or provider attestation of positive clinical response (such as improved muscle function, muscle strength, or disease stabilization based on prescriber's assessment) • Patient is on concurrent corticosteroid treatment unless contraindicated or intolerant • Medication is prescribed at an FDA approved dose according to body weight <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
Review/Revision Date: 7/2025	

Field Name	Field Description
Prior Authorization Group Description	Elevidys
Drugs	Elevidys (delandistrogene moxeparvovec-rokl)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	<ul style="list-style-type: none"> • Any deletion in exon 8 and/or exon 9 in the Duchenne Muscular Dystrophy (DMD) gene • Concurrent use with an exon skipping drugs (such as Exondys 51, Amondys 45, Vyondys 53, Viltepsa)
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or provider who specializes in the treatment of DMD
Coverage Duration	If all the criteria are met, the initial request will be approved for a one-time treatment .
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Medication is prescribed at an FDA approved dose • Documentation of weight • Genetically confirmed diagnosis of DMD and copies of testing were submitted with request • Attestation patient is ambulatory • Attestation patient has anti-recombinant adeno-associated virus serotype rh74 (anti-AAVrh74) total binding antibody titers of less than 1:400 • Attestation prescriber has assessed the safety and monitoring requirements in the labeling and determined the patient is an appropriate candidate for Elevidys, including: <ul style="list-style-type: none"> ○ liver function ○ platelet counts and troponin-I levels ○ current or recent infections ○ recent vaccinations <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
Revision/Review Date: 12/2025	

Field Name	Field Description
Prior Authorization Group Description	Encelto
Drugs	Encelto (revakinagene taroretcel-lwey)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the 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 an ophthalmologist or specialist in the treatment of macular telangiectasia (MacTel) type 2
Coverage Duration	If all criteria are met, the request will be approved for a single implant per eye per lifetime.
Other Criteria	<p><u>Initial Authorization</u></p> <ul style="list-style-type: none"> • Confirmed diagnosis of idiopathic MacTel type 2 • Inner segment (IS)/outer segment (OS) photoreceptor (PR) break (loss) in ellipsoid zone (EZ) between 0.16 and 2.00 mm² measured by spectral domain-optical coherence tomography (SD-OCT) • Best corrected visual acuity (BCVA) score of 54 letters or better (20/80 or better Snellen equivalent) measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) chart • Prescriber attests that member has no evidence of neovascular MacTel type 2 • Member has not previously received an Encelto implant for treated eye <p>***Reauthorizations are not permitted, as members are limited to a single implant per eye per lifetime.***</p>
Revision/Review Date: 7/2025	Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Immunoglobulin A (IgA) Nephropathy Agents
Drugs	Fabhalta (iptacopan), Filspari (sparsentan), Vanrafia (atrasentan), Voyxact (sibeprenlimab-szsi)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	For Filspari and Vanrafia only: <ul style="list-style-type: none"> • Pregnancy
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist
Coverage Duration	If the criteria are met, the criteria will be approved as follows: Initial requests: <ul style="list-style-type: none"> • 6 months: Fabhalta • 9 months: Filspari, Vanrafia, Voyxact Reauthorization: <ul style="list-style-type: none"> • 12 months: Fabhalta, Filspari, Vanrafia, Voyxact
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of primary IgA nephropathy verified by biopsy • Member is on an ACE inhibitor or ARB at a maximally tolerated dose OR there is a medical reason that they cannot be on one • Member is on an SGLT2 inhibitor at a maximally tolerated dose OR there is a medical reason that they cannot be on one • Member has proteinuria (defined as total urine protein ≥ 1 g/day) • Member has an estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73 m² • Medication is prescribed at an FDA approved dose • For Fabhalta: <ul style="list-style-type: none"> ○ Documentation patient complies with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria ○ Member is at risk for disease progression as defined by a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g ○ Documentation of trial and failure, intolerance, or contraindication to Filspari • For Filspari: <ul style="list-style-type: none"> ○ Documentation of baseline liver function ○ Attestation that member will discontinue use of renin-angiotensin-aldosterone system (RAAS) inhibitors, endothelin receptor antagonists, and/or aliskiren upon initiation of Filspari

<p>Revision/Review Date: 2/2026</p>	<ul style="list-style-type: none">• For Vanrafia:<ul style="list-style-type: none">○ Member is at risk for disease progression as defined by a urine protein-to-creatinine ratio (UPCR) \geq 1.5 g/g○ Documentation of trial and failure, intolerance, or contraindication to Filspari• For Voyxact:<ul style="list-style-type: none">○ Documentation of trial and failure, intolerance, or contraindication to Tarpeyo <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none">• Documentation of positive clinical response (e.g. decrease in UPCR, stabilization of eGFR)• Medication is prescribed at an FDA approved dose• For Filspari:<ul style="list-style-type: none">○ Documentation of liver function <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
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Field Name	Field Description
Prior Authorization Group Description	Enzyme Replacement Therapies for Fabry Disease
Drugs	Fabrazyme (agalsidase beta) Elfabrio (peguniigalsidase alfa)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to the FDA approved prescribing information
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, cardiologist, nephrologist or specialist experienced in the treatment of Fabry disease
Coverage Duration	Initial Authorization: If the criteria are met, the request will be approved for a 6-month duration. Reauthorization: If the criteria are met, the request will be approved for a 12-month duration.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Male members must have a documented diagnosis of Fabry disease confirmed by <u>one</u> of the following: <ol style="list-style-type: none"> 1. An undetectable (<1%) alpha galactosidase A (alpha-Gal-A) activity level OR 2. A deficient alpha-Gal- activity level AND a documented detection of pathogenic mutations in the galactosidase alpha (<i>GLA</i>) gene by molecular genetic testing • Female members must have a documented diagnosis of Fabry disease confirmed by detection of pathogenic mutations in the <i>GLA</i> gene by molecular genetic testing AND evidence of clinical manifestation of the disease (e.g. kidney, neurologic, cardiovascular, gastrointestinal) • Member must not be using concurrently with Galafold (migalastat) • Documentation of the member’s current weight • Request is for an FDA-approved dose <p><u>Re-Authorization:</u></p>

<p>Revision/Review Date: 7/2025</p>	<ul style="list-style-type: none">• Documentation that member has experienced an improvement in symptoms from baseline including but not limited to: decreased pain, decreased gastrointestinal manifestations, decrease in proteinuria, stabilization of increase in eGFR, reduction of left ventricular hypertrophy (LVH) on echocardiogram, or improved myocardial function, or has remained asymptomatic• Member must not be using concurrently with Galafold (migalastat)• Documentation of the member's current weight• Request is for an FDA-approved dose <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Forzinity (elamipretide)
Drugs	Forzinity (elamipretide)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	See “Other Criteria”
Required Medical Information	See “Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by a cardiologist, endocrinologist, hematologist, geneticist, neurologist, or other provider specializing in the treatment of Barth Syndrome.
Coverage Duration	If the criteria are met, the request will be approved for up to 6 months for initial requests, and 12 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 Revision/Review Date: 2/2026	<p>Initial Authorization:</p> <ul style="list-style-type: none"> • Diagnosis of Barth Syndrome confirmed via identification of mutations in the TAZ gene per genetic testing • Patient’s current weight is provided with the request and is ≥ 30 kg • Pediatrics: patient does not have renal impairment • Adults: patient is not on dialysis • Requested dose is within FDA approved dosing guidelines <p>Renewal Requests:</p> <ul style="list-style-type: none"> • Patient has not experienced a serious hypersensitivity reaction to Forzinity • Documentation or provider attestation of clinical benefit (i.e. 6-minute walk test, Total Fatigue Score on the Barth syndrome Symptom Assessment, muscle strength, cardiac function, etc.) <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	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>If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.</p>
Revision/Review Date:	10/2025

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

<p>Revision/Review Date 2/2026</p>	<p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Gene Therapy for Hemophilia B
Drugs	Hemgenix (etranacogene dezaparvovec)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Patient has previously received treatment with Hemgenix or Beqvez
Required Medical Information	See "Other Criteria"
Age Restrictions	Patient must be 18 years of age or older
Prescriber Restrictions	Prescriber must be a hematologist
Coverage Duration	If all the criteria are met, the initial request will be approved for a one-time treatment for one gene therapy agent for Hemophilia B.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of Hemophilia B (congenital Factor IX deficiency) with ONE of the following: <ul style="list-style-type: none"> ○ Currently using Factor IX prophylaxis therapy ○ Has current or historical life-threatening hemorrhage ○ Has repeated, serious spontaneous bleeding episodes • Documentation that patient has $\leq 2\%$ of normal circulating Factor IX) • Prescriber attests they have performed liver health assessments • Documented Factor IX inhibitor titer test showing the patient is negative for Factor IX inhibitors • Patient's weight • Medication is prescribed at an FDA approved dose <p>The safety and effectiveness of repeat administration of Hemgenix has not been evaluated and will not be approved.</p> <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>

Date: 7/2025

Field Name	Field Description
Prior Authorization Group Description	Hydroxyprogesterone caproate (generic Delalutin)
Drugs	Hydroxyprogesterone caproate (generic Delalutin)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Pregnancy
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a gynecologist or in consultation with a gynecologist
Coverage Duration	If all the criteria are met, the initial request will be approved for up to 6 months. For continuation of therapy, the request will be approved for up to 6 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Medication is prescribed at an FDA approved dose • If request is for preterm birth, do not approve • Request is for one of the following indications: <ul style="list-style-type: none"> ○ Amenorrhea or abnormal uterine bleeding due to hormonal imbalance ○ Production of secretory endometrium and desquamation ○ Test for endogenous estrogen production ○ Advanced uterine adenocarcinoma <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation or provider attestation of clinical benefit • Medication is prescribed at an FDA approved dose <p>If all the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>

Date: 4/2025

Field Name	Field Description
Prior Authorization Group Description	Topical mTOR Kinase Inhibitors
Drugs	Hyftor (sirolimus topical gel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	Member concomitantly taking an oral mTOR inhibitor
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be 6 years or older
Prescriber Restrictions	Prescriber must be a dermatologist, medical geneticist, neurologist, or other prescriber who specializes in the treatment of genetic or dermatologic disorders.
Coverage Duration	If the criteria are met, requests will be approved with up to a 3 month duration. Thereafter, reauthorization requests will be approved with up to a 6 month duration.
Other Criteria	<p>Initial Authorization:</p> <ul style="list-style-type: none"> • Member has a confirmed diagnosis of tuberous sclerosis complex (TSC) • Member has at least 3 facial angiofibromas measuring 2 mm or larger in diameter • Documentation of a comprehensive dermatologic evaluation has been provided • Prescriber attests that the member is not a candidate for laser therapy or surgery • Medication is being prescribed at an FDA approved dose <p>Reauthorization:</p> <ul style="list-style-type: none"> • Documentation has been provided indicating that the member has experienced a clinical benefit from treatment (e.g. improvement in size and color of angiofibromas) • Documentation of a comprehensive dermatologic evaluation has been provided • Prescriber attests that the member is not a candidate for laser therapy or surgery • Medication is being prescribed at an FDA approved dose
Revision/Review Date 4/2025	

Prior Authorization Group Description	Imcivree (setmelanotide)
Drugs	Imcivree (setmelanotide)
Covered Uses	Medically accepted indications are defined using the following 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	Prescribed by or in consultation with medical geneticist, endocrinologist, or specialist in metabolic disorders
Coverage Duration	If the criteria are met, the request will be approved for 6 months, or 12 months for BBS.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Requested dose is appropriate per labeling • Documentation of current weight and body mass index (BMI) • BMI/weight must be one of the following: <ol style="list-style-type: none"> 1. BMI of 27 - 29.9 kg/m² with one of the following weight-related comorbidities: coronary artery disease, diabetes, hypertension, dyslipidemia, or obstructive sleep apnea 2. BMI of 30 kg/m² or more 3. For pediatric patients with: <ul style="list-style-type: none"> - POMC, PCSK1, or LEPR Deficiency: weight must be ≥ 95th percentile for age on growth chart assessment - Bardet-Biedl syndrome: weight must be ≥ 97th percentile for age on growth chart assessment • Documentation of counseling regarding lifestyle changes and behavioral modification (e.g. healthy diet and increased physical activity) • The patient meets one of the following: <ol style="list-style-type: none"> 1. Diagnosis of Bardet-Biedl syndrome (BBS) 2. Obesity is related to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency AND: <ol style="list-style-type: none"> a. Deficiency is documented by an FDA-approved genetic test confirming variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance b. POMC, PCSK1, or LEPR variants classified as benign or likely benign will not be approved <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation of at least 5% reduction in body weight compared with baseline or 5% of baseline BMI for patients with continued growth potential OR • For patients who had a baseline BMI of 27 - 29.9 kg/m² with a weight-related comorbidity 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>
Revision/Review Date: 10/2025	

Field Name	Field Description
Prior Authorization Group Description	Immune Globulins
Drugs	<p>Gamunex-C (IV or SQ) (Immune Globulin) Bivigam (IV) (Immune Globulin) Cuvitru (SQ) (Immune Globulin) Flebogamma (IV) (Immune Globulin) Gammagard liquid (IV or SQ) (Immune Globulin) Gammagard SD (IV) (Immune Globulin) Gammaked (IV or SQ) (Immune Globulin) Gammaplex (IV) (Immune Globulin) Hizentra (SQ) (Immune Globulin) Octagam (IV) (Immune Globulin) Privigen (IV) (Immune Globulin) Asceniv (IV) (Immune Globulin-slra) Cutaquig (SQ) (Immune Globulin-hipp) Panzyga (IV) (Immune Globulin-ifas) Hyqvia (SQ) (Immune Globulin Human/Recombinant Human Hyaluronidase) Xembify (SQ) (Immune Globulin-klhw) Alyglo (IV) (Immune Globulin-stwk) Or any newly marketed immune globulin</p> <p style="text-align: center;">**Gamunex-C is the preferred product for the indications of primary immunodeficiency, chronic idiopathic thrombocytopenic purpura, and chronic inflammatory demyelinating polyneuropathy**</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"> • Documentation of diagnosis confirmed by a specialist • Member has tried and failed, or has a documented medical reason for not using, all other standard of care therapies as defined per recognized guidelines • Member’s height and weight are provided • Dosing will be calculated using ideal body weight (IBW), unless ONE of the following: <ul style="list-style-type: none"> ○ 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, or a documented specific antibody deficiency is provided
- 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 $< 20,000$ /ul and is at risk for intra-cerebral hemorrhage or has life threatening bleeding, or has an inadequate increase in platelets from corticosteroids or is unable to tolerate corticosteroids
 - Dose does not exceed 1g/kg daily for up to 2 days, or 400mg/kg daily for 5 days
- Chronic:
 - Duration of illness is greater than 12 months
 - Member has documented trial and failure of corticosteroids and splenectomy, or has a documented medical reason why they are not able to use corticosteroids or member is at high risk for post-splenectomy sepsis.
 - Dose does not exceed 1g/kg daily for up to 2 days, or 400mg/kg daily for 5 days
- If the request is for any medication other than Gamunex-C, the member has tried and failed, or has a documented medical reason for not using, Gamunex-C
- If criteria is met, approve for up to 5 days.

Kawasaki disease:

- Immunoglobulin is being given with high dose aspirin unless contraindicated
- Requested dose does not exceed a single 2g/kg dose

- If criteria is met, approve for 1 dose

Chronic B-cell lymphocytic leukemia:

- The patient has had recurrent infections requiring IV antibiotics or hospitalization and has a serum IgG of <500 mg/dL
- Dose does not exceed 500mg/kg every 3-4 weeks

- If criteria is met, approve for 3 months.

Bone marrow transplantation:

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

- If criteria is met, approve for 3 months.

Pediatric HIV:

- Patient is < 13 years of age
- Either patient's IgG level is < 400mg/dL or
- If patient's IgG level is ≥ 400 mg/dL than significant deficiency of humoral immunity as evidenced by ONE of the following:
 - Inability to produce an adequate immunologic response to specific antigens.
 - History of recurrent bacterial infections despite prophylactic antibiotics
- Dose does not exceed 400mg/kg/dose every 2-4 weeks

- If criteria is met, approve for 3 months.

Multifocal motor neuropathy (MMN):

- Duration of symptoms has been at least 1 month with disability.
- Nerve conduction studies were completed to rule out other possible conditions, and confirms the diagnosis of MMN.
- Dose does not exceed 2.4 g/kg/month administered over 2 to 5 days.

- If criteria is met, approve for up to 5 days for 6 months.

Chronic inflammatory demyelinating polyneuropathy (CIDP):

- Duration of symptoms has been at least 2 months with disability.
- Nerve conduction studies or a nerve biopsy were completed in order to rule out other possible conditions, and confirms the diagnosis of CIDP.

- Patient has tried and failed, or has a documented medical reason for not using, corticosteroids.
 - If the patient has severe and fulminant or pure motor CIDP a trial of corticosteroids is not required
- Dose is consistent with FDA approved package labeling, nationally recognized compendia, or peer-reviewed literature
- If the request is for any medication other than Gamunex-C, the member has tried and failed, or has a documented medical reason for not using, Gamunex-C
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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)
- Attestation that patient has been screened for malignancy
- For a diagnosis of DM, one of the following:
 - Member has tried and failed, or has a documented medical reason for not using both of the following:
 - methotrexate (MTX) OR azathioprine
 - rituximab.
 - Member has severe, life-threatening weakness or dysphagia
- For a diagnosis of cutaneous DM (i.e. amyopathic DM, hypomyopathic DM):

- Member has tried and failed, or has a documented medical reason for not using all of the following: MTX and mycophenolate mofetil.
- Dose does not exceed 2 g/kg administered over 2-5 days every 4 weeks.
- If criteria is met, approve for up to 3 months.

If criteria is met, the request will be approved for the duration listed above. If the criteria is not met, the request is referred to a Medical Director/Clinical reviewer for medical necessity review.

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

Revision/Review
Date 10/2025

Field Name	Field Description
Prior Authorization Group Description	Increlex
Drugs	Increlex (mecasermin [recombinant human insulin-like growth factor-1])
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	≥ 2 years to < 18 years
Prescriber Restrictions	Prescribed by or in consultation with an Endocrinologist or specialist in the treatment of pediatric growth disorders
Coverage Duration	If all of the conditions are met, the request will be approved for 12 months.
Other Criteria	<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 <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 7/2025	

Prior Authorization Group Description	InPen
Drugs	InPen
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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	Age 7 years and older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	If all of the criteria are met, the request will be approved 1 system per year
Other Criteria	<p><u>Initial Authorization</u></p> <ul style="list-style-type: none"> • Patient has a diagnosis of diabetes and requires use of insulin • Treatment with multiple daily doses (≥ 3) of insulin • Medical justification supports necessity of the digital component (i.e., rationale why insulin dose/usage cannot be calculated/tracked manually such as member has an intellectual disability, or no caregivers are available to assist with insulin dose calculation) <p><u>Reauthorization</u></p> <ul style="list-style-type: none"> • Patient has a diagnoses of diabetes and requires use of insulin • Continued use of multiple daily doses (≥ 3) of insulin • Medical justification supports continued necessity of the digital component <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date: 2/2025	

Field Name	Field Description
Prior Authorization Group Description	HIF-PH Inhibitors for CKD Anemia
Drugs	Vafseo (vadadustat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Diagnosis of uncontrolled hypertension
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be at least 18 years of age
Prescriber Restrictions	Prescriber must be a hematologist or nephrologist
Coverage Duration	If all conditions are met, the request will be approved with a 6-month duration.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Member has a diagnosis of chronic kidney disease (CKD) and has been undergoing dialysis for minimum time required by FDA-approved labeling • Member has a documented hemoglobin between 8.0 and 11.0 g/dL • Member has documentation of trial and failure, intolerance, contraindication, or inability to use erythropoietin stimulating agents (ESA) • The following lab results must be submitted and demonstrate normal values, otherwise, the member <u>MUST</u> be receiving, or is beginning therapy, to correct the deficiency: <ul style="list-style-type: none"> ○ Serum ferritin level (> 100ng/mL) ○ Transferrin saturation (TSAT) (> 20%) • Provider attests that member has no history of myocardial infarction, cerebrovascular event, or acute coronary syndrome in the past 3 months • Member will not be receiving concurrent treatment with an ESA • Request is for an FDA-approved dose • All submitted lab results have been drawn within 30 days of the request <p><u>Reauthorization:</u></p> <ul style="list-style-type: none"> • All submitted lab results have been drawn within 30 days of the reauthorization request. • Member has a documented increase in hemoglobin from baseline • The following lab results must be submitted and demonstrate normal values, otherwise, the member <u>MUST</u> be receiving, or is beginning therapy, to correct the deficiency:

<p>Revision/ Review Date: 10/2025</p>	<ul style="list-style-type: none">○ Serum ferritin level (> 100ng/mL)○ Transferrin saturation (TSAT) (> 20%)● Member will not be receiving concurrent treatment with an ESA● Request is for an FDA-approved dose <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary</p>
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Field Name	Field Description
Prior Authorization Group Description	Joenja
Drugs	Joenja (leniolisib)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Per prescribing information.
Prescriber Restrictions	Prescriber must be an immunologist, hematologist, medical geneticist, or other prescriber who specializes in the treatment of genetic or immunologic disorders.
Coverage Duration	If the criteria are met, requests will be approved with up to a 6-month duration. Thereafter, reauthorization requests will be approved with up to a 12-month duration.
Other Criteria	<p>Initial Authorization:</p> <ul style="list-style-type: none"> • Documentation of APDS/PASLI-associated PIK3CD/PIK3R1 mutation, confirmed by genetic testing. • Documentation of nodal and/or extranodal lymphoproliferation, clinical findings consistent with ADPS (including history of repeated oto-sino-pulmonary infections, recurrent herpesvirus infections), and/or organ dysfunction (e.g., lung, liver) • Prescriber attests that female patients with reproductive potential have been advised of the potential risk to a fetus, will use effective contraception and have had a negative pregnancy test prior to initiation of treatment. • Medication is being prescribed at an FDA approved dose <p>Reauthorization:</p> <ul style="list-style-type: none"> • Documentation has been submitted indicating member has experienced a clinical benefit from treatment (e.g., decreased lymph node size, increase in percentage of naïve B cells) • Prescriber attests that female patients with reproductive potential will use effective contraception • Medication is being prescribed at an FDA approved dose <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 7/2025	

Field Name	Field Description
Prior Authorization Group Description	Kebilidi (eladocagene exuparvovec-tneq)
Drugs	Kebilidi (eladocagene exuparvovec-tneq)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Previous treatment with gene therapy
Required Medical Information	See “Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a geneticist or neurologist.
Coverage Duration	If all the criteria are met, the request will be approved for one treatment per lifetime (4 infusions).
Other Criteria Review/Revision Date: 4/2025	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Medication is prescribed at an FDA approved dose • Documentation of genetically confirmed diagnosis of aromatic L-amino acid decarboxylase (AADC) deficiency evidenced by biallelic mutations in the <i>DDC</i> gene (copy of genetic test submitted with request) • Documentation of skull maturity confirmed by neuroimaging • Patient has classic clinical characteristics (e.g. oculogyric crises, hypotonia, developmental delay) of AADC deficiency that are not well-managed by symptomatic control drugs (i.e. dopamine agonists, monoamine oxidase inhibitor, pyridoxine, etc.) <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	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) ○ Bisphosphonate (in the setting of abnormal uptake on bone scan)

Revision/Review Date 4/2025	Re-authorization: <ul style="list-style-type: none">• Patient has demonstrated clinical benefit. Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.
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Field Name	Field Description
Prior Authorization Group Description	Kisunla
Drugs	Kisunla (donanemab-azbt)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Patients with moderate to severe Alzheimer’s Disease (AD) Patients with neurodegenerative disease caused by a condition other than AD
Required Medical Information	See “Other Criteria”
Age Restrictions	Age 60-85 years
Prescriber Restrictions	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 dementia consistent with Stage 3 or Stage 4 Alzheimer’s disease as evidenced by at least one of the following: <ul style="list-style-type: none"> ○ Clinical Dementia Rating Global (CDR-G) score of 0.5-1.0 ○ Mini-Mental State Examination (MMSE) score ≥ 20 and ≤ 28 ○ Montreal Cognitive Assessment (MoCA) score of ≥ 16 • The request is for an FDA approved dose • Documentation of BOTH of the following: <ul style="list-style-type: none"> ○ Recent, within past year, positive results for the presence of beta-amyloid plaques on a positron emission tomography (PET) scan or cerebrospinal fluid testing ○ Recent, within past year, baseline Magnetic Resonance Imaging (MRI) scan • Physician has assessed baseline disease severity utilizing an objective measure/tool (i.e., integrated Alzheimer's Disease Rating Scale [iADRS], Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog], Alzheimer's Disease Cooperative Study-instrumental Activities of Daily Living [ADCS-iADL], Clinical Dementia Rating-Sum of Boxes [CDR-SB], etc.) • No recent (past 1 year) history of stroke, seizures or transient ischemic attack (TIA), or findings on neuroimaging that indicate an increased risk for intracerebral hemorrhage <p><u>Reauthorization</u></p> <ul style="list-style-type: none"> • The request is for an FDA approved dose • Patient continues to have a diagnosis of MCI caused by AD or mild AD dementia consistent with Stage 3 or Stage 4 Alzheimer’s disease as evidenced by at least one of the following: <ul style="list-style-type: none"> ○ CDR-G score of 0.5-1.0 ○ MMSE score of 20-28 ○ MoCA score of ≥ 16

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Prior Authorization Group	Phenylalanine Hydroxylase Activators
Drug(s)	Sapropterin dihydrochloride (Kuvan), Sephience (sepiapterin),
Covered Uses	Medically accepted indications are defined using the following 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	Initial: If the criteria is met, the request will be approved for a duration of 1 month Reauthorization: If the criteria is met, sapropterin requests 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. Sephience requests will be approved for a duration of 1 month for patients who require a dose increase from their previous dose (up to a max dose of 60 mg/kg/day) due to non-responsiveness. For all other patients the request will be approved for a duration of 3 months
Other Criteria	INITIAL AUTHORIZATION: <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, receipts, or chart notes (within 30 days of request) that the patient is currently utilizing a Phe-restricted diet • For Sephience: Documented trial and failure, intolerance, or contraindication to sapropterin in combination with Phe- restricted diet • Documentation of the patient’s current weight. • The medication is being prescribed at an FDA approved dosage <p>REAUTHORIZATION: <i>For sapropterin: Patients that were dosed at 20mg/kg/day and did not have a decrease in Phe from baseline, are considered NON RESPONDERS and NO ADDITIONAL TREATMENT will be authorized.</i> <i>For Sephience: Patients that were dosed at 60 mg/kg/day and did not have a decrease in Phe from baseline, are considered NON RESPONDERS and NO ADDITIONAL TREATMENT will be authorized.</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). • 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>
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Field Name	Field Description
Prior Authorization Group Description	Lamzede
Drugs	Lamzede (velmanase alfa-tycv)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	“See Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a specialist in the treatment of alpha-mannosidosis or other lysosomal storage disorders
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months
Other Criteria	<p>Initial Authorization</p> <ul style="list-style-type: none"> • Diagnosis of alpha-mannosidosis as confirmed by one of the following: <ul style="list-style-type: none"> ○ Deficiency in alpha-mannosidase enzyme levels or activity in blood leukocytes ○ DNA testing • Prescriber attests that medication will only be used to treat non-central nervous system manifestations of alpha-mannosidosis • Patient’s weight • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines <p>Reauthorization</p> <ul style="list-style-type: none"> • Patient has demonstrated a clinical response (i.e., reduction in serum oligosaccharide concentrations, stabilization or improvement in 3-minute stair climbing test [3MSCT], 6-minute walking test [6-MWT], forced vital capacity [FVC], etc.) • Prescriber attests that medication will only be used to treat non-central nervous system manifestations of alpha-mannosidosis • Patient’s weight • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines
Revision/Review Date 4/2025	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	Lenmeldy
Drugs	Lenmeldy (atidarsagene autotemcel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by a neurologist, hematologist/oncologist, or geneticist
Coverage Duration	If all the criteria are met, the initial request will be approved for a one-time treatment.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Member has diagnosis of one of the following metachromatic leukodystrophies (MLD): <ul style="list-style-type: none"> ○ Pre-symptomatic late infantile (PSLI) MLD ○ Pre-symptomatic early juvenile (PSEJ) MLD ○ Early symptomatic early juvenile (ESEJ) MLD • Documentation patient has both of the following: <ul style="list-style-type: none"> ○ Arylsulfatase A (ARSA) activity below the normal range (normal range 31-198 nmol/mg/h) ○ Identification of two disease-causing ARSA alleles • Medication is prescribed at an FDA approved dose <p>The safety and effectiveness of repeat administration of Lenmeldy has not been evaluated and will not be approved.</p> <p>If all the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
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Field Name	Field Description
Prior Authorization Group Description	Leqembi
Drugs	Leqembi (lecanemab-irmb)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Patients with moderate to severe Alzheimer’s Disease (AD) Patients with neurodegenerative disease caused by a condition other than AD
Required Medical Information	See “Other Criteria”
Age Restrictions	age 50-90 years
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	For initial and reauthorizations: if all of the conditions are met, the request will be approved for 6 months.
Other Criteria	<p><u>Initial Authorization</u></p> <ul style="list-style-type: none"> • Diagnosis of mild cognitive impairment (MCI) caused by AD or mild AD consistent with Stage 3 or Stage 4 Alzheimer’s disease as evidenced by at least one of the following: <ul style="list-style-type: none"> ○ Clinical Dementia Rating Global (CDR-G) score of 0.5-1.0 and a Memory Box score of 0.5 or greater ○ Mini-Mental State Examination (MMSE) score ≥ 22 and ≤ 30 ○ Wechsler Memory Scale IV-Logical Memory (subscale) II (WMS-IV LMII) score at least 1 standard deviation below age-adjusted mean • The request is for an FDA approved dose • Documentation of BOTH of the following: <ul style="list-style-type: none"> ○ Recent, within past year, positive results for the presence of beta-amyloid plaques on a positron emission tomography (PET) scan or cerebrospinal fluid testing ○ Recent, within past year, baseline Magnetic Resonance Imaging (MRI) scan • Physician has assessed baseline disease severity utilizing an objective measure/tool (i.e., Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog-14], Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory-Mild Cognitive Impairment version [ADCS-ADL-MCI], Clinical Dementia Rating Sum of Boxes [CDR-SB], etc.)

- No recent (past 1 year) history of stroke, seizures or transient ischemic attack (TIA), or findings on neuroimaging that indicate an increased risk for intracerebral hemorrhage.

Reauthorization

- The request is for an FDA approved dose
- Patient continues to have a diagnosis of mild cognitive impairment (MCI) caused by AD or mild AD consistent with Stage 3 or Stage 4 Alzheimer’s disease as evidenced by at least one of the following:
 - CDR-G score of 0.5-1.0 and a Memory Box score of 0.5 or greater
 - MMSE score of 22-30
 - Wechsler Memory Scale IV-Logical Memory (subscale) II (WMS-IV LMII) score at least 1 standard deviation below age-adjusted mean
- Provider attestation of safety monitoring and management of amyloid related imaging abnormalities (ARIA) and intracerebral hemorrhage, as recommended per the manufacturer’s prescribing information.
- Documentation that member has experienced clinical benefit from the medication (such as: stabilization or decreased rate of decline in symptoms from baseline on CDR-SB, ADAS-Cog14, or ADCS MCI-ADL scales)
- No recent (past 1 year) history of stroke, seizures, or TIA

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If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.

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

I. Requirements for Prior Authorization of Lyfgenia (lovotibeglogene autotemcel)

A. Prescriptions That Require Prior Authorization

All prescriptions for Lyfgenia (lovotibeglogene autotemcel) must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Lyfgenia (lovotibeglogene autotemcel), the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed Lyfgenia (lovotibeglogene autotemcel) for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling; **AND**
2. Is age-appropriate according to FDA-approved package labeling; **AND**
3. Is prescribed a dose and number of treatments that are consistent with FDA-approved package labeling; **AND**
4. Is prescribed Lyfgenia (lovotibeglogene autotemcel) by a specialist at a qualified treatment center for Lyfgenia (lovotibeglogene autotemcel); **AND**
5. Does not have a contraindication to the prescribed drug; **AND**
6. Is clinically stable for transplantation based on the prescriber's assessment; **AND**
7. For treatment of sickle cell disease, **both** of the following:
 - a. Has sickle cell disease with confirmatory genetic testing
 - b. **One** of the following:
 - i. Has a history of vaso-occlusive episodes (e.g., pain crises, acute chest syndrome, splenic sequestration, priapism) that required a medical facility visit (e.g., emergency department, hospital)
 - ii. Is currently receiving chronic transfusion therapy for recurrent vaso-occlusive episodes.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for Lyfgenia (lovotibeglogene autotemcel). If the guidelines in Section B. are met, the reviewer will

prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of Lyfgenia (lovotibeglogene autotemcel) will be approved for 18 months.

E. References

1. Lyfgenia [prescribing information]. Somerville, MA: bluebird bio, Inc; December 2023.
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3. Connor RF, Fosmarin AG, Tirnauer JS. What's new in hematology. UpToDate [internet database]. Waltham, MA: UpToDate Inc. Updated February 29, 2024. Accessed March 18, 2024.
4. Fitzjugh C. Investigational therapies for sickle cell disease. UpToDate [internet database]. DeBaun MR, Tirnauer JS, eds. Waltham, MA: UpToDate Inc. Updated December 22, 2023. Accessed March 15, 2024.

Field Name	Field Description
Prior Authorization Group Description	Atovaquone Suspension
Drugs	Atovaquone (Mepron) suspension
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 6 month duration.
Other Criteria	<p><u>Treatment/Prevention of <i>Pneumocystis jirovecii</i> pneumonia</u></p> <ul style="list-style-type: none"> • Diagnosis of mild to moderate <i>Pneumocystis jirovecii</i> pneumonia (PCP) or diagnosis with the need to prevent PCP infection • Documented trial and failure with therapeutic doses or intolerance to trimethoprim- sulfamethoxazole (TMP-SMX). • Documented trial and failure with therapeutic doses or intolerance to dapsone. <p><u>Treatment/Prevention of <i>Toxoplasma gondii</i> encephalitis in patients with HIV:</u></p> <ul style="list-style-type: none"> • Diagnosis of <i>Toxoplasma gondii</i> encephalitis or documentation of supporting diagnosis for prophylaxis • Documented trial and failure with therapeutic doses or intolerance to trimethoprim- sulfamethoxazole (TMP-SMX). <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Mucopolysaccharidosis II (Hunter Syndrome) Agents
Drugs	Elaprase (idursulfase)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	“See Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a specialist in the management Mucopolysaccharidosis II (geneticist, endocrinologist, neurologist, rheumatologist, etc.)
Coverage Duration	Initial Authorization: 6 months Reauthorization: 12 months
Other Criteria	<p>Initial Authorization</p> <ul style="list-style-type: none"> ● Diagnosis of Mucopolysaccharidosis II as confirmed by one of the following: <ul style="list-style-type: none"> ○ Enzyme assay demonstrating a deficiency of iduronate 2-sulfatase activity ○ Genetic testing ● Patient’s weight ● Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines <p>Reauthorization</p> <ul style="list-style-type: none"> ● Patient has demonstrated a beneficial response (i.e., stabilization or improvement in 6-minute walk test [6-MWT], forced vital capacity [FVC]), urinary glycosaminoglycan (GAG) levels, liver volume, spleen volume, etc.) ● Patient’s weight ● Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Multaq
Drugs	Multaq (dronedarone)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Pregnancy
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	Request must be from a cardiologist or electrophysiologist.
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria	<ul style="list-style-type: none"> • Diagnosis of paroxysmal or persistent atrial fibrillation (AF) or atrial flutter (AFL) with a recent episode. • Must not have NYHA Class IV heart failure or symptomatic heart failure with recent decompensation requiring hospitalization or referral to a specialized heart failure clinic • Must have AF that can be cardioverted into normal sinus rhythm, or is currently in sinus rhythm • Prescriber attests women of childbearing potential have been counseled regarding appropriate contraceptives <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Myasthenia Gravis Agents
Drugs	Rystiggo (rozanolixizumab), Soliris (eculizumab), Ultomiris (ravulizumab), Vyvgart (efgartigimod), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase), Zilbrysq (zilucoplan), BVEMV (eculizumab-aeeb), Epysqli (eculizumab-aagh), Imaavy (nipocalimab-aahu)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or rheumatologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of generalized myasthenia gravis (gMG) • Patient has a positive serological test for one of the following: <ul style="list-style-type: none"> ○ Anti-AChR antibodies ○ Anti-muscle-specific tyrosine kinase (MuSK) antibodies (Imaavy and Rystiggo only) • Patient has a Myasthenia Gravis Foundation of America (MGFA) clinical classification of class II, III or IV • For adults: patient has tried and failed, or has contraindication, to one of the following: <ul style="list-style-type: none"> ○ Two (2) or more conventional therapies (i.e. acetylcholinesterase inhibitors, corticosteroids, non-steroidal immunosuppressive therapies) ○ Failed at least 1 conventional therapy and required chronic plasmapheresis or plasma exchange or intravenous immunoglobulin • For eculizumab in patients 6-17 years: one of the following: <ul style="list-style-type: none"> ○ Trial and failure of at least 1 conventional therapy (i.e.

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- acetylcholinesterase inhibitors, corticosteroids, non-steroidal immunosuppressive therapies)
- Patient requires maintenance plasma exchange or intravenous immunoglobulin to control symptoms
 - Medication is prescribed at an FDA approved dose
 - Patient is not using agents covered by this policy concurrently (i.e. no concurrent use of Imaavy, Vyvgart, Vyvgart Hytrulo, Rystiggo, Soliris, Ultomiris, BKEMV, Epysqli or Zilbrysq)
 - For Vyvgart Hytrulo, patient has tried and failed, or has contraindication, to Vyvgart
 - Requests for Imaavy, Soliris (eculizumab), BKEMV (eculizumab-aeab), Epysqli (eculizumab-aagh), Ultomiris (ravulizumab), and Zilbrysq (zilucoplan) will also require all of the following:
 - For adults: patient has tried and failed, or has contraindication, to Vyvgart, Vyvgart Hytrulo, or Rystiggo.
 - Additionally, if the request is for Soliris or BKEMV, member must also have a documented trial and failure or intolerance to Epysqli or a medical reason why Epysqli cannot be used.
 - All ages: documentation patient complies with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against meningococcal infections in patients receiving a complement inhibitor.

Re-Authorization:

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

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

Vyvgart, Vyvgart Hytrulo, or Rystiggo.

- Additionally, if the request is for Soliris or BKEMV, member must also have a documented trial and failure or intolerance to Epysqli or a medical reason why Epysqli cannot be used.
- All ages: documentation patient complies with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against meningococcal infections in patients receiving a complement inhibitor.

Re-Authorization:

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

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

Field Name	Field Description
Prior Authorization Group Description	Omisirge
Drugs	Omisirge (omidubicel-only)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Patient has previously received this medication
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	If all the criteria are met, the initial request will be approved for a one-time treatment.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Patient has a hematologic malignancy planned for umbilical cord blood transplantation (UCBT) following myeloablative conditioning • Prescriber attests that the patient is eligible for myeloablative allogeneic hematopoietic stem cell transplantation (HSCT) AND does not have a readily available matched related donor, matched unrelated donor, mismatched unrelated donor, or haploidentical donor • Patient has not received a prior allogenic HSCT • Patient does not have known allergy to dimethyl sulfoxide (DMSO), Dextran 40, gentamicin, human serum albumin, or bovine material <p>The safety and effectiveness of repeat administration of Omisirge have not been evaluated and will not be approved.</p> <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Oxervate
Drugs	Oxervate (cenegermin-bkjb)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, an ophthalmologist or optometrist
Coverage Duration	If all of the criteria are met, the request will be approved for a one-time 8-week treatment course per eye. Requests for retreatment of the same eye within one year will be reviewed on a case-by-case basis based on chart documentation of previous response to therapy and clinical rationale for re-treatment
Other Criteria	<ul style="list-style-type: none"> • Documented diagnosis of Stage 2 or 3 neurotrophic keratitis • Documented treatment failure with at least one conventional non-surgical treatment for neurotrophic keratitis (i.e., artificial tear products, therapeutic soft contact lenses)
Revision/Review Date 10/2025	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Palynziq
Drugs	Palynziq (pegvaliase-pqpz)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	None
Required Medical Information	See “other criteria”
Age Restrictions	None
Prescriber Restrictions	Specialist experienced in the treatment of phenylketonuria (PKU).
Coverage Duration	Initial Authorizations: 12 months Dose Increases (to 40 mg or 60 mg daily): 16 weeks Reauthorization: 12 months
Other Criteria	<p><u>INITIAL AUTHORIZATION:</u></p> <ul style="list-style-type: none"> • Documentation of a confirmed diagnosis of Phenylketonuria (PKU); AND • Documentation the member’s blood phenylalanine (Phe) level is greater than 600 micromol/L(include lab results; must be within the past 90 days) • Documentation or prescriber attestation that the member has attempted control of PKU through a Phe restricted diet with Phe-free medical products/foods in conjunction with dietician or nutritionist. (Examples include Phenyl-Free [phenylalanine free diet powder], Loplex, Periflex, Phlex-10, PKU 2, PKU 3, XPhe Maxamaid, XPhe Maxamum) • Member has previously received sapropterin (Kuvan) and either had an inadequate response, was a non-responder (defined as members who were dosed at 20 mg/kg/day and did not have a decrease in blood Phe level after 1 month), or has a documented medical reason why sapropterin (Kuvan) cannot be used • The medication is being prescribed at a dose no greater than the FDA approved maximum initial dose of 20 mg SQ once daily. <p><u>DOSE INCREASES:</u></p> <ul style="list-style-type: none"> • Documentation of recent blood Phe level results (within the past 90 days). • Confirmation Phe control has not been achieved after adequate timeframe on the current dosing regimen: <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

<p>Revision/Review Date: 4/2025</p>	<ul style="list-style-type: none">○ For requests for a dose of 60 mg per day, the patient has been on 40 mg once daily continuously for at least 16 weeks and has not achieved adequate control● The medication is being prescribed at an FDA approved dose (maximum of 60 mg once daily). <p><u>REAUTHORIZATION:</u></p> <ul style="list-style-type: none">● Documentation of recent blood Phe level results (within the previous 90 days); AND● The medication is being prescribed at an FDA approved dose; AND● Member has achieved a reduction in blood phenylalanine concentration from pre-treatment baseline. <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Peanut Allergy Immunotherapy Agents (FDA Approved)
Drugs	Palforzia [Peanut (<i>Arachis hypogaea</i>) Allergen Powder-dnfp] capsule/sachet
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Use of Palforzia concomitantly with Xolair
Required Medical Information	See "Other Criteria"
Age Restrictions	Initiation: Patient is age 1-17 years. Up dosing and maintenance: Patient is age \geq 1 year
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>***All initial authorizations to be approved for all strengths and dosage forms of Palforzia***</p> <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 initial dose escalation • Patient is able to comply with the daily dosing requirements • Patient does not have recurrent asthma exacerbations or persistent loss of asthma control • Patient has been prescribed and has acquired (as demonstrated by pharmacy claims or documentation) injectable epinephrine <p>***All re-authorizations to be approved for all strengths and dosage forms of Palforzia***</p>
Revision/Review Date 4/2025	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically

	necessary.
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Field Name	Field Description
Prior Authorization Group Description	Adrenergic, alpha-receptor-blocking agent
Drug(s)	Phenoxybenzamine (Dibenzylamine)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or specialist in the management of pheochromocytoma.
Coverage Duration	If the conditions are met, the request will be approved for up to a 14-day duration for perioperative management or up to a 6 month duration for non-surgical initial requests. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of pheochromocytoma • Documented use for either perioperative management or long term use when surgery is contraindicated • Documented trial and failure, intolerance, or contraindication to doxazosin • Medication is prescribed at an FDA approved dose <p><u>Re-Authorization</u></p> <ul style="list-style-type: none"> • Documented long term use when surgery is contraindicated • Documentation or provider attestation that demonstrates a clinical benefit • Medication is prescribed at an FDA approved dose <p>Revision/Review Date: 2/2026</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	Primary Hyperoxaluria Agents
Drugs	Oxlumo (lumasiran) Rivfloza (nedosiran)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a nephrologist, urologist, hepatologist, endocrinologist or consultation with one of these specialists
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria	<p><u>Initial Authorization</u></p> <ul style="list-style-type: none"> • Diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by one of the following: <ul style="list-style-type: none"> ○ Genetic testing confirming at least one mutation at the AGXT gene ○ Liver biopsy demonstrating absent or significantly reduced AGT activity • Metabolic testing demonstrating one of the following: <ul style="list-style-type: none"> ○ Oxlumo or Rivfloza <ul style="list-style-type: none"> ▪ Increased urinary oxalate excretion (≥ 0.5 mmol/1.73 m²per day[45 mg/1.73 m²per day]) ▪ Increased urinary oxalate:creatinine ratio relative to normative values for age ○ Oxlumo only: Increased plasma oxalate level (≥ 20 μmol/L) • For Rivfloza: member has relatively preserved kidney function (e.g., EGFR ≥ 30 mL/min/1.73 m²) • Member is concurrently using pyridoxine or has tried and failed previous pyridoxine therapy for at least 3 months, or has a medical reason for not using pyridoxine • Member has no history of liver transplant • Medication is prescribed at an FDA approved dose • Patient is not using Oxlumo and Rivfloza concurrently

<p>Revision/Review Date 2/2026</p>	<p><u>Reauthorization</u></p> <ul style="list-style-type: none">• Members previously using pyridoxine will continue to use pyridoxine, or have a medical reason for not using pyridoxine• Documentation has been provided that demonstrates a clinical benefit (e.g. symptomatic improvement, reduction in urinary oxalate, urinary oxalate:creatinine ratio, or plasma oxalate levels from baseline)• Medication is prescribed at an FDA approved dose• Patient is not using Oxlumo and Rivfloza concurrently <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Dendritic Cell Tumor Peptide Immunotherapy
Drugs	Provenge (sipuleucel-T) TisagenlecleucelTisagenlecleucel
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Small cell/neuroendocrine prostate cancer
Required Medical Information	See “Other Criteria”
Age Restrictions	See “Other Criteria”
Prescriber Restrictions	Prescriber must be an oncologist or urologist
Coverage Duration	If all the criteria are met, the request will be approved for 3 doses per lifetime
<p data-bbox="151 869 334 907">Other Criteria</p> <p data-bbox="128 1541 354 1612">Revision/Review Date 4/2025</p>	<p data-bbox="402 869 699 907"><u>Initial Authorization:</u></p> <ul data-bbox="451 913 1490 1507" 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 data-bbox="402 1514 639 1551"><u>Reauthorization:</u></p> <ul data-bbox="451 1558 1317 1591" style="list-style-type: none"> • Treatment exceeding 3 doses per lifetime will not be authorized <p data-bbox="402 1633 1479 1694">Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>

Prior Authorization Group Description	Dojolvi
Drugs	Dojolvi (triheptanoin)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescriber is a specialist in the treatment of the indicated condition
Coverage Duration	Initial: 6 months Renewal: 12 months
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Member has a molecularly confirmed diagnosis of a long-chain fatty acid oxidation disorder (LC-FAOD) • Documentation of at least two of the following: <ul style="list-style-type: none"> ○ Disease specific elevation of acylcarnitines on a newborn blood spot or in plasma ○ Low enzyme activity in cultured fibroblasts ○ One or more known pathogenic mutations in either the <i>CPT2</i>, <i>ACADVL</i>, <i>HADHA</i>, or <i>HADHB</i> gene • Attestation or documentation member will not be receiving any other medium-chain triglyceride products while taking Dojolvi • Documentation of member’s daily caloric intake (DCI) • Dose is within FDA-indicated limits and does not exceed 35% of DCI <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation submitted indicating the member has experienced a clinical benefit (e.g. increased left ventricular ejection fraction, reduced left ventricular wall mass, reduced maximum heart rate, decreased incidence of rhabdomyolysis) • Documentation of member’s DCI • Dose is within FDA-indicated limits and does not exceed 35% of DCI <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date: 2/2026	

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) Ultomiris (ravulizumab-cwyz)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	For Enspryng, Uplizna, Soliris, Ultomiris: Anti-aquaporin-4 (AQP4) antibody negative neuromyelitis optica spectrum disorder (NMOSD)
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a specialist who is experienced in the treatment of NMOSD (such as immunologist, neurologist or hematologist)
Coverage Duration	If all of the conditions are met, requests will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <p><u>For rituximab (Rituxan, Truxima, Riabni, or Ruxience):</u></p> <ul style="list-style-type: none"> • Member has a diagnosis of NMOSD • Documentation indicating that the patient has been screened for HBV (hepatitis B virus) prior to initiation of treatment • Dosing is supported by compendia or standard of care guidelines • If the request is for any medication other than Ruxience (rituximab-pvvr) or Riabni (rituximab-arrx), there is a documented trial and failure of Ruxience or Riabni, or medical reason why (e.g. intolerance, hypersensitivity, contraindication) they cannot be used <p><u>For Enspryng:</u></p> <ul style="list-style-type: none"> • Member has a diagnosis of anti-aquaporin-4 (AQP4) antibody positive NMOSD • Provider attests to completion of the following assessments prior to the first dose of Enspryng as outlined in the prescribing information: <ul style="list-style-type: none"> ○ Hepatitis B virus screening ○ Tuberculosis screening ○ Liver transaminase screening ○ Patient has not received live or attenuated-live virus vaccines within 4 weeks before the start of Enspryng therapy • Documented trial and failure of rituximab (Rituxan, Truxima, Riabni, or Ruxience), azathioprine, or mycophenolate mofetil, or medical reason why (e.g., intolerance, hypersensitivity, contraindication) they cannot be used • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines <p>Exceptions:</p>

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 or Ultomiris

For Uplizna:

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

Exceptions:

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

For Soliris/Ultomiris:

- Member has a diagnosis of anti-aquaporin-4 (AQP4) antibody **positive** NMOSD
- Documentation patient complies with most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria.
- Antimicrobial prophylaxis with oral antibiotics (penicillin, or macrolides if penicillin-allergic) for two weeks if the meningococcal vaccine is administered < 2 weeks before starting therapy or a documented medical reason why the patient cannot receive oral antibiotic prophylaxis.
- Documented trial and failure of, or medical reason why (e.g. intolerance, hypersensitivity, contraindication) why the following cannot be used (one from each bullet below):
 - 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.

Revision/Review Date
10/2025

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 10/2025	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	Pompe Disease Agents
Drugs	Lumizyme (alglucosidase alfa) Nexviazyme (avalglucosidase alfa-ngpt) injection Pombiliti (cipaglucosidase alfa-atga) + Opfolda (miglustat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to covered uses
Prescriber Restrictions	Prescribed by, or in consultation with, a specialist in the treatment of Pompe disease, such as a genetic or metabolic specialist, neurologist, cardiologist, or pediatrician.
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <p>For infantile onset Pompe Disease (Lumizyme only):</p> <ul style="list-style-type: none"> • Patient has a diagnosis of infantile-onset Pompe Disease, confirmed by one of the following: <ul style="list-style-type: none"> ○ Enzyme assay showing a deficiency of acid alpha-glucosidase (GAA) activity in the blood, skin, or muscle ○ Genetic testing showing a mutation in the GAA gene • Requested dose is appropriate per prescribing information (documentation of patient weight must be submitted with request) • Requested regimen will not be used in combination with other enzyme replacement therapies <p>For late onset Pompe Disease (Lumizyme, Nexviazyme, or Pombiliti + Opfolda):</p> <ul style="list-style-type: none"> • Patient has a diagnosis of late-onset (non-infantile) Pompe Disease, confirmed by one of the following: <ul style="list-style-type: none"> ○ Enzyme assay showing a deficiency of acid alpha-glucosidase (GAA) activity in the blood, skin, or muscle ○ Genetic testing showing a mutation in the GAA gene • Documentation patient has measurable signs or symptoms of Pompe disease • Results of a baseline 6-minute walk test (6MWT) and percent-predicted forced vital capacity (FVC) are provided (not required for patients who are not old enough to walk and/or not old enough to perform spirometry)

<p>Revision/Review Date: 2/2025</p>	<ul style="list-style-type: none">• Requested dose is appropriate per prescribing information (documentation of patient weight must be submitted with request)• Requested regimen will not be used in combination with other enzyme replacement therapies (Exception: Pombiliti + Opfolda are to be used together)• Additionally for Nexviazyme: Patients < 30 kg must provide documentation of a trial and therapy failure of, or a medical reason why Lumizyme may not be used.• Additionally for Pombiliti + Opfolda: Patient must have trial and failure of another enzyme therapy (Lumizyme or Nexviazyme) <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none">• Documentation or provider attestation of positive clinical response to therapy<ul style="list-style-type: none">○ Infantile onset: provider attestation of member benefit○ Late onset: improvement, stabilization, or slowing of progression of percent-predicted FVC and/or 6MWT or provider attestation of member benefit for members not old enough to walk or perform spirometry• Requested dose is appropriate per prescribing information (documentation of patient weight must be submitted with request)• Requested regimen will not be used in combination with other enzyme replacement therapies (Exception: Pombiliti + Opfolda are to be used together) <p style="text-align: center;">Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Pyruvate Kinase Activators
Drugs	Pyrukynd (mitapivat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Age \geq 18 years
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	If the conditions are met, the request will be approved for a 6-month duration for initial requests and a 6-month duration for renewal requests. **If the conditions are not met: may approve up to 14 days of a Pyrukynd Taper Pack to allow for discontinuation tapering
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • The prescribed dose is within FDA approved dosing guidelines • Diagnosis of hemolytic anemia with pyruvate kinase deficiency (PKD) • Documentation of at least two variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, of which at least one is a missense variant • Documentation that the member is <u>not</u> homozygous for the R479H variant • Documentation that the member <u>does not have</u> two non-missense variants of the PKLR gene, without the presence of another missense variant in the PKLR gene • Documentation of ONE of the following: <ul style="list-style-type: none"> ○ The member does not regularly require blood transfusions (defined as requiring <u>less than or equal to</u> 3 red blood cell (RBC) transfusions in the past 52 weeks and no transfusions in the past 3 months) AND hemoglobin (Hb) level \leq 10 g/dL ○ The member has required more than or equal to 6 RBC transfusions in the past 12 months <ul style="list-style-type: none"> ▪ Documentation of the number of transfusions and the number of red blood cell (RBC) units transfused • Prescriber attests that the member does not have moderate or severe hepatic dysfunction and will monitor liver function monthly for the first 6 months of treatment • Prescriber attests that the member does not have a history of a prior bone marrow or stem cell transplant • The member is not concurrently using hematopoietic-stimulating agents (e.g. Procrit or Retacrit) • Prescriber attests the member is taking at least 0.8mg of folic acid daily <p><u>Reauthorization:</u></p> <ul style="list-style-type: none"> • The prescribed dose is within FDA approved dosing guidelines

- For the first reauthorization, documentation of benefit: increase in Hb ≥ 1.5 g/dL over baseline OR a reduction in transfusions, defined as $\geq 33\%$ reduction in the number of red blood cell (RBC) units transfused over baseline
- For subsequent reauthorizations: documentation of benefit: stabilization in Hb levels OR a sustained reduction in transfusions
- If the reauthorization criteria are not met, may authorize up to 14 days of a Pyrukynd Taper Pack to allow for tapering. To reduce the risk of acute hemolysis, abrupt discontinuation of Pyrukynd should be avoided.

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

Revision/Review Date:
7/2025

Prior Authorization Group Description	Reblozyl (luspatercept-aamt)
Drugs	Reblozyl (luspatercept-aamt) vial for subcutaneous injection
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Members are excluded if they have hemoglobin S/beta-thalassemia, isolated alpha-thalassemia
Required Medical Information	See “other criteria”
Age Restrictions	Member must be 18 years of age or older
Prescriber Restrictions	Prescriber must be a hematologist or oncologist
Coverage Duration	Initial and reauthorization requests will be approved for 6 months.
Other Criteria	<p>Criteria for initial approval:</p> <ul style="list-style-type: none"> • Requested dose is appropriate per labeling • The member’s weight has been provided with the request • The member’s most recent hemoglobin level (within the last month) has been provided with the request • Diagnosis appropriate per Covered Uses • For requests for anemia due to beta thalassemia, documentation of all of the following is required: <ul style="list-style-type: none"> ○ Member requires regular red blood cell (RBC) transfusions (defined as at least 6 RBC units received over the last 6 months). • For requests for anemia due to myelodysplastic syndrome, documentation of all of the following is required: <ul style="list-style-type: none"> ○ Myelodysplastic Syndrome Revised International Prognostic Scoring System (IPSS-R) categorization as very low, low, or intermediate risk of progression. ○ Member has required transfusion of 2 or more RBC units within an 8 week period in the last 4 months ○ Hemoglobin less than 10 g/dl <p>Reauthorization:</p> <ul style="list-style-type: none"> • For diagnosis of anemia due to beta thalassemia, documentation of the following: <ul style="list-style-type: none"> ○ Fewer transfusions compared with baseline AND ○ A reduction in transfusion requirement of at least 2 RBC units compared with baseline • Diagnosis of anemia due to myelodysplastic syndrome: documentation of ONE of the following: <ul style="list-style-type: none"> ○ Hemoglobin increase of at least 1.5 g/dl from baseline over a period of 8-12 weeks OR ○ Reduction in red blood cell transfusion by at least 4 units over a period of 8-12 weeks compared with baseline transfusion requirement
Revision/Review Date: 10/2025	If the above conditions are not met, the request will be referred to a Medical Director for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	Fecal Microbiota
Drugs	Rebyota (fecal microbiota, live-jslm) Vowst (fecal micromiota spores, live-brpk)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Treatment of Clostridioides difficile infection (CDI)
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If all the criteria are met, the request will be approved for 1 treatment course
Other Criteria Date: 7/2025	<ul style="list-style-type: none"> • Medication is prescribed at an FDA approved dose • Diagnosis of at least 1 recurrent episode of CDI (≥ 2 total CDI episodes) • Current episode of CDI must be controlled (< 3 unformed/loose stools/day for 2 consecutive days) • Positive stool test for C. difficile within 30 days before prior authorization request • Administration will occur 24–72 hours following completion of antibiotic course for CDI treatment • For Vowst only: attestation patient will bowel cleanse using magnesium citrate or polyethylene glycol electrolyte solution the day before the first dose of Vowst <p>*Rebyota and Vowst are limited to 1 treatment course*</p> <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>

Field Name	Field Description
Prior Authorization Group Description	Adrenal Enzyme Inhibitors for Cushing's Syndrome
Drugs	Recorlev (levoketoconazole), Isturisa (osilodrostat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	<ul style="list-style-type: none"> • Patients with a non-endogenous source of hypercortisolism, such as exogenous source of glucocorticoids or therapeutic use of ACTH. • Patient has a diagnosis of pituitary or adrenal carcinoma
Required Medical Information	See "Other Criteria"
Age Restrictions	Per FDA approved package insert
Prescriber Restrictions	Prescriber must be an endocrinologist or in consultation with an endocrinologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
<p data-bbox="126 911 347 953">Other Criteria</p> <p data-bbox="126 1457 347 1541">Revision/Review Date: 2/2026</p>	<p data-bbox="396 911 688 953"><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Patient has a diagnosis of endogenous Cushing's syndrome. • Patient is not a candidate for surgery, surgery is not an option, or prior surgery has not been curative. • Documented baseline urinary free cortisol (UFC) test ≥ 1.3 times ULN (within the past 30 days). • Medication is prescribed at an FDA approved dose. • For Isturisa, provider must also attest that baseline electrocardiogram (ECG) has been obtained and hypokalemia and/or hypomagnesemia has been corrected prior to initiating therapy if present • Member has had a documented trial and failure of one of the following: <ul style="list-style-type: none"> ○ ketoconazole ○ Metopirone (metyrapone) ○ Lysodren (mitotane) ○ cabergoline ○ Signifor/Signifor LAR (pasireotide) ○ etomidate • OR • Member has a documented medical reason (e.g. contraindication, intolerance, hypersensitivity) as to why these medications cannot be used <p data-bbox="396 1814 646 1856"><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation or provider attestation of positive clinical response (i.e. decrease in urinary free cortisol from baseline.) • Medication is prescribed at an FDA approved dose

	If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.
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Field Name	Field Description
Prior Authorization Group Description	Rezdiffra
Drugs	Rezdiffra (resmetirom)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	<ul style="list-style-type: none"> • Patients with decompensated cirrhosis •
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a hepatologist, gastroenterologist, endocrinologist, or a specialist in the treatment of liver disease.
Coverage Duration	If all of the criteria are met, the initial and reauthorization requests will be approved for up to a 12 month duration
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis • Documentation of stage F2 to F3 fibrosis confirmed by biopsy or a noninvasive test (NIT) • Prescriber attestation to providing lifestyle counseling on nutrition and exercise • Prescriber attestation that member avoids excess alcohol intake • The drug is being prescribed at an FDA approved dose according to the member's weight <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • The member has clinically benefited from the medication (e.g. the resolution of steatohepatitis and no worsening of liver fibrosis, or at least one stage improvement in liver fibrosis and no worsening of steatohepatitis) • The member continues to have a fibrosis stage of ≤ 3 • The drug is being prescribed at an FDA approved dose according to the member's weight
Review/Revision Date: 10/2025	If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	Rhapsido
Drugs	Rhapsido (remibrutinib)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by, or in consultation with, an allergist, immunologist, or dermatologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Medication is prescribed at an FDA approved dose • Diagnosis of chronic spontaneous urticaria for at least 6 weeks with uncontrolled symptoms • Patient has had at least a 2-week trial and failure of, or has a contraindication to, at least two different H1 antihistamines (e.g. cetirizine, levocetirizine, loratadine, desloratadine, fexofenadine) at four times the standard FDA-approved dose • Patient has had at least a 2-month trial of, or has a contraindication to, Xolair (omalizumab) <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation or provider attestation of positive clinical response (i.e. change from baseline in weekly itch severity score, etc.) • Medication is prescribed at an FDA approved dose <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
Date: 2/2026	

Field Name	Field Description
Prior Authorization Group Description	Roctavian
Drugs	Roctavian (valoctocogene roxaparvovec-rvox)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Prior use of gene therapy for Hemophilia A
Required Medical Information	See “Other Criteria”
Age Restrictions	Patient must be 18 years of age and older
Prescriber Restrictions	Prescriber must be a hematologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for a one-time treatment.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of severe hemophilia A (congenital factor VIII deficiency with factor VIII activity < 1 IU/dL) • Documentation of a current prophylactic regimen of Factor VIII infusions or bispecific monoclonal antibodies (i.e. Hemlibra) • Documented FDA-approved anti-AAV5 antibody test showing the patient is negative for anti-AAV5 antibodies • Documented Factor VIII inhibitor titer test showing the patient is negative for Factor VIII inhibitors • Prescriber attestation of performed liver health assessments • Patient weight • Medication is prescribed at an FDA approved dose <p>The safety and effectiveness of repeat administration of Roctavian has not been evaluated and will not be approved.</p>
Revision/Review Date: 10/2025	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Rituximab

Drugs:

Rituxan (rituximab)

Rituxan Hycela (rituximab/hyaluronidase human, recombinant)

Truxima (rituximab-abbs)

Ruxience (rituximab-pvvr)

Riabni (rituximab-arrx)

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

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 2 preferred biologics indicated for rheumatoid arthritis, or has documented medical reason (intolerance, hypersensitivity, etc.) for not taking the preferred therapies to manage their medical condition.
- Documentation indicating that rituximab is being used concurrently with methotrexate, or a medical reason why methotrexate cannot be used.
- Documentation indicating that the patient has been screened for Hepatitis B Virus (HBV) prior to initiation of treatment.
- Rituximab is being prescribed at an FDA approved dosage.
- If the request is for any medication other than Ruxience (rituximab-pvvr) or Riabni (rituximab-arrx), there is a documented trial and failure of Ruxience or Riabni, or medical reason why (e.g. intolerance, hypersensitivity, contraindication) they cannot be used.

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

Reauthorization

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

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

PEMPHIGUS VULGARIS

Initial Authorization

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

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

Reauthorization

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

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

ONCOLOGY INDICATIONS

Initial Authorization:

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

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

Reauthorization

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

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

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

Initial Authorization:

- The medication is being recommended and prescribed by a rheumatologist or nephrologist.
- The patient is 2 years of age or older and has a documented clinical diagnosis of GPA (Wegener's

Granulomatosis), eosinophilic granulomatosis with polyangiitis (EGPA), or MPA AND the prescriber indicates whether there is severe or non-severe disease.

- Documentation indicating that rituximab is being used concurrently with glucocorticoids.
- Documentation the patient will be receiving PJP prophylaxis (ex. TMP/SMX, dapsone, atovaquone) during treatment or the prescriber has provided a medical reason for not prescribing PJP prophylaxis
- Documentation indicating that the patient has been screened for HBV prior to initiation of treatment.
- Rituximab is being prescribed at an FDA approved dosage.
- If the patient is 18 years of age or older, and the request is for any medication other than Ruxience (rituximab-pvvr) Riabni (rituximab-arrx), there is a documented trial and failure of Ruxience or Riabni, or medical reason why (e.g. intolerance, hypersensitivity, contraindication) they cannot be used.

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

Re-authorization:

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

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

DERMATOMYOSITIS (DM) and POLYMYOSITIS (PM)

Initial Authorization:

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

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

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

Re-authorization:

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

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

OTHER MEDICALLY ACCEPTED INDICATIONS

Initial Authorization:

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

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

Re-authorization:

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

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

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

Revision/Review Date: 7/2025

Field Name	Field Description
Prior Authorization Group Description	Treatments for Plasminogen Deficiency Type 1 (PLD1)
Drugs	Ryplazim (human plasma-derived plasminogen)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a hematologist, medical geneticist, or other specialist in the treatment of rare blood or genetic disorders
Coverage Duration	If all of the criteria are met, the initial request will be approved for 12 weeks. Reauthorization requests will be approved for 12 weeks if the member has not had a documented positive response to therapy and for 12 months if the member has had a documented positive response to therapy.
Other Criteria	<p>Initial Authorization</p> <ul style="list-style-type: none"> • Member must have a diagnosis of PLD1 (i.e. hypoplasminogenemia) • Member must have a documented history of lesions or other symptoms consistent with the diagnosis (e.g. ligneous conjunctivitis, oral, respiratory, gastrointestinal, urogenital, integumentary, or central nervous system manifestations) • Member must have baseline plasminogen activity levels $\leq 45\%$ <ul style="list-style-type: none"> ○ If the member received plasminogen supplementation with fresh frozen plasma, prescriber attests that a 7-day washout period was performed before obtaining baseline plasminogen activity levels. • The request is for an FDA approved dose <p>Reauthorization</p> <ul style="list-style-type: none"> • ONE of the following is true: <ul style="list-style-type: none"> ○ Member has a documented positive response to therapy (e.g. reduction in number or size of lesions, no new or recurring lesions) ○ Member has not had a documented positive response to therapy and ONE of the following: <ul style="list-style-type: none"> ▪ If confirmed plasminogen activity levels are $\geq 10\%$ above baseline, then appropriate dosing frequency adjustments must be made. ▪ If confirmed plasminogen activity levels are $< 10\%$ above baseline, then appropriate dosing frequency adjustments must be made AND the prescriber must

<p>Revision/Review Date 4/2025</p>	<p>provide a medical justification as to why therapy should be continued.</p> <ul style="list-style-type: none">• The request is for an FDA approved dose <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	SMN2 Splicing Modifiers for the Treatment of Spinal Muscular Atrophy (SMA)
Drugs	Evrysdi (risdiplam) Spinraza (nusinersen)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	<ul style="list-style-type: none"> Concomitant use of Evrysdi and Spinraza
Required Medical Information	For Evrysdi: Patient's body weight
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	<p>For Evrysdi: If all of the conditions are met, the request will be approved for 6 months for initial approval, followed by 12 months for reauthorization requests.</p> <p>For Spinraza: If all of the conditions are met, the request will be approved for 6 months for 5 doses (4 loading doses and 1st maintenance dose) for initial approval, and 12 months for 3 additional maintenance doses for reauthorization requests.</p> <p>If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.</p>
Other Criteria	<p><u>Initial approval</u></p> <ul style="list-style-type: none"> Member has a confirmed diagnosis of SMA 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) Baseline motor function or motor milestone achievement was submitted with request [e.g. CHOP Infant Test of Neuromuscular Disorders (CHOP-INTEND) or Hammersmith Infant Neurological Examination (HINE) for Type 1 or Hammersmith Functional Motor Scale Expanded Scores (HFMSE) for Type II and Type III, or 6 minute walk test in subjects able to walk, Revised Upper Limb Module (RULM), Motor Function Measure 32 (MFM-32)] The request is for an FDA approved dose <p><u>Reauthorization</u></p> <ul style="list-style-type: none"> Documentation of clinical response based on the prescriber's assessment

Revision/Review Date 2/2026	<ul style="list-style-type: none"><li data-bbox="537 100 1114 134">• The request is for an FDA approved dose <p data-bbox="488 180 1386 296">Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Complement Inhibitors
Drugs	Fabhalta (iptacopan), Soliris (eculizumab), Ultomiris (ravulizumab), Empaveli (pegcetacoplan), Voydeya (danicopan), PiaSky (crovalimab-akkz) BKEMV (eculizumab-aeab), Epysqli (eculizumab-aagh)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a hematologist, nephrologist, neurologist, oncologist, ophthalmologist, or other appropriate specialist.
Coverage Duration	<p>If the criteria are met, the criteria will be approved as follows:</p> <p>For eculizumab (Soliris, BKEMV, Epysqli), Ultomiris (ravulizumab), Empaveli (pegcetacoplan), and Voydeya (danicopan): initial request will be approved for up to 3 month duration; reauthorization requests will be approved for up to 6 months.</p> <p>For Fabhalta (iptacopan) and PiaSky (crovalimab-akkz): initial request will be approved for up to 6 month duration; reauthorization requests will be approved for up to 12 months.</p>
Other Criteria	<p>Initial Authorization:</p> <ul style="list-style-type: none"> • The request is for a dose that is FDA approved or in nationally recognized compendia in accordance with the patient’s diagnosis, age and concomitant medical conditions; AND • For Fabhalta (iptacopan), eculizumab (Soliris, BKEMV, Epysqli), Ultomiris (ravulizumab), Empaveli (pegcetacoplan), PiaSky (crovalimab-akkz) and Voydeya (danicopan): <ul style="list-style-type: none"> ○ Documentation patient complies with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria. • For Soliris or BKEMV, patient must have a documented trial and failure or intolerance to Epysqli or a medical reason why Epysqli cannot be used <p>Paroxysmal Nocturnal Hemoglobinuria (PNH):</p> <ul style="list-style-type: none"> • Documentation of diagnosis by high sensitivity flow cytometry • Presence of 1 or more of the following PNH-related signs or symptoms:

- Fatigue, hemoglobinuria, abdominal pain, shortness of breath (dyspnea), anemia, history of a major adverse vascular event (including thrombosis), dysphagia, erectile dysfunction, or history of pRBC transfusion due to PNH.
- Adults: For Ultomiris (ravulizumab), Empaveli (pegcetacoplan), Fabhalta (iptacopan), or PiaSky (crovalimab-akkz) patient must have a documented trial and failure or intolerance to Epysqli or a medical reason why Epysqli cannot be used.
- For Voydeya (danicopan):
 - Member has been receiving eculizumab (Soliris, BKEMV, Epysqli) or Ultomiris (ravulizumab) therapy for at least 6 months
 - Member has clinically evident extravascular hemolysis [defined as anemia (Hgb \leq 9.5 gram/deciliter) with absolute reticulocyte count \geq 120 x 10⁹/liter] despite treatment with eculizumab (Soliris, BKEMV, Epysqli) or Ultomiris (ravulizumab)
 - Voydeya (danicopan) will be used as add-on therapy to eculizumab (Soliris, BKEMV, Epysqli) or Ultomiris (ravulizumab)

Generalized Myasthenia Gravis (gMG):

- Refer to the “Myasthenia Gravis Agents” policy

Neuromyelitis Optica Spectrum Disorder (NMOSD)

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

IgA Nephropathy:

- Refer to the ”IgA Nephropathy Agents” policy

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

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

Geographic Atrophy (GA):

- Diagnosis of GA secondary to age-related macular degeneration (AMD)
- Absence of choroidal neovascularization (CNV) in treated eye
- Best-corrected visual acuity (BCVA) of 24 letters (approximately 20/320) or better using Early Treatment Diabetic Retinopathy Study (ETDRS)

<p>Revision/Review Date 7/2025</p>	<ul style="list-style-type: none"> • GA lesion size ≥ 2.5 and ≤ 17.5 mm² with at least 1 lesion ≥ 1.25 mm² <p>Complement 3 Glomerulopathy (C3G):</p> <ul style="list-style-type: none"> • Diagnosis of C3G as confirmed by renal biopsy • Patient's serum C3 level is reduced (defined as less than 0.85 x lower limit of the central laboratory normal range) • Patient's urine protein to creatinine ratio (UPCR) is ≥ 1.0 g/g • Patient has an eGFR ≥ 30 mL/min/1.73 m² • Patient has been taking maximally recommended or tolerated dose of an angiotensin converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB) for at least 90 days, or a medical reason is provided why this is inappropriate • Patient has a trial and therapy failure of mycophenolate and glucocorticoids, or a medical reason is provided why this is inappropriate. • Patient does not have recurrent C3G post kidney transplant <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Provider has submitted documentation of clinical response to therapy (e.g., reduction in disease severity, improvement in quality of life scores, increase in Hgb, reduced need for blood transfusions, slowing of growth rate of GA lesions, etc.); AND • The request is for a dose that is FDA approved or in nationally recognized compendia in accordance with the patient's diagnosis, age, and concomitant medical condition; AND • If the request is for aHUS/Complement Mediated HUS <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>
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Field Name	Field Description
Prior Authorization Group Description	Somatostatin Analogs and Growth Hormone Receptor Antagonists
Drugs	Octreotide (Sandostatin) Sandostatin LAR (octreotide) Lanreotide 120 mg/0.5 mL Lanreotide (Somatuline Depot) () 60 mg/0.2 mL, 90 mg/0.3 mL, 120 mg/0.5mL Mycapssa (octreotide) Signifor (pasireotide) Signifor LAR (pasireotide) Somavert (pegvisomant)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA) Drug Package Insert (PPI). ** Non-FDA approved (i.e. off-label) uses; refer to the “Off-Label Use” policy for non-oncology indications, and the “Oncology Drugs” policy for off-label oncology uses**
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Per FDA approved package insert
Prescriber Restrictions	Prescriber must be a specialist with appropriate expertise in treating the condition in question (such as an endocrinologist, neurologist/neurosurgeon, oncologist, etc.). Consultation with appropriate specialist for the condition in question is also acceptable.
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<u>Initial Authorization</u> <u>For all FDA approved indications (including FDA-approved oncology related uses)</u> <ul style="list-style-type: none"> • Medication requested is for an FDA approved indication and dose • If the provider is requesting therapy with more than one somatostatin analog or a somatostatin analog and a growth hormone receptor antagonist, then documentation must be submitted as to why patient is unable to be treated with monotherapy, or a medical reason was provided why monotherapy is not appropriate. <u>For Acromegaly</u> <ul style="list-style-type: none"> • Patient has had an inadequate response to, or medical reason why, surgical treatment cannot be used.

- If the patient mild disease (e.g. mild signs and symptoms of growth hormone excess, modest elevations in IGF-1) there is a documented trial of a dopamine agonist (e.g. bromocriptine mesylate, cabergoline) at a therapeutically appropriate dose or a documented medical reason why a dopamine agonist cannot be used
- **Additionally for Mycapssa:**
 - Patient has showed clinical response to and tolerates treatment with octreotide or lanreotide therapy
 - Clinical justification is provided as to why patient cannot continue use of injectable somatostatin analog therapy
- **Additionally for Somavert:**
 - Patient has had an inadequate response to therapy with a somatostatin analog, or has a documented medical reason why a somatostatin analog cannot be used
- **Additionally for Signifor LAR:**
 - Patient has had an inadequate response to therapy with either lanreotide (Somatuline Depot) or octreotide (Sandostain, Sandostatin LAR), or has a documented medical reason why these somatostatin analogs cannot be used.

For Cushing's Disease (pasireotide products only)

- Patient must have had inadequate response, or medical reason why surgical treatment cannot be used

Reauthorization

- Medication requested is for an FDA approved indication and dose
- Documentation has been provided that demonstrates a clinical benefit (e.g. improvement in laboratory values, improvement or stabilization of clinical signs/symptoms, etc.)

Revision/Review
Date 4/2025

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

Field Name	Field Description
Prior Authorization Group Description	Skyclarys (omaveloxolone)
Drugs	Skyclarys (omaveloxolone)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Per FDA-approved prescribing information
Prescriber Restrictions	Prescriber must be a neurologist or in consultation with a neurologist or specialist with expertise in treating patients with Friedreich’s Ataxia.
Coverage Duration	If all the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of Friedreich’s Ataxia, confirmed via genetic testing (must submit documentation) • 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 to Skyclarys therapy (i.e. improvement in symptoms, slowing of disease progression, etc.) • Medication is prescribed at an FDA approved dose <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 7/2025	

Field Name	Field Description
Prior Authorization Group Description	Skysona
Drugs	Skysona (elivaldogene autotemcel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	<ul style="list-style-type: none"> • Cerebral adrenoleukodystrophy secondary to head trauma • Positive for human immunodeficiency virus type 1 or 2
Required Medical Information	See “Other Criteria”
Age Restrictions	See “Other Criteria”
Prescriber Restrictions	Prescriber must be a specialist in the disease being treated.
Coverage Duration	If all the criteria are met, the initial request will be approved for a one-time treatment.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Member has a diagnosis of early, active cerebral adrenoleukodystrophy (CALD) defined as all of the following: <ul style="list-style-type: none"> ○ elevated very long chain fatty acid (VLCFA) levels ○ confirmed mutations in the ABCD1 gene ○ asymptomatic or mildly symptomatic (neurologic function score, NFS ≤ 1) ○ Gadolinium enhancement on brain magnetic resonance imaging (MRI) of demyelinating lesions and Loes scores of 0.5-9 • Member is a male 4-17 years of age • Medication is prescribed at an FDA approved dose • Member has not had a prior allogeneic hematopoietic stem-cell transplant (HSCT) • Member has no HLA-matched donor for HSCT <p><u>Re-Authorization:</u> The safety and effectiveness of repeat administration of Skysona have not been evaluated and will not be approved.</p>
Revision/Review Date: 2/2026	

Field Name	Field Description
Prior Authorization Group Description	Desmopressin nasal spray
Drugs	Desmopressin 1.5 mg/mL nasal spray
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	≥ 11 months
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria	<p><u>Initial Authorization</u> One of the following:</p> <ul style="list-style-type: none"> • Diagnosis of Hemophilia A with Factor VIII coagulant activity levels greater than 5%. • Hemophilia A carrier • Diagnosis of mild to moderate Type 1 (classic) von Willebrand’s disease with Factor VIII coagulant activity levels greater than 5%. • Diagnosis of mild to moderate Type 2A, 2M, or 2N von Willebrand’s disease and documentation of a desmopressin trial and response <ul style="list-style-type: none"> ○ A single unit of desmopressin nasal spray will be approved for a desmopressin trial <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Sohonos
Drugs	Sohonos (palovarotene)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	<ul style="list-style-type: none"> • Pregnancy • Use in patients younger than 8 years of age for females and 10 years of age for males
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with an orthopedic specialist or provider who specializes in rare connective tissue diseases
Coverage Duration	If all of the criteria are met, the initial or reauthorization request will be approved for up to 12 months taking into account patient specific scenarios.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Documented diagnosis of fibrodysplasia ossificans progressiva (FOP) • Documented genetic testing of ACVR1 R206H mutation • Attestation that patient is not pregnant and appropriate contraception methods will be used at least 1 month before treatment, during treatment, and 1 month after the last dose (if applicable) • Documentation of weight for patients younger than 14 years old • Medication is prescribed at an FDA approved dose <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation or provider attestation of clinical benefit (i.e. volume reduction of heterotopic ossification) or worsening (i.e. flare-up presence and/or worsening of flare-ups) • Attestation that patient is not pregnant and appropriate contraception methods will be used at least 1 month before treatment, during treatment, and 1 month after the last dose (if applicable) • Documentation of weight for patients younger than 14 years old • Medication is prescribed at an FDA approved dose <p>Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Synagis (palivizumab)
Drugs	Synagis (palivizumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	A maximum of 5 doses may be approved within the Respiratory Syncytial Virus (RSV) season. Requests for additional doses will be reviewed on a case-by case basis based on CDC surveillance reports, state/local health department recommendations, and other current medical literature.
Other Criteria	<p><u>Must have documented medical reason for not using Beyfortus (niresvimab) AND</u></p> <p><u>Infants less than 1 year of age at the onset of the respiratory syncytial virus (RSV) season (which typically starts November 1st, but may vary seasonally) AND have one of the following indications:</u></p> <ul style="list-style-type: none"> • Born at less than 29 weeks, 0 days gestation • Born at less than 32 weeks, 0 days gestation AND had chronic lung disease of prematurity defined as greater than 21% oxygen for at least 28 days after birth • Born at any gestational age with hemodynamically significant heart disease including: <ul style="list-style-type: none"> ○ Cyanotic heart disease in consultation with a pediatric cardiologist ○ Acyanotic Heart disease with one of the following: <ul style="list-style-type: none"> ▪ On heart failure medication and expected to require cardiac surgical procedure ▪ Moderate to severe pulmonary hypertension • Cystic fibrosis with clinical evidence of chronic lung disease (CLD) and/or nutritional compromise in the first year of life • Born at any gestational age with pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the lower airway <p><u>Infants less than 2 years of age at the onset of the RSV season (which typically starts November 1st, but may vary seasonally) AND have one 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

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- 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:
 - Solid organ or hematopoietic stem cell transplant recipient
 - Chemotherapy recipient
- Born at any gestational age and receiving a cardiac transplant

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

Field Name	Field Description
Prior Authorization Group Description	Insulin-Like Growth Factor-1 Receptor (Igf-1r) Antagonists For Thyroid Eye Disease
Drugs	Tepezza (teprotumumab-trbw)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Member must be 18 years age or older
Prescriber Restrictions	Prescriber must be an ophthalmologist, endocrinologist, or specialist with expertise in the treatment of Grave’s disease with thyroid eye disease.
Coverage Duration	If all of the criteria are met, the request will be approved for up to 24 weeks of treatment (8 total infusions). Retreatment requests will not be allowed beyond the 8 dose limit.
Other Criteria	<p><u>Initial Authorization:</u></p> <p>Tepezza is approved when all of the following are met:</p> <ul style="list-style-type: none"> • Dosing does not exceed dosing guidelines as outlined in the package insert • Patient has a confirmed diagnosis of Graves’ disease • Documentation of moderate-severe thyroid eye disease as evidenced by one or more of the following: <ul style="list-style-type: none"> ○ Lid retraction of >2mm ○ Moderate or severe soft-tissue involvement ○ Proptosis \geq3mm above normal values for race and sex ○ Periodic or constant diplopia • Patient must be euthyroid or thyroxine and free triiodothyronine levels are less than 50% above or below normal limits (submit laboratory results with request), or has been initiated on antithyroid medication. • Patients of reproductive potential: attestation the patient is not pregnant, and appropriate contraception methods will be used before, during, and 6 months after the last infusion • Patient has had a trial and therapy failure of, or contraindication to: <ul style="list-style-type: none"> ○ For active disease: oral or IV glucocorticoids unless

<p>Revision/Review Date 7/2025</p>	<p>disease is moderate-to-severe with significant proptosis (≥ 3 mm above normal for race and sex) and/or diplopia is present</p> <ul style="list-style-type: none">○ For chronic/inactive disease: rehabilitative surgery <p><u>Re-authorization:</u></p> <ul style="list-style-type: none">• Retreatment or renewal requests beyond a total of 24 weeks of treatment (8 total infusions) will not be allowed. <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Transthyretin-mediated Amyloidosis Agents
Drugs	<p><u>Preferred:</u> Polyneuropathy – Onpattro (patisiran), Amvuttra (vutrisiran), Wainua (eplontersen) Cardiomyopathy – Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis), Attruby (acoramidis)</p> <p><u>Non-preferred:</u> Cardiomyopathy – Amvuttra (vutrisiran) 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	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy the request will be approved for 6 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Regimen does not exceed FDA-approved dose/frequency • Patient has not undergone a liver or heart transplant • Requests for use multiple agents (different mechanism of action) in this policy for mixed polyneuropathy-cardiomyopathy phenotypes will only be considered if patient meets clinical criteria requirements for each section. <p>• Polyneuropathy-Type If the request is for Onpattro, Amvuttra, or Wainua:</p> <ul style="list-style-type: none"> • Patient has diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis as evidenced by documented transthyretin variant by genotyping • One of the following: <ul style="list-style-type: none"> ○ Patient has baseline polyneuropathy disability (PND) score \leq IIIb ○ Patient has a baseline FAP Stage 1 or 2 ○ Patient has baseline neuropathy impairment (NIS) score \geq 5 and \leq 130 • Patient has clinical signs/symptoms of neuropathy • <p>• Cardiomyopathy-Type</p>

If the request is for Vyndaqel, Vyndamax, Attruby, or Amyuttra:

- Patient has a confirmed diagnosis of cardiomyopathy of wild-type or hereditary transthyretin-mediated 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.
- For Amvuttra, patient has contraindication to/or previous trial and failure or continued clinical progression with use of Vyndaqel, Vyndamax or Attruby

Re-authorization (for continuing and new patients to the plan) :

- Patient's regimen does not exceed FDA-approved dose/frequency for the agent
- Patient has not undergone a liver or heart transplant
- Requests for use multiple agents (different mechanism of action) in this policy for mixed polyneuropathy-cardiomyopathy phenotypes will only be considered if patient meets clinical criteria requirements for each section.
- Documented positive clinical response to therapy from baseline (stabilization/slowing of disease progression, improved neurological impairment, motor functions, improved NIS score, stabilization/reduced rate of decline in 6 minute walk test, etc.)
- If the request is for Vyndaqel/Vyndamax/Attruby/Amyuttra
 - Patient has continued NYHA functional class I, II, or III heart failure symptoms

Continuation of Therapy Provision:

Members with history (within the past 90 days) of a non-formulary product are not required to try a formulary agent prior to receiving the non-formulary product.

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

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Field Name	Field Description
Prior Authorization Group Description	Verquvo
Drugs	Verquvo (vericiguat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Pregnancy
Required Medical Information	See “Other Criteria”
Age Restrictions	Patient must be 18 years or older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist
Coverage Duration	If all of the conditions are met, the request will be approved for 12 month duration.
Other Criteria	<ol style="list-style-type: none"> 1. Medication is prescribed at an FDA approved dose 2. The medication is being used for the treatment of symptomatic chronic heart failure with reduced ejection fraction (less than 45%) 3. Documentation that the patient has had a previous hospitalization for heart failure or has required outpatient IV diuretics 4. Member is currently being prescribed the following treatment regimens, or documentation has been provided that the member is not able to tolerate or has a contraindication to any of these agents: <ol style="list-style-type: none"> a. Angiotensin-converting enzyme (ACE) inhibitor OR angiotensin receptor blocker (ARB) OR angiotensin receptor/neprilysin inhibitor b. Mineralocorticoid receptor antagonist (e.g. spironolactone) c. Evidence based beta-blocker (i.e., bisoprolol, carvedilol, metoprolol succinate) d. Farxiga or Jardiance 5. Patient is not concomitantly using a phosphodiesterase-5 (PDE-5) enzyme inhibitor (e.g. sildenafil) 6. Negative pregnancy test (for females of reproductive age; as indicated) within 30 days of request 7. Prescriber attests to discussing with females of reproductive potential the need to use effective forms of contraception during treatment and for one month after stopping treatment
Revision/Review Date 7/2025	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	Vijoice
Drugs	Vijoice (alpelisib)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	≥ 2 years
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, dermatologist, vascular surgeon, hematologist/oncologist, or other specialist in the treatment of PIK3CA-Related Overgrowth Spectrum (PROS)
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of PROS • Documented evidence of a mutation in the PIK3CA gene • Patient has at least one target lesion identified on imaging • Prescriber attests the patient’s condition is severe or life-threatening and necessitates systemic treatment • Medication is prescribed at an FDA approved dose <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation of a positive clinical response • Prescriber attests the patient does not have any serious adverse events or unacceptable toxicity • Medication is prescribed at an FDA approved dose <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
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Field Name	Field Description
Prior Authorization Group Description	Vimizim (elosulfase alfa)
Drugs	Vimizim (elosulfase alfa)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	Patient must be 5 years of age or older.
Prescriber Restrictions	Prescriber is, or is collaborating with another provider who is, a specialist in the treatment of Morquio A syndrome or other lysosomal storage disorders.
Coverage Duration	6 months
Other Criteria	<p><u>Initial Authorization (new to therapy):</u></p> <ul style="list-style-type: none"> • Patient has confirmed diagnosis of mucopolysaccharidosis IVA (MPS IVA, or Morquio A syndrome) via one of the following: <ul style="list-style-type: none"> ○ Genetic testing ○ Analysis of N-Acetylgalactosamine 6-sulfatase (GALNS) activity in leukocytes or fibroblasts • Documentation of patient weight Patient must have completed a 6-minute walk test for baseline evaluation (must submit results with request) <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Patient shows signs of improvement from baseline in a 6-minute walk test (must submit results with request) <p><u>Re-authorization for members new to the plan previously treated with Vimizim:</u></p> <ul style="list-style-type: none"> • Patient has confirmed genetic diagnosis of mucopolysaccharidosis IVA (MPS IVA, or Morquio A syndrome) via one of the following: <ul style="list-style-type: none"> ○ Genetic testing ○ Analysis of N-Acetylgalactosamine 6-sulfatase (GALNS) activity in leukocytes or fibroblasts • Documentation of patient weight Patient must have completed a 6-minute walk test for baseline evaluation, and patient shows signs of improvement from baseline in a recent 6-minute walk test (must submit both results with request). • If a baseline 6-minute walk test was not completed prior to initiation of Vimizim therapy, then: <ul style="list-style-type: none"> ○ A current test must be completed (must submit results with request). ○ Continued authorizations for Vimizim for patients without a completed baseline 6-minute walk test

<p>Revision/Review Date 7/2025</p>	<p>evaluation prior to initiation of therapy must continue to be able to walk in subsequent evaluations.</p> <ul style="list-style-type: none">○ If patient is established on Vimizim therapy prior to enrollment on the plan, but is not able to walk, then medical justification is required as to how the patient continues to receive benefit from Vimizim therapy. <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Presbyopia Agents
Drugs	Vuity (pilocarpine HCl ophthalmic solution) Qlosi (pilocarpine HCl ophthalmic solution) Vizz (aceclidine ophthalmic solution)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Vuity: 40-55 years Qlosi: 45-64 years Vizz: 45-75 years
Prescriber Restrictions	Prescribed by or in consultation with an optometrist or ophthalmologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of presbyopia • Trial and failure or contraindication to corrective lenses (i.e., eye glasses, contact lenses) • Medication is prescribed at an FDA approved dose <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation or provider attestation of positive clinical response • Medication is prescribed at an FDA approved dose <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Sleep Disorder Therapy
Drugs	Formulary status: Non-preferred, Prior Authorization Required <ul style="list-style-type: none"> • Sodium oxybate solution • Xyrem (sodium oxybate) solution • Xywav (calcium, magnesium, potassium, and sodium oxybates) • Lumryz (sodium oxybate) packet
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Wakix: severe hepatic impairment (Child-Pugh class C) Sodium oxybate (Xyrem/Xywav/Lumryz): Succinic semialdehyde dehydrogenase deficiency
Required Medical Information	See “Other Criteria”
Age Restrictions	Per FDA approved prescribing information.
Prescriber Restrictions	Prescribed by or in consultation with a sleep specialist, neurologist, or other specialist in the treatment of the member’s diagnosis (does not apply for diagnosis of shift-work disorder)
Coverage Duration	. Requests for sodium oxybate products will be approved with up to a 3 month duration.
Other Criteria	<p><u>For all requests:</u></p> <ul style="list-style-type: none"> • Medication is being prescribed at an FDA approved dose <p><u>Sodium Oxybate (Xyrem/Xywav/Lumryz) initial authorization</u></p> <ul style="list-style-type: none"> • Medication is not being taken concurrently with sedative hypnotics • 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, ALL of the following: <ul style="list-style-type: none"> ▪ Either modafinil or armodafinil (not required for members under 18) ▪ Sunosi (solriamfetol) (not required for members under 18) ▪ Wakix (pitolisant) ○ For Xyrem or Xywav or Lumryz: documented trial and failure of, or medical reason for not using generic sodium oxybate. • 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: <ul style="list-style-type: none"> ▪ Wakix (pitolisant) (not required for members under 18) ○ For Xyrem or Xywav or Lumryz: documented trial and failure of, or medical reason for not using generic sodium oxybate. • For a diagnosis of idiopathic hypersomnia (Xywav only): <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>Revision/Review Date: 10/2025</p>	<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, reduction in frequency of cataplexy attacks)• Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary
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Field Name	Field Description
Prior Authorization Group Description	Sublingual Allergenic Extracts
Drugs	Grastek (timothy grass pollen allergen extract) Odactra (house dust mite allergen extract) Oralair (sweet vernal/orchard/rye/timothy/Kentucky blue grass mixed pollen allergenic extract) Ragwitek (Short ragweed pollen allergenic extract)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to Package Insert
Prescriber Restrictions	Prescriber is an allergist or immunologist
Coverage Duration	If all of the conditions are met, the request will be approved for a 12 month duration.
Other Criteria	<p><u>Initial authorization:</u></p> <p><u>For all requests:</u></p> <ul style="list-style-type: none"> • Requested allergenic extract is being used to treat allergic rhinitis with or without conjunctivitis • Member has had a document trial and failure of, or intolerance to, an intranasal corticosteroid (e.g. fluticasone) used in combination with at least one of the following: <ul style="list-style-type: none"> ○ Oral antihistamine (e.g. cetirizine) ○ Intranasal antihistamine (e.g. azelastine) ○ Oral leukotriene receptor antagonist (montelukast) • Patient has been prescribed (as demonstrated by pharmacy claims or documentation) injectable epinephrine <p><u>Grastek:</u></p> <ul style="list-style-type: none"> • Diagnosis has been confirmed by positive skin or in vitro testing to Timothy Grass, or cross reactive, pollen <p><u>Odactra:</u></p> <ul style="list-style-type: none"> • Diagnosis has been confirmed by either positive skin test to house dust mite allergen extract OR positive in vitro testing for IgE antibodies to <i>Dermatophagoides farinae</i> or <i>Dermatophagoides pteronyssinus</i> <p><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>Revision/Review Date 10/2025</p>	<p><u>Reauthorization:</u></p> <p><u>For all requests:</u></p> <ul style="list-style-type: none">• Member has experienced a reduction in symptoms associated with allergic rhinitis <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
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Field Name	Field Description
Prior Authorization Group Description	Tecelra
Drugs	Tecelra (afamitresgene autoleucel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	<ul style="list-style-type: none"> • Homozygous or heterozygous for HLA-A*02:05P
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be an oncologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for a one-time treatment.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of unresectable or metastatic synovial sarcoma • Documentation that patient is HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive • Documentation that the tumor expresses the MAGE-A4 antigen • Documentation of treatment with prior chemotherapy • Member must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 • Medication is being prescribed at an FDA approved dose <p>The safety and effectiveness of repeat administration of Tecelra has not been evaluated and will not be approved.</p> <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
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Field Name	Field Description
Prior Authorization Group Description	Epidermolysis Bullosa Agents
Drugs	Vyjuvek (beremagene geperpavec-svdt), Filsuvez (birch triterpenes)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	<ul style="list-style-type: none"> • Other forms of epidermolysis bullosa, such as epidermolysis bullosa simplex, kindler epidermolysis bullosa • Concurrent use of Vyjuvek and Filsuvez
Required Medical Information	See “Other Criteria”
Age Restrictions	Per prescribing information
Prescriber Restrictions	Prescriber must be a dermatologist, geneticist, or specialist experienced in the treatment of epidermolysis bullosa.
Coverage Duration	If all of the criteria are met, the initial request will be approved for two (2) months. Subsequent requests will be approved for six (6) months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Patient has a diagnosis of dystrophic or junctional epidermolysis bullosa, with genetic mutation(s) confirmed via genetic testing. • Requested product is FDA approved for the patient’s epidermolysis bullosa subtype • Documentation is provided that wound(s) to be treated are clean with adequate granulation tissue, excellent vascularization, and do not appear infected • Documentation is provided that there is no evidence of, or history of squamous cell carcinoma in the wound(s) to be treated • Medication is prescribed at an FDA approved dose, and maximum dispensable amount is not exceeded <ul style="list-style-type: none"> ○ Vyjuvek: Requests exceeding more than one vial per week will not be approved. ○ Filsuvez: documentation of size of treatment area(s) and frequency of dressing changes is required. One tube of Filsuvez covers up to 250 cm² surface area per single use tube. Requests exceeding a quantity sufficient to cover the treatment area more than once daily will not be approved. Rounding to the next whole tube size necessary is allowed. <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation or provider attestation of positive clinical response (i.e. improvement in wound appearance, wound closure, healing, etc.) • Documentation indicating need for continued treatment is needed (either to partially healed wounds or to other wound sites)

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

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

Field Name	Field Description
Prior Authorization Group Description	Vykat XR (diazoxide choline)
Drugs	Vykat XR (diazoxide choline)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist, psychiatrist, or other physician with expertise in the treatment of Prader-Willi syndrome (PWS)
Coverage Duration	If all the criteria are met, the initial and reauthorization requests will be approved for 6 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Medication is prescribed at an FDA approved dose • Documentation of patient’s body weight • Diagnosis of PWS confirmed by genetic testing (copies of test must be submitted with request) • Documentation patient experiences symptoms of hyperphagia related to PWS (e.g. food-seeking behaviors, food aggression, etc.) <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation of positive clinical response in hyperphagic symptoms (i.e. decrease in food-related aggression or food-seeking behavior, etc.) • Medication is prescribed at an FDA approved dose • Documentation of patient’s body weight <p>If all the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
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Field Name	Field Description
Prior Authorization Group Description	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Agents
Drugs	Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase) **If the request is for an immunoglobulin for CIDP, please refer to the Immune Globulins criteria**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Per FDA-approved labeling
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or neuromuscular specialist.
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 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of CIDP confirmed by electrodiagnostic test results (e.g. electromyography or nerve conduction studies) • Patient has progressive or relapsing/remitting disease course for ≥ 2 months • Patient has an inadequate response, significant intolerance, or contraindication to intravenous immunoglobulin (IVIG) or subcutaneous immunoglobulin (SCIG) • 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 significant clinical improvement in neurologic symptoms or stabilization of disease • 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: 10/2025	

Field Name	Field Description
Prior Authorization Group Description	Enzyme Replacement Therapy for Acid Sphingomyelinase Deficiency (ASMD)
Drugs	Xenpozyme (olipudase alfa-rpcp)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, a specialist experienced in the treatment of ASMD
Coverage Duration	If all the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Medication is prescribed at an FDA approved dose • Member has a diagnosis of ASMD confirmed by one of the following: <ul style="list-style-type: none"> ○ Deficiency in acid sphingomyelinase (ASM) enzyme activity (as measured by peripheral blood leukocytes, cultured skin fibroblasts, or dried blood spots) ○ Sphingomyelin phosphodiesterase-1 (SMPD1) gene mutation • Member has a clinical presentation consistent with ASMD type B or type A/B • Documentation of members height and weight • Documentation of baseline ALT and AST within 1 month prior to initiation of treatment <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation or provider attestation of positive clinical response (i.e. improvement in splenomegaly, hepatomegaly, pulmonary function, etc.) • Medication is prescribed at an FDA approved dose <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>

Date: 2/2026

Field Name	Field Description
Prior Authorization Group Description	Xolremdi
Drugs	Xolremdi (mavorixafor)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	12 years of age and older
Prescriber Restrictions	Prescriber must be an immunologist or a hematologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of WHIM (warts, hypogammaglobulinemia, infections and myelokathexis) syndrome confirmed by genotype variant of chemokine receptor 4 (CXCR4) and absolute neutrophil count (ANC) of ≤ 400 cells/μL • Documentation of baseline ANC and absolute lymphocyte count (ALC) • Documentation of member weight • Medication is prescribed at an FDA approved dose <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation or provider attestation of positive clinical response (i.e. improvement from baseline in ANC and/or ALC) • Documentation of member weight • Medication is prescribed at an FDA approved dose <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
Date: 7/2025	

Field Name	Field Description
Prior Authorization Group Description	Yorvipath
Drugs	Yorvipath (palopegteriparatide)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Members with acute postsurgical hypoparathyroidism (HP) or those who are at increased risk for osteosarcoma
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be 18 years of age or older
Prescriber Restrictions	Prescriber must be an endocrinologist or in consultation with an endocrinologist.
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Confirmed diagnosis of chronic HP of postsurgical, autoimmune, genetic, or idiopathic origins, for at least 6 months • Provider attestation that patient is currently receiving conventional therapy, including active vitamin D (calcitriol) and elemental calcium, and that patient's disease cannot be adequately controlled on conventional therapy alone • Current labs (within 60 days of request) have been submitted for the following: <ul style="list-style-type: none"> ○ Albumin-corrected serum calcium (must be ≥ 7.8mg/dL to start therapy) ○ Serum vitamin D level (must be ≥ 20 ng/mL to start therapy) • Medication is prescribed at an FDA approved dose <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation of a recent albumin-corrected serum calcium in the lower-half of the normal reference range or just below the normal reference range (~8–9 mg/dL) • ONE of the following: <ul style="list-style-type: none"> ○ Patient no longer requires active vitamin D or therapeutic doses of calcium, OR ○ Patient has had a significant reduction in required dosages of active vitamin D or therapeutic doses of calcium and is still actively titrating doses of Yorvipath • Medication is prescribed at an FDA approved dose <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>
Date: 2/2025	

Field Name	Field Description
Prior Authorization Group Description	Zevaskyn
Drugs	Zevaskyn (prademagene zamikeracel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Receipt of any prior chemical or biologic product for the treatment of recessive dystrophic epidermolysis bullosa (RDEB), including Vyjuvek and Filsuvez at the same wound site
Required Medical Information	See “Other Criteria”
Age Restrictions	Per prescribing information
Prescriber Restrictions	Prescriber must be a specialist experienced in the treatment of epidermolysis bullosa.
Coverage Duration	If all of the criteria are met, the request will be approved for one treatment cycle only.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Patient has a diagnosis of RDEB with genetic testing confirming mutations in both COL7A1 genes • Presence of RDEB wounds with ALL of the following characteristics: <ul style="list-style-type: none"> ○ Open chronically for ≥ 6 months ○ Categorized as Stage 2 (partial-thickness) ○ Have an area of ≥ 20 cm² • Documentation is provided that there is no evidence of, or history of squamous cell carcinoma in the wound(s) to be treated • Medication is prescribed at an FDA approved dose <p>The safety and effectiveness of repeat administration of Zevaskyn to the same treatment site have not been evaluated and will not be approved.</p> <p>Revision/Review Date: 10/2025</p> <p>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>

Field Name	Field Description
Prior Authorization Group Description	Zolgensma (onasemnogene abeparvovec-xioi)
Drugs	Zolgensma (onasemnogene abeparvovec-xioi)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	<ul style="list-style-type: none"> • Patient has previously received this medication • Advanced spinal muscular atrophy (SMA) (e.g., complete paralysis of limbs, permanent ventilator-dependence) • Administration to premature neonates before reaching full-term gestational age
Required Medical Information	Patient's body weight
Age Restrictions	Patient must be less than 2 years of age
Prescriber Restrictions	Neurologist
Coverage Duration	Authorization will be placed for 1 dose.
Other Criteria	<p>Patient must meet all of the following criteria:</p> <ul style="list-style-type: none"> • Diagnosis of Spinal Muscular Atrophy (SMA) • Bi-allelic mutations in the survival motor neuron 1 (SMN1) gene • Baseline anti-AAV9 antibody titers of $\leq 1:50$ measured using an enzyme-linked immunosorbent assay (ELISA) • Dosing is consistent with FDA approved labeling <p>The safety and effectiveness of repeat administration of Zolgensma have not been evaluated and will not be approved.</p> <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 10/2025	

I. Requirements for Prior Authorization of Zynteglo (betibeglogene autotemcel)

A. Prescriptions That Require Prior Authorization

All prescriptions for Zynteglo (betibeglogene autotemcel) must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Zynteglo (betibeglogene autotemcel), the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed Zynteglo (betibeglogene autotemcel) for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling; **AND**
2. Is age-appropriate according to FDA-approved package labeling; **AND**
3. Is prescribed a dose and number of treatments that are consistent with FDA-approved package labeling; **AND**
4. Is prescribed Zynteglo (betibeglogene autotemcel) by a specialist at a qualified treatment center for Zynteglo (betibeglogene autotemcel); **AND**
5. Does not have a contraindication to the prescribed medication; **AND**
6. Is not a prior recipient of gene therapy or an allogeneic hematopoietic stem cell transplant; **AND**
7. For treatment of transfusion-dependent β -thalassemia, **both** of the following:
 - i. Has genetic testing confirming diagnosis of β -thalassemia
 - ii. Has a history of at least 100 mL/kg/year or 8 transfusion episodes/year of packed red blood cell transfusions in the prior 2 years.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for Zynteglo (betibeglogene autotemcel). If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for

prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of Zynteglo (betibeglogene autotemcel) will be approved for 18 months for 1 infusion.

E. References

1. Zynteglo [prescribing information]. Somerville, MA: bluebird bio, Inc.; August 2022.
2. Cappellini MD, Farmakis D, Porter J, Taher A, eds. 2021 Guidelines for the Management of Transfusion Dependent Thalassaemia (TDT). 4th ed. Thalassaemia International Federation (TIF). Available at: <https://thalassaemia.org.cy/>. Accessed March 2024.
3. Connor RF, Fosmarin AG, Tirnauer JS. What's new in hematology. UpToDate [internet database]. Waltham, MA: UpToDate Inc. Updated February 29, 2024. Accessed March 18, 2024.