# 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 or approved off-label compendial use and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

## 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

## Approved Off-label Compendial Use

Prevention of bleeding episodes in patient with hemophilia A or B with inhibitors, acquired hemophilia, congenital Factor VII deficiency, and Glanzmann's thrombasthenia.

## Coverage Guidelines

The individual must meet the following criteria for authorization:

- The request is for treatment or prevention of bleeding episodes or perioperative management of bleeding in the following conditions:
    - Hemophilia A or B with inhibitors;
    - Acquired hemophilia;
    - Congenital Factor VII deficiency;
    - Glanzmann's thrombasthenia;
- For Glanzmann's thrombasthenia, disease is refractory to platelet transfusion;
- NovoSeven is prescribed by or in consultation with a hematologist or a 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<br>• 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 |
|---|---|
| Congenital Hemophilia A or B with inhibitors | Minor:<br>• 90 mcg/kg immediately before surgery and repeat every 2 hours for the duration of surgery<br>• 90 mcg/kg every 2 hours after surgery for 48 hours, then every 2-6 hours until healing has occurred<br>Major:<br>• 90 mcg/kg immediately before surgery and repeat every 2 hours for the duration of surgery<br>• 90 mcg/kg every 2 hours after surgery for 5 days, then every 4 hours until healing has occurred |
| 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<br>• 90 mcg/kg every 2-6 hours to prevent post-operative bleeding |

## References


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