| MEDICAL POLICY STATEMENT | | |
|---|---|---|
| **Effective Date** | **Next Annual Review Date** | **Last Review / Revision Date** |
| **06/15/2011** | **9/26/15** | **9/26/14** |
| **Author** | | |
| **Laura Walters, RPh,<br>Tim Smith, RPh,<br>Dr. Stephen Lucht** | | |

CareSource

CSMG Medical Policy Statements are derived from literature based and supported clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services are those health care services or supplies which are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative and are not provided mainly for the convenience of the member or provider.

## A. SUBJECT

**Immune Globulin (IVIG, IGIV, or IMIG or SCIG)**

- Gammaked
- Carimune, Carimune NF
- Flebogamma, Flebogamma DIF
- GamaSTAN S/D
- Gammagard Liquid, Gammagard S/D Less IgA
- Gammaplex
- Gamunex
- Polygam
- Hizentra
- Octagam
- Privigen

NOTE: See Medical policy on Synagis for RSV-IVG

## B. Background

The CareSource Medication Policies are therapy class policies that are used as a guide when determining health care coverage for our members with benefit plans covering prescription drugs. Medication Policies are written on selected prescription drugs requiring prior authorization or Step-Therapy. The Medication Policy is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

The intent of the **Immune Globulin** (PA) Program is to encourage appropriate selection of patients for therapy according to product labeling and/or clinical guidelines and/or clinical studies, and also to encourage use of preferred agents.

## C. POLICY

CareSource will approve the use of and consider Immune Globulin (IVIG) use as medically necessary when the following criteria have been met for:

Acquired red cell aplasia, as indicated by **1 or more** of the following:

- Acute disseminated encephalomyelitis – may be effective in patients not responding to corticosteroids
- Allogeneic bone marrow or stem cell transplant and all of the following:
  - Serum IgG less than 400 mg/dL (4 g/L)
  - Severe infection
- Autoimmune bullous disease, as indicated by **ALL** of the following:
  - Contraindications to, failure of (refractory to), or significant side effects from systemic corticosteroids or immunosuppressive treatment
  - Dermatologic condition, as indicated by **1 or more** of the following:
    - Bullous pemphigoid
    - Epidermolysis bullosa acquisita
    - Linear IgA bullous dermatosis
    - Mucous membrane (cicatricial) pemphigoid
    - Pemphigoid gestationis
    - Pemphigus foliaceus
    - Pemphigus vulgaris
- Autoimmune hemolytic anemia for severe life-threatening disease (not for routine use in acute or chronic disease)
- Chronic inflammatory demyelinating polyneuropathy
- Dermatomyositis or polymyositis refractory to other immunosuppressive therapy or if IVIG is being used as a steroid-sparing option
- Fetal-neonatal alloimmune thrombocytopenia, as indicated by **1 or more** of the following:
  - Newborn, if thrombocytopenia persists after transfusion of antigen-negative compatible platelets
  - Pregnant woman and **1 or more** of the following:
    - Family history of disease
    - Platelet alloantibodies found on screening
    - Previously affected pregnancy
- Guillain-Barre syndrome, as indicated by **ALL** of the following:
  - Diagnosis of Guillain-Barre syndrome
  - Four weeks or less have elapsed since symptom onset.
  - Symptom evaluation, as indicated by **1 or more** of the following:
    - Patient able to walk only with assistance, or worse symptom severity
    - Progressive symptoms
- Hemolytic disease of newborn, as indicated by **1 or more** of the following:
  - Total serum bilirubin level within 2 mg/dL (34 micromoles/L) of age-adjusted and gestation-adjusted threshold for initiation of exchange transfusion
  - Total serum bilirubin still rising despite intensive phototherapy
- Hemolytic transfusion reaction and **1 or more** of the following:
  - After incompatible blood transfusion for severe life-threatening disease unresponsive to other therapies

- Sickle cell disease and severe life-threatening post-transfusion hemolysis
- Hemolytic uremic syndrome or thrombotic thrombocytopenic purpura and inability to tolerate first-line therapy, including **1 or more** of the following:
  - For hemolytic uremic syndrome, hemodialysis and supportive care
  - For thrombotic thrombocytopenic purpura, plasma exchange
- Hemophagocytic syndrome, for severe life-threatening disease unresponsive to other therapies.
- HIV disease, with active bleeding and platelet count less than 10,000/$mm^3$ (10 x$10^9$/L)
  - Hypogammaglobulinemia, primary or secondary, as indicated by **1 or more** of the following:
    - Following allogeneic stem cell transplant and low serum IgG level
  - Hematologic malignancy (e.g., chronic lymphocytic leukemia) and **ALL** of the following:
    - History of severe infection(s)
    - Low serum IgG level
  - HIV-positive and **ALL** of the following:
    - Age 18 years or younger
    - Low serum IgG level
    - Recurrent bacterial infection despite treatment with antiretroviral and antibacterial agents
    - Primary hypogammaglobulinemia
    - Serum IgG less than 400 mg/dL (4 g/L) and inadequate immunization response (i.e., 4-fold increase in titers) to protein and polysaccharide antigens
- Idiopathic (immune) thrombocytopenic purpura and need for rapid rise in platelet count to prevent or control bleeding
- Kawasaki disease – reduces the incidence of coronary artery aneurysms
- Kidney transplant and **1 or more** of the following:
  - Postoperative IVIG needed for **ALL** of the following:
    - Antibody-mediated transplant rejection
    - Planned plasmapheresis
  - Preoperative and perioperative IVIG needed for **ALL** of the following:
    - Kidney transplant recipient has baseline anti-HLA antibody titer less than 1:16 to donor kidney.
    - Living donor transplant
- Lambert-Eaton syndrome, when steroids and other immunosuppressive treatments do not control symptoms
- Multifocal motor neuropathy
- Myasthenia gravis, as indicated by **ALL** of the following:
  - IVIG not to be used for chronic maintenance therapy
  - Need for treatment of myasthenia gravis, as indicated by **1 or more** of the following:
    - Adult or juvenile myasthenia gravis and **1 or more** of the following:
      - Acute crisis
      - Need for stabilization before surgery
      - Severe exacerbation
      - Symptomatic patient resistant to or intolerant of immunosuppressive therapy
    - Neonatal myasthenia gravis
- Opsoclonus-myoclonus syndrome
- Post-transfusion purpura

- Pregnancy-associated idiopathic (immune) thrombocytopenic purpura**,** as indicated by **1 or more** of the following:
  - Any bleeding during pregnancy
  - Platelet count less than 10,000/$mm^3$ (10 x$10^9$/L) at any time during pregnancy
  - Platelet count between 10,000/$mm^3$ (10 x$10^9$/L) and 30,000/$mm^3$ (30 x$10^9$/L) in second or third trimester
- Primary immunodeficiency as indicated by **1 or more** of the following:
  - Agammaglobulinemia (eg, less than 0.2 g/dL (2 g/L))
  - Combined variable immunodeficiency (CVID)
  - Hyper-IgM syndrome (HIM)
  - Primary hypogammaglobulinemia
  - Serum IgG less than 400 mg/dL (4 g/L) and inadequate immunization response (i.e., 4-fold increase in titers) to protein and polysaccharide antigens
- Rasmussen encephalitis, for short-term amelioration prior to definitive surgical therapy
- Stevens-Johnson syndrome or toxic epidermal necrolysis for severe life-threatening disease
- Stiff Person syndrome, with failure of, or inability to receive or tolerate, GABA agonist medication
- Systemic lupus erythematosus – severely ill patients not responding to standard therapy, in those with concomitant infections

**All other uses of IVIG are considered experimental/investigational and therefore, will follow CareSource's off label policy.**

**Note: Documented diagnosis must be confirmed by portions of the individual's medical record which will confirm the presence of disease and will need to be supplied with prior authorization request. These medical records may include, but not limited to test reports, chart notes from provider's office or hospital admission notes.**

**Refer to the product package insert for dosing, administration and safety guidelines.**

**Conditions of Coverage**

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| **J-Code** | Gammaked J1561<br>Gammagard Liquid J1569<br>Gammagard S/D J1566<br>Gamunex J1561<br>Octagam J1568<br>Polygam S/D J1566<br>Privigen J1459<br>Carimune J1566<br>Flebogamma J1572<br>GammaSTAN S/D J1560<br>Gammaplex J1557<br>Hizentra J1559<br>Immune Globulin (non-lyophilized), not otherwise specified J1599<br>Gamma Globulin Injection J1460, J1560 |
| **Place Of** | Office, Outpatient, Home |

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| **Service** | *****Preferred place of service is in the home*.** This medication can be self-administered and can be billed through the pharmacy benefit.<br><br>**Note:** CareSource supports administering injectable medications in various setting, as long as those services are furnished in the most appropriate and cost-effective setting and that are supportive of the patient's medical condition and unique needs and condition. The decision on the most appropriate setting for administration is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of the specific medication. |
| **Authorization Period** | Approved initial authorizations are valid for 3 months. Continued treatment may be considered when the member has shown biological response to treatment. A reauthorization after successful initiation period will be placed for 1 year. ALL authorizations are subject to continued eligibility. |

## D. REVIEW / REVISION HISTORY

8/2013, 9/26/2014

## E. REFERENCES


1. Immune Globulin Intravenous (IVIG). (2014, January 1). Retrieved January 1, 2014, from http://careweb.careguidelines.com/ed18/index.html

2. Lexi-Comp Online. (2014). AHFS DI. *IVIG*. Retrieved May 30, 2014 from Lexi-Comp Online with AHFS.

3. Vo AA, Petrozzino J, Yeung K, Sinha A, Kahwaji J, Peng A, Villicana R, Mackowiak J, Jordan SC. Efficacy, outcomes, and cost-effectiveness of desensitization using IVIG and rituximab. *Transplantation*. 2013 Mar 27;95(6):852-8. doi: 10.1097/TP.0b013e3182802f88.


**The medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.**

**9/30/14**

**Chief Medical Officer** **Date**

**9/26/2014**

**Director of Specialty Pharmacy** **Date**