Reference number
3997-A

JURISDICTION SPECIFIC MEDICARE PART B

Intravenous Immune Globulin (IVIG):

Alyglo, 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 humoral immunodeficiency (e.g., common variable immunodeficiency, congenital agammaglobulinemia, severe combined immunodeficiency, X-linked immunodeficiency hyperimmunoglobulin M, Wiskott-Aldrich syndrome)
B. Idiopathic thrombocytopenia purpura (ITP)
C. B-cell chronic lymphocytic leukemia (CLL)
D. Multifocal motor neuropathy
E. Multiple myeloma
F. Hypogammaglobulinemia following lymphoma treatment with B cell-depleting therapies
G. Hematopoietic stem cell transplantation
H. Human Leukocyte Antigen (HLA) and ABO desensitization for prevention of acute humoral rejection following renal transplantation
I. Antibody mediated solid organ transplant rejection
J. Hypogammaglobulinemia following solid organ transplants
K. Systemic capillary leak syndrome
L. Lambert-Eaton myasthenic syndrome
M. Relapsing-remitting multiple sclerosis
N. Neuromyelitis optica (Devic syndrome)
O. Autoimmune encephalitis
P. Susac syndrome
Q. Inclusion body myositis
R. Immune mediated necrotizing myopathy
S. Overlap syndrome with myositis including anti-synthetase syndrome
T. Systemic lupus erythematosus
U. Toxic epidermal necrolysis
V. Steven-Johnson syndrome
W. Severe scleromyxedema
X. Thyroid eye disease (Grave's disease)
Y. Guillain-Barre syndrome
Z. Chronic inflammatory demyelinating polyneuropathy (CIDP)
AA. Myasthenia gravis
BB. Polymyositis
CC. Dermatomyositis
DD. Kawasaki disease
EE. Autoimmune hemolytic anemia

FF. Autoimmune mucocutaneous blistering diseases
1. Pemphigus vulgaris
2. Pemphigus foliaceus
3. Bullous pemphigoid
4. Mucous membrane pemphigoid (cicatricial pemphigoid)
5. Epidermolysis bullosa acquisita

GG. Stiff-man (stiff-person) syndrome

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. CRITERIA FOR APPROVAL

A. Multiple myeloma

Authorization of 6 months may be granted for the treatment of multiple myeloma when both of the following are met:
1. Member has recurrent infections with hypogammaglobulinemia
2. Member has sub protective antibody levels following immunization against diphtheria, tetanus, or pneumococcal infection

B. Hypogammaglobulinemia following lymphoma treatment with B cell-depleting therapies

Authorization of 6 months may be granted for post lymphoma treatment utilizing B-cell depleting therapies with both of the following are met:
1. Member has recurrent infections with hypogammaglobulinemia
2. Member has sub protective antibody levels following immunization against diphtheria, tetanus, or pneumococcal infection

C. Hematopoietic stem cell transplants

Authorization of 6 month may be granted for recipients of hematopoietic stem cell transplants when either of the following is met:
1. Member has severe combined immunodeficiency (SCID) or other primary immunodeficiencies who are functionally agammaglobulinemic because of weak B-cell engraftment
2. Member has had an allogeneic transplant with chronic graft versus host disease, recurring bacterial infections, and sub protective antibody levels following immunization against diphtheria, tetanus, or pneumococcal infection

D. Antibody mediated solid organ transplant rejection

Authorization of 6 month may be granted for the treatment of antibody mediated solid organ transplant rejection when used in combination with rituximab and plasma exchange.

E. Myasthenia gravis

Authorization of 6 months may be granted for treatment of moderate to severe myasthenia gravis.

F. Neuromyelitis optica (Devic syndrome)

Authorization of 6 months may be granted for the treatment of neuromyelitis optica (Devic syndrome) when both of the following are met:
1. Member has had severe relapses that did not respond to corticosteroids
2. Member is not a candidate for plasma exchange

G. Autoimmune hemolytic anemia
Authorization of 6 months may be granted for the treatment of autoimmune hemolytic anemia when other treatment approaches have failed (e.g., corticosteroids, rituximab, azathioprine, cyclophosphamide).

H. Lambert-Eaton myasthenic syndrome
Authorization of 6 months may be granted for the treatment of Lambert-Eaton myasthenic syndrome in members who fail to respond or do not tolerate other treatments (e.g., amifampridine, pyridostigmine).

I. Susac syndrome
Authorization of 6 months may be granted for the treatment of Susac syndrome when used in combination with high-dose intravenous corticosteroids.

J. Polymyositis
Authorization of 6 months may be granted for the treatment of severe forms of polymyositis that is resistant to treatment with glucocorticoids and immunosuppressants (e.g., methotrexate, azathioprine, mycophenolate mofetil).

K. Inclusion body myositis
Authorization of 6 months may be granted for the treatment of severe forms of inclusion body myositis with dysphagia in members who are treatment resistant.

L. Immune mediated necrotizing myopathy
Authorization of 6 months may be granted for the treatment of immune mediated necrotizing myopathy that is resistant to treatment with glucocorticoids and immunosuppressants (e.g., methotrexate, azathioprine, mycophenolate mofetil).

M. Overlap syndrome with myositis including anti-synthetase syndrome
Authorization of 6 months may be granted for the treatment of overlap syndrome with myositis including anti-synthetase syndrome that is resistant to treatment with glucocorticoids and immunosuppressants (e.g., methotrexate, azathioprine, mycophenolate mofetil).

N. Systemic lupus erythematosus
Authorization of 6 months may be granted for the treatment of severe systemic lupus erythematosus in members who fail to respond or do not tolerate other treatment (e.g., corticosteroids, hydroxychloroquine, cyclophosphamide, rituximab).

O. Autoimmune encephalitis
Authorization of 1 month may be granted for the treatment of autoimmune encephalitis when infection has been ruled out.

P. Thyroid eye disease (Grave's disease)
Authorization of 6 months may be granted for the treatment of thyroid eye disease (Grave's disease) when the member has failed treatment or has a contraindication to teprotumumab.

Q. 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

R. Guillain-Barre syndrome, Kawasaki disease, toxic epidermal necrolysis, Steven-Johnson syndrome

Authorization of 1 month may be granted for the treatment of Guillain-Barre syndrome, Kawasaki disease, toxic epidermal necrolysis, and Steven-Johnson syndrome.

S. All other indications

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

III. REFERENCES

1. Intravenous Immune Globulin (IVIG) LCD (L35093) Version R18. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed May 10, 2023.
2. Billing and Coding: Intravenous Immune Globulin (IVIG) (A56786) Version R7. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed May 10, 2023.
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 10, 2023

