

Prior Authorization DRUG Guidelines

GAMMAGARD® (immune globulin)

Effective Date: 7/24/12

Date Developed: 7/3/12 by Albert Reeves MD

Last Approval Date: 1/26/16, 1/24/17, 1/23/18

(Archived 1/22/19)

GAMMAGARD® is a Blood Product Derivative; Immune Globulin

Other brand names of Immune Globulin: Carimune® NF; Flebogamma® DIF; GamaSTAN™ SD; Gammunex-C Gammaplex®; Gamumex® [DSC]; Hizentra®; Octagam®; Privigen®; Vivaglobin® [DSC]

Pre-Authorization Criteria: immune thrombocytopenia; primary immunodeficiency states; secondary immunodeficiency in chronic lymphocytic leukemia, pediatric HIV infection, Parvovirus B19 infection, and allogeneic bone marrow transplantation; Kawasaki syndrome; prevention of graft versus host disease and infection in adult hematopoietic cell transplantation; certain neuromuscular disorders, such as chronic inflammatory demyelinating polyneuropathy (CIDP), Guillain-Barre syndrome, myasthenia gravis and polymyositis/dermatomyositis

NOTE: VCHCP requires that Gamumex®-C be prescribed by a Hematologist-Oncologist, Neurologist, Infectious Disease or Immunologist

VCHCP requires that GAMMAGARD be prescribed by a pediatric or adult infectious disease specialist or pediatric or adult hematologist/oncologist .

Administration:

Gammagard® Liquid:

Injection sites: ≤8 simultaneous injection sites

Initial infusion rate:

<40 kg: 15 mL/hour per injection site (maximum volume: 20 mL per injection site)

≥40 kg: 20 mL/hour per injection site (maximum volume: 30 mL per injection site)

Maintenance infusion rate:

<40 kg: 15-20 mL/hour per injection site (maximum volume: 20 mL per injection site)

≥40 kg: 20-30 mL/hour per injection site (maximum volume: 30 mL per injection site)

Dosing: Adult

Gammagard S/D®: 2.5 g [contains albumin (human), glucose, glycine, natural rubber/natural latex in packaging, polyethylene glycol, polysorbate 80; IgA <2.2 mcg/mL]

Gammagard S/D®: 5 g [contains albumin (human), glucose, glycine, natural rubber/natural latex in packaging, polyethylene glycol, polysorbate 80; IgA <1 mcg/mL]

Gammagard S/D®: 5 g [contains albumin (human), glucose, glycine, natural rubber/natural latex in packaging, polyethylene glycol, polysorbate 80; IgA <2.2 mcg/mL]

Gammagard S/D®: 10 g [contains albumin (human), glucose, glycine, natural rubber/natural latex in packaging, polyethylene glycol, polysorbate 80; IgA <1 mcg/mL]

Gammagard S/D®: 10 g [contains albumin (human), glucose, glycine, natural rubber/natural latex in packaging, polyethylene glycol, polysorbate 80; IgA <2.2 mcg/mL]

Gammagard® Liquid: 10% [100 mg/mL] (10 mL, 25 mL, 50 mL, 100 mL, 200 mL) [sucrose free; contains glycine]

Warnings/Precautions

Boxed warnings:

- Renal impairment: See “Concerns related to adverse effects” below.

Concerns related to adverse effects:

- Anaphylaxis/hypersensitivity reactions: Hypersensitivity and anaphylactic reactions can occur; a severe fall in blood pressure may rarely occur with anaphylactic reaction; immediate treatment (including epinephrine 1:1000) should be available.
- Aseptic meningitis: Aseptic meningitis syndrome (AMS) has been reported with immune globulin administration (rare); may occur with high doses ($\geq 1\text{--}2$ g/kg [product-dependent]) and/or rapid infusion. Syndrome usually appears within several hours to 2 days following treatment; usually resolves within several days after product is discontinued. Patients with a migraine history may be at higher risk for AMS.

- Hematoma: Increased risk of hematoma formation when administered subcutaneously for the treatment of ITP.
- Hemolysis: Intravenous immune globulin has been associated with antiglobulin hemolysis; monitor for signs of hemolytic anemia.
- Hyperproteinemia: Hyperproteinemia, increased serum viscosity, and hyponatremia may occur; distinguish hyponatremia from pseudohyponatremia to prevent volume depletion, a further increase in serum viscosity and a higher risk of thrombotic events.
- Infusion reactions: Patients should be monitored for adverse events during and after the infusion. Stop administration with signs of infusion reaction (fever, chills, nausea, vomiting, and rarely shock). Risk may be increased with initial treatment, when switching brands of immune globulin, and with treatment interruptions of >8 weeks.
- Pulmonary edema: Monitor for transfusion-related acute lung injury (TRALI); noncardiogenic pulmonary edema has been reported with intravenous immune globulin use. TRALI is characterized by severe respiratory distress, pulmonary edema, hypoxemia, and fever in the presence of normal left ventricular function. Usually occurs within 1-6 hours after infusion.
- Renal impairment: **[U.S. Boxed Warning]: I.V. formulation only: Acute renal dysfunction (increased serum creatinine, oliguria, acute renal failure, osmotic nephrosis) can rarely occur; usually within 7 days of use (more likely with products stabilized with sucrose). Use with caution in the elderly, patients with renal disease, diabetes mellitus, volume depletion, sepsis, paraproteinemia, and nephrotoxic medications due to risk of renal dysfunction. In patients at risk of renal dysfunction, the rate of infusion and**

concentration of solution should be minimized. Discontinue if renal function deteriorates.

- Thrombotic events: Thrombotic events have been reported with administration of intravenous immune globulin and subcutaneous immune globulin; use with caution in patients with a history of atherosclerosis or cardiovascular and/or thrombotic risk factors or patients with known/suspected hyperviscosity. Consider a baseline assessment of blood viscosity in patients at risk for hyperviscosity.

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