Clinical Policy: Factor VIII (Human, Recombinant)

Reference Number: CP.PHAR.215
Effective Date: 05.01.16
Last Review Date: 02.18
Line of Business: Medicaid

Coding Implications
Revision Log

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

Description

The following are Factor VIII products (human, recombinant) requiring prior authorization: (Human – Hemofil M®, Koate®, Koate-DVI®, Monoclate-P®; Recombinant - Advate®, Adynovate®, Afstyla®, Eloctate®, Helixate FS®, Kogenate FS®, Kogenate FS with Vial Adapter®, Kogenate FS with Bio-Set®, Kovaltry®, NovoEight®, Nuwiq®, Obizur®, Recombinate®, ReFacto®, Xyntha®, 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, Helixate FS, Hemofil M, Koate-DVI, Kogenate FS, Kovaltry, Monoclate-P, Novoeight, Nuwiq, Recombinate, ReFacto, Xyntha
- Perioperative management:
  - Children and adults: Advate, Adynovate, Afstyla, Eloctate, Helixate FS, Hemofil M, Koate-DVI, Kogenate FS, Kovaltry, Monoclate-P, Novoeight, Nuwiq, Recombinate, ReFacto, Xyntha
- Routine prophylaxis to prevent or reduce the frequency of bleeding episodes:
  - Children and adults: Advate, Adynovate, Afstyla, Eloctate, Helixate FS, Kogenate FS, Kovaltry, Novoeight, Nuwiq, ReFacto (short-term)
- 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
- Treatment of 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 BU.

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Factor VIII products are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Congenital Hemophilia A (must meet all)**:**

1. Diagnosis of congenital hemophilia A;
2. Prescribed by or in consultation with a hematologist;
3. The requested product is prescribed for one of the following purposes (a, b, or c):
   a. Control and prevention of bleeding episodes (all products except Obizur);
   b. Perioperative management (all products except Obizur);
   c. Routine prophylaxis to prevent or reduce the frequency of bleeding episodes, and
      i. Request is for Advate, Adynovate, Eloctate, Helixate FS, Kogenate FS, Novoeight, Nuwiq, or ReFacto;
4. Member does not have von Willebrand disease (VWD);
5. 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 not available;
6. If Xyntha is prescribed, member has failed a trial of Advate (e.g., inhibitor production or hypersensitivity), unless contraindicated or clinically significant adverse effects are experienced, or Advate is not available;
7. Dose does not exceed the FDA approved maximum recommended dose for the relevant indications.

Approval duration: 3 months (bleeding episodes/surgery)
6 months (routine prophylaxis)

B. Acquired Hemophilia A (must meet all)**:**

1. Request is for Obizur;
2. Diagnosis of acquired hemophilia A;
3. Prescribed by or in consultation with a hematologist;
4. Request is for the control and prevention of bleeding episodes;
5. Member does not have congenital hemophilia A or VWD;
6. Dose does not exceed the FDA approved maximum recommended dose for the relevant indications.

Approval duration: 3 months (acute bleed) or 6 months (prophylaxis)

C. Other diagnoses/indications

1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Congenital Hemophilia A (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;

2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed the FDA approved maximum recommended dose for the relevant indications.

Approval duration: 3 months (bleeding episodes/surgery)
6 months (routine prophylaxis)

B. Acquired Hemophilia A (must meet all)**:**
1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed the FDA approved maximum recommended dose for the relevant indications.

Approval duration: 3 months (acute bleed) or 6 months (prophylaxis)

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
VWD: von Willebrand disease

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and 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	Injection: 0.3 mcg/kg IV every 48 hours Nasal spray: 1 spray intranasally in each nostril

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	≥ 50 kg: 1 spray intranasally in each nostril; may repeat based on laboratory response and clinical condition	

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.

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	50 IU/kg single dose or 30 IU/kg/repeated dose

Drug Name	Indication	Dosing Regimen	Maximum Dose
		Moderate episodes: 15-30 IU/kg IV every 12-24 hours Major episodes: initial 40-50 IU/kg IV followed by 20-25 IU/kg IV every 8-24 hours (Kogenate FS: every 8-12 hours)	
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 followed by a repeat dose of 40-50 IU/kg	Minor surgery: 40 IU/kg/dose Major surgery: 60 IU/kg/dose

Drug Name	Indication	Dosing Regimen	Maximum Dose
		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 (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 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 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
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

Drug Name	Indication	Dosing Regimen	Maximum Dose
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 (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
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

Drug Name	Indication	Dosing Regimen	Maximum 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: 20-40 IU/kg IV every 12-24 hours Moderate episodes: 30-60 IU/kg IV every 12-24 hours Major episodes: 60-100 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 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	25 IU/kg every 8 hours until the bleeding episode is resolved

Drug Name	Indication	Dosing Regimen	Maximum Dose
Antihemophilic factor – human (Monoclate-P)	Control and prevention of bleeding episodes	Minor episodes: will generally subside with a single infusion if a level of 30% or more is attained 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	25 IU/kg every 8 hours until the bleeding episode is resolved
Antihemophilic factor – human (Hemofil M)	Perioperative management	Minor surgery: 60-80 IU/kg as a single infusion Major surgery: 80-100 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 – human (Monoclate-P)	Perioperative management	Minor surgery: 15-25 IU/kg IV as a single dose followed by 10-15 IU/kg every 8-12 hours if needed Major surgery: a dose sufficient to	Minor surgery: 25 IU/kg/dose

Drug Name	Indication	Dosing Regimen	Maximum Dose
		achieve a level 80-100% of normal is given one hour prior to surgery. A second dose, half the size of the priming dose, is given 5 hours after the first dose.	

VI. Product Availability

Drug Name	Availability
Antihemophilic factor – recombinant (Advate)	Vial: 250, 500, 1000, 1500, 2000, 3000, 4000 IU
Antihemophilic factor – recombinant (Adynovate)	Vial: 250, 500, 750, 1000, 1500, 2000, 3000 IU
Antihemophilic factor – recombinant (Afstyla)	Vial: 250, 500, 1000, 1500, 2000, 2500, 3000 IU
Antihemophilic factor – recombinant (Eloctate)	Vial: 250, 500, 750, 1000, 1500, 2000, 3000 4000, 5000, 6000 IU
Antihemophilic factor – recombinant (Helixate FS, Kogenate FS, Kovaltry)	Vial: 250, 500, 1000, 2000, 3000 IU
Antihemophilic factor – recombinant (Novoeight)	Vial: 250, 500, 1000, 1500, 2000, 3000 IU
Antihemophilic factor – recombinant (Nuwiq)	Vial: 250, 500, 1000, 2000, 2500, 3000, 4000 IU
Antihemophilic factor – recombinant (Recombinate, Xyntha)	Vial: 250, 500, 1000, 2000 IU
Antihemophilic factor – recombinant (Xyntha Solofuse)	Prefilled syringe: 250, 500, 1000, 2000, 3000 IU
Antihemophilic factor – recombinant (Obizur)	Vial: 500 IU
Antihemophilic factor – human (Hemofil M)	Vial: 250, 500, 1000, 1700 IU
Antihemophilic factor – human (Koate-DVI)	Vial: 250, 500, 1000 IU
Antihemophilic factor – human (Monoclate-P)	Vial: 250, 500, 1000, 1500 IU

VII. References

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14. Xyntha Prescribing Information. Philadelphia, PA: Wyeth Pharmaceuticals, Inc.; October 2014. Available at: www.xyntha.com. Accessed November 27, 2017.
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16. Kovaltry Prescribing Information. Whippany, NJ: Bayer HealthCare LLC; March 2016. Available at: www.kovaltry-us.com. Accessed November 27, 2017.
17. Srivastava A, Brewer AK, Mauser-Bunschoten EP, et al. Guidelines for the management of hemophilia. *Haemophilia.* Jan 2013; 19(1): e1-47.
18. 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.

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
C9137	Injection, factor VIII (antihemophilic factor, recombinant) PEGylated, 1 IU
C9138	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), per IU
J7190	Factor VIII (antihemophilic factor, human) per IU
J7192	Factor VIII (antihemophilic factor, recombinant) per IU, not otherwise specified

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy split from CP.PHAR.12.Blood Factors and converted to new template. Added Kovaltry; removed requests for documentation; added 12 and older per PI indications if Adynovate. Removed preferencing for Helixate before Kogenate and Refacto. Under initial criteria, removed requirement for "severe hemophilia" and "history of 2 or more joint bleeds for prophylaxis indication." Non-prophylactic approval duration changed to 3 months initially with one 3-month re-auth. Removed denial based on inhibitor titer of ≥5 BU/mL. Reviewed by specialist.	04.01.16	05.16
Product updates: Afstyla added (new drug); Adynovate updated to include perioperative management and use in children; Koate added - Koate-DVI being phased out; Kogenate is available via three different PIs as Kogenate FS, Kogenate FS with Vial Adapter and Kogenate FS with Bio-Set; Obizur added (new drug for acquired hemophilia); ReFacto – removed "short term" use from criteria; Xyntha Solofuse added (same indications as Xyntha). Required trial of desmopressin is edited to avoid necessity of testing for coagulation factors. Safety information removed. Removed age >18 age restriction for Obizur per specialist recommendation. Wording for uses of all blood factor products made consistent across all policies. Per specialist review, for	04.01.17	05.17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
congenital hemophilia A, opened indications for routine prophylaxis up to all drugs listed in the policy, except Obizur. Approval periods across all blood factor policies made consistent. Efficacy statement added to renewal criteria. Hemophilias are specified as "congenital" versus "acquired" across blood factor policies where indicated. Reviewed by specialist- hematologist/internal medicine.		
Changed to new Centene Medicaid template	10.01.17	
1Q18 annual review: - No significant changes. - References reviewed and updated.	11.27.17	02.18

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. The Health Plan 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. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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 Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. 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. The Health Plan 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 the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.