



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: Human Coagulation Factor VIIa (rFVIIa) (Recombinant)

Brand Name: NovoSeven®

Medication Class: Hemophilia therapy agent

FDA Approved Uses:

- Treatment of bleeding episodes and prevention of bleeding in surgical interventions in patients with hemophilia A or B with inhibitors to factor VIII or factor IX and in patients with congenital factor VII deficiency

Available Dosage Forms: Sterile, lyophilized powder for reconstitution for intravenous use only

Usual Dose:

- Hemophilia A or B with inhibitors: 90 mcg/kg IV q2 - 6 hrs
- Congenital factor VII deficiency: 15 - 30 mcg/kg q4 - 6 hrs

Duration of Therapy: Dose and frequency should be based on individual until hemostasis is achieved or until the treatment is judged ineffective

Criteria for Use: *(bullet points below are all inclusive unless otherwise noted)*

- Patients with hemorrhage due to hemophilia A or B with inhibitors to factor VIII or IX
- Patients with hemorrhage due to congenital factor VIII deficiency
- Evaluation of hemostasis should be done before starting the medication

Criteria for Continuation of Therapy: until hemostasis is achieved or until the treatment is judged ineffective

Cautions:

- Possibility of thrombotic adverse events, especially for patients with DIC (disseminated intravascular coagulation), advanced atherosclerotic disease, crush injury, septicemia, or concomitant with aPCCs / PCCs (activated or nonactivated prothrombin complex concentrates)
- Possibility of hypersensitivity reactions
- Efficacy with prolonged infusions and data evaluating this agent's long-term adverse effects are limited.
- Pregnancy and lactation

Monitoring:

- Evidence of hemostasis
- PT (prothrombin time), aPTT (activated partial thromboplastin time)
- FVII:C (Factor VII clotting activity)



Contraindications:

- Hypersensitivity to factor VII or any component of the formulation
- Hypersensitivity to mouse, hamster, or bovine proteins

Not Approved if:

- Patients have infection, thrombosis, CAD, or stroke
- Being used for any indication not approved by the FDA

P&T Approval: _____ Date: _____