

**Novoseven RT (coagulation factor VIIa [recombinant])  
SevenFact (factor VIIa [recombinant])  
Effective 03/01/2021**

<b>Plan</b>	<input checked="" type="checkbox"/> MassHealth <input type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	N/A		

**Overview**

Recombinant factor VIIa, a vitamin K-dependent glycoprotein, promotes hemostasis by activating the extrinsic pathway of the coagulation cascade.

NovoSeven is approved for:

1. Congenital factor VII deficiency
2. Hemophilia A with Inhibitors
3. Hemophilia B with Inhibitors
4. Glanzmann’s Thrombasthenia
5. Acquired Hemophilia
6. Acquired von Willebrand Syndrome
7. Inhibitors to Factor XI

SevenFact is approved for:

1. Hemophilia A with Inhibitors
2. Hemophilia B with Inhibitors

**Coverage Guidelines**

**Congenital Factor VII Deficiency**

Authorization for NovoSeven may be granted for treatment of congenital factor VII deficiency.

**Hemophilia A with Inhibitors**



Authorization may be granted for NovoSeven or SevenFact for the treatment of hemophilia A with inhibitors (see Appendix) when the inhibitor titer is  $\geq 5$  Bethesda units per milliliter (BU/mL) or the member has a history of an inhibitor titer  $\geq 5$  BU.

### **Hemophilia B with Inhibitors**

Authorization may be granted for NovoSeven or SevenFact for the treatment of hemophilia B with inhibitors (see Appendix) when the inhibitor titer is  $\geq 5$  Bethesda units per milliliter (BU/mL) or the member has a history of an inhibitor titer  $\geq 5$  BU.

### **Glanzmann's Thrombasthenia**

Authorization may be granted for NovoSeven for the treatment of Glanzmann's thrombasthenia.

### **Acquired Hemophilia**

Authorization may be granted for NovoSeven for the treatment of acquired hemophilia.

### **Acquired von Willebrand Syndrome**

Authorization may be granted for NovoSeven for the treatment of acquired von Willebrand syndrome when other therapies failed to control the member's condition (e.g., desmopressin or factor VIII/von Willebrand factor).

### **Inhibitors to Factor XI**

Authorization may be granted for NovoSeven for the treatment of inhibitors to factor XI.

### **Continuation of Therapy**

Reauthorization requires physician documentation of continuation of therapy and positive response to therapy.

### **Limitations**

1. Initial approvals and reauthorizations will be granted for 36 months

### **Appendix**

#### **Appendix: Inhibitors - Bethesda Units (BU)**

The presence of inhibitors is confirmed by a specific blood test called the Bethesda inhibitor assay.

- High-titer inhibitors:
  - $> 5$  BU/mL
  - Inhibitors act strongly and quickly neutralize factor
- Low-titer inhibitors:
  - $< 5$  BU/mL
  - Inhibitors act weakly and slowly neutralize factor

### **References**

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### **Review History**

01/23/2020 – Transitioned from SGM to Custom Criteria; added SevenFact to criteria. Effective 03/01/21.

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