Subject: Intravenous and Subcutaneous Immunoglobulin*

Effective Date: April 29, 2003

Department(s): Utilization Management

Policy: The use of intravenous and subcutaneous immunoglobulin is reimbursable under Plans administered by QualCare, Inc., for the indications listed below.

Objective: To provide proper and consistent reimbursement for and to ensure appropriate utilization of a specific therapeutic agent.

Procedure: 1. A letter of medical necessity must document the presence of one of the following conditions:

A. Immunologic diseases

- A primary immunodeficiency involving generalized hypogammaglobulinemia (279.0, 279.2)
- Immune thrombocytopenic purpura (ITP) (287.3)
- Secondary immunosuppression involving generalized hypogammaglobulinemia (e.g., with major surgery, extensive burns (948, 949), stem cell transplant recipients (V42.8) with severe infections)
- Steroid-resistant graft-versus-host disease with hypogammaglobulinemia (279.5)
- Post-transfusion purpura (287.2, 287.4)
- Neonatal alloimmune thrombocytopenia (776.1)
- Neonatal hemochromatosis
- IgG subclass deficiencies (279.0) with severe infection
- Preparation of renal transplant recipient from ABO-incompatible live donor in absence of more compatible donor
- Hemolytic disease of newborn (773.0, 773.1) (with phototherapy)
- Autoimmune hemolytic anemia (warm type) (283.0)
- Chronic granulomatous disease (288.1)
- Acute antibody mediated kidney allograft rejection

B. Neurologic diseases
- Chronic inflammatory demyelinating polyneuropathies (357.8)
- Guillain-Barré syndrome (357.0)
- Multifocal motor neuropathy (357.8)
- Myasthenia gravis, including Eaton-Lambert paraneoplastic myasthenic syndrome (358.0, 358.1)
- Relapsing-remitting multiple sclerosis (340)†
- Clinically Isolated Syndrome (if there is evidence of demyelination suggestive of multiple sclerosis)

C. Inflammatory/infectious diseases
- Kawasaki disease (446.1)
- HIV infection (042) in children ≤ 13 years of age
- Parvovirus B19 infection (079.38) with red cell aplasia
- Severe infection in hyperimmunoglobulinemia E syndrome
- Staphylococcal or streptococcal toxic shock syndrome (040.82)
- Hepatitis A prophylaxis when vaccine or intramuscular immunoglobulin can’t be administered

D. Malignant diseases
- B-cell chronic lymphocytic leukemia (CLL) (204.10, 204.11)
- Multiple myeloma (203.00, 203.11)
- Allogeneic (not autologous) bone marrow transplantation (V42.8)

E. Rheumatologic diseases
- Polymyositis (710.4)
- Dermatomyositis (710.3)
- Stiff- person (Moersch-Woltmann) syndrome (333.91)†
- Systemic lupus erythematosus (695.4)†
- Autoimmune mucocutaneous blistering diseases† (such as pemphigus(694.4), pemphigoid (694.5, 694.6), [where steroid therapy has either failed or is not expected to take effect rapidly enough, in the opinion of a dermatologist or rheumatologist])
- Churg-Strauss Syndrome (446.4)†
F. Other clinical entities
   - Secondary recurrent spontaneous miscarriage (recurrent pregnancy loss (646.33) in a patient whose prior pregnancy/pregnancies had not been complicated by spontaneous miscarriage)

2. Investigational/experimental indications for IVIG which are not covered include but are not limited to the following:
   - Autism (299)
   - Inclusion body myositis (729.1)
   - Neonatal infection prevention and/or control
   - Autoimmune chronic urticaria (708)
   - Angioedema (277.6)
   - Primary recurrent (at least 2) spontaneous miscarriage (634.9)
   - Clostridium Difficile enteritis(008.45)
   - IgM antimyelin-associated glycoprotein paraprotein-associated peripheral neuropathy(no specific ICD code)

3. All requests for IVIG are subject to review by the Medical Director.

4. In conditions indicated by the dagger (†) the letter of medical necessity must document failure of standard or conventional therapy as part of the medical necessity for the use of IVIG.

References


Daoud YJ, Amin KG. Comparison of Cost of Immune Globulin Intravenous Therapy to Conventional Immunosuppressive Therapy in Treating Patients with Autoimmune Mucocutaneous Blistering Diseases. *Int Immunopharmacol* 2006;6(4):600-606 (Apr)
Ahmed AR. Use of Intravenous Immunoglobulin Therapy in Autoimmune Blistering Diseases. *Int Immunopharmacol* 2006;6(4):557-578 (Apr)


Dalakas MC. Intravenous immunoglobulin in autoimmune neuromuscular diseases. *JAMA* 2004;291(19):2367-2375 (Sep 22)


*Consistent with Summary Plan Description (SPD). When there is discordance between this policy and the SPD, the provisions of the SPD prevail.*