GAMMAGARD LIQUID [Immune Globulin Infusion (Human)] 10% Coding Guide

The information contained in this Coding Reference Guide is provided for informational purposes only and is current as of November 2014. Every reasonable effort has been made to verify the accuracy of the information; however, this guide is not intended to provide specific guidance on how to utilize, code, bill, or charge for any product or service. Health care providers should contact payers for guidance on appropriate coding and are responsible for any decisions on how to utilize, code, bill, or charge for product services.

Health care providers must also make the ultimate determination as to when to use a specific product based on clinical appropriateness for a particular patient. Third-party payment for medical products and services is affected by numerous factors, and Baxter cannot guarantee success in obtaining insurance payments.

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Intravenous or subcutaneous administration of GAMMAGARD LIQUID [Immune Globulin Infusion (Human)] 10%§

Quick Reference for Diagnostic and Billing Codes

This guide provides you with a convenient reference for the information you need to bill payers for GAMMAGARD LIQUID. Inside you will find:

- HCPCS Codes*
- NDC Numbers
- Hospital Revenue Code
- CPT® Codes†

The treating physician is responsible for ensuring accurate and appropriate diagnostic coding and billing to obtain reimbursement.

For additional information please contact the GAMMAGARD Reimbursement Hotline: 1-877-655-GARD (4273), Monday - Friday, 8:30 AM - 5:30 PM ET‡

§Approved for intravenous and subcutaneous administration in Primary Immunodeficiency and intravenous administration in Multifocal Motor Neuropathy

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‡For confidentiality purposes, calls will be answered by a third party contracted by Baxter Healthcare.

Please see Indications and Detailed Important Risk Information for GAMMAGARD LIQUID and accompanying full Prescribing Information, including Boxed Warning.

GAMMAGARD LIQUID [Immune Globulin Infusion (Human)] 10%

Indications

GAMMAGARD LIQUID is indicated as replacement therapy for primary humoral immunodeficiency (PI) in adult and pediatric patients two years of age or older. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

GAMMAGARD LIQUID is indicated as a maintenance therapy to improve muscle strength and disability in adult patients with Multifocal Motor Neuropathy (MMN).

Detailed Important Risk Information

WARNING: THROMBOSIS, RENAL DYSFUNCTION and ACUTE RENAL FAILURE

- **Thrombosis may occur with immune globulin products, including GAMMAGARD LIQUID. Risk factors may include advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors.**
- **Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur in predisposed patients with immune globulin intravenous (IGIV) products including GAMMAGARD LIQUID. Renal dysfunction and acute failure occur more commonly with IGIV products containing sucrose. GAMMAGARD LIQUID does not contain sucrose.**
- **For patients at risk of thrombosis, administer GAMMAGARD LIQUID at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk of hyperviscosity.**

CONTRAINDICATIONS

- GAMMAGARD LIQUID is contraindicated in patients who have a history of anaphylactic or severe systemic hypersensitivity reactions to the administration of human immune globulin. GAMMAGARD LIQUID is

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HCPCS Codes

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HCPCS code	Description
J1569*	Injection, immune globulin (GAMMAGARD LIQUID), intravenous, non-lyophilized (eg, liquid), 500 mg
J1569JB†	

*The HCPCS code currently assigned to GAMMAGARD LIQUID, J1569, only describes the intravenous route of administration. Providers are advised to contact the payer for the appropriate HCPCS code when GAMMAGARD LIQUID is administered subcutaneously.

†Medicare DME MAC coding guidance for GAMMAGARD LIQUID with the subcutaneous route of administration via a pump.

Home Infusion Therapy (for IVIG or SCIG)

HCPCS code	Description
S9338	Home infusion therapy, immunotherapy, administrative services, professional pharmacy services, care coordination and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

Health care providers should contact payers for guidance on appropriate coding.

NDC Numbers

GAMMAGARD LIQUID

NDC Number	Grams
0944-2700-02	1.0
0944-2700-03	2.5
0944-2700-04	5.0
0944-2700-05	10.0
0944-2700-06	20.0
0944-2700-07	30.0

Hospital Revenue Code

Code	Description
0636	Pharmacy, drugs requiring detailed coding

CPT® Codes

Intravenous Administration

CPT code	Description
96365	IV infusion for therapy, prophylaxis, or diagnosis; initial, up to 1 hour
96366 (add-on code)	IV infusion for therapy, prophylaxis, or diagnosis; each additional hour (List separately in addition to code for primary procedure)
96367 (add-on code)	IV infusion for therapy, prophylaxis, or diagnosis; additional sequential infusion, up to 1 hour (List separately in addition to code for primary procedure)
96368 (add-on code)	IV infusion for therapy, prophylaxis, or diagnosis; concurrent infusion (List separately in addition to code for primary procedure)

Subcutaneous Administration

CPT code	Description
96369	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); initial, up to 1 hour, including pump set-up and establishment of subcutaneous infusion site(s) Excludes infusions of 15 minutes or less (96372)
96370	Each additional hour (List separately in addition to code for primary procedure) Includes infusions of more than 30 minutes beyond 1 hour
96371	Additional pump set-up with establishment of new subcutaneous infusion site(s) (List separately in addition to code for primary procedure)

contraindicated in IgA-deficient patients with antibodies to IgA and a history of hypersensitivity.

WARNINGS and PRECAUTIONS

- **HYPERSENSITIVITY:** IgA deficient patients with antibodies to IgA are at greater risk of developing potentially severe hypersensitivity and anaphylactic reactions. In case of hypersensitivity, discontinue GAMMAGARD LIQUID infusion immediately and institute appropriate treatment.
- **RENAL DYSFUNCTION/FAILURE:** Monitor renal function, including blood urea nitrogen, serum creatinine, and urine output in patients at risk of acute renal failure. Ensure that patients with pre-existing renal insufficiency are not volume depleted. For patients at risk for renal dysfunction or thrombotic events, administer GAMMAGARD LIQUID at the minimum infusion rate practicable.
- **Hyperproteinemia, increased serum viscosity, and hyponatremia** may occur in patients receiving GAMMAGARD LIQUID.
- **THROMBOSIS:** Thrombosis may occur following treatment with immune globulin products, including GAMMAGARD LIQUID. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.
- **Aseptic Meningitis Syndrome** (AMS) may occur with IGIV treatment, and has been reported with intravenous (IV) use of GAMMAGARD LIQUID. AMS may occur more frequently with high dose (2 g/kg) IGIV treatment and/or rapid infusion of IGIV.
- **Hemolytic anemia** can develop subsequent to GAMMAGARD LIQUID treatment due to enhanced RBC sequestration. Risk factors may include: high doses (e.g., ≥2 g/kg cumulative dose), non-O blood group, and underlying inflammation. Monitor patients for clinical signs and symptoms of hemolysis and delayed hemolytic anemia.
- **Transfusion-Related Acute Lung Injury (TRALI):** Non-cardiogenic pulmonary edema has been reported in patients following treatment with IGIV products, including GAMMAGARD LIQUID. Monitor patients for pulmonary adverse reactions.

CONTINUED ON BACK PANEL

- GAMMAGARD LIQUID is made from human blood. It may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and theoretically, the Creutzfeldt-Jakob disease agent. No confirmed cases of viral transmission or vCJD have been associated with GAMMAGARD LIQUID.
- Passive transfer of antibodies may transiently impair the immune responses to live attenuated virus vaccines such as mumps, rubella, varicella, and measles. This passive transfer may also yield false positive serological testing results, with the potential for misleading interpretation.

ADVERSE REACTIONS

The serious adverse reaction that occurred during the PI (IV administration) clinical trials was aseptic meningitis. No serious adverse reactions were observed during the PI subcutaneous (SC) administration clinical trial. The serious adverse reactions in the MMN (IV administration) clinical trial were pulmonary embolism and blurred vision. The most common adverse reactions observed in ≥ 5% of patients in the clinical trials were:

PI (IV administration): Headache, fatigue, pyrexia, nausea, chills, rigors, pain in extremity, diarrhea, migraine, dizziness, vomiting, cough, urticaria, asthma, pharyngolaryngeal pain, rash, arthralgia, myalgia, oedema peripheral, pruritus, and cardiac murmur.

PI (SC administration): Infusion site (local) event, headache, fatigue, heart rate increased, pyrexia, abdominal pain upper, nausea, vomiting, asthma, blood pressure systolic increased, diarrhea, ear pain, aphthous stomatitis, migraine, oropharyngeal pain, and pain in extremity.

MMN (IV administration): Headache, chest discomfort, muscle spasms, muscular weakness, nausea, oropharyngeal pain, and pain in extremity.

Please see the accompanying full Prescribing Information, including Boxed Warning.

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