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

Reference Number: ERX.SPA.189
Effective Date: 01.11.17
Last Review Date: 02.22
Line of Business: Commercial, Medicaid

Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

**Description**
Factor VIIa, recombinant (NovoSeven® RT) and coagulation factor VIIa (recombinant)-jncw (SevenFact®) are coagulation factors.

**FDA Approved Indication(s)**
NovoSeven RT is indicated for the treatment of bleeding episodes and perioperative management in:

- Adults and children with hemophilia A or B with inhibitors, congenital factor VII 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.*

*Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.*

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 or b):
   a. Congenital or acquired hemophilia A or B with inhibitors;
   b. Congenital factor VII deficiency (NovoSeven RT requests only);
2. Prescribed by or in consultation with a hematologist;
3. For SevenFact requests only: Age ≥ 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);
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**

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**II. Continued Therapy**

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
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. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   **Approval duration: Duration of request or 3 months (whichever is less)**; or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**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 – ERX.PA.01 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

*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

| Drug Name | Indication | Dosing Regimen | Maximum Dose |
|---|---|---|---|
| Factor VIIa, recombinant (NovoSeven RT) | Treatment of bleeding episodes | <u>Congenital hemophilia A or B with inhibitors:</u><br>• 90 mcg/kg IV every 2 hrs, adjustable based on severity of bleeding until hemostasis is achieved<br>• 90 mcg/kg IV every 3-6 hrs after hemostasis is achieved for severe bleeds<br><br><u>Congenital factor VII deficiency:</u><br>15-30 mcg/kg IV every 4-6 hrs until hemostasis is achieved<br><br><u>Glanzmann's thrombasthenia:</u><br>90 mcg/kg IV every 2-6 hrs until hemostasis is achieved<br><br><u>Acquired hemophilia:</u><br>70-90 mcg/kg IV every 2-3 hrs until hemostasis is achieved | Congenital factor VII deficiency: 30 mcg/kg every 4 hrs<br><br>All other indications: 90 mcg/kg every 2 hrs |
| Factor VIIa, recombinant (NovoSeven RT) | Peri-operative management | <u>Congenital hemophilia A or B with inhibitors:</u><br>*Minor surgery:*<br>• 90 mcg/kg IV immediately before surgery, repeat every 2 hrs during surgery<br>• 90 mcg/kg IV every 2 hrs after surgery for 48 hours, then every 2-6 hrs until healing has occurred<br><br>*Major surgery:*<br>• 90 mcg/kg IV immediately before surgery, repeat every 2 hrs during surgery<br>• 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<br>• Additional boluses can be given<br><br><u>Congenital factor VII deficiency:</u><br>15-30 mcg/kg IV immediately before surgery and every 4-6 hours for the duration of surgery and until hemostasis is achieved<br>Note: doses as low as 10 mcg/kg can be effective<br><br><u>Glanzmann's thrombasthenia:</u><br>• 90 mcg/kg IV immediately before surgery and repeat every 2 hrs for the duration of the procedure<br>• 90 mcg/kg IV every 2-6 hrs to prevent post-operative bleeding<br>• Higher doses of 100-140 mcg/kg can be used for surgical patients who have | Congenital factor VII deficiency: 30 mcg/kg every 4 hrs<br><br>Glanzmann's thrombasthenia: 140 mcg/kg every 2 hrs<br><br>All other indications: 90 mcg/kg every 2 hrs |

| Drug Name | Indication | Dosing Regimen | Maximum Dose |
|---|---|---|---|
| | | clinical refractoriness with or without platelet-specific antibodies<br><br>Acquired hemophilia:<br>70-90 mcg/kg immediately before surgery and every 2-3 hrs for the duration of surgery and until hemostasis is achieved | |
| Coagulation factor VIIa (recombinant)-jncw (SevenFact) | Treatment and control of bleeding episodes | For mild or moderate bleeds:<br>75 mcg/kg IV every 3 hrs until hemostasis is achieved<br>OR<br>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<br><br>For severe bleeds:<br>225 mcg/kg, followed if necessary 6 hrs later with 75 mcg/kg every 2 hrs | 75 mcg/kg every 3 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, 5 mg |

## VII. References

1. NovoSeven RT Prescribing Information. Plainsboro, NJ: Novo Nordisk Inc.; July 2020. Available at www.novosevenrt.com. Accessed November 23, 2021.
2. SevenFact Prescribing Information. Louisville, KY: HEMA Biologics; April 2020. Available at: https://www.fda.gov/vaccines-blood-biologics/sevenfact. Accessed November 23, 2021.
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 Hemophilia Foundation (NHF): Database of treatment guidelines. Available at https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-Scientific-Advisory-Council-MASAC/MASAC-Recommendations. Accessed December 1, 2020.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| 1Q18 annual review:<br>- Added efficacy statement to renewal criteria.<br>- Added requirement that acquired hemophilia be evidenced by the presence of factor VIII inhibitors. | 11.29.17 | 02.18 |
| 1Q 2019 annual review: no significant changes; references reviewed and updated. | 09.26.18 | 02.19 |
| 1Q 2020 annual review: no significant changes; references reviewed and updated. | 11.27.19 | 02.20 |
| RT4: Added newly approved product SevenFact to the policy. | 04.21.20 | |
| 1Q 2021 annual review: added requirement for documentation of member's body weight for calculation of appropriate dosage; clarified covered | 12.01.20 | 02.21 |

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| indications for SevenFact to align with FDA label; references reviewed and updated. | | |
| 1Q 2022 annual review: no significant changes; references reviewed and updated. | 11.23.21 | 02.22 |

**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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.