Reference number(s)
4792-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
Alyglo
Asceniv
Bivigam
Flebogamma DIF
Gammagard Liquid
Gammagard S/D
Gammaplex
Gammaked
Gamunex
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.

- Immunodeficiency Syndrome
- Primary thrombocytopenia
- Alloimmune thrombocytopenia, refractoriness to platelet transfusions.
- Post-transfusion purpura

- Lymphoid Leukemia
- Autoimmune hemolytic anemia
- Immune-mediated neutropenia
- Multiple Myeloma
- Pediatric intractable epilepsy
- Guillain-Barre syndrome
- Myasthenia gravis (MG)
- Lambert-Eaton Syndrome
- Chronic inflammatory demyelinating polyneuropathy (CIDP)
- Multifocal motor neuropathy
- Dermatomyositis
- Polymyositis
- Systemic lupus erythematosus (SLE)
- Systemic sclerosis dermatomyositis overlap syndrome
- Kawasaki disease
- Severe Vasculitic Syndromes, systemic (polyarteritis nodosa), Churg-Strauss Vasculitis, livedoid vasculitis (atrophie blanche)
- Stevens-Johnson Syndrome
- Toxic Epidermal Necrolysis
- Pemphigoid gestationis
- Pyoderma gangrenosum
- Neonatal alloimmune thrombocytopenia
- High risk pregnancy with history of infant with fetal-neonatal thrombocytopenia
- Wiskott-Aldrich Syndrome
- Anemia due to pure red cell aplasia
- Human Immunodeficiency Virus (HIV) infection
- Autoimmune mucocutaneous blistering disease
- Stiff-man syndrome
- Desensitization for a pre-kidney transplantation
- Post-transplantation to prevent rejection
- Scleromyxedema, mucinosis of the skin, focal mucinosis, lichen myxedematosus, or reticular erythematous mucinosis

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

Immunodeficiency Syndrome

Authorization of 6 months may be granted for treatment of immunodeficiency syndrome, including congenital agammaglobulinemia, such as x-linked agammaglobulinemia, common variable hypoglobulinemia, X-linked immunodeficiency with hyper-IgM, combined immunodeficiency.

Primary Thrombocytopenia

Authorization of 6 months may be granted for treatment of primary thrombocytopenia.

Alloimmune Thrombocytopenia, Refractoriness to Platelet Transfusions

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

- The condition is refractory to platelet transfusions.
- The member has severe thrombocytopenia of documented immune basis for whom other modalities for the member's condition have been unsuccessful or contraindicated.

Post-Transfusion Purpura

Authorization of 6 months may be granted for treatment of post-transfusion purpura as first-line therapy when the member has been severely affected by the condition.

Lymphoid Leukemia

Authorization of 6 months may be granted for the treatment of lymphoid leukemia when the member has either of the following:

- Hypogammaglobulinemia
- Recurrent bacterial infections

Autoimmune Hemolytic Anemia

Authorization of 6 months may be granted for treatment of autoimmune hemolytic anemia when the member has warm-type autoimmune hemolytic anemia that does not respond to corticosteroids.

Immune-Mediated Neutropenia

Authorization of 6 months may be granted for treatment of severe immune-mediated neutropenia that does not respond to other modalities or other modalities are contraindicated.

Multiple Myeloma

Authorization of 6 months may be granted for the treatment of stable (plateau phase) multiple myeloma when the member has a high risk of recurrent infections.

Pediatric Intractable Epilepsy

Authorization of 6 months may be granted for the treatment of pediatric intractable epilepsy when all of the following criteria are met:

- The member is a candidate for surgical resection.
- The requested medication is used as a last resort.

Guillain-Barre Syndrome

Authorization of 1 month may be granted for the treatment of Guillain-Barre syndrome when IVIG is used as an equivalent alternative to plasma exchange.

Myasthenia Gravis

Authorization of 1 month may be granted for treatment of severe myasthenia gravis when all of the following criteria are met:

- IVIG will be used to treat acute severe decompensation.
- Other treatments have been unsuccessful or are contraindicated.

Lambert-Eaton Syndrome

Authorization of 6 months may be granted for the treatment of Lambert-Eaton Syndrome when IVIG will be directed at decreasing the autoimmune response.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

Authorization of 6 months may be granted for treatment of adults with chronic inflammatory demyelinating polyneuropathy when IVIG will be used as an equivalent alternative to plasma exchange.

Multifocal Motor Neuropathy

Authorization of 6 months may be granted for treatment of multifocal motor neuropathy when all of the following criteria are met:

- The disease has been diagnosed on the basis of electrophysiologic findings that rule out other possible conditions that may not respond to IVIG treatment.
- IVIG will be used to treat disease that is progressive and symptomatic.

Dermatomyositis, Polymyositis, Stiff-man Syndrome, Systemic Lupus Erythematosus, Systemic Sclerosis Dermatomyositis Overlap Syndrome, Severe Vasculitic Syndromes, Systemic (Polyarteritis Nodosa), Churg-Strauss Vasculitis and Livedoid Vasculitis (Atrophie Blanche)

Authorization of 6 months may be granted for treatment of severe active disease when other interventions have been unsuccessful or intolerable for the following indications:

- Dermatomyositis
- Polymyositis
- Stiff-man syndrome
- Systemic lupus erythematosus
- Systemic sclerosis dermatomyositis overlap syndrome
- Severe vasculitic syndromes, systemic (polyarteritis nodosa), Churg-Strauss vasculitis, livedoid vasculitis (atrophie blanche)

Kawasaki Disease

Authorization of 1 month may be granted for the treatment of Kawasaki disease.

Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)

Authorization of 1 month may be granted for treatment of SJS or TEN when the condition is refractory to conventional therapy.

Pemphigoid Gestationis and Pyoderma Gangrenosum

Authorization of 6 months may be granted for treatment of pemphigoid gestationis or pyoderma gangrenosum when the condition is refractory to conventional therapy.

Neonatal Alloimmune Thrombocytopenia

Authorization of 6 months may be granted for treatment of severely thrombocytopenic, symptomatic neonates with neonatal alloimmune thrombocytopenia when all of the following criteria are met:

- There is a high risk of developing intracranial hemorrhage.
- Other interventions have been unsuccessful, became intolerable, or are contraindicated.

High Risk Pregnancy with History of Infant with Fetal-Neonatal Thrombocytopenia

Authorization of 6 months may be granted for treatment of high-risk pregnancy when the member has a history of a previously affected infant with fetal-neonatal thrombocytopenia.

Wiskott-Aldrich Syndrome

Authorization of 6 months may be granted for the treatment of Wiskott-Aldrich Syndrome.

Anemia due to Pure Red Cell Aplasia

Authorization of 6 months may be granted for the treatment of anemia due to pure red cell aplasia.

Human Immunodeficiency Virus (HIV) Infection

Authorization of 6 months may be granted to reduce significant bacterial infections in members infected with HIV when all of the following criteria are met:

- The member is younger than 13 years of age.
- There is evidence of either qualitative or quantitative humoral immunologic defects.
- The member continues to have current bacterial infections despite appropriate antimicrobial prophylaxis:
- Dose does not exceed 400 mg/kg body weight every 28 days

Autoimmune Mucocutaneous Blistering Diseases

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

- The 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 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 along with conventional treatment(s).
- IVIG will be used for short-term control of the member's condition and will not be used as maintenance therapy.

Desensitization for a Pre-Kidney Transplantation

Authorization of 6 months may be granted for desensitization for a pre-kidney transplantation when the member has a panel reactive antibody (PRA) of 80% or below.

Post Transplantation to Prevent Rejection

Authorization of 6 months may be granted to prevent rejection post transplantation.

Scleromyxedema, Mucinosis of the Skin, Focal Mucinosis, Lichen Myxedematosus, or Reticular Erythematous Mucinosis

Authorization of 6 months may be granted for treatment of scleromyxedema, mucinosis of the skin, focal mucinosis, lichen myxedematosus, or reticular erythematous mucinosis

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Guillain-Barre Syndrome, Kawasaki Disease, Myasthenia Gravis, Stevens-Johnson Syndrome (SJS), and Toxic Epidermal Necrolysis (TEN)

Authorization for 1 month may be granted when all of the following criteria are met:

- The member is currently receiving therapy with IVIG
- The member is receiving benefit from therapy. Benefit is defined as an objective response to therapy.

All Other Indications

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

- The member is currently receiving therapy with IVIG
- IVIG is being used to treat an indication listed in the coverage criteria section
- The member is receiving benefit from therapy. Benefit is defined as an objective response to therapy.

References

1. Immune Globulins LCD (L34771) 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: Immune Globulins (A57554) Version R9. 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=IAAAACAAAAAAAA%3d%3d&. Accessed May 14, 2024.