AvMed

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-877-535-1391**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Feiba® (Anti-Inhibitor Coagulant Complex) (J7198) (Medical)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Dosing Limits:

A. Quantity Limit (max daily dose) [NDC Unit]

- Feiba 500 units vial = 12 vials per 30 days
- Feiba 1000 units vial = 12 vials per 30 days
- Feiba 2500 units vial = 24 vials per 30 days

(Continued on next page)

B. Max Units (per dose and over time) [HCPCS Unit]:

- ❑ 50 to 100 units per kg per dose
  - Joint hemorrhage, mucous membrane bleeding, soft tissue hemorrhage, other severe hemorrhage, perioperative management: maximum: 100 units/kg/dose, 200 units/kg/day
  - Routine Prophylaxis: 85 units/kg every other day
- ❑ 119,000 billable units per 28-day supply

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Part I. Initial Authorization

- ❑ Diagnosis of congenital factor VIII (Hemophilia A) or factor IX (Hemophilia B) deficiency has been confirmed by blood coagulation testing
- ❑ Member has inhibitors to factor VIII or factor IX with a current or historical titer of ≥ 5 Bethesda Units (BU) (Submit documentation)
- ❑ Member has a trial history and inadequate response to bypassing agents, NovoSeven or Sevenfact, unless otherwise contraindicated (Provider must provide documented history)
- ❑ If member was treated with prior gene therapy for hemophilia A (e.g., Roctavian® (valoctocogene roxaparvovec)); or prior gene therapy for hemophilia B (e.g., Hemgenix® (etranacogene dezaparvovec-drlb), Beqvez™ (fidanacogene elaparvovec-dzkt)) and requires factor replacement therapy, documentation is submitted to show that FIX activity levels have decreased and/or bleeding has **NOT** been controlled
- ❑ Requested medication will be used as treatment in at least **ONE** of the following:
  - ❑ On-demand treatment and control of bleeding episodes (episodic treatment of acute hemorrhage) **(Authorization will be approved for 3 months)**

    Please Attach On-Demand Treatment Dosing Calculations [Dosage regimen to adhere to most current recommended FDA-label and/or compendia recommendations (see Part III)]
  - ❑ Perioperative management **(Authorizations valid for 1 month)**

    Name Description of Procedure: _____

    Date of Procedure: _____

    Dosage regimen must adhere to most current recommended FDA-label and/or compendia recommendations (see Part III):

    _____
  - ❑ Routine prophylaxis **(Authorization will be approved for a 3-month period)**

    Dosage regimen must adhere to most current recommended FDA-label and/or compendia recommendations (see Part III):

    _____

(Continued on next page)

- ❑ **FOR ROUTINE PROPHYLAXIS:** Requested medication will be used as treatment in at least **ONE** of the following:
  - ❑ Severe factor VIII deficiency (factor VIII level of <1%) or severe factor IX deficiency (a Factor IX level of <1%) **AND** member must meet **ONE** of the following:
    - ❑ Member has a history of life-threatening hemorrhage requiring on-demand use of Factor VIII therapy
    - ❑ Member has a history of repeated, serious spontaneous bleeding episodes requiring on-demand use of Factor VIII therapy

Part II. Renewal Clinical Authorization

- ❑ Requested medication will be used as treatment in at least **ONE** of the following if applicable:
  - ❑ On-demand treatment and control of bleeding episodes **(Authorization will be approved for 6 months)**

    Please Attach On-Demand Treatment Dosing Calculations [Dosage regimen to adhere to most current recommended FDA-label and/or compendia recommendations (see Part III)]
  - ❑ Perioperative management **- only for NovoSeven RT (NO RENEWAL AUTHORIZATIONS – PLEASE COMPLETE PART I)**
  - ❑ Routine prophylaxis **- only for NovoSeven RT (Authorization will be approved for a 12-month period)**

    Dosage regimen must adhere to most current recommended FDA-label and/or compendia recommendations (see part III):

    _____

    NOTE: Provider must submit clinical rationale (i.e., past medical records, weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy) for an increase in dose
- ❑ Provider must confirm **ALL** the following:
  - ❑ Member has experienced an absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: anaphylaxis and hypersensitivity reactions (e.g., angioedema, chest tightness, hypotension, urticaria, wheezing, dyspnea, etc.), thromboembolic events (pulmonary embolism, venous thrombosis, and arterial thrombosis), development of neutralizing antibodies (inhibitors), nephrotic syndrome, etc.
  - ❑ Member continues to meet criteria in Part I and other indication-specific relevant criteria such as concomitant therapy requirements, inadequate response to bypassing agents, performance status, etc.
  - ❑ Member has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline)

(Continued on next page)

Part III. Dosage/Administration

Indication	Dose
Control and prevention of acute bleeding for Congenital Hemophilia A / Hemophilia B with inhibitors	**Joint hemorrhage** Administer 50 – 100 units/kg IV every 12 hours until pain and acute disabilities are improved **Mucous Membrane Bleeding** Administer 50 – 100 units/kg IV every 6 hours for at least 1 day or until bleeding is resolved **Soft tissue hemorrhage** Administer 100 units/kg IV every 12 hours until resolution of bleed **Other severe hemorrhage** Administer 100 units/kg IV every 6 – 12 hours until resolution of bleed
Routine Prophylaxis for Congenital Hemophilia A/Hemophilia B with inhibitors	Administer 85 units/kg IV every other day
Perioperative management for Congenital Hemophilia A/Hemophilia B with inhibitors	**Preoperative** Administer 50 – 100 units/kg IV administered as a one-time dose immediately prior to surgery **Postoperative** Administer 50 – 100 units/kg IV administered every 6 – 12 hours postoperatively until resolution of bleed and healing is achieved

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy**

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.

***Approved by Pharmacy and Therapeutics Committee**: 9/25/2025
REVISED/UPDATED/REFORMATTED: ~~10/16/2025~~, **12/12/2025**