

**Novoseven RT (coagulation factor VIIa [recombinant])**  
**SevenFact (factor VIIa [recombinant])**  
**Effective 01/01/2026**

<b>Plan</b>	<input type="checkbox"/> MassHealth UPPL <input checked="" 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 type="checkbox"/> Medical Benefit		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Medical Benefit</b> <b>Pharmacy Benefit</b>	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
<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.

NovoSevenRT 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

Compendial uses of Novoseven RT:

1. Acquired von Willebrand Syndrome
2. Inhibitors to Factor XI

SevenFact is approved for:

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

**Coverage Guidelines**

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

**OR**

Authorization may be granted when the following diagnosis-specific criteria are met:

**Congenital Factor VII Deficiency (NovoSevenRT ONLY)**

1. Diagnosis of congenital factor VII deficiency
2. Request is for NovoSevenRT

### **Hemophilia A with Inhibitors (NovoSevenRT, SevenFact)**

1. Diagnosis of Hemophilia A with inhibitors (see Appendix)
2. Member meets ONE of the following:
  - a. Inhibitor titer is  $\geq$  5 Bethesda units per millimeter (BU/mL)
  - b. Member has a history of inhibitor titer  $\geq$  5 BU

### **Hemophilia B with Inhibitors (NovoSevenRT, SevenFact)**

1. Diagnosis of Hemophilia B with inhibitors (see Appendix)
2. Member meets ONE of the following:
  - a. Inhibitor titer is  $\geq$  5 Bethesda units per millimeter (BU/mL)
  - b. Member has a history of inhibitor titer  $\geq$  5 BU

### **Glanzmann's Thrombasthenia (NovoSevenRT ONLY)**

1. Diagnosis of Glanzmann's thrombasthenia
2. Request is for NovoSevenRT

### **Acquired Hemophilia (NovoSevenRT ONLY)**

1. Diagnosis of acquired hemophilia
2. Request is for NovoSevenRT

### **Acquired von Willebrand Syndrome (NovoSevenRT ONLY)**

1. Diagnosis of acquired von Willebrand Syndrome
2. Other therapies have failed to control the member's condition (e.g., desmopressin or factor VIII/von Willebrand factor)
3. Request is for NovoSevenRT

### **Inhibitors to Factor XI (NovoSevenRT ONLY)**

1. Request is for treatment of inhibitors to factor XI.
2. Request is for NovoSevenRT

### **Continuation of Therapy**

Requests for reauthorization will be approved when the following criteria are met:

1. Member has had a positive response to therapy (e.g., reduced frequency or severity of bleeds).

### **Limitations**

1. Initial reauthorization approvals 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**



1. Duga S, Salomon O. Congenital factor XI deficiency: an update. *Semin Thromb Hemost*. 2013;39(6):621-631.
2. Federici AB, Budde U, Castaman G, Rand JH, Tiede A. Current diagnostic and therapeutic approaches to patients with acquired von Willebrand syndrome: a 2013 update. *Semin Thromb Hemost*. 2013;39(2):191-201.
3. National Hemophelia Foundation. MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders. Revised April 2018. MASAC Document # 253. Accessed December 3, 2019.
4. National Institutes of Health. The diagnosis, evaluation, and management of von Willebrand disease. Bethesda, MD: US Dept of Health and Human Services, National Institutes of Health; 2007. NIH publication No. 08-5832
5. NovoSeven RT (coagulation factor VIIa [recombinant]) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc.; July 2020.
6. O'Connell NM. Factor XI deficiency – from molecular genetics to clinical management. *Blood Coagul Fibrinolysis*. 2003;14(Suppl 1):S59-S64.
7. Rajpurkar M, Chitlur M, Recht M, Cooper DL. Use of recombinant activated factor VII in patients with Glanzmann's thrombasthenia: a review of the literature. *Haemophilia*. 2014;20(4):464-471.
8. Salomon O, Zivelin A, Livnat T, Seligsohn U. Inhibitors to factor XI in patients with severe factor XI deficiency. *Semin Hematol*. 2006;43(1 Suppl 1):S10-S12.
9. SevenFact (factor VIIa [recombinant]-jncw) [prescribing information]. Louisville, KY: HEMA Biologics; June 2024.
10. Srivastava A, Brewer AK, Mauser-Bunschoten EP, et al. Guidelines for the management of hemophilia. *Haemophilia*. 2013;19(1):e1-e47.
11. Tiede A, Rand J, Budde U, et al. How I treat the acquired von Willebrand syndrome. *Blood*.
12. World Federation of Hemophilia. Platelet function disorders. <http://www1.wfh.org/publication/files/pdf-1147.pdf>. 2008. Accessed December 10, 2019.
13. World Federation of Hemophilia. What are inherited platelet function disorders? <http://www1.wfh.org/publication/files/pdf-1336.pdf>. 2010. Accessed December 10, 2019.

### Review History

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

05/14/2025 – Reviewed at May P&T. Formatting updates made throughout policy. Clarified which uses for NovoSevenRT are not FDA-approved but supported by compendia. Added language for members who are new to the plan. Updated reauthorization criteria to remove documentation requirement and provide examples of clinical benefit to therapy. Effective 08/01/2025.

10/08/2025 – Reviewed at October P&T. Updated policy to reflect that it no longer applies to the medical benefit. Effective 01/01/2026.

