Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

catamaran™

IV/IM/SC IMMUNE GLOBULINS

GPI CODING:

Flebogamma	19100020******	Gamastan	19100020002200
Gammagard	19100020******	Hizentra	191000202020**
Gammagard S/D	191000201021**	Octagam	19100020******
Gammaplex	19100020******	Privigen	19100020******
Gamunex	19100020******	Vivaglobin	19100020202020
Gamunex C	19100020******	Carimune NF	19100020******

DESCRIPTION:

Immune globulin is a solution that contains antibodies, primarily immunoglobulin G (IgG), extracted from pooled human blood donors. It is used for treatment of immune deficiencies, inflammatory/ autoimmune diseases, and acute infections, but is also frequently used off-label for a variety of disorders. Gamunex/Gamunex-C and Gammagard Liquid may be administered intravenously or subcutaneously for primary immunodeficiencies.

APPROVAL DURATION:

All indications: 1 year

CRITERIA FOR IVIG/IMIG/SCIG

I. A trial of Gamunex/Gamunex-C is required when a nonpreferred IVIG/IMIG/SCIG product is requested, with the following exceptions:
   A. Gammagard S/D or Flebogamma is requested for patients with IgA deficiency who have tested positive for anti-IgA antibodies **OR**
   B. Patient has tried Gamunex/Gamunex-C and experienced a hypersensitivity reaction or infusion reaction that did not respond to slowing the infusion rate and required other supportive treatment (eg, stopping the infusion, antihistamine)

II. IVIG/IMIG/SCIG requests may be approved based on the following FDA-approved indications
   A. Treatment of primary immunodeficiencies, including:
      i. Hypogammaglobulinemia **OR**
      ii. Congenital agammaglobulinemia (X-linked agammaglobulinemia) **OR**
      iii. Common variable immunodeficiency **OR**
      iv. X-linked immunodeficiency with hyperimmunoglobulin M **OR**
      v. Severe combined immunodeficiency **OR**
      vi. Wiskott-Aldrich syndrome

   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)

III. IVIG/IMIG 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 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. Refractory dermatomyositis (after trial and faiure of corticosteroids) **OR**
   G. Lambert-Eaton myasthenic syndrome treatment **OR**
   H. Guillain-Barre syndrome (acute demyelinating polyneuropathy) **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/IMIG/SCIG is used as a second-line treatment) **OR**
   L. Myasthenia gravis, severe refractory **OR**
   M. Severe polymyositis (after trial and failure of other therapies) **OR**
   N. Prior to a medically necessary renal transplantation for suppression of anti-HLA antibodies in patients with high panel reactive antibody levels **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 cytomegalovirus infection **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:
      I. Pemphigus vulgaris **OR**
      II. Pemphigus foliaceus **OR**
      III. Bullous pemphigoid **OR**
      IV. Mucous membrane pemphigoid **OR**
      V. Epidermolysis bullosa acquisita

IV. IVIG/IMIG/SCIG may NOT be approved for treatment of recurrent spontaneous abortion (RSA)
V. Gamunex-C and Gammagard Liquid for subcutaneous use may be approved for primary immunodeficiency disease only