

## **Clinical Policy: Factor VIIa, Recombinant (NovoSeven RT, SevenFact)**

Reference Number: CP.PHAR.220

Effective Date: 05.01.16

Last Review Date: 02.25

Line of Business: Commercial, HIM, Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### **Description**

Coagulation factor VIIa, recombinant (NovoSeven<sup>®</sup> RT) and coagulation factor VIIa (recombinant)-jncw (SevenFact<sup>®</sup>) are coagulation factors.

### **FDA Approved Indication(s)**

NovoSeven RT is indicated for treatment of bleeding episodes and perioperative management in:

- Adults and children with hemophilia A or B with inhibitors, congenital factor VII (FVII) deficiency, and Glanzmann's thrombasthenia with refractoriness to platelet transfusions, with or without antibodies to platelets
- Adults with acquired hemophilia

SevenFact is indicated for the treatment and control of bleeding episodes occurring in adults and adolescents (12 years of age and older) with hemophilia A or B with inhibitors.

Limitation(s) of use: SevenFact is not indicated for treatment of congenital factor VII deficiency.

### **Policy/Criteria**

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that NovoSeven RT and SevenFact are **medically necessary** when the following criteria are met:

#### **I. Initial Approval Criteria**

##### **A. Hemophilia A or B with Inhibitors, Congenital Factor VII Deficiency (must meet all):**

1. Diagnosis of one of the following (a, b, or c):
  - a. Congenital hemophilia A or B with inhibitors;
  - b. Acquired hemophilia (NovoSeven RT requests only);
  - c. Congenital factor VII deficiency (NovoSeven RT requests only);
2. Prescribed by or in consultation with a hematologist;
3. For SevenFact requests only: Age  $\geq$  12 years;
4. Request is for one of the following uses (a or b):
  - a. Control and prevention of bleeding episodes;
  - b. Perioperative management (NovoSeven RT requests only);
5. Documentation of member's current body weight (in kg);

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6. Dose does not exceed one of the following (a or b):
  - a. For NovoSeven requests (i or ii):
    - i. Hemophilia: 90 mcg/kg every 2 hours;
    - ii. Congenital factor VII deficiency: 30 mcg/kg every 4 hours;
  - b. For SevenFact requests: 75 mcg/kg every 2 hours.

**Approval duration: 3 months**

**B. Glanzmann's Thrombasthenia (must meet all):**

1. Diagnosis of Glanzmann's thrombasthenia;
2. Request is for NovoSeven RT;
3. Prescribed by or in consultation with a hematologist;
4. Condition is refractory to platelet transfusions;
5. Request is for one of the following uses (a or b):
  - a. Control and prevention of bleeding episodes;
  - b. Perioperative management;
6. Documentation of member's current body weight (in kg);
7. Dose does not exceed 90 mcg/kg every two hours.

**Approval duration: 3 months**

**C. Other diagnoses/indications (must meet 1 or 2):**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**II. Continued Therapy****A. All Indications in Section I (must meet all):**

1. Member meets one of the following (a or b):
  - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
  - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);

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2. Member is responding positively to therapy;
3. Documentation of member's current body weight (in kg);
4. If request is for a dose increase, new dose does not exceed one of the following (a or b):
  - a. For NovoSeven requests (i or ii):
    - i. Hemophilia: 90 mcg/kg every 2 hours;
    - ii. Congenital factor VII deficiency: 30 mcg/kg every 4 hours;
  - b. For SevenFact requests: 75 mcg/kg every 2 hours.

**Approval duration: 3 months**

**B. Other diagnoses/indications (must meet 1 or 2):**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

*Appendix B: Therapeutic Alternatives*

Not applicable

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*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s):
  - NovoSeven RT: none reported
  - SevenFact: known allergy to rabbits or rabbit proteins; severe hypersensitivity reaction to SevenFact or any of its components
- Boxed warning(s): thrombosis

*Appendix D: General Information*

- Congenital hemophilia A is a deficiency of factor VIII.
- Congenital hemophilia B is a deficiency of factor IX.
- Acquired hemophilia is evidenced by presence of coagulation factor inhibitors (autoantibodies).

**V. Dosage and Administration**

<b>Drug Name</b>	<b>Indication</b>	<b>Dosing Regimen</b>	<b>Maximum Dose</b>
Factor VIIa, recombinant (NovoSeven RT)	Treatment of bleeding episodes	<p><u>Congenital hemophilia A or B with inhibitors:</u></p> <ul style="list-style-type: none"> <li>• 90 mcg/kg IV every 2 hrs, adjustable based on severity of bleeding until hemostasis is achieved</li> <li>• 90 mcg/kg IV every 3-6 hrs after hemostasis is achieved for severe bleeds</li> </ul> <p><u>Congenital factor VII deficiency:</u> 15-30 mcg/kg IV every 4-6 hrs until hemostasis is achieved</p> <p><u>Glanzmann’s thrombasthenia:</u> 90 mcg/kg IV every 2-6 hrs until hemostasis is achieved</p> <p><u>Acquired hemophilia:</u> 70-90 mcg/kg IV every 2-3 hrs until hemostasis is achieved</p>	<p>Congenital factor VII deficiency: 30 mcg/kg every 4 hrs</p> <p>All other indications: 90 mcg/kg every 2 hrs</p>
Factor VIIa, recombinant (NovoSeven RT)	Peri-operative management	<p><u>Congenital hemophilia A or B with inhibitors:</u></p> <p><i>Minor surgery:</i></p> <ul style="list-style-type: none"> <li>• 90 mcg/kg IV immediately before surgery, repeat every 2 hrs during surgery</li> <li>• 90 mcg/kg IV every 2 hrs after surgery for 48 hours, then every</li> </ul>	<p>Congenital factor VII deficiency: 30 mcg/kg every 4 hrs</p> <p>Glanzmann’s thrombasthenia: 140 mcg/kg every 2 hrs</p>

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Drug Name	Indication	Dosing Regimen	Maximum Dose
		<p>2-6 hrs until healing has occurred</p> <p><i>Major surgery:</i></p> <ul style="list-style-type: none"> <li>• 90 mcg/kg IV immediately before surgery, repeat every 2 hrs during surgery</li> <li>• 90 mcg/kg IV every 2 hrs after surgery for 5 days, then every 4 hrs or by continuous infusion at 50 mcg/kg/hr until healing has occurred</li> <li>• Additional boluses can be given</li> </ul> <p><u>Congenital factor VII deficiency:</u> 15-30 mcg/kg IV immediately before surgery and every 4-6 hours for the duration of surgery and until hemostasis is achieved Note: doses as low as 10 mcg/kg can be effective</p> <p><u>Glanzmann’s thrombasthenia:</u></p> <ul style="list-style-type: none"> <li>• 90 mcg/kg IV immediately before surgery and repeat every 2 hrs for the duration of the procedure</li> <li>• 90 mcg/kg IV every 2-6 hrs to prevent post-operative bleeding</li> <li>• Higher doses of 100-140 mcg/kg can be used for surgical patients who have clinical refractoriness with or without platelet-specific antibodies</li> </ul> <p><u>Acquired hemophilia:</u> 70-90 mcg/kg immediately before surgery and every 2-3 hrs for the duration of surgery and until hemostasis is achieved</p>	<p>All other indications: 90 mcg/kg every 2 hrs</p>
Coagulation factor VIIa (recombinant)-	Treatment and control of bleeding episodes	<p><u>For mild or moderate bleeds:</u> 75 mcg/kg IV every 3 hrs until hemostasis is achieved OR</p>	75 mcg/kg every 3 hrs

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Drug Name	Indication	Dosing Regimen	Maximum Dose
jncw (SevenFact)		Initial dose of 225 mcg/kg; if hemostasis is not achieved within 9 hrs, additional 75 mcg/kg every 3 hrs as needed to achieve hemostasis  <u>For severe bleeds:</u> 225 mcg/kg, followed if necessary 6 hrs later with 75 mcg/kg every 2 hrs	

**VI. Product Availability**

Drug Name	Availability
Factor VIIa, recombinant (NovoSeven RT)	Powder for reconstitution in single-use vials: 1 mg, 2 mg, 5 mg, 8 mg
Coagulation factor VIIa (recombinant)-jncw (SevenFact)	Lyophilized powder for reconstitution in single-use vials: 1 mg, 2 mg, 5 mg

**VII. References**

1. NovoSeven RT Prescribing Information. Plainsboro, NJ: Novo Nordisk, Inc.; July 2020. Available at <http://www.novosevenrt.com>. Accessed October 29, 2024.
2. SevenFact Prescribing Information. Louisville, KY: HEMA Biologics; June 2024. Available at: <https://www.fda.gov/media/136610/download?attachment>. Accessed October 29, 2024.
3. Srivastava A, Brewer AK, Mauser-Bunschoten EP, et al. Guidelines for the management of hemophilia. Haemophilia. Jan 2013; 19(1): e1-47.
4. Medical and Scientific Advisory Council (MASAC) of the National Bleeding Disorders Foundation (formerly National Hemophilia Foundation): Database of treatment guidelines. Available at <https://www.hemophilia.org/healthcare-professionals/guidelines-on-care/masac-documents>. Accessed November 18, 2024.
5. Rezende SM, Neumann I, Angchaisuksiri P, et al. International Society on Thrombosis and Haemostasis clinical practice guideline for treatment of congenital hemophilia A and B based on the Grading of Recommendations Assessment, Development, and Evaluation methodology. J Thromb Haemost. 2024;22(9):2629-2652.

**Coding Implications**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J7189	Factor VIIa (antihemophilic factor, recombinant), (NovoSeven RT), per 1 mcg
J7212	Factor VIIa (antihemophilic factor, recombinant)-jncw (SevenFact), per 1 mcg

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2021 annual review: added commercial line of business; added requirement for documentation of member’s body weight for calculation of appropriate dosage; clarified covered indications for SevenFact to align with FDA label; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	12.01.20	02.21
1Q 2022 annual review: no significant changes; references reviewed and updated.	11.23.21	02.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.05.22	
1Q 2023 annual review: no significant changes; references reviewed and updated.	11.09.22	02.23
1Q 2024 annual review: no significant changes; references reviewed and updated.	10.29.23	02.24
RT4: added new vial strength of 2 mg; updated HCPCS codes.	07.08.24	
1Q 2025 annual review: clarified that acquired hemophilia indication is applicable to NovoSeven RT only; references reviewed and updated.	10.29.24	02.25

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a



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discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note: For Medicaid members,** when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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