



# Pharmacy Prior Authorization Criteria



## PRIOR AUTHORIZATION CRITERIA

Effective 03/30/2026

Please use the Ohio Unified Preferred Drug List Criteria for any medical drugs reviews that fall within the state policies:

<https://medicaid.ohio.gov/stakeholders-and-partners/phm/unified-pdl>

The following are examples of State Policies that include medical drugs:

- Cardiovascular Agents: Pulmonary Arterial Hypertension\*LEGACY CATEGORY
- Endocrine Agents: Osteoporosis- Bone Ossification Enhancers
- Immunomodulator Agents: Systemic Inflammatory Disease
- Respiratory Agents: Monoclonal Antibodies-Anti-IL/Anti-IgE
- Blood Formation, Coagulation, and Thrombosis Agents: Hematopoietic Agents
- Endocrine Agents: Endometriosis, Endocrine Agents: Uterine Fibroids
- Central Nervous System (CNS) Agents: Multiple Sclerosis\* LEGACY CATEGORY
- Respiratory Agents: Hereditary Angioedema
- Blood Formation, Coagulation, and Thrombosis Agents: Colony Stimulating Factors

Field Name	Field Description
Prior Authorization Group Description	<b>5-Hydroxytryptamine-3 Serotonin Receptor Antagonists (5-HT3 RA), Substance P/Neurokinin 1 Receptor Antagonists (NK1 RA), and Combination Agents</b>
Drugs	<p><u>Preferred (Step 1):</u>  5-HT3 RA: ondansetron (Zofran) IV solution, injection (IV/SQ) solution or granisetron (Kytril) IV solution</p> <p>NK1 RA: fosaprepitant (Emend) IV emulsion</p> <p><u>Preferred (Step 2):</u>  5-HT3 RA palonosetron (Aloxi) 0.25 mg/2 mL IV solution</p> <p><u>Non-Preferred:</u>  Sustol (granisetron ER) SQ injection, palonosetron (Aloxi) 0.25 mg/5 mL IV solution, Cinvanti (aprepitant) IV emulsion, Varubi (rolapitant) IV emulsion, Akynzeo (palonosetron/netupitant), IV solution, Focinvez (fosaprepitant), Posfrea (palonosetron) IV solution</p> <p>Any other newly marketed agent</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	None
Required Medical Information	See “Other Criteria”
Age Restrictions	None
Prescriber Restrictions	Prescribed by a specialist in the field to treat the patient’s respective medical condition
Coverage Duration	If all of the conditions are met, the request will be approved for up to 6 months or as long as recommended by the medical compendium and/or per the NCCN/ASCO standard of care guidelines.
Other Criteria	<ul style="list-style-type: none"> <li>• The medication is being requested for a Food and Drug Administration (FDA) approved indication or a medical condition that is supported by the medical compendium, the National Comprehensive Cancer Network (NCCN), and/or American Society of Clinical Oncology (ASCO) standard of care guidelines for antiemetic therapy.</li> <li>• The requested dosing of the 5-HT3 RA and/or NK1 RA is within FDA approved, NCCN/ASCO or other medical compendia standard of care guidelines</li> <li>• Patients meeting one of the following criteria may receive the generic 5-HT3 RA palonosetron hydrochloride 0.25 mg/2 mL without prior trial and failure of ondansetron/granisetron <ul style="list-style-type: none"> <li>○ Adult patients receiving an antineoplastic agent with</li> </ul> </li> </ul>

<p>Revision/Review Date 10/2025</p>	<p>HIGH or MODERATE emetic risk per the NCCN Practice Guidelines</p> <ul style="list-style-type: none"><li>○ Pediatric patients receiving an antineoplastic agent with HIGH emetic risk per the NCCN Practice Guidelines who are unable to receive dexamethasone</li><li>● For all other patients, if the medication request is for any 5-HT3 RA other than ondansetron, granisetron or an NK1-RA other than fosaprepitant IV emulsion:<ul style="list-style-type: none"><li>○ The patient has a documented treatment failure after receiving an adequate trial of a preferred 5-HT3 RA and a preferred NK1 RA and/or has a documented medical reason (intolerance, hypersensitivity, contraindication, etc.) for not utilizing these medications to treat their medical condition.</li></ul></li></ul> <p><b>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</b></p>
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Prior Authorization Group Description	<b>Adakveo (crizanlizumab-tmca)</b>
Drugs	Adakveo (crizanlizumab-tmca)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	Member must be 16 years of age or older
Prescriber Restrictions	Prescriber must be a hematologist or sickle cell specialist
Coverage Duration	If the criteria are met, requests may be approved for 12 months.
Other Criteria	<p><b>Initial Authorization:</b></p> <ul style="list-style-type: none"> <li>• Member has a confirmed diagnosis of sickle cell disease</li> <li>• Documentation was provided that the member has had 2 or more pain crises in the last 12 months</li> <li>• 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)</li> <li>• Documentation of the member’s current weight</li> <li>• Request is for an FDA-approved dose</li> </ul> <p><b>Reauthorization:</b></p> <ul style="list-style-type: none"> <li>• Documentation has been submitted that the member has demonstrated or maintained ONE of the following changes from baseline: <ul style="list-style-type: none"> <li>○ Reduction in pain crises</li> <li>○ Increased time between crises</li> <li>○ Decrease in days hospitalized</li> </ul> </li> <li>• Documentation of the member’s current weight</li> <li>• Request is for an FDA-approved dose</li> </ul> <p><b>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</b></p>
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Field Name	Field Description
Prior Authorization Group Description	<b>Adzynma</b>
Drugs	Adzynma (ADAMTS13, recombinant-krhn)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a hematologist, oncologist, intensive care specialist, or specialist in the treatment of rare genetic hematologic diseases
Coverage Duration	<p><u>On-demand therapy</u>: If all criteria are met, the request will be approved for 1 month.</p> <p><u>Prophylactic therapy</u>: If all criteria are met, the initial request will be approved for 6 months. Reauthorization requests will be approved for 12 months.</p>
Other Criteria	<p><b><u>Initial Authorization</u></b></p> <ul style="list-style-type: none"> <li>• Diagnosis of congenital thrombotic thrombocytopenic purpura (cTTP) as confirmed by BOTH of the following: <ul style="list-style-type: none"> <li>○ Molecular genetic testing</li> <li>○ ADAMTS13 activity &lt;10%</li> </ul> </li> <li>• 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])</li> <li>• If request is for prophylactic therapy, member must also have a history of at least one documented TTP event</li> <li>• Member’s weight</li> <li>• Request is for an FDA-approved dose</li> </ul> <p><b><u>Reauthorization</u></b></p> <ul style="list-style-type: none"> <li>• 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)</li> <li>• Member’s weight</li> <li>• Request is for an FDA-approved dose</li> </ul>

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**Medical Director/clinical reviewer may 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	<b>Agents to Treat Gaucher’s Disease</b>
Drugs	Cerezyme (imiglucerase), Vpriv (velaglucerase alfa), Elelyso (taliglucerase alfa)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	None
Required Medical Information	See “Other Criteria”
Age Restrictions	Per package insert
Prescriber Restrictions	Prescriber is a specialist in treatment of Gaucher’s Disease (e.g., endocrinologist, hematologist or geneticist), or is in consultation with a specialist
Coverage Duration	If all of the conditions are met, the request will be approved with 6-month duration.
Other Criteria	<p><b><u>Initial Authorization:</u></b>  Cerezyme, Vpriv, or Elelyso initial authorization:</p> <ul style="list-style-type: none"> <li>• Patient has a confirmed diagnosis of Gaucher’s disease, type 1 (GD1)  Request is for an FDA approved dose</li> </ul> <p><b><u>Re-Authorization criteria for all agents:</u></b></p> <ul style="list-style-type: none"> <li>• Documentation has been provided that patient has obtained clinical benefit from medication (e.g., increased platelet count, improvement in anemia, PFT’s, improvement in radiographic scans, improved quality of life)</li> <li>• Request is for an FDA approved dose</li> </ul> <p><b>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</b></p>
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Field Name	Field Description
Prior Authorization Group Description	<b>Alpha-1 Proteinase Inhibitors (Human)</b>
Drugs	<p><b><u>Preferred:</u></b> Prolastin-C</p> <p><b><u>Non-Preferred:</u></b> Aralast NP Glassia Zemaira Or any other newly marketed agent</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or specialist in the treatment of AAT
Coverage Duration	The request will be approved for up to a 12 month duration.
Other Criteria	<p><b>Initial Authorization:</b></p> <ul style="list-style-type: none"> <li>• Documented diagnosis of a congenital deficiency of alpha-1 antitrypsin (AAT) (serum AAT level &lt; 11 micromol/L [approximately 57 mg/dL using nephelometry or 80mg/dl by radial immunodiffusion]).</li> <li>• 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]</li> <li>• Documentation was submitted (member’s pulmonary function test results) indicating airflow obstruction by spirometry (forced expiratory volume in 1 second [FEV<sub>1</sub>] ≤ 65% of predicted), or provider has documented additional medical information demonstrating medical necessity</li> <li>• Documentation was submitted indicating member is a non-smoker or an ex-smoker (eg. smoking cessation treatment)</li> <li>• Documentation of the member’s current weight</li> <li>• The Alpha-1 Proteinase Inhibitor (human) is being prescribed at an FDA approved dosage</li> <li>• If the medication request is for an Alpha1-Proteinase Inhibitor (human) product other than Prolastin-C, the patient has a</li> </ul>

<p>Revision/Review Date 2/2026</p>	<p>documented medical reason (intolerance, hypersensitivity, contraindication, treatment failure, etc.) for not using Prolastin-C to treat their medical condition</p> <p><b>Reauthorization:</b></p> <ul style="list-style-type: none"><li>• Documentation of the member's current weight</li><li>• Documentation was submitted indicating member is a non-smoker or an ex-smoker (e.g. smoking cessation treatment)</li><li>• 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)</li><li>• The Alpha-1 Proteinase Inhibitor (human) is being prescribed at an FDA approved dosage</li></ul> <p><b>Clinical reviewer/Medical Director must override criteria when, in his/her professional judgment, the requested item is medically necessary.</b></p>
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Field Name	Field Description
Prior Authorization Group Description	<b>Anti-CD19 CAR-T Immunotherapies</b>
Drugs	Kymriah (tisagenlecleucel), Yescarta (axicabtagene ciloleucel), Tecartus (brexucabtagene autoleucel), Breyanzi (lisocabtagene maraleucel), Aucatzyl (obecabtagene autoleucel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Patients with primary central nervous system lymphoma
Required Medical Information	See “Other Criteria”
Age Restrictions	See “Other Criteria”
Prescriber Restrictions	Prescriber must be an oncologist, hematologist or other appropriate specialist .
Coverage Duration	<p>If all the criteria are met, the initial request will be approved for a single treatment regimen per lifetime.</p> <ul style="list-style-type: none"> <li>• Kymriah, Yescarta, Tecartus, Breyanzi :a one-time infusion</li> <li>• Aucatzyl: a split-dose infusion administered on day 1 and day 10 (± 2 days)</li> </ul>
Other Criteria	<p><b><u>Initial authorization:</u></b></p> <ul style="list-style-type: none"> <li>• Patient must not have received prior anti-CD19 CAR-T therapy.</li> <li>• Patient will be screened for HBV, HCV, and HIV in accordance with clinical guidelines.</li> <li>• Patient does not have an active infection or inflammatory disorder.</li> <li>• Patient will not receive live virus vaccines for at least 6 weeks prior to the start of lymphodepleting chemotherapy and until immune recovery following treatment.</li> <li>• Use is supported by a labeled indication or NCCN guidelines</li> </ul> <p><b><u>Leukemia</u></b></p> <p><b>B-cell precursor Acute Lymphoblastic Leukemia (ALL):</b></p> <ul style="list-style-type: none"> <li>• If the request is for Kymriah <ul style="list-style-type: none"> <li>○ Patient is 25 years of age or younger</li> <li>○ ALL that is refractory or in second or later relapse</li> </ul> </li> <li>• If the request is for Tecartus or Aucatzyl <ul style="list-style-type: none"> <li>○ Patient is 18 years of age or older</li> <li>○ ALL that is relapsed or refractory</li> </ul> </li> </ul>

**Chronic Lymphocytic Leukemia (CLL):**

- If the request is for Breyanzi
  - Patient is 18 years of age or older
  - Patient has relapsed/refractory disease defined as failure of two or more lines of therapy, including a Bruton tyrosine kinase (BTK) inhibitor AND a B-cell lymphoma 2 (BCL-2) inhibitor

**Non-Hodgkin's Lymphoma (NHL)**

**Follicular Lymphoma (FL):**

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

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

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

**Mantle Cell Lymphoma (MCL):**

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

**Small Lymphocytic Lymphoma (SLL):**

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

**Re-authorization:**

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

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

Revision/Review  
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Prior Authorization Group Description	<b>Anti-FGF23 Monoclonal Antibodies</b>
Drugs	Crysvita (burosumab) SQ solution, or any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: The Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	See Other Criteria
Required Medical Information	See Other Criteria
Age Restrictions	X-linked hypophosphatemia (XLH): 6 months of age or older Tumor-induced osteomalacia (TIO): 2 years of age and older
Prescriber Restrictions	Prescribed by, or in consultation with, an endocrinologist, nephrologist, molecular geneticist, or other specialist experienced in the treatment of metabolic bone disorders
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months and reauthorization requests will be approved for 12 months.
Other Criteria	<p><b><u>Initial Authorization:</u></b></p> <p><b>For X-linked hypophosphatemia (XLH):</b></p> <ul style="list-style-type: none"> <li>• Diagnosis of XLH</li> <li>• Dosing is appropriate as per labeling or is supported by compendia or standard of care guidelines</li> <li>• Labs, as follows: <ul style="list-style-type: none"> <li>○ Serum phosphorus below normal for patient age</li> <li>○ eGFR &gt; 30 mL/min/1.73 m<sup>2</sup> or CrCl ≥ 30 mL/min</li> </ul> </li> <li>• Patient will not use concurrent oral phosphate and/or active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol)</li> <li>• Additionally, for adults: <ul style="list-style-type: none"> <li>○ Clinical signs and symptoms of XLH (e.g. bone/joint pain, fractures, osteomalacia, osteoarthritis, enthesopathies, spinal stenosis impaired mobility, presence or history of lower limb deformities, etc.)</li> <li>○ Trial and failure of, or contraindication to, combination therapy with oral phosphate and active vitamin D (calcitriol) for a minimum of 8 weeks</li> </ul> </li> </ul> <p><b>For tumor-induced osteomalacia (TIO):</b></p> <ul style="list-style-type: none"> <li>• Diagnosis of FGF23-related hypophosphatemia in TIO</li> <li>• Dosing is appropriate as per labeling or is supported by compendia or standard of care guidelines</li> </ul>

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- The tumor(s) is/are not amenable to surgical excision or cannot be located
- Labs, as follows:
  - Serum phosphorus below normal for patient age
  - eGFR > 30 mL/min/1.73 m<sup>2</sup> or CrCl ≥ 30 mL/min
- Patient will not use concurrent oral phosphate and/or active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol)

**Re-authorization:**

**For XLH or TIO:**

- Documented effectiveness as evidenced by at least one of the following:
  - Serum phosphorus within normal limits for patient age
  - Clinical improvement (e.g. improved rickets, improved bone histomorphometry, increased growth velocity, increased mobility, decrease in bone fractures, improved fracture healing, reduction in bone-related pain)
- 25-hydroxyvitamin D level and, if abnormally low, documented supplementation with cholecalciferol or ergocalciferol
- Patient is not concurrently using oral phosphate and/or active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol)
- Dosing continues to be appropriate as per labeling or is supported by compendia or standard of care guidelines

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

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

<p>Revision/Review Date 4/2025</p>	<ul style="list-style-type: none"><li>• Based on the prescriber's assessment the member continues to have clinical benefit</li><li>• Attestation of renal function monitoring is provided with request</li><li>• The request is for an FDA approved dose</li></ul> <p><b>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</b></p>
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Field Name	Field Description
Prior Authorization Group Description	<b>B-Cell Maturation Antigen (BCMA) Directed Chimeric Antigen Receptor (CAR) T-Cell Therapy</b>
Drugs	Abecma (idecabtagene vicleucel), Carvykti (ciltacabtagene autoleucel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Member must be 18 years or older
Prescriber Restrictions	Prescriber must be a hematologist, an oncologist, or other appropriate specialist
Coverage Duration	If all the criteria are met, the initial request will be approved for a one – time infusion per lifetime.
Other Criteria	<p><b><u>Initial Authorization</u></b></p> <ul style="list-style-type: none"> <li>• Member has a diagnosis of relapsed or refractory multiple myeloma (RRMM)</li> <li>• For Abecma, member must have also received at least 2 prior lines of therapy including: <ul style="list-style-type: none"> <li>○ An immunomodulatory agent (e.g. lenalidomide, pomalidomide, thalidomide)</li> <li>○ A proteasome inhibitor (e.g. bortezomib, carfilzomib, ixazomib)</li> <li>○ An anti-CD38 monoclonal antibody (e.g. daratumumab, isatuximab)</li> </ul> </li> <li>• For Carvykti, member must also be refractory to lenalidomide AND have received at least 1 prior line of therapy including: <ul style="list-style-type: none"> <li>○ An immunomodulatory agent (e.g. lenalidomide, pomalidomide, thalidomide)</li> <li>○ A proteasome inhibitor (e.g. bortezomib, carfilzomib, ixazomib)</li> </ul> </li> <li>• Member does not have an active infection or inflammatory disorder</li> <li>• Member will be screened for cytomegalovirus (CMV), hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines</li> <li>• Member will not receive live virus vaccines for at least 6 weeks prior to the start of lymphodepleting chemotherapy and until immune recovery following treatment</li> <li>• Member has not previously received a BCMA CAR-T therapy</li> </ul> <p><b><u>Re-authorization:</u></b></p>

<p>Revision/Review Date: 7/2025</p>	<ul style="list-style-type: none"><li>• Treatment exceeding 1 dose per lifetime will not be authorized.</li></ul> <p><b>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</b></p>
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Field Name	Field Description
Prior Authorization Group Description	<b>Benlysta (belimumab)</b>
Drugs	Benlysta (belimumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	Severe active central nervous system lupus
Required Medical Information	See “other criteria”
Age Restrictions	Must be at least 5 years of age
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist or nephrologist
Coverage Duration	If all the criteria are met initial authorization requests may be approved for up to 6 months. Reauthorization requests may be approved for up to 12 months.
Other Criteria	<p><b><u>Initial Authorization:</u></b></p> <ul style="list-style-type: none"> <li>• <u>Active systemic lupus erythematosus (SLE)</u> <ul style="list-style-type: none"> <li>○ Provider attestation that the patient is positive for autoantibodies (or antinuclear antibodies or anti–double-stranded DNA [anti-dsDNA] antibodies)</li> <li>○ The member has tried and failed both of the following (or contraindication/inability to use these medications): <ul style="list-style-type: none"> <li>▪ Hydroxychloroquine</li> <li>▪ One other immunosuppressant [e.g., methotrexate, azathioprine, calcineurin inhibitors or mycophenolate]</li> </ul> </li> </ul> </li> <li>• <u>Active lupus nephritis</u> <ul style="list-style-type: none"> <li>○ Provider attestation of diagnosis confirmed by kidney biopsy</li> <li>○ The member has tried and failed, or has a medical reason for not using, both of the following <ul style="list-style-type: none"> <li>▪ Cyclophosphamide or tacrolimus</li> <li>▪ Mycophenolate</li> </ul> </li> </ul> </li> <li>• Provider states the member will not be receiving concomitant therapy with the following: <ul style="list-style-type: none"> <li>○ B-cell targeted therapy including (but not limited to) rituximab</li> <li>○ Interferon receptor antagonist, type 1 including (but not limited to) Saphnelo (anifrolumab)</li> </ul> </li> <li>• Dosing is appropriate per labeling</li> </ul> <p><b><u>Criteria for Reauthorization:</u></b></p> <ul style="list-style-type: none"> <li>• Documentation or provider attestation of positive clinical response as indicated by one of the following: <ul style="list-style-type: none"> <li>○ Fewer flares that required steroid treatment</li> </ul> </li> </ul>

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- 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	<b>Blincyto</b>
Drugs	Blincyto (blinatumomab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restriction	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist/hematologist
Coverage Duration	The request will be approved for up to a 12 month duration.
Other Criteria	<p><b>Initial Authorization:</b></p> <ul style="list-style-type: none"> <li>• Patient has a diagnosis of one of the following forms of Acute Lymphoblastic Leukemia (ALL): <ul style="list-style-type: none"> <li>a) Relapsed CD19-positive B-cell precursor ALL</li> <li>b) Refractory CD19-positive B-cell precursor ALL</li> <li>c) CD19-positive B-cell precursor ALL in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%</li> <li>d) CD19-positive Philadelphia chromosome-negative B-cell precursor ALL in the consolidation phase of multiphase chemotherapy</li> </ul> </li> <li>• Provider attests to monitor patient for Cytokine Release Syndrome (CRS) and neurological toxicities</li> </ul> <p><b>Reauthorization:</b></p> <ul style="list-style-type: none"> <li>• Provider attests to treatment response or stabilization of disease</li> <li>• Prescriber attests to monitor patient for Cytokine Release Syndrome (CRS) and neurological toxicities</li> </ul> <p><b>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</b></p>
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Field Name	Field Description
Prior Authorization Group Description	<b>Botulinum Toxins A&amp;B</b>
Drugs	<p><b>Preferred Agents for FDA approved indications:</b>            IncobotulinumtoxinA (Xeomin)            AbobotulinumtoxinA (Dysport)</p> <p><b>Non-preferred Agents:</b>            OnabotulinumtoxinA (Botox)            RimabotulinumtoxinB (Myobloc)            DaxibotulinumtoxinA (Daxxify)            Or any newly marketed agent</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	According to package insert
Prescriber Restrictions	None
Coverage Duration	If all of the conditions are met, the request will be approved for 12 month duration.
Other Criteria	<p><b>**The use of these medications for cosmetic purposes is NOT a covered benefit under the Medical Assistance program**</b></p> <p><b>For Initial Approval:</b></p> <ul style="list-style-type: none"> <li>• The drug is being used for a medically accepted indication and dose as outlined in Covered Uses</li> <li>• 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</li> <li>• If the diagnosis is <b>Chronic Migraines</b> (<math>\geq 15</math> days per month with headache lasting 4 hours a day or longer), the member has tried and failed, or has a medical reason for not using one drug from two of the following categories for at least 4 weeks each at a minimum effective dose:           <ul style="list-style-type: none"> <li>○ Beta blockers (e.g. propranolol, timolol, etc.)</li> <li>○ Amitriptyline or venlafaxine</li> <li>○ Topiramate, divalproex ER or DR, or valproic acid</li> </ul> </li> </ul>

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- 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**,
  - Documentation is provided that the member has had sialorrhea lasting at least 3 months
  - The member has tried and failed, or has a medical reason for not using, an anticholinergic medication (e.g. glycopyrrolate, hyoscyamine, benztropine)
- If the request is for a non-preferred agent, the member tried and failed a preferred agent if appropriate for the requested indication

**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	<b>Brineura (cerliponase alfa)</b>
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	<p><b><u>Initial Authorization:</u></b></p> <ul style="list-style-type: none"> <li>• Documentation of confirmed diagnosis of neuronal ceroid lipofuscinosis type 2 (CLN2) with one of the following: <ul style="list-style-type: none"> <li>○ Lab results demonstrating deficient TPP1 enzyme activity</li> <li>○ Identification of causative mutations in the TPP1/CLN2 gene</li> </ul> </li> <li>• Documentation of baseline CLN2 Clinical Rating Scale motor +language score. Baseline CLN2 score must be &gt; 0.</li> <li>• Medication is prescribed at an FDA approved dose</li> </ul> <p><b><u>Re-authorization:</u></b></p> <ul style="list-style-type: none"> <li>• Documentation of CLN2 Clinical Rating Scale motor +language score has remained &gt; 0</li> <li>• Medication is prescribed at an FDA approved dose</li> </ul>
Revision/Review Date: 7/2025	<b>Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</b>

Field Name	Field Description
Prior Authorization Group Description	<b>Calcitonin Gene-Related Peptide (CGRP) Antagonists for Headache Prevention</b>
Drugs	Vyepi (eptinezumab) and any newly marketed drug in the class
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Request for indication of chronic cluster headaches
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, migraine specialist, pain specialist, or other specialist in the treatment of headaches
Coverage Duration	If the criteria are met, the initial authorization request will be approved for 6 months. Reauthorization may be approved for 6 months.
Other Criteria	<p><b><u>Criteria for Initial Authorization:</u></b></p> <p><b>Migraine Headache Prophylaxis:</b></p> <ul style="list-style-type: none"> <li>• Diagnosis of episodic migraine or chronic migraine</li> <li>• Provider should note on the prior authorization request the number of headache days per month</li> <li>• Requested dose is within FDA approved dosing guidelines</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Trial and failure (or a medical justification for not using e.g. hypersensitivity, baseline bradycardia or hypotension, adverse events experienced from previous trial, etc.) with at least one of the following: <ul style="list-style-type: none"> <li>○ Beta-adrenergic blockers</li> <li>○ Topiramate or divalproex ER or DR</li> <li>○ Amitriptyline or venlafaxine</li> <li>○ Frovatriptan, zolmitriptan or naratriptan (for menstrual migraine prophylaxis)</li> </ul> </li> </ul> <p><b><u>Criteria for Re-Authorization:</u></b></p> <p><b>Migraine:</b></p> <ul style="list-style-type: none"> <li>• Reduction of <math>\geq 50\%</math> in the number of headache days per month relative to pre-treatment baseline (clinical benefit)</li> <li>• Provider should note on the prior authorization request the number of headache days per month</li> </ul>

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**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	<b>Chelating Agents</b>
Drugs	<ul style="list-style-type: none"> <li>• <b>Deferoxamine Mesylate (Desferal) Vial</b></li> <li>• <b>Pentetate calcium trisodium ampule</b></li> <li>• <b>Pentetate zinc trisdoium ampule</b></li> <li>• <b>Calcium Disodium Versenate (edetate calcium disodium) ampule</b></li> </ul>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	See “other criteria”
Prescriber Restrictions	N/A
Coverage Duration	If the above conditions are met, the request will be approved with a 6 month duration.
Other Criteria	<ul style="list-style-type: none"> <li>• The drug is requested for an appropriate use (per the references outlined in “Covered Uses”)</li> <li>• The dose requested is appropriate for the requested use (per the references outlined in “Covered Uses”)</li> </ul>
Revision/Review Date 7/2025	<b>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</b>

Field Name	Field Description
Prior Authorization Group Description	<b>Complement Inhibitors</b>
Drugs	Empaveli (pegcetacoplan), Fabhalta (iptacopan), Izervay (avacincaptad pegol injection), Soliris (eculizumab), Syfovre (pegcetacoplan injection), Ultomiris (ravulizumab), Voydeya (danicipan), PiaSky (crovalimab-akkz), BKEMV (eculizumab-aeeb), Epysqli (eculizumab-aagh)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a hematologist, nephrologist, neurologist, oncologist, ophthalmologist, or other appropriate specialist.
Coverage Duration	<p>If the criteria are met, the criteria will be approved as follows:</p> <p>Initial Requests</p> <ul style="list-style-type: none"> <li>• 3 months: eculizumab (Soliris, BKEMV, Epysqli), Ultomiris (ravulizumab), Empaveli (pegcetacoplan), Voydeya (danicipan)</li> <li>• 6 months: Fabhalta (iptacopan). PiaSky (crovalimab-akkz)</li> <li>• 12 months: Syfovre (pegcetacoplan), Izervay (avacincaptad pegol)</li> </ul> <p>Reauthorization</p> <ul style="list-style-type: none"> <li>• 6 months: eculizumab (Soliris, BKEMV, Epysqli), Ultomiris (ravulizumab), Empaveli (pegcetacoplan), Voydeya (danicipan)</li> <li>• 12 months: Syfovre (pegcetacoplan), Fabhalta (iptacopan), PiaSky (crovalimab-akkz)</li> </ul> <p>No Reauthorization</p> <p>Izervay (avacincaptad pegol)</p>
Other Criteria	<p><b><u>Initial Authorization:</u></b></p> <ul style="list-style-type: none"> <li>• The request is for a dose that is FDA approved or in nationally recognized compendia in accordance with the patient’s diagnosis, age, body weight, and concomitant medical conditions; <b>AND</b></li> <li>• For Fabhalta (iptacopan), eculizumab (Soliris, BKEMV, Epysqli), Ultomiris (ravulizumab), Empaveli (pegcetacoplan), PiaSky (crovalimab-akkz), and Voydeya (danicipan) <ul style="list-style-type: none"> <li>○ Documentation patient complies with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria.</li> </ul> </li> </ul>

- For Soliris or BKEMV, patient must have a documented trial and failure or intolerance to Epysqli or a medical reason why Epysqli cannot be used.

**Paroxysmal Nocturnal Hemoglobinuria (PNH):**

- Documentation of diagnosis by high sensitivity flow cytometry
- Presence of 1 or more of the following PNH-related signs or symptoms:
  - Fatigue, hemoglobinuria, abdominal pain, shortness of breath (dyspnea), anemia, history of a major adverse vascular event (including thrombosis), dysphagia, erectile dysfunction, or history of pRBC transfusion due to PNH.
- 
- Adults: For Ultomiris (ravulizumab), Empaveli (pegcetacoplan), Fabhalta (iptacopan), or PiaSky (crovalimab-akkz) patient must have a documented trial and failure or intolerance to Epysqli or a medical reason why Epysqli cannot be used. For Voydeya (danicopan):
  - Member has been receiving eculizumab (Soliris, BKEMV, Epysqli) or Ultomiris (ravulizumab) therapy for at least 6 months
  - Member has clinically evident extravascular hemolysis [defined as anemia (Hgb  $\leq$ 9.5 gram/deciliter) with absolute reticulocyte count  $\geq$ 120 x 10<sup>9</sup>/liter] despite treatment with eculizumab (Soliris, BKEMV, Epysqli) or Ultomiris (ravulizumab)
  - Voydeya (danicopan) will be used as add-on therapy to eculizumab (Soliris, BKEMV, Epysqli) or Ultomiris (ravulizumab)

**Generalized Myasthenia Gravis (gMG):**

- Refer to the “Myasthenia Gravis Agents” policy

**Neuromyelitis Optica Spectrum Disorder (NMOSD)**

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

**IgA Nephropathy:**

- Refer to the “IgA Nephropathy Agents” policy

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

- Documentation of confirmed diagnosis as evidenced by complement genotyping and complement antibodies; **OR**

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- Provider attestation treatment is being used empirically and delay in therapy will lead to unacceptable risk to the patient

**Geographic Atrophy (GA):**

- If the request is for Syfovre (pegcetacoplan injection), member must be  $\geq 60$  years of age
- If the request is for Izervay (avacincaptad pegol injection), member must be  $\geq 50$  years of age
- Diagnosis of GA secondary to age-related macular degeneration (AMD)
- Absence of choroidal neovascularization (CNV) in treated eye
- Best-corrected visual acuity (BCVA) of 24 letters (approximately 20/320) or better using Early Treatment Diabetic Retinopathy Study (ETDRS)
- GA lesion size  $\geq 2.5$  and  $\leq 17.5$  mm<sup>2</sup> with at least 1 lesion  $\geq 1.25$  mm<sup>2</sup>

**Complement 3 Glomerulopathy (C3G):**

- Diagnosis of C3G as confirmed by renal biopsy
- Patient's serum C3 level is reduced (defined as less than 0.85 x lower limit of the central laboratory normal range)
- Patient's urine protein to creatinine ratio (UPCR) is  $\geq 1.0$  g/g
- Patient has an eGFR  $\geq 30$  mL/min/1.73 m<sup>2</sup>
- Patient has been taking maximally recommended or tolerated dose of an angiotensin converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB) for at least 90 days, or a medical reason is provided why this is inappropriate
- Patient has a trial and therapy failure of mycophenolate and glucocorticoids, or a medical reason is provided why this is inappropriate.
- Patient does not have recurrent C3G post kidney transplant

**Re-Authorization:**

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

	<p>diagnosis, age, body weight, and concomitant medical condition; <b>AND</b></p> <ul style="list-style-type: none"><li>• If the request is for aHUS/Complement Mediated HUS<ul style="list-style-type: none"><li>○ Documentation of confirmed diagnosis as evidenced by complement genotyping and complement antibodies</li></ul></li></ul> <p><b>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</b></p>
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Field Name	Field Description
Prior Authorization Group Description	<b>Dose Rounding Limit Exception Criteria</b>
Drugs	<b>Bevacizumab products (Avastin, Mvasi, Zirabev, Vegzelma, Alymsys, Avzivi, Jobvene) for oncologic indications</b>
Covered Uses	All medically accepted indications. Medically accepted indications are defined using the following compendia resources: the Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), American Hospital Formulary Service Drug Information (AHFS-DI), and DRUGDEX Information System. The reviewer may also reference disease state specific standard of care guidelines.
Scope	Requests for drugs exceeding the health plan's dose rounding limits. For members 18 years of age and older, the dose will be rounded down to the nearest whole vial size if the rounded dose falls within 10% of the requested dose.
Criteria	<ul style="list-style-type: none"> <li>• If the drug is subject to other criteria, the member must meet criteria for approval.</li> <li>• The provider has submitted justification why the dose-rounding will be inadequate based on the member's condition and treatment history. Exceptions may include but are not limited to: <ul style="list-style-type: none"> <li>○ Member previously demonstrated a suboptimal or partial response to therapy at a rounded dose</li> <li>○ Rounded dose is unavailable due to manufacturer supply/shortage issues</li> <li>○ Provider has a documented medical reason why dose rounding is inappropriate for the member</li> </ul> </li> </ul> <p style="text-align: center;"><b>Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.</b></p>
Coverage Duration	6 months
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Field Name	Field Description
Prior Authorization Group Description	<b>Emergency Use Authorization (EUA) Drugs/Products for COVID-19</b>
Drugs	Any drug/product approved by EUA for COVID-19
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Emergency Use Authorization for the drug/product in question, and the Drug Package Insert (PPI).
Exclusion Criteria	See “Other Criteria”
Required Medical Information	See “Other Criteria”
Age Restrictions	As outlined within current FDA Emergency Use Authorization (EUA) guidelines
Prescriber Restrictions	N/A
Coverage Duration	As outlined within current FDA Emergency Use Authorization (EUA) guidelines
Other Criteria	<p>Emergency Use Authorization for COVID-19 related drugs/products (all must apply):</p> <ul style="list-style-type: none"> <li>• The requested drug/product has a currently active Emergency Use Authorization as issued by the U.S. Food and Drug Administration.</li> <li>• 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.).</li> <li>• Attestation that the provider is not requesting reimbursement for ingredient cost of drug when drug is provided by U.S. government at no charge</li> </ul>
Revision/Review Date 2/2026	<b>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</b>

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

Field Name	Field Description
Prior Authorization Group Description	<b>Enzyme Replacement Therapies for Fabry Disease</b>
Drugs	Fabrazyme (agalsidase beta) Elfabrio (peguniigalsidase alfa)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to the FDA approved prescribing information
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, cardiologist, nephrologist or specialist experienced in the treatment of Fabry disease
Coverage Duration	Initial Authorization: If the criteria are met, the request will be approved for a 6-month duration. Reauthorization: If the criteria are met, the request will be approved for a 12-month duration.
Other Criteria	<p><b><u>Initial Authorization:</u></b></p> <ul style="list-style-type: none"> <li>• Male members must have a documented diagnosis of Fabry disease confirmed by <u>one</u> of the following: <ol style="list-style-type: none"> <li>1. An undetectable (&lt;1%) alpha galactosidase A (alpha-Gal-A) activity level OR</li> <li>2. A deficient alpha-Gal- activity level AND a documented detection of pathogenic mutations in the galactosidase alpha (<i>GLA</i>) gene by molecular genetic testing</li> </ol> </li> <li>• Female members must have a documented diagnosis of Fabry disease confirmed by detection of pathogenic mutations in the <i>GLA</i> gene by molecular genetic testing AND evidence of clinical manifestation of the disease (e.g. kidney, neurologic, cardiovascular, gastrointestinal)</li> <li>• Member must not be using concurrently with Galafold (migalastat)</li> <li>• Documentation of the member’s current weight</li> <li>• Request is for an FDA-approved dose</li> </ul> <p><b><u>Re-Authorization:</u></b></p>

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- Documentation that member has experienced an improvement in symptoms from baseline including but not limited to: decreased pain, decreased gastrointestinal manifestations, decrease in proteinuria, stabilization of increase in eGFR, reduction of left ventricular hypertrophy (LVH) on echocardiogram, or improved myocardial function, or has remained asymptomatic
- Member must not be using concurrently with Galafold (migalastat)
- Documentation of the member's current weight
- Request is for an FDA-approved dose

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

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

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- Documentation is provided that wound(s) to be treated are clean with adequate granulation tissue, excellent vascularization, and do not appear infected
- Documentation is provided that there is no evidence of, or history of squamous cell carcinoma in the wound(s) to be treated
- Medication is prescribed at an FDA approved dose, and maximum weekly dispensing amount is not exceeded.
  - Vyjuvek: Requests exceeding more than one vial per week will not be approved.
  - Filsuvez: documentation of size of treatment area(s) and frequency of dressing changes is required. One tube of Filsuvez covers up to 250 cm<sup>2</sup> surface area. Requests exceeding a quantity sufficient to cover the treatment area more than once daily will not be approved.

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

Field Name	Field Description
Prior Authorization Group Description	<b>Fecal Microbiota</b>
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
<p data-bbox="245 894 430 926">Other Criteria</p> <p data-bbox="245 1331 430 1362">Date: 7/2025-</p>	<ul data-bbox="493 894 1365 1346" style="list-style-type: none"> <li>• Medication is prescribed at an FDA approved dose</li> <li>• Diagnosis of at least 1 recurrent episode of CDI (<math>\geq 2</math> total CDI episodes)</li> <li>• Current episode of CDI must be controlled (<math>&lt; 3</math> unformed/loose stools/day for 2 consecutive days)</li> <li>• Positive stool test for C. difficile within 30 days before prior authorization request</li> <li>• Administration will occur 24–72 hours following completion of antibiotic course for CDI treatment</li> <li>• For Vowst only: attestation patient will bowel cleanse using magnesium citrate or polyethylene glycol electrolyte solution the day before the first dose of Vowst</li> </ul> <p data-bbox="493 1381 1195 1413">*Rebyota and Vowst are limited to 1 treatment course*</p> <p data-bbox="493 1461 1377 1528"><b>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</b></p>

Field Name	Field Description
Prior Authorization Group Description	<b>Generalized Pustular Psoriasis (GPP) Agents</b>
Drugs	Spevigo (spesolimab-abzo)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Per package insert
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist or geneticist
Coverage Duration	<p>Acute Flares (IV vial): If all of the criteria are met, the request will be approved for up to 2 doses.</p> <p>Maintenance Treatment (SQ syringe): If all criteria are met, the initial request will be approved for 12 months. Reauthorization requests will be approved for 12 months.</p>
Other Criteria	<p><b><u>Initial Authorization</u></b></p> <ul style="list-style-type: none"> <li>• Diagnosis of generalized pustular psoriasis (GPP)</li> <li>• If request is for an acute GPP flare (IV vial), member must be experiencing an acute flare of GPP of moderate to severe intensity as defined by having all of the following: <ul style="list-style-type: none"> <li>○ Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of 3 or greater</li> <li>○ Presence of fresh pustules (new appearance or worsening of pustules)</li> <li>○ GPPPGA pustulation sub score of 2 or greater</li> <li>○ At least 5% of body surface area covered with erythema and the presence of pustules</li> </ul> </li> <li>• If request is for maintenance treatment of GPP (SQ syringe), member must have all of the following: <ul style="list-style-type: none"> <li>○ History of at least two GPP flares in the past year of moderate to severe intensity</li> <li>○ GPPPGA score of 0 or 1</li> <li>○ Documented trial and failure, intolerance, or contraindication to TWO of the following: oral retinoids, methotrexate, and cyclosporine</li> </ul> </li> <li>• Medication is prescribed at an FDA approved dose</li> </ul>

Date: 7/2025

**Reauthorization**

- 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.**

Field Name	Field Description
Prior Authorization Group Description	<p><b>Gonadotropin Releasing Hormone Agonists (GNRH)</b></p> <p><b>**IF DIAGNOSIS IS CANCER, USE ONCOLOGY CRITERIA**</b></p>
Drug(s)	<p><b>Preferred GNRH Agonist(s) for their respective indications:</b> Lupron Depot (leuprolide acetate) and Lupron Depot-Ped (leuprolide acetate)</p> <p><b>Non-Preferred GNRH Agonist(s):</b> Fensolvi (leuprolide acetate), Supprelin LA (histrelin acetate), Trelstar (triptorelin pamoate), Triptodur (triptorelin pamoate), and any newly marketed GnRH agonist.</p>
Covered Uses	<p>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per the National Comprehensive Cancer Network (NCCN), the American Society of Clinical Oncology (ASCO), the American College of Obstetricians and Gynecologists (ACOG), or the American Academy of Pediatrics (AAP) standard of care guidelines.</p>
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert if not detailed in "Other Criteria"
Prescriber Restrictions	Prescriber must be a specialist in the field to treat the member's condition.
Coverage Duration	<p>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.</p>
Other Criteria	<p><b><u>INITIAL AUTHORIZATION for ALL REQUESTS:</u></b></p> <ul style="list-style-type: none"> <li>• The medication is being prescribed for an FDA approved/standard of care guideline indication and within FDA approved/standard of care dosing guidelines.</li> </ul> <p><u>AND the member meets the following for the respective diagnosis:</u></p> <p><u>Central precocious puberty (CPP)</u></p> <ul style="list-style-type: none"> <li>• Onset of secondary sexual characteristics occurred when member was aged less than 8 years for females or aged less than 9 years for males</li> <li>• 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. <ul style="list-style-type: none"> <li>○ Patients with low or intermediate basal levels of LH should have a GnRH stimulation test to clarify the diagnosis.</li> </ul> </li> </ul>

- *If basal levels of LH are markedly elevated [e.g. more than 0.3mIU/ml (where IU- International units)] in a child with precocious puberty, then a diagnosis of CPP can be made without proceeding to a GnRH stimulation test.*

- Brain magnetic resonance imaging (MRI) has been performed for all boys with CPP and for girls with onset of secondary sexual characteristics before the age of six years of age to rule out a tumor.
- 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

Endometrial thinning

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

**REAUTHORIZATION for all requests:**

- 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.

AND meets the following per diagnosis:

Central precocious puberty (CPP)

- 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

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

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- The following lab results must be submitted and demonstrate normal values, otherwise, the member **MUST** be receiving, or is beginning therapy, to correct the deficiency:
  - Serum ferritin level (> 100ng/mL)
  - Transferrin saturation (TSAT) (> 20%)
- Member will not be receiving concurrent treatment with an ESA
- Request is for an FDA-approved dose

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

Field Name	Field Description
Prior Authorization Group Desc	<b>Hyaluronic Acid Derivatives</b>
Drug(s)	<p><b><u>Preferred:</u></b> Euflexxa</p> <p><b><u>Non-Preferred:</u></b> Gel-One, Gelsyn-3, GenVisc 850, Hyalgan, Supartz FX, TriVisc, Visco-3, Durolane, Hymovis, Monovisc, Orthovisc, Synvisc, Synvisc-One, Triluron, or any newly marketed agent</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), or the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See other criteria
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber is a rheumatologist, orthopedist, sports medicine specialist, or physiatrist
Coverage Duration	If all of the criteria are met, the request will be approved for one complete course of treatment (based on the FDA labeled dose of the drug requested).
Other Criteria	<p><b><u>Initial Authorization:</u></b></p> <ul style="list-style-type: none"> <li>• A diagnosis of Osteoarthritis (OA)/Degenerative joint disease (DJD) of the knee.</li> <li>• Documentation (in claim history or provider statement) that the member has had trials of at least 2 oral alternatives (e.g. acetaminophen-containing products, oral NSAIDs, other oral analgesics, etc.) AND a topical NSAID without improvement in pain/function or has a medical reason (intolerance, hypersensitivity, contraindication, etc.) for not being able to utilize these therapies</li> <li>• Documentation has been provided that the member has tried and failed two intraarticular steroid injections, per affected knee, or the member has a medical reason for not being able to utilize steroid injections.</li> <li>• If the request is for any other product other than Euflexxa, the member has a documented medical reason (intolerance, hypersensitivity, contraindication, etc) for not using Euflexxa</li> </ul> <p><b><u>Reauthorization:</u></b></p> <ul style="list-style-type: none"> <li>• Documentation was submitted that the patient had a response to the treated knee(s) that lasted at least 6 months (e.g. decreased</li> </ul>

<p>Revision/Review Date: 2/2026</p>	<p>joint pain or stiffness, improved range of motion, etc.).</p> <ul style="list-style-type: none"><li>• Documentation was submitted that the patient has a return of symptoms of osteoarthritis that has not responded to acetaminophen-containing products, oral or topical NSAIDs, or other oral analgesics or has a medical reason (intolerance, hypersensitivity, contraindication, etc.) for not being able to utilize these therapies.</li><li>• If the request is for any other product other than Euflexxa, the member has a documented medical reason (intolerance, hypersensitivity, contraindication, etc) for not using Euflexxa.</li></ul> <p><b>Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</b></p>
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Field Name	Field Description
Prior Authorization Group Description	<b>Hydroxyprogesterone caproate (generic Delalutin)</b>
Drugs	Hydroxyprogesterone caproate (generic Delalutin)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Pregnancy
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a gynecologist or in consultation with a gynecologist
Coverage Duration	If all the criteria are met, the initial request will be approved for up to 6 months. For continuation of therapy, the request will be approved for up to 6 months.
Other Criteria	<p><b><u>Initial Authorization:</u></b></p> <ul style="list-style-type: none"> <li>• Medication is prescribed at an FDA approved dose</li> <li>• If request is for preterm birth, do not approve</li> <li>• Request is for one of the following indications: <ul style="list-style-type: none"> <li>○ Amenorrhea or abnormal uterine bleeding due to hormonal imbalance</li> <li>○ Production of secretory endometrium and desquamation</li> <li>○ Test for endogenous estrogen production</li> <li>○ Advanced uterine adenocarcinoma</li> </ul> </li> </ul> <p><b><u>Re-Authorization:</u></b></p> <ul style="list-style-type: none"> <li>• Documentation or provider attestation of clinical benefit</li> <li>• Medication is prescribed at an FDA approved dose</li> </ul> <p><b>If all the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</b></p>
Date: 4/2025	

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

<p>Revision/Review Date 7/2025</p>	<p><b><u>Re-authorization:</u></b></p> <ul style="list-style-type: none"><li>• Retreatment or renewal requests beyond a total of 24 weeks of treatment (8 total infusions) will not be allowed.</li></ul> <p><b>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</b></p>
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Field Name	Field Description
Prior Authorization Group Description	<b>Immune Globulins</b>
Drugs	<p>Gamunex-C (IV or SQ) (Immune Globulin)  Bivigam (IV) (Immune Globulin)  Cuvitru (SQ) (Immune Globulin)  Flebogamma (IV) (Immune Globulin)  Gammagard liquid (IV or SQ) (Immune Globulin)  Gammagard SD (IV) (Immune Globulin)  Gammaked (IV or SQ) (Immune Globulin)  Gammaplex (IV) (Immune Globulin)  Hizentra (SQ) (Immune Globulin)  Octagam (IV) (Immune Globulin)  Privigen (IV) (Immune Globulin)  Asceniv (IV) (Immune Globulin-slra)  Cutaquig (SQ) (Immune Globulin-hipp)  Panzyga (IV) (Immune Globulin-ifas)  Hyqvia (SQ) (Immune Globulin Human/Recombinant Human Hyaluronidase)  Xembify (SQ) (Immune Globulin-klhw)  Alyglo (IV) (Immune Globulin-stwk)  Or any newly marketed immune globulin</p> <p style="text-align: center;"><b>**Gamunex-C is the preferred product for the indications of primary immunodeficiency, chronic idiopathic thrombocytopenic purpura, and chronic inflammatory demyelinating polyneuropathy**</b></p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	See “other criteria”
Coverage Duration	If the criteria are met the request will be approved for a 3 month duration unless otherwise specified in the diagnosis specific “Other Criteria” section below.
Other Criteria	<p><b><u>All Requests:</u></b></p> <ul style="list-style-type: none"> <li>• Documentation of diagnosis confirmed by a specialist</li> <li>• Member has tried and failed, or has a documented medical reason</li> </ul>

for not using, all other standard of care therapies as defined per recognized guidelines

- Member's height and weight are provided
- Dosing will be calculated using ideal body weight (IBW), unless ONE of the following:
  - If the member's actual weight is less than their IBW, then dosing will be calculated using their actual weight
  - If the member's body mass index (BMI) is  $\geq 30$  kg/m<sup>2</sup> OR if their actual weight is greater than 20% of their IBW, then dosing will be calculated using adjusted body weight (adjBW)

**Primary Immunodeficiency\*:**

- Patient's IgG level is provided and below normal for requested indication, or a documented specific antibody deficiency is provided
- Clinically significant deficiency of humoral immunity as evidenced by ONE of the following:
  - Inability to produce an adequate immunologic response to specific antigens.
  - History of recurrent infections despite prophylactic antibiotics
- Dose is consistent with FDA approved package labeling, nationally recognized compendia, or peer-reviewed literature
- If the request is for any medication other than Gamunex-C, the member has tried and failed, or has a documented medical reason for not using, Gamunex-C
  
- If criteria is met, approve for 6 months.

\*Primary Immunodeficiency includes, but is not limited to, the following: Congenital agammaglobulinemia, hypogammaglobulinemia (Common Variable Immunodeficiency, CVID), severe combined immunodeficiency (SCID), Wiskott-Aldrich syndrome, X-linked agammaglobulinemia or Bruton's agammaglobulinemia, hypergammaglobulinemia, X-linked hyper IgM syndrome

**Idiopathic Thrombocytopenic Purpura, acute and chronic:**

- Acute:
  - Patient has active bleeding, requires an urgent invasive procedure, is deferring splenectomy, has platelet counts < 20,000/ul and is at risk for intra-cerebral hemorrhage or has life threatening bleeding, or has an inadequate increase in platelets from corticosteroids or is unable to tolerate corticosteroids
  - Dose does not exceed 1g/kg daily for up to 2 days, or

400mg/kg daily for 5 days

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

**Kawasaki disease:**

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

**Chronic B-cell lymphocytic leukemia:**

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

**Bone marrow transplantation:**

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

**Pediatric HIV:**

- Patient is < 13 years of age
- Either patient's IgG level is < 400mg/dL or
- If patient's IgG level is  $\geq$  400 mg/dL than significant deficiency of humoral immunity as evidenced by ONE of the following:

- Inability to produce an adequate immunologic response to specific antigens.
- History of recurrent bacterial infections despite prophylactic antibiotics
- Dose does not exceed 400mg/kg/dose every 2-4 weeks
- If criteria is met, approve for 3 months.

**Multifocal motor neuropathy (MMN):**

- Duration of symptoms has been at least 1 month with disability.
- Nerve conduction studies were completed to rule out other possible conditions, and confirms the diagnosis of MMN.
- Dose does not exceed 2.4 g/kg/month administered over 2 to 5 days.
- If criteria is met, approve for up to 5 days for 6 months.

**Chronic inflammatory demyelinating polyneuropathy (CIDP):**

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

**Guillain-Barre syndrome:**

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

**Myasthenia Gravis:**

- Acute:

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

**Dermatomyositis (DM):**

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

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	<p>If criteria is met, the request will be approved for the duration listed above. If the criteria is not met, the request is referred to a Medical Director/Clinical reviewer for medical necessity review.</p>
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**Medical Director/Clinical Reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary**

Field Name	Field Description
Prior Authorization Group	<b>Injectable/Infusible Bone-Modifying Agents for Oncology Indications</b>
Drugs	<p><b>Preferred Bone-Modifying Agent(s):</b> Pamidronate disodium, Zoledronic Acid</p> <p><b>Non-preferred Bone-Modifying Agent(s):</b> Xgeva, Prolia (denosumab)</p>
Covered Uses	The request is for an FDA approved indication or for a medically accepted indications as defined or as supported by the medical compendium (Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI) , Drug Package Insert) as defined in the Social Security Act 1927, or per the National Comprehensive Cancer Network (NCCN), the American Society of Clinical Oncology (ASCO), or the National Institutes of Health (NIH) Consensus Panel standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber is an oncologist
Coverage Duration	6 months
Other Criteria	<ul style="list-style-type: none"> <li>• The request is for an approved/accepted indication at an approved dose</li> <li>• If the request is for Xgeva (denosumab) or an Xgeva biosimilar, the patient has a documented trial and failure of Bilprevda (denosumab-nxxp), or has a medical reason (intolerance, hypersensitivity, contraindication, renal insufficiency, etc.) for not utilizing this agent to manage their medical condition</li> <li>• If the request is for Prolia (denosumab) or a Prolia biosimilar, the patient has a documented trial and failure of Bilyos (denosumab-nxxp), or has a medical reason (intolerance, hypersensitivity, contraindication, renal insufficiency, etc.) for not utilizing this agent to manage their medical condition</li> <li>• If the request is for, Xgeva (denosumab) for any of the indications below, the patient has a documented trial and failure of generic pamidronate OR zoledronic acid that is consistent with claims history, or has a documented medical reason (intolerance, hypersensitivity, contraindication, renal insufficiency, etc.) for not utilizing one of these agents to manage their medical condition <ul style="list-style-type: none"> <li>○ Bone metastases from solid tumors</li> <li>○ Hypercalcemia of malignancy</li> <li>○ Multiple myeloma osteolytic lesions</li> </ul> </li> </ul>

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- If the request is for Xgeva (denosumab) for treating Giant cell tumor of bone, documentation has been submitted that the tumor is unresectable, that surgical resection is likely to result in morbidity (e.g. denosumab therapy is being used to aide in the possibility of resection with tumor shrinkage), or that disease has recurred.
- If the request if for Prolia (denosumab) for breast cancer, the patient has a documented trial and failure of generic pamidronate OR zoledronic acid that is consistent with claims history, or has a documented medical reason (intolerance, hypersensitivity, contraindication, renal insufficiency, etc.) for not utilizing one of these agents to manage their medical condition
- If the request is for Prolia (denosumab) for prostate cancer, approve.

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

Field Name	Field Description
Prior Authorization Group Description	<b>Kisunla</b>
Drugs	Kisunla (donanemab-azbt)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Patients with moderate to severe Alzheimer’s Disease (AD) Patients with neurodegenerative disease caused by a condition other than AD
Required Medical Information	See “Other Criteria”
Age Restrictions	Age 60-85 years
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	For initial authorization: the request will be approved in accordance with the FDA-indicated titration schedule for up to 6 months For reauthorization: if all of the conditions are met, the request will be approved for 6 months.
Other Criteria	<p><b><u>Initial Authorization</u></b></p> <ul style="list-style-type: none"> <li>• Diagnosis of mild cognitive impairment (MCI) caused by AD or mild AD dementia consistent with Stage 3 or Stage 4 Alzheimer’s disease as evidenced by at least one of the following: <ul style="list-style-type: none"> <li>○ Clinical Dementia Rating Global (CDR-G) score of 0.5-1.0</li> <li>○ Mini-Mental State Examination (MMSE) score <math>\geq 20</math> and <math>\leq 28</math></li> <li>○ Montreal Cognitive Assessment (MoCA) score of <math>\geq 16</math></li> </ul> </li> <li>• The request is for an FDA approved dose</li> <li>• Documentation of BOTH of the following: <ul style="list-style-type: none"> <li>○ Recent, within past year, positive results for the presence of beta-amyloid plaques on a positron emission tomography (PET) scan or cerebrospinal fluid testing</li> <li>○ Recent, within past year, baseline Magnetic Resonance Imaging (MRI) scan</li> </ul> </li> <li>• Physician has assessed baseline disease severity utilizing an objective measure/tool (i.e., integrated Alzheimer's Disease Rating Scale [iADRS], Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog], Alzheimer's Disease Cooperative Study-instrumental Activities of Daily Living [ADCS-iADL], Clinical Dementia Rating-Sum of Boxes [CDR-SB], etc.)</li> </ul>

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

**Reauthorization**

- The request is for an FDA approved dose
- Patient continues to have a diagnosis of MCI caused by AD or mild AD dementia consistent with Stage 3 or Stage 4 Alzheimer’s disease as evidenced by at least one of the following:
  - CDR-G score of 0.5-1.0
  - MMSE score of 20-28
  - MoCA score of  $\geq 16$
- 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 (i.e., stabilization or decreased rate of decline in symptoms from baseline on CDR-SB, iADRS, ADAS-Cog, or ADCS-iADL scales)
- No recent (past 1 year) history of stroke, seizures or TIA

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

Field Name	Field Description
Prior Authorization Group Description	<b>Lamzede</b>
Drugs	Lamzede (velmanase alfa-tycv)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	“See Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a specialist in the treatment of alpha-mannosidosis or other lysosomal storage disorders
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months
Other Criteria	<p><b>Initial Authorization</b></p> <ul style="list-style-type: none"> <li>• Diagnosis of alpha-mannosidosis as confirmed by one of the following: <ul style="list-style-type: none"> <li>○ Deficiency in alpha-mannosidase enzyme levels or activity in blood leukocytes</li> <li>○ DNA testing</li> </ul> </li> <li>• Prescriber attests that medication will only be used to treat non-central nervous system manifestations of alpha-mannosidosis</li> <li>• Patient’s weight</li> <li>• Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines</li> </ul> <p><b>Reauthorization</b></p> <ul style="list-style-type: none"> <li>• Patient has demonstrated a clinical response (i.e., reduction in serum oligosaccharide concentrations, stabilization or improvement in 3-minute stair climbing test [3MSCT], 6-minute walking test [6-MWT], forced vital capacity [FVC], etc.)</li> <li>• Prescriber attests that medication will only be used to treat non-central nervous system manifestations of alpha-mannosidosis</li> <li>• Patient’s weight</li> <li>• Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines</li> </ul> <p><b>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</b></p>
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Field Name	Field Description
Prior Authorization Group Description	<b>Leqembi</b>
Drugs	Leqembi (lecanemab-irmb)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Patients with moderate to severe Alzheimer’s Disease (AD) Patients with neurodegenerative disease caused by a condition other than AD
Required Medical Information	See “Other Criteria”
Age Restrictions	age 50-90 years
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	For initial and reauthorizations: if all of the conditions are met, the request will be approved for 6 months.
Other Criteria	<p><b><u>Initial Authorization</u></b></p> <ul style="list-style-type: none"> <li>• Diagnosis of mild cognitive impairment (MCI) caused by AD or mild AD consistent with Stage 3 or Stage 4 Alzheimer’s disease as evidenced by at least one of the following: <ul style="list-style-type: none"> <li>○ Clinical Dementia Rating Global (CDR-G) score of 0.5-1.0 and a Memory Box score of 0.5 or greater</li> <li>○ Mini-Mental State Examination (MMSE) score <math>\geq 22</math> and <math>\leq 30</math></li> <li>○ Wechsler Memory Scale IV-Logical Memory (subscale) II (WMS-IV LMII) score at least 1 standard deviation below age-adjusted mean</li> </ul> </li> <li>• The request is for an FDA approved dose</li> <li>• Documentation of BOTH of the following: <ul style="list-style-type: none"> <li>○ Recent, within past year, positive results for the presence of beta-amyloid plaques on a positron emission tomography (PET) scan or cerebrospinal fluid testing</li> <li>○ Recent, within past year, baseline Magnetic Resonance Imaging (MRI) scan</li> </ul> </li> <li>• 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.)</li> </ul>

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

**Reauthorization**

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

**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.**

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Field Name	Field Description
Prior Authorization Group Description	<b>Leqvio</b>
Drugs	Leqvio (inclisiran)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	See “Other Criteria”
Prescriber Restrictions	Prescriber must be cardiologist or specialist in treatment of lipid disorders
Coverage Duration	If the criteria are met, the initial request will be approved for up to a 3 month duration, and the reauthorization request will be approved for up to a 12 month duration; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	<p><b><u>Initial Authorization</u></b>  <b>For All Requests:</b></p> <ul style="list-style-type: none"> <li>• Request is appropriate for member (e.g. age) as indicated in package labeling or standard of care guidelines</li> <li>• Patient has tried and failed atorvastatin 40mg-80mg or rosuvastatin 20-40mg (consistently for 3 months via claim history or chart notes). If patient is not able to tolerate atorvastatin or rosuvastatin, documentation was provided that patient is taking another statin at the highest tolerated dose, or a medical reason was provided why the member is not able to use these therapies.</li> <li>• Patient has tried and failed ezetimibe at a maximal tolerated dose or a medical reason was provided why the member is not able to use this therapy.</li> <li>• 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.</li> </ul>

- Documentation was provided indicating provider has counseled member on smoking cessation and following a “heart healthy diet”.

AND the member meets the following for the respective diagnosis:

Familial Hypercholesterolemia (FH):

- Member has a diagnosis of familial hypercholesterolemia as evidenced by one of the following:
  - Documentation provided including two fasting lipid panel lab reports with abnormal low density lipoprotein (LDL) levels  $\geq 190$  for FH in adults or  $\geq 160$  for FH in children.
  - Results of positive genetic testing for an LDL-C-raising gene defect (LDL receptor, apoB, or PCSK9)
  - LDL remains above goal despite maximally tolerated LDL-lowering therapy

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

- If the diagnosis is primary severe hyperlipidemia (i.e. LDL  $\geq 190$  mg/dL)
  - LDL remains  $\geq 100$  mg/dL despite maximally tolerated LDL-lowering therapy
- If the diagnosis is secondary ASCVD prevention
  - LDL remains  $\geq 55$  mg/dL or non-HDL (i.e. total cholesterol minus HDL)  $\geq 85$  mg/dL despite maximally tolerated LDL-lowering therapy
  - And ONE of the following:
    - Documented history of multiple major ASCVD events (acute coronary syndrome within past 12 months, history of myocardial infarction, history of ischemic stroke, symptomatic peripheral artery disease)
    - Documented history of 1 major ASCVD event (acute coronary syndrome within past 12 months, history of myocardial infarction, history of ischemic stroke, symptomatic peripheral

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Prior Authorization Group Description	<b>Medications without specific criteria</b>
Drugs	Medications without 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	Per package insert
Prescriber Restrictions	N/A
Coverage Duration	If the criteria is met, the request will be approved for up to a 12 month duration (depending on the diagnosis and usual treatment duration).
Other Criteria	<b><u>Authorization:</u></b> <ul style="list-style-type: none"> <li>• Appropriate diagnosis/indication</li> <li>• Appropriate dose of medication based on age (i.e., pediatric and elderly populations) and indication.</li> </ul>
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Field Name	Field Description
Prior Authorization Group Description	<b>Mucopolysaccharidosis II (Hunter Syndrome) Agents</b>
Drugs	<b>Elaprase (idursulfase)</b>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	“See Other Criteria”
Age Restrictions	Patient is $\geq$ 16 months of age
Prescriber Restrictions	Prescribed by or in consultation with a specialist in the management Mucopolysaccharidosis II (geneticist, endocrinologist, neurologist, rheumatologist, etc.)
Coverage Duration	Initial Authorization: 6 months Reauthorization: 12 months
Other Criteria	<p><b>Initial Authorization</b></p> <ul style="list-style-type: none"> <li>• Diagnosis of Mucopolysaccharidosis II as confirmed by one of the following: <ul style="list-style-type: none"> <li>○ Enzyme assay demonstrating a deficiency of iduronate 2-sulfatase activity</li> <li>○ Genetic testing</li> </ul> </li> <li>• Patient’s weight</li> <li>• Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines</li> </ul> <p><b>Reauthorization</b></p> <ul style="list-style-type: none"> <li>• Patient has demonstrated a beneficial response (i.e., stabilization or improvement in 6-minute walk test [6-MWT], forced vital capacity [FVC]), urinary glycosaminoglycan (GAG) levels, liver volume, spleen volume, etc.)</li> <li>• Patient’s weight</li> <li>• Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines</li> </ul> <p><b>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</b></p>
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Field Name	Field Description
Prior Authorization Group Description	<b>Mucopolysaccharidosis VI (Maroteaux-Lamy Syndrome) Agents</b>
Drugs	<b>Naglazyme (galsulfase)</b>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	“See Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months Renewal: 12 months
Other Criteria	<p><b>Initial Authorization</b></p> <ul style="list-style-type: none"> <li>• Diagnosis of Mucopolysaccharidosis VI as confirmed by one of the following: <ul style="list-style-type: none"> <li>○ Enzyme assay demonstrating a deficiency in N-acetylgalactosamine 4-sulfatase (arylsulfatase B) enzyme activity</li> <li>○ DNA testing</li> </ul> </li> <li>• Patient’s weight</li> <li>• Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines</li> </ul> <p><b>Reauthorization</b></p> <ul style="list-style-type: none"> <li>• 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.)</li> <li>• Patient’s weight</li> <li>• Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines</li> </ul> <p><b>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</b></p>
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Field Name	Field Description
Prior Authorization Group Description	<b>Myasthenia Gravis Agents</b>
Drugs	Rystiggo (rozanolixizumab), Soliris (eculizumab), Ultomiris (ravulizumab), Vyvgart (efgartigimod), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase), Zilbrysq (zilucoplan), BVEMV (eculizumab-aeeb), Epysqli (eculizumab-aagh), Imaavy (nipocalimab-aahu)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or rheumatologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<p><b><u>Initial Authorization:</u></b></p> <ul style="list-style-type: none"> <li>• Diagnosis of generalized myasthenia gravis (gMG)</li> <li>• Patient has a positive serological test for one of the following: <ul style="list-style-type: none"> <li>○ Anti-AChR antibodies</li> <li>○ Anti-muscle-specific tyrosine kinase (MuSK) antibodies (Imaavy and Rystiggo only)</li> </ul> </li> <li>• Patient has a Myasthenia Gravis Foundation of America (MGFA) clinical classification of class II, III or IV</li> <li>• For adults: patient has tried and failed, or has contraindication, to one of the following: <ul style="list-style-type: none"> <li>○ Two (2) or more conventional therapies (i.e. acetylcholinesterase inhibitors, corticosteroids, non-steroidal immunosuppressive therapies)</li> <li>○ Failed at least 1 conventional therapy and required chronic plasmapheresis or plasma exchange or intravenous immunoglobulin</li> </ul> </li> <li>• For eculizumab in patients 6-17 years: one of the following: <ul style="list-style-type: none"> <li>○ Trial and failure of at least 1 conventional therapy (i.e. acetylcholinesterase inhibitors, corticosteroids, non-steroidal immunosuppressive therapies)</li> <li>○ Patient requires maintenance plasma exchange or intravenous immunoglobulin to control symptoms</li> </ul> </li> <li>• Medication is prescribed at an FDA approved dose</li> </ul>

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

**Re-Authorization:**

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

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

Field Name	Field Description
Prior Authorization Group Description	<b>Natriuretic Peptides for Achondroplasia</b>
Drugs	Voxzogo (vosoritide)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Hypochondroplasia or short stature condition other than achondroplasia
Required Medical Information	See “Other Criteria”
Age Restrictions	According to FDA approved prescribing information
Prescriber Restrictions	Prescribed by, or in consultation with, an endocrinologist, medical geneticist, or other specialist for the treatment of achondroplasia
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<p><b><u>Initial Authorization:</u></b></p> <ul style="list-style-type: none"> <li>• Member has a diagnosis of achondroplasia as confirmed via genetic testing</li> <li>• Prescriber attests patient has open epiphyses</li> <li>• Documentation of baseline growth velocity</li> <li>• Medication is prescribed at an FDA approved dose</li> </ul> <p><b><u>Re-Authorization:</u></b></p> <ul style="list-style-type: none"> <li>• Documentation of positive clinical response to therapy (as demonstrated by improvement over baseline in annualized growth velocity)</li> <li>• Prescriber attests patient has open epiphyses</li> <li>• Medication is prescribed at an FDA approved dose</li> </ul> <p><b>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</b></p>
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Field Name	Field Description
Prior Authorization Group Description	<b>Neuromyelitis Optica Spectrum Disorder (NMOSD) Agents</b>
Drugs	Step 1: Rituximab (Rituxan, Truxima, Riabni, Ruxience), Step 2: Enspryng (satralizumab-mwge) Uplizna (inebilizumab-cdon) Step 3: Soliris (eculizumab) Ultomiris (ravulizumab-cwyz)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	For Enspryng, Uplizna, Soliris, Ultomiris: Anti-aquaporin-4 (AQP4) antibody <b>negative</b> neuromyelitis optica spectrum disorder (NMOSD)
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a specialist who is experienced in the treatment of NMOSD (such as immunologist, neurologist or hematologist)
Coverage Duration	If all of the conditions are met, requests will be approved for 12 months.
Other Criteria	<p><b><u>Initial Authorization:</u></b></p> <p><u>For rituximab (Rituxan, Truxima, Riabni, or Ruxience):</u></p> <ul style="list-style-type: none"> <li>• Member has a diagnosis of NMOSD</li> <li>• Documentation indicating that the patient has been screened for HBV (hepatitis B virus) prior to initiation of treatment</li> <li>• Dosing is supported by compendia or standard of care guidelines</li> <li>• If the request is for any medication other than Ruxience (rituximab-pvvr) or Riabni (rituximab-arrx), there is a documented trial and failure of Ruxience or Riabni, or medical reason why (e.g. intolerance, hypersensitivity, contraindication) they cannot be used</li> </ul> <p><u>For Enspryng:</u></p> <ul style="list-style-type: none"> <li>• Member has a diagnosis of anti-aquaporin-4 (AQP4) antibody <b>positive</b> NMOSD</li> <li>• Provider attests to completion of the following assessments prior to the first dose of Enspryng as outlined in the prescribing information:             <ul style="list-style-type: none"> <li>○ Hepatitis B virus screening</li> <li>○ Tuberculosis screening</li> </ul> </li> </ul>

- Liver transaminase screening
- Patient has not received live or attenuated-live virus vaccines within 4 weeks before the start of Enspryng therapy
- Documented trial and failure of rituximab (Rituxan, Truxima, Riabni, or Ruxience), azathioprine, or mycophenolate mofetil, or medical reason why (e.g., intolerance, hypersensitivity, contraindication) they cannot be used
- Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines

Exceptions:

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

For Uplizna:

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

Exceptions:

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

For Soliris/Ultomiris:

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

<p>Revision/Review Date 10/2025</p>	<ul style="list-style-type: none"><li>• Documentation patient complies with most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria.</li><li>• Antimicrobial prophylaxis with oral antibiotics (penicillin, or macrolides if penicillin-allergic) for two weeks if the meningococcal vaccine is administered &lt; 2 weeks before starting therapy or a documented medical reason why the patient cannot receive oral antibiotic prophylaxis.</li><li>• Documented trial and failure of, or medical reason why (e.g. intolerance, hypersensitivity, contraindication) why the following cannot be used (one from each bullet below):<ul style="list-style-type: none"><li>○ Rituximab (Rituxan, Truxima, Riabni, or Ruxience), azathioprine, or mycophenolate mofetil</li><li>○ Enspryng</li><li>○ Uplizna</li></ul></li><li>• Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines</li></ul> <p><b><u>Reauthorization:</u></b></p> <ul style="list-style-type: none"><li>• Documentation that the prescriber has evaluated the member and recommends continuation of therapy (clinical benefit)</li><li>• Request is for an FDA approved/medically accepted dose</li></ul> <p><b>Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</b></p>
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Field Name	Field Description
Prior Authorization Group Description	<b>Off-Label Uses Criteria</b>
Drugs	<b>Medications with off-label uses</b>
Covered Uses	Off-label uses: Medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criterion is met, the request will be approved for up to a 12 month duration (depending on the diagnosis and usual treatment duration).
Other Criteria	<p><b><u>Authorization:</u></b></p> <ol style="list-style-type: none"> <li>1. One of the following: <ol style="list-style-type: none"> <li>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.</li> <li>b. No other formulary medication has a medically accepted use for the patient’s specific diagnosis as referenced in the medical compendia</li> </ol> <p style="text-align: center;"><b>AND</b></p> </li> <li>2. One of the following: <ol style="list-style-type: none"> <li>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)</li> <li>b. Requested use can be supported by at least two published peer reviewed clinical studies</li> </ol> <p style="text-align: center;"><b>AND</b></p> </li> </ol>

<p>Revision/Review Date 4/2025</p>	<p>3. Medication is being requested at an appropriate dose per literature</p> <p><b>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</b></p>
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Field Name	Field Description
Prior Authorization Group Description	<b>Omisirge</b>
Drugs	<b>Omisirge (omidubicel-only)</b>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Patient has previously received this medication
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	If all the criteria are met, the initial request will be approved for a one-time treatment.
Other Criteria	<p><b><u>Initial Authorization:</u></b></p> <ul style="list-style-type: none"> <li>• Patient has a hematologic malignancy planned for umbilical cord blood transplantation (UCBT) following myeloablative conditioning</li> <li>• 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</li> <li>• Patient has not received a prior allogenic HSCT</li> <li>• Patient does not have known allergy to dimethyl sulfoxide (DMSO), Dextran 40, gentamicin, human serum albumin, or bovine material</li> </ul> <p><b>The safety and effectiveness of repeat administration of Omisirge have not been evaluated and will not be approved.</b></p> <p><b>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</b></p>
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Field Name	Field Description
Prior Authorization Group	<b>Oncology Drugs/Therapies</b>
Drugs	Oral and Injectable Oncology Medications (specialty or non-specialty) without product specific criteria when requested for an oncology diagnosis
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI) , and the Drug Package Insert, and/or per the National Comprehensive Cancer Network (NCCN)
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert or NCCN guidelines
Prescriber Restrictions	Prescribed by or in consultation with an oncologist, or specialist in type of cancer being treated
Coverage Duration	If the criteria are met, the request will be approved for up to 6 month duration.
Other Criteria	<p><b>All of the following criteria must be met:</b></p> <ul style="list-style-type: none"> <li>• Requested use must be a labeled indication or be supported by NCCN Category 1 or 2A level of evidence. If the request is for an off-label use supported by NCCN as Category 2B recommendation then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g. allergic reaction, contraindication)</li> <li>• Documentation has been provided of the results of all required genetic testing where required per product package insert</li> <li>• Documentation has been provided of the results of all required laboratory values and patient specific information (e.g. weight, ALT/AST, Creatine Kinase, etc.) necessary to ensure the patient has no contraindications to therapy per product package insert</li> <li>• The product is being prescribed at a dose and duration that is within FDA approved/NCCN guidelines.</li> <li>• If the request is for a reference biologic drug with either a biosimilar or interchangeable biologic drug currently available, documentation of one of the following: <ul style="list-style-type: none"> <li>○ The provider has verbally or in writing submitted a member specific reason why the reference biologic is required based on the member’s condition or treatment history; AND if the member had side effects or a reaction to the biosimilar or interchangeable biologic, the provider has completed and submitted an FDA MedWatch form to justify the member’s need to avoid</li> </ul> </li> </ul>

these drugs. The MedWatch form must be included with the prior authorization request

- The currently available biosimilar product does not have the same appropriate use (per the references outlined in “Covered Uses”) as the reference biologic product being requested

[Form FDA 3500 – Voluntary Reporting](#)

- **If the request is for abiraterone (Zytiga) 500 mg tablet, a documented medical reason why two tablets of generic abiraterone acetate 250 mg cannot be used**

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

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Field Name	Field Description
Prior Authorization Group Description	<b>Palynziq</b>
Drugs	Palynziq (pegvaliase-pqpz)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	None
Required Medical Information	See “other criteria”
Age Restrictions	None
Prescriber Restrictions	Specialist experienced in the treatment of phenylketonuria (PKU).
Coverage Duration	Initial Authorizations: 12 months Dose Increases (to 40 mg or 60 mg daily): 16 weeks Reauthorization: 12 months
Other Criteria	<p><b><u>INITIAL AUTHORIZATION:</u></b></p> <ul style="list-style-type: none"> <li>• Documentation of a confirmed diagnosis of Phenylketonuria (PKU); <b>AND</b></li> <li>• Documentation the member’s blood phenylalanine (Phe) level is greater than 600 micromol/L(include lab results; must be within the past 90 days)</li> <li>• 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)</li> <li>• 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</li> <li>• The medication is being prescribed at a dose no greater than the FDA approved maximum initial dose of 20 mg SQ once daily.</li> </ul> <p><b><u>DOSE INCREASES:</u></b></p> <ul style="list-style-type: none"> <li>• Documentation of recent blood Phe level results (within the past 90 days).</li> <li>• Confirmation Phe control has not been achieved after</li> </ul>

adequate timeframe on the current dosing regimen:

- 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).

**REAUTHORIZATION:**

- 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.**

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Field Name	Field Description
Prior Authorization Group Description	Papzimeos
Drugs	Papzimeos (zopapogene imadenovec)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States 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	18 years of age or older
Prescriber Restrictions	Prescribed by, or in consultation with a pulmonologist, otolaryngologist, oncologist, or other specialist in the treatment of recurrent respiratory papillomatosis
Coverage Duration	If the criteria are met, the request will be approved for up to a 12-week course of therapy. If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review. Renewal requests or requests for more than a one-time course of therapy will not be approved.
Other Criteria	<p><b>Initiation of Therapy:</b></p> <ul style="list-style-type: none"> <li>• Member has a diagnosis of recurrent respiratory papillomatosis</li> <li>• Documentation is provided confirming human papilloma type 6 or 11</li> <li>• Member has a history of voice or airway symptoms which have required 3 or more clinically indicated interventions (surgical resection or laser ablation of disease) in the previous 12 months</li> </ul> <p><b>Renewal Requests:</b></p> <p>Renewal requests or requests for more than a one-time course of therapy will not be approved.</p> <p><b>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</b></p>
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Field Name	Field Description
Prior Authorization Group Description	<b>Peanut Allergy Immunotherapy Agents (FDA Approved)</b>
Drugs	Palforzia [Peanut (Arachis hypogaea) Allergen Powder-dnfp] capsule/sachet
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Use of Palforzia concomitantly with Xolair
Required Medical Information	See “Other Criteria”
Age Restrictions	Initiation: Patient is age 4-17 years. Up dosing and maintenance: Patient is age $\geq$ 4 years
Prescriber Restrictions	Prescriber is a specialist in the area of allergy/immunology
Coverage Duration	6 months
Other Criteria	<p><b><u>Initial Authorization:</u></b> Palforzia is approved when all of the following criteria are met:</p> <ul style="list-style-type: none"> <li>• Patient has a confirmed diagnosis of peanut allergy</li> <li>• For patients starting initial dose escalation (new to therapy) <ul style="list-style-type: none"> <li>○ Patient has not had severe or life-threatening anaphylaxis within the previous 60 days</li> </ul> </li> <li>• Patient will follow a peanut-avoidant diet</li> <li>• Patient has been prescribed and has acquired (as demonstrated by pharmacy claims or documentation) injectable epinephrine</li> <li>• No history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease</li> <li>• Patient does not have uncontrolled asthma</li> </ul> <p><b><u>Criteria for Re-Authorization:</u></b> Palforzia is approved for re-authorization when all of the following criteria are met</p> <ul style="list-style-type: none"> <li>• Patient will follow a peanut-avoidant diet</li> <li>• Patient is able to tolerate at least the 3 mg dose daily</li> <li>• Patient is able to comply with the daily dosing requirements</li> <li>• Patient does not have recurrent asthma exacerbations or persistent loss of asthma control</li> <li>• Patient has been prescribed and has acquired (as demonstrated by pharmacy claims or documentation) injectable epinephrine</li> </ul> <p style="text-align: center;"><b>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</b></p>
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Field Name	Field Description
Prior Authorization Group Description	<b>Pompe Disease Agents</b>
Drugs	Lumizyme (alglucosidase alfa) Nexviazyme (avalglucosidase alfa-ngpt) injection Pombiliti (cipaglucosidase alfa-atga) + Opfolda (miglustat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	According to FDA approved prescribing information
Prescriber Restrictions	Prescribed by, or in consultation with, a specialist in the treatment of Pompe disease, such as a genetic or metabolic specialist, neurologist, cardiologist, or pediatrician.
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Other Criteria	<p><b><u>Initial Authorization:</u></b></p> <p>For infantile onset Pompe Disease (Lumizyme only):</p> <ul style="list-style-type: none"> <li>• Patient has a diagnosis of infantile-onset Pompe Disease, confirmed by one of the following: <ul style="list-style-type: none"> <li>○ Enzyme assay showing a deficiency of acid alpha-glucosidase (GAA) activity in the blood, skin, or muscle</li> <li>○ Genetic testing showing a mutation in the GAA gene</li> </ul> </li> <li>• Requested dose is appropriate per prescribing information (documentation of patient weight must be submitted with request)</li> <li>• Requested regimen will not be used in combination with other enzyme replacement therapies</li> </ul> <p>For late onset Pompe Disease (Lumizyme, Nexviazyme, or Pombiliti + Opfolda):</p> <ul style="list-style-type: none"> <li>• Patient has a diagnosis of late-onset (non-infantile) Pompe Disease, confirmed by one of the following: <ul style="list-style-type: none"> <li>○ Enzyme assay showing a deficiency of acid alpha-glucosidase (GAA) activity in the blood, skin, or muscle</li> <li>○ Genetic testing showing a mutation in the GAA gene</li> </ul> </li> <li>• Documentation patient has measurable signs or symptoms of Pompe disease</li> <li>• Results of a baseline 6-minute walk test (6MWT) and percent-predicted forced vital capacity (FVC) are provided (not required for patients who are not old enough to walk)</li> <li>• Requested dose is appropriate per prescribing information (documentation of patient weight must be submitted with request)</li> </ul>

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- Requested regimen will not be used in combination with other enzyme replacement therapies (Exception: Pombiliti + Opfolda are to be used together)
- Additionally for Nexviazyme: Patients < 30 kg must provide documentation of a trial and therapy failure of, or a medical reason why Lumizyme may not be used.
- Additionally for Pombiliti + Opfolda: Patient must have trial and failure of another enzyme therapy (Lumizyme or Nexviazyme)

**Re-Authorization:**

- Documentation or provider attestation of positive clinical response to therapy
  - Infantile onset: provider attestation of member benefit
  - Late onset: improvement, stabilization, or slowing of progression of percent-predicted FVC and/or 6MWT
- Requested dose is appropriate per prescribing information (documentation of patient weight must be submitted with request)
- Requested regimen will not be used in combination with other enzyme replacement therapies (Exception: Pombiliti + Opfolda are to be used together)

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

Field Name	Field Description
Prior Authorization Group Description	<b>Primary Hemophagocytic Lymphohistiocytosis (HLH) Agents</b>
Drugs	Gamifant (emapalumab-lzsg)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Members who have undergone hematopoietic stem cell transplantation (HSCT)
Required Medical Information	“See Other Criteria”
Age Restrictions	N/A
Prescriber Restrictions	Hematologist, Oncologist, Immunologist, Transplant Specialist, or other specialist experienced in the treatment of immunologic disorders
Coverage Duration	Initial Authorization: 1 month Reauthorization: 3 months
Other Criteria	<p><b>*Gamifant will only be approved for members who have not yet received HSCT and will be discontinued at the initiation of HSCT*</b></p> <p><b>Initial Authorization</b></p> <ul style="list-style-type: none"> <li>• Member has a diagnosis of Primary HLH</li> <li>• 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</li> <li>• Prescriber attests that the member is a candidate for hematopoietic stem cell transplant (HSCT)</li> <li>• Member has been screened for latent tuberculosis infection</li> <li>• Member has or will receive prophylactic pre-medications (e.g. antivirals, antibiotics, antifungals) for Herpes Zoster, <i>Pneumocystis jirovecii</i>, and other fungal infections</li> <li>• Dosing is consistent with FDA approved labeling</li> </ul> <p><b>Reauthorization</b></p> <ul style="list-style-type: none"> <li>• Member continues to meet initial authorization criteria</li> <li>• Member is receiving prophylactic pre-medications (e.g. antivirals, antibiotics, antifungals) for Herpes Zoster, <i>Pneumocystis jirovecii</i>, and other fungal infections</li> </ul> <p><b>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</b></p>
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Field Name	Field Description
Prior Authorization Group Description	<b>Primary Hyperoxaluria Agents</b>
Drugs	Oxlumo (lumasiran) Rivfloza (nedosiran)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a nephrologist, urologist, hepatologist, endocrinologist or consultation with one of these specialists
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria	<p><b><u>Initial Authorization</u></b></p> <ul style="list-style-type: none"> <li>• Diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by one of the following: <ul style="list-style-type: none"> <li>○ Genetic testing confirming at least one mutation at the AGXT gene</li> <li>○ Liver biopsy demonstrating absent or significantly reduced AGT activity</li> </ul> </li> <li>• Metabolic testing demonstrating one of the following: <ul style="list-style-type: none"> <li>○ Oxlumo or Rivfloza <ul style="list-style-type: none"> <li>▪ Increased urinary oxalate excretion (<math>\geq 0.5</math> mmol/1.73 m<sup>2</sup>per day[45 mg/1.73 m<sup>2</sup>per day])</li> <li>▪ Increased urinary oxalate:creatinine ratio relative to normative values for age</li> </ul> </li> <li>○ Oxlumo only: Increased plasma oxalate level (<math>\geq 20</math> <math>\mu</math>mol/L)</li> </ul> </li> <li>• For Rivfloza: member has relatively preserved kidney function (e.g., EGFR <math>\geq 30</math> mL/min/1.73 m<sup>2</sup>)</li> <li>• 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</li> <li>• Member has no history of liver transplant</li> <li>• Medication is prescribed at an FDA approved dose</li> </ul>

<p>Revision/Review Date 2/2026</p>	<ul style="list-style-type: none"><li>• Patient is not using Oxlumo and Rivfloza concurrently</li></ul> <p><b><u>Reauthorization</u></b></p> <ul style="list-style-type: none"><li>• Members previously using pyridoxine will continue to use pyridoxine, or have a medical reason for not using pyridoxine</li><li>• Documentation has been provided that demonstrates a clinical benefit (e.g. symptomatic improvement, reduction in urinary oxalate, urinary oxalate:creatinine ratio, or plasma oxalate levels from baseline)</li><li>• Medication is prescribed at an FDA approved dose</li><li>• Patient is not using Oxlumo and Rivfloza concurrently</li></ul> <p><b>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</b></p>
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Field Name	Field Description
Prior Authorization Group Description	<b>Qalsody</b>
Drugs	Qalsody (tofersen)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	See “Other Criteria”
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, neuromuscular specialist, or physician specializing in the treatment of amyotrophic lateral sclerosis (ALS)
Coverage Duration	If all the criteria are met, initial and renewal requests will be approved for 6 months
Other Criteria	<p><b><u>Initial Authorization:</u></b></p> <ul style="list-style-type: none"> <li>• Diagnosis of ALS</li> <li>• Documentation of genetic test confirming a mutation in the superoxide dismutase 1 (SOD1) gene</li> <li>• Member is not dependent on invasive ventilation or tracheostomy</li> <li>• Documentation of slow vital capacity (SVC) <math>\geq</math> 50%</li> <li>• Medication is prescribed at an FDA approved dose</li> </ul> <p><b><u>Re-Authorization:</u></b></p> <ul style="list-style-type: none"> <li>• 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)</li> <li>• Member is not dependent on invasive ventilation or tracheostomy</li> <li>• Medication is prescribed at an FDA approved dose</li> </ul> <p><b>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</b></p>
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Field Name	Field Description
Prior Authorization Group Description	<b>Radicava</b>
Drugs	Edaravone (Radicava), Radivaca ORS (edaravone) and any other newly marketed agent  *** riluzole (Rilutek) is Preferred and does not require prior authorization***
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	If the criteria are met, requests will be approved for up to 6 month duration
Other Criteria	<p><b>Initial Authorization:</b></p> <ul style="list-style-type: none"> <li>• Member must have a diagnosis of ALS</li> <li>• Member must have a documented baseline evaluation of functionality using the revised ALS functional rating scale (ALSFRS-R) score <math>\geq 2</math></li> <li>• Member’s disease duration is 2 years or less</li> <li>• Member has a baseline forced vital capacity (FVC) of <math>\geq 80\%</math></li> <li>• Member has been on riluzole (Rilutek), is beginning therapy as an adjunct to treatment with Radicava, or provider has provided a medical reason why patient is unable to use riluzole</li> <li>• Dose is within FDA approved limits</li> </ul> <p><b>Reauthorization:</b></p> <ul style="list-style-type: none"> <li>• Member is not ventilator-dependent</li> <li>• Provider documents clinical stabilization in symptoms (e.g. stabilization of ALSFRS-R score)</li> <li>• Dose is within FDA approved limits</li> </ul> <p><b>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</b></p>
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Prior Authorization Group Description	<b>Reblozyl (luspatercept-aamt)</b>
Drugs	Reblozyl (luspatercept-aamt) vial for subcutaneous injection
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Members are excluded if they have hemoglobin S/beta-thalassemia, isolated alpha-thalassemia
Required Medical Information	See “other criteria”
Age Restrictions	Member must be 18 years of age or older
Prescriber Restrictions	Prescriber must be a hematologist or oncologist
Coverage Duration	Initial and reauthorization requests will be approved for 6 months.
Other Criteria	<p><b>Criteria for initial approval:</b></p> <ul style="list-style-type: none"> <li>• Requested dose is appropriate per labeling</li> <li>• The member’s weight has been provided with the request</li> <li>• The member’s most recent hemoglobin level (within the last month) has been provided with the request</li> <li>• Diagnosis appropriate per Covered Uses</li> <li>• For requests for anemia due to beta thalassemia, documentation of all of the following is required: <ul style="list-style-type: none"> <li>○ Member requires regular red blood cell (RBC) transfusions (defined as at least 6 RBC units received over the last 6 months).</li> </ul> </li> <li>• For requests for anemia due to myelodysplastic syndrome, documentation of all of the following is required: <ul style="list-style-type: none"> <li>○ Myelodysplastic Syndrome Revised International Prognostic Scoring System (IPSS-R) categorization as very low, low, or intermediate risk of progression.</li> <li>○ Member has required transfusion of 2 or more RBC units within an 8 week period in the last 4 months</li> <li>○ Hemoglobin less than 10 g/dl</li> </ul> </li> </ul> <p><b>Reauthorization:</b></p> <ul style="list-style-type: none"> <li>• For diagnosis of anemia due to beta thalassemia, documentation of the following: <ul style="list-style-type: none"> <li>○ Fewer transfusions compared with baseline</li> <li>AND</li> <li>○ A reduction in transfusion requirement of at least 2 RBC units compared with baseline</li> </ul> </li> <li>• Diagnosis of anemia due to myelodysplastic syndrome: documentation of ONE of the following: <ul style="list-style-type: none"> <li>○ Hemoglobin increase of at least 1.5 g/dl from baseline over a period of 8-12 weeks</li> </ul> </li> </ul>

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## Rituximab

### Drugs:

Rituxan (rituximab)

Rituxan Hycela (rituximab/hyaluronidase human, recombinant)

Truxima (rituximab-abbs)

Ruxience (rituximab-pvvr)

Riabni (rituximab-arrx)

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

#### **MULTIPLE SCLEROSIS:**

- Refer to the “Healthcare Professional (HCP) administered/IV Disease Modifying Therapies (DMTs) for Multiple Sclerosis (MS)” policy

#### **NEUROMYELITIS OPTICA SPECTRUM DISORDER (NMOSD):**

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

#### **RHEUMATOID ARTHRITIS:**

##### **Initial Authorization**

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

- Documentation indicating that the patient has been screened for Hepatitis B Virus (HBV) prior to initiation of treatment.
- Rituximab is being prescribed at an FDA approved dosage.
- If the request is for any medication other than Ruxience (rituximab-pvvr) or Riabni (rituximab-arrx), there is a documented trial and failure of Ruxience or Riabni, or medical reason why (e.g. intolerance, hypersensitivity, contraindication) they cannot be used.

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

### **Reauthorization**

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

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

## **PEMPHIGUS VULGARIS**

### **Initial Authorization**

- The medication is being recommended and prescribed by a rheumatologist or dermatologist
- The patient is  $\geq 18$  years with a diagnosis of moderate to severe pemphigus vulgaris
- Documentation the patient will be receiving P. jirovecii pneumonia (PJP) prophylaxis (ex. TMP/SMX, dapsone, atovaquone) or the prescriber has provided a medical reason for not prescribing PJP prophylaxis
- Documentation indicating that the patient has been screened for HBV prior to initiation

of treatment

- Rituximab is being prescribed at an FDA approved dose/frequency
- Rituximab is being used in combination with a tapering course of glucocorticoids

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

### **Reauthorization**

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

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

## **ONCOLOGY INDICATIONS**

### **Initial Authorization:**

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

- If the request is for Rituxan Hycela (rituximab/hyaluronidase human, recombinant), all of the following: the patient has received at least one full dose of a rituximab product by intravenous infusion, the medication is being requested for a malignant condition, and there is a medical reason why the alternative rituximab product cannot be continued.

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

### **Reauthorization**

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

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

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

#### **Initial Authorization:**

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

Ruxience (rituximab-pvvr) Riabni (rituximab-arrx), there is a documented trial and failure of Ruxience or Riabni, or medical reason why (e.g. intolerance, hypersensitivity, contraindication) they cannot be used.

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

**Re-authorization:**

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

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

**DERMATOMYOSITIS (DM) and POLYMYOSITIS (PM)**

**Initial Authorization:**

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

of care guidelines and has a Class I or IIa recommendation).

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

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

### **Re-authorization:**

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

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

### **OTHER MEDICALLY ACCEPTED INDICATIONS**

#### **Initial Authorization:**

- The medication is prescribed for a non-FDA approved indication but is considered to be a medically accepted use of the medication per the medical compendia (Micromedex, American Hospital Formulary Service (AHFS), DrugPoints, the Drug Package Insert as defined in the Social Security Act and/or per the American Academy of Pediatrics (AAP) standard of care guidelines and has a Class I or Iia recommendation.
- The medication is prescribed at a medically accepted dose per the medical compendia as defined above.
- The medication is recommended and prescribed a specialist in the field to treat the member's respective medical condition.
- Documentation indicating that the patient has been screened for HBV prior to initiation of treatment.
- Documentation was submitted indicating that the member has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trial (including dates, doses of medications) of ALL first line medical therapies as recommended by the medical compendia and standard care

guidelines and/or has another documented medical reason (e.g. intolerance, contraindications, etc.) for not receiving or trying all first line medical treatment(s).

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

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

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

**Re-authorization:**

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

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

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

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

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Field Name	Field Description
Prior Authorization Group Description	SMN2 Splicing Modifiers for the Treatment of Spinal Muscular Atrophy (SMA)
Drugs	Spinraza (nusinersen) Evrysdi (risdiplam)
Covered Uses	Medically accepted indications are defined using the following 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	Concomitant use of Evrysdi and Spinraza
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	<p>For Evrysdi: If all of the conditions are met, the request will be approved for 6 months for initial approval, followed by 12 months for reauthorization requests.</p> <p>For Spinraza: If all of the conditions are met, the request will be approved for 6 months for 5 doses (4 loading doses and 1st maintenance dose) for initial approval, and 12 months for 3 additional maintenance doses for reauthorization requests.</p> <p>If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.</p>
Other Criteria	<p><b><u>Initial approval</u></b></p> <ul style="list-style-type: none"> <li>• Member has a confirmed diagnosis of SMA types I, II or III and the molecular genetic test with mutation analysis was submitted that is positive for the genetic deletion of the exon 7 of the survival motor neuron (SMN1)</li> <li>• For Spinraza: Documentation of genetic testing confirming either two or three copies of the SMN2 gene <b>OR</b> four copies of the SMN2 gene with symptomology of SMA</li> <li>• For Evrysdi: Documentation of genetic testing confirming two to four copies of the SMN2 gene</li> <li>• Baseline motor function or motor milestone achievement was submitted with request [e.g. CHOP Infant Test of Neuromuscular Disorders (CHOP-INTEND) or Hammersmith Infant Neurological Examination (HINE) for Type 1 or</li> </ul>

<p>Revision/Review Date 2/2026</p>	<p>Hammersmith Functional Motor Scale Expanded Scores (HFMSE) for Type II and Type III, or 6 minute walk test in subjects able to walk, Revised Upper Limb Module (RULM), Motor Function Measure 32 (MFM-32)]]]</p> <ul style="list-style-type: none"> <li>• The request is for an FDA approved dose</li> </ul> <p><b><u>Reauthorization</u></b></p> <ul style="list-style-type: none"> <li>• Documentation of clinical response was submitted with request (e.g. improvement or stabilization in motor function/motor milestone achievement scores using CHOP-INTEND or HFMSE, 6 minute walk test, RULM, MFM-32 or HINE improvement in more categories of motor milestones than worsening, patient remains permanent ventilation free if no prior ventilator support)</li> <li>• The request is for an FDA approved dose</li> </ul> <p><b>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</b></p>

Field Name	Field Description
Prior Authorization Group Description	<b>Somatostatin Analogs and Growth Hormone Receptor Antagonists</b>
Drugs	Octreotide (Sandostatin) Sandostatin LAR (octreotide) Lanreotide 120 mg/0.5 mL Lanreotide (Somatuline Depot) ( ) 60 mg/0.2 mL, 90 mg/0.3 mL, 120 mg/0.5mL Mycapssa (octreotide) Signifor (pasireotide) Signifor LAR (pasireotide) Somavert (pegvisomant)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA) Drug Package Insert (PPI).  ** Non-FDA approved (i.e. off-label) uses; refer to the “Off-Label Use” policy for non-oncology indications, and the “Oncology Drugs” policy for off-label oncology uses**
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Per FDA approved package insert
Prescriber Restrictions	Prescriber must be a specialist with appropriate expertise in treating the condition in question (such as an endocrinologist, neurologist/neurosurgeon, oncologist, etc.). Consultation with appropriate specialist for the condition in question is also acceptable.
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<p><b><u>Initial Authorization</u></b></p> <p><u>For all FDA approved indications (including FDA-approved oncology related uses)</u></p> <ul style="list-style-type: none"> <li>• Medication requested is for an FDA approved indication and dose</li> <li>• 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.</li> </ul> <p><u>For Acromegaly</u></p> <ul style="list-style-type: none"> <li>• Patient has had an inadequate response to, or medical reason why, surgical treatment cannot be used.</li> </ul>

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

For Cushing's Disease (pasireotide products only)

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

Reauthorization

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

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

Field Name	Field Description
Prior Authorization Group Description	<b>Spravato</b>
Drugs	<b>Spravato</b> (esketamine)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), 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	N/A
Coverage Duration	If all of the criteria are met, the initial request will be approved for 4 weeks. For continuation of therapy the request will be approved for 6 months.
Other Criteria	<p><b><u>Initial Authorization:</u></b></p> <ul style="list-style-type: none"> <li>• Member has a diagnosis of at least one of the following: <ul style="list-style-type: none"> <li>○ Major depressive disorder with treatment-resistant depression</li> <li>○ Major depressive disorder with acute suicidal ideation or behavior</li> </ul> </li> <li>• Medication is being prescribed at an FDA approved dosage.</li> <li>• If Spravato is being requested for a diagnosis of major depressive disorder with treatment-resistant depression (i.e. without suicidal ideation or behavior) the member has either: <ul style="list-style-type: none"> <li>○ Documented trial and failure of two preferred oral antidepressants (eg. SSRIs, SNRIs, TCAs) of at least a minimum effective dose for four (4) weeks or longer OR</li> <li>○ Medical justification as to why the patient cannot use preferred alternative(s).</li> </ul> </li> <li>• Requests for a diagnosis of major depressive disorder with acute suicidal ideation or behavior (not required for treatment resistant depression): <ul style="list-style-type: none"> <li>○ Prescriber attests Spravato will be used in conjunction with an oral antidepressant</li> </ul> </li> </ul> <p><b><u>Re-authorization:</u></b></p> <ul style="list-style-type: none"> <li>• Medication is prescribed at an FDA-approved dosage.</li> <li>• Medication is being used in conjunction with an oral antidepressant (not required for diagnosis of treatment resistant depression).</li> <li>• Documentation was submitted indicating the member has clinically benefited from therapy.</li> </ul>
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	<p><b>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</b></p>
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Field Name	Field Description
Prior Authorization Group Description	<b>Synagis (palivizumab)</b>
Drugs	Synagis (palivizumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	A maximum of 5 doses may be approved within the Respiratory Syncytial Virus (RSV) season. Requests for additional doses will be reviewed on a case-by case basis based on CDC surveillance reports, state/local health department recommendations, and other current medical literature.
Other Criteria	<p><u>Infants less than 1 year of age at the onset of the respiratory syncytial virus (RSV) season (which typically starts November 1<sup>st</sup>, but may vary seasonally) AND have one of the following indications:</u></p> <ul style="list-style-type: none"> <li>• Born at less than 29 weeks, 0 days gestation</li> <li>• Born at less than 32 weeks, 0 days gestation AND had chronic lung disease of prematurity defined as greater than 21% oxygen for at least 28 days after birth</li> <li>• Born at any gestational age with hemodynamically significant heart disease including: <ul style="list-style-type: none"> <li>○ Cyanotic heart disease in consultation with a pediatric cardiologist</li> <li>○ Acyanotic Heart disease with one of the following: <ul style="list-style-type: none"> <li>▪ On heart failure medication and expected to require cardiac surgical procedure</li> <li>▪ Moderate to severe pulmonary hypertension</li> </ul> </li> </ul> </li> <li>• Cystic fibrosis with clinical evidence of chronic lung disease (CLD) and/or nutritional compromise in the first year of life</li> <li>• Born at any gestational age with pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the lower airway</li> </ul> <p><u>Infants less than 2 years of age at the onset of the RSV season (which typically starts November 1<sup>st</sup>, but may vary seasonally) AND have one of the following indications:</u></p>

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- Born at less than 32 weeks, 0 days AND had a diagnosis of chronic lung disease of prematurity at birth as defined above AND had continued need for one of the following respiratory interventions in the 6 months preceding RSV season: Chronic steroids, chronic diuretics, supplemental oxygen
- Cystic fibrosis with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) or weight for length less than the 10th percentile
- Born at any gestational age and will be profoundly immunocompromised during the RSV season, including:
  - Solid organ or hematopoietic stem cell transplant recipient
  - Chemotherapy recipient
- Born at any gestational age and receiving a cardiac transplant

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

Field Name	Field Description
Prior Authorization Group Description	<b>Tecelra</b>
Drugs	Tecelra (afamitresgene autoleucel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	<ul style="list-style-type: none"> <li>• Homozygous or heterozygous for HLA-A*02:05P</li> </ul>
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be an oncologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for a one-time treatment.
Other Criteria	<p><b><u>Initial Authorization:</u></b></p> <ul style="list-style-type: none"> <li>• Diagnosis of unresectable or metastatic synovial sarcoma</li> <li>• Documentation that patient is HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive</li> <li>• Documentation that the tumor expresses the MAGE-A4 antigen</li> <li>• Documentation of treatment with prior chemotherapy</li> <li>• Member must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1</li> <li>• Medication is being prescribed at an FDA approved dose</li> </ul> <p><b>The safety and effectiveness of repeat administration of Tecelra has not been evaluated and will not be approved.</b></p> <p><b>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</b></p>
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Field Name	Field Description
Prior Authorization Group Description	<b>Transthyretin-mediated Amyloidosis Agents</b>
Drugs	<p><b><u>Preferred:</u></b>  Polyneuropathy – Onpattro (patisiran), Amvuttra (vutrisiran), Wainua (eplontersen)  Cardiomyopathy – Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis), Attruby (acoramidis)</p> <p><b><u>Non-preferred:</u></b>  Cardiomyopathy – Amvuttra (vutrisiran)  Or any other newly marketed agent</p>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “Other Criteria”
Age Restrictions	Patient must be 18 years of age or older
Prescriber Restrictions	Prescriber must be neurologist, cardiologist, or specialist in the treatment of amyloidosis
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy the request will be approved for 6 months.
Other Criteria	<p><b><u>Initial Authorization:</u></b></p> <ul style="list-style-type: none"> <li>• Regimen does not exceed FDA-approved dose/frequency</li> <li>• Patient has not undergone a liver or heart transplant</li> <li>• 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.</li> </ul> <p><b>Polyneuropathy-Type</b>  If the request is for Onpattro, Amvuttra, or Wainua:</p> <ul style="list-style-type: none"> <li>• Patient has diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis as evidenced by documented transthyretin variant by genotyping</li> <li>• One of the following: <ul style="list-style-type: none"> <li>○ Patient has baseline polyneuropathy disability (PND) score ≤ IIIb</li> <li>○ Patient has a baseline FAP Stage 1 or 2</li> </ul> </li> </ul>

- Patient has baseline neuropathy impairment (NIS) score  $\geq 5$  and  $\leq 130$
- 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

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

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

**Continuation of Therapy Provision:**

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

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

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

<p>Revision/Review Date 4/2025</p>	<p>adjustments must be made AND the prescriber must provide a medical justification as to why therapy should be continued.</p> <ul style="list-style-type: none"><li>• The request is for an FDA approved dose</li></ul> <p><b>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</b></p>
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Field Name	Field Description
Prior Authorization Group Description	<b>Type I Interferon (IFN) Receptor Antagonist</b>
Drugs	Saphnelo (anifrolumab-fnia)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	<ul style="list-style-type: none"> <li>• Severe active central nervous system lupus</li> <li>• Active lupus nephritis</li> </ul>
Required Medical Information	See “Other Criteria”
Age Restrictions	≥ 18 years
Prescriber Restrictions	Prescriber must be a rheumatologist or in consultation with a rheumatologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Other Criteria	<p><b><u>Initial Authorization:</u></b></p> <ul style="list-style-type: none"> <li>• Diagnosis of active moderate to severe systemic lupus erythematosus (SLE)</li> <li>• Member has tried all of the following (or there is a medical reason they cannot use these therapies) before Saphnelo: <ul style="list-style-type: none"> <li>○ Hydroxychloroquine + Glucocorticoids</li> <li>○ One other immunosuppressant (i.e., methotrexate, azathioprine, calcineurin inhibitors, or mycophenolate)</li> <li>○ Benlysta (belimumab), if member has autoantibody-positive SLE</li> </ul> </li> <li>• Prescriber attests member will not be using Saphnelo concurrently with Benlysta</li> <li>• Medication is prescribed at an FDA approved dose</li> </ul> <p><b><u>Re-Authorization:</u></b></p> <ul style="list-style-type: none"> <li>• Documentation or provider attestation of positive clinical response (i.e., reduction in signs and symptoms of SLE, fewer flares, reduced oral corticosteroid use, etc.)</li> <li>• Prescriber attests member will not be using Saphnelo concurrently with Benlysta</li> <li>• Medication is prescribed at an FDA approved dose</li> </ul> <p><b>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</b></p>
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Field Name	Field Description
Prior Authorization Group Description	<b>Vascular Endothelial Growth Factor (VEGF) Inhibitors for Ophthalmic Conditions</b>
Drugs	<p>Preferred Vascular Endothelial Growth Factor (VEGF) Inhibitor(s):</p> <ul style="list-style-type: none"> <li>• <b>Avastin</b> (bevacizumab)</li> <li>• <b>Byooviz</b> (ranibizumab-nuna)</li> <li>• <b>Cimerli</b> (ranibizumab-eqrn)</li> </ul> <p>Non-Preferred Vascular Endothelial Growth Factor (VEGF) Inhibitor(s):</p> <ul style="list-style-type: none"> <li>• <b>Beovu</b> (brolucizumab)</li> <li>• <b>Eylea</b> (aflibercept)</li> <li>• <b>Eylea HD</b> (aflibercept)</li> <li>• <b>Lucentis</b> (ranibizumab)</li> <li>• <b>Susvimo</b> (ranibizumab)</li> <li>• <b>Vabysmo</b> (faricimab)</li> <li>• Pavblu (aflibercept-ayyh)</li> <li>• <b>Any newly marketed agent in this class</b></li> </ul>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), 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	Approvable for adults 18 years of age and older only Eylea: approvable in pediatric patients for diagnosis of retinopathy of prematurity
Prescriber Restrictions	Ophthalmologist
Coverage Duration	If the above conditions are met, the request will be approved for 12 months.
Other Criteria	<p><u>Initial Authorization:</u></p> <p><b>Avastin:</b></p> <ul style="list-style-type: none"> <li>• Request is for compendia supported dosing for an ophthalmic indication</li> </ul> <p><b>Byooviz or Cimerli:</b></p> <ul style="list-style-type: none"> <li>• Request is for an FDA-approved dosing regimen</li> </ul> <p><b>Non-Preferred VEGF Inhibitor:</b></p> <ul style="list-style-type: none"> <li>• Request is for an FDA-approved dosing regimen; <b>AND</b></li> </ul>

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- 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:
  - ROP Zone 1 Stage 1+, 2+, 3 or 3+, or
  - ROP Zone II Stage 2+ or 3+, or
  - AP-ROP (aggressive posterior ROP)

Re-Authorization:

- Documentation or provider attestation of positive clinical response
- Medication is prescribed at an FDA approved or compendia supported 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	<b>Vimizim (elosulfase alfa)</b>
Drugs	Vimizim (elosulfase alfa)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	Patient must be 5 years of age or older.
Prescriber Restrictions	Prescriber is, or is collaborating with another provider who is, a specialist in the treatment of Morquio A syndrome or other lysosomal storage disorders.
Coverage Duration	6 months
Other Criteria	<p><b><u>Initial Authorization (new to therapy):</u></b></p> <ul style="list-style-type: none"> <li>• Patient has confirmed diagnosis of mucopolysaccharidosis IVA (MPS IVA, or Morquio A syndrome) via one of the following: <ul style="list-style-type: none"> <li>○ Genetic testing</li> <li>○ Analysis of N-Acetylgalactosamine 6-sulfatase (GALNS) activity in leukocytes or fibroblasts</li> </ul> </li> <li>• Documentation of patient weight Patient must have completed a 6-minute walk test for baseline evaluation (must submit results with request) and be able to walk a minimum of 30 meters at baseline.</li> </ul> <p><b><u>Re-Authorization:</u></b></p> <ul style="list-style-type: none"> <li>• Patient shows signs of improvement from baseline in a 6-minute walk test (must submit results with request)</li> </ul> <p><b><u>Re-authorization for members new to the plan previously treated with Vimizim:</u></b></p> <ul style="list-style-type: none"> <li>• Patient has confirmed genetic diagnosis of mucopolysaccharidosis IVA (MPS IVA, or Morquio A syndrome) via one of the following: <ul style="list-style-type: none"> <li>○ Genetic testing</li> <li>○ Analysis of N-Acetylgalactosamine 6-sulfatase (GALNS) activity in leukocytes or fibroblasts</li> </ul> </li> <li>• Documentation of patient weight Patient must have completed a 6-minute walk test for baseline evaluation, and patient shows signs of improvement from baseline in a recent 6-minute walk test (must submit both results with request).</li> <li>• If a baseline 6-minute walk test was not completed prior to initiation of Vimizim therapy, then:</li> </ul>

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- A current test must be completed and patient must be able to walk a minimum of 30 meters (must submit results with request).
- Continued authorizations for Vimizim for patients without a completed baseline 6-minute walk test evaluation prior to initiation of therapy must continue to be able to walk a minimum of 30 meters in subsequent evaluations.
- If patient is established on Vimizim therapy prior to enrollment on the plan, but is not able to walk a minimum of 30 meters, then medical justification is required as to how the patient continues to receive benefit from Vimizim therapy.

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

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

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