# Hemophilia Products – Factor VIII:
# Advate, Adynovate, Afstyla, Eloctate, Hemofil M, Koate/Koate DVI, Kogenate FS, Kovaltry, Novoeight, Nuwiq, Obizur, Recombinate, Xyntha/Xyntha Solofuse, Jivi, Esperoct, Altuviiio
## (Intravenous)

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## I. Length of Authorization

Coverage is provided for 3 months and may be renewed thereafter, unless otherwise specified*****.

*Note: The cumulative amount of medication the patient has on-hand will be taken into account for authorizations. Up to 5 'on-hand' doses for the treatment of acute bleeding episodes will be permitted at the time of the authorization request.*

*******Initial and renewal authorization periods may vary by specific covered indication*

## II. Dosing Limits

**A. Quantity Limit (max daily dose) [NDC unit]:**

- N/A

**B. Max Units (per dose and over time) [HCPCS Unit]:**

- Advate: 73,600 billable units per 28-day supply
- Adynovate: 36,800 billable units per 28-day supply
- Afstyla: 69,000 billable units per 28-day supply
- Eloctate: 40,250 billable units per 30-day supply
- Kogenate: 43,125 billable units per 30-day supply
- Kovaltry: 86,250 billable units per 30-day supply
- Novoeight: 82,800 billable units per 28-day supply
- Nuwiq: 86,250 billable units per 30-day supply
- Hemofil M: 55,200 billable units per 28-day supply
- Koate DVI: 55,200 billable units per 28-day supply
- Recombinate: 55,200 billable units per 28-day supply
- Xyntha/Xyntha Solofuse: 41,400 billable units per 28-day supply
- Obizur: 115,000 billable units per 90-day supply
- Jivi: 41,400 billable units per 30-day supply
- Esperoct: 40,250 billable units per 28 days
- Altuviiio: 23,000 units per 28 days

## III. Initial Approval Criteria [1-17,22,23]

| Hemophilia Management Program |
|---|
| Requirements for half-life study and inhibitor tests are a part of the hemophilia management program. This information is not meant to replace clinical decision making when initiating or modifying medication therapy and should only be used as a guide. |

Coverage is provided in the following conditions:

A. Advate, Eloctate **Φ**, Hemofil M, Koate/Koate DVI, Kogenate FS **Φ**, Novoeight, Recombinate, Xyntha/Xyntha Solofuse **Φ**, Nuwiq, Adynovate, Kovaltry, Afstyla, Jivi, Esperoct, Altuviiio

**Hemophilia A (congenital factor VIII deficiency) †**

- For Medicaid members, patient must have failed or experienced intolerable side effects to Xyntha; **AND**

- Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing; **AND**
- If the request is for Jivi, patient must be at least 12 years of age, or if request is for Altuviiio, patient must be at least 1 year of age; **AND**
- Will not be used for the treatment of von Willebrand's disease; **AND**
- Used as treatment in at least one of the following:
  - On-demand treatment and control of bleeding episodes **OR**
  - Perioperative management *(*Authorizations valid for 1 month)*; **OR**
  - Routine prophylaxis; **AND**
    - Used to reduce the frequency of bleeding episodes; **OR**
    - Used to reduce the frequency of bleeding episodes and reduce the risk of joint damage in children without pre-existing joint damage (***Kogenate-FS ONLY***); **AND**
      - Patient must have severe hemophilia A (factor VIII level of <1%); **OR**
      - Patient has at least two documented episodes of spontaneous bleeding into joints.

| Hemophilia Management Program |
|---|
| • If the request is for routine prophylaxis and the requested dose exceeds dosing limits under part II or if member BMI≥ 30, a half-life study should be performed to determine the appropriate dose and dosing interval.<br>• If the request is for Eloctate, Adynovate, Jivi, Esperoct, or Altuviiio the following criteria should be met:<br>  ○ Patient is not a suitable candidate for a standard non- EHL factor VIII product. |

- A half-life study must be scheduled to determine the appropriate dose and dosing interval of the EHL product when initiated.
- Prior to switching to Eloctate, Adynovate, Jivi, or Esperoct a half-life study should also be performed on current non- EHL factor VIII product to ensure that a clinical benefit will be achieved.

- If the request exceeds any of the following dosing limits, documentation must be submitted specifying why the member is not a suitable candidate for Hemlibra and alternative EHL factor VIII products.
  - 50 IU/kg every 4 days (total weekly dose of 87.5 IU/kg) for Eloctate
  - 40 IU/kg twice weekly (total weekly dose of 80 IU/kg) for Adynovate
  - 60 IU/kg every 5 days (total weekly dose of 84 IU/kg) for Jivi
  - 50 IU/kg every 4 days (total weekly dose of 87.5 IU/kg) for Esperoct
- For minimally treated patients (< 50 exposure days to factor products) previously receiving a different factor product, inhibitor testing is required at baseline, then at every comprehensive care visit (yearly for the mild and moderate patients, semi-annually for the severe patients)

B. Obizur [10]

**Acquired Hemophilia A (acquired factor VIII deficiency) † Φ**

- Patient is at least 18 years of age; **AND**
- Diagnosis of acquired factor VIII deficiency has been confirmed by blood coagulation testing; **AND**
- Used as on-demand treatment and control of bleeding episodes; **AND**
- Is NOT being used for congenital Hemophilia A OR von Willebrand disease; **AND**
- Patient does not have baseline anti-porcine factor VIII inhibitor titer >20 Bethesda Units (BU)

| Hemophilia Management Program |
|---|
| • For members with a BMI ≥ 30, a half-life study should be performed to determine the appropriate dose and dosing interval.<br>• For minimally treated patients (< 50 exposure days to factor products) previously receiving a different factor product, inhibitor testing is required at baseline, then at every comprehensive care visit (yearly for the mild and moderate patients, semi-annually for the severe patients) |

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

## IV. Dispensing Requirements for Rendering Providers (Hemophilia Management Program)

- Prescriptions cannot be filled without an expressed need from the patient, caregiver, or prescribing practitioner. Auto-filling is not allowed.
- Monthly, rendering provider must submit for authorization of dispensing quantity before delivering factor product. Information submitted must include:

- Original prescription information, requested amount to be dispensed, vial sizes available to be ordered from the manufacturer, and patient clinical history (including patient product inventory and bleed history)
- Factor dose should not exceed +1% of the prescribed dose and a maximum of three vials may be dispensed per dose. If unable to provide factor dosing within the required threshold, below the required threshold, the lowest possible dose able to be achieved above +1% should be dispensed. Prescribed dose should not be increased to meet assay management requirements.

– The cumulative amount of medication(s) the patient has on-hand should be taken into account when dispensing factor product. Patients should not have more than 5 extra doses on-hand for the treatment of acute bleeding episodes.
– Dispensing requirements for renderings providers are a part of the hemophilia management program. This information is not meant to replace clinical decision making when initiating or modifying medication therapy and should only be used as a guide.

## V. Renewal Criteria [1-17,22,23]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: anaphylaxis and hypersensitivity reactions (e.g., angioedema, chest tightness, dyspnea, wheezing, urticaria, pruritus, hypotension, etc.), thromboembolic events (thromboembolism, pulmonary embolism), development of neutralizing antibodies (inhibitors), etc.; **AND**
- Any increases in dose must be supported by an acceptable clinical rationale (i.e., weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy, etc.); **AND**
- The cumulative amount of medication(s) the patient has on-hand will be taken into account when authorizing. The authorization will allow up to 5 doses on-hand for the treatment of acute bleeding episodes as needed for the duration of the authorization; **AND**

**On-demand treatment of bleeding episodes and control of bleeding episodes**

- Renewals will be approved for a 6-month authorization period.

**Perioperative management of bleeding**

- Coverage may NOT be renewed

**Routine prophylaxis**

- Renewals will be approved for a 12-month authorization period; **AND**
- Patient has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline)

## VI. Dosage/Administration [1-16,22]

### Advate

| Indication | Dose |
|---|---|
| On-demand treatment and control of bleeding episodes<br>Congenital Hemophilia A | Dose (IU/kg) = desired factor VIII rise (IU/dL or % of normal) x 0.5 (IU/kg per IU/dL)<br>Minor<br>Circulating Factor VIII required (% of normal) (20-40%) = 10-20 IU/ kg -Repeat every 12-24 hours as needed (every 8 to 24 hours for patients underage of 6). Continue until the bleeding episode is resolved (as indicated by relief of pain) or healing is achieved (approximately 1 to 3 days).<br>Moderate<br>Circulating Factor VIII required (% of normal) (30-60%) = 15-30 IU/ kg - Repeat every 12-24 hours as needed (every 8 to 24 hours for patients underage of 6). Continue until the bleeding episode is resolved (as indicated by relief of pain) or healing is achieved (approximately 3 days or more).<br>Major<br>Circulating Factor VIII required (% of normal) (60-100%) = 30-50 IU/ kg - Repeat every 8-24 hours as needed (every 6 to 12 hours for patients underage of 6). Continue until the bleeding episode is resolved. |
| Routine prophylaxis<br>Congenital Hemophilia A | For prophylaxis regimen to prevent or reduce frequency of bleeding episodes, dose between 20 to 40 IU per kg every other day (3 to 4 times weekly). Alternatively, an every third day dosing regimen targeted to maintain FVIII trough levels ≥ 1% may be employed. Adjust dose based on the patient's clinical response. |
| Perioperative management<br>Congenital Hemophilia A | Minor<br>Circulating Factor VIII required (% of normal) (60-100%) = 30-50 IU/ kg –Single dose within one hour of the operation. Repeat after 12- 24 hours for optional additional dosing as needed to control bleeding.<br>Major<br>Circulating Factor VIII required (% of normal) (80-120%) = Preoperative: 40-60 IU/ kg to achieve 100% activity. Followed by a repeat dose every 8-24 hours (every 6 to 24 hours for patients under age of 6) postoperatively until healing is complete. |

### Adynovate

| Indication | Dose |
|---|---|
| On-demand treatment and control of bleeding episodes<br>Congenital Hemophilia A | Dose (IU) = Body Weight (kg) x Desired factor VIII rise (IU/dL or % of normal) x 0.5 (IU/kg per IU/dL)<br>Minor<br>Target Factor VIII level (IU/dL or % of normal) (20-40%) = 10-20 IU/kg -Repeat every 12-24 hours until the bleeding episode is resolved<br>Moderate |

| Indication | Dose |
|---|---|
| | Target Factor VIII level (IU/dL or % of normal) (30-60%) = 15-30 IU/kg - Repeat every 12-24 hours until the bleeding episode is resolved<br>Major<br>Target Factor VIII level (IU/dL or % of normal) (60-100%) = 30-50 IU/kg - Repeat every 8-24 hours until the bleeding episode is resolved. |
| Perioperative management Congenital Hemophilia A | Minor<br>Target Factor VIII required (% of normal) (60-100%) = 30-50 IU/ kg –Single dose within one hour of the operation. Repeat after 24 hours, if necessary, single dose or repeat as needed until bleeding is resolved.<br>Major<br>Target Factor VIII required (% of normal) (80-120%) (pre- and post- operative) = 40-60 IU/ kg within 1 hour of the operation to achieve 100% activity. Repeat dose every 8-24 hours (every 6 to 24 hours for patients under age of 12) to maintain FVIII activity within the target range and continue until adequate wound healing. |
| Routine prophylaxis Congenital Hemophilia A | Administer 40-50 IU per kg body weight 2 times per week in children and adults (12 years and older). Administer 55 IU per kg body weight 2 times per week in children (<12 years) with a maximum of 70 IU per kg. Adjust the dose based on the patient's clinical response. |

**Afstyla**

| Indication | Dose |
|---|---|
| On-demand treatment and control of bleeding episodes Congenital Hemophilia A | Dose (IU) = Body Weight (kg) x Desired factor VIII rise (IU/dL or % of normal) x 0.5 (IU/kg per IU/dL)<br>Minor<br>Target Factor VIII level (IU/dL or % of normal) 20-40% -Repeat every 12-24 hours until the bleeding episode is resolved.<br>Moderate<br>Target Factor VIII level (IU/dL or % of normal) 30-60%- Repeat every 12-24 hours until the bleeding episode is resolved.<br>Major<br>Target Factor VIII level (IU/dL or % of normal) 60-100%- Repeat every 8-24 hours until the bleeding episode is resolved. |
| Perioperative management Congenital Hemophilia A | Minor<br>Target Factor VIII level (IU/dL or % of normal) 30-60%- Repeat every 24 hours, for at least one day, until healing is achieved.<br>Major<br>Target Factor VIII level (IU/dL or % of normal) 80-100%- Repeat every 8-24 hours until adequate wound healing, then continue for at least another 7 days to maintain a Factor VIII activity of 30-60% (IU/dL). |

| Indication | Dose |
|---|---|
| Routine prophylaxis Congenital Hemophilia A | Adults and adolescents *(≥12yrs old)*: Administer 20-50 IU per kg body weight 2 to 3 times per week. Adjust the dose based on the patient's clinical response.<br>Children *(<12 yrs old)*: Administer 30-50 IU per kg body weight 2 to 3 times per week. Adjust the dose based on the patient's clinical response. |

## Altuviiio

| Indication | Dose |
|---|---|
| On-demand treatment and control of bleeding episodes<br>Congenital Hemophilia A | Minor/Moderate<br>Single dose of 50 IU/kg. For minor and moderate bleeding episodes occurring within 2 to 3 days after a prophylactic dose, a lower dose of 30 IU/kg dose may be used.<br>Additional doses of 30 or 50 IU/kg every 2 to 3 days may be considered.<br>Major<br>Single dose of 50 IU/kg. Additional doses of 30 or 50 IU/kg every 2 to 3 days can be considered.<br>*Note: For resumption of prophylaxis (if applicable) after treatment of a bleed, it is recommended to allow an interval of at least 72 hours between the last 50 IU/kg dose for treatment of a bleed and resuming prophylaxis dosing. Thereafter, prophylaxis can be continued as usual on the patient's regular schedule.* |
| Perioperative management<br>Congenital Hemophilia A | Minor<br>Single dose of 50 IU/kg. An additional dose of 30 or 50 IU/kg after 2 to 3 days may be considered.<br>Major<br>Single dose of 50 IU/kg. Additional doses of 30 or 50 IU/kg every 2 to 3 days may be administered as clinically needed for perioperative management. |
| Routine prophylaxis<br>Congenital Hemophilia A | The recommended dosing for routine prophylaxis for adults and children is 50 IU/kg of Altuviiio administered once weekly. |
| – For the dose of 50 IU/kg, the expected in vivo peak increase in Factor VIII level expressed as IU/dL (or % of normal) is estimated using the following formula:<br>– Estimated Increment of Factor VIII (IU/dL or % of normal) = 50 IU/kg x 2 (IU/dL per IU/kg)<br>– To achieve a specific target Factor VIII activity level, use the following formula: Dosage (IU) = Body Weight (kg) x Desired Factor VIII Increase (IU/dL or % normal) x 0.5 (IU/kg per IU/dL). | |

## Eloctate

| Indication | Dose |
|---|---|
| On-demand treatment and control of bleeding episodes<br>Congenital Hemophilia A | Dose (IU/kg) = Desired factor VIII rise (IU/dL or % of normal) x 0.5 (IU/kg per IU/dL)<br>Minor and Moderate<br>Circulating Factor VIII required (% of normal) (40-60%) = 20-30 IU/ kg -Repeat every 24-48 hours as needed (every 12 to 24 hours for patients under age of 6). Continue until the bleeding episode is resolved.<br>Major<br>Circulating Factor VIII required (% of normal) (80-100%) = 40-50 IU/ kg - Repeat every 12-24 hours as needed (every 8 to 24 hours for patients under age of 6). Continue until the bleeding episode is resolved (approximately 7-10 days). |
| Routine prophylaxis<br>Congenital Hemophilia A | Adults: The recommended starting regimen is 50 IU/kg administered every 4 days. The regimen may be adjusted based on patient response with dosing in the range of 25-65 IU/kg at 3–5-day intervals.<br>Children < 6 years of age: The recommended starting regimen is 50 IU/kg administered twice weekly. The regimen may be adjusted based on patient response with dosing in the range of 25-65 IU/kg at 3–5-day intervals. More frequent or higher doses up to 80 IU/kg may be required. |
| Perioperative management<br>Congenital Hemophilia A | Minor<br>Circulating Factor VIII required (% of normal) (50-80%) = 25-40 IU/ kg -Repeat every 24 hours as needed (every 12 to 24 hours for patients underage of 6). Continue at least 1 day until healing is achieved.<br>Major<br>Circulating Factor VIII required (% of normal) (80-120%) = Preoperative: 40-60 IU/ kg – Followed by a repeat dose of 40-50 IU/kg after 8-24 hours (6 to 24 hours for patients under age of 6). Continue every 24 hours until adequate wound healing; then continue therapy for at least 7 days to maintain FVII activity within the target range. |

## Esperoct

| Indication | Dose |
|---|---|
| On-demand treatment and control of bleeding episodes<br>Congenital Hemophilia A | One IU of Factor VIII activity corresponds to the quantity of Factor VIII in one milliliter of normal human plasma. The calculation of the required dosage of Factor VIII is based on the empirical finding that one IU of Factor VIII per kg body weight raises the plasma Factor VIII activity by two IU/dL.<br>*To achieve a specific target Factor VIII activity level, use the following formula: Dosage (IU) = Body Weight (kg) × Desired Factor VIII Increase (IU/dL or % normal) × 0.5 ;* ***OR*** |

| Type of bleeding | Adolescents/Adults ≥12 years Dose (IU/kg) | Children <12 years Dose (IU/kg) | Additional doses |
|---|---|---|---|
| **Minor**<br>Early hemarthrosis, mild muscle bleeding, or oral bleeding | 40 | 65 | One dose should be sufficient |

<table>
<tr><th>Indication</th><th>Dose</th></tr>
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<table>
<tr><td>Moderate<br>More extensive hemarthrosis, muscle bleeding, or hematoma</td><td>40</td><td>65</td><td>An additional dose may be administered after 24 hours</td></tr>
<tr><td>Major<br>Life- or limb-threatening hemorrhages, gastro- intestinal bleeding, intracranial, intra-abdominal or intrathoracic bleeding, fractures</td><td>50</td><td>65</td><td>Additional dose(s) may be administered approximately every 24 hours</td></tr>
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<tr><td>Routine prophylaxis<br>Congenital Hemophilia A</td><td>– Adults and adolescents (≥ 12 years): The recommended starting dose is 50 IU per kg body weight every 4 days. This regimen may be individually adjusted to less or more frequent dosing based on bleeding episodes.<br>– Children (< 12 years): A dose of 65 IU per kg body weight twice weekly. This regimen may be individually adjusted to less or more frequent dosing based on bleeding episodes.</td></tr>
<tr><td>Perioperative management<br>Congenital Hemophilia A</td><td>To achieve a specific target Factor VIII activity level, use the following formula: Dosage (IU) = Body Weight (kg) × Desired Factor VIII Increase (IU/dL or % normal) × 0.5 ; OR
<table>
<tr><th>Type of surgery</th><th>Adolescents/Adults ≥12 years Dose (IU/kg)</th><th>Children <12 years Dose (IU/kg)</th><th>Additional doses</th></tr>
<tr><td>Minor<br>Including tooth extraction</td><td>50</td><td>65</td><td>Additional dose(s) can be given after 24 hours if necessary</td></tr>
<tr><td>Major<br>Intracranial, intra-abdominal, intrathoracic, or joint replacement surgery</td><td>50</td><td>65</td><td>Additional doses can be given every 24 hours for the first week and then approximately every 48 hours until wound healing has occurred</td></tr>
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## Hemofil M

| Indication | Dose |
|---|---|
| On-demand treatment and control of bleeding episodes<br>Congenital Hemophilia A | Dose (IU/kg) = Desired factor VIII rise (IU/dL or % of normal) x 0.5 (IU/kg per IU/dL)<br><u>Early hemarthrosis or muscle bleed or oral bleed</u><br>Circulating Factor VIII required (% of normal) (20-40%) = - Begin infusion every 12 to 24 hours for one-three days until the bleeding episode as indicated by pain is resolved or healing is achieved.<br><u>More extensive hemarthrosis, muscle bleed, or hematoma</u><br>Circulating Factor VIII required (% of normal) (30-60%) = Repeat every 12-24 hours for usually three days or more until pain and disability are resolved.<br><u>Life threatening bleeds such as head injury, throat bleed, severe abdominal pain</u><br>Circulating Factor VIII Required (% of normal) (60-100%) = Repeat every 8-24 hours until the bleeding threat is resolved. |
| Perioperative management<br>Congenital Hemophilia A | <u>Minor</u><br>Circulating Factor VIII required (% of normal) (60-80%) A single infusion plus oral antifibrinolytic therapy within one hour is sufficient in approximately 70% of cases.<br><u>Major</u> |

| Indication | Dose |
|---|---|
| | Circulating Factor VIII required (% of normal) (80-100% pre- and post-operative): Repeat dose every 8-24 hours depending on state of healing. |

**Jivi**

| Indication | Dose |
|---|---|
| On-demand treatment and control of bleeding episodes Congenital Hemophilia A | Dose (IU/kg) = Desired factor VIII rise (IU/dL or % of normal) x reciprocal of expected recovery (or observed recovery, if available) (e.g., 0.5 for a recovery of 2 IU/dL per IU/kg)<br>Minor<br>Circulating Factor VIII required (% of normal) (20-40%) – 10-20IU/kg repeat dose every 24-48 hours until bleed resolves<br>Moderate<br>Circulating Factor VIII required (% of normal) (30-60%) – 15-30IU/kg repeat dose every 24-48 hours until bleed resolves<br>Major<br>Circulating Factor VIII Required (% of normal) (60-100%) – 30-50IU/kg repeat dose every 8-24 hours until bleed resolves |
| Perioperative management Congenital Hemophilia A | Minor<br>Circulating Factor VIII required (% of normal) (30-60%) – 15-30IU/kg repeat dose every 24 hours for at least 1 day until healing is achieved<br>Major<br>Circulating Factor VIII required (% of normal) (80-100%) – 40-50IU/kg repeat dose every 12-24 hours until adequate wound healing is complete, then continue therapy for at least another 7 days to maintain Factor VIII activity of 30–60% (IU/dL) |
| Routine prophylaxis Congenital Hemophilia A | The recommended initial regimen is 30–40 IU/kg twice weekly. Based on the bleeding episodes, the regimen may be adjusted to 45–60 IU/kg every 5 days or may be further individually adjusted to less or more frequent dosing. |

**Koate/Koate DVI**

| Indication | Dose |
|---|---|
| On-demand treatment and control of bleeding episodes Congenital Hemophilia A | Dose (IU/kg) = Desired factor VIII rise (IU/dL or % of normal) x 0.5 (IU/kg per IU/dL)<br>Mild<br>Circulating Factor VIII required (% of normal) (20%) = 10 IU/kg- Therapy need not be repeated unless there is evidence of further bleeding.<br>Moderate |

| Indication | Dose |
|---|---|
| | Circulating Factor VIII required (% of normal) (30-50%) = 15-25 IU/kg - If further therapy is required, repeated doses of 10-15 IU per kg every 8-12 hours may be given.<br>Severe<br>Circulating Factor VIII Required (% of normal) (80-100%) =40-50 IU/kg – followed by a maintenance dose of 20-25 IU per kg every 8-12 hours. |
| Routine prophylaxis Hemophilia A § | 25-40 IU/kg three times weekly or 15-30 IU/kg three times weekly. Adjust dosing regimen based on individual response. |
| Perioperative management Congenital Hemophilia A | For major surgical procedures, the Factor VIII level should be raised to approximately 100% by giving a preoperative dose of 50 IU/kg. The Factor VIII level should be checked to assure that the expected level is achieved before the patient goes to surgery. To maintain hemostatic levels, repeat infusions may be necessary every 6 to 12 hours initially, and for a total of 10 to 14 days until healing is complete. The intensity of Factor VIII replacement therapy required depends on the type of surgery and postoperative regimen employed. For minor surgical procedures, less intensive treatment schedules may provide adequate hemostasis. |

## Kogenate FS

| Indication | Dose |
|---|---|
| On-demand treatment and control of bleeding episodes Congenital Hemophilia A | Dose (IU/kg) = Desired factor VIII rise (IU/dL or % of normal) x 0.5 (IU/kg per IU/dL)<br>Minor<br>Circulating Factor VIII required (% of normal) (20-40%) = 10-20 IU/ kg -Repeat dose if there is evidence of further bleeding and continue until the bleeding episode is resolved.<br>Moderate<br>Circulating Factor VIII required (% of normal) (30-60%) = 15-30 IU/ kg - Repeat every 12-24 hours as needed. Continue until the bleeding episode is resolved.<br>Major<br>Circulating Factor VIII Required (% of normal) (80-100%) = Initial: 40-50 IU/ kg; Repeat 20-25 IU/kg every 8-12 hours until the bleeding episode is resolved. |
| Routine prophylaxis Congenital Hemophilia A | Routine Prophylaxis in Adults<br>25 units per kg of body weight three times per week.<br>Routine Prophylaxis in Children<br>25 IU/kg of body weight every other day. |
| Perioperative management Congenital Hemophilia A | Minor<br>Circulating Factor VIII required (% of normal) (30-60%) = 15-30 IU/ kg – Repeat every 12- 24 hours until bleeding is resolved. |

| Indication | Dose |
|---|---|
| | Major<br>Circulating Factor VIII required (% of normal) (100%) = Preoperative: 50 IU/ kg to achieve 100% activity. Followed by a repeat dose every 6-12 hours to keep FVIII activity in desired range. Continue until healing is complete. |

## Kovaltry

| Indication | Dose |
|---|---|
| On-demand treatment and control of bleeding episodes Congenital Hemophilia A | • Required dose (IU) = body weight (kg) x desired Factor VIII rise (% of normal or IU/dL) x reciprocal of expected/observed recovery (e.g., 0.5 for a recovery of 2 IU/dL per IU/kg)<br>• Estimated Increment of Factor VIII (IU/dL or % of normal) = [Total Dose (IU)/body weight (kg)] x 2 (IU/dL per IU/kg)<br>Minor<br>(Early hemarthrosis, minor muscle, oral bleeds)<br>Factor VIII level required (IU/dL or % of normal): 20-40 – repeat every 12-24 hours at least 1 day, until bleeding episode as indicated by pain is resolved or healing is achieved.<br>Moderate<br>(More extensive hemarthrosis, muscle bleeding, or hematoma)<br>Factor VIII level required (IU/dL or % of normal): 30-60 – repeat every 12-24 hours for 3 to 4 days or more until pain and acute disability are resolved.<br>Major<br>(Intracranial, intra-abdominal or intrathoracic hemorrhages, gastrointestinal bleeding, central nervous system bleeding, bleeding in the retropharyngeal or retroperitoneal spaces, or iliopsoas sheath, life or limb threatening hemorrhage)<br>Factor VIII level required (IU/dL or % of normal): 60-100 – repeat every 8-24 hours until bleeding is resolved. |
| Routine prophylaxis Congenital Hemophilia A | Individualize the patient's dose based on clinical response:<br>• Adults and adolescents: 20 to 40 IU of KOVALTRY per kg of body weight two or three times per week.<br>• Children ≤12 years old: 25 to 50 IU of KOVALTRY per kg body weight twice weekly, three times weekly, or every other day according to individual requirements |
| Perioperative management Congenital Hemophilia A | Minor<br>(Such as tooth extraction)<br>Factor VIII level required (IU/dL or % of normal): 30-60 (pre- and post-operative) – repeat every 24 hours at least 1 day until healing is achieved.<br>Major<br>(Such as intracranial, intraabdominal, intrathoracic, or joint replacement surgery)<br>Factor VIII level required (IU/dL or % of normal): 80-100 (pre- and post-operative) – repeat every 8-24 hours until adequate wound healing is complete, then |

| Indication | Dose |
|---|---|
| | continue therapy for at least another 7 days to maintain Factor VIII activity of 30-60% (IU/dL). |

## Novoeight

| Indication | Dose |
|---|---|
| On-demand treatment and control of bleeding episodes Congenital Hemophilia A | Dose (IU/kg) = Desired factor VIII rise (IU/dL or % of normal) x 0.5 (IU/kg per IU/dL)<br>Minor<br>Circulating Factor VIII required (% of normal) (20-40%), every 12 – 24 hours for at least 1 day until the bleeding episode is resolved<br>Moderate<br>Circulating Factor VIII required (% of normal) (30-60%), every 12 – 24 hours until pain and acute disability are resolved, approximately 3-4 days<br>Major<br>Circulating Factor VIII Required (% of normal) (60-100%), every 8 – 24 hours until resolution of bleed, approximately 7-10 days. |
| Perioperative management Hemophilia A | Dose (IU/kg) = Desired factor VIII rise (IU/dL or % of normal) x 0.5 (IU/kg per IU/dL)<br>Minor<br>Circulating Factor VIII required (% of normal) (30-60%) every 24 hours for at least 1 day until healing is achieved.<br>Major<br>Circulating Factor VIII required (% of normal) (80-100%) every 8 – 24 hours until adequate wound healing, then continue therapy for at least 7 days to maintain a factor VIII activity of 30 – 60% (IU/dL) |
| Routine prophylaxis Hemophilia A | Adults and adolescents (>12 yrs):<br>20-50 IU/kg three times weekly **OR**<br>20-40 IU/kg every other day<br>Children (<12 yrs):<br>25-60 IU/kg three times weekly **OR**<br>25-50 IU/kg every other day |

## NUWIQ

| Indication | Dose |
|---|---|
| On-demand treatment and control of bleeding episodes | Dose<br>Required IU = body weight (kg) x desired Factor VIII rise (%) (IU/dL) x 0.5 (IU/kg per IU/dL)<br>Expected Factor VIII rise (% of normal) = 2 x administered IU/body weight (kg)<br>Minor |

| Indication | Dose |
|---|---|
| Congenital Hemophilia A | Required peak post-infusion Factor VIII activity (% of normal or IU/dL): 20-40 every 12 – 24 hours for at least 1 day, until the bleeding episode is resolved<br>Moderate to Major<br>Required peak post-infusion Factor VIII activity (% of normal or IU/dL): 30-60 every 12 – 24 hours for 3-4 days or more until the bleeding episode is resolved<br>Life-threatening<br>Required peak post-infusion Factor VIII activity (% of normal or IU/dL): 60-100 every 8 – 24 hours bleeding risk is resolved |
| Routine prophylaxis Congenital Hemophilia A | Dose<br>Required IU = body weight (kg) x desired Factor VIII rise (%) (IU/dL) x 0.5 (IU/kg per IU/dL)<br>Expected Factor VIII rise (% of normal) = 2 x administered IU/body weight (kg)<br>Adolescents (12-17 years) and adults<br>30 – 40 IU/kg every other day<br>Children (2-11 years)<br>30 – 50 IU/kg every other day or three times per week |
| Perioperative management Congenital Hemophilia A | Dose<br>Required IU = body weight (kg) x desired Factor VIII rise (%) (IU/dL) x 0.5 (IU/kg per IU/dL)<br>Expected Factor VIII rise (% of normal) = 2 x administered IU/body weight (kg)<br>Minor<br>Required peak post-infusion Factor VIII activity (% of normal or IU/dL): 30-60 (pre- and post-operative) every 24 hours for at least 1 day until healing is achieved<br>Major<br>Required peak post-infusion Factor VIII activity (% of normal or IU/dL): 80-100 (pre- and post-operative) every 8 - 24 hours until adequate wound healing, then continue therapy for at least another 7 days to maintain Factor VIII activity of 30% to 60% (IU/dL) |

## Obizur

| Indication | Dose |
|---|---|
| On-demand treatment and control of bleeding episodes Acquired Hemophilia A | Minor and Moderate<br>Loading dose: 200IU/kg; Maintenance dose: Titrate to maintain recommended FVIII trough levels at 50-100 IU/dL every 4 to 12 hours<br>Major<br>Loading dose: 200 IU/kg; Maintenance dose: Titrate to maintain recommended FVIII trough levels at 100-200 (to treat an acute bleed), then 50-100 IU/dL (after acute bleed is controlled) every 4 to 12 hours |

## Recombinate

| Indication | Dose |
|---|---|
| On-demand treatment and control of bleeding episodes<br>Congenital Hemophilia A | Dose (IU/kg) = Desired factor VIII rise (IU/dL or % of normal) x 0.5 (IU/kg per IU/dL)<br>Early hemarthrosis or muscle bleed or oral bleed<br>Circulating Factor VIII required (% of normal) (20-40%) - Begin infusion every 12 to 24 hours for one-three days until the bleeding episode as indicated by pain is resolved or healing is achieved.<br>More extensive hemarthrosis, muscle bleed, or hematoma<br>Circulating Factor VIII required (% of normal) (30-60%) - Repeat every 12-24 hours for usually three days or more until pain and disability are resolved.<br>Life threatening bleeds such as head injury, throat bleed, severe abdominal pain<br>Circulating Factor VIII Required (% of normal) (60-100%) - Repeat every 8-24 hours until the bleeding threat is resolved. |
| Routine prophylaxis<br>Hemophilia A § | 25-40 IU/kg three times weekly or 15-30 IU/kg three times weekly. Adjust dosing regimen based on individual response. |
| Perioperative management<br>Congenital Hemophilia A | Minor<br>Circulating Factor VIII required (% of normal) (60-80%) - A single infusion plus oral antifibrinolytic therapy within one hour is sufficient in approximately 70% of cases.<br>Major<br>Circulating Factor VIII required (% of normal) (80-100% pre- and post-operative) - Repeat dose every 8-24 hours depending on state of healing. |

## Xyntha/Xyntha Solofuse

| Indication | Dose |
|---|---|
| On-demand treatment and control of bleeding episodes<br>Congenital Hemophilia A | Dose (IU/kg) = Desired factor VIII rise (IU/dL or % of normal) x 0.5 (IU/kg per IU/dL)<br>Minor<br>Circulating Factor VIII required (% of normal) (20-40%) - Repeat dose every 12-24 hours for least 1 day, depending upon the severity of the bleeding episode.<br>Moderate<br>Circulating Factor VIII required (% of normal) (30-60%) - Repeat every 12-24 hours as needed. Continue for 3-4 days or until adequate local hemostasis is achieved.<br>Major<br>Circulating Factor VIII Required (% of normal) (60-100%) - Repeat every 8-24 hours until bleeding is resolved. |
| Perioperative management | Minor<br>Circulating Factor VIII required (% of normal) (30-60%) - Repeat every 12- 24 hours. Continue for 3-4 days or until adequate local hemostasis is achieved. For |

| Indication | Dose |
|---|---|
| Congenital Hemophilia A | tooth extraction, a single infusion plus oral antifibrinolytic therapy within 1 hour may be sufficient.<br>Major<br>Circulating Factor VIII required (% of normal) (60-100%) - Repeat every 8-24 hours. Continue until threat is resolved, or in the case of surgery, until adequate local hemostasis and wound healing are achieved. |
| Routine prophylaxis Hemophilia A | Adults and adolescents (≥12 years): The recommended starting regimen is 30 IU/kg of Xyntha administered 3 times weekly.<br>Children (<12 years): The recommended starting regimen is 25 IU/kg of Xyntha administered every other day. More frequent or higher doses may be required in children <12 years of age to account for the higher clearance in this age group.<br>Note: Adjust the dosing regimen (dose or frequency) based on the patient's clinical response. |

§ Utrecht and/or Malmö protocols used as basis for dosing

## VII. Billing Code/Availability Information

HCPCS Code & NDC:

| Drug | Manufacturer | HCPCS Codes | 1 Billable Unit Equiv. | Vial Size | NDC |
|---|---|---|---|---|---|
| Advate | Baxalta US Inc | J7192 | 1 IU | 250 units | 00944-3051-02 |
| | | | | 500 units | 00944-3052-02 |
| | | | | 1000 units | 00944-3053-02 |
| | | | | 1500 units | 00944-3054-02 |
| | | | | 2000 units | 00944-3045-10 |
| | | | | 3000 units | 00944-3046-10 |
| | | | | 4000 units | 00944-3047-10 |
| Kogenate FS | Bayer HealthCare LLC | J7192 | 1 IU | 250 units | 00026-3782-25 |
| | | | | 500 units | 00026-3783-35 |
| | | | | 1000 units | 00026-3785-55 |
| | | | | 2000 units | 00026-3786-65 |
| | | | | 3000 units | 00026-3787-75 |
| Recombinate | Baxalta US Inc. | J7192 | 1 IU | 220-400 units | 00944-2841-10 |
| | | | | 401-800 units | 00944-2842-10 |
| | | | | 801-1240 units | 00944-2843-10 |
| | | | | 1241-1800 units | 00944-2844-10 |
| | | | | 1801-2400 units | 00944-2845-10 |
| Kovaltry | Bayer HealthCare LLC | J7211 | 1 IU | 250 units | 00026-3821-25 |
| | | | | 500 units | 00026-3822-25 |
| | | | | 1000 units | 00026-3824-25 |
| | | | | 2000 units | 00026-3826-50 |
| | | | | 3000 units | 00026-3828-50 |
| Eloctate | | J7205 | 1 IU | 250 units | 71104-0801-01 |

| | | | | | |
|---|---|---|---|---|---|
| | Bioverativ Therapeutics Inc. | | | 500 units | 71104-0802-01 |
| | | | | 750 units | 71104-0803-01 |
| | | | | 1000 units | 71104-0804-01 |
| | | | | 1500 units | 71104-0805-01 |
| | | | | 2000 units | 71104-0806-01 |
| | | | | 3000 units | 71104-0807-01 |
| | | | | 4000 units | 71104-0808-01 |
| | | | | 5000 units | 71104-0809-01 |
| | | | | 6000 units | 71104-0810-01 |
| Koate/Koate DVI | Grifols Therapeutics Inc | J7190 | 1 IU | 250 units | 76125-0250-20<br>76125-0253-25<br>76125-0256-20<br>76125-0257-25<br>76125-0258-02<br>76125-0259-02 |
| | | | | 500 units | 76125-0661-02<br>76125-0662-50<br>76125-0663-50<br>76125-0665-02<br>76125-0667-30<br>76125-0668-30 |
| | | | | 1000 units | 76125-0672-50<br>76125-0674-10<br>76125-0675-12<br>76125-0676-50<br>76125-0678-10<br>76125-0679-12 |
| Hemofil M | Takeda Pharmaceuticals USA, Inc. | J7190 | 1 IU | 250 units | 00944-3940-02 |
| | | | | 500 units | 00944-3942-02 |
| | | | | 1000 units | 00944-3944-02 |
| | | | | 1700 units | 00944-3946-02 |
| Novoeight | Novo Nordisk Inc. | J7182 | 1 IU | 250 units | 00169-7825-01 |
| | | | | 500 units | 00169-7850-01 |
| | | | | 1000 units | 00169-7810-01 |
| | | | | 1500 units | 00169-7815-01 |
| | | | | 2000 units | 00169-7820-01 |
| | | | | 3000 units | 00169-7830-01 |
| Nuwiq | Octapharma AB | J7209 | 1 IU | 250 units | 68982-0140-01 |
| | | | | 500 units | 68982-0142-01 |
| | | | | 1000 units | 68982-0144-01 |
| | | | | 1500 units | 68982-0154-01 |
| | | | | 2000 units | 68982-0146-01 |
| | | | | 2500 units | 68982-0148-01 |
| | | | | 3000 units | 68982-0150-01 |
| | | | | 4000 units | 68982-0152-01 |
| Obizur | Baxalta US Inc. | J7188 | 1 IU | 500 units | 00944-5001-xx |
| Xyntha/Xyntha Solofuse | Wyeth Pharmaceuticals LLC | J7185 | 1 IU | 250 units | 58394-0012-01<br>58394-0022-03 |
| | | | | 500 units | 58394-0013-01<br>58394-0023-03 |
| | | | | 1000 units | 58394-0014-01<br>58394-0024-03 |

| | | | | | |
|---|---|---|---|---|---|
| | | | | 2000 units | 58394-0015-01<br>58394-0025-03 |
| | | | | 3000 units | 58394-0016-03 |
| Afstyla | CSL Behring, LLC | J7210 | 1 IU | 250 units | 69911-0474-02 |
| | | | | 500 units | 69911-0475-02 |
| | | | | 1000 units | 69911-0476-02 |
| | | | | 1500 units | 69911-0480-02 |
| | | | | 2000 units | 69911-0477-02 |
| | | | | 2500 units | 69911-0481-02 |
| | | | | 3000 units | 69911-0478-02 |
| Adynovate | Baxalta US Inc. | J7207 | 1 IU | 250 units | 00944-4622-01 |
| | | | | 500 units | 00944-4623-01 |
| | | | | 750 units | 00944-4626-01 |
| | | | | 1000 units | 00944-4624-01 |
| | | | | 1500 units | 00944-4627-01 |
| | | | | 2000 units | 00944-4625-01 |
| | | | | 3000 units | 00944-4628-01 |
| Jivi | Bayer HealthCare LLC | J7208 | 1 IU | 500 units | 00026-3942-25 |
| | | | | 1000 units | 00026-3944-25 |
| | | | | 2000 units | 00026-3946-25 |
| | | | | 3000 units | 00026-3948-25 |
| Esperoct | Novo Nordisk Inc. | J7204 | 1 IU | 500 units | 00169-8500-01 |
| | | | | 1000 units | 00169-8100-01 |
| | | | | 1500 units | 00169-8150-01 |
| | | | | 2000 units | 00169-8200-01 |
| | | | | 3000 units | 00169-8300-01 |
| Altuviiio | Bioverativ Therapeutics Inc. | J7199 | N/A | 250 units | 71104-0978-01 |
| | | | | 500 units | 71104-0979-01 |
| | | | | 750 units | 71104-0980-01 |
| | | | | 1000 units | 71104-0981-01 |
| | | | | 2000 units | 71104-0982-01 |
| | | | | 3000 units | 71104-0983-01 |
| | | | | 4000 units | 71104-0984-01 |

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## Appendix 1 – Covered Diagnosis Codes

**Obizur**

| ICD-10 | ICD-10 Description |
|---|---|
| D68.311 | Acquired hemophilia |

**Advate, Eloctate, Hemofil M, Koate-DVI, Kogenate FS, Recombinate, Xyntha/ Xyntha Solofuse, Novoeight. NUWIQ, Adynovate, Kovaltry, Afstyla, Jivi, and Altuviiio**

| ICD-10 | ICD-10 Description |
|---|---|
| D66 | Hereditary factor VIII deficiency |

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA):

| **Jurisdiction(s): N** | **NCD/LCD Document (s):** A56482 |
|---|---|
| https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a56482&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP | |

| **Jurisdiction(s): J,M** | **NCD/LCD Document (s):** A56065 |
|---|---|
| https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a56065&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP | |

| **Jurisdiction(s): H,L** | **NCD/LCD Document (s):** A56433 |
|---|---|
| https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a56433&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP | |

| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | |
|---|---|---|
| **Jurisdiction** | **Applicable State/US Territory** | **Contractor** |
| E (1) | CA, HI, NV, AS, GU, CNMI | Noridian Healthcare Solutions, LLC |

| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | |
|---|---|---|
| **Jurisdiction** | **Applicable State/US Territory** | **Contractor** |
| F (2 & 3) | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ | Noridian Healthcare Solutions, LLC |
| 5 | KS, NE, IA, MO | Wisconsin Physicians Service Insurance Corp (WPS) |
| 6 | MN, WI, IL | National Government Services, Inc. (NGS) |
| H (4 & 7) | LA, AR, MS, TX, OK, CO, NM | Novitas Solutions, Inc. |
| 8 | MI, IN | Wisconsin Physicians Service Insurance Corp (WPS) |
| N (9) | FL, PR, VI | First Coast Service Options, Inc. |
| J (10) | TN, GA, AL | Palmetto GBA, LLC |
| M (11) | NC, SC, WV, VA (excluding below) | Palmetto GBA, LLC |
| L (12) | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc. |
| K (13 & 14) | NY, CT, MA, RI, VT, ME, NH | National Government Services, Inc. (NGS) |
| 15 | KY, OH | CGS Administrators, LLC |