# Factor VIII Concentrates

**Effective 06/01/2021**

<table>
<thead>
<tr>
<th>Plan</th>
<th>☑ MassHealth</th>
<th>☑ Commercial/Exchange</th>
<th>Program Type</th>
<th>☑ Prior Authorization</th>
<th>☑ Quantity Limit</th>
<th>☐ Step Therapy</th>
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<tbody>
<tr>
<td>Benefit</td>
<td>☑ Pharmacy Benefit</td>
<td>☑ Medical Benefit (NLX)</td>
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### 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**

<table>
<thead>
<tr>
<th>Plan</th>
<th>Phone</th>
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<tbody>
<tr>
<td>MassHealth</td>
<td>877-433-7643</td>
<td>866-255-7569</td>
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<tr>
<td>Commercial</td>
<td>800-294-5979</td>
<td>888-836-0730</td>
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<tr>
<td>Exchange</td>
<td>855-582-2022</td>
<td>855-245-2134</td>
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**Medical Specialty Medications (NLX)**

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<th>Phone</th>
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<tr>
<td>All Plans</td>
<td>844-345-2803</td>
<td>844-851-0882</td>
</tr>
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### 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

- Kogenate FS
- Jivi
- Kovaltry
- Novoeight
- Adynovate
- Recombinate
- Xyntha
- Esperoet
- Hemofil M
- Alphanate
- Humate-P
- Koate

### Non-Preferred Products

- Eloctate
- Nuwiq
- Advate
- Afstyla
-

399 Revolution Drive, Suite 810, Somerville, MA 02145 | allwayshealthpartners.org

AllWays Health Partners includes AllWays Health Partners, Inc. and AllWays Health Partners Insurance Company
Coverage Guidelines

Hemophilia A
Authorization may be granted for members new to AllWays Health Partners 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, Adynovate, Jivi, Kogenate FS, Kovaltry, 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 Kogenate FS may be granted for treatment of acquired hemophilia A.
2. Authorization of Advate, Alphanate, Hemofil M, Humate-P, Koate, Kogenate FS, Recombinate, or Xyntha for Acquired Hemophilia A may be granted if a member has had an inadequate response or intolerance to Kogenate FS.

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

Continuation of Therapy
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

<table>
<thead>
<tr>
<th>Bleeding Episodes Severity</th>
<th>Clotting Factor Level (% activity*)</th>
<th>Bleeding Episodes</th>
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<tbody>
<tr>
<td>Severe</td>
<td>&lt; 1%</td>
<td>Spontaneous bleeding episodes, predominantly into joints and muscles. Severe bleeding with trauma, injury or surgery</td>
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<tr>
<td>Moderate</td>
<td>1% to 5%</td>
<td>Occasional spontaneous bleeding episodes. Severe bleeding with trauma, injury or surgery</td>
</tr>
<tr>
<td>Mild</td>
<td>6% to 40%</td>
<td>Severe bleeding with serious injury, trauma or surgery</td>
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</table>

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
13. Humate-P (antihemophilic factor/von Willebrand factor complex) [prescribing information].
   Kankakee, IL: CSL Behring; September 2017.
14. Recombinate (antihemophilic factor [recombinant]) [prescribing information]. Lexington MA:
   Baxalta US Inc; June 2018.
18. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.;
   http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed
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   patients with severe von Willebrand disease who are undergoing elective surgery. J Thromb Haemost
   2019; 17:52.
20. Escobar MA, Brewer A, Caviglia H, et al. Recommendations on multidisciplinary management of
   December 12, 2019.
23. National Hemophilia Foundation. MASAC recommendations concerning products licensed for the
   2019.
24. National Hemophilia Foundation. MASAC recommendations regarding the treatment of von
   Willebrand disease. Revised November 2016. MASAC Document #244.
27. Leissinger C, Carcao M, Gill JC, et al. Desmopressin (DDAVP) in the management of patients with
28. Reding MT, NG HJ, Poulsen LH, et al. Safety and efficacy of BAY 94-9027, a prolonged-half-life
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.

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