Hospital Outpatient Sample
CMS-1450 Claim Form

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

The CMS-1450 Claim Form (also known as UB-04) is the standard claim form to bill Medicare Fee-For-Service (FFS). The sample here is intended to educate you on completing the form for billing GAMMAGARD LIQUID and associated services.

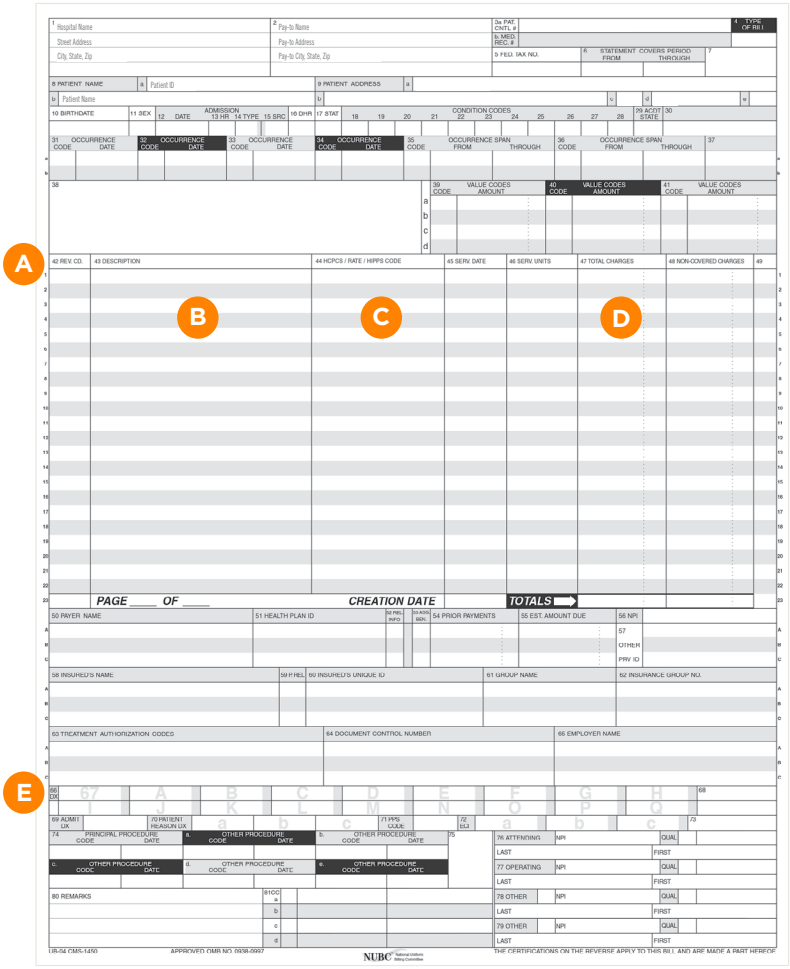
A **Revenue Codes | Box 42** List the 4-digit revenue code for each service described in Column B (Box 43). To assist in bill review, list revenue codes in ascending order

B **Description | Box 43** Enter a brief description that corresponds to the revenue code in Box 42 or HCPCS code in Box 44. List NDC code if applicable

C **Product and Procedure Codes | Box 44** Enter appropriate HCPCS and CPT® codes for Medicare and other payers, representing procedure performed

D **Total Charges | Box 47** Enter the total amount charged for each line of service

E **Diagnosis Code | Box 67** Enter the appropriate ICD-10-CM diagnosis code



Click here for a CMS-1450 Claim Form.

This billing guide does not represent a promise or guarantee of coverage and payment for any individual patient or treatment. Correct coding is the responsibility of the provider submitting a claim for the item or service. Please check with the payer to verify codes and any special billing requirements.

CMS=Centers for Medicare & Medicaid Services; CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; NDC=National Drug Code.

Looking for billing codes specific to GAMMAGARD LIQUID?
Click here for a billing and coding guide.

*For billing and coding assistance, Takeda Patient Support specialists are never more than a call away — **1-866-861-1750**, Monday through Friday, 8 AM to 8 PM ET.*

Takeda Patient Support
Your Source for Education and Access

Please see Important Safety Information on page 2 and click for Full Prescribing Information, including Boxed Warning regarding Thrombosis, Renal Dysfunction and Acute Renal Failure.

GAMMAGARD LIQUID

[Immune Globulin Infusion (Human)] 10%

INDICATIONS

GAMMAGARD LIQUID is indicated as a replacement therapy for primary humoral immunodeficiency (PI) in adult and pediatric patients two years of age or older, as a maintenance therapy to improve muscle strength and disability in adult patients with Multifocal Motor Neuropathy (MMN), and as a therapy to improve neuromuscular disability and impairment in adult patients with Chronic Inflammatory Demyelinating Polyneuropathy (CIDP).

LIMITATIONS OF USE (CIDP): GAMMAGARD LIQUID has not been studied in immunoglobulin-naive patients with CIDP. GAMMAGARD LIQUID maintenance therapy in CIDP has not been studied for periods longer than 6 months. After responding during an initial treatment period, not all patients require indefinite maintenance therapy with GAMMAGARD LIQUID in order to remain free of CIDP symptoms. Individualize the duration of any treatment beyond 6 months based upon the patient's response and demonstrated need for continued therapy.

GAMMAGARD LIQUID for PI is for intravenous or subcutaneous use.

GAMMAGARD LIQUID for MMN and CIDP is for intravenous use only.

IMPORTANT SAFETY INFORMATION

WARNING: THROMBOSIS, RENAL DYSFUNCTION, and ACUTE RENAL FAILURE

- **Thrombosis may occur with immune globulin (IG) 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. Patients predisposed to renal dysfunction include those with any degree of pre-existing renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Renal dysfunction and acute renal failure occur more commonly in patients receiving 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

- History of anaphylactic or severe systemic hypersensitivity reactions to human IG.
- IgA-deficient patients with antibodies to IgA and a history of hypersensitivity to human IG. Anaphylaxis has been reported with intravenous (IV) use of GAMMAGARD LIQUID.

Warnings and Precautions

Hypersensitivity: Severe hypersensitivity reactions may occur, even in patients who have tolerated previous treatment with human IG. If a hypersensitivity reaction occurs, discontinue infusion immediately and institute appropriate treatment. IgA-deficient patients with antibodies to IgA are at greater risk of developing potentially severe hypersensitivity reactions, including anaphylaxis.

Renal Dysfunction/Failure: Acute renal dysfunction/failure, acute tubular necrosis, proximal tubular nephropathy, osmotic nephrosis, and death may occur with IV use of IG products, especially those containing sucrose. Acute renal dysfunction/failure has been reported in association with infusions of GAMMAGARD LIQUID. Ensure patients are not volume depleted prior to infusion. In patients at risk due to pre-existing renal insufficiency or predisposition to acute renal failure, assess renal function before initiation and throughout treatment, and use the minimum infusion rate practicable for IV administration. If renal function deteriorates, consider discontinuation.

Hyperproteinemia, increased serum viscosity, and hyponatremia may occur. It is critical to distinguish true hyponatremia from a pseudohyponatremia because certain treatments may lead to volume depletion, a further increase in serum viscosity, and a predisposition to thromboembolic events.

Thrombosis: May occur following treatment with IG products and in the absence of known risk factors. In patients at risk, administer at the minimum dose and infusion rate practicable. Ensure adequate hydration before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

Aseptic Meningitis Syndrome: Has been reported with use of IG and may occur more frequently in females. Conduct a thorough neurological exam on patients exhibiting signs and symptoms, to rule out other causes of meningitis. Discontinuing IG treatment has resulted in remission within several days without sequelae.

Hemolysis: GAMMAGARD LIQUID contains blood group antibodies, which may cause a positive direct antiglobulin reaction and hemolysis. Monitor patients for signs and symptoms of hemolysis and delayed hemolytic anemia and, if present, perform appropriate confirmatory lab testing.

Transfusion-Related Acute Lung Injury: Non-cardiogenic pulmonary edema has been reported with IV-administered IG, including GAMMAGARD LIQUID. Monitor patients for pulmonary adverse reactions. If suspected, perform appropriate tests for presence of anti-neutrophil and anti-HLA antibodies in both product and patient serum. May be managed using oxygen therapy with adequate ventilatory support.

Transmittable Infectious Agents: Because GAMMAGARD LIQUID is made from human plasma, it may carry a risk of transmitting infectious agents (e.g., viruses, other pathogens). No confirmed cases of viral transmission or variant Creutzfeldt-Jakob disease (vCJD) have been associated with GAMMAGARD LIQUID.

Interference with Lab Tests: False positive serological test results and certain assay readings, with the potential for misleading interpretation, may occur as the result of passively transferred antibodies.

Adverse Reactions

The serious adverse reactions observed in clinical studies in PI was aseptic meningitis, and in MMN were pulmonary embolism and blurred vision.

The most common adverse reactions observed in ≥5% of patients were:

IV administration for PI: 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.

Subcutaneous administration for PI: Infusion site (local) event (rash, erythema, edema, hemorrhage, and irritation), 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.

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

IV administration for CIDP: Headache, pyrexia, anemia, leukopenia, neutropenia, illness, blood creatinine increased, dizziness, migraine, somnolence, tremor, nasal dryness, abdominal pain upper, vomiting, chills, nasopharyngitis, and pain in extremity.

Drug Interactions

Passive transfer of antibodies may transiently interfere with immune responses to live attenuated virus vaccines (e.g., measles, mumps, rubella, and varicella).

Please click for Full Prescribing Information.

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