Biotest

From Nature for Life

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TO WHOM IT MAY CONCERN

Re: BIVIGAM® HCPCS Code (J-Code)

Dear Customer,

Biotest Pharmaceuticals Corporation has been issued a J-Code from CMS for BIVIGAM®[Immune Globulin Intravenous (Human), 10% Liquid].

The J-Code issued to BIVIGAM is **J1556 and is** effective as of January 1, 2014.

HCPCS Code	Description	Billing Unit	Effective Date
J1556	**Injection, immune globulin (BIVIGAM), intravenous, non-lyophilized (e.g., liquid),**	**500 mg**	**1/1/2014**

If you have any questions or require additional information about BIVIGAM, please contact the BIVIGAM CareLine at 1-855-BIVIGAM (855-248-4426).

BIVIGAM® is a sugar-free, glycine stabilized 10% liquid intravenous immune globulin product BIVIGAM is packaged with a tamper-evident seal and an integrated hanger and is manufactured exclusively in the US for US healthcare professionals and patients.

For Full Prescribing Information and more information about the product, the indication and additional services, please visit www.BIVIGAM.com. For ordering information, please contact our customer support at 1.800.458.4244 and select Option 1.

Sincerely Yours,
Biotest Pharmaceuticals Corporation

Douglas Loock
Vice President Sales & Marketing

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Important Safety Information for BIVIGAM® [Immune Globulin Intravenous (Human), 10% Liquid]

BIVIGAM® [Immune Globulin Intravenous (Human), 10% Liquid] is indicated for the treatment of primary humoral immunodeficiency (PI). This includes, but is not limited to, the humoral immune defect in common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Warning: **Thrombosis may occur with immune globulin intravenous (IGIV) products, including BIVIGAM®. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, a history of venous or arterial thrombosis, the use of estrogens, indwelling vascular catheters, hyperviscosity and cardiovascular risk factors.**
Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with the administration of Immune Globulin Intravenous (Human) (IGIV) products in predisposed patients. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. BIVIGAM does not contain sucrose. For patients at risk of thrombosis, renal dysfunction, or renal failure, administer BIVIGAM at the minimum dose recommended and infusion rate practicable. Ensure adequate hydration in patients before administrations. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for viscosity. See full Prescribing Information for complete boxed warning.

BIVIGAM is contraindicated in patients who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin and in IgA-deficient patients with antibodies to IgA and history of hypersensitivity.

Hyperproteinemia, increased serum viscosity, and hyponatremia or pseudohyponatremia can occur in patients receiving IGIV therapy.

Aseptic meningitis syndrome (AMS) has been reported with IGIV treatments; AMS may occur more frequently in association with high doses (2 g/kg) and/or rapid infusion of IGIV.

As hemolysis can develop subsequent to treatment with IGIV products, monitor patients for hemolysis and hemolytic anemia.

Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]). If TRALI is suspected, test the product and patient for antineutrophil antibodies.

Because BIVIGAM is made from human blood, it may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

Serious adverse reactions observed in clinical trial subjects receiving BIVIGAM were vomiting and dehydration in one subject. The most common adverse reactions to BIVIGAM (reported in ≥5% of clinical study subjects) were headache, fatigue, infusion site reaction, nausea, sinusitis, blood pressure increase, diarrhea, dizziness, and lethargy.

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You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.
For more information about BIVIGAM please see full Prescribing Information.