



Factor VIII Concentrates – Hemophilia A
Effective January 1, 2021

Plan	<input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> MassHealth (PUF) <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Hemophilia A (factor VIII [factor 8] deficiency) and hemophilia B (factor IX [factor 9] deficiency) are X-linked inherited coagulation factor deficiencies that result in lifelong bleeding disorders. The availability of factor replacement products has dramatically improved care for individuals with these conditions. Factor VIII products are used to control and prevent bleeding episodes in adults and children with Hemophilia A, for perioperative management in adults and children with Hemophilia A, and for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children with Hemophilia A

Hemophilia A	
Recombinant Factor VIII Concentrates	
Advate antihemophilic factor [recombinant]	Novoeight antihemophilic factor [recombinant]
Afstyla antihemophilic factor [recombinant]	Nuwiq antihemophilic factor [recombinant]
Helixate FS antihemophilic factor [recombinant]	Recombate antihemophilic factor [recombinant]
Kogenate FS antihemophilic factor [recombinant]	Xyntha antihemophilic factor [recombinant] *
Kovaltry antihemophilic factor [recombinant]	
Extended Half-life Recombinant Factor VIII Concentrate	
Adynovate antihemophilic factor [recombinant], PEGylated	Jivi antihemophilic factor [recombinant], PEGylated-aucl
Eloctate antihemophilic factor [recombinant], Fc fusion protein	Esperoct antihemophilic factor [recombinant], Glycopegylated-exei
Human Plasma-Derived Factor VIII Concentrates	
Hemofil M antihemophilic factor [human] monoclonal antibody purified	Monoclata-P antihemophilic factor [human] monoclonal antibody purified



Human Plasma-Derived Factor VIII Concentrates That Contain Von Willebrand Factor	
Humate-P antihemophilic factor/von Willebrand factor complex [human]	Alphanate antihemophilic factor/von Willebrand factor complex [human]
Koate antihemophilic factor [human]	

* Preferred Drug

Coverage Guidelines

Hemophilia A

Authorization may be granted for members who members new to AllWays Health Partners are currently receiving treatment with the requested medication excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

OR

Authorization may be granted when ONE the following criteria are met, and documentation is provided:

1. Member has mild disease (see Appendix A) and has had an insufficient response to desmopressin or a documented clinical reason for not using desmopressin (see Appendix B).
2. Member has moderate or severe disease (see Appendix A).

Von Willebrand Disease (VWD)

Authorization of Alphanate, Humate-P, or Koate may be granted for treatment of VWD when ONE of the following criteria is met:

1. Member has type 1, 2A, 2M, or 2N VWD and has had an insufficient response to desmopressin or a documented clinical reason for not using desmopressin (see Appendix B).
2. Member has type 2B or type 3 VWD.

Acquired Hemophilia A

Authorization of Kogenate FS, Advate, Alphanate, Helixate FS, Hemofil M, Humate-P, Koate, Kogenate FS, Monoclate-P, Recombinate, or Xyntha* when used for the diagnosis of Acquired Hemophilia A.

* Preferred Drug

Acquired von Willebrand Syndrome

Authorization of Alphanate or Humate-P may be granted for treatment of acquired von Willebrand syndrome.

Continuation of Therapy

All members (including new members) requesting authorization for continuation must meet initial authorization criteria.

Limitations

Approvals will be granted for 36 months.

Appendices

Appendix A: Classification of Hemophilia by Clotting Factor (% activity) and Bleeding Episodes

Bleeding Episodes Severity	Clotting Factor Level % activity*	Bleeding Episodes
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Severe	< 1%	Spontaneous bleeding episodes, predominantly into joints and muscles Severe bleeding with trauma, injury or surgery
Moderate	1% to 5%	Occasional spontaneous bleeding episodes. Severe bleeding with trauma, injury or surgery
Mild	6% to 40%	Severe bleeding with serious injury, trauma or surgery

Appendix B: Clinical Reasons for Not Utilizing Desmopressin in Patients with Hemophilia A and Type 1, 2A, 2M and 2N (VWD)

- A. Age < 2 years
- B. Pregnancy
- C. Fluid/electrolyte imbalance
- D. High risk for cardiovascular or cerebrovascular disease (especially the elderly)
- E. Predisposition to thrombus formation
- F. Trauma requiring surgery
- G. Life-threatening bleed
- H. Contraindication or intolerance to desmopressin
- I. Severe type 1 von Willebrand disease

References

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Review History

11/18/2020 – Updated and reviewed at Nov P&T Mtg: Moved from SGM to custom template, Separated Comm/Exch vs. MassHealth; changed approval dates from indefinite to 36 months; Documented Xyntha as Preferred Drug

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