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.

Factor VIIa (Bypassing Agents for Hemophilia A and B) (MEDICAL)

Drug Requested: (Select one drug below)

Bypassing Agents (Coagulation Factor VII)	
❑ **J7189 NovoSeven® RT**	❑ **J7212 Sevenfact®**

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.

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Dosing Limits:

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

- NovoSeven RT 1000 mcg vial = 12 vials per 30 days
- NovoSeven RT 2000 mcg vial = 12 vials per 30 days
- NovoSeven RT 5000 mcg vial = 24 vials per 30 days
- NovoSeven RT 8000 mcg vial = 15 vials per 30 days
- Sevenfact 1 mg vial = 48 vials per 30 days
- Sevenfact 2 mg vial = 12 vials per 30 days
- Sevenfact 5 mg vial = 24 vials per 30 days

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

❑ 120,000 billable units per 30-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

❑ For NovoSeven® RT requests

❑ 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 with a current or historical titer of ≥ 5 Bethesda Units (BU) (Submit documentation)

❑ 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 **(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)]

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- ❑ 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 12-month period)**

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

  _____

- ❑ **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

❑ For Sevenfact® requests

- ❑ Member is at least 12 years of age
- ❑ Diagnosis of congenital factor VIII (Hemophilia A) or factor IX (Hemophilia B) deficiency has been confirmed by blood coagulation testing **[NOTE: Requested medication will NOT be approved for the treatment of congenital factor VII deficiency]**
- ❑ Member has inhibitors to Factor VIII with a current or historical titer of ≥ 5 Bethesda Units (BU) (Submit documentation)
- ❑ 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
- ❑ Provider is requesting medication only for on-demand treatment and control of bleeding episodes

  Please Attach On-Demand Treatment Dosing Calculations [Dosage regimen to adhere to most current recommended FDA-label and/or compendia recommendations (see Part III)]

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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 (not including prerequisite therapy), performance status, etc.
  - ❑ Member has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline)

Part III. Dosage/Administration

Indication	Dose
NovoSeven RT	
Control and prevention of bleeding: Congenital Hemophilia A or B with inhibitors	Hemostatic Administer 90 mcg/kg intravenously every 2 hours, adjustable based on severity of bleeding until hemostasis is achieved, or until the treatment has been judged to be inadequate. Post-Hemostatic Administer 90 mcg/kg intravenously every 3-6 hours after hemostasis is achieved for severe bleeds

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Indication	Dose
NovoSeven RT	
Control and prevention of bleeding: Congenital Hemophilia A or B with inhibitors	Hemostatic Administer 90 mcg/kg intravenously every 2 hours, adjustable based on severity of bleeding until hemostasis is achieved, or until the treatment has been judged to be inadequate. Post-Hemostatic Administer 90 mcg/kg intravenously every 3-6 hours after hemostasis is achieved for severe bleeds
Control and prevention of bleeding: Acquired Hemophilia	Administer 70-90 mcg/kg intravenously every 2-3 hours until hemostasis is achieved
Control and prevention of bleeding: Congenital Factor VII deficiency	Administer 15-30 mcg/kg intravenously every 4-6 hours until hemostasis is achieved
Control and prevention of bleeding: Glanzmann's Thrombasthenia	Administer 90 mcg/kg intravenously every 2-6 hours in severe bleeding episodes requiring systemic hemostatic therapy until hemostasis is achieved
Perioperative management Congenital Hemophilia A or B with inhibitors	**Minor** • Initial: Administer 90 mcg/kg intravenously immediately before surgery, repeat every 2 hours during surgery. • Post-Op: Administer 90 mcg/kg intravenously every 2 hours after surgery for 48 hours, then every 2-6 hours until healing has occurred. **Major** • Initial: Administer 90 mcg/kg intravenously immediately before surgery, repeat every 2 hours during surgery. **Post-Op:** Administer 90 mcg/kg intravenously every 2 hours after surgery for 5 days, then every 4 hours or by continuous infusion, via pump, at 50 mcg/kg/hr until healing occurs.
Perioperative management Acquired Hemophilia	Administer 70-90 mcg/kg intravenously immediately before surgery and every 2-3 hours for the duration of surgery and until hemostasis is achieved
Perioperative management Congenital Factor VII deficiency	Administer 15-30 mcg/kg intravenously immediately before surgery and every 4-6 hours for the duration of surgery and until hemostasis is achieved
Perioperative management Glanzmann's Thrombasthenia	Initial: Administer 90 mcg/kg intravenously immediately before surgery and repeat every 2 hours for the duration of the procedure. Post-Op: Administer 90 mcg/kg intravenously every 2-6 hours to prevent post-operative bleeding

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Indication	Dose
Sevenfact	
Control and treatment of bleeding: Congenital Hemophilia A or B with inhibitors	**For Mild or Moderate Bleeds:** • Administer 75 mcg/kg intravenously repeated every 3 hours until hemostasis is achieved **OR** • Initial dose of 225 mcg/kg. If hemostasis is not achieved within 9 hours, additional 75 mcg/kg doses may be administered every 3 hours as needed to achieve hemostasis **For Severe Bleeds:** • Administer 225 mcg/kg intravenously initially, followed if necessary 6 hours later with 75 mcg/kg every 2 hours until hemostasis 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 – Proprium Rx**

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.*