ILLINOIS DEPARTMENT OF Healthcare and Family Services

Immune Globulin, Gamma – Intravenous & Subcutanous (IVIG, SCIG)
Prior Authorization Criteria

All prescriptions for IVIG/SCIG will require prior authorization.

IVIG/SCIG contains at least 90 percent Immune globulin, Gamma (IgG), with distribution of IgG subclasses corresponding to normal serum, as well as trace amounts of IgA and IgM. IVIG/SCIG is used when an immediate increased level of circulating immunoglobulin is required to correct a deficiency state or modify an ongoing immunologic reaction. The purpose of this prior approval policy is to define specific criteria for coverage of IVIG/SCIG to ensure that these agents are used for labeled conditions or for conditions that have adequate supporting literature.

The following IVIG/SCIG products will require prior approval and will be covered for the below-listed indications. Requests for treatment of other conditions will be considered with clinical justification from the physician that is supported in the literature.

IVIG/SCIG Products	
Carimune® NF	Gamunex®-C*
Flebogamma® DIF	Hizentra®†
Gammagard® S/D	Octagam®
Gammagard® Liquid*	Privagen®
Gammaked™	Vivaglobin®† discontinued, but supplies still available
Gammaplex®	

*Can be administered intravenously or subcutaneously;

Approval Criteria: Approval will be given for IVIG/SCIG treatment for the following conditions:

1. Chronic lymphocytic leukemia (either with hypogammaglobulinemia or recurrent bacterial infections)
2. Congenital agammaglobulimemia
3. Severe Combined Immunodeficiency syndromes (SCID)
4. Common Variable Immunodeficiency
5. Wiskott-Aldrich Syndrome
6. Idiopathic thrombocytopenic purpura in patients with bleeding complications, unsafe platelet counts, or requiring invasive interventions.
7. Acute infective polyneuritis (Guillain-Barre syndrome) - recommended as an equivalent alternative to plasma exchange in children and adults
8. Chronic inflammatory demyelinating polyneuropathy (or CIDP) - recommended as an equivalent alternative to plasma exchange in children and adults
9. Acute febrile mucocutaneous lymph node syndrome (Kawasaki disease) when administered with aspirin within 10 days of symptom onset

10. Dermatomyositis/polymyositis - may be used in patients with severe active illness for who other interventions have been unsuccessful or intolerable
11. Autoimmune hemolytic anemia with hemoglobin < 7 or hepatomegaly (life-threatening)
12. Pure red cell aplasia (First line for viral PRCA associated with parvovirus and as alternative therapy for immunologic PRCA)
13. Multifocal motor neuropathy
14. Refractory Lennox Gastaut, West Syndrome
15. Bone marrow transplantation during the early transplant period in patients > 20 years
16. Hemolytic disease of the newborn (Erythroblastosis Fetalis) with established hyperbilirubinemia
17. Feto-neonatal alloimmune thrombyctopenia
18. Pediatric AIDS
    - 18.1 In conjunction with AZT or other antiretroviral treatment, to prevent mild to severe bacterial infection in children with CD4+ counts >200/uL
    - 18.2 In conjunction with AZT, to prevent maternal transmission of HIV infection
    - 18.3 HIV-positive children who either have been exposed to measles or who live in a high- prevalence measles area
    - 18.4 HIV-related immune thrombocytopenic purpura
19. Adult AIDS - HIV-associated thrombocytopenia in patients with severe bleeding
20. Moderate to severe myasthenia gravis
21. Lambert-Eaton myasthenic syndrome

References:

Anderson D, Ali K, Blanchette V, et al. Guidelines on the use of intravenous immunoglobulin for hematologic conditions. *Transfus Med Rev*. 2007;21(suppl 2):S9-S56.

Anon. Intravenous immunoglobulin (IVIG). *The Medical Letter*. 2006;48(1249/1250):101-103

Geyva-Dayan K, Shorer Z, Menascu S, et al. Immunoglobulin treatment for severe childhood epilepsy. *Ped Neurol*. 2012;46(6):375-381

Patwa HS, Chaudhry V, Katzberg H, Rae-Grant AD, So YI. Evidence-based guideline: intravenous immunoglobulin in the treatment of neuromuscular disorders: report of the Therapeutics and Technology Assessement Subcommittee of the American Academy of Neurology. *Neurology*. 2012;78(13):1009-1015.