Mass General Brigham
Health Plan

Factor VIII Concentrates
Effective 07/01/2025

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
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.

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

Coverage Guidelines
Authorization may be granted for members new to the plan within the last 90 days who are currently receiving treatment with the requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Hemophilia A
Authorization may be granted for the following preferred products: Advate, Adynovate, Afstyla, Altuviiio, Eloctate, Esperoct, Koate, Kovaltry, Novoeight, Nuwiq, Recombinate, Xyntha, or Xyntha Solofuse, when #1 or #2 are met:

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** requires the member meet #1 or #2 as well as documentation that the member has had an inadequate response or intolerance to one preferred product or clinical rationale why none of the preferred products is appropriate for the member

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

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), **OR**
2. Member has moderate or severe disease (see Appendix A), **OR**
3. Member has previously received treatment for hemophilia A with a factor VIII product **AND** the 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, Adynovate, Afstyla, Altuviiio, Eloctate, Esperoct, Koate, Kovaltry, Novoeight, Nuwiq, Recombinate, Xyntha, Xyntha Solofuse and Jivi may be granted for treatment of acquired hemophilia A.
2. Authorization of a non-preferred product requires the member meet #1 and documentation that the member has had an inadequate response or intolerance to one preferred product or clinical rationale why none of the preferred products is appropriate for the member

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 when the following criteria are met:

1. Initial criteria has been met
2. Member is experiencing a positive response to therapy (e.g., reduced frequency or severity of bleeds).

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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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.

06/14/2023 – Updated and reviewed for June P&T; Added new drug Altuviiio to criteria as a non-preferred agent. Effective 8/1/2023

07/10/20204 – Updated and reviewed for July P&T; Updated criteria to move Recombinate, Altuviiio, Koate, Eloctate, and Esperoct to preferred status; Updated criteria for nonpreferred products to require step through with one preferred agent or clinical rationale why none of the preferred agents is clinically appropriate; Clarified that members are considered new to the Plan if they joined within the previous 90 days; Effective 09/01/2024.
04/09/2025 – Reviewed and updated for April P&T. Updated reauthorization criteria to require member has had a positive response to therapy. Effective 07/01/2025.