Applicable Drugs: Advate, Adynovate, Afstyla, Alphanate, AlphaNine SD, Alprolix, Altuviiio, BeneFIX, Eloctate, Esperoct, Feiba, Hemofil M, Humate-P, Idelvion, Ixinity, Jivi, Koate, Koate-DVI, Kovaltry, NovoEight, NovoSeven RT, Nuwiq, Profilnine, Rebinyn, Recombinate, Rixubis, Sevenfact, Wilate, Xyntha, Xyntha Solofuse (antihemophilic factor recombinant)

Date of Origin: 4/22/2026

Date Last Reviewed / Revised: 4/22/2026

Prior Authorization Criteria

(May be considered medically necessary when criteria I through VII are met)

I. Documented diagnosis of one of the following conditions A through B AND must meet ALL criteria listed under applicable diagnosis.

   A. Congenital Hemophilia A (Factor VIII deficiency)

      i. Diagnosis of moderate to severe disease with documented baseline FVIII levels below 5% of normal FVIII activity (<0.05 IU/mL or <5 IU/dL)

      ii. Documentation of inhibitor status, if applicable

   B. Congenital Hemophilia B (Factor IX deficiency)

      i. Diagnosis of moderate to severe disease with documented baseline FIX levels below 5% of normal FIX activity (<0.05 IU/mL or <5 IU/dL)

      ii. Documentation of inhibitor status, if applicable

II. Documented patient weight.

III. Documentation of patient bleed history, including severity.

IV. Documentation of intended use (on-demand, prophylaxis, or peri-operative)

   A. For requests for on-demand treatment, there must be documentation that the prescriber has communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have more than 5 on-demand doses on hand.

V. Treatment is prescribed by or in consultation with a hematologist.

VI. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

VII. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

Exclusion Criteria

- Use for immune tolerance induction (ITI)

Other Criteria

- Age limitations apply for specific products:
  - Altuviiio: ≥ 1 year
  - Jivi: ≥ 12 years
  - Sevenfact: ≥ 12 years

Quantity / Days Supply Restrictions

- Quantity limits are dependent on patient weight and number of doses.
- For home supply limits (on-demand treatment), there may be no more than five on-demand doses on hand at any time, unless peri-operative need is documented.

Approval Length

- **Authorization:** 6 months
- **Re-Authorization:**
  - On-demand treatment: 6 months
  - Routine prophylaxis: 12 months

Appendix

Table 1: Select Product Details and FDA Labeled Indications

Agent	Factor Type	Half-Life Class	On-Demand / Bleed Control	Peri-Operative Management	Routine Prophylaxis
Advate	VIII	SHL	☑	☑	☑
Adynovate	VIII	EHL	☑	☑	☑
Afstyla	VIII	SHL	☑	☑	☑
Alphanate	VIII (± VWF)	SHL	☑	☑**	—
AlphaNine SD	IX	SHL	☑	—	—
Alprolix	IX	EHL	☑	☑	☑
Altuviiio	VIII	UHL	☑	☑	☑
BeneFIX	IX	SHL	☑	☑	☑
Eloctate	VIII	EHL	☑	☑	☑
Esperoct	VIII	EHL	☑	☑	☑
Feiba	Other (aPCC)	N/A	☑	☑	☑*

Agent	Factor Type	Half-Life Class	On-Demand / Bleed Control	Peri-Operative Management	Routine Prophylaxis
Hemofil M	VIII	SHL	☑	☑	☑
Humate-P	VIII (± VWF)	SHL	☑	☑	—
Idelvion	IX	EHL	☑	☑	☑
Ixinity	IX	SHL	☑	—	—
Jivi	VIII	EHL	☑	☑	☑
Koate	VIII	SHL	☑	☑	—
Koate-DVI	VIII	SHL	☑	☑	—
Kovaltry	VIII	SHL	☑	☑	☑
NovoEight	VIII	SHL	☑	☑	☑
NovoSeven RT	VIIa	N/A	☑*	☑*	—
Nuwiq	VIII	SHL	☑	☑	☑
Profilnine	IX	SHL	☑	—	—
Rebinyn	IX	EHL	☑	☑	☑
Recombinate	VIII	SHL	☑	☑	—
Rixubis	IX	SHL	☑	☑	☑
Sevenfact	VIIa	N/A	☑*	—	—
Wilate	VIII (± VWF)	SHL	☑	☑	☑
Xyntha	VIII	SHL	☑	☑	☑
Xyntha Solofuse	VIII	SHL	☑	☑	☑

*Not indicated for use in hemophilia without inhibitors. **Alphanate's peri-operative indication applies specifically to VWD patients where DDAVP is ineffective or contraindicated.
SHL = Standard Half-Life, EHL = Extended Half-Life, UHL = Ultra-Long Half-Life

Table 2: Products by Therapeutic Subclass

Factor VIII Products (Hemophilia A)	
Standard Half-Life (SHL) FVIII	Advate, Afstyla, Hemofil M, Koate, Koate-DVI, Novoeight, Nuwiq, Recombinate, Xyntha, Xyntha Solofuse
Extended Half-Life (EHL) FVIII	Adynovate, Eloctate, Esperoct, Jivi, Kovaltry
Ultra-Long Half-Life (UHL) FVIII	Altuviiio
Plasma-derived FVIII/VWF (von Willebrand Factor)	Alphanate, Humate-P, Wilate
Factor IX Products (Hemophilia B)	
Standard Half-Life (SHL) FIX	Alphanine SD, Benefix, Ixinity, Profilnine, Rixubis
Extended Half-Life (EHL) FIX	Alprolix, Idelvion, Rebinyn
Other Coagulation Products (non-FVIII/FIX; not used in Hemophilia without Inhibitors)	
Activated/Bypassing Agents	Feiba, Novoseven RT, Sevenfact

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DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.