Clinical Policy: Factor VIII (Human, Recombinant)

Reference Number:
LA.PHAR.215 Effective Date:
Last Review Date: 06.21
Line of Business: Medicaid

Coding Implications

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

Description

The following are factor VIII products requiring prior authorization: human – Hemofil M®, Koate-DVI®; recombinant – Advate®, Adynovate®, Afstyla®, Eloctate®, Esperoct®, Helixate FS®, Jivi®, Kogenate FS®, Kovaltry®, NovoEight®, Nuwiq®, Obizur®, Recombinate®, Xyntha®, and Xyntha® Solofuse®.

FDA Approved Indication(s)

Factor VIII products are indicated for patients with hemophilia A for the following uses:

- **Control and prevention of bleeding episodes:**
  - **Children and adults: Advate, Adynovate, Afstyla, Eloctate, Esperoct, Helixate FS, Hemofil M, Jivi (in previously treated patients ≥ 12 years of age only), Koate-DVI, Kogenate FS, Kovaltry, Novoeight, Nuwiq, Recombinate, Xyntha**
- **Perioperative management:**
  - **Children and adults: Advate, Adynovate, Afstyla, Eloctate, Esperoct, Helixate FS, Hemofil M, Jivi (in previously treated patients ≥ 12 years of age only), Koate-DVI, Kogenate FS, Kovaltry, Novoeight, Nuwiq, Recombinate, Xyntha**
- **Routine prophylaxis to prevent or reduce the frequency of bleeding episodes:**
  - **Adults only: Kogenate FS**
  - **Children and adults: Advate, Adynovate, Afstyla, Eloctate, Esperoct, Helixate FS, Jivi (in previously treated patients ≥ 12 years of age only), Kovaltry, Novoeight, Nuwiq, Xyntha**
- **Routine prophylaxis to prevent or reduce the frequency of bleeding episodes and to reduce the risk of joint damage in children without pre-existing joint damage:**
  - **Children: Helixate FS, Kogenate FS**
- **On-demand treatment and control of bleeding episodes in acquired hemophilia A:**
  - **Adults: Obizur**

Limitation(s) of use:

- **Factor VIII products are not indicated for treatment of von Willebrand disease.**
- **Obizur is not indicated for the treatment of congenital hemophilia A.**
- **Safety and efficacy of Obizur have not been established in patients with a baseline anti-porcine factor VIII inhibitor titer of > 20 Bethesda units (BU).**
- **Jivi is not indicated for use in children < 12 years of age due to a greater risk for hypersensitivity reactions.**
- **Jivi is not indicated for use in previously untreated patients.**

Policy/Criteria
Prior authorization is required. Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections that factor VIII products are medically necessary when the following criteria are met:

I. **Initial Approval Criteria**
   A. **Hemophilia A (must meet all):**
      1. **Diagnosis of one of the following (a or b):**
         a. **Congenital hemophilia A (factor VIII deficiency) (all products except Obizur);**
         b. **Acquired hemophilia A (Obizur only);**
      2. **Prescribed by or in consultation with a hematologist;**
      3. **Request is for one of the following uses (a, b, or c):**
         a. **Control and prevention of bleeding episodes;**
         b. **Perioperative management (all products except Obizur);**
         c. **Routine prophylaxis to prevent or reduce the frequency of bleeding episodes;**
      4. **For routine prophylaxis requests: Request is for Advate, Adynovate, Eloctate, Esperoct, Helixate FS, Jivi, Kogenate FS, Kovaltry, Novoeight, Nuwiq, or Xyntha, and member meets one of the following (a or b):**
         a. **Member has severe hemophilia (defined as factor VIII level of < 1%);**
         b. **Member has experienced at least one life-threatening or serious spontaneous bleed (*see Appendix D*);**
      5. **For all products except Obizur: If factor VIII coagulant activity levels are > 5%, failure of desmopressin acetate, unless contraindicated, clinically significant adverse effects are experienced, or an appropriate formulation of desmopressin acetate is unavailable;**
      6. **For Jivi: Member meets both of the following (a and b):**
         a. **Age ≥ 12 years;**
         b. **Has previously been treated for hemophilia A;**
      7. **Documentation of member's body weight (in kg);**
      8. **Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication.**

      Approval duration: 3 months (surgical/acute bleeding) or 6 months (prophylaxis)

   B. **Other diagnoses/indications**
      1. **Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.**

II. **Continued Therapy**
   A. **Hemophilia A (must meet all):**
      1. **Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;**
      2. **Member is responding positively to therapy;**
      3. **Documentation of member's body weight (in kg);**
      4. **If request is for a dose increase, new dose does not exceed the FDA-**

approved maximum recommended dose for the relevant indication.
Approval duration: 3 months (surgical/acute bleeding) or 6 months (prophylaxis)

B. Other diagnoses/indications (must meet 1 or 2):
1. **Currently receiving medication via Louisiana Healthcare Connections benefit and documentation supports positive response to therapy.**
Approval duration: Duration of request or 6 months (whichever is less); or
2. **Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.**

III. Diagnoses/Indications for which coverage is NOT authorized:
A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – LA.PMN.53 for Medicaid, or evidence of coverage documents;
B. Von Willebrand disease.

IV. Appendices/General Information
Appendix A: Abbreviation/Acronym Key
BU: Bethesda units
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
desmopressin acetate (Stimate® nasal spray; generic injection solution)	When Factor VIII coagulant activity levels are > 5% Injection: 0.3 mcg/kg IV every 48 hours Nasal spray: < 50 kg: 1 spray intranasally in one nostril only; may repeat based on laboratory response and clinical condition ≥ 50 kg: 1 spray intranasally in each nostril; may repeat based on	Injection: 0.3 mcg/kg IV every 48 hours Nasal spray: 1 spray intranasally in each nostril

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
- **Contraindication(s): life-threatening hypersensitivity reactions, including anaphylaxis, to the product and its constituents***
Including bovine, mouse, or hamster protein for Advate, Adynovate, Afstyla, Esperoct, Helixate FS, Hemofil M, Jivi, Kogenate FS, Kovaltry, Novoeight, Obizur, Recombinate, and Xyntha
- **Boxed warning(s): none reported**

Appendix D: General Information

- **Life-threatening bleeding episodes include, but are not limited to, bleeds in the following sites: intracranial, neck/throat, or gastrointestinal.**
- **Serious bleeding episodes include bleeds in the following site: joints (hemarthrosis).**
- **Spontaneous bleed is defined as a bleeding episode that occurs without apparent cause and is not the result of trauma.**

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Antihemophilic factor – recombinant (Advate, Adynovate, Afstyla, Kovaltry, Novoeight, Nuwiq, Recombinate, ReFacto, Xyntha)	Control and prevention of bleeding episodes	Minor episodes: 10- 20 IU/kg IV every 12-24 hours (Advate: 8-24 hours for age < 6 years) Moderate episodes: 15-30 IU/kg IV every 12-24 hours (Advate: 8-24 hours for age < 6 years) Major episodes: 30-50 IU/kg IV every 8-24 hours (Advate: 6-12 hours for age < 6 years)	50 IU/kg every 6 hours until the bleeding episode is resolved
Antihemophilic factor – recombinant (Eloctate)	Control and prevention of bleeding episodes	Minor and moderate episodes: 20-30 IU/kg every 24-48 hours (12-24 hours for age < 6 years) Major episodes: 40-50 IU/kg every 12-24 hours (8 to 24 hours for age < 6 years)	50 IU/kg every 8 hours until the bleeding episode is resolved
Antihemophilic factor – recombinant (Helixate FS, Kogenate FS)	Control and prevention of bleeding episodes	Minor episodes: 10- 20 IU/kg IV; repeat dose if there is evidence of further bleeding Moderate episodes: 15-30 IU/kg IV every 12-24 hours Major episodes: initial 40-50 IU/kg IV, followed by 20-25	50 IU/kg single dose or 30 IU/kg/repeated dose

Drug Name	Indication	Dosing Regimen	Maximum Dose
		IU/kg every 8-24 hours (Kogenate FS: every 8-12 hours)	
Antihemophilic factor – recombinant, glycopegylated (Esperoct)	Control and prevention of bleeding episodes	Minor to moderate episodes: 40-65 IU/kg IV; one dose should be sufficient for minor episodes; additional dose may be administered after 24 hours for moderate episodes. Major episodes: 50-65 IU/kg IV; additional doses may b eadministered approximately every 24 hours.	At least 12 years old: 40 IU/kg < 12 years old: 65 IU/kg
Antihemophilic factor – recombinant (Advate, Adynovate)	Perioperative management	Minor surgery: 30- 50 IU/kg IV as a single dose within 1 hour of the operation and every 12-24 hours (Adynovate: 24 hours) thereafter as needed to control bleeding Major surgery: 40- 60 IU/kg IV as a single dose preoperatively to achieve 100% activity and every 8- 24 hours thereafter to keep factor VIII activity in desired range (Advate: every 6-24 hours for age < 6 years; Adynovate: every 6-24 hours if age < 12 years)	Minor surgery: 50 IU/kg/dose Major surgery: 60 IU/kg/dose
Antihemophilic factor – recombinant (Eloctate)	Perioperative management	Minor surgery: 25-40 IU/kg every 24 hours (12-24 hours age < 6 years) Major surgery: pre-operative dose of 40-60 IU/kg	Minor surgery: 40 IU/kg/dose Major surgery: 60 IU/kg/dose

Drug Name	Indication	Dosing Regimen	Maximum Dose
		followed by a repeat dose of 40-50 IU/kg after 8-24 hours (6-24 hours for age < 6 years) and then every 24 hours to maintain Factor VIII activity within the target range	
Antihemophilic factor – recombinant, glycopegylated (Esperoct)	Perioperative management	Minor and major surgery: 50-65 IU/kg IV; additional doses can be administered after 24 hours if necessary for minor surgeries; additional doses can be administered approximately every 24 hours for the first week and then approximately every 48 hours until wound healing has occurred for major surgeries	At least 12 years old: 50 IU/kg < 12 years old: 65 IU/kg
Antihemophilic factor – recombinant (Helixate FS, Kogenate FS)	Perioperative management	Minor surgery: 15- 30 IU/kg IV every 12-24 hours Major surgery: pre-operative dose of 50 IU/kg IV followed by a repeat dose every 6- 12 hours to maintain Factor VIII activity within the target range	Minor surgery: 30 IU/kg/dose Major surgery: 50 IU/kg/dose
Antihemophilic factor – recombinant (Afstyla, Kovaltry, Novoeight, Nuwiq, Recombinate, Xyntha)	Perioperative management	Minor surgery: 15-30 IU/kg IV every 24 hours (Xyntha: every 12-24 hours) (Recombinate: 30- 40 IU/kg as a single infusion) Major surgery: 40-50 IU/kg IV every 8-24 hours (Xyntha: 30-50 IU/kg)	Minor surgery: 30 IU/kg/dose (Recombinate: 40 IU/kg/dose) Major surgery: 50 IU/kg every 8 hours

Drug Name	Indication	Dosing Regimen	Maximum Dose
Antihemophilic factor – recombinant (Xyntha)	Routine prophylaxis	30 IU/kg IV 3 times weekly < 12 years of age: 25 IU/kg every other day.	30 IU/kg/dose
Antihemophilic factor – recombinant (Advate)	Routine prophylaxis	20-40 IU/kg IV every other day (3 to 4 times weekly) OR Use every third day dosing regimen targeted to maintain Factor VIII trough levels ≥ 1%	40 IU/kg every other day
Antihemophilic factor – recombinant (Adynovate)	Routine prophylaxis	≥ 12 years of age: 40-50 IU/kg IV 2 times per week < 12 years of age: 55 IU/kg IV 2 times per week	70 IU/kg/dose
Antihemophilic factor – recombinant (Afstyla)	Routine prophylaxis	≥ 12 years of age: 20-50 IU/kg IV 2-3 times per week < 12 years of age: 30-50 IU/kg IV 2-3 times per week	50 IU/kg/dose
Antihemophilic factor – recombinant (Eloctate)	Routine prophylaxis	50 IU/kg IV every 4 days For children < 6 years of age: 50 IU/kg IV twice weekly	65 IU/kg/dose
Antihemophilic factor – recombinant, glycopegylated (Esperoct)	Routine prophylaxis	At least 12 years old: 50 IU/kg IV every 4 days < 12 years old: 65 IU/kg IV twice weekly	At least 12 years old: 50 IU/kg < 12 years old: 65 IU/kg
Antihemophilic factor – recombinant (Helixate FS, Kogenate FS)	Routine prophylaxis	Adults: 25 IU/kg IV three times per week Children: 25 IU/kg every other day	25 IU/kg/dose

Drug Name	Indication	Dosing Regimen	Maximum Dose
Antihemophilic factor – recombinant (Novoeight)	Routine prophylaxis	≥ 12 years of age: 20-50 IU/kg IV 3 times per week OR 20-40 IU/kg IV every other day < 12 years of age: 25-60 IU/kg IV 3 times per week OR 25-50 IU every other day	60 IU/kg/dose
Antihemophilic factor – recombinant (Nuwiq)	Routine prophylaxis	≥ 12 years of age: 30-40 IU/kg IV every other day < 12 years of age: 30-50 IU/kg IV every other day or 3 times/week	50 IU/kg/dose
Antihemophilic factor – recombinant (Kovaltry)	Routine prophylaxis	> 12 years of age: 20-40 IU/kg IV 2-3 times per week ≤ 12 years of age: 25-50 IU/kg twice or three times weekly or every other day according to individual requirements	50 IU/kg every other day
Antihemophilic factor – recombinant, porcine sequence (Obizur)	Treatment of bleeding episodes in acquired hemophilia A	200 IU/kg every 4-12 hours	200 IU every 4 hours
Antihemophilic factor – human (Hemofil M)	Control and prevention of bleeding episodes	Minor episodes: 10- 20 IU/kg IV every 12-24 hours Moderate episodes: 15-30 IU/kg IV every 12-24 hours Major episodes: 30- 50 IU/kg IV every 8-24 hours	100 IU/kg every 8 hours
Antihemophilic factor – human (Koate-DVI)	Control and prevention of bleeding episodes	Minor episodes: 10 IU/kg IV as a single dose; repeat only if	25 IU/kg every 8 hours until the bleeding episode is resolved

Drug Name	Indication	Dosing Regimen	Maximum Dose
		there is evidence of further bleeding Moderate episodes: 15-25 IU/kg IV as a single dose followed by 10-15 IU/kg every 8-12 hours if needed Major episodes: 40- 50 IU/kg IV as a single dose followed by 20-25 IU/kg IV every 8-12 hours	
Antihemophilic factor – human (Hemofil M)	Perioperative management	Minor surgery: 30- 40 IU/kg as a single infusion Major surgery: 40-50 IU/kg every 8-24 hours	Minor surgery: 80 IU/kg/dose Major surgery: 100 IU/kg every 8 hours
Antihemophilic factor – human (Koate-DVI)	Perioperative management	Major surgery: 50 IU/kg pre-operative dose followed by 50 IU/kg every 6-12 hours as needed Minor surgery: less intensive schedules may be adequate	Major surgery: 50 IU/kg every 6 hours
Antihemophilic factor – recombinant, PEGylated-aucl (Jivi)	Control and prevention of bleeding episodes	Minor episodes: 10-20 IU/kg every 24-48 hours Moderate episodes: 15-30 IU/kg every 24-48 hours Major episodes: 30-50 IU/kg every 8-24 hours	50 IU/kg every 8 hours
	Perioperative management	Minor surgery: 15-30 IU/kg every 24 hours Major surgery: 40-50 IU/kg every 12-24 hours	Minor surgery: 30 IU/kg/dose Major surgery: 50 IU/kg/dose

Drug Name	Indication	Dosing Regimen	Maximum Dose
	Routine prophylaxis	30-40 IU/kg twice weekly; may be adjusted to 45-60 IU/kg every 5 days with further individual adjustment to less or more frequent dosing	60 IU/kg/dose; frequency varies based on bleeding episodes

VI. Product Availability

Drug Name	Availability
Antihemophilic factor – recombinant	Vial: 250, 500, 1,000, 1,500, 2,000, 3,000, 4,000 IU
Antihemophilic factor – recombinant	Vial: 250, 500, 750, 1,000, 1,500, 2,000, 3,000 IU
Antihemophilic factor – recombinant	Vial: 250, 500, 1,000, 1,500, 2,000, 2,500, 3,000 IU
Antihemophilic factor – recombinant	Vial: 250, 500, 750, 1,000, 1,500, 2,000, 3,000 4,000, 5,000, 6,000 IU
Antihemophilic factor – recombinant, glycopegylated-exei	Vial: 500, 1,000, 1,500, 2,000, 3,000 IU
Antihemophilic factor – recombinant (Helixate FS, Kogenate FS,	Vial: 250, 500, 1,000, 2,000, 3,000 IU
Antihemophilic factor – recombinant	Vial: 250, 500, 1,000, 1,500, 2,000, 3,000 IU
Antihemophilic factor – recombinant	Vial: 250, 500, 1,000, 2,000, 2,500, 3,000, 4,000 IU
Antihemophilic factor – recombinant (Recombinate)	Vial: 220-400, 401-800, 801-1240, 1241-1800, 1801-2400 IU
Antihemophilic factor – recombinant (ReFacto, Xyntha)	Vial: 250, 500, 1,000, 2,000 IU
Antihemophilic factor – recombinant (Xyntha Solofuse)	Prefilled syringe: 250, 500, 1,000, 2,000, 3,000 IU
Antihemophilic factor – recombinant	Vial: 500 IU
Antihemophilic factor – human (Hemofil M)	Vial: 250, 500, 1,000, 1,700 IU
Antihemophilic factor – human (Koate-DVI)	Vial: 250, 500, 1,000 IU
Antihemophilic factor – recombinant, PEGylated- aucl (Jivi)	Vial: 500, 1,000, 2,000, 3,000 IU

VII. References

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19. 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 December 1, 2020.

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
J7207	Injection, factor VIII (antihemophilic factor, recombinant) PEGylated, 1 IU
J7209	Injection, factor VIII (antihemophilic factor, recombinant) (Nuwiq), 1 IU
J7182	Injection, factor VIII, (antihemophilic factor, recombinant), (NovoEight), per IU
J7185	Injection, factor VIII (antihemophilic factor, recombinant) (Xyntha), per IU
J7188	Injection, factor VIII (antihemophilic factor, recombinant) (Obizur), per IU
J7190	Factor VIII (antihemophilic factor, human) per IU
J7191	Factor VIII (antihemophilic factor, porcine) per IU
J7192	Factor VIII (antihemophilic factor, recombinant) per IU, not otherwise specified

Reviews, Revisions, and Approvals	Date
Converted corporate to local policy	06.2021

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. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

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