Pharmacy Policy

Blood Clotting Disorder Medications

Policy Number: 9.610
Version Number: 2.0
Version Effective Date: 3/1/2022

Product Applicability	☐ **All Plan⁺ Products**
Well Sense Health Plan ☐ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☒ MassHealth - MCO ☒ MassHealth - ACO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Advate
- Adynovate
- Afstyla
- Alphanate VWF
- Alphanine SD
- Alprolix
- Coagadex
- Corifact
- Eloctate
- Feiba
- Hemofil-M
- Humate-P
- Idelvion
- Ixinity
- Koate-DVI/Koate
- Kogenate FS
- Kovaltry
- Mononine
- Novoeight
- NovoSeven RT
- Nuwiq
- Obizur
- Profilnine SD
- Recombinate
- Rixubis
- Rebinyn
- Tretten
- Vonvendi
- Wilate

The Plan may authorize coverage of the above products for members meeting the following criteria:

⁺ *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

Covered Use	All FDA approved indications not otherwise excluded
Required Medical Information	For Factor VIII, IX and X products- Advate, Alphanate VWF, Afstyla, Adynovate, Eloctate, Hemofil M, Humate P, Kogenate FS, Koate, Kovaltry, Novoeight, Nuwiq, Obizur, Recombinate, Wilate, AlphaNine SD, Alprolix, Ixinity, Idelvion, Moninine, Profilnine, Rixubis, Rebinyn, Coagadex, 1. An acute bleeding episode for severe hemophilia (A or B) or Factor X deficiency ***(Coagadex only)*** or an acute bleeding episode due to trauma or surgery in members with mild to moderate hemophilia; ***OR*** 2. A diagnosis of severe hemophilia (A or B) requiring routine prophylaxis to prevent or reduce the frequency of bleeding episodes; ***OR*** 3. A diagnosis of hemophilia (A or B) or Factor X deficiency (Coagadex® only) requiring perioperative management to prevent surgical bleeding; ***OR*** 4. A diagnosis of Von Willebrand Disease at increased risk of bleeding due to a clinical situation (i.e. trauma, surgery, or menorrhagia) ***OR*** an acute bleeding episode For von Willebrand factor (VWF), recombinant human*:* - Vonvendi 1. A diagnosis of von Willebrand disease (VWD) and is going to be used for treatment (on demand) and control of bleeding episodes. For Factor VIIa or antiinhibitor complex – FEIBA, NovoSeven RT 1. A diagnosis acquired hemophilia, congenital factor VII deficiency, or Glanzmann's thrombasthenia ***(Novoseven RT only)*** with an acute bleeding episode or increased risk of bleeding due to a clinical situation (i.e. trauma or surgery); ***OR*** 2. Persistent inhibitors to factor concentrates has developed For Factor XIII – Corifact, Tretten Corifact 1. Prophylactic treatment is required for the diagnosis of factor XIII deficiency; ***OR*** 2. Perioperative management of surgical bleeding in adults and pediatric patients with factor XIII deficiency. Tretten 1. Prophylactic treatment is required for the diagnosis of factor XIII A-subunit deficiency
Age Restriction	Vonvendi: 18 years or older
Prescriber Restriction	None
Coverage Duration	12 months
Other criteria	None

Clinical Background Information and References

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4. Afstyla (antihemophilic factor [recombinant]) [prescribing information]. Kankakee, IL: CSL Behring LLC; May 2016.
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6. Helixate FS (antihemophilic factor [recombinant]) [prescribing information]. Kankakee, IL: CSL Behring LLC; Accessed Oct 2021.
7. Hemophilia of Georgia, for the World Federation of Hemophilia (WFH). Protocols for the treatment of hemophilia and von willebrand disease. Treatment of Hemophilia. 2008 Apr [cited 2008 Oct 13];14:1-14. Available from: http://www.wfh.org/2/docs/Publications/VWD_WomenBleedingDisorders/TOH-14-Protocols-Hemophilia-VWD-Revised2008.pdf. Accessed Dec 19, 2011
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12. Kogenate FS (antihemophilic factor [recombinant]) [prescribing information]. Whippany, NJ: Bayer HealthCare LLC; Accessed Oct 2021.
13. Kovaltry (antihemophilic factor [recombinant]) [prescribing information]. Whippany, NJ: Bayer HealthCare LLC; Accessed Oct 2021.
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16. Novoeight (antihemophilic factor [recombinant]) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; Accessed Oct 2021.

17. Nuwiq (antihemophilic factor [recombinant]) [prescribing information]. Paramus, NJ: Octapharma USA Inc; Accessed Oct 2021.
18. Rebinyn (Coagulation Factor IX (Recombinant), GlycoPEGylated) [prescribing information]. NJ:Novo Nordisk Inc.; Accessed Oct 2021.
19. Recombinate (antihemophilic factor [recombinant]) [prescribing information]. Lexington, MA: Baxalta US Inc; Accessed Oct 2021.
20. Rick, M. von Willebrand disease (VWD): Treatment of minor bleeding and routine care. Up TO Date. Current through Oct 2021. Accessed Oct 2021.
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Applicable coding:

Code	Medication
J7175	Injection, factor X (human), Coagadex
J7179	Injection, von willebrand factor (recombinant), (vonvendi)
J7180	Injection, factor XIII, Corifact
J7181	Injection, factor xiii a-subunit, (recombinant), per IU, Tretten
J7182	Injection, factor VIII, (antihemophilic factor, recombinant), (NovoEight), per IU
J7183	Injection, von Willebrand factor complex, per unit, Wilate
J7186	Injection, factor VIII/von Willebrand factor complex, per unit, Alphanate
J7187	Injection, vonWillebrand factor complex (Humate-P), per unit
J7188	Injection, factor VIII (antihemophilic factor, recombinant), per IU, Obizur
J7189	Factor VIIa (antihemophilic factor, recombinant), per 1 microgram, FEIBA® NF, NovoSeven® RT
J7190	Injection, factor VIII (antihemophilic factor, human), per unit, Koate-DVI, Monoclate-P, Hemofil M
J7191	Injection, factor VIII (antihemophilic factor, porcine), per unit
J7192	Injection, factor VIII (antihemophilic factor, recombinant) per unit, Helixate, Recombinate, Advate, Kogenate, Eloctate, Novoeight
J7193	Injection, factor IX (antihemophilic factor, purified) per unit, AlphaNine SD, Mononine
J7194	Injection, factor IX complex, per unit, Profilnine SD
J7195	Injection, factor IX (antihemophilic factor, recombinant) per unit, Alprolix, Benefix, Ixinity
J7198	Injection, antiinhibitor, per IU, FEIBA NF
J7199	Injection, hemophilia clotting factor, not otherwise classified.
J7210	Injection, factor VIII (antihemophilic factor, recombinant), Afstyla
J7202	Injection, factor ix, albumin fusion protein, (recombinant), idelvion
J7209	Injection, factor viii, (antihemophilic factor, recombinant), (nuwiq)
J7211	Injection, factor VIII (antihemophilic factor, recombinant), Kovaltry

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.165 Blood Clotting Disorder Medications Policy retired; new policy created; removed Benefix and Xyntha to covered to align with MH state PDL requirements; removed Helixate, Feiba NF and Monoclate P from policy due to product discontinuation;	1/1/2021	P&T Committee
11/11/2021	No recommended changes.	3/1/2022	P&T Committee

Next Review Date

2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.