Mass General Brigham
Health Plan

Factor VIII Concentrates
Effective 01/01/2023

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy when obtained through the pharmacy benefit.		
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

Preferred Products	Non-Preferred Products
Advate	Eloctate
Adynovate	Esperoct
Afstyla	Hemofil M
Kovaltry	Alphanate
Novoeight	Humate-P
Nuwiq	Koate
Xyntha	Kogenate FS
Xyntha Solofuse	Recombinate
Jivi	

Coverage Guidelines

Hemophilia A
Authorization may be granted for members new to the plan who are currently receiving treatment with excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for the following preferred products: Advate, Adynovate, Afstyla, Kovaltry, Novoeight, Nuwiq, Xyntha, Xyntha Solofuse, and Jivi, when 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).
3. Authorization of a non-preferred product will require documentation that the member has had an inadequate response or intolerance to all preferred products

Authorization of **Jivi** may be granted for treatment of hemophilia A when both of the following criteria are met:

1. Member has previously received treatment for hemophilia A with a factor VIII product.
2. Member is ≥ 12 years of age.

Von Willebrand Disease (VWD)
Authorization of Alphanate, Humate-P, or Koate may be granted for treatment of VWD when any 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

1. Authorization of Advate, Afstyla, Kovaltry, Novoeight, Nuwiq, Xyntha, Xyntha Solofuse and Jivi may be granted for treatment of acquired hemophilia A.
2. Authorization of a non-preferred product will require documentation that the member has had an inadequate response or intolerance to all preferred products

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

<u>Continuation of Therapy</u>
Reauthorization may be granted for all members, including new members, when all initial criteria has been met.

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
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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2. Jivi [package insert]. Whippany, NJ: Bayer HealthCare LLC; August 2018.
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7. Xyntha [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.; August 2019.
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Review History

11/18/2020-Updated: Moved from SGM to custom template, added preferred drug strategy, changed approval duration from indefinite to 36 months, references updated; P+T review

03/17/2021 – Updated and reviewed; Removed Monoclate-P and Helixate FS from criteria as products have been discontinued; references updated. Effective 06/01/2021.

11/16/2022 – Reviewed and Updated for Nov P&T. Updated preferred and non-preferred products. Preferred products include: Advate, Afstyla, Kovaltry, Novoeight, Nuwiq, Xyntha, Xyntha Solofuse and Jivi. Effective 01/01/2023.