Intravenous Immune Globulin (IVIG)

Bivigam, Carimune NF, Flebogamma DIF, Gammagard Liquid, Gammagard S/D, Gammaked, Gammaplex, Gamunex-C, Octagam, Panzyga, and Privigen

**Line(s) of Business:** Medicare Advantage

**Original Effective Date:** 10/01/2015

**Current Effective Date:** 10/17/2018

**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

**OTHER COVERED INDICATIONS**

- ITP in pregnancy
- Bone marrow/hematopoietic stem cell transplant recipients at risk for cytomegalovirus (CMV) infection
- Kidney/hematopoietic stem cell transplant recipients – treatment of rejection (antibody mediated)
- Desensitization for a pre-kidney transplantation in patients with a panel reactive antibody (PRA) of 80% or below
- Multiple myeloma
- Children with HIV who are less than 13 years of age
- Dermatomyositis
- Polymyositis
- Relapsing-remitting multiple sclerosis
- Guillain-Barre syndrome
- Myasthenia gravis
- Lambert-Eaton myasthenic syndrome
- Stiff-man syndrome
• Autoimmune mucocutaneous blistering diseases: pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane pemphigoid, and epidermolysis bullosa acquisita
• Autoimmune retinopathy

B. REQUIRED DOCUMENTATION

For the diagnosis of primary immunodeficiency, the following information is necessary to initiate the prior authorization review:

• Initial therapy
  o For primary immunodeficiency
    ▪ Laboratory evidence of immunoglobulin deficiency, which may include the following:
      ❖ Agammaglobulinemia (total IgG less than 200 mg/dL)
      ❖ Persistent hypogammaglobulinemia (total IgG less than 400 mg/dL, or at least two standard deviations below normal, on at least two occasions)
      ❖ Absence of B lymphocytes
    ▪ Inability to mount an adequate antibody response to inciting antigens, which may include the following:
      ❖ Lack of appropriate rise in antibody titer following provocation with a polysaccharide antigen. For example, an adequate response to the pneumococcal vaccine may be defined as at least a 4-fold increase in titers for at least 50% of serotypes tested.
      ❖ Lack of appropriate rise in antibody titer following provocation with a protein antigen. For example, an adequate response to tetanus/diphtheria vaccine may be defined as less than a 4-fold rise in titers 3-4 weeks after vaccine administration.

C. CRITERIA FOR APPROVAL

For Medicare Advantage members, the following National Coverage Determination and Local Coverage Determination policies apply:

• Intravenous Immune Globulin (IVIg) (L34314)
• Intravenous Immune Globulin for the Treatment of Autoimmune Mucocutaneous Blistering Diseases (250.3)

D. CONTINUATION OF THERAPY

Authorization for an additional 3 to 12 months depending on indication may be granted for continuation of therapy.

E. ADMINISTRATIVE GUIDELINES

Precertification is required. Please refer to the HMSA medical policy web site for the fax form.

F. IMPORTANT REMINDER

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.
This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA/CVS’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

G. REFERENCES


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