

Clinical Policy: Factor VIII (Human - Hemofil M, Koate-DVI; Recombinant - Advate, Adynovate, Afstyla, Eloctate, Esperoct, Helixate FS, Jivi, Kogenate FS, Kovaltry, Novoeight, Nuwig, Obizur, Recombinate, Xyntha)

Reference Number: ERX.SPA.184

Effective Date: 01.11.17 Last Review Date: 11.21

Line of Business: Commercial, Medicaid

Revision Log

See <u>Important Reminder</u> 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, Nuwig, 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:
 - o Children: Helixate FS, Kogenate FS
- On-demand treatment and control of bleeding episodes in acquired hemophilia A:
 - o 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

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that factor VIII products are **medically necessary** when the following criteria are met:

CLINICAL POLICYFactor VIII (Human, Recombinant)



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. If the request is for routine prophylaxis and the member has used a dosage that exceeds the maximum recommended dose for at least 4 of the last 6 months, then member must use Hemlibra® unless contraindicated or clinically significant adverse effects are experienced;
- 6. 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;
- 7. For Jivi: Member meets both of the following (a and b):
 - a. Age ≥ 12 years;
 - b. Has previously been treated for hemophilia A;
- 8. If request is for a non-preferred product, failure of 2 preferred products, unless contraindicated or clinically significant adverse effects are experienced;
- 9. Documentation of member's body weight (in kg);
- 10. 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 ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Hemophilia A (must meet all):

- Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
- 2. If the request is for routine prophylaxis and the member has used a dosage that exceeds the maximum recommended dose for at least 4 of the last 6 months, then member must use Hemlibra unless contraindicated or clinically significant adverse effects are experienced;
- 3. Member is responding positively to therapy;
- 4. Documentation of member's body weight (in kg);
- 5. 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 a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
 - Approval duration: Duration of request or 6 months (whichever is less); or
- 2. Refer to ERX.PA.01 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 ERX.PA.01 or evidence of coverage documents;
- B. Von Willebrand disease.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BU: Bethesda unit

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
desmopressin acetate (Stimate® nasal spray;	When Factor VIII coagulant activity levels are > 5%	Injection: 0.3 mcg/kg IV every 48 hours
generic injection solution)	Injection: 0.3 mcg/kg IV every 48 hours	Nasal spray: 1 spray intranasally in each nostril
,	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 laboratory response and clinical condition	•
Hemlibra (emicizumab- kxwh)	3 mg/kg per week IV during the first four weeks of therapy, followed by either 1.5 mg/kg per week, 3 mg/kg once every two weeks, or 6 mg/kg once every four weeks thereafter	6 mg/kg/month

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, 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	Control and	Minor episodes: 10-20 IU/kg IV	50 IU/kg every 6
recombinant	prevention of	every 12-24 hours (Advate: 8-24	hours until the
(Advate, Adynovate,	bleeding	hours for age < 6 years)	bleeding episode is
Afstyla, Kovaltry,	episodes		resolved
Novoeight, Nuwiq,		Moderate episodes: 15-30 IU/kg IV	
Recombinate,		every 12-24 hours (Advate: 8-24	
Xyntha)		hours for age < 6 years)	



Dww Nome	Indication	Decina Besimen	Maximum Daga
Drug Name	Indication	Dosing Regimen	Maximum Dose
		Major episodes: 30-50 IU/kg IV	
		every 8-24 hours (Advate: 6-12	
Antibonombilio fostor	Control and	hours for age < 6 years)	FO II I/Ica ayamı O
Antihemophilic factor – recombinant	Control and prevention of	Minor and moderate episodes: 20-30 IU/kg every 24-48 hours (12-24	50 IU/kg every 8 hours until the
(Eloctate)	bleeding	hours for age < 6 years)	bleeding episode is
(Elociale)	episodes	Hours for age < 0 years)	resolved
	episodes	Major episodes: 40-50 IU/kg every	resolved
		12-24 hours (8 to 24 hours for age	
		< 6 years)	
Antihemophilic factor	Control and	Minor to moderate episodes: 40-	At least 12 years
- recombinant,	prevention of	65 IU/kg IV; one dose should be	old: 40 IU/kg
glycopegylated	bleeding	sufficient for minor episodes;	
(Esperoct)	episodes	additional dose may be	< 12 years old: 65
, ,		administered after 24 hours for	IU/kg
		moderate episodes.	
		Major episodes: 50-65 IU/kg IV;	
		additional doses may be	
		administered approximately every	
Antihamanhilia faatar	Control and	24 hours.	EO II I/ka ainala
Antihemophilic factor – recombinant	prevention of	Minor episodes: 10-20 IU/kg IV; repeat dose if there is evidence of	50 IU/kg single dose or 30
(Helixate FS,	bleeding	further bleeding	IU/kg/repeated
Kogenate FS)	episodes		dose
rtogenate i oj	Cpisodes	Moderate episodes: 15-30 IU/kg IV	dosc
		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	Perioperative	Minor surgery: 30-50 IU/kg IV as a	Minor surgery: 50
- recombinant	management	single dose within 1 hour of the	IU/kg/dose
(Advate, Adynovate)		operation and every 12-24 hours	
		(Adynovate: 24 hours) thereafter	Major surgery: 60
		as needed to control bleeding	IU/kg/dose
		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)	
Antihemophilic factor	Perioperative	Minor surgery: 25-40 IU/kg every	Minor surgery: 40
recombinant	management	24 hours (12-24 hours age < 6	IU/kg/dose
(Eloctate)		years)	
			Major surgery: 60
		Major surgery: pre-operative dose	IU/kg/dose
		of 40-60 IU/kg 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	
		years) and then every 24 hours to	



Antihemophilic factor recombinant (Alstyla, Kovaltry, Novoeight, Nuwiq, Recombinant, Xyntha) Antihemophilic factor precombinant (Alstyla, Kovaltry, Novoeight, Nuwiq, Recombinant (Xyntha) Antihemophilic factor recombinant (Alstyla, Kovaltry, Novoeight, Nuwiq, Recombinant (Xyntha) Antihemophilic factor recombinant (Alstyla, Kovaltry, Novoeight, Nuwiq, Recombinant (Xyntha) Antihemophilic factor recombinant (Alstyla, Kovaltry, Novoeight, Nuwiq, Recombinant (Xyntha) Antihemophilic factor recombinant (Drug Nama	Indication	_	Maximum Dose
the target range Antihemophilic factor — recombinant, glycopegylated (Esperoct) Antihemophilic factor — recombinant (Afstyla, Kovaltry, Novoeight, Nuwiq, Recombinate, Xyntha) Antihemophilic factor — recombinant (Afstyla) Antihemophilic factor — recombinant (Advate) Antihemophilic factor — recombinant (Advate) Antihemophilic factor — recombinant (Afstyla) Antihemophilic factor — recombinant (Advate) Antihemophilic factor — recombinant (Afstyla) Antihemophilic factor — recombinant (Advate) Antihemophilic factor — recombinant (Afstyla) Antihemophilic factor — recombinant (Afstyla) Antihemophilic	Drug Warne	mulcation		Maximum Dose
Antihemophilic factor recombinant (Afstyla, Kovaltry, Nuvicapith,				
recombinant, glycopegylated (Esperoct) Major surgery: 15-30 IU/kg IV every 24 hours (Astyla, Kovaltry, Novoeight, Nuwiq, Recombinant (Xyntha) Antihemophilic factor recombinant (Xyntha) Antihemophilic factor recombinant (Advate) Antihemophilic factor recombinant (Advate) Antihemophilic factor recombinant (Astyla) Antihemophilic factor recombinant (Advate) Antihemophilic factor recombinant (Afstyla) Antihemophilic factor recombinant (Astyla) Anti	Antihemophilic factor	Perioperative		At least 12
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. Antihemophilic factor recombinant (Helixate FS) Antihemophilic factor recombinant (Afstyla) An				
Recombinate		managomoni		
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 Antihemophilic factor – recombinant (Helixate FS) Antihemophilic factor – recombinant (Afstyla) Antihemophilic factor – recombin]
Antihemophilic factor – recombinant (Afstyla) Antihemophilic factor – recombinant (Helixate FS) Antihemophilic factor – recombinant (Helixate FS) Antihemophilic factor – recombinant (Afstyla) Antihemophilic f				< 12 years old: 65
then approximately every 48 hours until wound healing has occurred for major surgeries Antihemophilic factor – recombinant (Helixate FS, Kogenate FS) Antihemophilic factor – recombinant (Adyavale) Antihemophilic factor – recombinant (Afstyla) Antihemophil			administered approximately every	IU/kg
Antihemophilic factor recombinant (Helixate FS) Antihemophilic factor recombinant (Helixate FS) Kogenate FS) Antihemophilic factor recombinant (Afstyla, Kovaltry, Notvoeight, Nuwiq, Recombinate, Xyntha) Antihemophilic factor recombinant (Xyntha) Antihemophilic factor recombinant				
Antihemophilic factor recombinant (Helixate FS) Kogenate FS) Antihemophilic factor - recombinant (Helixate FS) Kogenate FS) Antihemophilic factor - recombinant (Afstyla) Antihemophilic factor - recombinant (Advate) Antihemophilic factor - recombinant (Afstyla) Antihe				
Antihemophilic factor recombinant (Helixate FS) Kogenate FS) Antihemophilic factor recombinant (Helixate FS) Kogenate FS) Antihemophilic factor recombinant (Afstyla) Antihemophilic factor recombinant (Xyntha) Antihemophilic factor recombinant (Advate) Antihemophilic factor recombinant (Advate) Antihemophilic factor recombinant (Adynovate) Antihemophilic factor recombinant (Afstyla) Antihemophilic factor recombinant (Adynovate) Antihemophilic factor recombinant (Afstyla) Antihemophilic factor recombina			· ·	
recombinant (Helixate FS, Kogenate FS) 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 Antihemophilic factor – recombinant (Afstyla, Kovaltry, Novoeight, Nuwiq, Recombinate, Xyntha) Antihemophilic factor – recombinant (Xyntha) Antihemophilic factor – recombinant (Advate) Antihemophilic factor – recombinant (Advate) Antihemophilic factor – recombinant (Advate) Antihemophilic factor – recombinant (Adynovate) Antihemophilic factor – recombinant (Adynovate) Antihemophilic factor – recombinant (Adynovate) Antihemophilic factor – recombinant (Afstyla) Antihemophilic factor	A 4'1 1. '1'	D. d. a. a. a. tia		NA:
(Helixate FS, Kogenate FS) 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 Major surgery: 50 IU/kg/dose Antihemophilic factor – recombinant (Afstyla, Kovaltry, Novoeight, Nuwiq, Recombinate, Xyntha) Perioperative management management Minor surgery: 15-30 IU/kg IV every 24 hours (Xyntha: every 12-24 hours) (Recombinate: 30-40 IU/kg/dose) Minor surgery: 30 IU/kg/dose Antihemophilic factor – recombinant (Xyntha) Routine prophylaxis Major surgery: 40-50 IU/kg IV every 42-4 hours (Xyntha: 30-50 IU/kg) Major surgery: 30 IU/kg/dose) Antihemophilic factor – recombinant (Advate) Routine prophylaxis 30 IU/kg IV 3 times weekly 30 IU/kg/dose Antihemophilic factor – recombinant (Adynovate) Routine prophylaxis 20-40 IU/kg IV every other day (3 to 4 times weekly) 40 IU/kg every other day Antihemophilic factor – recombinant (Afstyla) Routine prophylaxis ≥ 12 years of age: 25 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 times per week 50 IU/kg/dose Antihemophilic factor – recombinant (Floator – recombinant (Afstyla) 23 times per week 50 IU/kg/IV every 4 days 50 IU/kg/dose Antihemophilic factor – recombinant (Floator – recombinant (Afstyla) For children < 6 years of age: 50	•			
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: 15-30 IU/kg IV every 24 hours (Xyntha; Novoeight, Nuwiq, Recombinate, Xyntha) Major surgery: 40-50 IU/kg IV every 8-24 hours (Xyntha: 30-40 IU/kg IV every 8-24 hours (Xyntha: 30-50 IU/kg IV every 8-24 hours (Xyntha: 30-50 IU/kg) Major surgery: 50 IU/kg/dose (Recombinate: 40 IU/kg/dose) IU/kg/dose (Recombinate: 40 IU/kg/dose) Major surgery: 50 IU/kg IV every 8-24 hours (Xyntha: 30-50 IU/kg IV every 8-24 hours (Xyntha: 30-50 IU/kg IV every 8 hours every 8-24 hours (Xyntha: 30-50 IU/kg IV every 8 hours every 8-24 hours (Xyntha: 30-50 IU/kg IV every 8 hours every 8-24 hours (Xyntha: 30-50 IU/kg IV every 8 hours every 8-24 hours (Xyntha: 30-50 IU/kg IV every 8 hours every 8-24 hours (Xyntha: 30-50 IU/kg IV 2 every other day.		management	every 12-24 hours	iU/kg/dose
Antihemophilic factor — recombinant (Xyntha) Antihemophilic factor — recombinant (Advate) Antihemophilic factor — recombinant (Afstyla)			Major surgery: pre-operative dose	Major surgery: 50
Antihemophilic factor recombinant (Advate) Antihemophilic factor recombinant (Advate) Antihemophilic factor recombinant (Afstyla, Kovaltry, Novoeight, Nuwiq, Recombinate, Xyntha) Antihemophilic factor recombinant (Adynovate) Antihemophilic factor recombinant (Afstyla) Antihemophilic f	Trogonato 1 0)			
Antihemophilic factor recombinant (Afstyla, Kovaltry, Novoeight, Nuwiq, Recombinate, Xyntha) Antihemophilic factor recombinant (Afstyla, Kovaltry, Novoeight, Nuwiq, Recombinate, Xyntha) Antihemophilic factor recombinant (Xyntha) Antihemophilic factor recombinant (Xyntha) Antihemophilic factor recombinant (Advate) Antihemophilic factor recombinant (Afstyla) Factor VIII activity within the target range week (Ayntha: augrey: 15-30 IU/kg IV every 24 hours (Xyntha: 30-40 IU/kg A-50 IU/kg IV augrey: 50 IU/kg/dose (Recombinate: 40 IU/kg/dose) Major surgery: 50 IU/kg IV 3 times weekly 30 IU/kg IV 3 times weekly 40 IU/kg/dose 40 IU/kg/dose 40 IU/kg/dose 40 IU/kg/dose 40 IU/kg/dose 70 IU/kg/dose 40 IU/kg/dose 70 IU/kg/dose 50 IU/kg/dose 70 IU/kg/dose 70 IU/kg/dose 70 IU/kg/dose 70 IU/kg/dose				,
Antihemophilic factor – recombinant (Afstyla, Kovaltry, Novoeight, Nuwiq, Recombinate, Xyntha) Antihemophilic factor – recombinant (Afstyla) Antihemophilic factor – recombinant (Advate) Antihemophilic factor – recombinant (Advavate) Antihemophilic factor – recombinant (Adfstyla) Antihemophilic factor – recombinant (Afstyla) Antihemophilic factor – recombinant (Filocotate) Antihemophilic factor – recombinat (Filocotate) Antihemophilic factor – recombinat (Filocotate) Antihemophilic factor – recombinat (Filocotate) Antihemophilic				
- recombinant (Afstyla, Kovaltry, Novoeight, Nuwiq, Recombinate, Xyntha) Antihemophilic factor - recombinant (Advate) Antihemophilic factor - recombinant (Advate) Antihemophilic factor - recombinant (Advate) Antihemophilic factor - recombinant (Afstyla) Antihemophilic factor - recombinant (Afstyla) Antihemophilic factor - recombinant (Advate) Antihemophilic factor - recombinant (Adynovate) Antihemophilic factor - recombinant (Adynovate) Antihemophilic factor - recombinant (Adynovate) Antihemophilic factor - recombinant (Afstyla) For children < 6 years of age: 50 IU/kg/dose (Recombinate: 40 IU/kg/dose) Major surgery: 50 IU/kg IV every 8 hours As IU/kg V 2 times weekly 30 IU/kg/dose Ya times weekly Antihemophilic factor - recombinant (Afstyla) For children < 6 years of age: 50 IU/kg/dose Antihemophilic factor - recombinant (Afstyla) For children < 6 years of age: 50				
(Afstyla, Kovaltry, Novoeight, Nuwiq, Recombinate, Recombinate, Xyntha) (Xyntha: every 12-24 hours) (Recombinate: 40 IU/kg/dose) (Recombinate: 40 IU/kg/dose) Antihemophilic factor – recombinant (Xyntha) Routine prophylaxis 30 IU/kg IV 3 times weekly 30 IU/kg lv every 6 Hours (Xyntha: 30-50 IU/kg) Antihemophilic factor – recombinant (Advate) Routine prophylaxis 20-40 IU/kg IV 2 times weekly) 30 IU/kg 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 70 IU/kg/dose Antihemophilic factor – recombinant (Afstyla) Routine prophylaxis ≥ 12 years of age: 20-50 IU/kg IV 2 times per week 50 IU/kg IV every 4 days 50 IU/kg/dose Antihemophilic factor – recombinant (Eloctate) Routine prophylaxis 50 IU/kg IV every 4 days 65 IU/kg/dose				
Novoeight, Nuwiq, Recombinate, Xyntha) Recombinate, Xyntha R		management		
Recombinate, Xyntha) Single infusion Major surgery: 50 Major surgery: 50 IU/kg IV every 8-24 hours (Xyntha: 30-50 IU/kg) Antihemophilic factor				
Xyntha)Major surgery: 40-50 IU/kg IV every 8-24 hours (Xyntha: 30-50 IU/kg)Major surgery: 50 IU/kg every 8 hoursAntihemophilic factor - recombinant (Xyntha)Routine prophylaxis30 IU/kg IV 3 times weekly < 12 years of age: 25 IU/kg every other day.30 IU/kg lV every other dayAntihemophilic factor - recombinant (Advate)Routine prophylaxis20-40 IU/kg IV every other day (3 to 4 times weekly)40 IU/kg every other dayAntihemophilic 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 < 12 years of age: 20-50 IU/kg IV 2-3 times per week70 IU/kg/doseAntihemophilic factor - recombinant (Afstyla)Routine prophylaxis≥ 12 years of age: 30-50 IU/kg IV 2-3 times per week50 IU/kg/doseAntihemophilic factor - recombinant (Eloctate)Routine prophylaxis50 IU/kg IV every 4 days50 IU/kg/doseFor children < 6 years of age: 50				IU/kg/dose)
Antihemophilic factor – recombinant (Xyntha) Routine prophylaxis 30 IU/kg IV 3 times weekly 30 IU/kg dose Antihemophilic factor – recombinant (Xyntha) Routine prophylaxis 20-40 IU/kg IV 2 times weekly 40 IU/kg every other day (3 to 4 times weekly) Antihemophilic factor – recombinant (Advate) Routine prophylaxis 20-40 IU/kg IV every other day (3 to 4 times weekly) 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 70 IU/kg/dose Antihemophilic factor – recombinant (Afstyla) Routine prophylaxis ≥ 12 years of age: 20-50 IU/kg IV 2 times per week 50 IU/kg/dose Antihemophilic factor – recombinant (Eloctate) Routine prophylaxis 50 IU/kg IV every 4 days 65 IU/kg/dose For children < 6 years of age: 50			single initiation)	Major surgery: 50
Antihemophilic factor recombinant (Xyntha) Antihemophilic factor recombinant (Xyntha) Antihemophilic factor recombinant (Advate) Antihemophilic factor recombinant (Advate) Antihemophilic factor recombinant (Advate) Antihemophilic factor recombinant (Advate) Antihemophilic factor recombinant (Adynovate) Antihemophilic factor recombinant (Adynovate) Antihemophilic factor recombinant (Afstyla) For children < 6 years of age: 50	Ayrıdıa)		Major surgery: 40-50 IU/kg IV	
Antihemophilic factor – recombinant (Xyntha) Antihemophilic factor – recombinant (Xyntha) Antihemophilic factor – recombinant (Advate) Antihemophilic factor – recombinant (Advate) Antihemophilic factor – recombinant (Advate) Antihemophilic factor – recombinant (Adstyla) Antihemophilic factor – recombinant (Afstyla) For children < 6 years of age: 50				l comg crany concare
recombinant (Xyntha) Antihemophilic factor - recombinant (Advate) Antihemophilic factor - recombinant (Advate) Antihemophilic factor - recombinant (Afstyla) Antihemophilic factor - recombinant (Adynovate) Antihemophilic factor - recombinant (Afstyla) For children < 6 years of age: 25 IU/kg every other day (3 to 4 times weekly) Altihemophilic factor Antihemophilic factor Prophylaxis For children < 6 years of age: 25 IU/kg every other day (3 to 4 times weekly) Altihemophilic factor Prophylaxis For children < 6 years of age: 50				
(Xyntha) < 12 years of age: 25 IU/kg every other day.			30 IU/kg IV 3 times weekly	30 IU/kg/dose
Antihemophilic factor - recombinant (Advate) Antihemophilic factor - recombinant (Advate) Routine prophylaxis OR Use every third day dosing regimen targeted to maintain Factor VIII trough levels ≥ 1% Antihemophilic factor - recombinant (Adynovate) Routine prophylaxis Antihemophilic factor - recombinant (Adynovate) Routine prophylaxis Antihemophilic factor - recombinant (Afstyla) Antihemophilic factor - recombinant (Afstyla) Routine prophylaxis Sol IU/kg IV every 4 days For children < 6 years of age: 50		prophylaxis		
Antihemophilic factor - recombinant (Advate) Routine prophylaxis OR Use every third day dosing regimen targeted to maintain Factor VIII trough levels ≥ 1% Antihemophilic factor - recombinant (Adynovate) Routine prophylaxis Antihemophilic factor - recombinant (Adynovate) Routine prophylaxis Antihemophilic factor - recombinant (Afstyla) Routine prophylaxis 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% ≥ 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 < 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 Antihemophilic factor - recombinant (Eloctate) Routine prophylaxis For children < 6 years of age: 50	(Xyntha)		< 12 years of age: 25 IU/kg every	
recombinant (Advate) DR Use every third day dosing regimen targeted to maintain Factor VIII trough levels ≥ 1% Antihemophilic factor - recombinant (Adynovate) Antihemophilic factor - recombinant (Afstyla) Antihemophilic factor - recombinant (Eloctate) For children < 6 years of age: 50 Antihemophilic factor - recombinant (Eloctate) For children < 6 years of age: 50 Other day other day other day other day other day other day Antihemophilic factor - 2 12 years of age: 40-50 IU/kg IV 2 2 10 IU/kg IV 2 2 12 years of age: 55 IU/kg IV 2 12 years of age: 30-50 IU/kg IV 2-3 times per week Antihemophilic factor - recombinant (Eloctate) For children < 6 years of age: 50				
(Advate) OR Use every third day dosing regimen targeted to maintain Factor VIII trough levels ≥ 1% Antihemophilic factor – recombinant (Adynovate) Antihemophilic factor – recombinant (Afstyla) Routine prophylaxis Eloctate) OR Use every third day dosing regimen targeted to maintain Factor VIII trough levels ≥ 1% ≥ 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 < 12 years of age: 20-50 IU/kg IV 2-3 times per week So IU/kg IV every 4 days For children < 6 years of age: 50				
OR Use every third day dosing regimen targeted to maintain Factor VIII trough levels ≥ 1% Antihemophilic factor – recombinant (Adynovate) Antihemophilic factor – recombinant (Afstyla) Antihemophilic factor – recombinant (Afstyla) Antihemophilic factor – recombinant (Eloctate) Antihemophilic factor – recombinant (Eloctate) OR Use every third day dosing regimen targeted to maintain Factor values age: 21% ≥ 12 years of age: 40-50 IU/kg IV 2 times per week < 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 So IU/kg IV every 4 days For children < 6 years of age: 50		prophylaxis	to 4 times weekly)	other day
Use every third day dosing regimen targeted to maintain Factor VIII trough levels ≥ 1% Antihemophilic factor – recombinant (Adynovate) Antihemophilic factor – recombinant (Afstyla) Antihemophilic factor – recombinant (Afstyla) Antihemophilic factor – recombinant (Eloctate) Antihemophilic factor – recombinant (Eloctate) Use every third day dosing regimen targeted to maintain Factor (Age: 21%) ≥ 12 years of age: 40-50 IU/kg IV 2 times per week < 12 years of age: 20-50 IU/kg IV 2 50 IU/kg/dose 12 years of age: 30-50 IU/kg IV 2 2-3 times per week 50 IU/kg IV every 4 days For children < 6 years of age: 50	(Advate)		OB	
regimen targeted to maintain Factor VIII trough levels ≥ 1% Antihemophilic factor - recombinant (Adynovate) Antihemophilic factor - recombinant (Afstyla) Antihemophilic factor - recombinant (Afstyla) Routine prophylaxis ≥ 12 years of age: 40-50 IU/kg IV 2 times per week < 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 Antihemophilic factor - recombinant (Eloctate) Routine prophylaxis For children < 6 years of age: 50			OK	
regimen targeted to maintain Factor VIII trough levels ≥ 1% Antihemophilic factor - recombinant (Adynovate) Antihemophilic factor - recombinant (Afstyla) Antihemophilic factor - recombinant (Afstyla) Routine prophylaxis ≥ 12 years of age: 40-50 IU/kg IV 2 times per week < 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 Antihemophilic factor - recombinant (Eloctate) Routine prophylaxis For children < 6 years of age: 50			Use every third day dosing	
Factor VIII trough levels ≥ 1% Antihemophilic factor — recombinant (Adynovate) Antihemophilic factor — recombinant (Afstyla) Antihemophilic factor — recombinant (Afstyla) Factor VIII trough levels ≥ 1% ≥ 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 ≥ 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 Antihemophilic factor — recombinant (Eloctate) For children < 6 years of age: 50				
Antihemophilic factor – recombinant (Adynovate) Routine prophylaxis ≥ 12 years of age: 40-50 IU/kg IV 2 times per week 70 IU/kg/dose Antihemophilic factor – recombinant (Afstyla) Routine prophylaxis ≥ 12 years of age: 55 IU/kg IV 2 times per week 50 IU/kg/dose Antihemophilic factor – recombinant (Eloctate) Routine prophylaxis 50 IU/kg IV every 4 days 65 IU/kg/dose				
- recombinant (Adynovate) prophylaxis times per week 4 2 years of age: 55 IU/kg IV 2 times per week Antihemophilic factor - recombinant (Afstyla) Routine prophylaxis ≥ 12 years of age: 20-50 IU/kg IV 2-3 times per week 50 IU/kg IV 2 times per week Antihemophilic factor - recombinant (Eloctate) Routine prophylaxis 50 IU/kg IV every 4 days 65 IU/kg/dose	Antihemophilic factor	Routine		70 IU/kg/dose
(Adynovate) < 12 years of age: 55 IU/kg IV 2 times per week				
Antihemophilic factor – recombinant (Afstyla) Routine prophylaxis ≥ 12 years of age: 20-50 IU/kg IV 2-3 times per week 50 IU/kg/dose Antihemophilic factor – recombinant (Eloctate) Routine prophylaxis 50 IU/kg IV 2-3 times per week 65 IU/kg/dose For children < 6 years of age: 50	(Adynovate)			
- recombinant (Afstyla) 2-3 times per week 				
(Afstyla) 4 12 years of age: 30-50 IU/kg IV 2-3 times per week Antihemophilic factor recombinant (Eloctate) Antihemophilic factor prophylaxis For children < 6 years of age: 50 65 IU/kg/dose For children < 6 years of age: 50				50 IU/kg/dose
Antihemophilic factor – recombinant (Eloctate) 2-3 times per week 50 IU/kg IV every 4 days 65 IU/kg/dose For children < 6 years of age: 50		prophylaxis		
Antihemophilic factor – recombinant (Eloctate) Routine prophylaxis 50 IU/kg IV every 4 days For children < 6 years of age: 50	(Aisiyia)			
recombinant(Eloctate)prophylaxisFor children < 6 years of age: 50	Antihemonhilic factor	Routine		65 II I/ka/dose
(Eloctate) For children < 6 years of age: 50	- recombinant		oo lo/kg iv every 4 days	55 TO/NG/GUSE
		1-	For children < 6 years of age: 50	
	, , , , , , , , , , , , , , , , , , ,			



Drug Name	Indication	Dosing Regimen	Maximum Dose
Antihemophilic factor	Routine	At least 12 years old: 50 IU/kg IV	At least 12
- recombinant,	prophylaxis	every 4 days	years old: 50
glycopegylated	,		ľU/kg
(Esperoct)		< 12 years old: 65 IU/kg IV twice	
		weekly	< 12 years old: 65
			IU/kg
Antihemophilic factor	Routine	Adults: 25 IU/kg IV three times per	25 IU/kg/dose
- recombinant	prophylaxis	week	
(Helixate FS,		01:11.00.00	
Kogenate FS)	Davitina	Children: 25 IU/kg every other day	00 11 1/1/
Antihemophilic factor – recombinant	Routine	≥ 12 years of age: 20-50 IU/kg IV 3	60 IU/kg/dose
(Novoeight)	prophylaxis	times per week OR 20-40 IU/kg IV every other day	
(Novoeignit)		every other day	
		< 12 years of age: 25-60 IU/kg IV 3	
		times per week OR 25-50 IU every	
		other day	
Antihemophilic factor	Routine	≥ 12 years of age: 30-40 IU/kg IV	50 IU/kg/dose
recombinant	prophylaxis	every other day	
(Nuwiq)			
		< 12 years of age: 30-50 IU/kg IV	
		every other day or 3 times/week	
Antihemophilic factor	Routine	> 12 years of age: 20-40 IU/kg IV	50 IU/kg every
- recombinant	prophylaxis	2-3 times per week	other day
(Kovaltry)		≤ 12 years of age: 25-50 IU/kg	
		twice or three times weekly or every other day according to	
		individual requirements	
Antihemophilic factor	Treatment of	200 IU/kg every 4-12 hours	200 IU every 4
- recombinant,	bleeding	200 long every 1 12 hears	hours
porcine sequence	episodes in		
(Obizur)	acquired		
	hemophilia A		
Antihemophilic factor	Control and	Minor episodes: 10-20 IU/kg IV	100 IU/kg every 8
- human (Hemofil M)	prevention of	every 12-24 hours	hours
	bleeding		
	episodes	Moderate episodes: 15-30 IU/kg IV	
		every 12-24 hours	
		Major episodes: 30-50 IU/kg IV	
		every 8-24 hours	
Antihemophilic factor	Control and	Minor episodes: 10 IU/kg IV as a	25 IU/kg every 8
– human (Koate-DVI)	prevention of	single dose; repeat only if there is	hours until the
	bleeding	evidence of further bleeding	bleeding episode is
	episodes		resolved
		Moderate episodes: 15-25 IU/kg IV	
		as a single dose followed by 10-15	
		IU/kg every 8-12 hours if needed	
		Major opioedes, 40 50 HJ/km N/	
		Major episodes: 40-50 IU/kg IV as a single dose followed by 20-25	
		IU/kg IV every 8-12 hours	
Antihemophilic factor	Perioperative	Minor surgery: 30-40 IU/kg as a	Minor surgery: 80
– human (Hemofil M)	management	single infusion	IU/kg/dose
	managomont	I Single initiation	1.5/11g/4000



Drug Name	Indication	Dosing Regimen	Maximum Dose
Antihemophilic factor – human (Koate-DVI)	Perioperative management	Major surgery: 40-50 IU/kg every 8-24 hours Major surgery: 50 IU/kg pre- operative dose followed by 50	Major surgery: 100 IU/kg every 8 hours Major surgery: 50 IU/kg every 6 hours
,	J	lU/kg every 6-12 hours as needed Minor surgery: less intensive schedules may be adequate	,
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	50 IU/kg every 8 hours
		Major episodes: 30-50 IU/kg every 8-24 hours	
	Perioperative management	Minor surgery: 15-30 IU/kg every 24 hours	Minor surgery: 30 IU/kg/dose
		Major surgery: 40-50 IU/kg every 12-24 hours	Major surgery: 50 IU/kg/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

Product Availability	Availability
Drug Name	Availability
Antihemophilic factor – recombinant	Vial: 250, 500, 1,000, 1,500, 2,000, 3,000, 4,000 IU
(Advate)	
Antihemophilic factor – recombinant	Vial: 250, 500, 750, 1,000, 1,500, 2,000, 3,000 IU
(Adynovate)	
Antihemophilic factor – recombinant	Vial: 250, 500, 1,000, 1,500, 2,000, 2,500, 3,000 IU
(Afstyla)	
Antihemophilic factor – recombinant	Vial: 250, 500, 750, 1,000, 1,500, 2,000, 3,000 4,000,
(Eloctate)	5,000, 6,000 IU
Antihemophilic factor – recombinant,	Vial: 500, 1,000, 1,500, 2,000, 3,000 IU
glycopegylated-exei (Esperoct)	
Antihemophilic factor – recombinant	Vial: 250, 500, 1,000, 2,000, 3,000 IU
(Helixate FS, Kogenate FS, Kovaltry)	
Antihemophilic factor – recombinant	Vial: 250, 500, 1,000, 1,500, 2,000, 3,000 IU
(Novoeight)	
Antihemophilic factor – recombinant	Vial: 250, 500, 1,000, 2,000, 2,500, 3,000, 4,000 IU
(Nuwig)	
Antihemophilic factor – recombinant	Vial: 220-400, 401-800, 801-1240, 1241-1800, 1801-
(Recombinate)	2400 IU
Antihemophilic factor – recombinant	Vial: 250, 500, 1,000, 2,000 IU
(Xyntha)	, , , , , -
Antihemophilic factor – recombinant	Prefilled syringe: 250, 500, 1,000, 2,000, 3,000 IU
(Xyntha Solofuse)	, 3
Antihemophilic factor – recombinant	Vial: 500 IU
(Obizur)	
_ <u> </u>	



Drug Name	Availability
Antihemophilic factor – human	Vial: 250, 500, 1,000, 1,700 IU
(Hemofil M)	
Antihemophilic factor – human (Koate-	Vial: 250, 500, 1,000 IU
DVI)	
Antihemophilic factor – recombinant,	Vial: 500, 1,000, 2,000, 3,000 IU
PEGylated-aucl (Jivi)	

VII. References

- 1. Advate Prescribing Information. Westlake Village, CA: Baxalta US, Inc.; December 2018. Available at: www.advate.com. Accessed December 1, 2020.
- 2. Adynovate Prescribing Information. Westlake Village, CA: Baxalta US, Inc.; May 2018. Available at: www.adynovate.com. Accessed December 1, 2020.
- 3. Afstyla Prescribing Information. Kankakee, IL: CSL Behring LLC; April 2020. Available at: http://labeling.cslbehring.com/PI/US/Afstyla/EN/Afstyla-Prescribing- Information.pdf. Accessed December 1, 2020.
- 4. Eloctate Prescribing Information. Cambridge, MA: Biogen, Inc.; September 2019. Available at: www.eloctate.com. Accessed December 1, 2020.
- 5. Esperoct Prescribing Information. Plainsboro, NJ: Novo Nordisk Inc.; October 2019. Available at: https://www.novo-pi.com/esperoct.pdf. Accessed December 1, 2020.
- 6. Helixate FS Prescribing Information. Whippany, NJ: Bayer HealthCare LLC; May 2016. Available at: http://www.helixate.com/. Accessed December 1, 2020.
- 7. Hemofil M Prescribing Information. Westlake Village, CA: Baxter Healthcare Corporation; June 2018. Available at: http://www.shirecontent.com/PI/PDFs/HEMOFILM USA ENG.pdf. December 1, 2020.
- 8. Jivi Prescribing Information. Whippany, NJ: Bayer HealthCare LLC; August 2018. Available at: www.jivi.com. Accessed December 1, 2020.
- 9. Koate-DVI Prescribing Information. Research Triangle Park, NC: Grifols Therapeutics, Inc.; June 2018. Available at: www.koate-dviusa.com. Accessed December 1, 2020.
- 10. Kogenate FS. Whippany, NJ: Bayer HealthCare LLC; December 2019. Available at: www.kogenatefs.com. Accessed December 1, 2020.
- 11. Kovaltry Prescribing Information. Whippany, NJ: Bayer HealthCare LLC; March 2016. Available at: www.kovaltry-us.com. Accessed December 1, 2020.
- 12. Novoeight Prescribing Information. Plainsboro, NJ: Novo Nordisk, Inc.; July 2020. Available at: http://www.novoeight.com/. Accessed December 1, 2020.
- 13. Nuwiq Prescribing Information. Hoboken, NJ: Octapharma; July 2017. Available at: www.nuwiq.com. Accessed December 1, 2020.
- 14. Obizur Prescribing Information. Westlake Village, CA: Baxalta US, Inc.; July 2020. Available at: www.obizur.com. Accessed December 1, 2020.
- 15. Recombinate Prescribing Information. Westlake Village, CA: Baxalta US Inc.; June 2018. Available at: www.recombinate.com. Accessed December 1, 2020.
- 16. Xyntha Prescribing Information. Philadelphia, PA: Wyeth Pharmaceuticals, Inc.; August 2020. Available at: www.xyntha.com. Accessed December 1, 2020.
- 17. Xyntha Solofuse Prescribing Information. Philadelphia, PA: Wyeth Pharmaceuticals, Inc.; August 2020. Available at: www.xyntha.com. Accessed December 1, 2020.
- 18. Srivastava A, Brewer AK, Mauser-Bunschoten EP, et al. Guidelines for the management of hemophilia. Haemophilia. Jan 2013; 19(1): e1-47.
- 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	12.16	01.17

CLINICAL POLICYFactor VIII (Human, Recombinant)



Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q17 Annual Review	10.09.17	11.17
Converted to new template.		
Updated FDA-approved indications based on package labeling for individual		
products.		
Removed age restriction from Adynovate as package labeling supports use		
in children < 12 years of age.		
1Q18 annual review:	11.27.17	02.18
- Added Afstyla to the policy under the same coverage guidelines as the		
other recombinant factor VIII products.		
- Removed age limit from Obizur based on specialist feedback gained		
during previous revision of the Medicaid policy.		
- Removed "short-term" from ReFacto.		
- Added requirement for positive response to therapy.		
1Q 2019 annual review: added Jivi; removed Monoclate-P since it is no	10.29.18	02.19
longer available on market; removed requirement for failure of Advate for	10.20.10	02.10
Xyntha requests per formulary status (both NF); allowed use of Kovaltry for		
routine prophylaxis per FDA indication; added requirement for failure of 2		
preferred products for non-preferred products; clarified that disease must be		
congenital for all products except Obizur; moved criterion that member does		
not have VWD to Section III Diagnoses/Indications Not Covered; decreased		
continued approval duration for prophylaxis from 12 to 6 months to align with		
other blood factor policies; references reviewed and updated.		
1Q 2020 annual review: no significant changes; added Esperoct as an RT4	11.27.19	02.20
policy update; references reviewed and updated.	11.27.19	02.20
Added 1 month approval duration for use post-valoctocogene gene therapy	04.17.20	05.20
administration in hemophilia A.	04.17.20	03.20
Added routine prophylaxis-specific requirement for severe hemophilia	05.27.20	08.20
classification or at least one life-threatening or serious spontaneous bleed	03.21.20	06.20
for classification of non-severe hemophilia; added requirement for prescriber		
attestation of not partaking in contact sports.	08.31.20	
RT4: Added newly FDA-approved indication for Xyntha - routine prophylaxis	08.31.20	
of bleeding episodes.	40.04.00	44.00
Removed requirement for prescriber attestation of not partaking in contact	10.01.20	11.20
sports.	40.04.00	00.04
1Q 2021 annual review: added requirement for documentation of member's	12.01.20	02.21
body weight for calculation of appropriate dosage; removed ReFacto from		
the policy as it is no longer available; removed references to valoctocogene		
roxaparvovec as it did not receive FDA approval and likely will not face FDA		
review again until at least late 2022; references reviewed and updated.		
Added a requirement for high utilizers of factor VIII products for routine	10.12.21	11.21
prophylaxis to use Hemlibra.		

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional

CLINICAL POLICY Factor VIII (Human, Recombinant)



medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

This policy is the property of Envolve Pharmacy Solutions. Unauthorized copying, use, and distribution of this Policy or any information contained herein is strictly prohibited. By accessing this policy, you agree to be bound by the foregoing terms and conditions, in addition to the Site Use Agreement for Health Plans associated with Envolve Pharmacy Solutions.

©2017 Envolve Pharmacy Solutions. All rights reserved. All materials are exclusively owned by Envolve Pharmacy Solutions and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Envolve Pharmacy Solutions. You may not alter or remove any trademark, copyright or other notice contained herein.