Reference number(s)
4451-A

JURISDICTION SPECIFIC MEDICARE PART B

INTRAVENOUS IMMUNOGLOBULIN (IVIG): Asceniv™, Bivigam®, Flebogamma® DIF, Gammagard® Liquid, Gammagard® S/D, Gammaked™, Gammaplex®, Gamunex®-C, Octagam®, Panzyga®, and Privigen®

POLICY

I. 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.

A. Primary immunodeficiency syndrome
B. Idiopathic thrombocytopenic purpura
C. Kawasaki disease
D. Hypogammaglobulinemia associated with B-cell chronic lymphocytic leukemia
E. Bone marrow transplant
F. Human immunodeficiency virus (HIV)
G. Autoimmune myopathies
H. Guillain-Barre syndrome
I. Hyperimmunoglobulinemia E syndrome
J. Lambert-Eaton myasthenic syndrome
K. Multifocal motor neuropathy (MMN)
L. Relapsing-remitting multiple sclerosis
M. Bone marrow suppression and pure red cell aplasia
N. Progressive pemphigus vulgaris
O. Pemphigus foliaceus
P. Bullous pemphigoid
Q. Mucous membrane pemphigoid
R. Epidermolysis bullosa acquisita
S. Stiff person syndrome
T. Myasthenia gravis
U. Prevention and/or treatment of organ rejection
V. Henoch-Schonlein purpura
W. Paraneoplastic visual loss
X. Chronic inflammatory demyelinating polyneuropathy (CIDP)
Y. Multiple myeloma

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

II. DOCUMENTATION

Legible documentation maintained in the member's medical record must be made available, upon request, for all submissions.

III. CRITERIA FOR APPROVAL

A. 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).

B. 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.

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

D. 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.

E. 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.

F. 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:
1. The requested drug will be used to reduce the risk of bacterial infections
2. The CD4 count is between 200 and 400 cells/mcL

G. 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).

H. Guillain-Barre syndrome
Authorization of 1 month may be granted for treatment of Guillain-Barre syndrome when both of the following criteria are met:
1. The member is 18 years of age or older
2. Guillain-Barre syndrome was diagnosed within the first 2 weeks of the illness.

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

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

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

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

M. 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.

N. 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:
1. Member has one of the following diagnoses: pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane pemphigoid (cicatricial pemphigoid), or epidermolysis bullosa acquisita
2. At least one of the following criteria is met regarding prior treatment with conventional therapy:
   a. Member has failed conventional therapy
   b. Member has a contraindication to conventional therapy
   c. 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
3. IVIG will be used for short-term control of the member's condition and will not be used as maintenance therapy

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

P. Myasthenia gravis
Authorization of 6 months may be granted for treatment of myasthenia gravis when all of the following criteria are met:
1. The member has profound, rapidly progressive and/or potentially life-threatening muscular weakness.
2. The member is refractory to, or intolerant of cholinesterase inhibitors, corticosteroids, and azathioprine.

Q. 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.

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

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

T. Chronic inflammatory demyelinating polyneuropathy

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

U. 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.

IV. REFERENCES

1. Intravenous Immunoglobulin (IVIG) (L34580) Version R20. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed October 13, 2022.
2. Billing and Coding: Intravenous Immunoglobulin (IVIG) (A56718) Version R13. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed October 13, 2022.
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 June 7, 2022.