

Jurisdiction Specific Medicare Part B Intravenous Immunoglobulin (IVIG)

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name
Alyglo
Asceniv
Bivigam
Flebogamma DIF
Gammagard Liquid
Gammagard S/D
Gammaked
Gammaplex
Gamunex-C
Octagam
Panzyga
Privigen
Yimmugo

Covered Uses

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

- Primary immunodeficiency syndrome
- Idiopathic thrombocytopenic purpura
- Kawasaki disease
- Hypogammaglobulinemia associated with B-cell chronic lymphocytic leukemia
- Bone marrow transplant

- Human immunodeficiency virus (HIV)
- Autoimmune myopathies
- Guillain-Barre syndrome
- Hyperimmunoglobulinemia E syndrome
- Lambert-Eaton myasthenic syndrome
- Multifocal motor neuropathy (MMN)
- Relapsing-remitting multiple sclerosis
- Bone marrow suppression and pure red cell aplasia
- Progressive pemphigus vulgaris
- Pemphigus foliaceus
- Bullous pemphigoid
- Mucous membrane pemphigoid
- Epidermolysis bullosa acquisita
- Stiff-person syndrome
- Myasthenia gravis
- Prevention and/or treatment of organ rejection
- Henoch-Schonlein purpura
- Paraneoplastic visual loss
- Chronic inflammatory demyelinating polyneuropathy (CIDP)
- Multiple myeloma

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

Primary Immunodeficiency Syndromes

Authorization of 6 months may be granted for treatment of primary immunodeficiency syndromes when IVIG will be used to replace or boost immunoglobulin G (IgG).

Idiopathic Thrombocytopenic Purpura

Authorization of 6 months may be granted for treatment of idiopathic thrombocytopenic purpura when a rapid rise in the platelet count is required such as prior to surgery, to control excessive bleeding, or to defer or avoid splenectomy.

Kawasaki Disease

Authorization of 1 month may be granted for treatment of Kawasaki disease when IVIG will be used in conjunction with aspirin.

B-cell Chronic Lymphocytic Leukemia

Authorization of 6 months may be granted for the prevention of recurrent bacterial infections in members with hypogammaglobulinemia associated with B-cell chronic lymphocytic leukemia.

Bone Marrow Transplant

Authorization of 6 months may be granted to decrease the risk of acute graft-versus-host disease, associated interstitial pneumonia and infections after bone marrow transplant in the first 100 days after transplantation.

Human Immunodeficiency Virus

Authorization of 6 months may be granted for treatment of children with human immunodeficiency virus (HIV) when both of the following criteria are met:

- The requested drug will be used to reduce the risk of bacterial infections
- The CD4 count is between 200 and 400 cells/mcL

Autoimmune Myopathies

Authorization of 6 months may be granted for the second-line treatment of certain autoimmune myopathies (dermatomyositis, polymyositis, myositis associated with antisynthetase syndrome, immune mediated necrotizing myopathy, and inclusion body myositis).

Guillain-Barre Syndrome

Authorization of 1 month may be granted for treatment of Guillain-Barre syndrome when both of the following criteria are met:

- The member is 18 years of age or older
- Guillain-Barre syndrome was diagnosed within the first 2 weeks of the illness.

Hyperimmunoglobulinemia E Syndrome

Authorization of 6 months may be granted for treatment of hyperimmunoglobulinemia E syndrome.

Lambert-Eaton Myasthenic Syndrome

Authorization of 6 months may be granted for treatment of Lambert-Eaton myasthenic syndrome (LEMS).

Multifocal Motor Neuropathy

Authorization of 6 months may be granted for treatment of multifocal motor neuropathy (MMN).

Relapsing-Remitting Multiple Sclerosis

Authorization of 6 months may be granted for treatment of relapsing-remitting multiple sclerosis (RRMS).

Parvovirus B19-induced Pure Red Cell Aplasia

Authorization of 6 months may be granted for treatment of severe anemia and pure red cell aplasia associated with bone marrow suppression with chronic parvovirus B19 viremia.

Autoimmune Mucocutaneous Blistering Diseases

Authorization of 6 months may be granted for treatment of biopsy proven autoimmune mucocutaneous blistering diseases when all of the following criteria are met:

- Member has one of the following diagnoses: pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane pemphigoid (cicatricial pemphigoid), or epidermolysis bullosa acquisita
- At least one of the following criteria is met regarding prior treatment with conventional therapy:
 - Member has failed conventional therapy
 - Member has a contraindication to conventional therapy
 - Member has rapidly progressive disease and a clinical response could not be affected quickly enough using conventional agents, and IVIG will be given in combination with conventional treatment
- IVIG will be used for short-term control of the member's condition and will not be used as maintenance therapy

Stiff-Person Syndrome

Authorization of 6 months may be granted for treatment of stiff person syndrome.

Myasthenia Gravis

Authorization of 6 months may be granted for treatment of myasthenia gravis when all of the following criteria are met:

- The member has profound, rapidly progressive and/or potentially life-threatening muscular weakness.
- The member is refractory to, or intolerant of cholinesterase inhibitors, corticosteroids, and azathioprine.

Organ Transplantation

Authorization of 6 months may be granted for prevention or treatment of organ rejection in members sensitized to living or cadaveric organ donors.

Henoch-Schonlein Purpura

Authorization of 6 months may be granted for treatment of Henoch-Schonlein purpura (Schonlein-Henoch).

Paraneoplastic Visual Loss

Authorization of 6 months may be granted for treatment of paraneoplastic visual loss.

Chronic Inflammatory Demyelinating Polyneuropathy

Authorization of 6 months may be granted for treatment of chronic inflammatory demyelinating polyneuropathy (CIDP).

Multiple Myeloma

Authorization of 6 months may be granted for the prevention of life-threatening infections due to reduced gamma globulins in members with multiple myeloma.

References

1. Intravenous Immunoglobulin (IVIG) (L34580) Version R22. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed May 14, 2024.
2. Billing and Coding: Intravenous Immunoglobulin (IVIG) (A56718) Version R16. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed May 14, 2024.
3. National Coverage Determination (NCD) for Intravenous Immune Globulin for the Treatment of Autoimmune Mucocutaneous Blistering Diseases (250.3- Version1). Accessed at: <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=158&ncdver=1&SearchType=Advanced&CoverageSelection=National&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&Keyword=Immune+Globulin&KeywordLookUp=Title&KeywordSearchType=Exact&kq=true&bc=IAAAACAAAAAAAAAA%3d%3d&>. Accessed May 14, 2024.