Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines

Medical Benefit Drugs

Intravenous Immune Globulin (IVIG) and Subcutaneous Immune Globulin (SCIG) Products

Effective: July 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together - MassHealth Accountable Care Partnership Plans.; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Immune globulin preparations are available as pre-mixed liquids or lyophilized powders with varying concentrations of IgG. The manufacture of commercial immune globulin products from pooled plasma is a complex multistep process consisting of fractionation, purification, stabilization, virus inactivation, and virus removal and as a result, immune globulin products differ with respect to formulation and composition. Product characteristics such as content (e.g., IgA concentration, stabilizer), volume, and osmolarity may be important considerations for some patients. However, comparative data are lacking and it is not known whether one specific product is superior for a particular disease or clinical setting.

For PID, compared with the intravenous route, the subcutaneous route may offer some advantages in terms of improved tolerability, better sustained blood levels of IgG, and ability to be self-administered at home. Clinical experience with subcutaneous administration of immune globulin for treating conditions other than PID is limited at this time and is generally not recommended.

Immune globulin is the standard treatment for PID. PID includes, but are not limited to, the humoral immune defect in common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies. Other FDA-approved indications for immune globulin include ITP, B-cell CLL, CIDP, and Kawasaki syndrome as outlined above. In addition, in clinical practice, immune globulin is frequently used for treating a variety of off-label conditions in various therapeutic areas such as neurology, hematology, infectious disease, stem cell transplant, dermatology, and rheumatology. However, many of these off-label or proposed uses lack quality evidence of clinical benefit. Given the increasing demand and limited supply of immune globulin, along with the potential risks and relatively high cost of therapy, the indications for use of immune globulin require careful consideration.

Food and Drug Administration (FDA) Approved Indications:

Specific FDA-approved uses vary for individual products. Currently available immune globulin intravenous [human] (IVIG) products may be labeled for the treatment of primary immunodeficiency diseases (PID), idiopathic thrombocytopenic purpura (ITP), Kawasaki disease (KD), B-cell chronic lymphocytic leukemia (CLL), chronic inflammatory demyelinating polyneuropathy

(CIDP), multifocal motor neuropathy (MMN) and/or dermatomyositis. Immune globulin subcutaneous [human] (SCIG) products are currently labeled for the treatment of PID only.

Table: FDA-approved indications for currently marketed immune globulin products:

Brand Name	PID	ITP	KD	CLL	CIDP	MMN	Dermatomyositis
Alyglo (I.V.)	X						
Asceniv (I.V.)	X						
Bivigam® (I.V.)	X						
Cutaquig® (S.C.)	X						
Cuvitru® (S.C.)	X						
Flebogamma® 10% DIF (I.V.)	X	X					
Flebogamma® 5% DIF (I.V.)	X						
Gammagard S/D® (I.V.)	X	X	X	X ^			
Gammagard® Liquid* (I.V. & S.C.)	X					X	
Gammaked®* (I.V. & S.C.)	X	X			X		
Gammaplex® 10% (I.V.)	X	X					
Gammaplex® 5% (I.V.)	X	X					
Gamunex-C® * (I.V. & S.C.)	X	X			X		
Hizentra® (S.C.)	X				X		
HyQvia® (S.C.)	X						
Octagam® 10% (I.V.)		X					X
Octagam® 5% (I.V.)	X						
Panzyga® (I.V.)	X	X			X		
Privigen® (I.V.)	X	X			X		
Qivigy 10% (I.V)	X						
Xembify® (S.C.)	X						
Yimmugo 10% (I.V.)	X						

*Gammagard Liquid, Gammaked and Gamunex-C, when administered subcutaneously, are FDA-approved for the treatment of PID syndromes only. Gammagard Liquid, Gammaked and Gamunex-C are not approved for subcutaneous use in patients with ITP or CIDP.

The plan may authorize coverage of Immune Globulin (see **Limitations** section for specific requirements for coverage of Hizentra®) when medically necessary and proven effective for Members with specific humoral immunodeficiencies or other clinical conditions as listed in the Coverage Guidelines below when the use of immune globulin, including but not limited to dosage, frequency, site of administration, and duration of therapy, is clinically appropriate and supported by evidence-based literature. Adjustments of dosage, frequency, site of administration, and duration of therapy must be reasonable and appropriate based on condition and severity, availability of alternative treatments, and prior response to immune globulin therapy.

The plan does not cover Intravenous Immune Globulin (IVIG) or Subcutaneous Immune Globulin (SCIG) for other medical conditions, diseases and disorders, including but not limited to conditions listed in the Limitations section of these Medical Necessity Guidelines, when its use is considered investigational or unproven, and is not supported by evidence-based literature.

NOTE: The health plan does not require prior authorization of any immune globulin product for Members < 18 years of age.

Note: Providers and Members enrolled with Harvard Pilgrim Health Care may reference the HPHC/OncoHealth guideline for coverage of oncology-related indications (marked with a ^ in the indications grid below) , located at https://oncohealth.us/medicalpolicies/harvardpilgrim/

Clinical Guideline Coverage Criteria

Initial Authorization Criteria

The Plan may authorize coverage of Intravenous Immune Globulin or Subcutaneous Immune Globulin (see Limitations section for specific requirements for coverage of Hizentra®) when **ALL** of the following criteria are met:

1. The medical diagnosis is listed in Covered Medical Conditions below

AND

2. A definitive diagnosis of the Covered Medical Condition has been made by a specialist and documented by clinical notes including appropriate positive findings on diagnostic testing and/or biopsy results

AND

3. The criteria specific for the Covered Medical Condition below are met and documented by clinical notes and laboratory test results as required

AND

4. The requested frequency and dosage of Intravenous Immune Globulin (IVIG) or Subcutaneous Immune Globulin (SCIG) is supported by evidence-based literature.

Reauthorization Criteria

The Plan may reauthorize coverage of Intravenous Immune Globulin (IVIG) or Subcutaneous Immune Globulin (SCIG) (see Limitations section for specific requirements for coverage of Hizentra®) when **ALL** of the following criteria are met:

1. The treated Covered Medical Condition has not resolved

AND

2. Documentation of sustained clinical benefit of Immune Globulin treatment as evidenced by medical records documenting current progress and the expected frequency and duration of any additional Intravenous Immune Globulin (IVIG) or Subcutaneous Immune Globulin (SCIG) use going forward has been submitted. Objective monitoring of progress using metric assessment may be used. Examples of these assessments may include: the Inflammatory Neuropathy Cause and Treatment (INCAT) scale, the Medical Research Council (MRC) scale, and activities of daily living (ADL) measurements

AND

3. The Member has been stabilized on or titrated to the minimum dosage and frequency to achieve sustained clinical effect where clinically appropriate

Covered Medical Conditions & Clinical Coverage Criteria

Covered Medical Condition	Clinical Coverage Criteria
Dermatology	
Autoimmune mucocutaneous blistering diseases (AMBDs): Bullous pemphigoid; Epidermolysis Bullosa Acquisita (EBA); Mucous membrane pemphigoid (a.k.a. Cicatrical Pemphigoid); Pemphigus Foliaceus; Pemphigus Vulgaris	**Authorization Criteria:** • Biopsy-proven diagnosis of AMBDs (including pathology report) • Documentation of **one (1)** of the following criteria: – Use only for short-term therapy, not as maintenance therapy, (see dosing recommendation for definition of treatment failure) – Failure of conventional therapy—defined as failure of disease control after a maximum dose of 60 mg daily of prednisone (or prednisone 1 mg/kg/day) for 6 weeks, with, or without a concurrently administered ISA, e.g., Imuran 150 mg per day or Cytoxan 100 mg per day for a maximum of 10-to-12 weeks – Significant adverse effects of conventional therapy -defined as adverse reactions that are potentially life-threatening, cause significant morbidity or inability to cope with activities of daily living, and require the intervention of a physician or drug therapy – Contraindications to conventional therapy, for systemic corticosteroids (existing diabetes, clinically significant osteoporosis, fractures, upper GI bleeding, posterior subcapsular cataracts, pseudotumor cerebri, bone marrow suppression, aplastic anemia, clinically significant psychological changes, steroid myopathy, glaucoma); and for immunosuppressive agents (significant persistent anemia, clinically significant neutropenia, clinically significant abnormal hepatic function, clinically significant impaired renal function, hemorraghic cystitis, clinically significant bone marrow suppression, history of malignancy) – Patients with rapidly progressive disease which significantly impacts activities of daily living, in spite of appropriate maximum, yet safe

	conventional systemic therapy – Patients with EBA with generalized cutaneous diseases with or without multiple mucosal involvement, that is rapid and progressive
Dermatomyositis/Polymyositis, including Juvenile	**Authorization Criteria:** • Biopsy-proven diagnosis • For the diagnosis of dermatomyositis, Member presents with skin lesions (i.e., heliotrope rash, Gottron's sign, or erythema on the extensor surface of extremity joints • For the diagnosis of both dermatomyositis and polymyositis the Member presents with at least **four (4)** of the following: – Elevated serum CK (creatine kinase) or aldolase level – Muscle pain on grasping or spontaneous pain – Myogenic changes on EMG (short duration, polyphasic motor unit potentials with spontaneous fibrillation potentials) – Non-destructive arthritis or arthralgias – Pathological findings compatible with inflammatory myositis – Positive anti-Jo-1 (histadyl tRNA synthetase) antibody – Proximal muscle weakness (upper or lower extremity and trunk) – Systemic inflammatory signs (e.g., fever, elevated serum CRP level or accelerated ESR of more than 20 mm/h by the Westergren method) • Failure, contraindication or intolerance to **both** first and second-line therapies: – **First-line**: corticosteroids (e.g., prednisone) – **Second-line**: Immunosuppressants (e.g., azathioprine, cyclosporine, methotrexate, Rituxan®) – At least a **four (4)-**month trial of standard therapies is required unless there is profound, rapidly progressive and / or potentially life-threatening muscular weakness refractory to prior therapy. – Refractory disease is evidenced by persistently elevated serum creatine kinase and / or lack of improvement on muscle strength improvement scales.
Pyoderma gangrenosum	**Authorization Criteria:** • Failure, contraindication or intolerance to at least **two (2)** of the following systemic therapies: – Systemic corticosteroids – Immunosuppressants (e.g., azathioprine, mercaptopurine, mycophenolate mofetil, cyclosporine, cyclophosphamide, chlorambucil) – Dapsone – Infliximab (Remicade®) – For localized pyoderma gangrenosum- intralesional injections of corticosteroids or cyclosporine.
Infectious Disease	
Acute disseminated encephalomyelitis	**Authorization Criteria:** • Failure, contraindication or intolerance to intravenous corticosteroid treatment.
Erythrovirus (formerly parvovirus) B19 Infection, chronic, with severe anemia (Pure Red Cell Aplasia)	**Authorization Criteria:** • Member has severe, refractory anemia with documented Erythrovirus B19 viremia.
HIV-associated thrombocytopenia – Adults	**Authorization Criteria:** • Documentation of one (1) of the following: – Platelet count is < 20,000/µL – Thrombocytopenic Member with significant bleeding – Failure of RhIG in Rh-positive patients

Immunology	
Primary Humoral Immunodeficiencies	
Common Variable Immunodeficiency (CVID)	**Authorization Criteria:** • IgG level must be below the normal range (>2 standard deviations below the age-specific mean) on at least **two (2)** occasions while the Member is clear of infections • Laboratory results showing low IgA and IgM levels • Documented recurrent bacterial infections resulting from low IgG or serious bacterial infections • Failure of prophylactic antibiotic therapy
Congenital agammaglobulinemia (X-linked agammaglobulinemia)	**Authorization Criteria:** • IgA, IgG and IgM levels must be below the normal range (**>2)** standard deviations below the age-specific mean) on at least two occasions while the Member is clear of infections • Documented recurrent bacterial infections resulting from low IgG or serious bacterial infections
Hypogammaglobulinemia (excluding IgA deficiency)	**Authorization Criteria:** • IgG level must be below the normal range (>2 standard deviations below the age-specific mean) on at least **two (2)** occasions while the Member is clear of infections • History of recurrent bacterial sinopulmonary infections requiring multiple courses or prolonged antibiotic therapy or failure of prophylactic antibiotic therapy • Management of underlying conditions such as asthma or allergic rhinitis that may predispose to recurrent infections where applicable
Selective IgG subclass deficiency	**Authorization Criteria:** • Deficiency of one or more IgG subclasses below the normal range (>2 standard deviations below the age-specific mean) assessed on at least **two (2)** occasions while the Member is free of infections • Unexplained recurrent or persistent severe bacterial infections despite appropriate treatment with all of the following: – Aggressive management of underlying conditions predisposing to recurrent sinopulmonary infections (e.g., asthma, allergic rhinitis) – Prophylactic antibiotics – Increased vigilance and appropriate antibiotic therapy for infections – Immunization with conjugate vaccines in patients who have not responded to polysaccharide vaccines • Inadequate response to protein and polysaccharide antigens, as determined by the following: – Documented inability to mount an antibody response to protein antigens (Serum antibody titers to tetanus and / or diphtheria should be obtained prior to immunization with diphtheria and / or tetanus vaccine and 3 to 4 weeks after immunization. An inadequate response is defined as less than a 4-fold rise in antibody titer and lack of protective antibody level) – Documented inability to mount an adequate antibody response to polysaccharide antigens (Serum antibody titers to ≥ 14 pneumococcus serotypes should be measured prior to immunization and 3 to 6 weeks after immunization with polyvalent pneumococcal polysaccharide vaccine. An inadequate response is defined as less than a 4-fold rise in titer over baseline in at least 30% of serotypes tested (in at least 50% of serotypes tested in children aged 2 to 5 years) and lack of protective antibody level [i.e., specific IgG concentration less than 1.3 mcg/ml])
Severe combined immunodeficiency (SCID)	**Authorization Criteria:** • Evidence of qualitative and/or quantitative antibody production deficiency – Laboratory findings of low T cells, low IgA, IgE and IgM supporting the diagnosis

	• Documented recurrent or serious bacterial infections directly attributable to this deficiency
Specific antibody deficiency (SAD)	**Authorization Criteria:** • Documented normal serum IgG, IgA, and IgM • Normal responses to protein antigens (tetanus and diphtheria toxoid or HiB) measured 3 – 4 weeks after immunization • Inadequate responsiveness to pneumococcal polysaccharide vaccine (Pneumovax 23 or 20) 4–8 weeks after vaccination as defined by: – Age ≥ 6 years, < 70% of serotypes are protective (i.e., ≥ 1.3 mcg/mL per serotype) • Inadequate responsiveness to pneumococcal conjugate vaccine (Prevnar 13 or 15) 4–8 weeks after vaccination as defined by: – Age ≥ 6 years, < 70% of serotypes are protective (i.e., ≥ 1.3 mcg/mL per serotype) • Unexplained recurrent or persistent severe bacterial infections despite appropriate treatment with all of the following: – Aggressive management of underlying conditions predisposing to recurrent sinopulmonary infections (e.g., asthma, allergic rhinitis) – Prophylactic antibiotics – Increased vigilance and appropriate antibiotic therapy for infections
Wiskott-Aldrich Syndrome	**Authorization Criteria:** • Confirmed diagnosis of Wiskott-Aldrich Syndrome • IgG level must be below the normal range (>2 standard deviations below the age-specific mean) on at least two occasions while the Member is clear of infections • Documented recurrent or serious bacterial infections
X-linked immunodeficiency with hyperimmunoglobulin M	**Authorization Criteria:** • IgG levels must be below the normal range (>2 standard deviations below the age-specific mean) on at least **two (2)** occasions while the Member is clear of infections • Flow cytometry testing is supportive of diagnosis • Documented recurrent bacterial infections resulting from low IgG or serious bacterial or opportunistic infections
Hematology / Oncology	
Autoimmune Hemolytic Anemia, warm-type	**Authorization Criteria:** • Failure, contraindication or intolerance to both corticosteroids and splenectomy
Bone Marrow Transplant / Stem Cell Transplant	**Authorization Criteria:** • At risk for cytomegalovirus infection, pneumonia, or graft-vs-host (GVH) disease • Allogeneic or syngeneic transplant recipients requiring prophylaxis within the first **100** days post-transplant • Documentation of one (1) of the following: – Bone marrow transplant recipients with steroid-resistant graft-versus-host disease who are hypogammaglobulinemic (IgG level < 400 mg/dL) within the first **100** days post- transplant – After **100** days post-transplant, Member is markedly hypogammaglobulinemic (IgG level < 400 mg/dL) or Member has CMV, EBV or RSV infection
Chronic Lymphocytic Leukemia (CLL) with hypogammaglobulinemia ^	**Authorization Criteria:** • An immunoglobulin G (IgG) level of less than 600 mg/dl • Documentation of **one (1)** of the following: – Evidence of specific antibody deficiency – Demonstrated recurrent bacterial infection defined as one severe bacterial infection within preceding 6 months or at least two (2) bacterial infections in a 1-year period

Fetal or neonatal alloimmune thrombocytopenia	**Authorization Criteria:** • Documentation of **one (1)** of the following: – The Member has experienced a previous pregnancy affected by fetal alloimmune thrombocytopenia – A cordocentesis at 20 weeks reveals fetal platelets <100,000/µL – The neonate with severe thrombocytopenia is at high risk for developing intracranial hemorrhage when washed irradiated maternal platelets are not available, have not been successful, have become intolerable, or are contraindicated
Idiopathic Thrombocytopenia Purpura (ITP) – Acute	**Authorization Criteria:** • Management of acute bleeding due to severe thrombocytopenia (platelet counts less than 30,000/µl) • Documentation of one (1) of the following: – To increase platelet counts prior to invasive major surgical procedures (e.g., splenectomy); – In patients with severe thrombocytopenia (platelet counts less than 20,000/µL) considered to be at risk for intracerebral hemorrhage
Idiopathic Thrombocytopenia Purpura (ITP) – Chronic	**Authorization Criteria:** • Prior treatment with corticosteroids and splenectomy • Duration of illness greater than **six (6)** months • Age of **ten (10)** years or older • No concurrent illness/disease explaining thrombocytopenia, • Platelet counts persistently at or below 20,000/µl
Management of Immunotherapy-Related Toxicities - Immune Checkpoint Inhibitor-Related Toxicities	**Authorization Criteria:** • Documentation the patient is receiving therapy with a checkpoint inhibitor • Documentation the use of the requested medication is for the management of one (1) of the following immunotherapy-related toxicities: – Myocarditis that is not improved within 24 to 48 hours of starting pulse-dose methylprednisolone – As adjunctive therapy to rituximab for severe or life-threatening bullous dermatitis – Steven-Johnson Syndrome or Toxic Epidermal Necrolysis – Moderate or severe steroid-refractory myalgias or myositis – Severe myasthenia gravis – As adjunctive therapy to methylprednisolone for moderate to severe Guillain-Barre Syndrome or severe peripheral neuropathy – In combination with methylprednisolone for severe encephalitis – Transverse myelitis – Moderate or severe pneumonitis if no improvement after 48 to 72 hours of corticosteroids
Management of CAR-T Cell Related Toxicities	**Authorization Criteria:** • Documentation the patient has received treatment with CAR-T cell therapy • Documentation of **one (1)** of the following: – Secondary diagnosis of hypogammaglobulinemia defined as both of the following: • IgG less than 600 mg/d • Patient has a history of serious or recurrent bacterial infections associated with CAR-T cell therapy – Both of the following: • The patient is experiencing cytokine release syndrome • Cytokine release syndrome is refractory to high-dose corticosteroids AND anti-interluekin-6 therapy
Multiple Myeloma (MM) or other immunoproliferative neoplasms ^	**Authorization Criteria:** • Documented failure or inability to tolerate chemotherapy or radiation therapy. • IgG level less than 600 mg/dL • Documentation of one (1) of the following:

	– Evidence of specific antibody deficiency – "Plateau Phase" multiple myeloma (greater than **three (3)** months since diagnosis) and at least **two (2)** significant infections in last year or a single life-threatening infection.
Neonatal autoimmune thrombocytopenia (NIT)	**Authorization Criteria:** • Documentation of one (1) of the following: – Platelet count is < 30,000/µL – Member has bleeding complications related to thrombocytopenia
Neonatal hemochromatosis, prophylaxis	**Authorization Criteria:** • Treatment of pregnant women with a history of pregnancy ending in documented neonatal hemochromatosis.
Paraneoplastic opsoclonus-myoclonus-ataxia associated with neuroblastoma	**Authorization Criteria:** • Treatment of paraneoplastic opsoclonus-myoclonus-ataxia associated with neuroblastoma.
Post-transfusion purpura	**Authorization Criteria:** • Platelet count less than 10,000/µL • 2 to 14 days post-transfusion with bleeding complications
Secondary Hypogammaglobulinemia Due to: • Chemotherapeutic agents • Plasma Cell Leukemia (PCL) • Solid Organ Transplant	**Authorization Criteria:** • IgG level below normal (> 2 standard deviations below age- specific mean) on at least two (2) occasions when the Member is clinically well • Documentation of **one (1)** of the following: – Documented recurrent bacterial infections attributed to low IgG or serious bacterial / fungal infections – Prophylaxis for Members with secondary hypogammaglobulinemia undergoing therapy that causes additional immunosuppression without demonstrated infections
Toxic epidermal necrolysis/ Stevens–Johnson syndrome (TEN/SJS)	**Authorization Criteria:** • Acute treatment for severe cases only
Neurology	
Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), also known as Chronic Relapsing Polyneuropathy, including diabetes mellitus-CIDP and multifocal acquired demyelinating sensory and motor neuropathy (MADSAM) variant	**Authorization Criteria:** • Definitive diagnosis by a neurologist • Symmetric or focal neurologic deficits with slowly progressive or relapsing course over **two (2)** months or longer with neurophysiological abnormalities • Nerve conduction study showing diffuse demyelination • Member is intolerant or refractory to therapeutic doses of corticosteroids OR for steroid sparing in the case of chronic steroid use
Guillain-Barre Syndrome (GBS) (acute) – Acute inflammatory demyelinating polyneuropathy (AIDP) a.k.a. acute infective polyneuritis (includes GBS variants: Miller-Fisher syndrome, pan autonomic polyneuropathy, acute pandysautonomia, acute motor axonal neuropathy, and acute motor and sensory axonal neuropathy)	**Authorization Criteria:** • The disorder has been diagnosed during the first **two (2)** weeks of the illness • Immune globulin is initiated within **one (1)** month of symptom onset. • Initial requests for therapy may be approved for **two (2)** courses of therapy • Documented functional disability: – Significant weakness such as inability to stand or walk without aid, respiratory or bulbar weakness, or Miller- Fisher syndrome (MFS) • Plasmapheresis is not used concomitantly
Guillain-Barre Syndrome (GBS) (chronic) – Chronic inflammatory demyelinating polyneuropathy (CIDP)	**Authorization Criteria:** • Diffuse demyelination on nerve conduction study • Progressive symptoms have been present for ≥ **two (2)** months • Symptomatic polyradiculoneuropathy as exhibited by both of the following: – Progressive or relapsing motor or sensory impairment of more than one limb – Widespread hyporeflexia or areflexia • Failure, contraindication or intolerance to therapeutic doses of corticosteroids

Lambert - Eaton Myasthenic Syndrome (LEMS)	**Authorization Criteria:** • Treatment is initiated during or after treatment of the underlying malignancy if applicable **AND** • Previous treatment with **one (1)** agent from any of the following therapeutic classes, **OR** contraindication **OR** clinical inappropriateness to **ALL** of the following therapeutic classes: – Acetylcholinesterase inhibitors (e.g., pyridostigmine) – Aminopyridines (e.g., Firdapse; Ampyra; 3,4-DAP) – Guanidine **OR** • Immune globulin is used as an alternative to plasma exchange if weakness is severe or when there is difficulty with venous access for plasmapheresis.
Multifocal motor neuropathy (MMN)	**Authorization Criteria:** • The Member must have a definitive diagnosis of progressive, symptomatic multifocal motor neuropathy by a neurologist. • Progressive symptoms present for at least **two (2)** months. • Slowly progressive or stepwise progressive, asymmetric limb weakness, or motor involvement having a motor nerve distribution in **two (2)** or more nerves • No objective sensory abnormalities except for minor vibration sense abnormalities in the lower limbs • Definite conduction block on one nerve or probable conduction block on **two (2)** nerves • Normal sensory nerve conduction in upper limb segments with CB and normal sensory nerve action potential (SNAP) amplitudes
Myasthenia Gravis (MG)	**Authorization Criteria:** • Acute myasthenic crisis with respiratory failure or impending respiratory failure with severe bulbar symptoms, when there is contraindication to plasmapheresis • Failure, contraindication or intolerance to other treatments (e.g., azathioprine, cyclosporine, or cyclophosphamide)
Relapsing/Remitting Multiple Sclerosis (RRMS)	**Authorization Criteria:** • The Member must have a definitive diagnosis of relapsing, remitting multiple sclerosis (RRMS) • Immune globulin therapy must be prescribed by a neurologist • The Member has a documented inadequate response to an appropriate trial with at least two (2) disease modifying Multiple Sclerosis agents
Stiff person syndrome, autoimmune, idiopathic, paraneoplastic (Moersch-Woltmann Syndrome)	**Authorization Criteria:** • Presence of anti-glutamic acid decarboxylase (anti-GAD) antibodies or anti-amphiphysin antibodies • Failure, contraindication or intolerance to standard medical therapy including: – Benzodiazepines (e.g., diazepam) – clonidine – Corticosteroids (e.g., prednisone, methylprednisolone, dexamethasone) – phenytoin – Skeletal muscle relaxants (e.g., baclofen, tizanidine)
Pediatric autoimmune neuropsychiatric disorder associated with group A streptococci (PANDAS)	**Authorization Criteria:** • Documented diagnosis of PANDAS made by or in consultation with a pediatric psychiatrist or pediatric neurologist **Note:** Coverage of Intravenous Immunoglobulin therapy for the treatment of PANDAS is limited to all New Hampshire, Massachusetts, and Rhode Island residents.

Rheumatology	
Kawasaki Disease/Acute febrile mucocutaneous lymph node syndrome	**Authorization Criteria:** • Fever present for at least five (5) days • Treatment is initiated within ten (10) days of onset of fever • Four (4) of the following five symptoms are present: – Mucous membrane changes such as a red tongue and dry fissured lips – Swelling of the hands and feet – Enlarged lymph nodes in the neck – Diffuse red rash covering most of the body – Redness of the eyes • Oral aspirin is used concurrently as follows: oral aspirin 100 mg/kg daily until the 14th day of illness, then 3-5 mg/kg for a period of five weeks.
Transplant	
Solid organ transplant	**Authorization Criteria:** • Prior to transplant / peri-transplant: – Immune globulin may be approved to reduce anti-HLA antibodies – Member is at high risk of antibody-mediated rejection in highly sensitized transplant recipients – ABO-incompatible organ transplant • Post-transplant, documentation of one (1) of the following: – Member experiences an antibody-mediated rejection – For treatment of CMV pneumonitis in combination with antiviral therapy – High risk Member for prevention of cytomegalovirus infection or pneumonia in combination with antiviral treatment
Other	
Birdshot (vitiliginous) retinochoroidopathy	**Authorization Criteria:** • Condition is not responsive to or Member has a contraindication to immunosuppressants (e.g., corticosteroids, cyclosporine)

Limitations

- The Plan does not cover the subcutaneous immune globulin, Hizentra® unless the Member is unable to tolerate intravenous immune globulin or requires subcutaneous administration of immune globulin. Coverage criteria for intravenous immune globulin apply.
- For requests on behalf of Massachusetts and Rhode Island residents, all Health Plan fully insured Massachusetts Commercial products, Rhode Island Commercial products, the GIC and Health Direct members with a diagnosis of PANDAS, authorizations will be granted for 12 months, with a quantity of two infusions. Requests for additional infusions within a 12-month period will be reviewed on an individual basis for medical necessity.
- For all other requests, initial authorizations for ongoing treatment are limited to a maximum of three (3) months. Subsequent reauthorization requests may be approved in six (6)-month intervals except for covered primary humoral immunodeficiencies which may be approved in 12-month intervals.
- As there is inadequate evidence of efficacy and/or safety of treatment with IVIg or SCIg for the following conditions, the plan considers these uses experimental / investigational and will not approve coverage of IVIg and SCIg for any of the following conditions including but not limited to:

  Hematologic / Oncologic Conditions
  - Acquired factor VIII inhibitors
  - Acute lymphoblastic leukemia
  - Acute myelogenous leukemia
  - Aplastic anemia
  - Diamond-Blackfan anemia
  - Hemophagocytic syndrome
  - Non-immune thrombocytopenia
  - Red cell aplasia
  - Thrombotic thrombocytopenic purpura

Immunological Conditions
- Cellular immunodeficiencies
- Complement deficiencies
- Selective IgA deficiency

Infectious Conditions
- Chronic mucocutaneous candidiasis (CMCC)
- Chronic sinusitis
- Lyme disease
- Post-infectious sequelae
- Recurrent otitis media
- Rheumatic fever

Neurologic Conditions
- Alzheimer's Disease
- Amyotrophic lateral sclerosis (ALS)
- Demyelinating optic neuritis
- Encephalopathy
- Epilepsy
- Multiple Sclerosis: primary progressive, secondary progressive, or progressive relapsing
- Parkinson's Disease
- Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) (Covered for Tufts Health Freedom plans members only when coverage criteria is met)
- Paraneoplastic syndromes other than Lambert-Eaton syndrome or paraneoplastic opsoclonus- myoclonus-ataxia associated with neuroblastoma
- Transverse myelopathy / myelitis

Rheumatologic Diseases
- Behçet's syndrome
- Inclusion body myositis
- Reiter's syndrome
- Rheumatoid arthritis
- Scleroderma
- Systemic Lupus Erythematosus
- Other vasculitides besides Kawasaki disease; including vasculitis associated with anti- neutrophil cytoplasmic antibodies (ANCA), Wegener's granulomatosis, polyarteritis nodosa, Goodpasture's syndrome, and vasculitis associated with other connective tissue diseases

Other Conditions
- Adrenoleukodystrophy
- Antiphospholipid syndrome
- Asthma
- Atopic dermatitis
- Chronic fatigue syndrome
- Cystic fibrosis
- Diabetes Mellitus
- Eczema
- Hemolytic uremic syndrome
- Henoch-Schönlein purpura (HSP)
- Idiopathic environmental illness
- Idiopathic lumbosacral flexopathy
- Idiopathic pulmonary fibrosis
- Organ transplant rejection
- Recent-onset dilated cardiomyopathy
- Recurrent fetal loss
- SICCA syndrome / Sjogren's syndrome
- Uveitis (except Birdshot [vitiliginous] retinochoroidopathy)

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J1552	INJECTION, IMMUNE GLOBULIN (ALYGLO), 500 MG
90283	Immune Globulin (IgIV), human, for intravenous use
90284	Immune globulin (SCIg), human, for use in subcutaneous infusions, 100 mg, each
J1554	Injection, immune globulin (asceniv), 500 mg
J1459	Injection, immune globulin (privigen), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1555	Injection, immune globulin (cuvitru), 100 mg
J1551	Injection, immune globulin (Cutaquig), 100 mg
J1556	Injection, immune globulin (bivigam), 500 mg
J1557	Injection, immune globulin, (gammaplex), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1558	Injection, immune globulin (xembify), 100 mg
J1559	Injection, immune globulin (hizentra), 100 mg
J1561	Injection, immune globulin, (gamunex), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1566	Injection, immune globulin, intravenous, lyophilized (e.g., powder), not otherwise specified, 500 mg (Only panglobulin NF and gammagard S/D should be billed using this code)
J1568	Injection, immune globulin, (octagam), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1569	Injection, immune globulin, (gammagard), intravenous, non-lyophilized, (e.g., liquid), 500 mg
J1572	Injection, immune globulin, (flebogamma/flebogamma DIF), intravenous, non- lyophilized (e.g., liquid), 500 mg
J1575	Injection, immune globulin/hyaluronidase, (hyqvia), 100 mg immune globulin
J1576	Injection, immune globulin (Panzyga), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1599	Injection, immune globulin, intravenous, non-lyophilized (e.g. liquid), not otherwise specified, 500 mg
J1553	Injection, immune globulin (Yimmugo), 100 mg
J1577	Injection, immune globulin (Qivigy), 100 mg

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Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)

Subsequent endorsement date(s) and changes made:

- Originally approved September 13, 2022 by P&T and September 21, 2022 by MPAC committees effective January 1, 2023
- Administrative update: June 2023 added Medical Benefit Drugs to title and updated MATogether and RITogether fax numbers to 617-673-0939
- Coding update per HCPCS level II quarterly release. Effective date July 1, 2023, the following HCPCS codes have been added: J1576
- November 14, 2023: Added coverage criteria for Management of CAR-T Cell Related Toxicites. Added specific clinical requirements to coverage criteria for Management of Immunotherapy-Related Toxicities - Immune Checkpoint Inhibitor-Related Toxicities (eff 2/1/24).
- April 1, 2024: Administrative Update: Added J Code J1554 to Medical Necessity Guideline and removed expired C Code C9072.
- July 9, 2024: Added Alyglo (J1599) to the Medical Necessity Guideline (eff 10/1/24)
- Administrative update: November 2024: Added J code J1552, effective 1/1/25.
- July 8, 2025: Clarified Myasthenia Gravis coverage criteria language to indicate "failure, contraindication or intolerance to other treatments (e.g., azathioprine, cyclosporine, or cyclophosphamide)." Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template (eff 8/1/25)
- July 14, 2026: Added Qivigy (J1577) and Yimmugo (J1553) to the medical necessity guideline, effective 7/1/26 (backdated).

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the

individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.