

Immune Globulin Injection



When requesting an immune globulin, the individual requiring treatment must be diagnosed with one of the following FDA-approved or approved off-label compendial requirements and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

The following intravenous immunoglobulin (IVIG) and subcutaneous immunoglobulin (SCIG) products are included in this policy: Bivigam[®], Carimune NF[®], Flebogamma DIF[®], Gammagard[®], Gammagard S/D[®], Gammaked[®], Gammaplex[®], Gamunex-C[®], Hizentra[®], HyQvia[®], Octagam[®], Privigen[®], and Cuvitru.

FDA-approved indications^{1-12,13,18,19,20}

- Treatment of primary humoral immunodeficiency (e.g., common variable immunodeficiency, X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, severe combined immunodeficiencies, etc.)
- Idiopathic thrombocytopenia purpura
- Maintenance therapy to improve muscle strength and disability in individuals with multifocal motor neuropathy
- Prevention of bacterial infections in hypogammaglobulinemia and/or recurrent bacterial infections associated with B-cell chronic lymphocytic leukemia
- Prevention of coronary artery aneurysms associated with Kawasaki disease
- Treatment of chronic inflammatory demyelinating polyneuropathy

Please note: the FDA-approved uses vary based on the respective immune globulin product.

Approved Off-label Compendial uses^{13,14,16,17,21-23}

- Autoimmune diseases
 - Autoimmune mucocutaneous blistering disease (i.e., pemphigus vulgaris or pemphigus foliaceus)
 - Dermatomyositis
 - Guillain-Barre syndrome
 - Myasthenia gravis, refractory
- Infectious and infection related diseases
 - Toxic shock syndrome
- Secondary immunodeficiencies
 - Multiple myeloma in the setting of recurrent life-threatening infection
 - To prevent serious bacterial infections in human immunodeficiency virus (HIV) infected pediatric individuals with hypogammaglobulinemia
- Transplant-related indications
 - Bone marrow transplant, to prevent infections and reduce the risk of developing graft-versus-host disease
 - Solid organ transplant
 - o Prophylaxis to reduce transplant rejection before transplant

- o Prophylaxis to reduce transplant rejection after transplant
- o Treatment of acute rejection

Coverage Guidelines

The individual has one of the following diagnoses and meets the criteria for coverage:

- Autoimmune diseases
 - Autoimmune mucocutaneous blistering disease^{13,17} (i.e., pemphigus vulgaris or pemphigus foliaceus)
 - o The individual has had an inadequate response, contraindication, or intolerance to corticosteroids and the immune globulin will be used short-term for this condition¹³
 - Chronic inflammatory demyelinating polyneuropathy^{5,7,13}
 - Dermatomyositis^{13,17,21}
 - o Is corticosteroid-resistant, or corticosteroids are contraindicated^{13,17,21}
 - Guillain-Barre syndrome as an equivalent alternative to plasma exchange^{13,21}
 - Idiopathic thrombocytopenia purpura^{2,5,7,11-13,18,20}
 - Multifocal motor neuropathy^{4,13}
 - Myasthenia gravis, refractory disease plus meets one of the following:^{13,22}
 - o As an adjuvant to other immunotherapies (e.g., prednisone, azathioprine, cyclosporine, or mycophenolate, etc.)²²
 - o As a “bridge” when initiating slower acting immunotherapies²²
 - o Used preoperatively before thymectomy²²
 - o For myasthenic crisis²²
- Infectious and infection related diseases
 - Kawasaki's disease^{13,17,18}
 - Toxic shock syndrome^{13,24}
- Primary and secondary immunodeficiencies
 - Recurrent bacterial infections associated with chronic lymphocytic leukemia^{13,15,18}
 - Common variable immunodeficiency^{1-10,12,13,16,20}
 - Congenital/X-linked agammaglobulinemia^{1-10,12,13,18-20}
 - Hyperimmunoglobulinemia E (hyper IgE) syndrome^{1-10,12,13,18,19}
 - Hypogammaglobulinemia^{16,18}
 - Multiple myeloma in the setting of recurrent life-threatening infection^{13,14}
 - Other primary humoral immunodeficiency^{1-10,12,13,18,19}
 - To prevent serious bacterial infections in human immunodeficiency virus (HIV) infected pediatric individuals with hypogammaglobulinemia (IgG < 400 mg/dL)^{13,23}
 - Severe combined immunodeficiencies^{1-10,12,13,18-20}
 - Wiskott-Aldrich syndrome^{1-10,12,13,18-20}
- Transplant-related indications¹³
 - Bone marrow transplant, to prevent infections and reduce the risk of developing graft-versus-host disease¹³
 - Solid organ transplant¹³
 - o Prophylaxis to reduce transplant rejection before transplant¹³
 - o Prophylaxis to reduce transplant rejection after transplant¹³
 - o Treatment of acute rejection¹³

Approval duration: 180 days

Safety Criteria^{1,12,18,19,20}

- *Thrombosis may occur with immune globulin products. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, the use of estrogens, indwelling vascular catheters, hyperviscosity and cardiovascular risk factors.
- *Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with the administration of immune globulin products in predisposed individuals. Renal dysfunction and acute renal failure occur more commonly in individuals receiving IVIG products containing sucrose.
- *For individuals at risk of thrombosis, renal dysfunction, or renal failure, administer immune globulin at the minimum dose and infusion rate practicable. Ensure adequate hydration in individuals before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in individuals at risk for hyperviscosity.
- *Contraindicated in IgA deficient individuals with antibodies to IgA and a history of hypersensitivity.
- *For Gammaplex only: Contraindicated in individuals with hereditary intolerance to fructose, also in infants and neonates for whom sucrose or fructose tolerance has not been established.
- *For Hizentra and Privigen only: Contraindicated in individuals with hyperprolinemia.
- *For HyQvia only: Contraindicated in individuals with a known systemic hypersensitivity to hyaluronidase

* Prescribers are alerted to the above safety concerns via educational points in the program.

References

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