PRIOR AUTHORIZATION CRITERIA

Effective Date 8/25/2025

Prior Authorization Group Description	**Medications without Drug or Class Specific Criteria**
Drugs	The criteria applies to **Non-PDL, Non-Formulary** products • Medications without drug or class specific prior authorization criteria • Brand drugs and reference biologics when a therapeutic equivalent generic drug or biosimilar/interchangeable biologic is available
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If all of the conditions are met, requests will be approved for up to 12 months (depending on the diagnosis and usual treatment duration)
Other Criteria	**Initial Authorization:** **All Requests:** • The drug is requested for an appropriate use (per the references outlined in "Covered Uses" • The dose requested is appropriate for the requested use (per the references outlined in "Covered Uses") • Patient meets one of the three following criteria: o Documented trial and failure or intolerance oftwo alternative preferred/formulary 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 formulary agent, only that agent must have been ineffective or not tolerated. o No other formulary drug/product has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia. o All other formulary drugs/products are contraindicated based on the patient's diagnosis, other medical conditions, or other current therapy.

Revision/Review Date: 11/2024	**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 currently available biosimilar product(s) does not have the same appropriate use (per the references outlined in "Covered Uses") as the reference biologic drug being requested Form FDA 3500 – Voluntary Reporting **Reauthorization:** • Documentation of provider attestation that demonstrates a clinical benefit • The requested drug is for a medically accepted dose as outlined in Covered Uses **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Prior Authorization Exception Criteria**
Covered Uses	All medically accepted indications. Medically accepted indications are defined using the following compendia resources: the Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), American Hospital Formulary Service Drug Information (AHFS-DI), and DRUGDEX Information System. The reviewer may also reference disease state specific standard of care guidelines.
Scope	Requests for exception to the drug's prior authorization criteria requirements
Coverage Duration	12 months

Criteria	• The provider either verbally or in writing has submitted a medical or member specific reason why prior authorization criteria all or in part is not applicable to the member.
	  o Medical and/or member specific reasons may include but are not limited to:
	  ▪ Uniqueness of the member's condition or other physical characteristics of the member's condition.
	  ▪ Psychiatric, intellectual, physical, cultural, and/or linguistic characteristics of the member which may inhibit the provider from obtaining all necessary prior authorization criteria requirements.
	
	Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.

Revision/Review Date:	11/2024

Field Name	Field Description
Prior Authorization Group Description	**Quantity Limit Exception Criteria**
Covered Uses	All medically accepted indications. Medically accepted indications are defined using the following compendia resources: the Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), American Hospital Formulary Service Drug Information (AHFS-DI), and DRUGDEX Information System. The reviewer may also reference disease state specific standard of care guidelines.
Scope	Requests for formulary drugs exceeding the health plan's published quantity limits
Criteria	• The provider has submitted a medical reason why the plan's quantity limit will be inadequate based on the member's condition and treatment history. **AND one of the following:** o The member has a documented treatment failure with the drug prescribed at the health plan's quantity limit AND the dose requested is supported by the Medical Compendia or current treatment guidelines. o The member requires a dose within prescribing guidelines that exceeds the plan's quantity limit. **Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.**
Coverage Duration	12 Months
Revision/Review Date	11/2024

Field Name	Field Description
Prior Authorization Group Description	**Safety Edit Exception Criteria**
Covered Uses	All medically accepted indications. Medically accepted indications are defined using the following compendia resources: the Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), American Hospital Formulary Service Drug Information (AHFS-DI), and DRUGDEX Information System. The reviewer may also reference disease state specific standard of care guidelines.
Scope	Requests for formulary drugs and for previously approved non-formulary drugs: • Exceeding the Food and Drug Administration (FDA) or compendia max dose recommendations • Exceeding the FDA dosing or compendia administration frequency recommendations • Exceeding the FDA or compendia duration of therapy recommendations • Duplication of therapy error at Point of Service (POS) • Age Restriction error at POS • Day Supply Limit error at POS • Concurrent Use error at POS • Drug Drug Interaction error at POS
Criteria	**Exceeding the Food and Drug Administration (FDA) or compendia maximum dose, administration frequency or duration of therapy recommendations.** • The member must have a documented treatment failure with the drug at the maximum dose based on patient age/weight, administration frequency, or duration of therapy per FDA or compendia. AND • The provider must submit a medical reason why the maximum dose, administration frequency or duration of therapy needs to be exceeded based on the member's condition or treatment history. **Duplication of therapy** <u>Transition from one agent to another</u> • If a provider has outlined a plan to transition a member to a similar drug or provided a dose titration schedule, the requested drug is approved for one month*. <u>Concurrent Therapy with two similar agents</u>

	• The provider must submit a medical reason why treatment with more than one drug in the same class is required based on the member's condition and treatment history. OR • The provider must submit disease state specific standard of care guidelines supporting concurrent therapy. **Age Restriction** • The provider must submit a medical reason why the drug is needed for a member whose age is outside of the plan's minimum or maximum age limit. AND • The indication and dose requested is supported by the Medical Compendia or current treatment guidelines. **Day Supply Limit** • An additional fill exceeding the day supply limit is needed based on a dose increase or is needed to achieve a total daily dose OR • The provider must submit a medical reason why an additional fill is needed outside of the plan's day supply limit. AND • The indication and dose requested is supported by the FDA, Medical Compendia or current treatment guidelines. **Concurrent Use/Drug-Drug Interaction** • The provider must submit a medical reason why treatment with both drugs is necessary for the member AND • The increased risk for side effects when taking the drugs together has been discussed with the member **Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.**
Coverage Duration Revision/Review Date: 11/2024	*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

Field Name	Field Description
Prior Authorization Group Description	**Step Therapy Exception Criteria**
Covered Uses	All medically accepted indications. Medically accepted indications are defined using the following compendia resources: the Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), American Hospital Formulary Service Drug Information (AHFS-DI), and DRUGDEX Information System. The reviewer may also reference disease state specific standard of care guidelines.
Scope	Requests for drugs on the plan's formulary with a step therapy restriction which do not meet step therapy requirements
Criteria	Requests for drugs on the plan's formulary with a step therapy restriction which do not meet step therapy requirements will be considered when the provider verbally or in writing has submitted a medical reason why: • Required step therapy drug(s) would be ineffective, or; • Required step therapy drug(s) have the potential to cause harm or deterioration of the member's condition, or; • The requested drug would be superior to the required prerequisite trial(s) with preferred drug(s). **Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.**
Coverage Duration	12 Months
Revision/Review Date:	11/2024

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

Revision/Review Date 4/2025	3. Medication is being requested at an appropriate dose per literature **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Adakveo (crizanlizumab-tmca)**
Drugs	Adakveo (crizanlizumab-tmca)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	Member must be 16 years of age or older
Prescriber Restrictions	Prescriber must be a hematologist or sickle cell specialist
Coverage Duration	If the criteria are met, requests may be approved for 12 months.
Other Criteria Revision/Review Date: 7/2025	**Initial Authorization:** • Member has a confirmed diagnosis of sickle cell disease • Documentation was provided that the member has been taking hydroxyurea at the maximum tolerated dose and has been compliant within the last 6 months (or a medical reason was provided why the patient is unable to use hydroxyurea) • Documentation of the member's current weight • Request is for an FDA-approved dose **Reauthorization:** • Documentation has been submitted that the member has demonstrated or maintained ONE of the following changes from baseline: o Reduction in pain crises o Increased time between crises or patient is stable o Decrease in days hospitalized • Documentation of the member's current weight • Request is for an FDA-approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Adrenal Enzyme Inhibitors for Cushing's Disease**
Drugs	Isturisa (osilodrostat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be ≥ 18 years of age
Prescriber Restrictions	Prescribed by, or in consultation with, an endocrinologist or other specialist in the treatment of metabolic disorders
Coverage Duration	Initial Authorization: If the criteria are met, the request will be approved for a 6-month duration. Reauthorization: If the criteria are met, the request will be approved for a 12-month duration.
Other Criteria	**Initial Authorization:** • Member has confirmed diagnosis of Cushing's Disease • Pituitary surgery is not an option or has not been curative • Provider attests baseline electrocardiogram (ECG) has been obtained and hypokalemia and/or hypomagnesemia has been corrected prior to initiating therapy if present • The medication is being prescribed at a dose that is consistent with FDA-approved package labeling, nationally recognized compendia or peer-reviewed literature • Documented baseline urinary free cortisol (UFC) test ≥ 1.3upper limit of normal (ULN) o UFC Normal Range = 3.5-45 mcg/24 hrs (9.66-124.2 nmol/24 hrs) • Member has had a documented trial and failure of one of the following: o ketoconazole o Metopirone (metyrapone) o Lysodren (mitotane) o cabergoline o Signifor/Signifor LAR (pasireotide) o etomidate **OR** Member has a documented medical reason (e.g. contraindication, intolerance, hypersensitivity) as to why these medications cannot be used

Revision/Review Date: 2/2025	**<u>Reauthorization:</u>** • Member has responded to therapy as defined by a documented urinary free cortisol (UFC) test ≤ the upper limit of normal (ULN) • The medication is being prescribed at a dose that is consistent with FDA-approved package labeling, nationally recognized compendia **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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

Revision/Review Date 11/2024	Oralair: • Diagnosis has been confirmed by positive skin, or in vitro, testing to Sweet Vernal, Orchard, Rye, Timothy, Kentucky Blue Grass, or cross reactive, pollen Ragwitek: • Diagnosis has been confirmed by positive skin, or in vitro, testing to Short Ragweed pollen **Reauthorization:** For all requests: • Member has experienced a reduction in symptoms associated with allergic rhinitis **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Alpha-1 Proteinase Inhibitors (Human)**
Drugs	**Preferred:** Prolastin-C **Non-Preferred:** Aralast NP Glassia Zemaira Or any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or specialist in the treatment of AAT
Coverage Duration	The request will be approved for up to a 12 month duration.
Other Criteria	**Initial Authorization:** • Documented diagnosis of a congenital deficiency of alpha-1 antitrypsin (AAT) (serum AAT level < 11 micromol/L [approximately 57 mg/dL using nephelometry or 80mg/dl by radial immunodiffusion]). • Documentation was submitted indicating the member has undergone genetic testing for AAT deficiency and is classified as phenotype PiZZ, PiSZ, PiZ(null) or Pi(null)(null) [NOTE: phenotypes PiMZ or PiMS are not candidates for treatment with Alpha1-Proteinase Inhibitors] • Documentation was submitted (member's pulmonary function test results) indicating airflow obstruction by spirometry (forced expiratory volume in 1 second [FEV_1] ≤ 65% of predicted), or provider has documented additional medical information demonstrating medical necessity • Documentation was submitted indicating member is a non-smoker or an ex-smoker (eg. smoking cessation treatment) • Documentation of the member's current weight • The Alpha-1 Proteinase Inhibitor (human) is being prescribed at an FDA approved dosage • If the medication request is for an Alpha1-Proteinase Inhibitor (human) product other than Prolastin-C, the patient has a

Revision/Review Date 2/2025	documented medical reason (intolerance, hypersensitivity, contraindication, treatment failure, etc.) for not using Prolastin-C to treat their medical condition **Reauthorization:** • Documentation of the member's current weight • Documentation was submitted indicating member is a non-smoker or an ex-smoker (e.g. smoking cessation treatment) • Documentation was submitted indicating the member has clinically benefited from therapy (i.e. stable lung function, improved PFTs, alpha-1 antitrypsin serum level maintained above 11 micromol/L [approximately 57 mg/dL using or 80 mg/dL by radial immunodiffusion], improved quality of life) • The Alpha-1 Proteinase Inhibitor (human) is being prescribed at an FDA approved dosage **Clinical reviewer/Medical Director must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

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	On-demand therapy: If all criteria are met, the request will be approved for 1 month. Prophylactic therapy: If all criteria are met, the initial request will be approved for 6 months. Reauthorization requests will be approved for 12 months.

Other Criteria	**Initial Authorization**
	• Diagnosis of congenital thrombotic thrombocytopenic purpura (cTTP) as confirmed by BOTH of the following:
	  o Molecular genetic testing
	  o 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
	
	Reauthorization
	• Documentation of positive clinical response to therapy (i.e., improvement in acute and subacute TTP events, platelet counts, microangiopathic hemolytic anemia episodes, or clinical symptoms)
	• Member's weight
	• Request is for an FDA-approved dose

Revision/Review Date: 4/2025	**Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Radicava**
Drugs	Edaravone (Radicava), Radicava ORS (edaravone) any other newly marketed agent * Note: for riluzole dosage forms, refer to drug-specific criteria*
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	If the criteria are met, requests will be approved for 12 months.
Other Criteria Revision/Review Date: 4/2025	Initial criteria for all requests: • Documented diagnosis of ALS • Dose is within FDA approved limits • Member is not ventilator dependent • Member must have a documented baseline evaluation of functionality using the revised ALS functional rating scale (ALSFRS-R) score ≥ 2 • Member's disease duration is 2 years or less • Member has a baseline forced vital capacity (FVC) of ≥80% • Member has been on riluzole, is beginning riluzole therapy as an adjunct to treatment with Radicava, or provider has provided a medical reason why patient is unable to use riluzole Reauthorization criteria: • Member is not ventilator dependent • Provider documents clinical stabilization in symptoms (e.g. stabilization of ALSFRS-R score) • Dose is within FDA approved limits **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Anti-FGF23 Monoclonal Antibodies**
Drugs	Crysvita (burosumab) SQ solution, or any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: The Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	See Other Criteria
Required Medical Information	See Other Criteria
Age Restrictions	X-linked hypophosphatemia (XLH): 6 months of age or older Tumor-induced osteomalacia (TIO): 2 years of age and older
Prescriber Restrictions	Prescribed by, or in consultation with, an endocrinologist, nephrologist, molecular geneticist, or other specialist experienced in the treatment of metabolic bone disorders
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months and reauthorization requests will be approved for 12 months.
Other Criteria	**<u>Initial Authorization:</u>** **For X-linked hypophosphatemia (XLH):** • Diagnosis of XLH • Dosing is appropriate as per labeling or is supported by compendia or standard of care guidelines • Labs, as follows: o Serum phosphorus below normal for patient age o eGFR > 30 mL/min/1.73 m2 or CrCl ≥ 30 mL/min • Patient will not use concurrent oral phosphate and/or active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol) • Additionally, for adults: o Clinical signs and symptoms of XLH (e.g. bone/joint pain, fractures, osteomalacia, osteoarthritis, ensethopathies, spinal stenosis impaired mobility, presence or history of lower limb deformities, etc.) o Trial and failure of, or contraindication to, combination therapy with oral phosphate and active vitamin D (calcitriol) for a minimum of 8 weeks **For tumor-induced osteomalacia (TIO):** • Diagnosis of FGF23-related hypophosphatemia in TIO • Dosing is appropriate as per labeling or is supported by compendia or standard of care guidelines

Revision/Review Date: 7/2025	• The tumor(s) is/are not amenable to surgical excision or cannot be located
	• Labs, as follows:
	  o Serum phosphorus below normal for patient age
	  o eGFR > 30 mL/min/1.73 m2 or CrCl ≥ 30 mL/min
	• Patient will not use concurrent oral phosphate and/or active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol)
	
	<u>Re-authorization:</u>
	
	For XLH or TIO:
	• Documented effectiveness as evidenced by at least one of the following:
	  o Serum phosphorus within normal limits for patient age
	  o Clinical improvement (e.g. improved rickets, improved bone histomorphometry, increased growth velocity, increased mobility, decrease in bone fractures, improved fracture healing, reduction in bone-related pain)
	• 25-hydroxyvitamin D level and, if abnormally low, documented supplementation with cholecalciferol or ergocalciferol
	• Patient is not concurrently using oral phosphate and/or active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol)
	• Dosing continues to be appropriate as per labeling or is supported by compendia or standard of care guidelines
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Antifibrotic Respiratory Tract Agents

Drugs:
Ofev (nintedanib esylate)
pirfenidone (Esbriet)

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

INITIAL CRITERIA:

For all requests:

- Patient is 18 years of age or older
- Prescriber is a pulmonologist or lung transplant specialist
- Provider attests that they have reviewed the patient's other medications, and have addressed all potential drug interactions
- Documentation has been provided that the patient does not smoke

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

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

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

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

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

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

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

REAUTHORIZATION CRITERIA:

- Prescriber is a pulmonologist or lung transplant specialist

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

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

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

Revision/Review Date: 7/2025

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

Revision/Review Date: 2/2025	○ Lower average daily oral prednisone dose ○ Improved daily function either as measured through a validated functional scale or through improved daily performance documented at clinic visits ○ Sustained improvement in laboratory measures of lupus activity • Dosing is appropriate per labeling **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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

Revision/Review Date 11/2024	• If the diagnosis is **Overactive Bladder**, the member has tried and failed 2 formulary drugs (e.g. oxybutynin)
	• If the diagnosis is **Hyperhidrosis,** the member has tried and failed a prescription strength antiperspirant (e.g. 20% aluminum chloride hexahydrate)
	• If the diagnosis is **Chronic Sialorrhea,**
	  o Documentation is provided that the member has had sialorrhea lasting at least 3 months
	  o The member has tried and failed, or has a medical reason for not using, an anticholinergic medication (e.g. glycopyrrolate, hyoscyamine, benztropine)
	• If the request is for a non-preferred agent, the member tried and failed a preferred agent if appropriate for the requested indication
	
	For Reauthorization:
	• Documentation of provider attestation that demonstrates a clinical benefit
	• The requested drug is for a medically accepted dose as outlined in Covered Uses
	
	Physician/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	**Brineura (cerliponase alfa)**
Drugs	Brineura (cerliponase alfa)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert, and/or per the National Comprehensive Cancer Network (NCCN)
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	If the criteria are met, the request will be approved for 12 months.

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

Revision/Review Date: 7/2025	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Prior Authorization Group Description	**Chelating Agents**
Drugs	**<u>Formulary</u>** Chemet (succimer) capsule **<u>Non-Formulary (PA required)</u>** deferasirox (Exjade) tablet for oral suspension deferasirox (Jadenu) tablet Jadenu (deferasirox) granule pack Ferriprox (deferiprone) tablet, solution deferoxamine mesylate (Desferal) vial penicillamine (Cuprimine, Depen, D-penamine) capsule, tablet radiogardase (Prussian blue) capsule trientine (Spyrine) capsule Cuvrior (trientine tetrahydrochloride) Galzin (zinc acetate) capsule pentetate calcium trisodium ampule pentetate zinc trisdoium ampule Calcium Disodium Versenate (edetate calcium disodium) ampule
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	See "other criteria"
Prescriber Restrictions	N/A
Coverage Duration	If the above conditions are met, the request will be approved for 6 months.
Other Criteria	**<u>Requests for deferasirox (Exjade, Jadenu) only:</u>** **Chronic iron overload due to blood transfusions:** ***Pediatric Population:*** • Member must be ≥ 2 years old and < 21 years old • Diagnosis of chronic iron overload due to blood transfusions • Member is receiving blood transfusions on a regular basis/participating in blood transfusion program • Serum ferritin concentration is consistently > 1000 mcg/L. If the serum ferritin levels fall consistently below 500 mcg/L, deferasirox (Exjade, Jadenu) must be discontinued

	• If the request is for deferasirox oral granules in packet member has had a documented trial and failure of deferasirox dispersible tablets or medical reason why deferasirox dispersible tablets cannot be used • The medication requested is being prescribed at an FDA-approved dose ***Adult Population:*** • Member must be ≥ 21 years old • Diagnosis of chronic iron overload due to blood transfusions • Member is receiving blood transfusions on a regular basis/participating in blood transfusion program • Serum ferritin concentration is consistently > 1000 mcg/L. If the serum ferritin levels fall consistently below 500 mcg/L, deferasirox (Exjade, Jadenu) must be discontinued • Documentation that member is unable to use deferoxamine (Desferal) parenterally • If the request is for deferasirox oral granules in packet member has had a documented trial and failure of deferasirox dispersible tablets or medical reason why deferasirox dispersible tablets cannot be used • The medication requested is being prescribed at an FDA-approved dose **Chronic iron overload in non-transfusion-dependent thalassemia syndromes:** • Member must be ≥ 10 years old • Diagnosis of thalassemia syndrome • Liver iron content (LIC) by liver biopsy of ≥ 5 mg Fe/g dry weight • At least 2 measurements of serum ferritin levels > 300 mcg/L at least one month apart • If the request is for deferasirox oral granules in packet member has had a documented trial and failure of deferasirox dispersible tablets or medical reason why deferasirox dispersible tablets cannot be used • The medication requested is being prescribed at an FDA-approved dose **Requests for Ferriprox (deferiprone) only:** **Transfusion Iron overload due to thalassemia syndrome, sickle cell disease or other anemias** • Patient must be ≥ 3 years old for oral solution or ≥ 8 years old for tablets • Diagnosis of thalassemia syndrome, sickle cell disease, or other anemia • Patient receiving blood transfusions on a regular basis/participating in blood transfusion program • Serum ferritin concentration is consistently > 1000 mcg/L. If the serum ferritin levels fall consistently below 500 mcg/L, Ferriprox must be discontinued • Documented patient is unable to use deferoxamine (Desferal) parenterally

	• If the request is for Ferriprox Twice a Day there is a documented medical reason why deferiprone 500 mg tablet and deferiprone 1,000 mg tablet cannot be used • The medication requested is being prescribed at an FDA approved dose **Requests for Wilson's Disease:** **Cuvrior (trientene tetrahydrochloride) only:** • Laboratory confirmed diagnosis of Wilson's disease supported by at least one appropriate diagnostic test (e.g., slit lamp 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 **Trientene (Syprine) only:** • 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
Revision/Review Date: 7/2025	**Requests for all other drugs and indications:** • The drug is requested for an appropriate use (per the references outlined in "Covered Uses") **and** The dose requested is appropriate for the requested use (per the references outlined in "Covered Uses") **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary**

Field Name	Field Description
Prior Authorization Group Description	**Continuous Glucose Monitors**
Drugs	Preferred: Freestyle Libre 14 Day, Freestyle Libre 2, FreeStyle Libre 3, Dexcom G6, Dexcom G7 Non-Preferred: Eversense (Sensor, Transmitter, and Reader components) And any newly marketed product in this class **This policy does not apply to continuous glucose monitor/insulin pump combination products reviewed and/or covered by the Medical Benefit including, but not limited to, the MiniMed. Requests for these products are referred to the plan's Utilization Management team for Review**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Patient must be age appropriate per prescribing information (PI)
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Other Criteria	• Diagnosis – diabetes **AND** • Meets criteria under 1 or 2 below: 1. Treatment with insulin (type 1, type 2, or gestational) **OR** 2. Treatment of Type 2 diabetes with an antihyperglycemic drug without insulin AND one of the following: o Frequent hypoglycemia, hypoglycemia unawareness, or concerns of nocturnal hypoglycemia o Gaining weight (more than 5 pounds of weight gain in the last 12 months) o HbA1C ≥ 7% o Need for medication changes or titration o Initiation of a lower carbohydrate diet o Patient is unable or reluctant to test their blood glucose via traditional glucometer. o Patient is taking two or more medications to manage their diabetes. o Patient works with a care team member to improve

Revision/Review Date 7/2025	diet and exercise choices. • If the request is for a non-preferred product, trial and failure of or medical reason why patient cannot use a preferred product. • If member is continuing use of a non-preferred CGM, trial of a preferred CGM first is not required **<u>Reauthorization for treatment of Type 2 Diabetes without insulin</u>** o Documentation of positive clinical response (i.e. improved HbA1C or reduced frequency of severe hypoglycemia episodes) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Cholbam**
Drugs	**Cholbam (cholic acid)**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	MD is a gastroenterologist OR hepatologist
Coverage Duration	If all of the conditions are met, the request will be approved for a 3 month duration for the first year of therapy, and then for a 6 month duration after one year of treatment.
Other Criteria	<u>Initial authorization:</u> • Patient has a confirmed diagnosis of: ➢ Bile acid synthesis disorder due to single enzyme defect (SEDs) OR ➢ Peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients that exhibit manifestations of liver disease, steatorrhea or complications from decreased fat soluble vitamin absorption • Current labs (within 30 days of request) have been submitted for the following: ➢ ALT/AST ➢ GGT (serum gamma glutamyltransferase) ➢ ALP (Alkaline phosphatase) ➢ Bilirubin ➢ INR <u>Re-authorization:</u> • Documentation has been submitted indicating clinical benefit/ liver function has improved since beginning treatment • For reauthorization after the first 3 months of treatment, lab results must show an improvement in liver function and there must be no evidence of biliary obstruction or cholestasis • Current labs (within 30 days of request) have been submitted for the following: ➢ ALT/AST

Revision/Review Date 11/2024	➢ GGT (serum gamma glutamyltransferase) ➢ ALP (Alkaline phosphatase) ➢ Bilirubin ➢ INR **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Agents**
Drugs	Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	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 Date: 11/2024	**Initial Authorization:** • 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 **Re-Authorization:** • Documentation or provider attestation of significant clinical improvement in neurologic symptoms or stabilization of disease • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

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

Other Criteria	**<u>Initial Authorization</u>:**
	• Member has a molecularly confirmed diagnosis of a long-chain fatty acid oxidation disorder (LC-FAOD)
	• Documentation of at least two of the following:
	  o Disease specific elevation of acylcarnitines on a newborn blood spot or in plasma
	  o Low enzyme activity in cultured fibroblasts
	  o One or more known pathogenic mutations in either the *CPT2, ACADVL, HADHA, or HADHB* gene
	• 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
	
	<u>Re-Authorization:</u>
	• Documentation submitted indicating the member has experienced a clinical benefit (e.g. increased left ventricular ejection fraction, reduced left ventricular wall mass, reduced maximum heart rate, decreased incidence of rhabdomyolysis)
	• Documentation of member's DCI
	• Dose is within FDA-indicated limits and does not exceed 35% of DCI

Revision/Review Date: 2/2025	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	**Doxylamine/Pyridoxine**
Drugs	Doxylamine 10 mg/Pyridoxine 10 mg (Diclegis) Bonjesta (doxylamine 20 mg/pyridoxine 20 mg)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be an obstetrician/gynecologist
Coverage Duration	If the criteria are met, the request will be approved for up to 9 (nine) months or the expected remaining duration of the pregnancy.
Other Criteria Revision/Review Date 2/2025	**Initial authorization:** • Diagnosis of nausea and vomiting due to pregnancy. **AND** • The member has tried and failed, or has an intolerance to, combination therapy with pyridoxine (vitamin B_6) and doxylamine single-ingredient products. **AND** • If the request is for Bonjesta, the member has tried and failed, or has an intolerance to, doxylamine 10 mg/pyridoxine 10 mg **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	**Emergency Use Authorization (EUA) Drugs/Products for COVID-19**
Drugs	Any drug/product approved by EUA for COVID-19
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Emergency Use Authorization for the drug/product in question, and the Drug Package Insert (PPI).
Exclusion Criteria	See "Other Criteria"
Required Medical Information	See "Other Criteria"
Age Restrictions	As outlined within current FDA Emergency Use Authorization (EUA) guidelines
Prescriber Restrictions	N/A
Coverage Duration	As outlined within current FDA Emergency Use Authorization (EUA) guidelines
Other Criteria	Emergency Use Authorization for COVID-19 related drugs/products (all must apply): • The requested drug/product has a currently active Emergency Use Authorization as issued by the U.S. Food and Drug Administration. • Use of the requested drug/product is consistent with the current terms and conditions of the emergency use authorization (such as appropriate age/weight, formulation, disease severity, concurrent use with other medications or medical interventions, etc.). • Attestation that the provider is not requesting reimbursement for ingredient cost of drug when drug is provided by U.S. government at no charge
Revision/Review Date 2/2025	**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	**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	• 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	**Initial Authorization:** • 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 o Vyjuvek: Requests exceeding more than one vial per week will not be approved. o 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. **Re-Authorization:**

Revision/Review Date: 4/2025	• Documentation or provider attestation of positive clinical response (i.e. improvement in wound appearance, wound closure, healing, etc.)
	• Documentation indicating need for continued treatment is needed (either to partially healed wounds or to other wound sites)
	• Documentation is provided that wound(s) to be treated are clean with adequate granulation tissue, excellent vascularization, and do not appear infected
	• Documentation is provided that there is no evidence of, or history of squamous cell carcinoma in the wound(s) to be treated
	• Medication is prescribed at an FDA approved dose, and maximum dispensable amount is not exceeded.
	  o Vyjuvek: Requests exceeding more than one vial per week will not be approved.
	  o 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.

Prior Authorization Group Description	**Gonadotropin Releasing Hormone Agonists (GNRH)** ****IF DIAGNOSIS IS GENDER DYSPHORIA, USE MEDICATIONS WITHOUT DRUG OR CLASS SPECIFIC CRITERIA****
Drug(s)	**Preferred GNRH Agonist(s) for their respective indications:** Lupron Depot (leuprolide acetate), Lupron Depot-Ped (leuprolide acetate) **Non-Preferred GNRH Agonist(s):** Fensolvi (leuprolide acetate), Supprelin LA (histrelin acetate), Synarel (nafarelin acetate), Trelstar (triptorelin pamoate), Triptodur (triptorelin pamoate), and any newly marketed GnRH agonist**.**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per the National Comprehensive Cancer Network (NCCN), the American Society of Clinical Oncology (ASCO), the American College of Obstetricians and Gynecologists (ACOG), or the American Academy of Pediatrics (AAP) standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert if not detailed in "Other Criteria"
Prescriber Restrictions	Prescriber must be a specialist in the field to treat the member's condition.
Coverage Duration	If all of the conditions are met, the request will be approved for up to 12 months if diagnosis is central precocious puberty, and up to 3-6 months as indicated below for other indications as recommended per FDA approved indications and/or as defined by the medical compendium or standard of care guidelines.
Other Criteria	**<u>INITIAL AUTHORIZATION for ALL REQUESTS:</u>** • The medication is being prescribed for an FDA approved/standard of care guideline indication and within FDA approved/standard of care dosing guidelines.

	AND the member meets the following for the respective diagnosis:
	
	Central precocious puberty (CPP)
	
	• Onset of secondary sexual characteristics occurred when member was aged less than 8 years for females or aged less than 9 years for males
	• Diagnosis is confirmed by a pubertal response to a GnRH stimulation test and/or measurement of gonadotropins (FSH/LH), and bone age advanced beyond chronological age.
	  o Patients with low or intermediate basal levels of LH should have a GnRH stimulation test to clarify the diagnosis.
	  ▪ *If basal levels of LH are markedly elevated [e.g. more than 0.3mlU/ml (where IU- International units)] in a child with precocious puberty, then a diagnosis of CPP can be made without proceeding to a GnRH stimulation test*.
	• Brain magnetic resonance imaging (MRI) has been performed for all boys with CPP and for girls with onset of secondary sexual characteristics before the age of six years of age to rule out a tumor.
	• If the request is for any agent other than Lupron Depot-Ped the member has had a documented trial and failure with Lupron Depot-Ped or a documented medical reason (e.g. intolerance, hypersensitivity, contraindication) was submitted why the member is not able to use Lupron Depot-Ped
	
	Endometriosis
	
	• For all therapies except Lupron, Lupron Depot, or Lupron Depot-Ped, member is ≥ 18 years of age
	• Member has a confirmed diagnosis (e.g. laparoscopy, etc.)
	• Documented trial and failure or medical reason for not using an analgesic pain reliever (e.g., NSAIDs, COX-2 inhibitors) taken in combination with combined estrogen progestin oral contraceptive pills (OCPs):
	  o If one of the following drugs has been tried previously, a trial of OCPs is not required: progestins, Orilissa (elagolix), danazol, or aromatase inhibitors (e.g. anastrozole, letrozole)
	• If the request is for any agent other than Lupron Depot/Ped, or Lupaneta Pack, the member has had a documented trial and failure with the preferred agents or a documented medical reason (e.g. intolerance, hypersensitivity, contraindication) was submitted why the member is not able to use these medications
	• Approval is 6 months
	
	Uterine leiomyomas (Fibroids)
	
	• Member has a confirmed diagnosis (e.g. pelvic examination, etc.)

Review Date 11/2024	• If the request is for any agent other than Lupron Depot the member has had a documented trial and failure with Lupron Depot or a documented medical reason (e.g. intolerance, hypersensitivity, contraindication) was submitted why the member is not able to use Lupron Depot • Approval is 3 months <u>Endometrial thinning</u> • Member has a confirmed diagnosis (e.g. pelvic examination, etc.) • Documentation indicates patient is scheduled for endometrial ablation for dysfunctional uterine bleeding. • Approval is 3 months **<u>REAUTHORIZATION for all requests:</u>** • The medication is being prescribed for an FDA approved indication and within FDA approved dosing guidelines. • Documentation was provided supporting continued treatment (e.g. patient still has symptoms), and medication is being continued as recommended in package insert or standard of care guidelines. <u>AND meets the following per diagnosis:</u> <u>Central precocious puberty (CPP)</u> • If the medication reauthorization is for central precocious puberty, the child is male and < 12 years or female and < 11 years of age OR a documented medical reason to continue treatment was provided with request, and includes current height and bone age <u>Endometriosis</u> • Provider has evaluated patient for osteoporosis (e.g. Dexascan), and patient is receiving “add back” hormonal therapy (norethindrone acetate 5 mg daily alone or with conjugated estrogen therapy) or an oral bisphosphonate AND calcium and vitamin D supplementation. • The patient has not received cumulative doses of the GnRH agonist greater than 12 months of therapy. <u>Fibroids</u> • The patient has not received cumulative doses of the GnRH agonist greater than 6 months of therapy

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

Prior Authorization Group Description	**Treatment of Hereditary Angioedema**
Drugs	icatibant (Firazyr) ***All other products are carved out and requests should go to Magellan***
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be an immunologist, allergist, rheumatologist, or hematologist
Coverage Duration	If criteria are met, the request will be approved for the standard FDA approved dosing per treatment episode with 5 refills for acute treatment for both initial and reauthorization.

Other Criteria
 	
Revision/Review Date: 4/2025
	Initial Criteria:
	• Diagnosis of hereditary angioedema (HAE)
	  o HAE with deficient or dysfunctional C1INH (e.g. type I, type II, or acquired C1INH deficiency
	  o HAE with normal C1INH:
	  ▪ If known origin, documentation of results of confirmatory genetic test (e.g. mutations in gene for factor XII, angiopoietin-1, plasminogen, kininogen-1, myoferlin, heparan sulfate-glucosamine 3-O-sulfotransferase 6)
	  ▪ If unknown origin (U-HAE), documentation of a prolonged trial of high-dose non-sedating antihistamines
	• The patient is not taking ACE inhibitors or estrogen containing oral contraceptives or hormone replacement therapy
	• Documentation submitted indicates the medication is being prescribed for an FDA approved indication at FDA approved dose.
	• The patient is receiving no other medications for acute treatment
	
	Renewal Criteria:
	• Documentation was submitted that the patient has clinically benefited from medication
	• The patient is receiving no other medications for acute treatment
	• The medication is being prescribed for an FDA approved indication at FDA approved dose
	
	NOTE: Medical Director/Clinical Reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary

Field Name	Field Description
Prior Authorization Group Description	**Immune Globulins**
Drugs	Gamunex-C (IV or SQ) (Immune Globulin) Bivigam (IV) (Immune Globulin) Cuvitru (SQ) (Immune Globulin) Flebogamma (IV) (Immune Globulin) Gamastan (IM) (Immune Globulin) Gamastan SD (IM) (Immune Globulin) Gammagard liquid (IV or SQ) (Immune Globulin) Gammagard SD (IV) (Immune Globulin) Gammaked (IV or SQ) (Immune Globulin) Gammaplex (IV) (Immune Globulin) Hizentra (SQ) (Immune Globulin) Octagam (IV) (Immune Globulin) Privigen (IV) (Immune Globulin) Asceniv (IV) (Immune Globulin-slra) Cutaquig (SQ) (Immune Globulin-hipp) Panzyga (IV) (Immune Globulin-ifas) Hyqvia (SQ) (Immune Globulin Human/Recombinant Human Hyaluronidase) Xembify (SQ) (Immune Globulin-klhw) Alyglo (IV) (Immune Globulin-stwk) Or any newly marketed immune globulin ****Gamunex-C is the preferred product for the indications of primary immunodeficiency, chronic idiopathic thrombocytopenic purpura, and chronic inflammatory demyelinating polyneuropathy****
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	See “other criteria”
Coverage Duration	If the criteria are met the request will be approved for a 3 month duration unless otherwise specified in the diagnosis specific “Other Criteria” section below.
Other Criteria	**<u>All Requests:</u>** • Documentation of diagnosis confirmed by a specialist

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

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

	• Patient is < 13 years of age
	• Either patient's IgG level is < 400mg/dL or
	• If patient's IgG level is ≥ 400 mg/dL than significant deficiency of humoral immunity as evidenced by ONE of the following:
	  o Inability to produce an adequate immunologic response to specific antigens.
	  o History of recurrent bacterial infections despite prophylactic antibiotics
	• Dose does not exceed 400mg/kg/dose every 2-4 weeks
	
	• If criteria is met, approve for 3 months.
	
	Multifocal motor neuropathy (MMN):
	• Duration of symptoms has been at least 1 month with disability.
	• Nerve conduction studies were completed to rule out other possible conditions, and confirms the diagnosis of MMN.
	• Dose does not exceed 2g/kg/month administered over 2 to 5 days.
	
	• If criteria is met, approve for up to 5 days for 3 months.
	
	Chronic inflammatory demyelinating polyneuropathy (CIDP):
	• Duration of symptoms has been at least 2 months with disability.
	• Nerve conduction studies or a nerve biopsy were completed in order to rule out other possible conditions, and confirms the diagnosis of CIDP.
	• Patient has tried and failed, or has a documented medical reason for not using, corticosteroids.
	  o If the patient has severe and fulminant or pure motor CIDP a trial of corticosteroids is not required
	• Dose is consistent with FDA approved package labeling, nationally recognized compendia, or peer-reviewed literature
	• If the request is for any medication other than Gamunex-C, the member has tried and failed, or has a documented medical reason for not using, Gamunex-C
	
	• If criteria is met, approve for up to 5 days for 3 months

Revision/Review Date 11/2024	**<u>Guillain-Barre syndrome</u>:** • Patient has severe disease with the inability to walk without aid • Onset of symptoms within the last 4 weeks • Dose does not exceed 2g/kg administered over 2-5 days • If criteria is met, approve for up to 5 days. **<u>Myasthenia Gravis:</u>** • <u>Acute:</u> o 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 o Dose does not exceed 2 g/kg administered over 2-5 days o If criteria is met, approve for up to 5 days • <u>Chronic:</u> o Diagnosis of refractory generalized myasthenia gravis o Patient has tried and failed, or has a documented medical reason for not using 2 or more immunosuppressive therapies (i.e. corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil) o Dose does not exceed 2 g/kg/month administered over 2-5 days o If criteria is met, approve for 3 months **<u>Dermatomyositis (DM):</u>** • One of the following: o Bohan and Peter score of 3 (i.e. definite DM) o Bohan and Peter score of 2 (i.e. probable DM) AND concurring diagnostic evaluation by ≥ 1 specialist (e.g. neurologist, rheumatologist, dermatologist) • Patient does NOT have any of the following: o Cancer (CA) associated myositis defined as myositis within 2 years of CA diagnosis (except basal or squamous cell skin cancer or carcinoma in situ of the cervix that has been excised and cure) o Active malignancy o Malignancy diagnosed within the previous 5 years o Breast CA within the previous 10 years • For a diagnosis of DM, one of the following: o Member has tried and failed, or has a documented medical reason for not using both of the following:

	▪ methotrexate (MTX) OR azathioprine ▪ rituximab. o Member has severe, life-threatening weakness or dysphagia • For a diagnosis of cutaneous DM (i.e. amyopathic DM, hypomyopathic DM): o 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. **Medical Director/Clinical Reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary**

Prior Authorization Group Description	**Infliximab Products**
Drugs	**PREFERRED:** Avsola (infliximab-axxq) Renflexis (infliximab-abda) infliximab **NON-PREFERRED :** Remicade (infliximab) Inflectra (infliximab-dyyb) Or any newly-marketed infliximab biosimilar/follow-on biologic
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by, or in consultation with, a specialist in the treatment of the applicable disease
Coverage Duration	If all of the conditions are met, the request will be approved for 12 months.
Other Criteria	**Initial Authorization for All Indications:** • The medication is being prescribed at an appropriate FDA-approved dose (for age and weight) • If the request is for a non-preferred product, documented (consistent with pharmacy claims/medical record data/chart notes, physician attestation) adequate trial of a preferred infliximab product. **Requests for Crohn's Disease**: • If the member has a diagnosis of severe-fulminant, moderate-severe, or perianal/fistulizing Crohn's disease – approve • If the member has a diagnosis of mild-to-moderate/low-risk Crohn's disease, the following is required: an adequate trial or a documented medical reason for not using conventional therapy to manage the condition (e.g. sulfasalazine, budesonide ER (Uceris), azathioprine, 6-mercaptopurine, or methotrexate) **Requests for Ulcerative Colitis**: • If the member has a diagnosis of moderate-severe ulcerative colitis – approve. • If the member has a diagnosis of mild-moderate ulcerative colitis, the following is required: an adequate trial of, or medical reason for not using, conventional therapy to manage the condition (e.g. oral aminosalicylates, azathioprine, 6-mercaptopurine, or oral corticosteroids)

Revision/Review Date: 11/2024	**Requests for Plaque Psoriasis:** • The member has had an adequate trial of, or medical reason for not using, a therapy in 3 of the following categories including at least 1 trial of systemic or phototherapy/PUVA(consistent with pharmacy claims/medical chart data): o Topical steroids o Topical calcipotriene, calcitriol, or tazarotene o Topical tacrolimus or pimecrolimus o Topical anthralin, coal tar, or salicylic acid o Oral methotrexate or cyclosporine o Oral acitretin o UVB phototherapy or PUVA (oral psoralen or topical methoxsalen plus UVA therapy) **Requests for Psoriatic Arthritis:** • The member has had an adequate trial of, or medical reason for not using ALL of the following (consistent with pharmacy claim/medical chart data): o At least one non-steroidal anti-inflammatory drug (NSAID) or cyclooxygenase-2 (COX-2) inhibitor o At least one conventional DMARD (e.g. leflunomide, methotrexate, sulfasalazine) • Member has axial symptoms/disease or enthesitis (i.e involving the plantar fascia and Achilles tendon insertion) and has tried and failed NSAID therapy **Requests for Rheumatoid Arthritis:** • The member has had an adequate trial or a documented medical reason for not using at least one conventional DMARD (e.g. leflunomide, methotrexate, sulfasalazine) **Requests for Spondyloarthritis:** • The member has had an adequate trial and failure or medical reason for not using two different nonsteroidal anti-inflammatory drugs (NSAIDs) or cyclooxegenase-2 (COX-2) inhibitors, each for at least two weeks **Reauthorization:** • The member has been receiving the medication and there is documentation that a clinical benefit was observed. **Continuation of Therapy Provision**: • Members with history (within the past 90 days) of a preferred infliximab product are not required to try the above-mentioned conventional therapies prior to receiving infliximab. **Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Prior Authorization Group Description	**Non-PDL Interleukin Receptor Antagonists for Eosinophilic Conditions**
Drugs	Cinqair (reslizumab) and any newly marketed agents not included on the PDL
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• When being used for relief of acute bronchospasm or status asthmaticus, or for the treatment of other eosinophilic conditions. • When used in combination with another monoclonal antibody for the treatment of asthma
Required Medical Information	See "other criteria"
Age Restrictions	Per package insert
Prescriber Restrictions	Prescriber must be an allergist, pulmonologist, immunologist, rheumatologist, other provider who specializes in the treatment of eosinophilic conditions, or in consultation with one of these specialists
Coverage Duration	If the above conditions are met, the initial request will be approved with a 4 month duration. All subsequent requests will be approved with a 6 month duration.
Other Criteria Revision/Review Date: 2/2025	**Initial Authorization:** Severe Asthma in Patients with Eosinophilic Phenotype: • Confirmed diagnosis of eosinophilic asthma • Documentation has been provided (within the last year of the date of the request) of an eosinophil count ≥ 400 cells/mcL • The patient has a documented baseline FEV_1 < 80% of predicted with evidence of reversibility by bronchodilator response. • Documentation has been provided indicating patient still is having significant symptoms with ≥1 exacerbation for (emergency room visits, hospital admissions) while compliant on a maximally tolerated inhaled corticosteroid with a long-acting B2 agonist (ICS/LABA) AND a long-acting muscarinic antagonist (LAMA). If the patient has not utilized these therapies, a documented medical reason must be provided why patient is unable to do so. • The prescribed dose is within FDA approved dosing guidelines **Re-Authorization:** • Documentation submitted indicates the member has clinically benefited from the medication (e.g. asthma: improved FEV1, reduced exacerbations • The prescribed dose is within FDA approved dosing guidelines **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Prior Authorization Group Description	**Agents for Homozygous Familial Hypercholesterolemia (HoFH)**
Drugs	**Preferred:** Evkeeza (evinacumab-dgnb) **Non-Preferred: Juxtapid (lomitapide)** ****Please refer to the "LIPOTROPICS: PCSK9 INHIBITORS" policy for requests for medications in that class****
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a cardiologist or specialist in the treatment of lipid disorders.
Coverage Duration	If the criteria are met, the initial request will be approved for up 6 months. Reauthorization requests will be approved for 12 months.

Other Criteria	**Initial Authorization:**
	• Documentation of a diagnosis of homozygous familial hypercholesterolemia (HoFH) via either:
	  o Genetic confirmation of two mutant alleles at the LDL receptor, ApoB, PCSK9 or ARH adaptor protein gene locus; OR
	  o A clinical diagnosis of HoFH which includes: untreated LDL-C >500 mg/dL (>13 mmol/L) or treated LDL-C ≥300 mg/dL (>8 mmol/L), AND
	  ▪ Cutaneous or tendon xanthoma before age 10 years, OR
	  ▪ Elevated LDL-C levels consistent with heterozygous FH in both parents.
	• Member has tried and failed atorvastatin 40mg-80mg or rosuvastatin 20-40mg (consistently for 3 months via claim history or chart notes). If member is not able to tolerate atorvastatin or rosuvastatin, documentation was provided that the member is taking another statin at the highest tolerated dose, or a medical reason was provided why the member is not able to use these therapies.
	• If prescriber indicates member is "statin intolerant", documentation was provided including description of the side effects, duration of therapy, "wash out", re-trial, and then change of agents.
	• Member has tried and failed ezetimibe at a maximal tolerated dose or a medical reason was provided why the member is not able to use ezetimibe
	• Member has documented trial and failure with PCSK9 inhibitor for at least 3 months, or a medical reason has been provided, why member is unable to use a PCSK9 inhibitor indicated for HoFH to manage their condition.
	• Documentation was provided indicating provider has counseled member on smoking cessation and following a "heart healthy diet".
	• Documentation was provided of current LDL level

Revision/Review Date: 2/2025	• If the request is for Juxtapid the member has had documented trial and failure with Evkeeza for at least 6 month or a medical reason has been provided why the member is unable to use Evkeeza **Reauthorization:** • Documentation submitted indicates that the member has obtained clinical benefit from the medication including repeat fasting lipid panel lab report, and the member has achieved or maintained a LDL reduction from the levels immediately prior to initiation of treatment. • The member's claim history shows consistent therapy (monthly fills). Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Immunoglobulin A (IgA) Nephropathy Agents
Drugs	Filspari (sparsentan), Tarpeyo (budesonide), Vanrafia (atrasentan)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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: • 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: 9 months Reauthorization: • 12 months: Filspari, Vanrafia • Reauthorization requests for Tarpeyo will not be allowed as the safety and efficacy of subsequent courses have not been established
Other Criteria	**<u>Initial Authorization:</u>** • 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 has proteinuria (defined as total urine protein ≥1 g/day) • Member has an estimated glomerular filtration rate (eGFR) ≥30 mL/min/1.73 m^2 • Medication is prescribed at an FDA approved dose • For Filspari: o Documentation of baseline liver function o Attestation that member will discontinue use of renin-angiotensin-aldosterone system (RAAS) inhibitors, endothelin receptor antagonists, and/or aliskiren upon initiation of Filspari • For Vanrafia: o Member is at risk for disease progression as defined by a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g **<u>Re-Authorization:</u>** • Documentation of positive clinical response (e.g. decrease in UPCR, stabilization of eGFR)

Date: 7/2025	• Medication is prescribed at an FDA approved dose • For Filspari: ○ Documentation of liver function ***Reauthorization requests will not be allowed as the safety and efficacy of subsequent courses of Tarpeyo have not been established*** **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Joenja**
Drugs	Joenja (leniolisib)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Per prescribing information.
Prescriber Restrictions	Prescriber must be an immunologist, hematologist, medical geneticist, or other prescriber who specializes in the treatment of genetic or immunologic disorders.
Coverage Duration	If the criteria are met, requests will be approved with up to a 6-month duration. Thereafter, reauthorization requests will be approved with up to a 12-month duration.
Other Criteria Revision/Review Date 7/2025	**Initial Authorization:** • Documentation of APDS/PASLI-associated PIK3CD/PIK3R1 mutation, confirmed by genetic testing. • Documentation of nodal and/or extranodal lymphoproliferation, history of repeated oto-sino-pulmonary infections and/or organ dysfunction (e.g., lung, liver) • Prescriber attests that the member is not currently taking immunosuppressive medication • Prescriber attests that female patients have been advised of the potential risk to a fetus, will use effective contraception and have had a negative pregnancy test prior to initiation of treatment • Medication is being prescribed at an FDA approved dose **Reauthorization:** • Documentation has been submitted indicating member has experienced a clinical benefit from treatment (e.g., decreased lymph node size, increase in percentage of naïve B cells) • Prescriber attests that female patients will use effective contraception and have had a negative pregnancy test • Medication is being prescribed at an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Lemtrada (alemtuzumab)**
Drug(s)	Lemtrada (alemtuzumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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 infected with HIV (human immunodeficiency virus)
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restriction	Prescribed by, or in consultation with, a neurologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 5 vials (60 mg). For continuation of therapy, if all criteria are met, the request will be approved for 3 vials (36 mg).
Other Criteria Review/Revision Date: 2/2025	**INITIAL AUTHORIZATION:** • The member has a clinical diagnosis of relapsing-remitting multiple sclerosis (MS) or active secondary progressive MS • The member has a documented trial of at least two disease-modifying drugs for MS (consistent with claims data or for new members to the health plan, consistent with medical chart history with dates and dosing), or has a documented medical reason (intolerance, hypersensitivity, etc) for not utilizing conventional disease-modifying treatment. • Lemtrada is being prescribed at an FDA-approved dose **CRITERIA FOR REAUTHORIZATION:** • The member has a clinical diagnosis of relapsing-remitting multiple sclerosis (MS) or active secondary progressive MS • A period of 12 months has elapsed since previous treatment • Lemtrada is being prescribed at an FDA-approved dose 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	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
 	
Revision/Review Date: 7/2025
	Initial Authorization:
	• Member has diagnosis of one of the following metachromatic leukodystrophies (MLD):
	  o Pre-symptomatic late infantile (PSLI) MLD
	  o Pre-symptomatic early juvenile (PSEJ) MLD
	  o Early symptomatic early juvenile (ESEJ) MLD
	• Documentation patient has both of the following:
	  o Arylsulfatase A (ARSA) activity below the normal range (normal range 31-198 nmol/mg/h)
	  o Identification of two disease-causing ARSA alleles
	• Medication is prescribed at an FDA approved dose
	
	The safety and effectiveness of repeat administration of Lenmeldy has not been evaluated and will not be approved.
	
	If all the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

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

Revision/Review Date 7/2025	• No recent (past 1 year) history of stroke, seizures or transient ischemic attack (TIA), or findings on neuroimaging that indicate an increased risk for intracerebral hemorrhage. **<u>Reauthorization</u>** • The request is for an FDA approved dose • Patient continues to have a diagnosis of mild cognitive impairment (MCI) caused by AD or mild AD consistent with Stage 3 or Stage 4 Alzheimer's disease as evidenced by at least one of the following: o CDR-G score of 0.5-1.0 and a Memory Box score of 0.5 or greater o MMSE score of 22-30 o Wechsler Memory Scale IV-Logical Memory (subscale) II (WMS-IV LMII) score at least 1 standard deviation below age-adjusted mean • Provider attestation of safety monitoring and management of amyloid related imaging abnormalities (ARIA) and intracerebral hemorrhage, as recommended per the manufacturer's prescribing information. • Documentation that member has experienced clinical benefit from the medication (such as: stabilization or decreased rate of decline in symptoms from baseline on CDR-SB, ADAS-Cog14, or ADCS MCI-ADL scales) • No recent (past 1 year) history of stroke, seizures, or TIA **If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.** **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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

Other Criteria
 	
Revision/Review Date: 2/2025
	• Patient has established atherosclerotic disease or multiple risk factors for cardiovascular disease
	• Patient is currently receiving statin therapy, or documentation has been provided that the member has a medical reason statin therapy is not appropriate
	• Documentation is provided that guideline directed medical therapies targeted to patient's specific risk factors are being maximized, such as medications targeted at reduction in cholesterol, blood pressure, antiplatelet therapies, and diabetes
	• Patient does not have pre-existing blood dyscrasias (ex. leukopenia, thrombocytopenia)
	• Patient does not have renal failure (CrCl less than 15 ml/min) or severe hepatic impairment
	• Patient is not currently taking medications contraindicated for concurrent use with Lodoco
	  o Strong CYP3A4 inhibitors (ex. atazanavir, clarithromycin, darunavir/ritonavir, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, tipranavir/ritonavir)
	  o P-glycoprotein inhibitors (ex. cyclosporine, ranolazine)
	
	Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	**Immunosuppressants for Lupus Nephritis**
Drugs	Lupkynis (voclosporin)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be 18 years of age or older
Prescriber Restrictions	Prescriber must be rheumatologist, nephrologist or other specialist in the treatment of autoimmune disorders
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Revision/Review Date 4/2025	**<u>Initial Authorization</u>** • Member must have a diagnosis of systemic lupus erythematosus (SLE) with a kidney biopsy indicating a histologic diagnosis of lupus nephritis (LN) Class III, IV, or V • Documentation that the member has a baseline eGFR > 45 mL/min/1.73m^2 • Documentation of the member's urine protein/creatinine ratio (UPCR) is provided • Member is concurrently being treated with background immunosuppressive therapy, or has a medical reason for not using background immunosuppressive therapy • Member is NOT concurrently being treated with cyclophosphamide • Medication is prescribed at an FDA approved dose **<u>Reauthorization</u>** • Documentation of improvement in renal function (i.e. reduction in UPCR or no confirmed decrease from baseline eGFR ≥ 20%) • Medication is prescribed at an FDA approved dose **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Mucopolysaccharidosis VI (Maroteaux-Lamy Syndrome) Agents**
Drugs	**Naglazyme (galsulfase)**
Covered Uses	*Carve out under pharmacy benefit, criteria apply to medically billed requests* Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	"See Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months Renewal: 12 months

Other Criteria	**Initial Authorization**
	• Diagnosis of Mucopolysaccharidosis VI as confirmed by one of the following:
	  o Enzyme assay demonstrating a deficiency in N-acetygalactosamine 4-sulfatase (arylsulfatase B) enzyme activity
	  o DNA testing
	• Patient's weight
	• Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines
	
	Reauthorization
	• Patient has demonstrated a beneficial response (i.e., stabilization or improvement in 12-minute walk test [12-MWT], 3-minute stair climb test, urinary glycosaminoglycan (GAG) levels, etc.)
	• Patient's weight
	• Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines

Revision/Review Date 11/2024	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Multaq**
Drugs	**Multaq (dronedarone)**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Pregnancy
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	Request must be from a cardiologist or electrophysiologist.
Coverage Duration	If the criteria are met, the request will be approved with up to a 12 month duration.
Other Criteria Revision/Review Date 4/2025	• 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 **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

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

Other Criteria	**Initial Authorization:**
	• Diagnosis of generalized myasthenia gravis (gMG)
	• Patient has a positive serological test for one of the following:
	  o Anti-AChR antibodies
	  o Anti-muscle-specific tyrosine kinase (MuSK) antibodies (Rystiggo only)
	• Patient has a Myasthenia Gravis Foundation of America (MGFA) clinical classification of class II, III or IV
	• Patient has tried and failed, or has contraindication, to one of the following:
	  o Two (2) or more conventional therapies (i.e. acetylcholinesterase inhibitors, corticosteroids, non-steroidal immunosuppressive therapies)
	  o Failed at least 1 conventional therapy and required chronic plasmapheresis or plasma exchange or intravenous immunoglobulin
	• Medication is prescribed at an FDA approved dose
	• Patient is not using agents covered by this policy concurrently (i.e. no concurrent use of Vyvgart, Vyvgart Hytrulo, or Rystiggo)
	• For Vyvgart Hytrulo, patient has tried and failed, or has contraindication, to Vyvgart
	
	Re-Authorization:

Revision/Review Date: 11/2024	• 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	**Natriuretic Peptides for Achondroplasia**
Drugs	Voxzogo (vosoritide) **The following criteria is for the medical benefit only. Voxzogo is carved out under the BCC pharmacy benefit**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Hypochondroplasia or short stature condition other than achondroplasia
Required Medical Information	See "Other Criteria"
Age Restrictions	According to FDA approved prescribing information
Prescriber Restrictions	Prescribed by, or in consultation with, an endocrinologist, medical geneticist, or other specialist for the treatment of achondroplasia
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 4/2025	**Initial Authorization:** • Member has a diagnosis of achondroplasia as confirmed via genetic testing • Prescriber attests patient has open epiphyses • Documentation of baseline growth velocity • Medication is prescribed at an FDA approved dose **Re-Authorization:** • Documentation of positive clinical response to therapy (as demonstrated by improvement over baseline in annualized growth velocity) • Prescriber attests patient has open epiphyses • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**Niemann-Pick Disease Type C**
Drugs	Miplyffa (arimoclomol) **is carved out for BCC** Aqneursa (levacetylleucine)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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 of Miplyffa and Aqneursa
Required Medical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a neurologist, geneticist, or specialist in the treatment of Niemann-Pick disease type C (NPC)
Coverage Duration	If all criteria are met, the request will be approved for 12 months.

Other Criteria
 	
Revision/Review Date: 2/2025
	<u>Initial Authorization</u>
	• Diagnosis of NPC as confirmed by genetic testing demonstrating one of the following:
	  o Mutations in both alleles of NPC1 gene or NPC2 gene
	  o Mutation in one allele of NPC1 or NPC2 AND either a positive filipin-staining or elevated cholestane triol/oxysterols (>2x the upper limit of normal)
	• Documentation that member has at least one neurological sign of NPC (i.e., cognitive decline, vertical supranuclear gaze palsy, ataxia, seizures, etc.)
	• Documentation that member is ambulatory
	• Member's weight
	• Request is for an FDA-approved dose
	
	<u>Reauthorization</u>
	• Documentation of positive clinical response to therapy (i.e., improvement or stabilization in ambulation, fine motor skills, swallowing, or speech)
	• Member's weight
	• Request is for an FDA-approved dose
	
	Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.

Prior Authorization Group Description	**Injectable/Infusible Bone-Modifying Agents for Osteoporosis and Paget's Disease**
Drugs	pamidronate, ibandronate (Boniva) injection, Prolia (denosumab), zoledronic acid (Reclast), Evenity (romosozumab), teriparatide (biosimilar) or any other newly marketed agent ****This criteria does not apply to Forteo or Tymlos, please see drug-specific criteria****
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	"See other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be an endocrinologist, rheumatologist, orthopedist, or obstetrician/gynecologist
Coverage Duration	If all of the conditions are met, requests will be approved for 1 year. ***EVENITY WILL ONLY BE APPROVED FOR A TOTAL DURATION OF 12 MONTHS***
Other Criteria	<u>For all requests:</u> • The medication is FDA-approved for indication and is being requested at an FDA approved dose <u>If the diagnosis is postmenopausal or male osteoporosis:</u> • If the request is for male osteoporosis or high risk postmenopausal osteoporosis with no prior fractures the member has a documented (consistent with pharmacy claims) adequate trial of an oral bisphosphonate or has a medical reason (e.g. intolerance, hypersensitivity, contraindication, etc.) for not using an oral bisphosphonate • If the request is for very high risk postmenopausal osteoporosis or postmenopausal osteoporosis with prior fractures a documented trial and failure of an oral bisphosphonate will not be required. o Very high risk is defined as having one or more of the following: ▪ History of fracture in the past 12 months ▪ Multiple fractures ▪ Fractures while on drugs causing skeletal harm (e.g. long-term glucocorticoids) ▪ Very low T scores (< -3.0) ▪ High risk for falls ▪ History of injurious falls ▪ Very high fracture probability as determined by fracture risk assessment tool (FRAX) (e.g. major osteoporosis fracture >30%, hip fracture > 4.5%)

Revision/Review Date: 11/2024	• Documentation was submitted indicating the member is a postmenopausal woman or a male member over 50 years of age and one of the following applies: o Bone mineral density (BMD) value consistent with osteoporosis (T-scores equal to or less than –2.5) o Has had an osteoporotic fracture o T-score between -1 and -2.5 at the femoral neck or spine and a 10 year hip fracture probability >3% or a 10 year major osteoporosis-related fracture probability >20% (based on the US-adapted WHO absolute fracture risk model) • If the request is for Evenity (romosozumab) the following apply to the patient: o Documented trial and failure of Prolia (denosumab) **AND EITHER** ibandronate (Boniva) injection **OR** zoledronic acid (Reclast) or has a medical reason (e.g. intolerance, contraindication, etc.) why these therapies are not suitable to be used o Has SEVERE osteoporosis (T-Score -3.5 or below, or T-Score of -2.5 or below plus a fragility fracture) o If the request is for Evenity (romosozumab), member does not have a history of a heart attack or stroke within the preceding year <u>If the diagnosis is Paget's disease:</u> • The member has a documented (consistent with pharmacy claims) adequate trial of an oral bisphosphonate or has a medical reason (e.g. intolerance, hypersensitivity, contraindication, etc.) for not using an oral bisphosphonate • Documentation (within 60 days of request) was submitted including member's serum alkaline phosphatase level of ≥ two times the upper limit of normal AND the member is symptomatic OR there is documentation of active disease <u>If the diagnosis is glucocorticoid-induced osteoporosis:</u> • The member has a documented (consistent with pharmacy claims) adequate trial of an oral bisphosphonate or has a medical reason (e.g. intolerance, hypersensitivity, contraindication, etc.) for not using an oral bisphosphonate • For members ≥ 40 years of age on long-term glucocorticoid therapy: o Documentation that the dosage of the oral glucocorticoid therapy is equivalent to a dose greater than 2.5 mg of prednisone daily o Member has a moderate to very high risk of fracture based on ONE of the following: ▪ History of osteoporotic fracture ▪ BMD less than or equal to -1 at the hip or spine ▪ FRAX 10-year risk for major osteoporotic fracture greater than or equal to10% (with glucocorticoid adjustment) ▪ FRAX 10-year risk for hip fracture greater than 1% (with glucocorticoid adjustment)

	• For adult members (all ages) receiving HIGH dose glucocorticoid therapy:
	  o Member has a moderate to very high risk of fracture based on ONE of the following:
	  ▪ History of prior fracture(s)
	  ▪ Glucocorticoid dose ≥30mg/day or cumulative ≥5 grams/year
	  ▪ Continuing glucocorticoid treatment ≥7.5mg/day for ≥6 months AND BMD Z score < -3 OR significant BMD loss (> least significant change of DXA)
	
	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	**Omisirge**
Drugs	**Omisirge (omidubicel-onlv)**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Patient has previously received this medication
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	If all the criteria are met, the initial request will be approved for a one-time treatment.
Other Criteria Review/Revision Date: 7/2025	**<u>Initial Authorization:</u>** • Patient has a hematologic malignancy planned for umbilical cord blood transplantation (UCBT) following myeloablative conditioning • Prescriber attests that the patient is eligible for myeloablative allogeneic hematopoietic stem cell transplantation (HSCT) AND does not have a readily available matched related donor, matched unrelated donor, mismatched unrelated donor, or haploidentical donor • Patient has not received a prior allogenic HSCT • Patient does not have known allergy to dimethyl sulfoxide (DMSO), Dextran 40, gentamicin, human serum albumin, or bovine material **The safety and effectiveness of repeat administration of Omisirge have not been evaluated and will not be approved.** **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Agents for Primary Biliary Cholangitis**
Drugs	Ocaliva (obeticholic acid), Iqirvo (elafibranor), Livdelzi (seladelpar)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restriction	Member must be 18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a hepatologist or gastroenterologist
Coverage Duration	For Ocaliva: If the criteria are met, the request will be approved for 5 mg once daily for a 3 month duration for initial authorization and up to 10 mg once daily for up to a 12 month duration for reauthorization. For Iqirvo and Livdelzi: If the criteria are met, the request will be approved for a 3 month duration for initial authorization and for up to a 12 month duration for reauthorization.
Other Criteria	**Initial Authorization:** • Diagnosis of primary biliary cholangitis (PBC) with confirmation of diagnosis by the following tests: a) Positive antimitochondrial antibody test b) Elevated serum alkaline phosphatase (ALP) level • Drug is being requested in addition to ursodeoxycholic acid (UDCA) due to patient having an inadequate response to UDCA monotherapy for at least 1 year, OR member has a documented medical reason (e.g., contraindication, intolerance, hypersensitivity) why UDCA cannot be used and is taking the requested drug as monotherapy • Prescriber attests the patient does not have complete biliary obstruction, decompensated cirrhosis (e.g., Child-Pugh Class B or C) • For Ocaliva, prescriber must also attest the patient does not have compensated cirrhosis (Child-Pugh Class A) with evidence of portal hypertension • Submission of the following test results within 30 days of request: a) Serum ALP b) Total bilirubin **Reauthorization:** • Provider attests that the patient has not developed complete biliary

Revision/Review Date 11/2024	obstruction, decompensated cirrhosis (e.g., Child-Pugh Class B or C) • For Ocaliva, prescriber must also attest the patient does not have compensated cirrhosis (Child-Pugh Class A) with evidence of portal hypertension • Submission of lab tests confirming each of the following: ○ A decrease in ALP of ≥ 15% from baseline ○ ALP is less than 1.67 times the upper limit normal (ULN); defined as 118 U/L for females and 124 U/L for males ○ Total bilirubin ≤ ULN defined as 1.1 mg/dL for females and 1.5 mg/dL for males ○ First reauthorization request for Ocaliva following 3 months at the 5 mg once daily dose can be authorized for the 10 mg once daily dose for 3 months without submission of lab tests confirming clinical benefit. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	Primary Hyperoxaluria Agents
Drugs	Oxlumo (lumasiran) Rivfloza (nedosiran) **is carved out for BCC**
Covered Uses	Medically accepted indications are defined using the following 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	**Initial Authorization**
	• Diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by one of the following:
	  o Genetic testing confirming at least one mutation at the AGXT gene
	  o Liver biopsy demonstrating absent or significantly reduced AGT activity
	• Metabolic testing demonstrating one of the following:
	  o Increased urinary oxalate excretion (≥ 0.5 mmol/1.73 m^2per day[45 mg/1.73 m^2per day])
	  o Increased urinary oxalate:creatinine ratio relative to normative values for age
	  o Increased plasma oxalate level (≥ 20 μmol/L)
	• Member is concurrently using pyridoxine or has tried and failed previous pyridoxine therapy for at least 3 months, or has a medical reason for not using pyridoxine
	• Member has no history of liver transplant
	• Medication is prescribed at an FDA approved dose
	• Patient is not using Oxlumo and Rivfloza concurrently

Revision/Review Date 2/2025	**<u>Reauthorization</u>** • Members previously using pyridoxine will continue to use pyridoxine, or have a medical reason for not using pyridoxine • Documentation has been provided that demonstrates a clinical benefit (e.g. symptomatic improvement, reduction in urinary or plasma oxalate levels from baseline) • Medication is prescribed at an FDA approved dose • Patient is not using Oxlumo and Rivfloza concurrently **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	**INITIAL AUTHORIZATION:** • 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. **DOSE INCREASES:** • Documentation of recent blood Phe level results (within the past 90 days). • Confirmation Phe control has not been achieved after adequate timeframe on the current dosing regimen:

Revision/Review Date: 4/2025	○ For requests for a dose of 40 mg per day, the patient has been on 20 mg once daily continuously for at least 24 weeks and has not achieved adequate control ○ For requests for a dose of 60 mg per day, the patient has been on 40 mg once daily continuously for at least 16 weeks and has not achieved adequate control • The medication is being prescribed at an FDA approved dose (maximum of 60 mg once daily). **<u>REAUTHORIZATION:</u>** • Documentation of recent blood Phe level results (within the previous 90 days); **AND** • The medication is being prescribed at an FDA approved dose; **AND** • Member has achieved a reduction in blood phenylalanine concentration from pre-treatment baseline.. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Primary Hemophagocytic Lymphohistiocytosis (HLH) Agents**
Drugs	Gamifant (emapalumab-lzsg)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Members who have undergone hematopoietic stem cell transplantation (HSCT)
Required Medical Information	"See Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Hematologist, Oncologist, Immunologist, Transplant Specialist, or other specialist experienced in the treatment of immunologic disorders
Coverage Duration	Initial Authorization: 1 month Reauthorization: 3 months
Other Criteria Revision/Review Date 4/2025	***Gamifant will only be approved for members who have not yet received HSCT and will be discontinued at the initiation of HSCT*** **Initial Authorization** • Member has a diagnosis of Primary HLH • Prescriber attests that member has not achieved a satisfactory response to or is intolerant to conventional HLH therapy (e.g. etoposide, dexamethasone) or has recurrent disease • Prescriber attests that the member is a candidate for hematopoietic stem cell transplant (HSCT) • Member has been screened for latent tuberculosis infection • Member has or will receive prophylactic pre-medications (e.g. antivirals, antibiotics, antifungals) for Herpes Zoster, *Pneumocystis jirovecii*, and other fungal infections • Dosing is consistent with FDA approved labeling **Reauthorization** • Member continues to meet initial authorization criteria • Member is receiving prophylactic pre-medications (e.g. antivirals, antibiotics, antifungals) for Herpes Zoster, *Pneumocystis jirovecii*, and other fungal infections **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Prior Authorization Group Description	**Injectable Prostacyclin Pulmonary Antihypertensives**
Drugs	epoprostenol (Flolan, Veletri) treprostinil (Remodulin) Any other newly marketed IV or subcutaneous PAH treatment agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by, or in consultation with, a pulmonologist or cardiologist
Coverage Duration	If all of the conditions are met, the request will be approved for 6 months. Members new to the plan may be approved for 6 months with documentation the requested dose has been stable for the previous 30 days.
Other Criteria Revision/Review Date: 2/2025	**<u>Initial Authorization:</u>** • Documentation of a confirmed diagnosis of pulmonary arterial hypertension (PAH) World Health Organization (WHO) Group1 • Medication is being used for an FDA approved functional class at a FDA approved dose • Documentation that the patient has undergone acute vasoreactivity testing and if the results were positive (defined as a fall in mean pulmonary arterial pressure [PAPm] of at least 10 mm Hg to ≤ 40 mm Hg with an increased or unchanged cardiac output), then documentation is provided that disease has progressed despite maximal medical treatment with a calcium channel blocker • Documentation of the patient's current weight **<u>Re-authorization:</u>** • Documentation has been submitted indicating the clinical benefit of therapy (e.g. improvement in functional class, improvement in 6-minute walk test, exercise capacity, or hemodynamics) • If dosing is being increased, documentation of the medical necessity to increase the dosage is provided • Medication is being used for an FDA-approved functional class at an FDA-approved dose. **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	**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 Revision/Review Date: 11/2024	**Initial Authorization:** • Diagnosis of severe hemophilia A (congenital factor VIII deficiency with factor VIII activity < 1 IU/dL) • Documentation of a current prophylactic regimen of Factor VIII infusions or bispecific monoclonal antibodies (i.e. Hemlibra) • Documented FDA-approved anti-AAV5 antibody test showing the patient is negative for anti-AAV5 antibodies • Documented Factor VIII inhibitor titer test showing the patient is negative for Factor VIII inhibitors • Prescriber attestation of performed liver health assessments • Patient weight • Medication is prescribed at an FDA approved dose **The safety and effectiveness of repeat administration of Roctavian has not been evaluated and will not be approved.** **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Qalsody**
Drugs	Qalsody (tofersen)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	See "Other Criteria"
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, neuromuscular specialist, or physician specializing in the treatment of amyotrophic lateral sclerosis (ALS)
Coverage Duration	If all the criteria are met, initial and renewal requests will be approved for 6 months
Other Criteria Review/Revision Date: 7/2025	**Initial Authorization:** • Diagnosis of ALS • Documentation of genetic test confirming a mutation in the superoxide dismutase 1 (SOD1) gene • Member is not dependent on invasive ventilation or tracheostomy • Documentation of slow vital capacity (SVC) ≥ 50% • Medication is prescribed at an FDA approved dose **Re-Authorization:** • Documentation or provider attestation of positive clinical response (e.g., reduction in the mean concentration of neurofilament light [NfL] chains in the plasma, reduction in concentration of SOD1 in cerebrospinal fluid (CSF), or improvement in the Revised ALS Functional Rating Scale (ALSFRS-R) total score) • Member is not dependent on invasive ventilation or tracheostomy • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Prior Authorization Group Description	**Reblozyl (luspatercept-aamt)**
Drugs	Reblozyl (luspatercept-aamt) vial for subcutaneous injection
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Members are excluded if they have hemoglobin S/beta-thalassemia, 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	**Criteria for initial approval:**
	• Requested dose is appropriate per labeling
	• The member's weight has been provided with the request
	• The member's most recent hemoglobin level (within the last month) has been provided with the request
	• Diagnosis appropriate per Covered Uses
	• For requests for anemia due to beta thalassemia, documentation of all of the following is required:
	  o Member requires regular 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:
	  o Myelodysplastic Syndrome Revised International Prognostic Scoring System (IPSS-R) categorization as very low, low, or intermediate risk of progression.
	  o Member has required transfusion of 2 or more RBC units within an 8 week period in the last 4 months
	  o Hemoglobin less than 10 g/dl
	Reauthorization:
	• For diagnosis of anemia due to beta thalassemia, documentation of the following:
	  o Fewer transfusions compared with baseline
	  AND
	  o 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:
	  o Hemoglobin increase of at least 1.5 g/dl from baseline over a period of 8-12 weeks

Revision/Review Date: 11/2024	OR o Reduction in red blood cell transfusion by at least 4 units over a period of 8-12 weeks compared with baseline transfusion requirement **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	• Medication is prescribed at an FDA approved dose • Diagnosis of at least 1 recurrent episode of CDI (≥2 total CDI episodes) • Current episode of CDI must be controlled (<3 unformed/loose stools/day for 2 consecutive days) • Positive stool test for C. difficile within 30 days before prior authorization request • Administration will occur 24–72 hours following completion of antibiotic course for CDI treatment • For Vowst only: attestation patient will bowel cleanse using magnesium citrate or polyethylene glycol electrolyte solution the day before the first dose of Vowst *Rebyota and Vowst are limited to 1 treatment course* **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Field Name	Field Description
Prior Authorization Group Description	**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	• Patients with decompensated cirrhosis • Patient with thyroid disease including: o active hyperthyroidism o untreated hypothyroidism (TSH >7 IU/L with symptoms of HT or >10 IU/L without symptoms)
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a hepatologist, gastroenterologist, or a specialist in the treatment of liver disease.
Coverage Duration	If all of the criteria are met, the initial and reauthorization requests will be approved for up to a 12 month duration
Other Criteria Date: 4/2025	**Initial Authorization:** • Diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis • Documentation of stage F2 to F3 fibrosis confirmed by biopsy or a noninvasive test (NIT) • Documentation of Nonalcoholic Fatty Liver Disease (NAFLD) Activity Score (NAS) of ≥ 4 • Prescriber attestation to providing lifestyle counseling on nutrition and exercise • Prescriber attestation that member avoids excess alcohol intake • The drug is being prescribed at an FDA approved dose according to the member's weight **Re-Authorization:** • 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 **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Prior Authorization Group Description	**Retinoic Acid Derivatives for Acne Treatment**
Drugs	***For tazarotene requests, refer to Tazorac/Tazarotene Common Formulary Prior Authorization criteria*** **Formulary (no prior authorization required):** OTC adapalene 0.1% gel adapalene/benzoyl peroxide 0.1%-2.5% gel adapalene 0.3% gel tretinoin 0.025% cream tretinoin 0.05% cream **Non-formulary:** adapalene (Differin) 0.1% lotion Rx adapalene (Differin) 0.1%, 0.3% gel Rx adapalene (Differin) 0.1% cream Rx adapalene/benzoyl peroxide (EpiDuo) 0.1%-2.5% gel adapalene/benzoyl peroxide (EpiDuo Forte) 0.3%-2.5% gel Aklief (trifarotene) 0.005% cream Altreno (tretinoin) 0.05% lotion Arazlo (tazarotene) 0.045% lotion clindamycin/tretinoin (Ziana) 1.2%-0.025% gel EpiDuo Forte (adapalene/benzoyl peroxide) 0.3%-2.5% gel tretinoin (Retin-A) 0.05%, 0.1% cream tretinoin (Retin-A, Atralin) 0.01%, 0.025%, 0.05% gel tretinoin microsphere (Retin-A Micro) 0.04%, 0.06%, 0.08%, 0.1% 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), 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	Limited to providers with an appropriate scope of practice
Coverage Duration	If the criteria are met, the request may be approved for a maximum of 50 g/30 days of a generic product (where applicable) for up to 12 months.

Other Criteria	Criteria for initial authorization:
	• Member has a diagnosis of acne vulgaris
	• Documentation of trial and failure, intolerance, or contraindication to all of following:
	  o Benzoyl peroxide
	  o Topical erythromycin or clindamycin with or without benzoyl peroxide
	  o 2 fills of OTC adapalene gel in the previous 90 days
	• If the request is for a brand product/formulation, please refer to the Brand Name exception criteria
	
	Criteria for continuation of therapy:

Revision/Review Date: 2/2025	• Consistent use of the medication as documented in the medical history or as represented by the available pharmacy claims data • Documentation of improvement or satisfactory progress **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	**Rytelo**
Drugs	Rytelo (imetelstat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be 18 years of age and older
Prescriber Restrictions	Prescriber must be a hematologist or oncologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 6 months.
Other Criteria Revision/ Review Date: 11/2024	**<u>Initial Authorization:</u>** • Diagnosis of myelodysplastic syndromes (MDS) with transfusion-dependent anemia • Myelodysplastic Syndrome Revised International Prognostic Scoring System (IPSS-R) categorization as low or intermediate-1 risk of progression • Member has transfusion burden of 4 or more red blood cell (RBC) units within an 8-week period over the last 4 months • Prescriber attestation that complete blood cell count (CBC) will be obtained prior to initiation, weekly for first two cycles, and prior to each cycle thereafter • Member's weight has been provided with request • Medication is prescribed at an FDA approved dose **<u>Re-Authorization:</u>** • Documentation or provider attestation of reduction in RBC transfusion burden as compared with baseline • Provider attestation that patient is tolerating the medication and is not experiencing any serious adverse reactions • Member's weight has been provided with request • 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	**Scopolamine Patch**
Drugs	Scopolamine Patch (Transderm-Scop)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criteria are met, the request will be approved for the treatment of motion sickness and post-operative nausea and vomiting for a one (1) month duration and for the treatment of sialorrhea for a 12 month duration.
Other Criteria Revision/Review Date: 7/2025	**Initial Authorization:** Motion Sickness and Post-Operative Nausea and Vomiting: • Diagnosis of nausea and vomiting associated with motion sickness or nausea and vomiting associated with recovery from anesthesia and/or opiate analgesia and surgery. AND • Documented trial and failure at therapeutic doses of, intolerance to, or contraindication to two of the following: meclizine, diphenhydramine and dimenhydrinate. Sialorrhea • Documented trial and failure at therapeutic doses, intolerance or contraindication to glycopyrrolate. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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Field Name	Field Description
Prior Authorization Group Description	**Somatostatin Analogs and Growth Hormone Receptor Antagonists** **For generic octreotide vial requests, please refer to the Sandostatin/Octreotide PA criteria**
Drugs	<u>Formulary with PA:</u> Octreotide vial (refer to the Sandostatin / Octreotide PA criteria) <u>Non-Formulary:</u> Lanreotide (Somatuline Depot) Octreotide (Sandostatin LAR, Mycapssa) Pasireotide (Signifor, Signifor LAR) Pegvisomant (Somavert)
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.**
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Per FDA approved package insert
Prescriber Restrictions	Prescriber must be a specialist with appropriate expertise in treating the condition in question (such as an endocrinologist, neurologist/neurosurgeon, oncologist, etc.). Consultation with appropriate specialist for the condition in question is also acceptable.
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	**<u>Initial Authorization</u>** <u>For all FDA approved indications (including FDA-approved oncology related uses)</u> • Medication requested is for an FDA approved indication and dose • If the provider is requesting therapy with more than one somatostatin analog or a somatostatin analog and a growth hormone receptor antagonist, then documentation must be submitted as to why patient is unable to be treated with monotherapy, or a medical reason was provided why monotherapy is not appropriate. <u>For Acromegaly</u> • Patient has had an inadequate response to, or medical reason why, surgical treatment cannot be used.

Revision/Review Date 4/2025	• 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:** o Patient has showed clinical response to and tolerates treatment with octreotide or lanreotide therapy o Clinical justification is provided as to why patient cannot continue use of injectable somatostatin analog therapy • **Additionally for Somavert:** o 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:** o 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. <u>For Cushing's Disease (pasireotide products only)</u> • Patient must have had inadequate response, or medical reason why surgical treatment cannot be used • Requests for use of a somatostatin analog or growth hormone receptor antagonist in combination with radiotherapy will be approved **<u>Reauthorization</u>** • Medication requested is for an FDA approved indication and dose • Documentation has been provided that demonstrates a clinical benefit (e.g. improvement in laboratory values, improvement or stabilization of clinical signs/symptoms, etc.) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Generalized Pustular Psoriasis (GPP) Agents**
Drugs	Spevigo (spesolimab-abzo)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Per package insert
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist or geneticist
Coverage Duration	Acute Flares (IV vial): If all of the criteria are met, the request will be approved for up to 2 doses. Maintenance Treatment (SQ syringe): If all criteria are met, the initial request will be approved for 12 months. Reauthorization requests will be approved for 12 months.
Other Criteria	**<u>Initial Authorization</u>** • Diagnosis of generalized pustular psoriasis (GPP) • If request is for an acute GPP flare (IV vial), member must be experiencing an acute flare of GPP of moderate to severe intensity as defined by having all of the following: o Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of 3 or greater o Presence of fresh pustules (new appearance or worsening of pustules) o GPPPGA pustulation sub score of 2 or greater o At least 5% of body surface area covered with erythema and the presence of pustules • If request is for maintenance treatment of GPP (SQ syringe), member must have all of the following: o History of at least two GPP flares in the past year of moderate to severe intensity o GPPPGA score of 0 or 1 o Documented trial and failure, intolerance, or contraindication to TWO of the following: oral retinoids, methotrexate, and cyclosporine • Medication is prescribed at an FDA approved dose

Date: 7/2025	**<u>Reuathorization</u>** • If request is for an acute GPP flare (IV vial), member must have achieved a clinical response, defined as achieving a GPPPGA score of 0 or 1, to previous treatment but is now experiencing a new flare • If request is for maintenance treatment of GPP (SQ syringe), member must have documentation of positive clinical response to therapy (i.e. reduction in GPP flares) • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Prior Authorization Group Description	**Agents for Thrombocytopenia**
Drugs	**<u>Preferred Thrombocytopenia Agent(s)</u>:** • Promacta (eltrombopag) • Doptelet (avatrombopag) **<u>Non-Preferred Thrombocytopenia Agent(s)</u>:** • Alvaiz (eltrombopag) • Nplate (romiplostim) • Mulpleta (lusutrombopag) • Tavalisse (fostamatinib)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	Per package insert
Prescriber Restrictions	Prescriber must be a hematologist
Coverage Duration	If the criteria are met, the requests for Promacta, Alvaiz, Nplate, and Tavalisse will be approved for 12 months. Mulpleta will be approved for a maximum of 7 days. Doptelet will be approved for 12 months if the request is for ITP or for a maximum of 5 days if the request is for thrombocytopenia associated with chronic liver disease in adult patients requiring elective surgery.

Other Criteria	**Chronic immune (idiopathic) thrombocytopenia (ITP):**
	• Platelet count < 30,000 cells/microL
	• Documented trial and failure, or intolerance, contraindication, to ONE of the following:
	  • Glucocorticoids
	  • Intravenous immune globulin (IVIG)
	  • Rituximab
	  • splenectomy
	• If the request is for Alvaiz, Doptelet, Nplate or Tavalisse, the member has a documented trial and failure, intolerance, or contraindication to Promacta
	
	Severe aplastic anemia (Promacta and Alvaiz only):
	  • Being prescribed in conjunction with at least one immunosuppressive agent OR there is a documented trial and failure, intolerance, or contraindication to at least one immunosuppressive agent
	  • Platelet count < 20,000 cells/microL OR platelet cout < 30,000 cells/microL with bleeding OR reticulocyte count < 20,000 cells/microL OR absolute neutrophil count < 500 cells/microL
	  • If the request is for Alvaiz, the member has a documented trial

Revision/Review Date 4/2025	and failure, intolerance, or contraindication to Promacta **Thrombocytopenia in patients with Hepatitis C infection** (Promacta and Alvaiz only): • Diagnosis of chronic hepatitis C • Platelet count < 50,000 cells/microL • Documented treatment with interferon-based therapy AND patient's degree of thrombocytopenia prevents the initiation or limits the ability to maintain interferon-based therapy • If the request is for Alvaiz, the member has a documented trial and failure, intolerance, or contraindication to Promacta **Thrombocytopenia associated with chronic liver disease in *adult* patients requiring elective surgery** (Doptelet and Mulpleta only): • Patient has a diagnosis of chronic liver disease and is scheduled to undergo a procedure • Platelet count < 50,000 cells/microL • For Mulpleta, approve if there is documentation of trial and failure, intolerance, or contraindication to use Doptelet **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Transthyretin-mediated Amyloidosis Agents**
Drugs	**<u>Preferred</u>:** Polyneurpathy – Onpattro (patisiran), Amvuttra (vutrisiran), Wainua (eplontersen) Cardiomyopathy – Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis), Attruby (acoramidis) **<u>Non-preferred</u>**: Cardiomyopathy – Amvuttra (vutrisiran) Or any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Patient must be 18 years of age or older
Prescriber Restrictions	Prescriber must be neurologist, cardiologist, or specialist in the treatment of amyloidosis
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy the request will be approved for 6 months.

Other Criteria	**<u>Initial Authorization</u>**:
	• Regimen does not exceed FDA-approved dose/frequency
	• Patient has not undergone a liver or heart transplant
	• 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.
	
	Polyneuropathy-Type
	If the request is for Onpattro, Amvuttra, or Wainua:
	• Patient has diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis as evidenced by documented transthyretin variant by genotyping
	• One of the following:
	  o Patient has baseline polyneuropathy disability (PND) score ≤ IIIb
	  o Patient has a baseline FAP Stage 1 or 2

	○ Patient has baseline neuropathy impairment (NIS) score ≥ 5 and ≤ 130 • Patient has clinical signs/symptoms of neuropathy **Cardiomyopathy-Type** 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 **<u>Re-authorization (for continuing and new patients to the plan)</u>** : • 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 **<u>Continuation of Therapy Provision:</u>** Members with history (within the past 90 days) of a non-formulary product are not required to try a formulary agent prior to receiving the non-formulary product. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**
Revision/Review Date:4/2025	

Field Name	Field Description
Prior Authorization Group Description	**Type I Interferon (IFN) Receptor Antagonist**
Drugs	Saphnelo (anifrolumab-fnia)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Severe active central nervous system lupus • Active lupus nephritis
Required Medical Information	See "Other Criteria"
Age Restrictions	≥ 18 years
Prescriber Restrictions	Prescriber must be a rheumatologist or in consultation with a rheumatologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Date: 11/2024	**<u>Initial Authorization:</u>** • Diagnosis of active moderate to severe systemic lupus erythematosus (SLE) • Member has tried all of the following (or there is a medical reason they cannot use these therapies) before Saphnelo: o Hydroxychloroquine + Glucocorticoids o One other immunosuppressant (i.e., methotrexate, azathioprine, calcineurin inhibitors, or mycophenolate) o Benlysta (belimumab), if member has autoantibody-positive SLE • Prescriber attests member will not be using Saphnelo concurrently with Benlysta • Medication is prescribed at an FDA approved dose **<u>Re-Authorization:</u>** • Documentation or provider attestation of positive clinical response (i.e., reduction in signs and symptoms of SLE, fewer flares, reduced oral corticosteroid use, etc.) • Prescriber attests member will not be using Saphnelo concurrently with Benlysta • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Prior Authorization Group Description	**Tysabri (natalizumab)**
Drugs	Tysabri (natalizumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Patients must be 18 years age or older
Prescriber Restrictions	Prescriber is a specialist, or is working in consultation with a specialist, in the treatment of the condition
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months.
Other Criteria	**Criteria for Initial Authorization for All Indications:** • The request is for an indication and dose as defined in Covered Uses • Indication-specific criteria below must also be met OR For off-label requests: The member has had an adequate trial of (or documented medical reason for not using) all first line therapies as recommended by the medical compendia or standard of care guidelines **Multiple Sclerosis** o Therapeutic failure of (or documented medical reason for not using) at least one of month of therapy each with TWO preferred agents ▪ For members with highly-active MS, a trial of Gilenya alone is acceptable OR • Member has a diagnosis of relapsing multiple sclerosis AND moderate to severe Crohn's disease **Crohn's Disease** • Documentation of one of the following: o Diagnosis of moderate-to-severe Crohn's disease AND has had an adequate trial (or documented medical reason for not using) the following: ▪ azathioprine or 6-mercaptupurine ▪ Humira o Diagnosis of relapsing multiple sclerosis AND moderate to severe Crohn's disease **Reauthorization Criteria:** • Documentation was provided that the prescriber has evaluated the member and recommends continuation of therapy based on clinical benefit. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**
Revision/Review Date: 11/2024	

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

Other Criteria
 	
Review/Revision Date: 2/2025
	<u>Initial Authorization:</u>
	• Medication is prescribed at an FDA approved dose
	• Diagnosis of stage 2 type 1 diabetes (T1D) confirmed by presence of at least two of the following autoantibodies:
	  o Glutamic acid decarboxylase 65 (GAD) autoantibody
	  o Insulin autoantibody (IAA)
	  o Insulinoma-associated antigen 2 autoantibody (IA-2A)
	  o Zinc transporter 8 autoantibody (ZnT8A)
	  o Islet cell autoantibody (ICA)
	• Abnormal glucose on an oral glucose-tolerance test (or alternative glycemic test if an oral glucose-tolerance test is not available)
	
	If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

Field Name	Field Description
Prior Authorization Group Description	**Vascular Endothelial Growth Factor (VEGF) Inhibitors for Ophthalmic Conditions**
Drugs	Preferred Vascular Endothelial Growth Factor (VEGF) Inhibitor(s): • **Avastin** (bevacizumab) • **Byooviz** (ranibizumab- nuna) • **Cimerli** (ranibizumab- eqrn) Non-Preferred Vascular Endothelial Growth Factor (VEGF) Inhibitor(s): • **Beovu** (brolucizumab) • **Eylea** (aflibercept) • **Eylea HD** (aflibercept) • **Lucentis** (ranibizumab) • **Susvimo** (ranibizumab) • **Vabysmo** (faricimab) • Pavblu (aflibercept-ayyh) • **Any newly marketed agent in this class**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	Eylea: approvable in pediatric patients for diagnosis of retinopathy of prematurity All other agents and indications: Approvable for adults 18 years of age and older only
Prescriber Restrictions	Ophthalmologist
Coverage Duration	If the above conditions are met, the request will be approved with a 3 month duration for initial and 12 months for renewal. Retinopathy of Prematurity: approvable for a 6 month duration for initial and renewal requests.
Other Criteria	**Avastin:** • Request is for compendia supported dosing for an ophthalmic indication **Byooviz or Cimerli:** • Request is for an FDA-approved dosing regimen

Revision/Review Date 7/2025	**Non-Preferred VEGF Inhibitor:** • Request is for an FDA-approved dosing regimen; **AND** • Documented trial and failure with a preferred VEGF inhibitor for all FDA-approved indications OR: a medical justification for not using a preferred VEGF inhibitor (e.g. experienced a severe ADR such as hypersensitivity, arterial thromboembolism, cerebrovascular accident, raised intraocular pressure, retinal detachment). • Requests for Eylea (aflibercept) may be approved for a diagnosis of retinopathy of prematurity without a trial and failure of a preferred VEGF inhibitor. Patients must have a diagnosis of retinopathy of prematurity in at least one eye with one of the following retinal findings: o ROP Zone 1 Stage 1+, 2+, 3 or 3+, or o ROP Zone II Stage 2+ or 3+, or o AP-ROP (aggressive posterior ROP) **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Veopoz**
Drugs	Veopoz (pozelimab-bbfg)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	• Patients with unresolved Neisseria meningitidis infection • Concurrent use of another complement inhibitor (i.e. Soliris)
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a physician with experience in managing complement related disorders (i.e., gastroenterologist, immunologist, cardiologist, etc.)
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria Revision/Review Date: 11/2024	**Initial Authorization:** • Medication is prescribed at an FDA approved dose • Diagnosis of CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease • Documentation of hypoalbuminemia (serum albumin <3.5 g/dL) • Documentation of patient weight **Re-Authorization:** • Documentation or provider attestation of positive clinical response (i.e. symptom improvement, normalization of labs such as serum albumin (3.5-5.5 g/dL) and IgG concentrations, reduced hospitalizations and severe adverse events, increased quality of life, etc.) • Documentation of patient weight • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**

Prior Authorization Group Description	**Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors for Huntington's Disease**
Drugs	tetrabenazine (Xenazine) or any other newly marketed agent *For Austedo requests, please refer to the Austedo criteria* *For Ingrezza requests, please refer to the Ingrezza criteria*
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	• Hepatic impairment • Concurrent use of monamine oxidase inhibitors (MAOIs), reserpine, Austedo, or Ingrezza (valbenzine)
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	If the criteria are met, the request will be approved for up to 12 months.
Other Criteria Revision/Review Date: 11/2024	**Initial Authorization:** • Patient must have diagnosis of moderate to severe Huntington's with chorea, with documented baseline Total Maximal Chorea (TMC) score provided • Prescriber attests that patient has had a baseline electrocardiogram (EKG) and is aware of the possible risk of QT prolongation • Attestation that the patient has no signs of hepatic impairment • Patient will not be receiving tetrabenazine and Austedo concurrently • Dose is within FDA approved limits **<u>Re-Authorization:</u>** • Prescriber attests that the member has received clinical benefit from therapy • Dose is within FDA approved limits **Physician/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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

Other Criteria
 	
Date: 2/2025
	Initial Authorization:
	• Medication is prescribed at an FDA approved dose
	• Member has a diagnosis of ASMD confirmed by one of the following:
	  o Deficiency in acid sphingomyelinase (ASM) enzyme activity (as measured by peripheral blood leukocytes, cultured skin fibroblasts, or dried blood spots)
	  o Sphingomyelin phosphodiesterase-1 (SMPD1) gene mutation
	• Member has a clinical presentation consistent with ASMD type B or type A/B
	• Documentation of members height and weight
	• Documentation of baseline ALT and AST within 1 month prior to initiation of treatment
	
	Re-Authorization:
	• Documentation or provider attestation of positive clinical response (i.e. improvement in splenomegaly, hepatomegaly, pulmonary function, etc.)
	• Medication is prescribed at an FDA approved dose
	
	If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.