

ABOBOTULINUMTOXINA

Products Affected

- DYSPOORT

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications.
Exclusion Criteria	Cosmetic uses
Required Medical Information	Conservative treatments, for example, physical therapy, oral medications, etc, have been tried or considered, have failed and/or are contraindicated
Age Restrictions	Must be 2 years of age or older
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	Maximum billing unit(s) equals 1500 units

AFLIBERCEPT

Products Affected

- EYLEA

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications.
Exclusion Criteria	
Required Medical Information	The patient has tried and failed or is intolerant to clinically appropriate alternatives such as bevacizumab, the patient does not have an active ocular or periocular infection, and the patient does not have an active intraocular inflammation.
Age Restrictions	The patient is 18 years of age or older
Prescriber Restrictions	Ophthalmologist
Coverage Duration	6 months
Other Criteria	Reauthorization Criteria: Renewable if the patient continues to meet the criteria for medical necessity.

ALGLUCOSIDASE ALFA

Products Affected

- LUMIZYME

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications.
Exclusion Criteria	Patient not to concurrently take Avalglucosidase Alfa-ngpt (Nexviazyme)
Required Medical Information	Patient has a diagnosis of Pompe disease confirmed by one of the following: genetic testing (i.e. confirmed GAA gene variants), alpha-glucosidase activity measurement, or enzyme assay demonstrating lysosomal acid alpha-glucosidase enzyme deficiency; Patient has documented baseline results of Forced Vital Capacity (FVC) and/or six Minute Walk Test (6MWT) or motor function such as Alberta Infant Motor Scale (AIMS); Patient has clinical signs and symptoms of disease (i.e. cardiomegaly, respiratory distress, muscle weakness, failure to thrive, skeletal myopathy, delay gross-motor development, etc.)
Age Restrictions	
Prescriber Restrictions	Must be prescribed by or in consultation with a neurologist, geneticist or other physician with specialty in treating Pompe disease
Coverage Duration	6 months
Other Criteria	The recommended dose is 20 mg/kg every two weeks Reauthorization Criteria: patient continues to meet initial approval criteria, and patient has shown clinical benefit (i.e. evidenced by change in FVC, 6-minute walk test, cardiac function, motor function assessed by AIMS) comparing to the baseline.

ANTINEOPLASTIC

Products Affected

- ADCETRIS
- ADRIAMYCIN
- ADRUCIL
- *alimta*
- AVASTIN 100 MG/4 ML VIAL P/F,SUV
- *bleomycin*
- *bortezomib*
- CAMPTOSAR
- *carboplatin*
- *cisplatin*
- *cyclophosphamide*
- *dacarbazine*
- *docetaxel*
- *doxorubicin*
- *etoposide*
- *fluorouracil*
- *gemcitabine*
- HERCEPTIN
- HERZUMA
- *ifosfamide*
- *irinotecan*
- KADCYLA
- KANJINTI
- KEYTRUDA
- *leucovorin calcium*
- *mesna*
- MVASI
- OGIVRI
- ONTRUZANT
- OPDIVO
- *oxaliplatin*
- *paclitaxel*
- *paclitaxel protein-bound*
- PARAPLATIN
- *pemetrexed disodium*
- PERJETA
- POLIVY
- *tecentriq*
- TRAZIMERA
- VELCADE
- *vinblastine*
- *vincristine*
- YERVOY
- ZEPZELCA
- ZIRABEV

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications.
Exclusion Criteria	
Required Medical Information	Must meet 1 of the following requirements: i. Confirmed diagnosis of FDA labeled indication, OR ii. Confirmed NCCN recommended regimen of category 2B or above AND b. Request for off-labeled use and/or non-preferred NCCN regimen requires clinical review by IEHP pharmacist
Age Restrictions	
Prescriber Restrictions	Specialist (e.g., Oncologist, Hematologist, Dermatologist, etc.)
Coverage Duration	6 months

PA Criteria	Criteria Details
Other Criteria	Reauthorization Criteria: a. Must meet the following requirement: i. Review by Clinical Pharmacist

CAR-T

Products Affected

- ABECMA
- BREYANZI
- KYMRIA
- TECARTUS
- YESCARTA

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications.
Exclusion Criteria	
Required Medical Information	See CAR-T Policy, requires clinical pharmacist review
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	

DENOSUMAB

Products Affected

- PROLIA
- XGEVA

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications.
Exclusion Criteria	
Required Medical Information	Hypocalcemia absent or treated with calcium (i.e. 1,000 mg daily) and vitamin D (i.e. 400 IU) as necessary. For PROLIA: postmenopausal women with osteoporosis at high risk of fracture, to increase bone mass in men with osteoporosis at high risk for fracture, to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer, to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. For XGEVA: prevention of skeletal related events in patients with bone metastases from solid tumors, for giant cell tumor of bone, for hypercalcemia of malignancy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	For PROLIA: 60 mg subcutaneously every six months. For XGEVA: 120 mg subcutaneously every four weeks

ECULIZUMAB

Products Affected

- SOLIRIS

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications.
Exclusion Criteria	
Required Medical Information	1. Vaccination against Neisseria meningitides at least two weeks prior to initiation unless treatment cannot be delayed; 2. must have one of the following diagnoses: (a) a diagnosis of Paroxysmal nocturnal hemoglobinuria (PNH) with documented baseline value for serum lactate dehydrogenase (LDH), patient is not on another terminal complement inhibitor, OR (b) a diagnosis of Atypical hemolytic uremic syndrome (aHUS) with documented baseline value for serum lactate dehydrogenase (LDH), patient is 2 months of age or older and has a weight of at least five kilograms, patient does not have Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS), patient is not on another terminal complement inhibitor, OR (c) a diagnosis of generalized Myasthenia Gravis (gMG) with positive serologic test for anti-acetylcholine antibodies, Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV, documented baseline MG-Activities of Daily Living (MG-ADL) total score greater than or equal to 6, and patient has had an inadequate treatment response, intolerance or contraindication to two or more immunosuppressants such as azathioprine, cyclophosphamide, cyclosporine, mycophenolate, tacrolimus, methotrexate, etc, and has had an inadequate treatment response, intolerance, or contraindication to chronic IVIG therapy, OR (d) a diagnosis of Neuromyelitis optica spectrum disorder (NMOSD) with positive serologic test for anti-aquaporin-4 immunoglobulin G (AQP4-IgG)/NMO-IgG antibodies.
Age Restrictions	Must be 2 months or older for aHUS diagnosis, must be 18 years of age or older for PNH, gMG or NMOSD diagnosis
Prescriber Restrictions	Prescriber must be enrolled in the Soliris REMS program
Coverage Duration	6 months

PA Criteria	Criteria Details
Other Criteria	Frequency of billing = 900 mg/90 units weekly for the first four weeks, followed by 1,200 mg/120 units for the fifth dose one week later, then 1200 mg /120 units every two weeks thereafter, maximum billing unit(s) = 1,200 mg = 120 units; Reauthorization Criteria: Patient must have a significant clinical response as evidenced by: documentation of a reduction in serum LDH from pretreatment baseline (PNH, aUHS), documentation of reduction of (MG-ADL) total score from baseline (gMG), or patient has had fewer relapses while on therapy (NMOSD)

EPOETIN

Products Affected

- EPOGEN
- PROCRIT

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications.
Exclusion Criteria	
Required Medical Information	Anemia in CKD: Documentation to show hemoglobin level is less than 10 g/dL prior to initiation; Chemotherapy-associated anemia in non-myeloid malignancies: hemoglobin level below 10 g/dL and minimum of two additional months of planned chemotherapy; Anti-retroviral therapy treated HIV-infected patients: documentation on symptomatic anemia and have serum erythropoietin concentrations less than 500 IU/L
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	

HP ACTHAR

Products Affected

- *acthar*

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications.
Exclusion Criteria	
Required Medical Information	Acute exacerbation of multiple sclerosis: Failure or clinically significant adverse effects to corticosteroid therapy (i.e., prednisone, intravenous methylprednisolone, etc.), Documentation of concurrent multiple sclerosis agents (i.e., Avonex, Betaseron, Glatiramer, etc.)
Age Restrictions	Infantile spasms: must be less than 24 months old; Acute exacerbation of multiple sclerosis: must be 18 years of age or older
Prescriber Restrictions	Neurologist or Pediatrician
Coverage Duration	6 months
Other Criteria	

HYALURONAN

Products Affected

- DUROLANE
- EUFLEXXA
- GEL-ONE
- GELSYN-3
- GENVISC 850
- HYALGAN
- MONOVISC
- ORTHOVISC
- SUPARTZ FX
- SYNOJOYNT
- TRILURON
- VISCO-3

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications.
Exclusion Criteria	
Required Medical Information	Must have documented failure, inadequate response, or intolerance to at least two of the following pharmacologic therapies: Two oral or topical anti-inflammatory drugs (NSAIDs), acetaminophen, one or more trials in the last 12 months of intra-articular steroid injections unless intolerant or contraindicated, and at least one course of physical therapy for knee osteoarthritis, no contraindications to the injections (active joint infection, bleeding disorder), For treatment continuation: Patient has successfully used hyaluronic acid derivatives in the same knee (there must be at least a six-month interval before approval of a repeat course)
Age Restrictions	Synojoynt, Durolane and Visco-3: Must be 22 years of age or older, Triluron, Hyalgan, Supartz and Euflexxa: Must be 18 years of age or older
Prescriber Restrictions	Orthopedics, Pain Management Specialist
Coverage Duration	6 months
Other Criteria	Must use modifiers RT, LT for applicable knee(s), Maximum billing units per knee per 180 days: 60 units (Durolane, Synojoynt, Triluron), 5 units (Hyalgan, Supartz), 3 units (Visco-3)

INCOBOTULINUMTOXINA

Products Affected

- XEOMIN

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications.
Exclusion Criteria	Cosmetic uses
Required Medical Information	Conservative treatments, for example, physical therapy, oral medications, etc, have been tried or considered, have failed and/or are contraindicated
Age Restrictions	Must be 18 years of age or older
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	Maximum billing unit(s) equals 400 units

INFLIXIMAB

Products Affected

- AVSOLA
- INFLECTRA
- INFLIXIMAB
- RENFLEXIS

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications. For chemotherapy-related indications, see PA ANTINEOPLASTIC
Exclusion Criteria	
Required Medical Information	Alternative, conventional therapy has been tried or considered, has failed, or is contra-indicated, patient was screened and showed absence of latent (untreated) tuberculosis prior to therapy initiation, patient has been screened for the presence of hepatitis B virus (HBV) prior to initiating treatment, and patient has no active infection.
Age Restrictions	Must be 6 years of age or older
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	Reauthorization Criteria: Patient continues to meet initial coverage criteria and patient has shown a positive clinical response such as symptoms improvement or lack of disease progression.

INTRAVENOUS IRON

Products Affected

- INJECTAFER

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications.
Exclusion Criteria	
Required Medical Information	Trial and failure of oral iron supplementation, and labs indicating deficiency, e.g. anemia, low iron saturation, etc.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	

IVIG

Products Affected

- GAMMAGARD LIQUID
- *gammaked*
- *gamunex-c*
- *octagam*

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications.
Exclusion Criteria	
Required Medical Information	Alternative, conventional therapy has been tried or considered, has failed, or is contra-indicated (i.e. corticosteroid therapy, azathioprine, methotrexate, or cyclophosphamide, immunosuppressive agents, plasmapheresis); Idiopathic Thrombocytopenia Purpura (ITP): Platelet counts persistently below 20,000 per cubic millimeter; Primary Immunodeficiency Syndrome (PID): documented IgG levels fall below 500 milligrams per deciliter
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	

LUSPATERCEPT

Products Affected

- REBLOZYL

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications.
Exclusion Criteria	Diagnosis of Hemoglobin S/beta-thalassemia or alpha (a)-thalassemia (for example, Hemoglobin H); patient is pregnant or breastfeeding; Active hepatitis C (HCV) infection, active infectious hepatitis B (HBV) as demonstrated by a positive HCV-RNA test of sufficient sensitivity, known human immunodeficiency virus (HIV) that is not controlled by antiretroviral (ART) therapy, recent deep vein thrombosis or stroke requiring medical intervention less than or equal to 24 weeks prior, major organ damage as evidenced by any of the following: Liver disease (with an ALT greater than 3x the ULN or history of evidence of cirrhosis), Heart disease (i.e. heart failure NYHA classification three or higher, or significant arrhythmia requiring treatment, or recent myocardial infarction within six months of treatment), Lung disease (i.e. pulmonary fibrosis or pulmonary hypertension which are clinically significant, that is, equal to or greater than Grade 3), Renal insufficiency (such as creatinine clearance less than 60 mL/min)
Required Medical Information	Patient has a clinically documented diagnosis of beta-thalassemia or Hemoglobin E/beta-thalassemia. Beta-thalassemia with mutation and/or multiplication of alpha globin is allowed. Patient is regularly transfused, defined as: 6-20 Red Blood Cell (RBC) units in the 24 weeks prior and no transfusion-free period for equal to or greater than 35 days during that period
Age Restrictions	Patient must be 18 years of age or older
Prescriber Restrictions	Must be prescribed by, or in consultation with, a hematologist, or other specialist with expertise in the diagnosis and treatment of thalassemia
Coverage Duration	6 months
Other Criteria	Frequency of billing equal to 1.25 mg/kg every three week; Reauthorization Criteria: Patient continues to meet the initial coverage criteria, patient has experienced a clinically significant reduction in transfusion burden from baseline, patient has an absence of unacceptable toxicity from the drug such as severe thromboembolic events or hypertension

MEPOLIZUMAB

Products Affected

- NUCALA

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications.
Exclusion Criteria	For Asthma: Patient will not use Nucala as monotherapy. Patient will not use Nucala in combination with another monoclonal antibody (for example, Cinqair, Dupixent, Fasenra, Xolair, etc.).
Required Medical Information	For Asthma: Patient must have asthma with an eosinophilic phenotype defined as blood eosinophils greater than or equal to 300 cells/microliter within previous 12 months or greater than or equal to 150 cells/microliter within six weeks of dosing; and patient has inadequate asthma control (for example, hospitalization or emergency medical care visit within the past year) despite current treatment with (1) inhaled corticosteroid AND (2) long-acting beta2-agonist, leukotriene modifier, or sustained release theophyllin at optimal dosages; For Eosinophilic Granulomatosis with Polyangiitis (EGPA): Patient has a history or the presence of an eosinophil count of more than 1000 cells/microliter or a blood eosinophil level of higher than 10 percent; Patient has two or more of the disease characteristics of EGPA (i.e. biopsy showing histopathological evidence, neuropathy, pulmonary infiltrates, cardiomyopathy, glomerulonephritis, ANCA positivity, etc.); Patient has had at least one relapse (requiring increase in oral corticosteroids dose, initiation or increased dose of immunosuppressive therapy or hospitalization) within 2 years prior to starting treatment with Nucala or has a refractory disease.
Age Restrictions	For Asthma: 6 years or older; For Eosinophilic Granulomatosis with Polyangiitis (EGPA): 18 years or older
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	Reauthorization Criteria: For Asthma: patient continues to meet initial coverage criteria; and asthma control has improved on Nucala treatment as demonstrated by AT LEAST ONE of the following: 1. A reduction in the frequency and/or severity of symptoms and exacerbations, 2. A reduction in the use of systemic corticosteroids, AND/OR 3. Improvement from baseline in forced expiratory volume in 1 second (FEV1); For

PA Criteria	Criteria Details
	Eosinophilic Granulomatosis with Polyangiitis (EGPA): patient continues to meet initial coverage criteria and patient has beneficial response to treatment with Nucala as demonstrated by ANY of the following: 1. A reduction in the frequency of relapses, 2. A reduction in the daily oral corticosteroid dose, OR 3. Absence of active vasculitis

NUSINERSEN

Products Affected

- SPINRAZA (PF)

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications.
Exclusion Criteria	
Required Medical Information	Genetic testing results demonstrate homozygous SMN1 deletion, or any combination of SMN1 deletions or other mutations that result in the functional loss of all SMN1 genes. In addition to demonstrating loss of functional SMN1 genes, genetic test results include the number of copies of SMN2. Pre-symptomatic: Defined by genetic testing demonstrating a homozygous SMN1 deletion or mutation, and less than or equal to three copies of SMN2 OR Symptomatic: Patient with clinical signs of SMA with level of function necessary to preserve communication, for instance finger or eye movements in response to prompt by examiner. For nusinersen, it can be safely administered intrathecally, taking into consideration the patients scoliosis status. Specifically, for older patients with SMA, the drug may only be authorized if beneficiary has any of the following: No scoliosis, scoliosis without spine surgery, scoliosis post spine surgery with preserved window of accessibility for intrathecal injection, under fluoroscopic or ultrasound guidance if needed, scoliosis post spine surgery for example, fusion) but with surgical placement of an indwelling catheter or establishment of a new window for IT accessibility, and the patient does not have a coexisting terminal condition or a condition with which the risk of nusinersen treatment outweighs the potential benefit.
Age Restrictions	
Prescriber Restrictions	Neurologist
Coverage Duration	6 months
Other Criteria	Medical note from neuromuscular specialist SCC containing: Patient demographics, including age of onset, results of genetic testing, including name of laboratory, number of copies of SMN2, and whether SMN1 sequencing was done, neurologic status, specifically if patient is non-sitter, sitter or walker, pulmonary status, nutrition and dietary status (with

PA Criteria	Criteria Details
	review by registered dietitian), and results of at least one neuromotor assessment with a score used to establish a clinical baseline, e.g. CHIP INTEND, HFMSE, TUG, RULM, that is appropriate for clinical status, e.g. non-sitters, sitters, walkers, and non-ambulatory older patients

OCRELIZUMAB

Products Affected

- OCREVUS

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications.
Exclusion Criteria	
Required Medical Information	Hepatitis B virus screening is required before the first dose.
Age Restrictions	
Prescriber Restrictions	Neurologist
Coverage Duration	6 months
Other Criteria	Start dose: 300 mg intravenous infusion, followed two weeks later by a second 300 mg intravenous infusion and subsequent doses: 600 mg intravenous infusion every six months

OMALIZUMAB

Products Affected

- XOLAIR

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications.
Exclusion Criteria	
Required Medical Information	For moderate-to-severe persistent asthma: A positive skin test or in vitro reactivity to a perennial aeroallergen; Symptoms are inadequately controlled with inhaled corticosteroids; Pre-treatment serum IgE level between 30 and 700 IU/ml; Persistent and uncontrolled asthma as defined by at least one of the following: (1) An ACQ score consistently greater than 1.5 (Asthma Control Questionnaire) or an ACT score less than 20 (Asthma Control Test), (2) Two or more exacerbations in the previous year, each requiring 3 or more days of treatment with systemic glucocorticoids, (3) A history of hospitalization, intensive care unit stay, or mechanical ventilation in the previous year, OR (4) A FEV1 (Forced Expiratory Volume in 1 second) at less than 80% of predicted after bronchodilator administration measured by pulmonary function testing or spirometry and documented by report and interpretation.
Age Restrictions	Six years and older
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	Reauthorization Criteria: Documentation of clinical improvement after the administration of omalizumab, as measured by parameters such as an asthma control questionnaire, a decreased use of beta-agonists, an increase in FEV1 from pre-treatment baseline, a reduction in acute exacerbations or hospitalizations, etc.

ONABOTULINUMTOXINA

Products Affected

- BOTOX

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications.
Exclusion Criteria	Cosmetic uses
Required Medical Information	For prophylaxis of chronic migraine: Diagnosis of chronic migraine, defined by all of the following: Greater than or equal to 15 headache days per month, greater than or equal to 8 migraine days per month, headaches last 4 hours per day or longer, and trial and failure, unless contraindicated or intolerant, to prophylactic therapy with one agent from two of the following therapeutic classes: antidepressant, antiepileptic, and beta-blocker. For overactive bladder: Diagnosis of overactive bladder and one of the following symptoms: urge urinary incontinence, urgency, frequency, and trial and failure, unless contraindicated or intolerant, to two anticholinergic medications. For other conditions: The patient had been unresponsive to conventional methods of treatments such as medication, physical therapy and other appropriate methods used to control or treat this condition.
Age Restrictions	Must be 2 years of age or older
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	Maximum billing unit(s) equals 400 units

RASBURICASE

Products Affected

- ELITEK

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications.
Exclusion Criteria	Diagnosis of Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	Safety and efficacy has been established only for a single course of treatment once daily for 5 days

RIMABOTULINUMTOXINB

Products Affected

- MYOBLOC

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications.
Exclusion Criteria	Cosmetic uses
Required Medical Information	The patient had been unresponsive to conventional methods of treatments such as medication, physical therapy and other appropriate methods used to control or treat this condition
Age Restrictions	Must be 18 years of age or older
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	Maximum billing unit(s) equals 5000 units

RITUXIMAB

Products Affected

- RIABNI
- RITUXAN
- RUXIENCE
- TRUXIMA

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications. For chemotherapy-related indications, see PA ANTINEOPLASTIC
Exclusion Criteria	
Required Medical Information	Alternative treatments have been tried or considered, have failed, or are contraindicated.
Age Restrictions	
Prescriber Restrictions	Specialist (e.g., Oncologist, Hematologist, Dermatologist, etc.)
Coverage Duration	6 months
Other Criteria	

ROMIPLOSTIM

Products Affected

- NPLATE

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications.
Exclusion Criteria	Patient not breast-feeding or pregnant
Required Medical Information	Insufficient response to therapy, as indicated by 1 or more of the following: Corticosteroids, Intravenous immunoglobulin (IVIG), or Splenectomy; Documented clinical condition increases risk of bleeding (i.e. Platelet count less than 30,000/mm ³).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	

TEPROTUMUMAB

Products Affected

- TEPEZZA

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications.
Exclusion Criteria	Patient must not have poorly controlled diabetes, Diabetic patient must have well controlled disease (defined as HgbA1c less than 9.0 percent at most recent clinic visit)
Required Medical Information	Requires clinical pharmacist review. Patient must have a clinical diagnosis of Graves disease associated with active thyroid eye disease (TED) with a clinical activity score (CAS) of greater than or equal to 4 for the most severely affected eye or patient has moderately to severely active TED, associated with at least one of the following: Lid retraction equal to or greater than 2 mm, moderate or severe soft tissue involvement, proptosis equal to or greater than 3 mm, diplopia, or corneal exposure. Patient must be euthyroid or with mild hypo- or hyperthyroidism defined as free thyroxine and free triiodothyronine levels less than 50 percent above or below the normal limits. Patient does not require surgical ophthalmological intervention. Patient has a contraindication, intolerance, or lack of response to glucocorticoids or a documented justification why the use of glucocorticoids is not appropriate.
Age Restrictions	Patient must be 18 years of age or older
Prescriber Restrictions	Must be prescribed by or in consultation with an ophthalmologist, endocrinologist or a physician who specializes in treatment of thyroid eye disease
Coverage Duration	6 months
Other Criteria	Maximum of 8 infusions and frequency of billing equal to 10 mg/kg initial dose, then 20 mg/kg every 3 weeks for 7 additional doses

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