

Title: Subcutaneous Immune Globulin (SCIG)

Origination: 08/01/07	Revised: 08/19/10	Annual Review: 12/15/11
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

Medication Summary

- Immunoglobulins are collected from the venous blood of donors, and come as a solution composed primarily of heterogeneous human IgG with trace amounts of IgA and IgM. The amount of each IgG subclass is similar to that of human plasma, although the titers against specific antigens vary among manufacturers. Immune globulins supply a broad spectrum of opsonizing and neutralizing IgG antibodies against a wide variety of bacterial and viral agents.
- Immunoglobulins are administered by intravenous (IV) infusion, subcutaneous (SC) infusion, or subcutaneous (SC) injection.
- Immune globulins are indicated for the treatment of primary immunodeficiencies (i.e. agammaglobulinemia, hypogammaglobulinemia, common variable immunodeficiency [CVID], Wiskott-Aldrich syndrome, and severe combined immunodeficiency [SCID]); prophylaxis of bacterial infections in members with hypogammaglobulinemia or recurrent bacterial infections associated with B-cell chronic lymphocytic leukemia (CLL); treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) to improve neuromuscular disability and impairment and prevent relapse; to prevent or control bleeding associated with idiopathic thrombocytopenia purpura (ITP); and for prevention of coronary artery aneurysms associated with Kawasaki disease.
- Currently available immune globulin products include Octagam, Hizentra, Carimune NF, Flebogamma, Gammagard Liquid and S/D, Gammar-P, Gamunex, Iveegam EN, Privigen, Polygam S/D, and Vivaglobin. These products differ in preparation, method, viral inactivation steps, stabilizing agent, osmolality and IgA content; therefore these products are not all the same.

Reference Statement

- Guidelines are compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

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Background Information, continued:

Eligibility Criteria

- Member must be eligible and have applicable benefit coverage within the specified date(s) of service.
- Prior authorization requests that do not meet clinical criteria in this procedure will be forwarded to a Clinical Pharmacist for review.

Exclusions

- History of anaphylactic or severe systemic response to immune globulin preparations.
- Anaphylactic or severe systemic reaction to polysorbate 80 (Hizentra only).
- Hyperprolinemia (Hizentra only).
- Selective IgA deficiency (serum IgA concentration <0.05g/L) who have known antibody against IgA and/or a history of hypersensitivity.

Additional Information

- Requests received for IVIg or SCIG for **Medicare Members** will be reviewed using CMS “LCD for Intravenous Immune Globulin (L29205)”; refer to Attachment A or view on-line at http://www.cms.hhs.gov/mcd/results_index.asp?from=%27lmpcontractor%27&contractor=197&name=First+Coast+Service+Options%2C+Inc%2E+%2809102%2C+MAC+%2D+Part+B%29&letter_range=4&retired

Procedure:

- 1.0 Request for *initial therapy* with SCIG requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following:
 - 1.1 Must meet the following criteria:
 - 1.1.1 Previous treatment with IVIG; **AND**
 - 1.1.2 Member has fluid restrictions; **OR**
 - 1.1.2 Member has poor venous access; **OR**
 - 1.1.2 Member has suffered from systemic hypersensitivity reactions to IVIG administration; **AND**

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Procedure, continued:

1.0 Request for *initial therapy* with SCIG requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying the following, continued:

1.2 Meets **one (1)** of the following:

1.2.1 Treatment of primary immune deficiency disorders including, but not limited to, congenital X-linked agammaglobulinemia, common variable immunodeficiency, and severe combined immunodeficiencies with:

1.2.1.1 IgG lab values of less than 600mg/dl; **AND**

1.2.1.2 Had at least one (1) bacterial infection directly attributed to Member's Immunodeficiency; **OR**

1.2.1.2 The Member has a deficiency in producing antibodies;

1.2.2 For Wiskott-Aldrich Syndrome (only) with:

1.2.2.1 IgM lab values less than 40mg/dl; **AND**

1.2.2.2 Had at least one (1) bacterial infection directly attributed to Member's Immunodeficiency; **OR**

1.2.2.2 The Member has a deficiency in producing antibodies;

1.2.3 Measles prophylaxis (Hizentra ONLY):

1.2.3.1 Members with immunoglobulin deficiency who have been exposed to measles or are at risk of measles exposure (e.g., due to U.S. outbreak or travel to endemic area outside of U.S.);

1.3 If criteria are met, SCIG is approvable for up to 180 days.

2.0 Request for *continuation of therapy* beyond initial authorization period with SCIG for the **above indications** requires documentation of **disease stabilization or improvement** from the Member's medical records maintained by the requesting independent practitioner:

2.1 If criteria are met, SCIG is approvable for up to 180 days.

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References:

1. Centers for Medicare & Medicaid Services, US Department of Health and Human Services. Local Coverage Determination (LCD) for Intravenous Immune Globulin (L29205). December 2008 update; effective 02/02/09.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2009. URL: <http://www.clinicalpharmacology.com>. Updated: October, 2009.
3. Carimune NF Immune Globulin Intravenous (Human) prescribing information. CSL Behring LLC. Kankakee, IL. January 2005.
4. Flebogamma Immune Globulin Intravenous (Human) 5% prescribing information. Grifols Biologicals, Inc. Los Angeles, CA. November 2006.
5. Gammar-P Immune Globulin Intravenous (Human). CSL Behring LLC. Kankakee, IL. August 2004.
6. Gammagard S/D Immune Globulin Intravenous (Human) prescribing information. Baxter Healthcare Corporation. Westlake Village, CA. October 2008.
7. Gammagard Liquid Immune Globulin Intravenous (Human) 10% prescribing information. Baxter Healthcare Corporation. Westlake Village, CA. April 2005.
8. Gamunex Immune Globulin Intravenous (Human) 10% prescribing information. Talecris Biotherapeutics, Inc. Research Triangle Park, NC. October 2008.
9. Iveegam EN Immune Globulin Intravenous (Human) prescribing information. Baxter Healthcare Corporation. Westlake Village, CA. April 2005.
10. Polygam S/D Immune Globulin Intravenous (Human) prescribing information. Baxter Healthcare Corporation. Westlake Village, CA. August 2002.
11. Privigen Immune Globulin Intravenous (Human) 10% prescribing information. CSL Behring LLC. Kankakee, IL. June 2009.
12. Vivaglobin Immune Globulin Subcutaneous (Human) prescribing information. CSL Behring LLC. Kankakee, IL. April 2007.

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Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.