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

Criteria

I. Initial Approval Criteria

A. Hemophilia A (must meet all):

1. Diagnosis of one of the following (a or b):
   a. Congenital hemophilia A (factor VIII deficiency);
   b. Acquired hemophilia A (Obizur only);
2. Prescribed by or in consultation with a hematologist;
3. Request is for any one of the following uses (a, b, c or d):
   a. Control and prevention of bleeding episodes;
   b. Perioperative management (all products except Obizur);
   c. Reduce the risk of joint damage in children without pre-existing joint damage : Request is for Helixate FS, Kogenate FS;
   d. Routine prophylaxis to prevent or reduce the frequency of bleeding episodes: Request is for Advate, Adynovate, Afstyla, Eloctate, Esperoct, Helixate FS, Jivi, Kogenate FS, Kovaltry, Novoeight, Nuwiq, or Xyntha, and member meets one of the following (i, ii, or iii):
      i. Member has previously used factor VIII for routine prophylaxis;
      ii. Member has severe to moderately severe hemophilia A (factor VIII ≤2% of normal);
      iii. Member has experienced at least one serious spontaneous bleed;
4. Documentation of member's body weight (in kg);
5. For Jivi®: Member meets both of the following (a and b):
   a. Age ≥ 12 years;
   b. Has previously been treated for hemophilia A;
6. Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication. (Refer to Dosing Information).

Approval Duration

Commercial: 3 months (surgical/acute bleeding) or 6 months (prophylaxis)

Medicaid: 3 months (surgical/acute bleeding) or 6 months (prophylaxis)

II. Continued Therapy Approval

A. Hemophilia A (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;

2. Member is responding positively to therapy;
3. Documentation of member's body weight (in kg);
4. If request is for a dose increase, new dose does not exceed the dose does not exceed the recommended maximum dose (Refer to Dosing Information).

Approval Duration
Commercial: 3 months (surgical/acute bleeding) or 6 months (prophylaxis)
Medicaid: 3 months (surgical/acute bleeding) or 6 months (prophylaxis)

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