Medical Necessity Guidelines: Antihemophilic factor VIII

Effective: January 1, 2023

Prior Authorization Required
If REQUIRED, submit supporting clinical documentation pertinent to service request.

Applies to:

Commercial Products
☐ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
☐ Tufts Health Plan Commercial products; Fax 617-673-0988
CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products
☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0988
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0988
☒ Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax 617-673-0956
  *The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

Senior Products
☒ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956
☒ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956
☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956
☒ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview
Hemophilia is a congenital condition caused in which there is a deficiency in a clotting factor, Hemophilia A by a deficiency of coagulant factor VIII and Hemophilia B by coagulant factor IX, both intrinsic pathway (contact activation) coagulation factors. Clotting factors are necessary to stop bleeding and allow wounds to close and heal. Acquired hemophilia is a sub-type that is caused by an autoimmune disorder disrupting clotting factor production rather than a genetic disorder. Von Willebrand Disease is a failure to produce the primary hemostasis (platelet activation) coagulation factor von Willebrand factor. Antihemophilic factors can be produced recombinantly, by a culture of cells into which the human gene for production of the factor has been grafted or produced by extraction from healthy human or porcine plasma.

Food and Drug Administration (FDA) Approved Indications:
ADVATE is a recombinant antihemophilic factor indicated for use in children and adults with hemophilia A for:
- Control and prevention of bleeding episodes
- Perioperative management
- Routine prophylaxis to prevent or reduce the frequency of bleeding episodes

ADVATE is not indicated for the treatment of von Willebrand disease.

ADYNOVATE is a human antihemophilic factor indicated in children and adults with hemophilia A (congenital factor VIII deficiency) for:
- On-demand treatment and control of bleeding episodes
- Perioperative management
- Routine prophylaxis to reduce the frequency of bleeding episodes
ADYNOVATE is not indicated for the treatment of von Willebrand disease.

AFSTYLA is a recombinant antihemophilic factor indicated in adults and children with hemophilia A (congenital Factor VIII deficiency) for:
- On-demand treatment and control of bleeding episodes
- Routine prophylaxis to reduce the frequency of bleeding episodes
- Perioperative management of bleeding.
AFSTYLA is not indicated for the treatment of von Willebrand disease.

ALPHANATE is indicated for:
- Control and prevention of bleeding in adult and pediatric patients with hemophilia A
- Surgical and/or invasive procedures in adult and pediatric patients with von Willebrand Disease in whom desmopressin (DDAVP) is either ineffective or contraindicated
ALPHANATE is not indicated for patients with severe VWD (Type 3) undergoing major surgery.

ELOCTATE is a recombinant DNA derived, antihemophilic factor indicated in adults and children with hemophilia A (congenital Factor VIII deficiency) for:
- On-demand treatment and control of bleeding episodes
- Perioperative management of bleeding
- Routine prophylaxis to reduce the frequency of bleeding episodes
ELOCTATE is not indicated for the treatment of von Willebrand disease.

ESPEROCT is a coagulation Factor VIII concentrate indicated for use in adults and children with hemophilia A for:
- On-demand treatment and control of bleeding episodes
- Perioperative management of bleeding
- Routine prophylaxis to reduce the frequency of bleeding episodes
ESPEROCT is not indicated for the treatment of von Willebrand Disease.

HEMOFIL M is indicated in hemophilia A (classical hemophilia) for the prevention and control of hemorrhagic episodes.
HEMOFIL M is not indicated in von Willebrand's disease.

HUMATE-P is an Antihemophilic Factor/von Willebrand Factor (VWF) Complex (Human) indicated for:
- Hemophilia A – Treatment and prevention of bleeding in adults
- Von Willebrand disease (VWD) – in adults and pediatric patients in the treatment of spontaneous and trauma-induced bleeding episodes, and prevention of excessive bleeding during and after surgery. This applies to patients with severe VWD as well as patients with mild to moderate VWD where the use of desmopressin is known or suspected to be inadequate
HUMATE-P is not indicated for the prophylaxis of spontaneous bleeding episodes in VWD.

JIVI is a recombinant DNA-derived, Factor VIII concentrate indicated for use in previously treated adults and adolescents (12 years of age and older) with hemophilia A (congenital Factor VIII deficiency) for:
- On-demand treatment and control of bleeding episodes
- Perioperative management of bleeding
- Routine prophylaxis to reduce the frequency of bleeding episodes
JIVI is not indicated for use in children < 12 years of age due to a greater risk for hypersensitivity reactions; use in previously untreated patients (PUPs); for the treatment of von Willebrand disease.

KOĀTE/KOATE-DVI is a human plasma-derived antihemophilic factor indicated for the control and prevention of bleeding episodes or in order to perform emergency and elective surgery in patients with hemophilia A (hereditary Factor VIII deficiency)
KOĀTE/Koate-DVI is not indicated for the treatment of von Willebrand disease.

KOVALTRY is a recombinant, human DNA sequence derived, full length Factor VIII concentrate indicated for use in adults and
children with hemophilia A (congenital Factor VIII deficiency) for:
- On-demand treatment and control of bleeding episodes
- Perioperative management of bleeding
- Routine prophylaxis to reduce the frequency of bleeding episodes

KOVALTRY is not indicated for the treatment of von Willebrand disease.

NOVOEIGHT is an Antihemophilic Factor (Recombinant) indicated for use in adults and children with hemophilia A for:
- On-demand treatment and control of bleeding episodes
- Perioperative management
- Routine prophylaxis to reduce the frequency of bleeding episodes

NOVOEIGHT is not indicated for the treatment of von Willebrand disease.

NUWIQ is a recombinant antihemophilic factor [blood coagulation factor VIII (Factor VIII)] indicated in adults and children with Hemophilia A for:
- On-demand treatment and control of bleeding episodes
- Perioperative management
- Routine prophylaxis to reduce the frequency of bleeding episodes

NUWIQ is not indicated for the treatment of von Willebrand disease.

OBIZUR is an antihemophilic factor indicated for the on-demand treatment and control of bleeding episodes in adults with acquired hemophilia A. The safety and efficacy of OBIZUR has not been established in patients with a baseline anti-porcine factor VIII inhibitor titer of greater than 20 BU.

OBIZUR is not indicated for the treatment of congenital hemophilia A or von Willebrand disease.

RECOMBINATE is indicated in hemophilia A (classical hemophilia) for the prevention and control of hemorrhagic episodes.
- RECOMBINATE is also indicated in the perioperative management of patients with hemophilia A (classical hemophilia).
- RECOMBINATE can be of therapeutic value in patients with acquired Factor VIII inhibitors not exceeding 10 Bethesda Units per mL

WILATE is indicated in children and adults with von Willebrand disease for:
- On-demand treatment and control of bleeding episodes
- Perioperative management of bleeding

WILATE is also indicated in adolescents and adults with hemophilia A for:
- Routine prophylaxis to reduce the frequency of bleeding episodes
- On-demand treatment and control of bleeding episodes

XYNTHA/XYNTHA SOLOFUSE is a recombinant antihemophilic factor indicated in adults and children with hemophilia A for:
- On-demand treatment and control of bleeding episodes
- Perioperative management
- Routine prophylaxis to reduce the frequency of bleeding episodes.

XYNTHA is not indicated in patients with von Willebrand's disease.

CMS NATIONAL COVERAGE POLICY
Covered Indications
Medicare provides coverage of these factor products through Part A and B coverage. In Part B, Medicare provides coverage in two manners, one of an 'incident to' event where the provider has a cost of the factor and administers, whereby the claim will demonstrate the factor product code and administration codes. Medicare also provides coverage for self-administered blood-clotting factors for hemophilia patients who are competent to use such factors to control bleeding without medical supervision. Medicare covers blood-clotting factors for the following conditions:
- Factor VIII deficiency (classic hemophilia, hemophilia A).
• Factor IX deficiency (hemophilia B, Christmas disease, plasma thromboplastin component).
• Congenital factor XI deficiency (Hemophilia C).
• Von Willebrand’s disease.
• Acquired hemophilia (acquired Factor VIII autoantibodies most frequently) and other coagulation factor deficiencies, intrinsic circulating anticoagulants, antibodies or inhibitors.
• Congenital deficiencies of other clotting factors (such as congenital afibrinogenemia and others).

Other diagnoses may be applicable based on U.S. Food and Drug Administration (FDA) label, but the list above indicates CMS designation of add-on payment for inpatient care and additional coverage would not be acceptable to the system for Part A.

Note: Refer to Center for Medicare and Medicaid Local Coverage Determination (LCD) for Hemophilia Factor Products (L35111) at https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35111.

Clinical Guideline Coverage Criteria

Hemophilia A:
1. The Plan may authorize coverage of Antihemophilic factor VIII (Advate, Adynovate, Afstyla, Alphanate, Eloctate, Esperoc, Hemofil-M, Humate-P, Jivi, Koate, Kovaltry, Novoeight, Nuwiq, Recombinate, Xyntha) for Members with Hemophilia A

Acquired Hemophilia A:
1. The Plan may authorize coverage of non-extended half-life Antihemophilic factor VIII (Advate, Alphanate, Hemofil-M, Humate-P, Jivi, Koate, Novoeight, Obizur, Recombinate, Xyntha) for Members with Acquired Hemophilia A

Von Willebrand Disease:
1. The Plan may authorize coverage of Antihemophilic factor VIII with von Willebrand factor (Alphanate, Humate-P, Wilate) for Members with von Willebrand Disease when documentation confirms either of the following:
   a. Type 2B, type 3, or severe type 1 vWD or
   b. Type 1-2N vWD with any ONE of the following:
      i. Inadequate response, contraindication, or inadequate response to desmopressin
      ii. Emergent use
      iii. Pregnancy
      iv. High cardiovascular and/or cerebrovascular disease risk
      v. Age < 2 years

Acquired Von Willebrand Disease:
1. The Plan may authorize coverage of Antihemophilic factor VIII with von Willebrand factor (Alphanate, Humate-P, Wilate) for Members with Acquired von Willebrand Disease.

Limitations

• Any indications other than FDA-approved indications are considered experimental or investigational and will not be approved by the health plan

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>J7182</td>
<td>Injection, factor VIII, (antihemophilic factor, recombinant), (Novoeight), per IU</td>
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<tr>
<td>J7185</td>
<td>Injection, factor VIII (antihemophilic factor, recombinant) (Xyntha), per IU</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>J7188</td>
<td>Injection, factor VIII (antihemophilic factor, recombinant), (OBIZUR), per i.u.</td>
</tr>
<tr>
<td>J7190</td>
<td>Factor VIII (antihemophilic factor [human]) per IU</td>
</tr>
<tr>
<td>J7192</td>
<td>Factor VIII (antihemophilic factor, recombinant) per IU, not otherwise specified</td>
</tr>
<tr>
<td>J7204</td>
<td>Injection, Factor VIII, antihemophilic factor (recombinant), (Esperoct), glycopegylated-exei, per IU</td>
</tr>
<tr>
<td>J7205</td>
<td>Injection, factor VIII, Fc fusion protein, (recombinant), per IU</td>
</tr>
<tr>
<td>J7207</td>
<td>Injection, factor VIII, (antihemophilic factor, recombinant), pegylated, 1 IU (Adynovate)</td>
</tr>
<tr>
<td>J7208</td>
<td>Injection, factor viii, (antihemophilic factor, recombinant), pegylated-auc, (jivi), 1 i.u</td>
</tr>
<tr>
<td>J7209</td>
<td>Injection, factor VIII, (antihemophilic factor, recombinant), (Nuwiq), 1 IU</td>
</tr>
<tr>
<td>J7210</td>
<td>Injection, factor VIII, (antihemophilic factor, recombinant), (Afstyla), 1 IU</td>
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<tr>
<td>J7211</td>
<td>Injection, factor VIII, (antihemophilic factor, recombinant), (Kovaltry), 1 IU</td>
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References:

Approval And Revision History
September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)
September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)

Background, Product and Disclaimer Information
Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines,
along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member’s health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.