

<b>Clinical Policy Title:</b>	Factor VIII (Human, Recombinant)
<b>Policy Number:</b>	RxA.800
<b>Drug(s) Applied:</b>	Advate <sup>®</sup> , Adynovate <sup>®</sup> , Altuviiio, Afstyla <sup>®</sup> , Eloctate <sup>®</sup> , Hemofil M <sup>®</sup> , Jivi <sup>®</sup> , Koate-DVI <sup>®</sup> , Helixate FS <sup>®</sup> , Kogenate FS <sup>®</sup> , Kovaltry <sup>®</sup> , Novoeight <sup>®</sup> , Nuwiq <sup>®</sup> , Obizur, Recombinate <sup>®</sup> , Xyntha <sup>®</sup> , and Xyntha <sup>®</sup> Solofuse <sup>®</sup> .  Long acting:
<b>Original Policy Date:</b>	10/19/2023
<b>Last Review Date:</b>	3/1/2024
<b>Line of Business Policy Applies to:</b>	All lines of business (except Medicare)

## Criteria

### I. Initial Approval Criteria

#### A. Acquired and Congenital Hemophilia A (must meet all):

1. Diagnosis of acquired or congenital hemophilia A (factor VIII deficiency);
2. Request is for any one of the following uses (refer to appendix for medication and approved indication):
  - a. On-demand treatment and control of bleeding episode;
  - b. Perioperative management;
  - c. Routine prophylaxis to reduce the frequency of bleeding episodes and patient meets one of the following (i, ii, or iii):
    - i. Previously used factor VIII for routine prophylaxis;
    - ii. Severe to moderately severe hemophilia A (factor VIII  $\leq$ 2% of normal);
    - iii. Experienced at least one serious spontaneous bleed;
  - d. Reduce the risk of joint damage in children without pre-existing joint damage;
3. Prescribed by or in consultation with a hematologist;

#### Approval Duration

**All Lines of Business (except Medicare):** 3 months (surgical/acute bleeding) or 6 months (prophylaxis)

### II. Continued Therapy Approval

#### A. Hemophilia A (must meet all):

1. Member is currently receiving or has been treated with this medication within the past 90 days

#### Approval Duration

**All Lines of Business (except Medicare):** 3(surgical/acute bleeding) or 6 months (prophylaxis)

## Appendix A: FDA-Approved Indications per Drug

Medication	FDA Approved Indication
Advate	Congenital Hemophilia: <ol style="list-style-type: none"> <li>1. Control and prevention of bleeding episodes.</li> <li>2. Perioperative management.</li> </ol>

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

	3. Routine prophylaxis to prevent or reduce the frequency of bleeding episodes.
Adynovate Altuviio Afstyla, Eloctate Jivi Kovaltry Novoeight Nuwiq Xyntha Xyntha Solofuse	Congenital Hemophilia: 1. On-demand treatment and control of bleeding episodes 2. Perioperative management 3. Routine prophylaxis to reduce the frequency of bleeding episodes
Hemofil M Koate-DVI	Congenital Hemophilia: 1. Control and prevention of bleeding episodes.
Kogenate FS	Congenital Hemophilia: 1. On-demand treatment and control of bleeding episodes 2. Perioperative management of bleeding 3. Routine prophylaxis to reduce the frequency of bleeding episodes 4. Reduce the risk of joint damage in children without pre-existing joint damage.
Obizur	<u>Acquired</u> Hemophilia 1. On-demand treatment and control of bleeding episodes
Recombinate	Congenital Hemophilia: 1. Control and prevention of bleeding episodes 2. Perioperative management

**References**

1. Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation (NHF): Database of treatment guidelines. Available at: <https://www.hemophilia.org/healthcare-professionals/guidelines-on-care/masac%20documents>. Accessed July 24, 2023.
2. Srivastava A, Santagostino E, Dougall A, et al. Wfh guidelines for the management of hemophilia, 3rd edition. Haemophilia. 2020;26 Suppl 6:1-158. Available at: <https://pubmed.ncbi.nlm.nih.gov/32744769/>. Accessed July 24, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	07/24/2023	10/19/2023