

POLICY NAME	Immune Globulin Products	POLICY #	1815P
--------------------	--------------------------	-----------------	-------

Criteria

Coverage Criteria for Immunodeficiency Disorders

- ☐ Common Variable Immunodeficiency (CVID), Hypogammaglobulinemia (excluding IgA deficiency), or X-linked immunodeficiency Statement of the Policy Criteria
 - Documented serum IgG level below the lower limits of normal of the laboratory's reported value
- ☐ Immunosuppression related to B-cell chronic lymphocytic leukemia (CLL)
 - Documentation to support hypogammaglobulinemia or recurrent bacterial infections
- ☐ Immunosuppression related to multiple myeloma
 - Documentation to support diagnosis of multiple myeloma and hypogammaglobulinemia or recurrent infections
- ☐ Selective IgG subclass deficiencies
 - Documented serum immune globulin (Ex IgG, IgM, etc) level below the lower limits of normal of the laboratory's reported value
 - Documented history of recurrent infections causing extended antibiotic use

Coverage Criteria for Infection related conditions (Cutaquig, Cuvitru, Gammagard, Gamunex, Hizentra, Hyqvia, Octagam, Panzyga, Privigen Only)

- ☐ HIV
 - Children: diagnosis of HIV in children who either have been exposed to measles or who live in a high-prevalence measles area, HIV-related immune thrombocytopenic purpura
 - Adults: diagnosis of HIV-ITP who have severe bleeding
- ☐ Chronic enteroviral meningoencephalitis
- ☐ Staphylococcal or streptococcal toxic shock syndrome

Coverage Criteria for transplant related conditions

- ☐ Cytomegalovirus (CMV) viremia in solid organ transplants or cancer
- ☐ Bone marrow transplantation
 - Confirmed allogeneic bone marrow transplant within the last 100 days
 - Documented hypogammaglobulinemia with intent to prevent GVHD or infection

- ☐ Prevention or treatment of acute humoral rejection in renal transplants

Coverage Criteria for blood related conditions (Flebogamma, Gammaplex, Gammaked, Gamunex, Octagam, Panzyga, Privigen Only)

- ☐ Autoimmune hemolytic anemia with hemoglobin < 7 or hepatomegaly
- ☐ Hemolytic disease of newborn (Erythroblastosis Fetalis)
- ☐ Idiopathic thrombocytopenic purpura (ITP)
 - Diagnosis of ITP in patients with bleeding complications, unsafe platelet counts, or requiring invasive interventions
- ☐ Post-transfusion purpura
- ☐ Rasmussen syndrome
 - Diagnosis of Rasmussen syndrome with persistent disease symptoms despite surgical treatment (or not a candidate for surgery)
- ☐ Thrombocytopenia secondary to chronic condition
 - Thrombocytopenia related to hepatitis C infection, HIV or pregnancy
 - Documentation of unsafe platelet level

Coverage Criteria for nervous system related conditions

- ☐ Acute disseminated encephalomyelitis
 - Documented trial and failure of intravenous corticosteroids
- ☐ Guillain-Barre syndrome
 - Diagnosis of Guillain-Barre Syndrome with severe disease requiring aid to walk
 - Prescribed by or in consultation with a neurologist (nervous system doctor)
- ☐ Chronic inflammatory demyelinating polyneuropathy (CIDP)
 - Diagnosis of chronic inflammatory demyelinating polyneuropathy as confirmed by progressive or relapsing motor or sensory impairment of more than one limb for more than 2 months
 - Prescribed by or in consultation with a neurologist (nervous system doctor)
 - Documented trial and failure, intolerance or contraindication to corticosteroids (such as prednisone)
- ☐ IgM antimyelin-associated glycoprotein paraprotein-associated peripheral neuropathy
- ☐ Lambert-Eaton myasthenic syndrome (LEMS)
 - Diagnosis of Lambert-Eaton myasthenic syndrome (LEMS)
 - Prescribed by or in consultation with a neurologist (nervous system doctor)
 - Documented trial and failure with immunomodulator therapy (azathioprine, corticosteroids, etc)

- ☐ **Lennox Gastaut**
 - Diagnosis of Lennox Gastaut seizures
 - Prescribed by or in consultation with a neurologist (nervous system doctor)
 - Documented trial and failure with traditional anti-epileptics (lamotrigine, phenytoin, etc)
- ☐ **Moersch-Woltmann (Stiff-person) syndrome**
 - Diagnosis of stiff-person syndrome
 - Prescribed by or in consultation with a neurologist (nervous system doctor)
 - Documented trial and failure to benzodiazepines and/or baclofen, tizanidine, etc
- ☐ **Multifocal motor neuropathy (Gammagard only)**
 - Diagnosis of multifocal motor neuropathy as supported by weakness with continued progression over at least one month
 - Prescribed by or in consultation with a neurologist (nervous system doctor)
- ☐ **Myasthenia gravis (chronic or exacerbation)**
 - Diagnosis of generalized myasthenia gravis
 - Documentation to support exacerbation in symptoms over the last month
 - Prescribed by or in consultation with a neurologist (nervous system doctor)

Coverage Criteria for musculoskeletal related conditions

- ☐ **Dermatomyositis or polymyositis (Octagam only)**
 - Diagnosis of dermatomyositis or polymyositis
 - Documented trial and failure to immunosuppressive therapy (azathioprine, corticosteroids, etc)
- ☐ **Kawasaki disease (Gammagard only)**
 - Acute treatment only when given in conjunction with aspirin within 10 days of symptom onset
- ☐ **Severe rheumatoid arthritis refractory to conventional treatments (methotrexate, etc)**

Coverage Criteria for skin related conditions

- ☐ **Autoimmune bullous disease such as pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane pemphigoid, and epidermolysis bullosa acquisita**
 - Diagnosis of a supported autoimmune bullous disease that is extensive and debilitating
 - Documented trial and failure of corticosteroids with immunosuppressives

Coverage Criteria for eye related conditions

- ☐ **Birdshot retinochoroidopathy**
- ☐ **Autoimmune uveitis**
 - Diagnosis of refractory autoimmune uveitis
 - Documented trial and failure with corticosteroids in addition to immunosuppressants

- ☐ Graves' ophthalmopathy

Coverage Criteria for lung related conditions

- ☐ Churg-Strauss syndrome
 - Documented trial with corticosteroids in addition to cyclophosphamide