

NovoSeven RT® (coagulation factor VIIa [recombinant])

When requesting NovoSeven RT®, the individual requiring treatment must be diagnosed with one of the following FDA-approved indication 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 request is for treatment or prevention of bleeding episodes or perioperative management of bleeding in individuals with hemophilia A or B with inhibitors, acquired hemophilia, congenital Factor VII deficiency, and Glanzmann's thrombasthenia.
- For Glanzmann's thrombasthenia, disease is refractory to platelet transfusion.

Approval duration (initial): 3 months

Approval duration (renewal): 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
Congenital Hemophilia A or B with inhibitors	Minor: 90 mcg/kg immediately before surgery and repeat every 2 hours for the duration of surgery 90 mcg/kg every 2 hours after surgery for 48 hours, then every 2-6 hours until healing has occurred Major: 90 mcg/kg immediately before surgery and repeat every 2 hours for the duration of surgery 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 90 mcg/kg every 2-6 hours to prevent post-operative bleeding

References

1. NovoSeven RT prescribing information. Plainsboro, NJ; Novo Nordisk Inc. July 2020.
2. National Hemophilia Foundation for all bleeding disorders. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. MASAC Document #284. Revised April 2024.
3. World Federation of Hemophilia. Guidelines for the Management of Hemophilia. 3rd edition. Haemophilia.2020;00:1-158.
4. Factor VIIa recombinant (NovoSeven RT®). Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. [Updated; January 24, 2024; Accessed August 2, 2024].
5. National Hemophilia Foundation. MASAC Recommendation on Administration of Inhibitor Bypassing Agents in the Home for Patients with Hemophilia and Inhibitors. MASAC Document #274. Revised September 2022.
6. National Hemophilia Foundation for all bleeding disorders. MASAC Recommendation Concerning Prophylaxis for Hemophilia A and B with and without Inhibitors. MASAC Document #267. Revised April 2022.