

2-20-07



# CIGNA HEALTHCARE COVERAGE POSITION

**Subject Immune Globulin Intravenous (Human) (IGIV): Carimune™ NF, Flebogamma®, Gammagard™, Gamunex®, Iivegam® EN, Octagam®, Polygam® S/D**

Revised Date ..... 9/15/2006  
Original Effective Date ..... 8/01/2005  
Coverage Position Number ..... 5026

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## Hyperlink to Related Coverage Positions

### INSTRUCTIONS FOR USE

Coverage Positions are intended to supplement certain standard CIGNA HealthCare benefit plans. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Positions are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Position. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Positions. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Positions and; 4) the specific facts of the particular situation. Coverage Positions relate exclusively to the administration of health benefit plans. Coverage Positions are not recommendations for treatment and should never be used as treatment guidelines. ©2006 CIGNA Health Corporation

## Coverage Position

**CIGNA HealthCare covers immune globulin intravenous (human) (IGIV) as medically necessary when ANY of the following indications are met:**

- treatment of primary immunodeficiency syndrome, such as:
  - congenital / X-linked agammaglobulinemia
  - hypogammaglobulinemia
  - common variable immunodeficiency
  - X-linked immunodeficiency with hyperimmunoglobulin M
  - severe combined immunodeficiency
  - Wiskott-Aldrich syndrome
- treatment of idiopathic thrombocytopenic purpura
- treatment of Kawasaki disease in conjunction with aspirin within ten days of onset of symptoms
- prevention of recurrent bacterial infections in patients with hypogammaglobulinemia associated with B-cell chronic lymphocytic leukemia (CLL)
- prevention of the risk of infection in bone marrow transplantation (BMT) in recipients who are age 20 or older in the first 100 days after transplantation
- prevention of mild to severe bacterial infections in ANY of the following:
  - human immunodeficiency virus (HIV)-infected children with CD4+ counts > 200/µl, when used in conjunction with zidovudine or other antiretroviral treatment
  - HIV-positive children and adolescents who either have been exposed to measles or live in a high-prevalence measles area
  - maternal-fetal transmission of HIV in women who are in their third trimester of pregnancy, when used in conjunction with zidovudine or other antiretroviral treatment

- treatment of dermatomyositis or polymyositis in patients who have failed standard medical therapy (e.g., corticosteroids and/or immunosuppressants) or when steroids are contraindicated
- treatment of Guillain-Barré syndrome (i.e., acute inflammatory demyelinating polyneuropathy (AIDP) and chronic inflammatory demyelinating polyneuropathy (CIDP)
- treatment of hyperimmunoglobulinemia E syndrome
- treatment of Lambert-Eaton myasthenic syndrome (LEMS)
- treatment of multifocal motor neuropathy (MMN) in patients who have a failure, contraindication, or intolerance to standard medical therapy
- • treatment of relapsing-remitting multiple sclerosis (MS) in patients who have a failure, contraindication, or intolerance to standard medical therapy (e.g., interferon beta-1a, interferon beta-1b)
- prevention of, and as a treatment adjunct in, infections in some high-risk, preterm, low-birth-weight neonates
- treatment of chronic parvovirus B19 infection and severe anemia associated with bone marrow suppression
- treatment of neonatal isoimmune hemolytic disease in conjunction with phototherapy
- use in allosensitized solid organ transplants
- prevention of infection in patients with multiple myeloma
- treatment of stiff person syndrome (Moersch-Woltmann Syndrome) in patients who have a failure, contraindication, or intolerance to standard medical therapy (e.g., diazepam, baclofen, phenytoin, clonidine, or tizanidine)
- treatment of fetal alloimmune thrombocytopenia when fetal thrombocytopenia is documented or there is evidence of fetal symptoms (i.e., intracranial hemorrhage in utero)
- prevention of the risk of infection in allogeneic hematopoietic stem cell transplant (HSCT) recipients who experience severe hypogammaglobulinemia (i.e., Immunoglobulin G [IgG] less than 400 mg/dL) within the first 100 days after transplant
- treatment of acute myasthenic crisis with decompensation when there is a failure, contraindication, or intolerance to other therapies (IGIV therapy should not exceed two to five days in length)
- treatment of staphylococcal or streptococcal toxic shock syndrome when the infection is refractory to several hours of aggressive therapy, an undrainable focus is present, or the patient has persistent oliguria with pulmonary edema

**CIGNA HealthCare does not cover immune globulin intravenous (human) (IGIV) for the following indications because it is considered experimental, investigational or unproven (this list may not be all inclusive):**

- amyotrophic lateral sclerosis
- intractable pediatric epilepsy
- autoimmune neutropenia
- immune mediated blistering diseases including ANY of the following:
  - > pemphigus
  - > paraneoplastic pemphigus
  - > pemphigoid
  - > linear IgA bullous disease
  - > cicatricial pemphigoid
  - > epidermolysis bullosa acquisita
  - > Stevens-Johnson syndrome (bullous erythema multiforme)
  - > toxic epidermal necrolysis
- recurrent spontaneous miscarriage