Subcutaneous Gammagard® Liquid (immune globulin human) is indicated for the treatment of primary humoral immunodeficiency. Immune globulin serves as IgG replacement therapy for those with primary humoral immunodeficiency, such as agammaglobulinaemia, hypogammaglobulinaemia, CVID, or SCID. Adverse effects include headache, fever, fatigue, nausea, chills, or pain in extremities.

**Recommended authorization criteria**

**FDA-Approved Indications**

1. **Immunodeficiency, primary humoral (treatment).** Approve in patients who meet the following criteria (a AND b AND c):
   a. IVIG is prescribed by or in consultation with an allergist/immunologist, immunologist, otolaryngologist or an infectious diseases physician AND
   b. Patient has previously received immune globulin intravenously or subcutaneously AND
   c. Patient has one of the following primary humoral or combined immune deficiencies (i, ii, iii, iv, v, OR vi):
      i. CVID or unspecified hypogammaglobulinemia AND meets the following criteria (1, 2, 3 AND 4):
         1. Patient has a documented history of significant recurrent or persistent, severe bacterial infections AND
         2. Infections are responding inadequately to treatment with antibiotics and/or appropriate prophylaxis with antibiotics OR the patient has multiple antibiotic hypersensitivities that interfere with treatment AND
         3. Other disorders that may increase susceptibility to infection such as allergy or anatomic defects, have been sought out and treated aggressively if present AND
         4. The patient has at least one of the following:
            - Reduced total serum IgG level OR
            - Reduced IgG1 and IgG3 subclass levels or reduced IgG1 alone OR
            - Markedly impaired antibody response to protein (e.g., tetanus, diphtheria) antigen OR antibody testing with a polysaccharide antigen (pneumococcus) OR
      ii. X-linked agammaglobulinemia (Bruton’s agammaglobulinemia, congenital agammaglobulinemia) OR
      iii. SCID OR
      iv. Wiskott-Aldrich syndrome OR
      v. Hyper-IgM syndromes, X-linked or autosomal recessive OR
      vi. Other combined immunodeficiencies with significant hypogammaglobulinemia or antibody production AND the patient has frequent and severe infections
Exclusions (Limitations)

1. Selective IgA deficiency as the sole immunologic abnormality.
2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Endorsed: 7/17/2013
Approved: 8/13/2013
Revised:
Reviewed:

References