PHARMACY
PRIOR AUTHORIZATION
CRITERIA

Effective 7/21/2023

Field Name	Field Description
Prior Authorization Group Description	**Diabetic Testing Supplies**
Drugs	**Diabetic Testing Supplies (e.g. glucometers, test strips, lancets, syringes, pen needles)**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If the criterion is met, the request will be approved for up to a 12 month duration (depending on the diagnosis and usual treatment duration). If criterion is not met, the request will be referred to a clinician for medical necessity review.
Other Criteria Revision/Review Date 10/2022	**Initial Authorization:** For approval of **Non-Preferred** products at least one of the following criteria must be met: • Member is legally blind or has reduced visual acuity so that they are unable to see the numbers on ALL of the preferred meter and the requested meter has a feature that enables the patient to use the meter that is not available on any of the preferred meters. The member (not a caregiver) must be the one using the monitor/strips OR • Member is currently using an insulin pump that needs specific meter compatibility to accurately dose insulin OR • Preferred meter is not compatible with insulin pump recipient is using OR • Member is unable to change to a preferred meter and strip combination due to a cognitive or developmental disability OR • Changing to a preferred meter and strip combination would create undue hardship for the member **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group	**Oncology Drugs**
Drugs	Oral and Injectable Oncology Medications (specialty or non-specialty) without medication specific criteria when requested for an oncology diagnosis
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI) , and the Drug Package Insert, and/or per the National Comprehensive Cancer Network (NCCN)
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescriber is an oncologist, or specialist in type of cancer being treated
Coverage Duration	If the criteria are met, the request will be approved for up to 6 month duration; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	**All of the following criteria must be met:** • Requested use must be a labeled indication or be supported by NCCN Category 1 or 2A level of evidence. If the request is for an off-label use supported by NCCN as Category 2B recommendation then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g. allergic reaction, contraindication) • Documentation has been provided of the results of all required genetic testing where required per drug package insert • Documentation has been provided of the results of all required laboratory values and patient specific information (e.g. weight, ALT/AST, Creatine Kinase, etc.) necessary to ensure the patient has no contraindications to therapy per drug package insert • The medication is being prescribed at a dose that is within FDA approved/NCCN guidelines. • If the request is for a reference biologic drug with either a biosimilar or interchangeable biologic drug currently available, documentation of one of the following: o The provider has verbally or in writing submitted a member specific reason why the reference biologic is required based on the member's condition or treatment history

Revision/Review 10/2022	○ The currently available biosimilar product does not have the same appropriate use (per the references outlined in "Covered Uses") as the reference biologic drug being requested • 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.**

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

	• The provider must submit a medical reason why treatment with more than one drug in the same class is required based on the member's condition and treatment history. OR • The provider must submit disease state specific standard of care guidelines supporting concurrent therapy. **Age Restriction** • The provider must submit a medical reason why the drug is needed for a member whose age is outside of the plan's minimum or maximum age limit. AND • The indication and dose requested is supported by the Medical Compendia or current treatment guidelines. **<u>Day Supply Limit</u>** • An additional fill exceeding the day supply limit is needed based on a dose increase or is needed to achieve a total daily dose OR • The provider must submit a medical reason why an additional fill is needed outside of the plan's day supply limit. AND • The indication and dose requested is supported by the FDA, Medical Compendia or current treatment guidelines. **Concurrent Use/Drug Drug Interaction:** • The provider must submit a medical reason why treatment with both drugs is necessary for the member AND • The increased risk for side effects when taking the drugs together has been discussed with the member **Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.**
Coverage Duration	*One month approval for Duplication of therapy when transitioning from one agent to another. All Other Scenarios: 12 months
Revision/Review Date:	10/2022

Field Name	Field Description
Prior Authorization Group Description	**Specialty Drugs**
Drugs	Oral and injectable specialty drugs without drug or class specific prior authorization criteria *** The Oncology Drugs prior authorization criteria will be applied to oncology drugs without drug or class specific criteria***
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If all of the conditions are met, requests will be approved for up to 6 months. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria	**All of the following criteria must be met:** • The drug is requested through the medical benefit • The drug is requested for an appropriate use (per the references outlined in "Covered Uses" • The dose requested is appropriate for the requested use (per the references outlined in "Covered Uses") • Documentation has been provided of a trial and failure of an appropriate alternative first line therapy, if one exists, for the requested use (per the references outlined in "Covered Uses"**)** or has a medical reason why these drug(s) cannot be used (e.g. intolerance, contraindication) • If the request is for a reference biologic drug with either a biosimilar or interchangeable biologic drug currently available o The provider has either verbally or in writing submitted a member specific reason why the reference biologic is required based on the member's condition or treatment history
Revision/Review Date 7/2022	**Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Alpha-1 Proteinase Inhibitors (Human)**
Drugs	**Preferred:** Prolastin-C **Non-Preferred:** Aralast NP Glassia Zemaira Or any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or specialist in the treatment of AAT
Coverage Duration	The request will be approved for up to a 12 month duration
Other Criteria	****Drug is being requested through the member's medical benefit**** **Initial Authorization:** • Documented diagnosis of a congenital deficiency of alpha-1 antitrypsin (AAT) (serum AAT level < 11 micromol/L [approximately 57 mg/dL using nephelometry or 80mg/dl by radial immunodiffusion]). • Documentation was submitted indicating the member has undergone genetic testing for AAT deficiency and is classified as phenotype PiZZ, PiSZ, PiZ(null) or Pi(null)(null) [NOTE: phenotypes PiMZ or PiMS are not candidates for treatment with Alpha1-Proteinase Inhibitors] • Documentation was submitted (member's pulmonary function test results) indicating airflow obstruction by spirometry (forced expiratory volume in 1 second [FE_{V1}] ≤ 65% of predicted), or provider has documented additional medical information demonstrating medical necessity • Documentation was submitted indicating member is a non-smoker or an ex-smoker (eg. smoking cessation treatment) • Documentation of the member's current weight • The Alpha-1 Proteinase Inhibitor (human) is being prescribed at an FDA approved dosage

Revision/Review Date 1/2023	• If the medication request is for an Alpha1-Proteinase Inhibitor (human) product other than Prolastin-C, the patient has a documented medical reason (intolerance, hypersensitivity, contraindication, treatment failure, etc.) for not using Prolastin-C to treat their medical condition **Reauthorization:** • Documentation of the member's current weight • Documentation was submitted indicating member is a non-smoker or an ex-smoker (e.g. smoking cessation treatment) • Documentation was submitted indicating the member has clinically benefited from therapy (i.e. stable lung function, improved PFTs, alpha-1 antitrypsin serum level maintained above 11 micromol/L [approximately 57 mg/dL using or 80 mg/dL by radial immunodiffusion], improved quality of life) • The Alpha-1 Proteinase Inhibitor (human) is being prescribed at an FDA approved dosage **Clinical reviewer/Medical Director must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Anti-CD19 CAR-T Immunotherapies**
Drugs	Kymriah (tisagenlecleucel), Yescarta (axicabtagene ciloleucel), Tecartus (brexucabtagene autoleucel), Breyanzi (lisocabtagene maraleucel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Patients with primary central nervous system lymphoma
Required Medical Information	See "Other Criteria"
Age Restrictions	See "Other Criteria"
Prescriber Restrictions	Prescriber must be an oncologist, hematologist or other prescribers who specialize in the treatment of lymphoma.
Coverage Duration	If all the criteria are met, the initial request will be approved for a one – time infusion per lifetime.
Other Criteria	****Drug is being requested through the member's medical benefit**** **Initial authorization:** • Patient must not have received prior anti-CD19 CAR-T therapy. • Patient will be screened for HBV, HCV, and HIV in accordance with clinical guidelines. • Patient does not have an active infection or inflammatory disorder. • Patient has a life expectancy >12 weeks. • Patient will not receive live virus vaccines for at least 6 weeks prior to the start of lymphodepleting chemotherapy and until immune recovery following treatment. **Leukemia** **B-cell precursor Acute Lymphoblastic Leukemia (ALL):** • If the request is for Kymriah o Patient is 25 years of age or younger o ALL that is refractory or in second or later relapse • If the request is for Tecartus o Patient is 18 years of age or older o ALL that is relapsed or refractory **Non-Hodgkin's Lymphoma (NHL)**

	Mantle Cell Lymphoma (MCL): • If the request is for Tecartus: o Patient is 18 years of age or older o Patient has relapsed/refractory disease defined as failure of BOTH the following lines of therapy: ▪ Chemoimmunotherapy such as an anti-CD20 monoclonal antibody (e.g. Rituxan) + any chemotherapeutic agent ▪ Bruton Tyrosine Kinase (BTK) Inhibitor (e.g. Calquence, Imbruvica, Brukinsa) **Other forms of NHL:** • If the request is for Breyanzi (lisocabtagene maraleucel), Kymriah (tisagenlecleucel), Yescarta (axicabtagene ciloleucel) o Use is supported by a labeled indication or NCCN guidelines o Patient is 18 years of age or older o For Breyanzi: One of the following: ▪ Patient is refractory to first-line chemoimmunotherapy or relapses within 12 months of first-line chemoimmunotherapy ▪ Patient is refractory to first-line chemoimmunotherapy or relapses after first-line chemoimmunotherapy and is not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age ▪ Patient has failed two or more lines of systemic therapy o For Kymriah: Patient has relapsed/refractory disease defined as failure of two or more lines of systemic therapy o For Yescarta: Patient refractory to first-line chemoimmunotherapy or relapses within 12 months of first-line chemoimmunotherapy OR has failed two or more lines of systemic therapy **<u>Re-authorization</u>:** • Treatment exceeding 1 dose per lifetime will not be authorized. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**
Revision/Review Date: 10/2022	

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

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

Revision/Review Date: 7/2022	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**B-Cell Maturation Antigen (BCMA) Directed Chimeric Antigen Receptor (CAR) T-Cell Therapy**
Drugs	Abecma (idecabtagene vicleucel) , Carvykti (ciltacabtagene autoleucel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be 18 years or older
Prescriber Restrictions	Prescriber must be a hematologist, an oncologist, or other appropriate specialist
Coverage Duration	If all the criteria are met, the initial request will be approved for a one – time infusion per lifetime.
Other Criteria Revision/Review Date 7/2022	****Drug is being requested through the member's medical benefit**** **<u>Initial Authorization</u>** • Member has a diagnosis of relapsed or refractory multiple myeloma (RRMM) • Member must have received at least 4 prior lines of therapy, which must include ALL of the following: o An immunomodulatory agent (e.g. lenalidomide, pomalidomide, thalidomide) o A proteasome inhibitor (e.g. bortezomib, carfilzomib, ixazomib) o An anti-CD38 monoclonal antibody (e.g. daratumumab, isatuximab) • Member does not have an active infection • Member will be screened for cytomegalovirus (CMV), hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines • Member will not receive live virus vaccines for at least 6 weeks prior to the start of lymphodepleting chemotherapy and until immune recovery following treatment • Member has not previously received a BCMA CAR-T therapy **<u>Re-authorization:</u>** • Treatment exceeding 1 dose per lifetime will not be authorized. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Blincyto**
Drugs	Blincyto (blinatumomab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restriction	N/A
Prescriber Restrictions	Prescriber must be an oncologist/hematologist
Coverage Duration	The request will be approved for up to a 12 month duration
Other Criteria Revision/Review Date 1/2023	****Drug is being requested through the member's medical benefit**** **Initial Authorization:** • Patient has a diagnosis of one of the following forms of Acute Lymphoblastic Leukemia (ALL): a) Relapsed CD19-positive B-cell precursor ALL b) Refractory CD19-positive B-cell precursor ALL c) B-cell precursor CD-positive ALL in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1 • Provider attests to monitor patient for Cytokine Release Syndrome (CRS) and neurological toxicities **Reauthorization:** • Patient has a diagnosis of relapsed or refractory CD19-positive B-cell precursor ALL and has not exceeded 9 total cycles of Blincyto therapy • Provider attests to treatment response or stabilization of disease • Prescriber attests to monitor patient for Cytokine Release Syndrome (CRS) and neurological toxicities ***For CD19-positive B-cell precursor ALL with MRD, reauthorization is not allowed*** **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Brineura (cerliponase alfa)**
Drugs	Brineura (cerliponase alfa)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert, and/or per the National Comprehensive Cancer Network (NCCN)
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	Member must be 3 years of age or older
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	If the criteria are met, the request will be approved for 6 months.
Other Criteria Revision/Review Date: 7/2022	****Drug is being requested through the member's medical benefit**** **<u>Initial Authorization:</u>** • Documentation of confirmed diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2) with one of the following: o Lab results demonstrating deficient TPP1 enzyme activity o Identification of causative mutations in the TPP1/CLN2 gene • Documentation of baseline CLN2 Clinical Rating Scale motor +language score. Baseline CLN2 score must be > 0. • Prescribed dose is consistent with FDA-approved labeling **<u>Re-authorization:</u>** • Documentation of CLN2 Clinical Rating Scale motor +language score has remained > 0 • Prescribed dose is consistent with FDA-approved labeling **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	**Complement Inhibitors**
Drugs	**Soliris (eculizumab), Ultomiris (ravulizumab), Empaveli (pegcetacoplan)**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a hematologist, nephrologist, neurologist, oncologist, or other appropriate specialist.
Coverage Duration	If the criteria are met, the initial request will be approved for up to 3 month duration; reauthorization requests will be approved for up to 6 months. If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	****Drug is being requested through the member's medical benefit**** **<u>Initial Authorization:</u>** • The request is age appropriate according to FDA approved package labeling or nationally recognized compendia; **AND** • The request is for a dose that is FDA approved or in nationally recognized compendia in accordance with the patient's diagnosis, age and concomitant medical conditions; **AND** • Documentation of vaccination against meningococcal disease or a documented medical reason why the patient cannot receive vaccination or vaccination needs to be delayed; **AND** • Antimicrobial prophylaxis with oral antibiotics (penicillin, or macrolides if penicillin-allergic) for two weeks will be administered if the meningococcal vaccine is administered less than two weeks before starting therapy or a documented medical reason why the patient cannot receive oral antibiotic prophylaxis. **Paroxysmal Nocturnal Hemoglobinuria (PNH):** • Documentation of diagnosis by high sensitivity flow cytometry • Hemoglobin (Hgb) < 10.5 g/dL

	• If the request is for Empaveli (pegcetacoplan), documented trial and failure of, contraindication to, or medical reason for not using Soliris (eculizumab) or Ultomiris (ravulizumab) **Generalized Myasthenia Gravis (gMG):** • The request is for Soliris (eculizumab) or Ultomiris (ravulizumab) • Patient has a positive serologic test for anti-AChR antibodies; **AND** • Patient has a Myasthenia Gravis Foundation of America (MGFA) clinical classification of class II, III or IV at initiation of therapy; **AND** • Patient has a Myasthenia Gravis-specific Activities of Daily Living scale (MG-ADL) total score ≥ 6 at initiation of therapy; **AND** • One of the following: o Failed treatment over a total of 1 year or more with 2 or more immunosuppressive therapies (ISTs) either in combination or as monotherapy; **OR** o Failed at least 1 IST and required chronic plasmapheresis or plasma exchange or intravenous immunoglobulin; **OR** o Has a documented history of contraindications or intolerance to ISTs **Neuromyelitis Optica Spectrum Disorder (NMOSD)** • Refer to the "Neuromyelitis Optica Spectrum Disorder (NMOSD) Agents" policy **Atypical Hemolytic Uremic Syndrome (aHUS)/Complement-Mediated HUS)** • Documentation of confirmed diagnosis as evidenced by complement genotyping and complement antibodies; **OR** • Provider attestation treatment is being used empirically and delay in therapy will lead to unacceptable risk to the patient **<u>Re-Authorization:</u>** • Provider has submitted documentation of clinical response to therapy (e.g., reduction in disease severity, improvement in quality of life scores, reduced need for blood transfusions); **AND** • The request is for a dose that is FDA approved or in nationally recognized compendia in accordance with the patient's diagnosis, age, and concomitant medical condition; **AND**

Revision/Review Date 7/2022	• If the request is for aHUS/Complement Mediated HUS o Documentation of confirmed diagnosis as evidenced by complement genotyping and complement antibodies **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Continuous Glucose Monitors**
Drugs	Preferred: Freestyle Libre 14 Day, Freestyle Libre 2, FreeStyle Libre 3, Dexcom G6, Dexcom G7 Non-Preferred: Eversense (Sensor, Transmitter, and Reader components) And any newly marketed product in this class **This policy does not apply to continuous glucose monitor/insulin pump combination products reviewed and/or covered by the Medical Benefit including, but not limited to, the MiniMed. Requests for these products are referred to the plan's Utilization Management team for Review**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Diabetes not treated with insulin
Required Medical Information	See "Other Criteria"
Age Restrictions	Patient must be age appropriate per prescribing information (PI)
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the request will be approved for 6 months.
Other Criteria	**Initial Authorization** • Member meets ONE of the following: o Diagnosis of diabetes which requires the use of insulin more than two times daily o Evidence of level 2 or level 3 hypoglycemia o Diagnosis of glycogen storage disease type 1a • If the request is for a non-preferred product, trial and failure of, or medical reason why patient cannot use, a preferred product. • If member is continuing use of a non-preferred CGM, trial of a preferred CGM first is not required **Reauthorization** • Prescriber attests member has attended regular follow-up visits at least once every six months and continues to benefit from the use of a continuous glucose monitor

Revision/Review Date 1/2023	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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

Other Criteria
 	
Revision/Review Date 5/2022
	****Drug is being requested through the member's medical benefit****
	
	<u>Initial Authorization:</u>
	• Metastatic castrate resistant (hormone-refractory) prostate cancer (mCRPC) (consistent with medical chart history)
	  o Evidenced by soft tissue and/or bony metastases
	  o Patient does NOT have
	  ▪ M0CRPC (defined as CRPC whose only evidence of disseminated disease is an elevated serum PSA) is not authorized
	  ▪ Visceral metastases (e.g. liver, lung, adrenal, peritoneal, brain)
	• Patient is not currently being treated with systemic immunosuppressants (e.g. chemotherapy, corticosteroids) or, if the patient is being treated with immunosuppressants, the prescriber has provided a valid medical reason for combination therapy
	• Eastern Cooperative Oncology Group (ECOG) score 0-1
	• Serum testosterone <50 ng/dL (e.g. castration levels of testosterone)
	• Predicted survival of at least six months
	<u>Reauthorization:</u>
	• Treatment exceeding 3 doses per lifetime will not be authorized
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

Field Name	Field Description
Prior Authorization Group Description	Emergency Use Authorization (EUA) Drugs/Products for COVID-19
Drugs	Any drug/product authorized by EUA for COVID-19
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Emergency Use Authorization for the drug/product in question, and the Drug Package Insert (PPI).
Exclusion Criteria	See "Other Criteria"
Required Medical Information	See "Other Criteria"
Age Restrictions	As outlined within current FDA Emergency Use Authorization (EUA) guidelines
Prescriber Restrictions	N/A
Coverage Duration	As outlined within current FDA Emergency Use Authorization (EUA) guidelines
Other Criteria	Emergency Use Authorization for COVID-19 related drugs/products (all must apply): • The requested drug/product has a currently active Emergency Use Authorization as issued by the U.S. Food and Drug Administration. • Use of the requested drug/product is consistent with the current terms and conditions of the emergency use authorization (such as appropriate age/weight, formulation, disease severity, concurrent use with other medications or medical interventions, etc.). • By submitting an authorization request the prescriber attests they are not requesting reimbursement for ingredient cost of the drug when it is provided by U.S. government at no change. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**
Revision/Review Date	1/2023

Field Name	Field Description
Prior Authorization Group Description	**Fabrazyme**
Drugs	Fabrazyme (agalsidase beta)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	Members should be greater than or equal to 2 years of age
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, cardiologist, nephrologist or specialist experienced in the treatment of Fabry disease
Coverage Duration	Initial Authorization: If the criteria are met, the request will be approved for a 6-month duration. Reauthorization: If the criteria are met, the request will be approved for a 12-month duration.
Other Criteria	****Drug is being requested through the member's medical benefit**** **<u>Initial Authorization</u>:** • Male members must have a documented diagnosis of Fabry disease confirmed by one of the following: 1. An undetectable (<3%) alpha galactosidase A (alpha-Gal-A) activity level OR 2. A deficient (3-35%) alpha-Gal- activity level AND a documented detection of pathogenic mutations in the galactosidase alpha (*GLA*) gene by molecular genetic testing • Female members must have a documented diagnosis of Fabry disease confirmed by detection of pathogenic mutations in the *GLA* gene by molecular genetic testing AND evidence of clinical manifestation of the disease (e.g. kidney, neurologic, cardiovascular, gastrointestinal) • Member must not be using concurrently with Galafold (migalastat) • Documentation of the member's current weight • Request is for an FDA-approved dose

Revision/Review Date: 10/2022	**<u>Re-Authorization:</u>** • Documentation that member has experienced an improvement in symptoms from baseline including but not limited to: decreased pain, decreased gastrointestinal manifestations, decrease in proteinuria, stabilization of increase in eGFR, reduction of left ventricular hypertrophy (LVH) on echocardiogram, or improved myocardial function, or has remained asymptomatic • Member must not be using concurrently with Galafold (migalastat) • Documentation of the member's current weight • Request is for an FDA-approved dose If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review. **Physician/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Insulin-Like Growth Factor-1 Receptor (Igf-1r) Antagonists For Thyroid Eye Disease**
Drugs	Tepezza (teprotumumab-trbw)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Member must be 18 years age or older
Prescriber Restrictions	Prescriber must be an ophthalmologist, endocrinologist, or specialist with expertise in the treatment of Grave's disease with thyroid eye disease.
Coverage Duration	If all of the criteria are met, the request will be approved for up to 24 weeks of treatment (8 total infusions). Retreatment requests will not be allowed beyond the 8 dose limit.
Other Criteria	****Drug is being requested through the member's medical benefit**** **<u>Initial Authorization:</u>** Tepezza is approved when all of the following are met: • Dosing does not exceed dosing guidelines as outlined in the package insert • Patient has a confirmed diagnosis of Graves' disease • Documentation of active moderate-severe thyroid eye disease as evidenced by one or more of the following: o Lid retraction of >2mm o Moderate or severe soft-tissue involvement o Proptosis ≥3mm above normal values for race and sex o Periodic or constant diplopia • Patients Clinical Activity Score must be ≥4 (must be submitted with request) • Patient must be euthyroid or thyroxine and free triiodothyronine levels are less than 50% above or below normal limits (submit laboratory results with request) • Patients of reproductive potential: attestation the patient is not pregnant, and appropriate contraception methods will be

Revision/Review Date 5/2022	used before, during, and 6 months after the last infusion • Patient has had a trial and therapy failure of, or contraindication to, oral or IV glucocorticoids to treat their condition **<u>Re-authorization:</u>** • Retreatment or renewal requests beyond a total of 24 weeks of treatment (8 total infusions) will not be allowed. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Field Name	Field Description
Prior Authorization Group Description	**Insulin Pumps**
Drugs	Omnipod Dash Intro Kit, Omnipod Dash Pods, Omnipod 5 G6 Intro Kit, Omnipod 5 G6 Pods **This policy does not apply to pumps reviewed and/or covered by the Medical Benefit including, but not limited to V-Go 24-hour disposable system and t:slim X2, and continuous glucose monitor/insulin pumps such as MiniMed. Requests for these products are referred to the plan's Utilization Management team for review.**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	None
Required Medical Information	See "Other Criteria"
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist, a certified diabetes care and education specialist (CDCES), or an obstetrician/gynecologist
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months. If the criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.
Other Criteria	**Initial Authorization** • Diagnosis – diabetes • One of the following o Type 1 diabetes or other insulin-deficient forms of diabetes (e.g. cystic-fibrosis related diabetes) o Treatment with multiple daily doses (≥ 3) of insulin o Pregnancy o Continuation of therapy for patient new to plan **Reauthorization** • One of the following: o Type 1 diabetes or other insulin-deficient form of diabetes

Revision/Review Date 9/2022	○ Continued use of multiple daily injections (≥ 3) of insulin ○ Initial approval was based on continuation of therapy for patient new to plan. • There are no new safety signals relating to the use or improper use of the pump • Continuation of therapy based on a diagnosis of pregnancy alone is not eligible for reauthorization **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

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

Revision/Review Date 6/2021	• Member is receiving prophylactic pre-medications (e.g. antivirals, antibiotics, antifungals) for Herpes Zoster, *Pneumocystis jirovecii*, and other fungal infections • HSCT has not yet been initiated for member **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**

Rituximab

Drugs:

Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human, recombinant)
Truxima (rituximab-abbs)
Ruxience (rituximab-pvvr)
Riabni (rituximab-arrx)

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

MULTIPLE SCLEROSIS:

Initial Authorization

- The medication is being prescribed at a dose consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature
- The medication is being prescribed by a neurologist
- Attestation that the patient has been screened for and does not have active hepatitis B virus (HBV)
- For requests for Clinically Isolated Syndrome (CIS), Relapsing Remitting MS (RRMS), Secondary Progressive MS (SPMS): documented trial of at least two preferred agents or a documented medical reason (e.g. contraindication, intolerance, hypersensitivity, etc.) for not utilizing preferred multiple sclerosis disease-modifying agents
    - For patients with "highly active" MS, a prior trial with Gilenya (fingolimod), Lemtrada (alemtuzumab), or Tysabri (natalizumab) will be acceptable.
- For requests for Primary Progressive MS (PPMS) approve if all other criteria have been met
- 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) it cannot be used
- If the request is for Rituxan Hycela (rituximab/hyaluronidase), all of the above AND documented medical reason why the patient cannot use Rituxan (rituximab).

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.

Reauthorization

- Documentation that the prescriber has evaluated the member and recommends continuation of therapy (clinical benefit)
- The medication is being prescribed at a dose consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

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.

NEUORMYELITIS OPTICA SPECTRUM DISORDER (NMOSD):

Initial Authorization

- Member has a diagnosis of NMOSD
- Documentation indicating that the patient has been screened for HBV (hepatitis B virus) prior to initiation of treatment
- Dosing is supported by compendia or standard of care guidelines
- If the request is for any medication other than Ruxience (rituximab-pvvr), there is a documented trial and failure of Ruxience (rituximab-pvvr), or medical reason why (e.g. intolerance, hypersensitivity, contraindication) it cannot be used

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.

Reauthorization

- Documentation that the prescriber has evaluated the member and recommends continuation of therapy (clinical benefit)
- Request is for an FDA approved/medically accepted dose

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.

RHEUMATOID ARTHRITIS:

Initial Authorization

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

Reauthorization

- The member has been receiving rituximab and documentation is provided that a rheumatologist has reevaluated the member and recommends continuation of therapy.
- Documentation was provided indicating that the patient had clinical benefit from receiving rituximab therapy.
- At least 16 weeks (4 months) has elapsed since the previous course of rituximab therapy.

- Documentation indicating that rituximab is being used concurrently with methotrexate.
- Rituximab is being prescribed at an FDA approved dosage.

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

PEMPHIGUS VULGARIS

Initial Authorization

- The medication is being recommended and prescribed by a rheumatologist or dermatologist
- The patient is ≥ 18 years with a diagnosis of moderate to severe pemphigus vulgaris
- Documentation the patient will be receiving P. jirovecii pneumonia (PJP) prophylaxis (ex. TMP/SMX, dapsone, atovaquone) or the prescriber has provided a medical reason for not prescribing 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 the an indication supported by a NCCN category 1 or 2A level of evidence
- Documentation of CD20 positive disease
- Documentation indicating that the patient has been screened for HBV prior to initiation of treatment.
- Rituximab is being prescribed at a dose that is within FDA approved guidelines and/or is supported by the medical compendium as defined by the Social Security Act and/or the National Comprehensive Cancer Network (NCCN) or American Society of Clinical Oncology (ASCO) standard of care guidelines.
- If the request is for any medication other than Ruxience (rituximab-pvvr) there is a documented trial and failure of Ruxience (rituximab-pvvr), or medical reason why (e.g. intolerance, hypersensitivity, contraindication) Ruxience (rituximab-pvvr) cannot be used.
- If the request is for Rituxan Hycela (rituximab/hyaluronidase human, recombinant):
    - The patient has received at least one full dose of a rituximab product by intravenous infusion
    - The medication is being requested for a malignant condition
    - There is a medical reason why the alternative rituximab product cannot be continued

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

Reauthorization

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

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

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

Initial Authorization:

- The medication is being recommended and prescribed by a rheumatologist or nephrologist.
- The patient is 2 years of age or older and has a documented clinical diagnosis of GPA (Wegener's Granulomatosis) or MPA.
- For non-severe disease the patient has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trial of three months (including dates, doses) of glucocorticoid (i.e. prednisone) AND methotrexate ordocumentation includes a medical reason (intolerance, hypersensitivity, etc.) why patient is not able to use these therapies to manage their medical condition.
- For severe disease, a trial of glucocorticoid and methotrexate is not required
- Documentation indicating that rituximab is being used concurrently with glucocorticoids.
- Documentation the patient will be receiving PJP prophylaxis (ex. TMP/SMX, dapsone, atovaquone) during treatment or the prescriber has provided a medical reason for not prescribing PJP prophylaxis
- Documentation indicating that the patient has been screened for HBV prior to initiation of treatment.
- Rituximab is being prescribed at an FDA approved dosage.
- If the patient is 18 years of age or older, and the request is for any medication other than Ruxience (rituximab-pvvr) there is a documented trial and failure of Ruxience (rituximab-pvvr), or medical reason why (e.g. intolerance, hypersensitivity, contraindication) Ruxience (rituximab-pvvr) cannot be used.

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

Re-authorization:

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

- Rituximab is being prescribed at an FDA approved dose.

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

DERMATOMYOSITIS (DM) and POLYMYOSITIS (PM)

Initial Authorization:

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

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

Re-authorization:

- Rituximab is being recommended and prescribed by a neurologist, rheumatologist, or dermatologist.

- Documentation was provided indicating that the patient had clinical benefit from receiving rituximab therapy.
- Rituximab is prescribed at a medically accepted dose per the medical compendia.

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

OTHER MEDICALLY ACCEPTED INDICATIONS

Initial Authorization:

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

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

Re-authorization:

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

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

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

Revision/Review Date: 7/2022

Field Name	Field Description
Prior Authorization Group Description	Treatments for Plasminogen Deficiency Type 1 (PLD1)
Drugs	Ryplazim (human plasma-derived plasminogen)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a hematologist, medical geneticist, or other specialist in the treatment of rare blood or genetic disorders
Coverage Duration	If all of the criteria are met, the initial request will be approved for 12 weeks. Reauthorization requests will be approved for 12 weeks if the member has not had a documented positive response to therapy and for 12 months if the member has had a documented positive response to therapy. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria	****Drug is being requested through the member's medical benefit**** Initial Authorization • Member must have a diagnosis of PLD1 (i.e. hypoplasminogenemia) • Member must have a documented history of lesions or other symptoms consistent with the diagnosis (e.g. ligneous conjunctivitis, oral, respiratory, gastrointestinal, urogenital, integumentary, or central nervous system manifestations) • Member must have baseline plasminogen activity levels ≤ 45% o If the member received plasminogen supplementation with fresh frozen plasma, prescriber attests that a 7-day washout period was performed before obtaining baseline plasminogen activity levels. • The request is for an FDA approved dose Reauthorization • ONE of the following is true: o Member has a documented positive response to therapy (e.g. reduction in number or size of lesions, no new or recurring lesions) o Member has not had a documented positive response to therapy and ONE of the following:

Revision/Review Date 5/2022	▪ If confirmed plasminogen activity levels are ≥ 10% above baseline, then appropriate dosing frequency adjustments must be made. ▪ If confirmed plasminogen activity levels are < 10% above baseline, then appropriate dosing frequency adjustments must be made AND the prescriber must provide a medical justification as to why therapy should be continued. • The request is for an FDA approved dose **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	**Vascular Endothelial Growth Factor (VEGF) Inhibitors for Ophthalmic Conditions**
Drugs	Preferred Vascular Endothelial Growth Factor (VEGF) Inhibitor(s): • **Avastin** (bevacizumab) • **Byooviz** (ranibizumab-eqrn) • **Cimerli** (ranibizumab-nuna) Non-Preferred Vascular Endothelial Growth Factor (VEGF) Inhibitor(s): • **Beovu** (brolucizumab) • **Eylea** (afibercept) • **Lucentis** (ranibizumab) • **Susvimo** (ranibizumab) • **Vabysmo** (faricimab) • **Any newly marketed agent in this class**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	Approvable for adults 18 years of age and older only
Prescriber Restrictions	Ophthalmologist
Coverage Duration	If the above conditions are met, the request will be approved with a 3 month duration for initial and 12 months for renewal; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	****Drug is being requested through the member's medical benefit**** **Avastin:** • Request is for compendia supported dosing for an ophthalmic indication **Byooviz or Cimerli:** • Request is for an FDA-approved dosing regimen **Non-Preferred VEGF Inhibitor:** • Request is for an FDA-approved dosing regimen; **AND**

Revision/Review Date 10/2022	• 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). **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	Vyvgart
Drugs	Vyvgart (efgartigimod)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	≥ 18 years
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or rheumatologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria Revision/Review Date: 05/2022	****Drug is being requested through the member's medical benefit**** Initial Authorization: • Diagnosis of generalized myasthenia gravis (gMG) • Patient has a positive serological test for anti-AChR antibodies • Patient has a Myasthenia Gravis Foundation of America (MGFA) clinical classification of class II, III or IV • Patient has an MG-Activities of Daily Living (MG-ADL) score ≥5 • Patient has tried and failed, or has contraindication, to 2 or more conventional therapies (i.e. acetylcholinesterase inhibitors, corticosteroids, non-steroidal immunosuppressive therapies) • Medication is prescribed at an FDA approved dose Re-Authorization: • Patient has improved signs and symptoms of MG and/or at least a 2-point improvement in MG-ADL score from pre-treatment baseline • Medication is prescribed at an FDA approved dose **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**