curative

Factor VIII Prior Authorization

Drug(s) Applied:	**Advate** (antihemophilic factor (FVIII) recombinant, intravenous solution) **Adynovate** **Afstyla** **Eloctate** **Esperoct** **Hemofil M** **Humate-P (for VWD)** **Jivi** **Koate** **Kogentate FS** **Kovaltry** **Novoeight** **Wilate (for VWD)** **Xyntha**

VWD = von Willebrand disease

Criteria:
Drug(s) Applied will be approved when the requested medication is being used for an FDA approved indication and all of the following criteria are met:

I. Initial Approval Criteria
   A. **Hemophilia A (also known as Factor VIII deficiency or classic hemophilia)** as indicated by chart notes within past 90 days
      1. If requested agent is Wilate, patient must try and fail Koate first **and**
      2. ONE of the following:
         a) Patient is currently experiencing a bleed AND BOTH of the following:
            (1) Patient is out of medication **and**
            (2) Patient needs to receive a ONE TIME emergency supply of medication **or**
         b) The requested agent is being used for ONE of the following:
            (1) Prophylaxis AND the patient will NOT be using the requested agent in combination with Hemlibra (emicizumab-kxwh) **or**
            (2) On-demand use for bleeds **or**
            (3) Peri-operative management of bleeding **and**
      3. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., hematology)

Approval Duration: 12 months

B. **von Willebrand disease (VWD)** as indicated by chart notes within past 90 days
   1. ONE of the following:
      a) Patient is currently experiencing a bleed AND BOTH of the following:
         (1) Patient is out of medication **and**
         (2) Patient needs to receive a ONE TIME emergency supply of medication **or**
      b) Patient has type 1 (excluding type 1C), 2A, 2M or 2N VWD and ONE of the following:
         (1) Patient has tried and had an inadequate response to desmopressin (e.g., DDAVP injection, Stimate nasal spray) **or**
         (2) Patient did not respond to a DDAVP trial with 1 and 4 hour post infusion bloodwork **or**
         (3) Patient has an intolerance or hypersensitivity to desmopressin, a FDA labeled contraindication to desmopressin OR prescriber has provided information supporting why the patient cannot use desmopressin (e.g., shortage in marketplace) **or**
         (4) Patient has type 1C, 2B or 3 VWD **and**
      c) The requested agent will be used for ONE of the following:
         (1) Prophylaxis **or**
         (2) On-demand use for bleeds **or**
         (3) Peri-operative management of bleeding **and**
      d) Patient will NOT be using the requested agent in combination with another agent in the same category (e.g., Factor VIII agents, Factor VIII and von Willebrand Factor combination agents) **and**
      e) Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., hematology)

   Approval Duration: 12 months

II. Continued Therapy Approval as follows
   A. **Hemophilia A without inhibitors or von Willebrand disease** as indicated by chart notes within past 12 months
      1. Patient has been previously approved for the requested agent through the plan's Prior Authorization process (if current request is for a ONE TIME emergency use or the patient ONLY has previous approval(s) for emergency use, must use Initial Evaluation) **and**
      2. If the patient is using the requested agent for prophylaxis, then ONE of the following:
         a) Patient has a diagnosis of hemophilia A AND the patient will NOT be using the requested agent in combination with Hemlibra (emicizumab-kxwh) **or**

b) Patient has another diagnosis **and**

3. ONE of the following:
    a) Prescriber has verified that the patient does not have greater than 5 on-demand doses on hand **or**
    b) Prescriber has provided information in support of the patient having more than 5 on-demand doses on hand **and**
4. Patient will NOT be using the requested agent in combination with another agent in the same category (e.g., Factor VIII agents, Factor VIII and von Willebrand Factor combination agents) included in this program **and**
5. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., hematology)

Approval Duration: 12 months

Policy Owned by: Curative PBM team