

**LSU HEALTH SCIENCES CENTER  
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**PROTOCOL FOR DISPENSING RECOMBINANT FACTOR VII a**

**Guidelines for appropriate use of rFVIIa**

**Purpose:** Recombinant activated factor VII (rFVIIa) is a vitamin K dependent glycoprotein structurally similar to human factor VIIa. FDA approved indications include the treatment of severe bleeding episodes in hemophilia A and B patients who have inhibitors to factor VIII or to factor IX. rFVIIa has also been shown to be useful in treating humans for ongoing coagulopathic bleeding despite surgical control following major trauma. The use of rFVIIa outside of the treatment of hemophilia represents off-label use of the drug. When used for trauma victims, all instances of use of this drug will be reviewed at the monthly multi-disciplinary Trauma Performance Improvement Committee meeting as part of that committee's standing agenda.

**Policy:** Recombinant activated factor VII will be dispensed for the treatment of hemophilia patients with demonstrated inhibitors to factor VIII or factor IX replacement therapy. Consult with the Transfusion Service Medical Director is required prior to issue. rFVIIa will be dispensed for treatment of coagulopathic bleeding in trauma when the following criteria have been met:

1. The patient has been transfused with at least one complete blood volume (approximately 10 units of red blood cells for an averaged size 70 kg adult) **AND** has received 1 unit of apheresis platelets and 6 units of FFP. (Note: FFP given as bolus, not FFP drip)
2. Surgical control of all bleeding has been performed or is in progress.
3. Patient with Traumatic Brain Injury who is anticoagulated.
4. A coagulopathy exists as follows:
  - PT >23 or
  - aPTT > 53 seconds, or
  - INR >2, or
  - Fibrinogen <100mg/dl, or
  - No detectable D-Dimers by the D-Dimer test, or
  - In the judgement of the Attending Trauma Surgeon, there is ongoing life-threatening coagulopathic bleeding without a surgically correctable cause (even in the absence of immediately available laboratory data).

5. The coagulopathy is not responsive to blood component therapy (as above) and the Attending Trauma Surgeon determines that continued ongoing bleeding will lead to imminent death if the coagulopathy is not immediately corrected.

6. Efforts to keep the patient normothermic are in progress.

7. Efforts to correct acidosis are in progress.

8. Approval of Trauma Center Medical Director (Dr. Cuthbert Simpkins, pager 2752).

rFVIIa will NOT be dispensed for treatment of coagulopathic bleeding in trauma if the above criteria have not been met. However, the senior-attending physician responsible for the care of the patient may authorize exceptions to this policy for the initial dose on a case by case basis. Standard laboratory tests: fibrinogen, aPTT, PT, INR, and D-Dimer will be sent in all cases prior to administration of rFVIIa (although test results may not yet be available). Subsequent doses will be provided only after consultation with and the approval of the on call physician for the blood bank. A blood bank supervisor will notify the blood bank medical director of any rFVIIa use as soon as possible.

**Relative Contraindications:**

1. Known history of atherosclerotic coronary artery disease, ischemic cerebrovascular disease (CVA), or thromboembolic disease.
2. Patients with crush injury or septicemia.

**Absolute Contraindications:**

1. Ongoing uncontrolled surgical bleeding (e.g. Grade V splenic laceration)
2. Active DIC

**Dosage:**

1. Initial dose: Recombinant Factor VII (rFVIIa) 90mcg/kg (based on ideal body weight) reconstituted and given as IV bolus over 2-5 minutes.
2. Consider additional RBC's, apheresis platelets, FFP and/or cryoprecipitate transfusion prior to a second dose.
3. If hemostasis is not achieved, consider a second dose of 60-90 mcg/kg.

4. rFVIIa is supplied as 1.2mg/vial, 2.4mg/vial, and 4.8mg/vials.

**Potential Adverse Events (<1%)**

1. Myocardial Infarction/ Pulmonary Embolism/ Deep Vein Thrombosis
2. Ischemic CVA
3. Ischemic Nephropathy
4. Mesenteric Ischemia
5. Other thromboembolic events
6. Development of FVII inhibitors

**Information for Patients:**

Whenever possible, patients receiving rFVIIa should be informed of the benefits and risks associated with treatment. Patients should be warned about the early signs of hypersensitivity reactions, including hives, urticaria, tightness of the chest, wheezing, hypertension, and anaphylaxis.