

POLICY NAME	Immune Globulin Products	POLICY #	1815P
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Criteria

Coverage Criteria for Immunodeficiency Disorders

- ☐ **1.1** 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
- ☐ **1.2** Immunosuppression related to B-cell chronic lymphocytic leukemia (CLL)
 - Documentation to support hypogammaglobulinemia or recurrent bacterial infections
- ☐ **1.3** Immunosuppression related to multiple myeloma
 - Documentation to support diagnosis of multiple myeloma and hypogammaglobulinemia or recurrent infections
- ☐ **1.4** 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)

- ☐ **2.1** 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
- ☐ **2.2** Chronic enteroviral meningoencephalitis
- ☐ **2.3** Staphylococcal or streptococcal toxic shock syndrome

Coverage Criteria for transplant related conditions

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

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

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

- ☐ 4.1 Autoimmune hemolytic anemia with hemoglobin < 7 or hepatomegaly
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- ☐ 4.2 Hemolytic disease of newborn (Erythroblastosis Fetalis)
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- ☐ 4.3 Idiopathic thrombocytopenic purpura (ITP)
- Diagnosis of ITP in patients with bleeding complications, unsafe platelet counts, or requiring invasive interventions
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- ☐ 4.4 Post-transfusion purpura
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- ☐ 4.5 Rasmussen syndrome
- Diagnosis of Rasmussen syndrome with persistent disease symptoms despite surgical treatment (or not a candidate for surgery)
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- ☐ 4.6 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

- ☐ 5.1 Acute disseminated encephalomyelitis
- Documented trial and failure of intravenous corticosteroids
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- ☐ 5.2 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)
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- ☐ 5.3 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)
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- ☐ 5.4 IgM antimyelin-associated glycoprotein paraprotein-associated peripheral neuropathy
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- ☐ 5.5 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)
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- ☐ 5.6 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)

☐ **5.7 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

☐ **5.8 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)

☐ **5.9 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

☐ **6.1 Dermatomyositis or polymyositis (Octagam only)**

- Diagnosis of dermatomyositis or polymyositis
- Documented trial and failure to immunosuppressive therapy (azathioprine, corticosteroids, etc)

☐ **6.2 Kawasaki disease (Gammagard only)**

- Acute treatment only when given in conjunction with aspirin within 10 days of symptom onset

☐ **6.3 Severe rheumatoid arthritis refractory to conventional treatments (methotrexate, etc)**

Coverage Criteria for skin related conditions

☐ **7.1 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

☐ **8.1 Birdshot retinochoroidopathy**

☐ **8.2 Autoimmune uveitis**

- Diagnosis of refractory autoimmune uveitis
- Documented trial and failure with corticosteroids in addition to immunosuppressants

☐ **8.3 Graves' ophthalmopathy**

Coverage Criteria for lung related conditions



9.1 Churg-Strauss syndrome

- Documented trial with corticosteroids in addition to cyclophosphamide