PHARMACY PRIOR AUTHORIZATION

Parenteral Immune Globulins Clinical Guideline (Non-PDL)

Preferred Immune Globulins: Gamunex-C, Gammagard, Gammagard SD, Gammaked, Flebogamma DIF

Non-preferred Immune Globulins: Asceniv, Bivigam, Carimune NF, Cutaquig, Cuvitru, Gamastan, Gammaplex, Hizentra, Hyqvia, Octagam, Panzyga, Privigen, Xembify

Authorization Guidelines:

Documentation of ALL the following:

I. The dose prescribed is within the FDA-approved range for the indication or is supported by compendia/peer-reviewed literature

II. Request is not for experimental/investigational use or for a clinical trial

III. Products are not interchangeable, selection of product should be based on member factors including diagnosis, past history and individual comorbidities

IV. The use of parenteral immunoglobulin therapy is approved for members with any of the following conditions:

1. Acquired red cell aplasia


3. Autoimmune mucocutaneous blistering diseases: pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane pemphigoid (a.k.a., cicatrical pemphigoid), gestational pemphigoid, linear IgA disease, and epidermolysis bullosa acquisita.

   a) The diagnosis has been proven by biopsy and confirmed by pathology report; and

   b) The condition is rapidly progressing, extensive or debilitating; and
c) Corticosteroids or immuno-suppressive agents have failed or the member has experienced significant complications from standard treatment, such as diabetes or steroid-induced osteoporosis.

4. Autoimmune hemolytic anemia, refractory: documentation of an inadequate response or contraindication to corticosteroids or splenectomy

5. Autoimmune neutropenia, refractory: documentation that treatment with Granulocyte-Colony Stimulating Factors (G-CSF) is not appropriate.

6. B-cell chronic lymphocytic leukemia (CLL): For persons with hypogammaglobulinemia associated with CLL and recurrent infections or specific antibody deficiency
   a) IgG level less than 600 mg/dL; and
   b) One (1) severe bacterial infection within preceding 6 months or 2 or more bacterial infections in 1 year OR evidence of specific antibody deficiency

7. Birdshot (vitiligenous) retinochoroidopathy: documentation of an inadequate response to immunosuppressive agents (e.g., corticosteroids, cyclosporine)

8. Chronic inflammatory demyelinating polyneuropathy [also known as Chronic Relapsing Polyneuropathy, including diabetes mellitus-CIDP and multifocal acquired demyelinating sensory and motor neuropathy (MADSAM) variant]
   a) Documentation of symmetric or focal neurologic deficits with slowly progressive or relapsing course over 2 months or longer (with neurophysiological abnormalities).

9. Churg-Strauss Syndrome (CSS) (allergic granulomatosis)
   a) Documentation that IVIG will be used as adjunctive therapy for persons with severe active illness for whom other interventions have been unsuccessful, have become intolerable, or are contraindicated
10. Dermatomyositis: Member is intolerant or refractory to 1st (corticosteroids) and 2nd line (immunosuppressants) therapies

11. Enteroviral meningoencephalitis

12. Guillain-Barré syndrome (GBS) and GBS variants [infective polyneuritis (includes GBS variants: Miller-Fisher syndrome [MFS], pan autonomic polyneuropathy, acute pandysautonomia, acute motor axonal neuropathy (AMAN), and acute motor and sensory axonal neuropathy (AMSAN))]
   a) Severe GBS with significant weakness such as inability to stand or walk without aid, respiratory or bulbar weakness, or Miller-Fisher syndrome (MFS); and
   b) The disorder has been diagnosed during the first 2 weeks of the illness; and
   c) IVIG is initiated within one month of symptom onset.

13. Hemolytic disease of newborn, to decrease need for exchange transfusion

14. HIV infected children; bacterial control or prevention. Documentation of any of the following:
   a) Serum IgG concentration less than 400 mg/dL;
   b) Recurrent serious bacterial infections, i.e., defined as two or more infections such as bacteremia, meningitis, or pneumonia in a 1-year period
   c) Failure to form antibodies to common antigens, such as measles, pneumococcal, and/or Haemophilus influenzae type b vaccine;
   d) Member lives in area where measles is highly prevalent and has not developed an antibody response after two doses of measles, mumps, and rubella virus vaccine live;
   e) Exposure to measles;
f) Chronic bronchiectasis that is suboptimally responsive to antimicrobial and pulmonary therapy.

15. HIV-associated thrombocytopenia:
   a) Significant bleeding in thrombocytopenic members or platelet count less than 20,000/ul; and
   b) Failure of RhIG in Rh-positive patients.

16. Hyperimmunoglobulinemia E syndrome: For treatment of severe eczema

17. Immune or idiopathic thrombocytopenic purpura (ITP):

   ITP (Adults)
   a) Other causes of thrombocytopenia have been ruled out; and
   b) Unresponsive to corticosteroid therapy; and
   c) Documentation of ONE of the following:
      1. Management of acute bleeding due to severe thrombocytopenia (platelet counts less than 30,000/ul); or
      2. To increase platelet counts prior to invasive major surgical procedures (e.g., splenectomy), or
      3. To defer or avoid splenectomy; or
      4. In members with severe thrombocytopenia (platelet counts less than 20,000/ul) considered to be at risk for intra-cerebral hemorrhage.

   ITP (Chronic Refractory)
   a) Age of 10 years or older; and
   b) Duration of illness of greater than 6 months; and
   c) No concurrent illness/disease explaining thrombocytopenia; and
   d) Prior treatment with corticosteroids and splenectomy has failed or member is at high-risk for post-splenectomy sepsis.

   ITP (Pediatrics)
   a) Acute ITP:
      1. IVIG as initial therapy if platelet count less than 20,000/ul, especially when member has emergency bleeding or is at risk for severe life-threatening bleeding; or
2. Persons with severe thrombocytopenia (platelet counts less than 20,000/ul) considered to be at risk for intra-cerebral hemorrhage.

b) Chronic ITP:
   1. In high-risk persons when platelet count low or person symptomatic; and
   2. Failure of other therapies, or
   3. Member is a high risk for post-splenectomy sepsis.

ITP (Pregnancy)
   a) Refractory to steroids with platelet counts less than 10,000/ul in the 3rd trimester; or
   b) Platelet counts less than 30,000/ul associated with bleeding before vaginal delivery or C-section; or
   c) Pregnant women who have previously delivered infants with autoimmune thrombocytopenia; or
   d) Pregnant women who have platelet counts less than 50,000/ul during the current pregnancy; or
   e) Pregnant women with past history of splenectomy.

18. Kawasaki disease (mucocutaneous lymph node syndrome)
19. Lambert-Eaton myasthenic syndrome: documentation of the following
   a) No response to anticholinesterases (e.g., pyridostigmine),
      dalfampridine (Ampyra) or Firdapse (amifampridine)
20. Moersch-Woltmann (Stiff-man) syndrome: Documentation of trial and failure with benzodiazepines and/or baclofen, phenytoin, clonidine, tizanidine.
21. Multifocal motor neuropathy
22. Multiple myeloma: documentation of recurrent, serious infections despite the use of prophylactic antibiotics.
23. Myasthenia gravis: documentation of treatment of acute myasthenic crisis with decompensation (respiratory failure, or disabling weakness requiring hospital admission)).

24. Neonatal alloimmune thrombocytopenia (NAIT) (also known as fetal alloimmune thrombocytopenia or FAIT)

25. Neonatal hemochromatosis, prophylaxis: documentation that member is pregnant with a history of pregnancy that ended in neonatal hemochromatosis

26. Opsoclonus-myoclonus

27. Paraneoplastic opsoclonus-myoclonus-ataxia associated with neuroblastoma

28. Parvovirus B19 infection, chronic, with severe anemia

29. Polymyositis in persons who are resistant to first- and second-line therapies

30. Post-transfusion purpura:
   a) Decreased platelets (less than 10,000/ul) and 2 to 14 days post-transfusion

31. Preparation for thymoma surgery (to prevent myasthenia exacerbation)

32. Primary humoral immunodeficiency diseases (such as congenital agammaglobulinemia (X-linked agammaglobulinemia), hypogammaglobulinemia, common variable immunodeficiency, X-linked immunodeficiency with hyperimmunoglobulin M, Wiscott-Aldrich syndrome, immunodeficiency with thymoma (Good syndrome), hyper IgM syndromes, and severe combined immunodeficiency)
   a) Agammaglobulinemia (total IgG less than 200 mg/dL or infants with BTK gene and/or absence of B lymphocytes));
   or
b) Persistent hypogammaglobulinemia (total IgG less than 400 mg/dL or two standard deviations below the mean for age) with recurrent bacterial infections and for adults and children older than 2 years old: lack of response to protein or polysaccharide antigens (inability to make IgG antibody against diphtheria and tetanus toxoids, pneumococcal polysaccharide vaccine, or both) or

c) Selective IgG subclass deficiencies

1. Deficiency of one or more IgG subclasses to levels less than 2 standard deviations below the age-specific mean and
2. Member has recurrent or persistent severe bacterial infections despite adequate treatment and
3. For adults and children older than 2 years old, documentation of an inability to mount an adequate response to protein and polysaccharide antigens or

d) Evidence of recurrent severe difficult-to-treat infections (e.g., recurrent otitis media, bronchiectasis, recurrent infections requiring IV antibiotics, multiple antibiotic hypersensitivities, chronic or recurrent sinusitis) and for adults and children older than 2 years old, documentation of normal total IgG levels with severe polysaccharide non-responsiveness and

33. Rasmussen encephalitis (Rasmussen's syndrome): documentation of inadequate response or inability to tolerate anti-epileptic drugs and corticosteroids.

34. Relapsing-remitting multiple sclerosis (MS): documentation of the following...
a) Severe manifestations of relapsing-remitting MS (not primary or secondary progressive MS); and

b) Standard approaches (i.e., interferons (Betaseron, Avonex, Rebif), glatiramer (Copaxone)) have failed, become intolerable, or are contraindicated.

35. Renal transplantation from live donor with ABO incompatibility or positive cross-match, where a suitable non-reactive live or cadaveric donor is unavailable (preparative regimen)

36. Secondary immunosuppression associated with major surgery (such as cardiac transplants) and certain diseases (extensive burns, or collagen-vascular diseases)

37. Selective IgG subclass deficiencies with severe infection:
   a) Deficiency of one or more IgG subclasses to levels less than 2 standard deviations below the age-specific mean and
   b) Member has recurrent or persistent severe bacterial infections despite adequate treatment and
   c) For adults and children older than 2 years old, documentation of an inability to mount an adequate response to protein and polysaccharide antigens

38. Solid organ transplantation, for allosensitized members undergoing solid organ transplant

39. Staphylococcal toxic shock syndrome

40. Stem cell or bone marrow transplantation:
   a) Prophylaxis in allogeneic or syngeneic transplant members within the first 100 days post-transplant;
b) After 100 days post-transplant, member has IgG level less than 400 mg/dL and one of the following:
   1. Member has primary immunodeficiency or
   2. Member has CMV, EBV, or RSV infection

c) Steroid-resistant graft-versus-host disease in bone marrow transplant members 20 years of age or older, in the first 100 days post-transplant, and with IgG level less than 400 mg/dL.

41. Systemic lupus erythematosus (SLE), for members with severe active SLE for whom other interventions have been unsuccessful, have become intolerable, or are contraindicated

42. Toxic epidermal necrolysis and Steven-Johnson syndrome

43. Toxic shock syndrome or toxic necrotizing fasciitis due to group A streptococcus.

Criteria for Renewal

- Supporting documentation showing clinical improvement or stabilization of the disease state.

Duration

- Initial approval: 6 months
- Renewal: 6 months

Initial Approval Duration for Specific Indications:

- Autoimmune hemolytic anemia: 5 days
- Guillain-Barre Syndrome: 5 days
- Idiopathic thrombocytopenic purpura (acute): 5 days
- Post-transfusion purpura: 5 days
- Chronic inflammatory demyelinating polyneuropathy: 3 months
References:


