Mass General Brigham
Health Plan

Novoseven RT (coagulation factor VIIa [recombinant])
SevenFact (factor VIIa [recombinant])
Effective 08/01/2025

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 and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | 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

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 ≥ 5 Bethesda units per millimeter (BU/mL)
    b. Member has a history of inhibitor titer ≥ 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 ≥ 5 Bethesda units per millimeter (BU/mL)
    b. Member has a history of inhibitor titer ≥ 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

<u>Continuation of Therapy</u>

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 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.
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9. 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.
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11. Srivastava A, Brewer AK, Mauser-Bunschoten EP, et al. Guidelines for the management of hemophilia. Haemophilia. 2013;19(1):e1-e47.
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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.