Clinical Policy: Factor VIII/von Willebrand factor complex (Human - Alphanate, Humate-P, Wilate)

Reference Number: ERX.SPMN.198
Effective Date: 01/17

See Important Reminder at the end of this policy for important regulatory and legal information.

Policy/Criteria

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that factor VIII/von Willebrand factor complex (Human – Alphanate®, Humate-P®, Wilate®) is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Hemophilia A (must meet all):
      1. Prescribed by or in consultation with a hematologist;
      2. Diagnosis of hemophilia A and request is for treatment and/or prevention of bleeding;
      3. If factor VIII coagulant activity levels are > 5%, member has contraindication to or has failed desmopressin acetate, or an appropriate formulation of desmopressin acetate is not available;
      4. Request is for one the following (a or b):
         a. Alphanate;
         b. Humate-P, and age ≥ 18 years.

      Approval duration: 3 months

   B. von Willebrand Disease (must meet all):
      2. Prescribed by or in consultation with a hematologist;
      3. For Humate P/Wilate, prescribed agent will be used for spontaneous and trauma-induced bleeding episode or perioperative management of bleeding, and member meets one of the following (a or b):
         a. Diagnosis of von Willebrand disease (vWD) type 1 or 2, and desmopressin is inadequate or contraindicated;
         b. Diagnosis of vWD type 3;
      4. For Alphanate, prescribed agent will be used for perioperative management of bleeding, and member meets one of the following (a or b):
         a. Diagnosis of vWD type 1 or 2, and desmopressin is inadequate or contraindicated;
         b. Diagnosis of vWD type 3, and member is NOT undergoing major surgery.

      Approval duration: 3 months

   C. Other diagnoses/indications: Refer to ERX.SPMN.16 - Global Biopharm Policy.
II. Continued Approval
   A. All Indications (must meet all):
      1. Currently receiving medication via health plan benefit or member has previously met all initial approval criteria.

      Approval duration: 3 months

   B. Other diagnoses/indications (must meet 1 or 2):
      1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy; or
      2. Refer to ERX.SPMN.16 - Global Biopharm Policy.

Background

Description/Mechanism of Action:
Factor VIII and vWF, obtained from pooled human plasma, are used to replace endogenous factor VIII and vWF in patients with hemophilia or vWD. Factor VIII in conjunction with activated factor IX, activates factor X which converts prothrombin to thrombin and fibrinogen to fibrin. vWF promotes platelet aggregation and adhesion to damaged vascular endothelium and acts as a stabilizing carrier protein for factor VIII. (Circulating levels of functional vWF are measured as ristocetin cofactor activity [vWF:RCo].)

Formulations (from human plasma):
Injection, powder for reconstitution containing factor VIII and VWF:RCo; packaged with diluent:
   - Alphanate
   - Humate-P
   - Wilate

FDA Approved Indications:
Alphanate is indicated for:

- Hemophilia A:
  - Control and prevention of bleeding in adults and pediatric patients with hemophilia A.
- von Willebrand disease:
  - Surgical and/or invasive procedures in adults and pediatric patients with vWD in whom desmopressin (DDAVP) is either ineffective or contraindicated.

Limitations of use: Alphanate is not indicated for patients with severe vWD (type 3) undergoing major surgery.

Humate-P is indicated for:

- Hemophilia A:
  - Treatment and prevention of bleeding in adults with hemophilia A (classical hemophilia).
- von Willebrand disease:
  - Treatment of spontaneous and trauma-induced bleeding episodes;
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- Prevention of excessive bleeding during and after surgery in patients with severe vWD as well as patients with mild or moderate disease where use of desmopressin (DDAVP) is known or suspected to be inadequate.

Limitations of use: Controlled clinical trials to evaluate the safety and efficacy of prophylactic dosing with Humate-P to prevent spontaneous bleeding have not been conducted in vWD subjects.

Wilate is indicated for:

- von Willebrand disease:
  - In children and adults with vWD disease for:
    - On-demand treatment and control of bleeding episodes;
    - Perioperative management of bleeding.

Limitations of use: Wilate is not indicated for the treatment of hemophilia A.

**Appendices**

**Appendix A: Abbreviation Key**

- vWD: von Willebrand disease
- vWF: von Willebrand factor

**Coding Implications**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tr>
<td>J7183</td>
<td>Injection, von Willebrand factor complex (human), Wilate, 1 IU vWF:RCo</td>
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<tr>
<td>J7186</td>
<td>Injection, antihemophilic factor VIII/von Willebrand factor complex (human), per factor VIII i.u.</td>
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<tr>
<td>J7187</td>
<td>Injection, von Willebrand factor complex (Humate-P), per IU VWF:RCo</td>
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**Reviews, Revisions, and Approvals**

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<tr>
<th>Date</th>
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**References**

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**Important Reminder**
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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