Mass General Brigham
Health Plan

Novoseven RT (coagulation factor VIIa [recombinant])
Effective 07/01/2026

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	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

Coverage Guidelines
If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted when all of the following diagnosis-specific criteria are met:

Congenital Factor VII Deficiency
1. Diagnosis of congenital factor VII deficiency

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

Hemophilia B with Inhibitors

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

Glanzmann's Thrombasthenia

1. Diagnosis of Glanzmann's thrombasthenia

Acquired Hemophilia

1. Diagnosis of acquired hemophilia

Acquired von Willebrand Syndrome

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)

Inhibitors to Factor XI

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

<u>Continuation of Therapy</u>

Requests for reauthorization will be approved when all of 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 12 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.
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3. National Hemophilia 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. Srivastava A, Brewer AK, Mauser-Bunschoten EP, et al. Guidelines for the management of hemophilia. Haemophilia. 2013;19(1):e1-e47.
10. Tiede A, Rand J, Budde U, et al. How I treat the acquired von Willebrand syndrome. Blood.
11. World Federation of Hemophilia. Platelet function disorders. http://www1.wfh.org/publication/files/pdf-1147.pdf. 2008. Accessed December 10, 2019.
12. 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.
04/15/2026 – Reviewed and updated at April P&T. Updated language for members who are new to the Plan. Removed SevenFact from the policy, as agent is moving to nonformulary status. Updated approval length to 12 months. Effective 07/01/2026.