Medical Department Procedure Manual

Section: Chapter 7A Prescription Medication Prior Authorization  Number: 07.080
Title: Subcutaneous Immune Globulin (SCIG)  Page 1 of 5

Approval: Robert Bonnell, M.D., Med. Dir.  DATES - Origination: 08/01/07
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Purpose:

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

Implementation Information:

1.0 Under the supervision of the Clinical Pharmacy Management (CPM) Director, the CPM staff is responsible for the development of guidelines and criteria for use by the Medical Department.

2.0 Staff utilizing this procedure is monitored, as indicated, via individual departmental audit process(es).

3.0 On an annual basis or more often when indicated, the Medical Department Procedures are reviewed by medical staff for the purpose of developing, revising, or archiving:

   3.1 Medical Department staff has access to the Medical Department Procedure Manual and receives notice from management when procedures are developed, revised, or archived.

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.
Background Information, continued:

Medication Summary, continued:

- 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.

Coverage Guidelines

- 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.

Exclusion Criteria

- 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

- AvMed’s Clinical Pharmacists are licensed by the State of Florida.
- AvMed’s Medical Directors are Board Certified physicians licensed by the State of Florida.
- 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=%27lmrpcontractor%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
1.1.3 Member has poor venous access; OR
1.1.4 Member has suffered from systemic hypersensitivity reactions to IVIG administration; AND

1.2 Meets one (1) of the following:

1.2.1 Treatment of primary immune deficiency disorders including, but not limited to, congential 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
1.2.1.3 The Member has a deficiency in producing antibodies;
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, continued:

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, may approve SCIG 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 criterion is met, may approve SCIG for up to 180 days.
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Title: Subcutaneous Immune Globulin (SCIG) Page 5 of 5

References: