

**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             | ☑                         | ☑                         | ☑*                  |
| Hemofil M    | VIII         | SHL             | ☑                         | ☑                         | ☑                   |
| Humate-P     | VIII (± VWF) | SHL             | ☑                         | ☑                         | —                   |
| Idelvion     | IX           | EHL             | ☑                         | ☑                         | ☑                   |
| Ixinity      | IX           | SHL             | ☑                         | —                         | —                   |

| Agent           | Factor Type  | Half-Life Class | On-Demand / Bleed Control | Peri-Operative Management | Routine Prophylaxis |
|-----------------|--------------|-----------------|---------------------------|---------------------------|---------------------|
| 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             | ☑                         | —                         | —                   |
| Rebinyln        | 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, Rebinyln                                                                         |
| 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.