

Intravenous Immune Globulins (Flebogamma DIF, Gammagard Liquid, Gammagard S/D, Gammaked, Gammaplex, Gamunex-C, Octagam, Privigen)



When requesting Intravenous Immune Globulins (Flebogamma DIF, Gammagard Liquid, Gammagard S/D, Gammaked, Gammaplex, Gamunex-C, Octagam, Privigen), the individual requiring treatment must be diagnosed with an FDA-approved indication or an approved compendial use and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved indications

Intravenous Immune globulin (IVIG) injection is indicated for the treatment of:

- Primary humoral immunodeficiency including but not limited to, congenital agammaglobulinemia, common variable immunodeficiency, x-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.
- Idiopathic thrombocytopenia purpura (ITP) to raise platelet counts to prevent bleeding or to allow a patient with ITP to undergo surgery
- Chronic inflammatory demyelinating polyneuropathy (CIDP) to improve neuromuscular disability and impairment and for maintenance therapy to prevent relapse
- Multifocal motor neuropathy (MMN) to improve muscle strength and disability
- Prevention of bacterial infections in hypogammaglobulinemia and/or recurrent bacterial infections associated with B-cell chronic lymphocytic leukemia
- Prevention of coronary artery aneurysms associated with Kawasaki syndrome

Approved Off-label Compendial uses

- Secondary humoral immunodeficiency
- Guillain-Barre syndrome
- Dermatomyositis or polymyositis
- Myasthenia gravis
- Lambert-Eaton myasthenic syndrome
- Post-exposure prophylaxis of measles
- Post-exposure prophylaxis of varicella

Coverage Guidelines

For all approved indications, the individual must meet **ALL** of the following criteria for approval:

- For an individual with immunoglobulin A (IgA) deficiency, does not have antibodies to IgA AND a history of hypersensitivity
- For Privigen request, an individual does not have hyperprolinemia type I or II

For primary humoral immunodeficiency

- For an initial authorization, an individual has serum immunoglobulin G (IgG) level less than 400 mg/dL
- For re-authorization, there have been decrease in the occurrence of infections with IVIG treatments

For secondary humoral immunodeficiency:

- An individual must have one of the following diseases/conditions: chronic lymphocytic leukemia, human immunodeficiency virus (HIV) infection in pediatrics, post hematopoietic stem cell transplantation, or post bone marrow transplantation
- For an initial authorization, an individual has serum IgG level less than 400 mg/dL
- For re-authorization, there have been decrease in the occurrence of infection with IVIG treatments

For multifocal motor neuropathy, prevention of coronary artery aneurysms associated with Kawasaki syndrome, chronic inflammatory demyelinating polyneuropathy, and Guillain-Barre syndrome:

- For re-authorization, an individual's condition has improved or stabilized with IVIG treatments

For immune thrombocytopenic purpura, dermatomyositis/polymyositis, myasthenia gravis, and Lambert-Eaton myasthenic syndrome:

- For an initial authorization, disease is refractory to standard treatment(s)
- For re-authorization, an individual's condition has improved or stabilized with IVIG treatments

Approval duration (initial and renewal): 6 months

For post-exposure prophylaxis of measles:

- Has been exposed to measles less than 6 days previously **AND**
- Does not have laboratory evidence of measles immunity or confirmation of prior measles infection **AND**
- At increased risk for severe measles and complications

For post-exposure prophylaxis of varicella:

- Varicella Zoster Immune Globulin (VZIG) is not available

Approval duration: one dose (30 days)

Dosing Recommendations

Flebogamma/Octagam

Primary immunodeficiency (PI): the recommended dose is 300 to 600 mg/kg administered every 3 to 4 weeks

Idiopathic thrombocytopenic purpura (ITP): the recommended dose is 1 g/kg administered intravenously daily for 2 consecutive days

Gammagard Liquid

PI: the recommended dose is 300 to 600 mg/kg administered intravenously every 3 to 4 weeks. For subcutaneous administration, the recommended dose is 1.37 x previous intravenous dose

Multifocal motor neuropathy (MMN): The recommended dose is 0.5 to 2.4 g/kg per month based on clinical response

Gammagard S/D

PI: the recommended dose is 300 to 600 mg/kg administered every 3 to 4 weeks

B-cell chronic lymphocytic leukemia: The recommended dose is 400 mg/kg every 3 to 4 weeks

Kawasaki syndrome: The recommended dose is a single 1 g/kg or a dose of 400 mg/kg for 4 consecutive days beginning within seven days of the onset of fever

ITP: the recommended dose is 1 g/kg. The need for additional doses can be determined by clinical response and platelet count. Up to three separate doses may be given on alternate days if required.

Gammaked/Gamunex-C

PI: the recommended dose is 300 to 600 mg/kg administered intravenously every 3 to 4 weeks. For subcutaneous administration, the recommended dose is 1.37 x current IV dose in grams/IV dose intervals in weeks

ITP: the recommended dose is 2 g/kg, divided in two doses of 1 g/kg given intravenously on two consecutive days or into five doses of 0.4 g/kg given on five consecutive days.

Chronic inflammatory demyelinating polyneuropathy (CIDP): the recommended dose is loading dose 2 g/kg administered intravenously in divided doses over 2 to 4 consecutive days following with maintenance dose of 1 g/kg is administered over 1 day or divided into 2 doses of 0.5 g/kg given on 2 consecutive days, every 3 weeks.

Gammaplex

PI: The recommended dose is 300 to 800 mg/kg administered every 3-4 weeks

ITP: The recommended dose is 1 g/kg administered intravenously for 2 consecutive days

Privigen

PI: The recommended dose is 200 to 800 mg/kg administered intravenously every 3-4 weeks

ITP: The recommended dose is 1 g/kg administered intravenously for 2 consecutive days

CIPD: The recommended dose is loading dose 2 g/kg administered intravenously in divided doses over 2 to 5 consecutive days following with maintenance dose of 1 g/kg administered in 1 to 2 infusions on consecutive days, every 3 weeks.

References

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6. Gamunex-C prescribing information. Research Triangle Park, NC. Grifols Therapeutics Inc. March 2017.
7. Privigen prescribing information. Kankakee, IL. CSL Behring LLC. September 2017.
8. Octagam 5% prescribing information. Hoboken, NJ. Octapharma USA Inc. October 2014.
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