Alphanate®

antihemophilic factor/von Willebrand factor complex (human)

ALPHANATE Coding and Billing

Coding System	Code	Description
Product HCPCS	J7186	Injection antihemophilic factor VIII/Von Willebrand factor complex (human), per factor VIII IU
Administration CPT	96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
Administration CPT	96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour
ICD-10-CM	D66.0	Hereditary factor VIII deficiency
ICD-10-CM	D68.0	Von Willebrand's disease
Product NDC	68516-4611-01	250 IU FVIII range (5 mL diluent)
Product NDC	68516-4612-01	500 IU FVIII range (5 mL diluent)
Product NDC	68516-4613-02	1000 IU FVIII range (10 mL diluent)
Product NDC	68516-4614-02	1500 IU FVIII range (10 mL diluent)
Product NDC	68516-4615-02	2000 IU FVIII range (10 mL diluent)

CPT, Current Procedural Terminology
HCPCS, Healthcare Common Procedure Coding System
ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification
NDC, National Drug Code

The information contained in this guide is provided for informational purposes only and is subject to change. Providers are encouraged to contact their payers for specific information. Coding rules and guidelines are subject to payer discretion and should always be verified by the paying entity. Healthcare providers make the ultimate determination as to when to use a specific product, based on clinical appropriateness for a patient. This guide is not intended to provide specific guidance on how to use, code, bill, or charge for any product or service. Third-party payment for medical products and services is affected by numerous factors, and Grifols cannot make any representation or guarantee concerning reimbursement or coverage for any service or item.

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Indications

ALPHANATE® (antihemophilic factor/von Willebrand factor complex [human]) is indicated for:

- Control and prevention of bleeding episodes and perioperative management in adult and pediatric patients with factor VIII (FVIII) deficiency due to hemophilia A
- Surgical and/or invasive procedures in adult and pediatric patients with von Willebrand disease (VWD) in whom desmopressin (DDAVP) is either ineffective or contraindicated. It is not indicated for patients with severe VWD (type 3) undergoing major surgery

Important Safety Information

ALPHANATE is contraindicated in patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components.

Anaphylaxis and severe hypersensitivity reactions are possible with ALPHANATE. Discontinue use of ALPHANATE if hypersensitivity symptoms occur, and initiate appropriate treatment.

Development of procoagulant activity-neutralizing antibodies (inhibitors) has been detected in patients receiving FVIII-containing products. Carefully monitor patients treated with AHF products for the development of FVIII inhibitors by appropriate clinical observations and laboratory tests.

Thromboembolic events have been reported with AHF/VWF complex (human) in VWD patients, especially in the setting of known risk factors.

Intravascular hemolysis may occur with infusion of large doses of AHF/VWF complex (human).

Rapid administration of a FVIII concentrate may result in vasomotor reactions.

Because ALPHANATE is made from human plasma, it may carry a risk of transmitting infectious agents, eg, viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent, despite steps designed to reduce this risk.

Monitor for development of FVIII and VWF inhibitors. Perform appropriate assays to determine if FVIII and/or VWF inhibitor(s) are present if bleeding is not controlled with expected dose of ALPHANATE.

The most frequent adverse drug reactions reported with ALPHANATE in >1% of infusions were pruritus, headache, back pain, paresthesia, respiratory distress, facial edema, pain, rash, and chills.

Please see full Prescribing Information available at www.alphanate.com/HCP.

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