### Factor VIII Concentrates – Hemophilia A
**Effective 06/01/2021**

<table>
<thead>
<tr>
<th>Plan</th>
<th>☐ MassHealth</th>
<th>☑ MassHealth (PUF)</th>
<th>☐ Commercial/Exchange</th>
<th>Program Type</th>
<th>☑ Prior Authorization</th>
<th>☐ Quantity Limit</th>
<th>☐ Step Therapy</th>
</tr>
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<tbody>
<tr>
<td>Benefit</td>
<td>☑ Pharmacy Benefit</td>
<td>☑ Medical Benefit (NLX)</td>
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<tr>
<td>Specialty Limitations</td>
<td>This medication has been designated specialty and must be filled at a contracted specialty pharmacy when filled through the pharmacy benefit.</td>
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### 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

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**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.

<table>
<thead>
<tr>
<th>Recombinant Factor VIII Concentrates</th>
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<tbody>
<tr>
<td>Advate antihemophilic factor [recombinant]</td>
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<tr>
<td>Afstyla antihemophilic factor [recombinant]</td>
</tr>
<tr>
<td>Kogenate FS antihemophilic factor [recombinant]</td>
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<tr>
<td>Kovaltry antihemophilic factor [recombinant]</td>
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</table>

**Extended Half-life Recombinant Factor VIII Concentrate**

| Adynovate antihemophilic factor [recombinant], PEGylated | Jivi antihemophilic factor [recombinant], PEGylated-aeull |
| 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 |         |

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AllWays Health Partners includes AllWays Health Partners, Inc. and AllWays Health Partners Insurance Company.
Human Plasma-Derived Factor VIII Concentrates That Contain Von Willebrand Factor

| Koate antihemophilic factor [human] | |

* Preferred Drug

Coverage Guidelines

Hemophilia A
Authorization may be granted for members 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
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, Hemofil M, Humate-P, Koate, Kogenate FS, 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

<table>
<thead>
<tr>
<th>Bleeding Episodes Severity</th>
<th>Clotting Factor Level % activity*</th>
<th>Bleeding Episodes</th>
</tr>
</thead>
</table>

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### Table

<table>
<thead>
<tr>
<th>Severity</th>
<th>Range</th>
<th>Description</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>
</tr>
<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>
</tr>
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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


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

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