Reference number(s)
3950-A

Jurisdiction Specific Medicare Part B Intravenous Immune Globulin (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	Generic Name
Alyglo	immune globulin
Asceniv	immune globulin
Bivigam	immune globulin
Flebogamma DIF	immune globulin
Gammagard Liquid	immune globulin
Gammagard Liquid ERC	Immune globulin
Gammagard S/D	immune globulin
Gammaked	immune globulin
Gammaplex	immune globulin
Gamunex-C	immune globulin
Octagam	immune globulin
Panzyga	immune globulin
Privigen	immune globulin
Yimmugo	Immune globulin

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
- Idiopathic thrombocytopenic purpura (ITP)
- Chronic inflammatory demyelinating polyneuropathy
- Multifocal motor neuropathy
- Kawasaki syndrome

- B-cell chronic lymphocytic leukemia (CLL)
- Dermatomyositis
- Prevention of infections in patients with acquired hypogammaglobulinemia secondary to malignancy
- Acquired thrombocytopenia
- Antiphospholipid syndrome
- Asthma
- Autoimmune hemolytic anemia
- Autoimmune neutropenia
- Autoimmune retinopathy
- Secondary hypogammaglobulinemia
- Chronic graft versus host disease (GVHD)
- Scleromyxedema
- Systemic capillary leak syndrome (Clarkson's disease)
- Immune-mediated necrotizing myositis
- Bone marrow transplant
- Hematopoietic stem cell transplant
- Cerebellar ataxia due to Epstein-Barr virus infection
- Clostridium difficile colitis
- Adjunct to Crohn's disease treatment
- Cytomegalovirus treatment and prophylaxis
- Desensitization therapy – heart transplant
- Diabetic amyotrophy
- Hopkins' syndrome
- Acute disseminated encephalomyelitis
- Prophylaxis of enteritis due to rotavirus
- Epilepsy
- Gastroenteritis
- Granulomatosis with polyangiitis
- Guillain-Barre syndrome
- Hemolytic disease of fetus or newborn due to RhD isoimmunization, prophylaxis
- Hemophagocytic syndrome
- Induction of Factor VIII immune tolerance
- Measles (Rubeola) prophylaxis
- Moderate and severe immune checkpoint inhibitor-related toxicities
- Hypogammaglobulinemia from CAR-T therapy
- Herpes gestationis
- Prevention of bacterial infections in HIV infected patients
- Prevention of bacterial infections in post-surgical or ICU patients
- Isaacs syndrome
- Japanese encephalitis virus disease
- Severe IgA nephropathy
- Lambert-Eaton myasthenic syndrome

- Linear IgA dermatosis
- Lysinuric protein intolerance
- Prevention of bacterial infections in patients with multiple myeloma
- Multiple sclerosis
- Myasthenia gravis
- Myocarditis
- Prevention and treatment of bacterial infections in high-risk, preterm, low-birth-weight neonates
- Neonatal jaundice
- Otitis media
- Paraneoplastic visual loss
- Polyarteritis nodosa
- Polymyositis
- Post-transplant lymphoproliferative disorder
- Pure red cell aplasia
- Pyoderma gangrenosum
- Renal transplant rejection
- Respiratory syncytial virus infection
- Sepsis
- Stevens-Johnson syndrome
- Stiff-person syndrome
- Systemic lupus erythematosus
- Systemic onset juvenile chronic arthritis
- Systemic vasculitis
- Tetanus treatment and prophylaxis
- Fetal or neonatal thrombocytopenia
- Toxic epidermal necrolysis
- Toxic necrotizing fasciitis
- Toxic shock syndrome
- Heart transplant rejection
- Desensitization of highly sensitized patients awaiting renal transplantation
- Uveitis
- Varicella prophylaxis
- Von Willebrand disorder
- Pemphigus vulgaris
- Pemphigus foliaceus
- Bullous pemphigoid
- Mucous membrane pemphigoid (cicatricial pemphigoid)
- Epidermolysis bullosa acquisita
- Susac syndrome

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.

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3950-A

Coverage Criteria

Pure Red Cell Aplasia[1]

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

Hematopoietic Stem Cell Transplantation[1]

Authorization of 6 months may be granted for hematopoietic stem cell transplantation to prevent the risk of acute graft versus host disease, associated interstitial pneumonia (infectious or idiopathic) and infections (e.g., cytomegalovirus infections [CMV], varicella-zoster virus infection, and recurrent bacterial infection) when all of the following are met:

- The member is 20 years of age or older.
- IVIG will be used during the first 100 days after transplantation.
- IVIG will not be used for autologous transplants.

Chronic Graft versus Host Disease (GVHD)[1]

Authorization of 6 months may be granted for chronic graft versus host disease when all of the following criteria are met:

- Member has laboratory proven hypogammaglobulinemia with IgG levels <400 mg/dl.
- Member has at least one acute infection requiring hospitalization and/or parenteral antibiotics.
- Member has a confirmed diagnosis of chronic graft versus host disease.
- Member is at least 100 days post-transplant.

Systemic Lupus Erythematosus[1]

Authorization of 6 months may be granted for treatment of severe active systemic lupus erythematosus when other interventions have been unsuccessful, have become intolerable or are contraindicated.

Autoimmune Retinopathy[1]

Authorization of 6 months may be granted for treatment autoimmune retinopathy that is sight threatening and refractory to corticosteroids and immunosuppressant therapy.

Stiff-Man Syndrome[1]

Authorization of 6 months may be granted for treatment of stiff-man syndrome when both of the following criteria are met:

- Diagnosis has been confirmed by anti-glutamic acid decarboxylase (GAD antibody testing.

- Member had an inadequate response to first-line treatment (benzodiazepines [e.g., diazepam] and/or baclofen).

Susac Syndrome[1]

Authorization of 6 months may be granted for treatment of Susac syndrome when the member's disease is refractory or relapsing.

Autoimmune Mucocutaneous Blistering Diseases[5]

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

Acquired thrombocytopenia, acute disseminated encephalomyelitis, Guillain-Barre syndrome, Japanese encephalitis virus disease, Kawasaki disease, measles (rubeola) prophylaxis, moderate and severe immune checkpoint inhibitor-related toxicities, tetanus treatment and prophylaxis, toxic epidermal necrolysis, toxic shock syndrome, toxic necrotizing fasciitis, Steven-Johnson syndrome, varicella prophylaxis[1,3,4,5]

Authorization of 1 month may be granted for the treatment of acquired thrombocytopenia, acute disseminated encephalomyelitis, Guillain-Barre syndrome, Japanese encephalitis virus disease, Kawasaki disease, measles (rubeola) prophylaxis, moderate and severe immune checkpoint inhibitor-related toxicities, tetanus treatment and prophylaxis, toxic epidermal necrolysis, toxic shock syndrome, toxic necrotizing fasciitis, Steven-Johnson syndrome, varicella prophylaxis.

All Other Indications[1,3,4,5]

Authorization of 6 months may be granted for treatment of all other approvable indications listed in the covered use section of this document.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. When dose and/or frequency are different from the FDA-approved labeling, literature support for the specific schedule chosen should be available.

References

1. Off-Label Use of Intravenous Immune Globulin (IVIG) (L39314) Version R1. Available at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39314&ver=7&bc=0. Accessed May 14, 2025.
2. Billing and Coding: Off-Label Use of Intravenous Immune Globulin (IVIG) (A59105) Version R5. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed May 14, 2025.
3. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed May 14, 2025.
4. Micromedex Solutions [database online]. Truven Health Analytics, Greenwood Village, CO. Available at: https://www.micromedexsolutions.com. Accessed May 14, 2025.
5. 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=IAAAACAAAAAAAA%3d%3d&. Accessed May 14, 2025.