Appendix Y

COLORADO
Department of Health Care Policy & Financing

Physician-Administered Drug Prior Authorization Procedures, Coverage Policies and Drug Utilization Criteria
For the Health First Colorado Medical Benefit

Physician-Administered Drugs (PADs) requiring a prior authorization (PA) for the Health First Colorado medical benefit are listed in this document. Prior authorization criteria is based on FDA product labeling, CMS approved compendia, clinical practice guidelines, and peer-reviewed medical literature.

Physician-Administered Drugs and Medical Billing

PADs include any medication or medication formulation that requires administration by a healthcare professional, including cases where FDA package labeling for a medication specifies that administration should be performed by or under the direct supervision of a healthcare professional. PADs administered in a provider's office or clinic should be billed through the Health First Colorado medical benefit using the standard buy-and-bill process following procedures in the PAD Billing Manual (found on the PAD Resources Page at https://www.colorado.gov/hcpf/physician-administered-drugs).

PAD criteria listed on Appendix Y applies specifically to medications billed through the Health First Colorado medical benefit.

- Only PADs administered by a healthcare professional in the member's home or in a long-term care facility should be billed through the Health First Colorado pharmacy benefit (see "Medical VS. Pharmacy Benefit Medication Coverage" section below).

Prior Authorization Procedures

- Prior authorization requests may be submitted via the Acentra PAR portal at https://portal.kepro.com/. For PA assistance or questions, you may contact Acentra via the following methods:

  Phone: (720) 689 - 6340
  Fax: (833) 923 - 2359
  Email: COproviderissue@kepro.com

- PA forms can be signed by anyone who has authority under Colorado law to prescribe the medication. Assistants of authorized persons cannot sign the PA form.
- Physicians or assistants who are acting as the agents of the physicians may request a PA by phone.
- Please note that initiating therapy with a requested drug product, including non-preferred drugs, prior to a PA request being reviewed and approved does not necessitate approval of the PA request. This includes initiating therapy by administration in the inpatient setting, by using office samples or by any other means.
- All PA requests are coded online into the PA system.

Trial and Failure

- Generally, failure is defined as lack of efficacy, allergy, intolerable side effects, contraindication to therapy or significant drug-drug interaction. For medications that use a varying definition of failure, the definition will be noted in the medication's specific criteria, below.

Medical VS. Pharmacy Benefit Medication Coverage

- For more information about pharmacy benefits versus medical benefits please see the Pharmaceutical Benefit Help Guide (found on the PAD resources page at https://hcpf.colorado.gov/physician-administered-drugs).

- Medications administered by a healthcare professional or self-administered in the member's home or long-term care facility should be billed through the Health First Colorado pharmacy benefit following the standards and procedures outlined in the Pharmacy Billing Manual (found on the Pharmacy Resources Page at https://hcpf.colorado.gov/pharmacy-resources).
- PADs are medications administered in a doctor's office, clinic, outpatient hospital or dialysis unit are only to be billed by those facilities through the Health First Colorado medical benefit using the standard buy-and-bill process and following procedures outlined in the PAD Billing Manual (located at https://www.colorado.gov/hcpf/physician-administered-drugs). PAD criteria listed on Appendix Y applies specifically to drug products when billed through the Health First Colorado medical benefit, when administered in the clinic or office setting.

HCPCS	Drug	Criteria	PAR Length
J0172	**Aduhelm (aducanumab-avwa)**	**Aduhelm** (aducanumab-avwa) may be approved if the member meets ALL the following criteria: a. Member has documented diagnosis of mild cognitive impairment or mild dementia stage of Alzheimer's disease, the population in which treatment was initiated in clinical trials, as evidenced by ALL the following: i. Positron Emission Tomography (PET) scan OR lumbar puncture positive for amyloid beta plaque ii. Clinical Dementia Rating global score (CDR-GS) of 0.5 or 1 (available at https://otm.wustl.edu/cdr-terms-agreement/) iii. Mini-Mental State Examination (MMSE) score of 24-30 OR Montreal Cognitive Assessment (moCA) Test score of 19-25 **AND** b. Member is ≥ 50 years of age **AND** c. The prescriber attests that member has been counseled on the approval and safety status of Aduhelm (aducanumab-avwa) being approved under accelerated approval based on reduction in amyloid beta plaques **AND** d. Prior to initiation of medication, the prescriber attests that the member meets ALL the following: i. Member has had a brain MRI within the prior one year to treatment initiation, showing no signs or history of localized superficial siderosis, ≥ 10 brain microhemorrhages, and/or brain hemorrhage > 1 cm ii. Attestation that MRI will be completed prior to the 7th (1st dose at 10 mg/kg) and 12th (6th dose at 10 mg/kg) infusion **AND** e. Member does not have any of the following: i. Any medical or neurological condition other than Alzheimer's Disease that might be a contributing cause of the subject's cognitive	See criteria

		impairment including (but not limited to) stroke/vascular dementia, tumor, dementia with Lewy bodies [DLB], frontotemporal dementia [FTD] or normal pressure hydrocephalus ii. Contraindications to PET, CT scan, or MRI iii. History of or increased risk of amyloid related imaging abnormalities ARIA-edema (ARIA-E) or ARIA-hemosiderin deposition (ARIA-H) iv. History of unstable angina, myocardial infarction, chronic heart failure, or clinically significant conduction abnormalities, stroke, transient ischemic attack (TIA), or unexplained loss of consciousness within 1 year prior to initiation of medication v. History of bleeding abnormalities or taking any form of anticoagulation therapy **AND** f. Medication is prescribed by or in consultation with a neurologist **AND** g. The prescribed regimen meets FDA-approved labeled dosing: i. Infusion 1 and 2: 1 mg/kg over approximately 1 hour every 4 weeks ii. Infusion 3 and 4: 3 mg/kg over approximately 1 hour every 4 weeks iii. Infusion 5 and 6: 6 mg/kg over approximately 1 hour every 4 weeks iv. Infusion 7 and beyond: 10 mg/kg over approximately 1 hour every 4 weeks Initial approval period: 6 months Second prior authorization: an additional 6 months of therapy may be approved with provider attestation that a follow-up MRI will be (or has been) completed prior to the 7th infusion Subsequent approval: an additional 6 months of therapy may be approved with provider attestation that a follow-up MRI will be (or has been) completed prior to the 12th infusion Maximum dose: 10 mg/kg IV every 4 weeks The above coverage standards will continue to be reviewed and evaluated for any applicable changes due to the evolving nature of factors including disease course, available treatment options and available peer-reviewed medical literature and clinical evidence. If request is for use outside of stated coverage standards, support with peer reviewed medical literature and/or subsequent clinical rationale shall be provided and will be evaluated at the time of request.	

		Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).	
J0897	**BONE RESORPTION INHIBITORS** **Prolia,** **Xgeva** **(denosumab)**	**Prolia** (denosumab) may be approved for members meeting all the following criteria: a. Member has one of the following diagnoses: i. Postmenopausal osteoporosis with high fracture risk ii. Osteoporosis iii. Bone loss in men receiving androgen deprivation therapy in prostate cancer iv. Bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer OR b. Member is considered very high risk for fracture defined as any one of the following: a fracture within the past 12 months, experience of fractures while receiving approved osteoporosis therapy (i.e.), a history of multiple fractures, experience of a fracture while receiving medications that cause skeletal harm (e.g. long-term glucocorticoids), very low T-score (e.g. < -3.0), high risk for falls or a history of injurious falls, or very high fracture probability by FRAX® AND c. Member has serum calcium greater than 8.5mg/dL AND d. Member is taking calcium 1000 mg daily and at least 400 IU vitamin D daily AND e. For members not considered very high risk of fracture, member has trial and failure of bisphosphonate for one year (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) AND f. Member meets ANY of the following criteria: i. has a history of an osteoporotic vertebral or hip fracture ii. has a pre-treatment T-score of < -2.5 iii. has a pre-treatment T-score of < -1 but > -2.5 AND either of the following: 1. Pre-treatment FRAX score of > 20% for any major fracture 2. Pre-treatment FRAX score of > 3% for hip fracture iv. Maximum dose of medication is 60mg every 6 months g. Member who is at very high risk of fracture and is currently stable on medication may continue to receive prior authorization approval to continue. **Xgeva** (denosumab) may be approved if member meets ONE of the following indications:	One year

		a. Prevention of skeletal-related events in members with multiple myeloma or in members with bone metastasis from solid tumors b. Giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity c. Hypercalcemia of Malignancy, refractory to bisphosphonate therapy d. If member is currently receiving and stabilized on medication, they may continue to receive prior authorization approval to continue.	
J0585, **J0586,** **J0587,** **J0588**	**BOTULINUM TOXIN AGENTS** **Botox®** **Dysport®** **Myobloc®** **Xeomin**	Botulinum toxin agents may be approved if the member meets the following criteria: **Botox** (onabotulinumtoxinA) may be approved if the member meets ALL the following criteria: a. If administered for <u>Chronic Migraine, prophylaxis</u> i. Member is 18 years of age or older AND ii. Member has a diagnosis of chronic migraine, which is defined as headaches occurring 15 days or more monthly, where at least 8 of these days per month for at least 3 months are migraine days with or without aura AND iii. Member has trial and failure of topiramate AND iv. Dosing interval no sooner than every 12 weeks v. Reauthorization requests may be approved if member has shown a clinical reduction in number of migraine days per month OR b. If administered for one of the following indications, member must meet the following age requirements and dosing must be no sooner than every 12 weeks i. <u>Overactive Bladder</u> 1. Member is 18 years of age or older ii. <u>Spasticity</u> 1. Member is 2 years of age or older iii. <u>Cervical Dystonia</u> 1. Member is 16 years of age or older iv. <u>Primary Axillary Hyperhidrosis</u> 1. Member is 18 years of age or older v. <u>Blepharospasm and Strabismus</u> 1. Member is 12 years of age or older **Dysport** (abobotulinumtoxinA)may be approved if the member meets ALL the following criteria for each indication: a. If being administered for <u>cervical dystonia</u> i. Member has a diagnosis of cervical dystonia AND ii. Member is 18 years of age or older AND iii. Dosing interval is no sooner than every 12 weeks AND	One year

		iv. Initial dose of 500 units followed by a maximum maintenance dose of 1000 units administered intramuscularly OR b. If being administered for spasticity i. Member is 2 years of age or older AND ii. Dosing interval is no sooner than every 12 weeks iii. Maximum dose is 1500 units administered intramuscularly **Myobloc** (rimabotulinumtoxinB) may be approved if the member meets ALL the following criteria: a. Member is 18 years of age or older AND b. If being administered for cervical dystonia i. Member has a diagnosis of cervical dystonia AND ii. Dosing interval is no sooner than every 12 weeks AND iii. Maximum dose of 10,000 units OR c. If being administered for chronic sialorrhea i. Member has a diagnosis of chronic sialorrhea AND ii. Dosing interval is no sooner than every 12 weeks AND iii. Maximum Initial dose is 3,000 units **Xeomin** (incobotulinumtoxinA) may be approved if member meets ALL the following criteria for each indication: a. If being administered for one of the following indications: 1. Blepharospasm 2. Cervical dystonia ii. Member is at least 18 years of age AND iii. Dosing frequency is no sooner than every 12 weeks AND iv. If administered for blepharospasm, maximum dose 100 units per treatment session b. If being administered for the chronic sialorrhea i. Member is 2 years of age or older AND ii. Member weighs more than 12 kg AND iii. Dosing frequency is no sooner than every 16 weeks AND iv. Maximum dose of 100 units c. If administered for the treatment of upper limb spasticity i. Member is 2 years of age or older AND ii. For members between 2 and 17 years of age, spasticity is not caused by cerebral palsy AND iii. Dosing frequency is no sooner than every 12 weeks AND	

		iv. Maximum dose of 200 units per single upper limb, or 400 units total ***Not approved for Cosmetic Purposes***	
J2786	**Cinqair (reslizumab)**	**Cinqair** (reslizumab) may be approved for members meeting all the following criteria: a. Member is 18 years of age or older AND b. Member has diagnosis of severe asthma with an eosinophilic phenotype AND c. Member has a blood eosinophil count of greater than or equal to 400 cells/mcL AND d. Medication is being used as a maintenance adjunctive therapy AND e. Member's symptoms remain uncontrolled despite adherence to concomitant treatment with a medium to high-dose inhaled corticosteroids and long acting beta2-agonist AND f. Member has uncontrolled disease characterized by the following: i. Asthmatic symptoms occurring throughout the day ii. Nighttime awakenings occurring 7 times per week iii. Use of Short Acting Beta-Agonist for symptom control several times per day iv. Lung Function, characterized by FEV1 is less than 60% v. Asthma exacerbations requiring oral systemic corticosteroids, occurring more frequently and intensely than mild or moderate asthma AND g. Baseline FEV1 and frequency of asthma exacerbations per month are provided AND h. Maximum dose of 3 mg/kg every 4 weeks i. Reauthorization may be approved if member meets one of the following: i. Improvement in lung function, measured in FEV1 OR ii. Reduction in the number of asthma exacerbations, defined as a decrease in use of oral or systemic corticosteroids and/or reduced asthma related hospitalizations and/or ER visits	One year
J1427 **J1428** **J1429**	**DUCHENNE MUSCULAR DYSTROPHY AGENTS** **Viltepso (viltolarsen)** **Exondys 51 (eteplirsen)** **Vyondys 53 (golodirsen)**	**Viltepso** (viltolarsen) may be approved for members meeting the following criteria: a. Member must have genetic testing confirming mutation of the Duchenne muscular dystrophy (DMD) gene that is amenable to exon 53 skipping AND b. Medication is prescribed by or in consultation with a neurologist or a provider who specializes in treatment of DMD (i.e. neurologist, cardiologist, pulmonologist, or physical medicine and rehabilitation physician) AND c. Serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio should be measured before starting Viltepso (viltolarsen). Consider measurement of glomerular filtration rate prior to initiation of Viltepso (viltolarsen) AND	Initial authorization 6 months, continuation authorization is for one year

		d. Members with known renal function impairment should be closely monitored during treatment with Viltepso (viltolarsen), as renal toxicity has occurred with similar drugs AND e. If the member is ambulatory, functional level determination of baseline assessment of ambulatory function is required OR if not ambulatory, member must have a baseline Brooke Upper Extremity Function Scale score or Forced Vital Capacity (FVC) documented AND f. Provider and patient or caregiver are aware that continued US FDA approval of Viltepso (viltolarsen) for Duchenne muscular dystrophy (DMD) may be contingent upon verification and description of clinical benefit in a confirmatory trial. Reauthorization: After 24 weeks of treatment with Viltepso (viltolarsen), member may receive approval to continue therapy for one year if the following criteria are met: a. Member has shown no intolerable adverse effects related to Viltepso (viltolarsen) treatment at a dose of 80mg/kg IV once a week AND b. Member has normal renal function or stable renal function if known impairment AND c. Provider attests that treatment with Viltepso (viltolarsen) is necessary to help member improve or maintain functional capacity based on assessment of trajectory from baseline for ambulatory or upper extremity function or Forced Vital Capacity (FVC). <u>Maximum dose:</u> 80 mg/kg administered as an IV infusion once weekly (documentation of patient's current weight with the date the weight was obtained) Members currently stabilized on a Viltepso (viltolarsen) regimen administered in a physician's office or clinical setting that was initiated prior to 1/1/2023 may receive prior authorization approval for continuation of therapy without meeting the above criteria. **Exondys 51** (eteplirsen) may be approved if the following criteria are met: a. Member must have genetic testing confirming mutation of the Duchenne Muscular Dystrophy (DMD) gene that is amenable to exon 51 skipping AND b. Medication is prescribed by or in consultation with a neurologist or a provider who specializes in treatment of DMD (i.e. neurologist, cardiologist, pulmonologist, or physical medicine and rehabilitation physician) AND c. The member must be on corticosteroids at baseline or has a contraindication to corticosteroids AND d. If the member is ambulatory, functional level determination of baseline assessment of ambulatory function is required OR if not ambulatory, member must have a	

		Brooke Upper Extremity Function Scale of five or less documented OR a Forced Vital Capacity (FVC) of 30% or more. Reauthorization: a. Provider attests that treatment with Exondys 51 (eteplirsen) is necessary to help member improve or maintain functional capacity based on assessment of trajectory from baseline for ambulatory or upper extremity function or Forced Vital Capacity (FVC). Maximum Dose: 30 mg/kg per week (documentation of patient's current weight with the date the weight was obtained) Members currently stabilized on a Exondys 51 (eteplirsen) regimen administered in a physician's office or clinical setting that was initiated prior to 1/1/2023 may receive prior authorization approval for continuation of therapy without meeting the above criteria. **Vyondys 53** (golodirsen) may be approved if all the following criteria are met: a. Member must have genetic testing confirming mutation of the Duchenne Muscular Dystrophy (DMD) gene that is amenable to exon 53 skipping AND b. Medication is prescribed by or in consultation with a neurologist or a provider who specializes in treatment of DMD (i.e., neurologist, cardiologist, pulmonologist or physical medicine and rehabilitation physician) AND c. The member must be on corticosteroids at baseline or has a contraindication to corticosteroids AND d. If the member is ambulatory, functional level determination of baseline assessment of ambulatory function is required OR if not ambulatory, member must have a Brooke Upper Extremity Function Scale of five or less documented OR a Forced Vital Capacity of 30% or more. Reauthorization: a. Provider attests that treatment with Vyondys 53 (golodirsen) is necessary to help member improve or maintain functional capacity based on assessment of trajectory from baseline for ambulatory or upper extremity function or Forced Vital Capacity (FVC). Maximum Dose: 30 mg/kg per week (documentation of patient's current weight with the date the weight was obtained)	

		Members currently stabilized on a Vyondys 53 (golodirsen) regimen administered in a physician's office or clinical setting that was initiated prior to 1/1/2023 may receive prior authorization approval for continuation of therapy without meeting the above criteria. *All above coverage standards for all above medications will continue to be reviewed and evaluated for any applicable changes due to the evolving nature of factors including disease course, available treatment options, and available peer-reviewed medical literature and clinical evidence.	
J1413	**Elevidys (delandistrogene moxeparvovec-rokl)**	**Elevidys** (delandistrogene moxeparvovec-rokl) may be approved if the following criteria are met: a. Member is aged 4 through 5 years **AND** b. Member has a diagnosis of Duchenne Muscular Dystrophy (DMD) with a confirmed mutation in the *DMD* gene **AND** c. Member is ambulatory and provider has performed and documented a functional level determination of baseline assessment of ambulatory function **AND** d. Member does not have either of these conditions: i. elevated anti-AAVrh74 total binding antibody titers (≥1:400) based on ELISA testing ii. any deletion in exon 8 and/or exon 9 in the *DMD* gene e. Requested medication is being prescribed by or in consultation with a neurologist or a provider who specializes in treatment of DMD (such as a pediatric neurologist, cardiologist, physical medicine and rehabilitation specialist, or pulmonary specialist) **AND** f. Provider attests that baseline liver function (clinical exam, GGT, total bilirubin), platelet count, and troponin-I will be assessed prior to Elevidys infusion and also monitored following the infusion according to product labeling **AND** g. The member must be on corticosteroids at baseline or prescriber provides clinical rationale for not using corticosteroids AND h. Provider has evaluated, and member has received, all age-appropriate vaccinations as recommended by current immunization guidelines prior to initiation of the corticosteroid regimen **AND** i. Provider and patient or caregiver are aware that continued US FDA approval of Elevidys (delandistrogene moxeparvovec) for Duchenne muscular dystrophy (DMD) may be contingent upon verification and description of clinical benefit in confirmatory trial(s). j. Above coverage standards will continue to be reviewed and evaluated for any applicable changes due to the evolving nature of factors including disease course, available treatment options, and available peer-reviewed medical literature and clinical evidence.	One dose

		Maximum dose: one kit containing 70 single-dose 10 mL vials Approval will be placed to allow for one treatment course	
J2508	**Elfabrio (pegunigalsidase alfa)**	**Elfabrio** (pegunigalsidase alfa) may be approved if the following criteria are met: a. Member is ≥ 18 years of age **AND** b. Member has a confirmed diagnosis of Fabry disease **AND** c. The medication is being prescribed by or in consultation with a neurologist or metabolic disease provider **AND** d. Member has an eGFR ≥ 30 mL/min **AND** e. Member has been counseled regarding use of highly effective contraceptive method(s) while receiving treatment Maximum dose: 1 mg/kg every two weeks, based on actual body weight	One year
J3380	**Entyvio (vedolizumab)**	**Entyvio** (vedolizumab) may be approved for members meeting all the following criteria: a. Member is 18 years of age or older AND b. Member has a diagnosis of moderately-to-severely active ulcerative colitis or moderately-to-severely active Crohn's disease AND c. Member has had an inadequate response with, intolerance to, or demonstrated a dependence on corticosteroids AND d. Member is not receiving medication in combination with Cimzia, Enbrel, Humira, infliximab, Simponi, or Tysabri AND e. For members with Crohn's disease i. Medication is initiated and titrated per FDA-labeled dosing for Crohn's Disease ii. Member has trialed and failed therapy with Humira OR an infliximab-containing product OR the member is ≥ 65 years of age with increased risk of serious infection. f. For members with Ulcerative Colitis i. Medication is initiated and titrated per FDA-labeled dosing for Ulcerative Colitis ii. Member has trialed and failed Humira OR an infliximab-containing product OR Simponi OR the member is ≥ 65 years of age with increased risk of serious infection. †Failure is defined as lack of efficacy, allergy, intolerable side effects, contraindication to therapy, or significant drug-drug interaction. Maximum of 300mg IV infusion at 0, 2, and 6 weeks and then every 8 weeks	One year

J0178	**Eylea (aflibercept)**	**Eylea** (aflibercept) may be approved for members meeting all the following criteria: a. Member is 18 years of age or older AND b. Member has a definitive diagnosis of one of the following and dosing is appropriate for the specified diagnosis as follows: i. Neovascular (Wet) Age-Related Macular Degeneration 1. Maximum dose of 2 mg (0.05 mL) administered every 4 weeks for the first 12 weeks, followed by 2 mg (0.05 mL) every 8 weeks thereafter ii. Diabetic macular edema 1. Maximum dose of 2 mg (0.05 mL) administered every 8 weeks iii. Macular edema following retinal vein occlusion 1. Maximum dose of 2 mg (0.05 mL) administered every 4 weeks iv. Diabetic retinopathy 1. Maximum dose of 2 mg (0.05 mL) administered every 8 weeks c. AND d. Medication is prescribed by or in consultation with an ophthalmologist AND e. Medication is not being used in combination with any other anti-vascular endothelial growth factor (VEGF) medication AND f. Member does not have any of the following: i. Ocular or periocular infection ii. Active intraocular inflammation iii. Hypersensitivity to requested medication Reauthorization criteria: Reauthorization may be approved if member met initial approval criteria at the time of initiation of therapy AND the provider attests that the member has shown clinical improvement defined as an improvement or stabilization in visual acuity	One year
J0517	**Fasenra (benralizumab)**	**Fasenra** (benralizumab) may be approved for members meeting all the following criteria: a. Member is 12 years of age or older AND b. Member has diagnosis of severe asthma with eosinophilic phenotype based on a blood eosinophil level of ≥ 150/mcL AND c. Member's severe asthma has been refractory to recommended evidence-based, guideline-supported pharmacologic therapies AND d. The requested medication is being prescribed as add-on therapy to existing asthma regimen AND e. The requested medication will not be used concomitantly with other biologic products indicated for asthma	One year

		Reauthorization may be approved if member meets one of the following: a. Improvement in lung function, measured in FEV1 OR b. Reduction in the number of asthma exacerbations, defined as a decrease in use of oral or systemic corticosteroids and/or reduced asthma related hospitalizations and/or ER visits Maximum dose: 30mg subcutaneous injection every 4 weeks for 3 doses, then every 8 weeks thereafter	
J1459, **J1556,** **J1557,** **J1561,** **J1566,** **J1568,** **J1569,** **J1572,** **J1576,** **J1599**	**IMMUNE GLOBULINS** **Privigen,** **Bivigam,** **Gammaplex,** **Gammaked, Gamunex-C, Gamunex,** **Gammagard S/D,** **Octagam 5%, 10%,** **Gammagard Liquid,** **Flebogamma DIF,** **Panzyga** **Asceniv**	May be approved for members meeting one of the approved conditions listed and for doses not exceeding FDA-approved maximum (Table 1). a. Approved Conditions for Immune Globulin Use: i. Primary Humoral Immunodeficiency disorders including: 1. Common Variable Immunodeficiency (CVID) 2. Severe Combined Immunodeficiency (SCID) 3. X-Linked Agammaglobulinemia 4. X-Linked with Hyperimmunoglobulin M (IgM) Immunodeficiency 5. Wiskott-Aldrich Syndrome 6. Members < 13 years of age with pediatric Human Immunodeficiency Virus (HIV) and CD-4 count > 200/mm3 ii. Neurological disorders including: 1. Guillain-Barré Syndrome 2. Relapsing-Remitting Multiple Sclerosis 3. Chronic Inflammatory Demyelinating Polyneuropathy 4. Myasthenia Gravis 5. Polymyositis and Dermatomyositis 6. Multifocal Motor Neuropathy iii. Kawasaki Syndrome iv. Chronic Lymphocytic Leukemia (CLL) v. Autoimmune Neutropenia (AN) with absolute neutrophil count < 800 mm and history of recurrent bacterial infections vi. Autoimmune Hemolytic Anemia (AHA) vii. Liver or Intestinal Transplant viii. Immune Thrombocytopenia Purpura (ITP) including: 1. Requiring preoperative therapy for undergoing elective splenectomy with platelet count < 20,000 2. Members with active bleeding & platelet count <30,000 3. Pregnant members with platelet counts <10,000 in the third trimester	One year

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4. Pregnant members with platelet count 10,000 to 30,000 who are bleeding
ix. Multisystem Inflammatory Syndrome in Children (MIS-C)
<table>
<tr><th colspan="2">Table 1: FDA-Approved Maximum Immune Globulin Dosing</th></tr>
<tr><td>Gammaked</td><td>2 g/kg</td></tr>
<tr><td>Gamunex-C</td><td>2 g/kg</td></tr>
<tr><td>Octagam</td><td>2 g/kg</td></tr>
<tr><td>Gammagard Liquid</td><td>2.4 g/kg/month</td></tr>
<tr><td>Gammaplex 5% - IV Infusion</td><td>2 g/kg</td></tr>
<tr><td>Privigen - IV Infusion</td><td>2 g/kg</td></tr>
<tr><td>Asceniv</td><td>800 mg/kg every 3 weeks</td></tr>
<tr><td>Panzyga</td><td>2 g/kg</td></tr>
<tr><td>Bivigam</td><td>800 mg/kg every 3 weeks</td></tr>
<tr><td>Flebogamma DIF</td><td>600 mg/kg every 3 weeks</td></tr>
<tr><td>Gammagard S/D</td><td>1 g/kg</td></tr>
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<td>J0490
J0491</td>
<td><u>Lupus Agents</u>
Benlysta (belimumab)
Saphnelo (anifrolumab)</td>
<td>Benlysta (belimumab) may be approved if the following criteria are met:
a. For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member’s home or in a long term care facility AND
b. Member is age ≥ 5 years and has active, autoantibody-positive systemic lupus erythematosus (SLE) and receiving standard therapy OR has active lupus nephritis and is receiving standard therapy AND
c. Member has incomplete response to standard therapy from at least two of the following therapeutic classes: antimalarials, immunosuppressants and glucocorticoids; AND
d. Member maintains standard therapy while on medication AND
e. Member is not receiving other biologics or intravenous cyclophosphamide AND
f. The product is NOT being prescribed for severe active lupus nephritis or severe active central nervous system lupus

Maximum dosage of 10 mg/kg at 2-week intervals for the first 3 doses and 4-week intervals thereafter</td>
<td>One year</td>
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		Saphnelo (anifrolumab) may be approved if member meets the following criteria: a. Member is ≥ 18 years of age with active, autoantibody-positive, moderate to severe systemic lupus erythematosus (SLE) AND is currently receiving standard therapy b. AND c. The product is NOT being prescribed for severe active lupus nephritis or severe active central nervous system lupus AND d. Member has had incomplete response to standard therapy from at least two of the following therapeutic classes: antimalarials, immunosuppressants and glucocorticoids AND e. Member will maintain standard therapy for SLE while receiving requested medication therapy f. Prescriber acknowledges that there are limited human data available for the use of anifrolumab in pregnancy and data are insufficient to inform on drug-associated risks. A registry monitors pregnancy outcome in women exposed to anifrolumab during pregnancy. Maximum Dose: 300 mg IV every 4 weeks Quantity Limit: One 300 mg vial/28 days	
J2329 **J0202** **J2350** **J2323**	**Multiple Sclerosis Agents** **Briumvi (ublituximab)** **Lemtrada (alemtuzumab)** **Ocrevus (ocrelizumab)** **Tysabri (natalizumab)**	**Briumvi (ublituximab**) may be approved if the following criteria are met: a. Member is ≥ 18 years of age **AND** b. Member has a relapsing form of multiple sclerosis (MS) **AND** c. Member has experienced at least one relapse in the prior year or two relapses in the prior two years **AND** d. Member has had trial and failure of any two high efficacy disease modifying therapies (such as ofatumumab, fingolimod, rituximab, ocrelizumab, alemtuzumab). Failure is defined as allergy, intolerable side effects, significant drug-drug interaction, or lack of efficacy. Lack of efficacy is defined as one of the following: i. On MRI, presence of any new spinal lesions, cerebellar or brainstem lesions, or change in brain atrophy **OR** ii. Signs and symptoms on clinical exam consistent with functional limitations that last one month or longer **AND** e. Member does not have active hepatitis B virus (HBV) infection **AND** f. Briumvi (ublituximab) is prescribed by or in consultation with a neurologist or a physician that specializes in the treatment of multiple sclerosis **AND** g. Member does not have low serum immunoglobulins, based on quantitative tests performed before initiating treatment, **AND**	One Year

		h. Prescriber attests that appropriate premedication (such as a corticosteroid and antihistamine) will be administered prior to each Briumvi (ublituximab) infusion **AND** i. For members of childbearing potential: a. Member is not pregnant and prescriber acknowledges that pregnancy testing is recommended for members of reproductive potential prior to each infusion **AND** b. Member has been counseled regarding the use of highly effective contraceptive methods while receiving treatment with Briumvi and for at least 6 months after stopping Briumvi Quantity limit: Four 150 mg/6 mL single-dose vials for the first 2 weeks (initial dose), and three 150 mg/6 mL single-dose vials every 24 weeks thereafter Exemption: If member is currently receiving and stabilized on ublituximab, they may receive prior authorization approval to continue therapy. **Lemtrada (alemtuzumab)** may be approved if member meets the following criteria: a. Member is 18 years of age or older AND b. Member has a relapsing form of multiple sclerosis AND c. Member has experienced one relapse within the prior year or two relapses within the prior two years AND d. Member has trial and failure* of Tysabri (natalizumab), Ocrevus (ocrelizumab), or two preferred agents in the "Disease Modifying Therapies" PDL drug class that are FDA-labelled for use for the same prescribed indication." AND e. Medication is administered by or in consultation with a neurologist or a physician that specializes in the treatment of multiple sclerosis AND f. For members with known psychiatric conditions, peer-to-peer consultation with member's behavioral health provider will be conducted prior to the member's receiving treatment with a high dose corticosteroid as part of the medication's premedication procedure AND g. Baseline skin exam and thyroid function assessment are completed and documented prior to initiation of treatment with the medication AND h. Prescriber is enrolled in the Lemtrada Risk Evaluation and Mitigation Strategy (REMS) program	

i. Exemption: If member is currently receiving and stabilized on Lemtrada (alemtuzumab), they may continue to receive prior authorization approval to continue.

Ocrevus (ocrelizumab) may be approved for initial therapy if member meets the following criteria:

a. Medication is administered by or in consultation with a neurologist or a physician that specializes in the treatment of multiple sclerosis AND
b. <u>If administered for Relapsing Forms of Multiple Sclerosis (MS)</u>
   i. Member is 18 years of age or older AND
   ii. Member does not have active hepatitis B infection or hypogammaglobulinemia at baseline AND
   iii. Member has a relapsing form of multiple sclerosis AND
   iv. Member has experienced one relapse within the prior year or two relapses within the prior two years AND
   v. Request meets one of the following:
      1. Member has had a trial and failure* of any high-efficacy disease-modifying therapies OR trial and failure* of any preferred product in the PDL "Multiple Sclerosis Agents" drug class
      OR
      2. Member with highly active relapsing MS (based on measures of relapsing activity and MRI markers of disease activity such as numbers of galolinium-enhanced lesions).

OR

c. <u>If administered for Primary Progressive Multiple Sclerosis</u>
   i. Member is 18 years of age or older AND
   ii. Member is not concomitantly taking disease modifying therapies.

<u>Maximum maintenance dose</u>: 600 mg every 6 months

<u>Exemption</u>: If member is currently receiving and stabilized on Ocrevus, they may continue to receive prior authorization approval to continue

Tysabri (natalizumab) may be approved for initial therapy if the following criteria are met:

		a. Medication is not currently being used in combination with immunosuppressants (azathioprine, 6-mercaptopurine, methotrexate) or TNF-alpha inhibitors (adalimumab, certolizumab pegol, infliximab) AND b. Member does not have anti-JC virus antibodies at baseline AND c. <u>If administered for induction of remission of moderate to severe Crohn's disease</u> i. The member is ≥ 18 years of age AND ii. Prescriber and member are enrolled in the CD TOUCH® REMS program AND iii. Member has tried and failed aminosalicylates AND iv. Member has tried and failed corticosteroids AND v. Member has tried and failed immunomodulators AND vi. Member has tried and failed two TNF-alpha inhibitors (e.g. adalimumab, certolizumab pegol, infliximab) AND vii. Medication is administered by or in consultation with a gastroenterologist. d. <u>If administered for relapsing remitting multiple sclerosis (RRMS)</u> i. The member is ≥ 18 years of age AND ii. Prescriber and member are enrolled in the MS TOUCH® REMS program AND iii. Medication is administered by or in consultation with a neurologist or a physician that specializes in the treatment of multiple sclerosis iv. Request meets one of the following: 1. Member has trial and failure* of any two high efficacy disease modifying therapies (such as ofatumumab, fingolimod, rituximab, ocrelizumab, alemtuzumab) OR 2. Member with highly active relapsing MS (based on measures of relapsing activity and MRI markers of disease activity such as numbers of galolinium-enhanced lesions) has had a trial and failure* of any high-efficacy disease-modifying therapy (such as ofatumumab, fingolimod, rituximab, alemtuzumab) <u>Exemption</u>: If member is currently receiving and stabilized on Tysabri, they may continue to receive prior authorization approval to continue. *Failure is defined as intolerable side effects, drug-drug interaction, contraindication, or lack of efficacy. Lack of efficacy is defined as one of the following: 1. One of the following on MRI: presence of any new spinal lesions, cerebellar or brainstem lesions, or change in brain atrophy OR	

		2. On clinical exam, signs and symptoms consistent with functional limitations that last one month or longer	
J2796	**Nplate (romiplostim)**	**Nplate** (romiplostim) may be approved if the member meets the following criteria: a. Member does not have thrombocytopenia due to myelodysplastic syndrome (MDS) or any cause of thrombocytopenia other than immune thrombocytopenia AND b. Medication is not being used in an attempt to normalize platelet counts AND c. If being administered for <u>hematopoietic subsyndrome of acute radiation syndrome,</u> member has been acutely exposed to myelosuppressive radiation levels greater than 2 gray (Gy) OR d. If being administered for <u>immune thrombocytopenia (ITP)</u> i. Member has had an insufficient response to corticosteroids, immunoglobulins, or splenectomy AND ii. Member has ITP whose degree of thrombocytopenia and clinical condition increases the risk for bleeding as indicated by a platelet count of ≤ 30,000/mm^3 AND iii. Laboratory value for platelet count is current (e.g., drawn within the previous 28 days) AND iv. If being administered for <u>Acute ITP</u> 1. Member is at least 18 years of age or older OR If being administered for <u>Chronic ITP</u> 1. Member is at least 1 years of age or older AND 2. Member has had chronic ITP for at least 6 months Maximum weekly dose of 10 mcg/kg Reauthorization may be approved for ITP if member met the initial indication-specific approval criteria above and member responded to treatment by achieving and maintaining a platelet count of ≥ 50,000/mm^3, but <450,000/mm^3	One year
J2182	**Nucala (mepolizumab)**	**Nucala** (mepolizumab) may be approved if member meets ALL the following criteria for the appropriate indication: a. Initial approval if administered for <u>asthma</u>: i. Member is 6 years of age or older AND ii. Member has diagnosis of severe asthma with an eosinophilic phenotype AND	One year

iii. Member has a blood eosinophil count of greater than or equal to 150 cells/mcL within 6 weeks of dosing or greater than or equal to 300 cells/mcL in the previous 12 months AND
iv. Member has had 2 or more asthma exacerbations requiring use of oral or systemic corticosteroids and/or hospitalizations and/or ER visits OR
v. Member requires daily use of oral corticosteroids AND
vi. Baseline FEV1 and frequency of asthma exacerbations per month are provided
vii. Member has trialed and failed‡ two preferred agents (FASENRA and XOLAIR).
viii. Dosing Limits: 100mg every 4 weeks (members ≥ 12 years of age); 40mg every 4 weeks (members 6-11 years of age)

‡Failure is defined as a lack of efficacy with a three-month trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions.

b. Reauthorization for asthma indication may be approved if member has shown clinical improvement as documented by one of the following
   i. Improvement in lung function, measured in FEV1 OR
   ii. Reduction in the number of asthma exacerbations, defined as a decrease in use of oral or systemic corticosteroids and/or reduced asthma related hospitalizations and/or ER visits
c. If administered for eosinophilic granulomatosis with polyangiitis (EGPA)
   i. Member is 18 years of age or older AND
   ii. Member has been diagnosed with relapsing or refractory EGPA at least 6 months prior to request as demonstrated by ALL the following:
      1. Member has a diagnosis of asthma AND
      2. Member has a blood eosinophil count of greater than or equal to 1000 cells/mcL or a blood eosinophil level of 10% AND
      3. Member has the presence of two of the following EGPA characteristics:
         - ❑ Histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
         - ❑ Neuropathy
         - ❑ Pulmonary infiltrates
         - ❑ Sinonasal abnormality
         - ❑ Cardiomyopathy
         - ❑ Glomerulonephritis

		❑ Alveolar hemorrhage ❑ Palpable purpura ❑ Antineutrophil cytoplasmic antibody (ANCA) positive 4. Member is on a stable dose of corticosteroids for at least 4 weeks prior to request AND 5. Dose of 300 mg once every 4 weeks iii. If administered for <u>hypereosinophilic syndrome (HES):</u> 1. Member is 12 years of age or older AND 2. Member has a diagnosis for HES for at least 6 months that is non-hematologic secondary HES AND 3. Member has a blood eosinophil count of greater than or equal to 1000 cells/mcL AND 4. Member has a history of two or more HES flares (defined as worsening clinical symptoms or blood eosinophil counts requiring an increase in therapy) AND 5. Member has been on stable dose of HES therapy for at least 4 weeks, at time of request, including at least one of the following: ❑ Oral corticosteroids ❑ Immunosuppressive therapy ❑ Cytotoxic therapy AND 6. Dose of 300 mg once every 4 weeks	
J0129	**Orencia (abatacept)**	**Orencia** (abatacept) may be approved if meeting the following criteria: a. Member has a diagnosis of moderate to severe rheumatoid arthritis or polyarticular juvenile idiopathic arthritis (pJIA) AND has trialed and failed* all preferred agents in the "Targeted Immune Modulators" PDL drug class that are FDA-labeled for use for the prescribed indication OR b. Member is an adult with a diagnosis of psoriatic arthritis AND has trialed and failed‡ Humira (adalimumab) or Enbrel AND Xeljanz IR AND Taltz or Otezla OR c. The requested medication is being prescribed for the prophylaxis of acute graft versus host disease (aGVHD) in combination with a calcineurin inhibitor and methotrexate in patients undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor. *Failure is defined as lack of efficacy with a three-month trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction. Note that trial and failure of	One year

<table>
<tr><td></td><td></td><td>preferred TNF inhibitors will not be required when prescribed for pJIA in members with documented clinical features of lupus.

Members currently stabilized on Orencia (abatacept) regimen that was initiated prior to 1/1/2023 may receive prior authorization approval for continuation of therapy without meeting the above criteria.</td><td></td></tr>
<tr><td>J0224</td><td>Oxlumo (lumasiran)</td><td>Oxlumo (lumasiran) may be approved if all the following criteria are met:
a. Member has a diagnosis of Primary hyperoxaluria type 1 (PH1) confirmed by either:
i. Genetic testing that demonstrates a mutation of the alanine glyoxylate aminotransferase (AGXT) gene OR
ii. Liver enzyme analysis demonstrating absent or significantly reduced AGXT
b. Medication is being prescribed by, or in consultation with a nephrologist, neurologist, or other healthcare provider with expertise in treating PH1
c. Member has documented baseline urinary oxalate excretion or plasma oxalate concentrations

Reauthorization: Member demonstrates response to medication as indicated by a positive clinical response from baseline urinary oxalate excretion or plasma oxalate concentration

Maximum dose: weight-based dosing regimen as shown in the following table (documentation of patient’s current weight with the date the weight was obtained)

<table><tr><th>Body Weight</th><th>Loading Dose</th><th>Maintenance Dose</th></tr><tr><td>Less than 10 kg</td><td>6 mg/kg once monthly for three doses</td><td>3 mg/kg once monthly, beginning one month after the last loading dose</td></tr><tr><td>10 kg to less than 20 kg</td><td>6 mg/kg once monthly for three doses</td><td>6 mg/kg once every three months, beginning one month after the last loading dose</td></tr><tr><td>20 kg and above</td><td>3 mg/kg once monthly for three doses</td><td>3 mg/kg once every three months, beginning one month after the last loading dose</td></tr></table>
Members currently stabilized on a Oxlumo (lumasiran) regimen that was initiated prior to 1/1/2023 may receive prior authorization approval for continuation of therapy without meeting the above criteria.</td><td>One year</td></tr>
<tr><td></td><td><u>Pompe Disease Agents</u></td><td>Lumizyme (alglucosidase alfa) may be approved if member meets the following criteria:</td><td>One year</td></tr>
</table>

J0221 **J0219**	**Lumizyme (alglucosidase alfa)** **Nexviazyme (avalglucosidase)**	a. Member has a definitive diagnosis of Pompe disease confirmed by one of the following: i. Deficiency of acid alpha-glucosidase (GAA) enzyme activity OR ii. Detection of biallelic pathogenic variants in the GAA by molecular genetic testing AND b. The Request meets one of the following based on indicated use: i. If being administered for <u>infantile-onset Pompe disease</u> 1. Member has documented baseline age appropriate assessments, including motor function tests, muscle weakness, respiratory function, cardiac involvement testing, percent predicted forced vital capacity (FVC), and 6-minute walk test (6MWT) OR ii. If being administered for <u>Late-onset Pompe disease</u> 1. Member has documented baseline age appropriate assessments, including motor function tests, muscle weakness, respiratory function, cardiac involvement testing, FVC and 6MWT Reauthorization may be approved if member met initial approval criteria at the time of initiation of therapy AND meets the following: a. Member is being monitored for antibody formation and hypersensitivity AND b. Request meets the following based on indicated use: i. <u>For infantile-onset disease</u>: the member has shown clinical improvement defined as an improvement or stabilization in muscle weakness, motor function, respiratory function, cardiac involvement, percent predicted FVC, and/or 6MWT OR ii. <u>For late-onset disease</u>: the member has shown clinical improvement defined as an improvement or stabilization in percent predicted FVC and/or 6MWT Maximum dosage of 20 mg/kg administered every 2 weeks **Nexviazyme** (avalglucosidase alfa-ngpt) may be approved if member meets the following criteria: a. Member is 1 year of age or older AND b. Member has a definitive diagnosis of Pompe disease confirmed by one of the following: i. Deficiency of acid alpha-glucosidase (GAA) enzyme activity OR	

		ii. Detection of biallelic pathogenic variants in the GAA by molecular genetic testing AND c. Member has a diagnosis of late-onset (non-infantile) Pompe disease AND d. Medication is not being used in combination with other enzyme replacement therapies AND e. Member has documented baseline age appropriate assessments, including motor function tests, muscle weakness, respiratory function, cardiac involvement testing, percent predicted FVC and 6MWT f. Product is being prescribed by a provider specializing in the treatment of Pompe disease AND g. Prescriber will consider administering antihistamines, antipyretics, and/or corticosteroids prior to Nexviazyme (avalglucosidase alpha) administration to reduce the risk of severe infusion-associated reactions. Reauthorization may be approved if member met initial approval criteria at the time of initiation of therapy AND meets the following: a. Member has shown clinical improvement defined as an improvement or stabilization in percent predicted FVC and/or 6MWT AND b. Member is being monitored for antibody formation and hypersensitivity Maximum weight dependent dosage: Members ≥30 kg, 20 mg/kg administered every 2 weeks Members ≤30 kg, 40 mg/kg administered every 2 weeks	
J1745	**Remicade (infliximab)**	**Remicade** (infliximab) may be approved with trial & failure of Renflexis (infliximab abda) AND if meeting all the following criteria: a. Member has one of the following diagnoses: i. Crohn's disease and is 6 years or older ii. Ulcerative colitis and is 6 years or older iii. Rheumatoid arthritis and is 4 years or older iv. Psoriatic arthritis and is 18 years or older v. Ankylosing spondylitis and is 18 years or older vi. Juvenile idiopathic arthritis and is 4 years or older vii. Plaque psoriasis in adults viii. Hydradenitis suppurativa (HS) AND b. Member meets one of the following, based on prescribed indication:	One year

		i. For continuation of infliximab therapy that was initiated in the hospital setting for treating severe ulcerative colitis, no additional medication trial is required OR ii. For treatment of moderate to severe hidradenitis suppurativa, no additional medication trial is required OR iii. For all other prescribed indications, the member has trialed and failed†* all preferred agents in the Targeted Immune Modulators PDL drug class that are FDA labeled for use for the prescribed indication (with only one preferred TNF inhibitor trial required). ** Members ≥ 50 years of age with an additional CV risk factor, will not need a trial and failure of Xeljanz IR. *Renflexis does not require a prior authorization on the medical benefit.	
J9333	**Rystiggo (rozanolixizumab)**	**Rystiggo** (rozanolixizumab) may be approved if the following criteria are met: a. Member is ≥ 18 years of age **AND** b. Member has a diagnosis of generalized myasthenia gravis that falls within Myasthenia Gravis Foundation of America (MGFA) Class II to IVa disease, **AND** c. Member has a positive serologic test for anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibodies **AND** d. Requested product is being prescribed by or in consultation with a neurologist **AND** e. A baseline Quantitative Myasthenia Gravis (QMG) assessment has been documented, **AND** f. Patient has a MG-Activities of Daily Living (MG-ADL) total score of ≥3 (with at least 3 points from non-ocular symptoms), **AND** g. Patient has failed† treatment over at least 1 year with at least 2 immunosuppressive therapies (such as azathioprine, cyclosporine, tacrolimus, mycophenolate), or has failed at least 1 immunosuppressive therapy and required chronic therapeutic plasma exchange or intravenous immunoglobulin (IVIG) **AND** h. As a precaution, consider discontinuation or Rystiggo and use of alternative therapies in members receiving long term therapy with medications that bind to the human Fc receptor (such as IVIG, other immunoglobulins, or other C5 complement inhibitors). † Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction	Initial: 6 months Reauthorization: One year

		Initial Approval: 6 months Reauthorization: Reauthorization for one year may be approved with prescriber attestation that member has experienced a positive clinical response to rozanolixizumab based on documented Quantitative Myasthenia Gravis (QMG) assessment AND/OR MG-Activities of Daily Living (MG-ADL) score Maximum dose: 840 mg (6 mL) by subcutaneous infusion every 6 weeks Quantity limit: three 280 mg/2 mL single-dose vials every 6 weeks Continuation of Therapy: Members who are currently stabilized on the requested medication may receive approval to continue treatment on that medication	
J1602	**Simponi (golimumab)**	**Simponi** (golimumab) may receive approval if meeting the following: a. The request meets one of the following: i. Member has a diagnosis of moderate to severe rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, or ankylosing spondylitis AND has trialed and failed‡ all preferred agents in the "Targeted Immune Modulators" PDL drug class that are FDA-labeled for use for the prescribed indication OR ii. Member is an adult with a diagnosis of psoriatic arthritis AND has trialed and failed‡ Humira (adalimumab) or Enbrel AND Xeljanz IR AND Taltz or Otezla. OR b. If the request is for use of the subcutaneous formulation for treating moderately to severely active ulcerative colitis, all the following criteria are met: i. Member is ≥ 18 years of age AND ii. Member has trialed and failed‡ all preferred agents in the "Targeted Immune Modulators" PDL drug class that are FDA-labeled for use for the prescribed indication AND iii. Member has demonstrated corticosteroid dependence or has had an inadequate response to (or failed to tolerate) oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine for inducing and maintaining clinical response, improving endoscopic appearance of the mucosa during induction, inducing clinical remission, or achieving and sustaining clinical remission in induction responders.	One year

		Members currently stabilized on a Simponi (golimumab) regimen that was initiated prior to 1/1/2023 may receive prior authorization approval for continuation of therapy without meeting the above criteria. ‡Failure is defined as lack of efficacy, allergy, intolerable side effects, contraindication to therapy, or significant drug-drug interaction. Note that trial and failure of Xeljanz IR will not be required when prescribed for ulcerative colitis for members ≥ 50 years of age that have an additional CV risk factor.	
J1300	**Soliris (eculizumab)**	**Soliris** (eculizumab) may be approved for members meeting all the following criteria: a. Member is diagnosed with either Paroxysmal Nocturnal Hemoglobinuria (PNH), Atypical Hemolytic Uremic Syndrome (aHUS), Generalized Mysthenia Gravis (gMG), or Neuromyleitis Optica Spectrum Disorder (NMOSD) AND b. Member does not have a systemic infection AND c. Member must be administered a meningococcal vaccine at least two weeks prior to initiation of therapy and revaccinated according to current medical guidelines for vaccine use AND d. Prescriber is enrolled in the Soliris (eculizumab) Risk Evaluation and Mitigation Strategy (REMS) program AND e. Medication is administered by or in consultation with a hematologist for PNH and by or in consultation with a hematologist or nephrologist for aHUS and by or in consultation with a neurologist for gMG or NMOSD AND f. Member meets criteria listed below based on specific diagnosis: <u>Paroxysmal Nocturnal Hemoglobinuria</u> a. Member is 18 years of age or older AND b. Diagnosis of PHN must be accompanied by detection of PNH clones by flow cytometry diagnostic testing AND c. Member demonstrate the presence of at least 2 different glycosylphosphatidylinositol (GPI) protein deficiencies (e.g. CD55, CD59, etc.) within at least 2 different cell lines (granulocytes, monocytes, erythrocytes) AND d. Member has one of the following indications for therapy: i. Presence of a thrombotic event ii. Presence of organ damage secondary to chronic hemolysis iii. Member is pregnant and potential benefit outweighs potential fetal risk iv. Member is transfusion dependent v. Member has high LDH activity (defined as ≥1.5 x ULN) with clinical symptoms AND a. Member has documented baseline values for one or more of the following: i. Serum lactate dehydrogenase (LDH) ii. Hemoglobin level	One year

		iii. Packed RBC transfusion requirement Atypical Hemolytic Uremic Syndrome a. Member is 2 months or older AND b. Thrombotic Thrombocytopenic Purpura (TTP) has been ruled out by evaluating ADAMTS13 level (ADAMTS-13 activity level > 10%); AND c. Shiga toxin E. coli related hemolytic uremic syndrome (STECHUS) has been ruled out; AND d. Other causes have been identified and are being treated appropriately such as coexisting diseases or conditions (e.g. bone marrow transplantation, solid organ transplantation, malignancy, autoimmune disorder, drug-induced, malignant hypertension, HIV infection, etc.), Streptococcus pneumonia or Influenza A (H1N1) infection, or cobalamin deficiency AND e. Documented baseline values for one or more of the following: i. Serum lactate dehydrogenase (LDH) ii. Serum creatinine/eGFR iii. Platelet count iv. Plasma exchange/infusion requirement Generalized Myasthenia Gravis a. Member is 18 years or older AND b. Member has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease; AND c. Member has a positive serologic test for anti-acetylcholine receptor (AchR) antibodies; AND d. Physician has assessed the baseline Quantitative Myasthenia Gravis (QMG) score; AND e. Member has a MG-Activities of Daily Living (MG-ADL) total score of ≥6; AND f. Member has failed treatment over at least 1 year with at least 2 immunosuppressive therapies (e.g. azathioprine, cyclosporine, mycophenolate, etc), or has failed at least 1 immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG) Neuromyelitis Optica Spectrum Disorder a. Member is 18 years or older AND b. Member has a past medical history of one of the following: i. Optic neuritis ii. Acute myelitis iii. Area postrema syndrome; episode of otherwise unexplained hiccups or nausea and vomiting iv. Acute brainstem syndrome v. Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions	

		vi. Symptomatic cerebral syndrome with NMOSD-typical brain lesions AND c. Member has a positive serologic test for anti-aquaporin-4 immunoglobulin G (AQP4-IgG)/NMP-IgG antibodies; AND d. Diagnosis of multiple sclerosis or other diagnoses have been ruled out AND e. Member has not failed a previous course of therapy AND f. Member has a history of failure, contraindication, or intolerance to rituximab therapy AND g. Member has at least one of the following: i. History of at least two relapses during the previous 12 months prior to initiating medication ii. History of at least three relapses during the previous 24 months, at least one relapse occurring within the past 12 months prior to initiating medications AND h. Member is not receiving medication in combination with any of the following: i. Disease modifying therapies for the treatment of multiple sclerosis (such as Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab), etc.) OR ii. Anti-IL6 therapy <u>Exemption</u>: If a member is currently receiving and stabilized on Soliris, they may continue to receive prior authorization approval to continue if the member meets the appropriate diagnosis and age requirements <u>Maximum dose:</u> 900mg weekly for 4 weeks induction followed by 1200mg every 2 weeks maintenance dose	
J3357	**Stelara (subcutaneous injection)**	**Stelara** (ustekinumab) **<u>subcutaneous injection</u>** use may receive approval if meeting the following: a. If administered for <u>Crohn's disease</u> or <u>Ulcerative Colitis</u> i. The member has a diagnosis of moderate-to-severely active Crohn's disease or moderate-to-severely active ulcerative colitis AND ii. The member is ≥ 18 years of age AND iii. The member has trialed and failed‡ all preferred agents in the Targeted Immune Modulators PDL drug class that are FDA-labeled for use for the prescribed indication AND iv. Prescriber acknowledges that loading dose administration prior to approval of STELARA for maintenance therapy using the above criteria should be avoided and will not result in an automatic approval of STELARA for maintenance therapy AND	See criteria

		v. Prior authorization approval may be given for an initial 16-week supply and authorization approval for continuation may be provided based on clinical response. b. If administered for psoriatic arthritis i. Member has trial and failure‡ of HUMIRA (adalimumab) or ENBREL AND XELJANZ IR AND TALTZ or OTEZLA AND ii. Prior authorization approval may be given for an initial 16-week course and authorization approval for continuation may be provided based on clinical response c. If administered for plaque psoriasis i. Member has trial and failure‡ of one indicated first line agent (HUMIRA (adalimumab) or ENBREL) AND two indicated second line agents (TALTZ, OTEZLA), AND ii. Prior authorization approval may be given for an initial 16-week course and authorization approval for continuation may be provided based on clinical response. *Members currently stabilized on a Stelara (ustekinumab) regimen that was initiated prior to 1/1/2023 may receive prior authorization approval for continuation of therapy without meeting the above criteria. ‡Failure is defined as lack of efficacy with a three-month trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction. Note that trial and failure of Xeljanz XR will not be required when prescribed for ulcerative colitis for members ≥ 50 years of age that have an additional CV risk factor.	
J3358	**Stelara (intravenous (IV) injection)**	**Stelara** (ustekinumab) **IV injection** may be approved if meeting the following criteria: a. The member has a diagnosis of moderate-to-severely active Crohn's disease or moderate-to-severely active ulcerative colitis AND b. The member is ≥ 18 years of age AND c. The member has trialed and failed‡ all preferred agents in the Targeted Immune Modulators PDL drug class that are FDA-labeled for use for the prescribed indication AND d. If meeting criteria listed above, prior authorization approval will be placed based on the following: i. If maintenance subcutaneous therapy will be billed as a medical claim for administration in the doctor's office or other clinical setting, initial 16-week approval will be placed for initial IV dosage (one dose) and subcutaneous formulations (HCPCS J3357) and one-year prior	See criteria

		authorization approval for continuation of subcutaneous maintenance therapy may be provided based on clinical response OR ii. If maintenance subcutaneous therapy will be dispensed by a pharmacy for self-administration by the member or for administration in the member's home or LTCF, initial approval will be for initial intravenous dose only. Maximum Dose: 520 mg initial IV dose for members weighing > 85 Kg (187 pounds) Quantity Limit: For initial IV infusion, four 130 mg/26 mL single-dose vials *Members currently stabilized on a Stelara (ustekinumab) regimen that was initiated prior to 1/1/2023 may receive prior authorization approval for continuation of therapy without meeting the above criteria. ‡Failure is defined as lack of efficacy, allergy, intolerable side effects, contraindication to therapy, or significant drug-drug interaction. Note that trial and failure of Xeljanz IR will not be required when prescribed for ulcerative colitis for members ≥ 50 years of age that have an additional CV risk factor.	
J3241	**Tepezza**	**Tepezza** may be approved if the member meets the following criteria: a. Member is 18 years of age or older AND b. Member has a documented diagnosis of Thyroid Eye Disease (TED) AND c. Member's prescriber must be in consultation with an ophthalmologist or endocrinologist AND d. Member does not require immediate surgical ophthalmological intervention AND e. Member does not currently require orbital (eye) surgery and is not planning corrective surgery/irradiation during therapy AND f. Member is euthyroid, mild hypothyroid, mild hyperthyroid (defined as free thyroxine (FT4) and free triiodothyronine (FT3) levels less than 50% above or below the normal limits) or seeking care for dysthyroid state from an endocrinologist or other provider experienced in the treatment of thyroid diseases AND g. Member does not have corneal decompensation unresponsive to medical management AND h. Member had an inadequate response, or there is a contraindication or intolerance, to high-dose intravenous glucocorticoids AND i. Member is not pregnant prior to initiation of therapy and effective forms of contraception will be implemented during treatment and for 6 months after the last dose of teprotumumab. If member becomes pregnant during treatment, Tepezza should be discontinued, AND	One year

		j. If member is diabetic, member is being managed by an endocrinologist or other provider experienced in the treatment and stabilization of diabetes AND k. Authorization will be issued for one course of therapy of eight infusions Maximum Dose: Eight infusions per one year	
J2356	**Tezspire**	**Tezspire** (tezepelumab-ekko) may be approved if the following criteria are met: a. Member is 12 years of age or older AND b. Member has a diagnosis of severe asthma that is uncontrolled or inadequately controlled as demonstrated by i. 2 or more asthma exacerbations requiring use of oral or systemic corticosteroids and/or hospitalizations and/or ER visits in the year prior to medication initiation c. Medication is being administered as add-on therapy (not monotherapy) AND d. Member is taking a high dose inhaled corticosteroid and a long-acting beta agonist AND e. Medication will not be used in concomitantly with other biologics indicated for asthma AND f. Member has documented baseline FEV1 Reauthorization may be approved if member has shown clinical improvement as documented by one of the following a. Improvement in lung function, measured in FEV1 b. Reduction in the number of asthma exacerbations, defined as a decrease in use of oral or systemic corticosteroids and/or reduced asthma related hospitalizations and/or ER visits Maximum dose: 210 mg once every 4 weeks Members currently stabilized on a Tezspire (tezepelumab-ekko) regimen that was initiated prior to 1/1/2023 may receive prior authorization approval for continuation of therapy without meeting the above criteria.	One year
J1303	**Ultomiris**	**Ultomiris** (ravulizumab-cwvz) may be approved if member meets the following criteria: a. Member is diagnosed with either Paroxysmal Nocturnal Hemoglobinuria (PNH), Atypical Hemolytic Uremic Syndrome (aHUS), or Generalized Myasthenia Gravis (gMG) AND b. Member has been vaccinated for meningococcal disease according to current ACIP guidelines at least two weeks prior to medication initiation OR	One year

c. Member is receiving 2 weeks of antibacterial drug prophylaxis if meningococcal vaccination cannot be administered at least 2 weeks prior to starting requested medication AND
d. Member does not have unresolved *Neisseria meningitidis* or any systemic infection
e. Prescriber is enrolled in the Ultomiris Risk Evaluation and Mitigation Strategy (REMS) program AND
f. Medication is administered by or in consultation with a hematologist for PNH and by or in consultation with a hematologist or nephrologist for aHUS and by or in consultation with a neurologist for gMG AND
g. Member meets criteria listed below for specific diagnosis:
    i. <u>Paroxysmal nocturnal hemoglobinuria (PNH)</u>
        1. Member is one month of age or older if prescribing the IV formulation OR is ≥ 18 years of age if prescribing the subcutaneous formulation AND
        2. Diagnosis of PNH must be accompanied by detection of PNH clones by flow cytometry diagnostic testing AND
        3. Baseline values are documented for the following:
            - ❑ Serum lactate dehydrogenase (LDH)
            - ❑ Hemoglobin levels
            - ❑ Packed RBC transfusion requirement

        AND
        4. Member has one of the following indications for therapy:
            - ❑ Presence of a thrombotic event
            - ❑ Presence of organ dysfunction secondary to chronic hemolysis
            - ❑ Member is transfusion dependent
            - ❑ Member has uncontrolled pain secondary to chronic hemolysis
    ii. <u>Atypical hemolytic uremic syndrome (aHUS)</u>
        1. Member is one month of age or older if prescribing the IV formulation OR is ≥ 18 years of age if prescribing the subcutaneous formulation AND
        2. Member does not have Shiga toxin E. coli related HUS (STEC-HUS) AND
        3. Thrombotic Thrombocytopenic Purpura (TTP) has been ruled out by evaluating ADAMTS13 level or a trial of plasma exchange did not result in clinical improvement AND
        4. Baseline values are documented for the following:

		❑ Serum LDH ❑ Serum creatinine/eGFR ❑ Platelet count ❑ Dialysis requirement iii. <u>Generalized myasthenia gravis</u> 1. Member is 18 years of age or older AND 2. Member has a positive serologic test for anti-acetylcholine receptor (AchR) antibodies 3. Member has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease; AND 4. Member has a MG-Activities of Daily Living (MG-ADL) total score of ≥6; AND 5. Member has trial and failure of treatment over at least 1 year with at least 2 immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate, etc.), or has failed at least 1 immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG) Maximum dose: 3.6 g every 8 weeks (IV infusion) 490 mg once weekly (subcutaneous administration)	
J3032	**Vyepti (eptinezumab)**	**Vyepti** (eptinezumab-jjmr) may be approved if member meets the following criteria: a. Member is 18 years of age or older AND b. Member has a diagnosis of episodic (fewer than 15 headache days monthly) or chronic migraine (headaches occurring 15 days or more monthly, where at least 8 of these days per month for at least 3 months are migraine days with or without aura) AND c. Member has tried and failed two oral preventive pharmacological agents listed as Level A per the most current American Headache Society/American Academy of Neurology guidelines (such as divalproex, topiramate, metoprolol, propranolol). Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction AND d. The requested medication is not being used in combination with another CGRP medication AND	Initial: 6 months Continued: One year

		e. Member has trial and failure of all preferred calcitonin gene-related peptide inhibitors (CGRPis) indicated for preventative therapy listed on the pharmacy benefit preferred drug list AND f. Initial dose is no more than 100 mg every 3 months i. If 300 mg is requested, the member has tried and had an inadequate response (no less than 30% reduction in headache frequency in a 4-week period) to the 100 mg dosage. g. Initial authorization will be limited to 6 months. Continuation (12-month authorization) will require documentation of clinically relevant improvement with no less than 30% reduction in headache frequency in a 4-week period. Maximum dose: 300 mg IV every 3 months	
J3401	**Vyjuvek (beremagene geperpavec-svdt)**	**Vyjuvek** (beremagene geperpavec-svdt) may be approved if the following criteria are met: a. Member is ≥ 6 months of age, **AND** b. Member has a documented diagnosis of dystrophic epidermolysis bullosa **AND** c. Member must have undergone genetic testing confirming mutation(s) in the *collagen type VII alpha 1 chain (COL7A1)* gene **AND** d. The requested medication is being prescribed by or in consultation with a provider who has expertise in treating dystrophic epidermolysis bullosa **AND** e. Member has been counseled regarding use of highly effective contraceptive method(s) while receiving treatment <u>Reauthorization</u>: Prescribing provider attests that clinical condition is improving on Vyjevek therapy	One year
J2357	**Xolair (omalizumab)**	**Xolair** (omalizumab) may be approved if member meets ALL the following criteria for the appropriate indication: a. If administered for the treatment of <u>asthma</u>: i. Member is 6 years of age or older AND ii. Member has a diagnosis of moderate to severe asthma persistent asthma whose symptoms are inadequately controlled with inhaled corticosteroids with one of the following: 1. A pre-treatment IgE serum concentration greater than or equal to 30 IU per mL OR 2. A positive skin test or in vitro reactivity to a perennial inhaled allergen AND iii. Member's moderate to severe asthma has been refractory to recommended evidence-based, guideline-supported pharmacologic therapies AND	One year

		iv. Medication is being prescribed as add-on therapy to existing asthma regimen AND v. Medication will not be used concomitantly with other biologics indicated for asthma AND vi. Maximum dose of 750mg every 4 weeks b. Reauthorization for asthma indication may be approved if member has shown clinical improvement as documented by one of the following i. Improvement in lung function, measured in FEV1 OR ii. Reduction in the number of asthma exacerbations, defined as a decrease in use of oral or systemic corticosteroids and/or reduced asthma related hospitalizations and/or ER visits c. If administered for the treatment of chronic idiopathic urticaria (CIU) i. Member is 12 years of age or older AND ii. Member is diagnosed with chronic idiopathic urticaria AND iii. Member is symptomatic despite H1 antihistamine treatment AND iv. Member has tried and failed at least three of the following: 1. Hydroxyzine or doxepin (**must include**) 2. High-dose second generation H1 antihistamine 3. H2 antihistamine 4. First-generation antihistamine 5. Leukotriene receptor antagonist AND v. Prescriber attests that the need for continued therapy will be periodically reassessed (as the appropriate duration of therapy for CIU has currently not been evaluated) AND vi. Exemption: Member who is currently stable on Xolair for chronic idiopathic urticaria may continue to receive prior authorization approval to continue. d. If administered for the treatment of chronic rhinosinusitis with nasal polyps: i. If the member has a concomitant diagnosis of asthma or chronic idiopathic urticaria, then criteria listed above for the respective diagnoses are met AND ii. Member is 18 years of age or older AND iii. Member has a pre-treatment IgE level greater than or equal to 30 IU per mL AND iv. Member has tried and failed at least two intranasal corticosteroids (see Intranasal Rhinitis Agents PDL class). Failure is defined as lack of efficacy with a 2-week trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction v. AND	

		vi. Member is *currently* adherent to intranasal corticosteroid therapy AND vii. Member has a baseline bilateral endoscopic nasal polyps score indicating the need for treatment AND viii. Medication is being prescribed by or in consultation with a qualified subspecialist such as an allergist, ear/nose/throat specialist, immunologist, rheumatologist, or pulmonologist AND ix. Maximum dose for nasal polyps is 600 mg subcutaneously every 2 weeks e. Reauthorization for the chronic rhinosinusitis with nasal polyps indication may be approved if member has shown clinical improvement as indicated by the following: i. Initial approval criteria were met at the time of initiation of therapy AND ii. Provider attests that member has documented improvement in bilateral endoscopic nasal polyps score, AND iii. Provider attests that member is being periodically reassessed for need for continued therapy based on disease severity and/or level of symptom control	