SPECIALTY GUIDELINE MANAGEMENT

Intravenous Immune Globulin (IVIG):
Bivigam®, Carimune® NF, Flebogamma® DIF, Gammagard® Liquid, Gammagard® S/D, Gammaked™, Gammaplex®, Gamunex®-C, Octagam®, and Privigen®

POLICY
A. INDICATIONS
The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
- Primary immunodeficiency
- Idiopathic thrombocytopenic purpura
- Chronic inflammatory demyelinating polyneuropathy
- Multifocal motor neuropathy
- Kawasaki syndrome
- B-cell chronic lymphocytic leukemia

Compendial Uses
- Dermatomyositis
- Polymyositis
- Myasthenia gravis
- Guillain-Barre syndrome
- Lambert-Eaton myasthenic syndrome
- Fetal/neonatal alloimmune thrombocytopenia
- Parvovirus B19-induced pure red cell aplasia
- Prophylaxis of bacterial infections in pediatric human immunodeficiency virus (HIV) infection
- Prophylaxis of bacterial infections in bone marrow transplant (BMT)/hematopoietic stem cell transplant (HSCT) recipients

All other indications are considered experimental/investigational and are not a covered benefit.

B. EXCLUSIONS
1. Immunoglobulin A (IgA) deficiency with antibodies to IgA and a history of hypersensitivity
2. History of anaphylaxis or severe systemic reaction to the administration of human immune globulin or product components
3. Hyperprolinemia in those prescribed Privigen (contains the stabilizer L-proline)

C. CRITERIA FOR APPROVAL
1. Primary Immunodeficiency
   a. Authorization of 24 months may be granted to members who are prescribed IVIG for primary immunodeficiency.
   b. Gammagard Liquid, Gamunex-C, and Gammaked may be administered intravenously or subcutaneously for primary immunodeficiency.

2. Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
   a. Authorization of 24 months may be granted to members who are prescribed IVIG for CIDP.

3. Multifocal Motor Neuropathy (MMN)
   a. Authorization of 12 months may be granted to members who are prescribed IVIG for MMN.
4. Dermatomyositis or Polymyositis
   a. Authorization of 12 months may be granted to members who are prescribed IVIG for dermatomyositis or polymyositis and ONE of the following criteria is met:
      i. Standard first-line treatments (corticosteroids or immunosuppressants) have been tried but were unsuccessful or not tolerated, OR
      ii. Member is unable to receive standard first-line therapy because of a contraindication or other clinical reason.

5. Guillain-Barre Syndrome (GBS)
   a. Authorization of 12 months may be granted to members who are prescribed IVIG for GBS and BOTH of the following criteria are met:
      i. Physical mobility is severely affected such that member requires an aid to walk, AND
      ii. IVIG therapy will be initiated within 2 weeks of symptom onset.

6. Myasthenia Gravis
   a. Authorization of 12 months may be granted to members who are prescribed IVIG for myasthenia gravis.

7. Lambert-Eaton Myasthenic Syndrome (LEMS)
   a. Authorization of 12 months may be granted to members who are prescribed IVIG for LEMS.

8. Idiopathic Thrombocytopenic Purpura (ITP)
   a. Authorization of 6 months may be granted for members who are prescribed IVIG for ITP.

9. Parvovirus B19-induced Pure Red Cell Aplasia (PRCA)
   a. Authorization of 6 months may be granted for members who are prescribed IVIG for parvovirus B19-induced PRCA.

10. Kawasaki Syndrome
    a. Authorization of 6 months may be granted for members who are prescribed IVIG for Kawasaki syndrome.

11. Fetal/Neonatal Alloimmune Thrombocytopenia (F/NAIT)
    a. Authorization of 6 months may be granted for members who are prescribed IVIG for F/NAIT.

12. B-cell Chronic Lymphocytic Leukemia (CLL)
    a. Authorization of 6 months may be granted to members with CLL and BOTH of the following criteria are met:
       i. IVIG is prescribed for prophylaxis of bacterial infections, AND
       ii. Member has hypogammaglobulinemia (pretreatment serum IgG <500 mg/dL) OR member has a history of recurrent bacterial infections.

13. Prophylaxis of Bacterial Infections in HIV-Infected Pediatric Patients
    a. Authorization of 6 months may be granted to pediatric members with HIV infection and ALL of the following criteria are met:
       i. IVIG is prescribed for prophylaxis of bacterial infections, AND
       ii. Member is ≤ 12 years of age, AND
       iii. Member has hypogammaglobulinemia (pretreatment serum IgG <400 mg/dL) OR member has a history of recurrent bacterial infections.

14. Prophylaxis of Bacterial Infections in BMT/HSCT Recipients
    a. Authorization of 6 months may be granted to members who are BMT/HSCT recipients and meet BOTH of the following criteria:
       i. IVIG is prescribed for prophylaxis of bacterial infections, AND
       ii. Member has hypogammaglobulinemia (pretreatment serum IgG <400 mg/dL)
D. OTHER CRITERIA

1. When Gammagard Liquid, Gamunex-C and Gammaked will be administered subcutaneously, they may be approved for primary immunodeficiency only.

2. Members with impaired renal function or with any of the following risk factors for renal dysfunction who are prescribed IVIG for intravenous administration must receive the minimum dose or concentration available and at the minimum rate of infusion practicable:
   a. Pre-existing renal insufficiency
   b. Diabetes mellitus
   c. Advanced age (older than 65 years of age)
   d. Volume depletion
   e. Sepsis
   f. Paraproteinemia
   g. Receiving known nephrotoxic drug(s)

3. Members with any of the following risk factors for thrombosis who are prescribed IVIG for intravenous or subcutaneous administration must receive the minimum dose or concentration available and at the minimum rate of infusion practicable:
   a. Advanced age (45 years of age or older)
   b. Prolonged immobilization
   c. Hypercoagulable condition
   d. History of venous or arterial thrombosis
   e. Use of estrogens
   f. Indwelling central vascular catheter
   g. Hyperviscosity
   h. Cardiovascular risk factor(s)

E. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

F. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

REFERENCES


