

## **Specialty Pharmacy Program**

### **Intravenous Immune Globulin (IVIG):**

**Carimune NF**  
**Flebogamma 5% DIF**  
**Flebogamma 10% DIF**  
**Gammagard 10% Liquid**  
**Gammagard S/D**  
**Gammaplex 5% Liquid**  
**Gamunex/Gamunex-C 10% Liquid**  
**Octagam 5% Liquid**  
**Privigen 10% Liquid**

#### **DESCRIPTION**

Intravenous immune globulin (IVIG) contains antibodies normally present in adult human blood. IVIG products are indicated for replacement therapy in patients with primary immunodeficiencies. Certain IVIG products are also indicated for the treatment of idiopathic thrombocytopenic purpura, chronic inflammatory demyelinating polyneuropathy, Kawasaki syndrome, and B-cell chronic lymphocytic leukemia.

#### **APPROVAL DURATION**

Approval duration: 1 year

#### **APPROVAL CRITERIA**

- I. IVIG requests may be approved based on the following FDA-approved indications:
  - A. Treatment of primary immunodeficiencies, including:
    - 1. Hypogammaglobulinemia **OR**
    - 2. Congenital agammaglobulinemia (X-linked agammaglobulinemia) **OR**
    - 3. Common variable immunodeficiency **OR**
    - 4. X-linked immunodeficiency with hyperimmunoglobulin M **OR**
    - 5. Severe combined immunodeficiency **OR**
    - 6. Wiskott-Aldrich syndrome
      - a. Gamunex/Gamunex-C may be administered intravenously or subcutaneously for primary immunodeficiencies
  - OR**
  - B. Treatment of idiopathic thrombocytopenic purpura (ITP) **OR**
  - C. Treatment of Kawasaki Syndrome **OR**
  - D. Patients with hypogammaglobulinemia and/or recurrent bacterial infection associated with B-cell chronic lymphocytic leukemia (CLL) **OR**
  - E. Chronic inflammatory demyelinating polyneuropathy (CIDP)
    - a. IVIG should be considered as a first-line treatment of CIDP.
    - b. IVIG is used alone or following therapeutic plasma exchange to prolong its effect. IVIG is considered easier to use than repeated therapeutic plasma exchange and to have fewer complications than long-term glucocorticoid therapy.

- II. IVIG requests may be approved based on the following medically accepted uses:
- A. To reduce the risk of graft-versus-host disease associated with interstitial pneumonia (infectious or idiopathic) and infections (cytomegalovirus infections, Varicella-zoster virus infection, and recurrent bacterial infection) in allogeneic bone marrow transplant (BMT) patients in the first 100 days after transplantation **OR**
  - B. Prevention of infection in HIV infected pediatric patients **OR**
  - C. Prevention of infection in bone marrow transplant patients **OR**
  - D. Antenatal alloimmune thrombocytopenia **OR**
  - E. Autoimmune neutropenia **OR**
  - F. Dermatomyositis, refractory; (IVIG is used as a second line treatment of dermatomyositis. Corticosteroids are first-line treatments of dermatomyositis) **OR**
  - G. Lambert-Eaton myasthenic syndrome treatment **OR**
  - H. Guillain-Barre Syndrome (acute demyelinating polyneuropathy) as an equivalent alternative to plasma exchange **OR**
  - I. Hyperimmunoglobulinemia E syndrome (HIE) treatment **OR**
  - J. Multifocal motor neuropathy in patients with elevated anti GM1 antibodies and motor conduction block **OR**
  - K. Multiple sclerosis, relapsing-remitting treatment (IVIG is used as a second-line treatment of relapsing-remitting multiple sclerosis) **OR**
  - L. Myasthenia gravis, severe refractory **OR**
  - M. Polymyositis; routine use of IVIG is not recommended. IVIG may be considered in patients with severe polymyositis for whom other treatments have been unsuccessful, have become intolerable, or are contraindicated **OR**
  - N. Prior to a medically necessary renal transplantation for suppression of panel reactive anti-HLA antibodies in patients with high panel reactive antibody (PRA) levels to human leukocyte antigens (HLA) **OR**
  - O. Prevention of infections in high-risk, preterm, low birth weight neonates **OR**
  - P. Stiff-person syndrome not controlled by other therapies **OR**
  - Q. Toxic shock syndrome caused by staphylococcal or streptococcal organisms refractory to several hours of aggressive therapy **OR**
  - R. Solid organ transplant recipients at risk for CMV **OR**
  - S. Treatment of chronic parvovirus B19 infection associated with bone marrow suppression and severe anemia **OR**
  - T. Refractory auto-immune mucocutaneous blistering diseases including:
    - 1. Pemphigus vulgaris **OR**
    - 2. Pemphigus foliaceus **OR**
    - 3. Bullous pemphigoid **OR**
    - 4. Mucous membrane pemphigoid **OR**
    - 5. Epidermolysis bullosa acquisita.

III. IVIG may NOT be approved for treatment of recurrent spontaneous abortion (RSA).

IV. Gamunex-C for subcutaneous use may be approved for primary immunodeficiency disease only.