

## **NovoSeven RT® (coagulation factor VIIa [recombinant])**

When requesting NovoSeven RT®, the individual requiring treatment must be diagnosed with one of the following FDA-approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

### **FDA-Approved Indications**

NovoSeven RT is a coagulation factor VIIa 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
- Treatment of bleeding episodes and perioperative management in adults with acquired hemophilia

### **Coverage Guidelines**

#### **Congenital Factor VII Deficiency**

The request is authorized if NovoSeven RT is prescribed by or in consultation with a hemophilia specialist.

#### **Glanzmann's Thrombasthenia**

The individual must meet **BOTH** of the following criteria for authorization:

1. Is refractory to platelet transfusions;
2. NovoSeven RT is prescribed by or in consultation with a hematologist.

#### **Acquired Hemophilia**

The individual must meet **BOTH** of the following criteria for authorization:

1. Is 18 years of age or older;
2. NovoSeven RT is prescribed by or in consultation with a hemophilia specialist.

#### **Hemophilia A with Inhibitors**

The individual must meet the following criteria for authorization:

1. Meets **one** of the following:
  - a. Has a positive inhibitor titer of greater than or equal to 5 Bethesda Units; OR

- b. Has a history of an inhibitor with anamnestic response to Factor VIII replacement therapy, which precludes the use of Factor VIII replacement to treat bleeding episodes; OR
  - c. Has a history of an inhibitor with refractory hemostatic response to increased Factor VIII dosing, which precludes the use of Factor VIII replacement to treat bleeding episodes;
2. NovoSeven RT is prescribed by or in consultation with hemophilia specialist.

## Hemophilia B with Inhibitors

The individual must meet the following criteria for authorization:

- 1. Meets **one** of the following:
  - a. Has a positive inhibitor titer of greater than or equal to 5 Bethesda Units; OR
  - b. Has a history of an inhibitor with anamnestic response to Factor IX replacement therapy, which precludes the use of Factor IX replacement to treat bleeding episodes; OR
  - c. Has a history of an inhibitor with refractory hemostatic response to increased Factor IX dosing, which precludes the use of Factor IX replacement to treat bleeding episodes;
- 2. NovoSeven RT is prescribed by or in consultation with hemophilia specialist.

**Approval duration: 12 months**

## Dosing Recommendations

**For intravenous use only**

**Bleeding episodes:**

| Indication                                   | Dosing Recommendation                                                                                                                                        |
|----------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Congenital Hemophilia A or B with Inhibitors | 90 mcg/kg every 2 hours based on severity of bleeding until hemostasis is achieved. 90 mcg/kg every 3-6 hours after hemostasis is achieved for severe bleeds |
| Acquired Hemophilia                          | 70-90 mcg/kg every 2-3 hours until hemostasis is achieved                                                                                                    |
| Congenital Factor VII Deficiency             | 15-30 mcg/kg every 4-6 hours until hemostasis is achieved                                                                                                    |
| Glanzmann's Thrombasthenia                   | 90 mcg/kg every 2-6 hours until hemostasis is achieved                                                                                                       |

**Peri-operative management:**

| Indication | Dosing Recommendation |
|------------|-----------------------|
|------------|-----------------------|

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|----------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Congenital Hemophilia A or B with inhibitors | <p>Minor:</p> <ul style="list-style-type: none"> <li>90 mcg/kg immediately before surgery and repeat every 2 hours for the duration of surgery</li> <li>90 mcg/kg every 2 hours after surgery for 48 hours, then every 2-6 hours until healing has occurred</li> </ul> <p>Major:</p> <ul style="list-style-type: none"> <li>90 mcg/kg immediately before surgery and repeat every 2 hours for the duration of surgery</li> <li>90 mcg/kg every 2 hours after surgery for 5 days, then every 4 hours until healing has occurred</li> </ul> |
| Acquired Hemophilia                          | 70-90 mcg/kg immediately before surgery and every 2-3 hours for the duration of surgery and until hemostasis is achieved                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Congenital Factor VII Deficiency             | 15-30 mcg/kg immediately before surgery and every 4-6 hours for the duration of surgery and until hemostasis is achieved                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Glanzmann's Thrombasthenia                   | 90 mcg/kg immediately before surgery and repeat every 2 hours for the duration of surgery. 90 mcg/kg every 2-6 hours to prevent post-operative bleeding                                                                                                                                                                                                                                                                                                                                                                                   |

## References

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11. Bosch J, Thabut D, Bendtsen F, et al; European Study Group on rFVIIa in UGI Haemorrhage. Recombinant Factor VIIa for upper gastrointestinal bleeding in patients with cirrhosis: a randomized, double-blind trial. *Gastroenterology*. 2004;127(4):1123-30.
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13. Garcia-Tsao G, Abraldes JG, Berzigotti A, Bosch J. Portal hypertensive bleeding in cirrhosis: risk stratification, diagnosis, and management: 2016 practice guidance by the American Association for the study of liver diseases. *Hepatology*. 2017;65(1):310-335.