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

Reference Number: PA.CP.PHAR.216
Effective Date: 01/18
Last Review Date: 07/18

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for factor VIII/von Willebrand factor complex (Alphanate®, Humate-P®, Wilate®).

FDA Approved Indication(s)
Alphanate is indicated for:

- Hemophilia A:
  - Control and prevention of bleeding episodes and perioperative management in adults and pediatric patients with Factor VIII deficiency due to hemophilia A.
- Von Willebrand disease:
  - Surgical and/or invasive procedures in adults and pediatric patients with von Willebrand Disease (VWD) in whom desmopressin (DDAVP) is either ineffective or contraindicated.

Limitation(s) 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).
- In adult and pediatric patients with Von Willebrand disease (VWD):
  - Treatment of spontaneous and trauma-induced bleeding episodes;
  - Prevention of excessive bleeding during and after surgery in patients with severe VWD as well as patients with mild to moderate disease where use of desmopressin (DDAVP) is known or suspected to be inadequate.

Limitation(s) 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 von Willebrand disease (VWD) disease for:
    - On-demand treatment and control of bleeding episodes;
    - Perioperative management of bleeding.

Limitation(s) of use: Wilate is not indicated for the treatment of hemophilia A.

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness that Alphanate, Humate-P, and Wilate are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Congenital Hemophilia A – Alphanate/Humate-P (must meet all):

1. Diagnosis of congenital hemophilia A (factor VIII deficiency);
2. Prescribed by or in consultation with a hematologist;
3. Request is for one of the following (a or b):
   a. Control or prevention of bleeding episodes;
   b. Perioperative management (Alphanate only);
4. If factor VIII coagulant activity levels are >5%, member has failed a trial of desmopressin acetate, unless contraindicated or clinically significant adverse effects are experienced, or an appropriate formulation of desmopressin acetate is unavailable;
5. Dose does not exceed the FDA approved maximum recommended dose for the relevant indications.

Approval duration: 3 months

B. Von Willebrand Disease (must meet all)**:**

1. Diagnosis of VWD (types 1, 2, or 3);
2. Prescribed by or in consultation with a hematologist;
3. Request is for one of the following (a or b):
   a. Spontaneous and trauma-induced bleeding episodes (Humate-P and Wilate only);
   b. Perioperative management;
4. Dose does not exceed the FDA approved maximum recommended dose for the relevant indications.

Approval duration: 3 months

C. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. All indications listed in Section I (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria, or the Continuity of Care policy applies (*see PA.LTSS.PHAR.01*);
2. Member is responding positively to therapy.

Approval duration: 3 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy, or the Continuity of Care policy applies (*see PA.LTSS.PHAR.01*).

Approval duration: Duration of request or 6 months (whichever is less); or

2. 2. Refer to PA.CP.PMN.53

Background

Description/Mechanism of Action:

Factor VIII (FVIII) and von Willebrand factor (VWF), obtained from pooled human plasma, are used to replace endogenous FVIII and VWF in patients with hemophilia or VWD. FVIII 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 FVIII. Circulating levels of functional VWF are measured as ristocetin cofactor activity (VWF:RCo).

Formulations (from human plasma):

Solution, Reconstituted, IV:

- Alphanate
  - FVIII 250 units and VWF:RCo > 400 units per 1000 units FVIII
  - FVIII 500 units and VWF:RCo > 400 units per 1000 units FVIII
  - FVIII 1000 units and VWF:RCo > 400 units per 1000 units FVIII
  - FVIII 1500 units and VWF:RCo > 400 units per 1000 units FVIII
  - FVIII 2000 units and VWF:RCo > 400 units per 1000 units FVIII
- Humate-P
  - FVIII 250 units and VWF:RCo 600 units
  - FVIII 500 units and VWF:RCo 1200 units
  - FVIII 1000 units and VWF:RCo 2400 units
- Wilate
  - FVIII 500 units and VWF:RCo 500 units
  - FVIII 1000 units and VWF:RCo 1000 units

Appendices

Appendix A: Abbreviation Key

IV: intravenous
RCo: ristocetin cofactor
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.

HCPCS Codes	Description
J7183	Injection, von Willebrand factor complex (human), Wilate, 1 IU vWF:RCo
J7186	Injection, antihemophilic factor VIII/von Willebrand factor complex (human), per factor VIII i.u.
J7187	Injection, von Willebrand factor complex (Humate-P), per IU VWF:RCO

Reviews, Revisions, and Approvals	Date	Approval Date
Removed ages. Dose guidelines delineated. References reviewed and updated.	02/18	

References

1. Alphanate Prescribing Information. Los Angeles, CA: Grifols Biologicals Inc.; March 2015. Available at http://www.alphanate.com. Accessed November 27, 2017.
2. Humate-P Prescribing Information. Kankakee, IL: CSL Behring, LLC; September 2016. Available at http://labeling.cslbehring.com/PI/US/Humate-P/EN/Humate-P-Prescribing-Information.pdf. Accessed November 27, 2017.
3. Wilate Prescribing Information. Hoboken, NJ: Octapharma USA Inc.; August 2015. Available at http://www.wilateusa.com/images/PDF_Files/WILATE_FPI_US_additional_Perioperative_Indication_8_2015.pdf. Accessed November 27, 2017.
4. Srivastava A, Brewer AK, Mauser-Bunschoten EP, et al. Guidelines for the management of hemophilia. Haemophilia. Jan 2013; 19(1): e1-47.
5. Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation (NHF): Database of treatment guidelines. Available at https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-Scientific-Advisory-Council-MASAC/MASAC-Recommendations. Accessed November 27, 2017.