Mass General Brigham
Health Plan

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

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.

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 ≥ 5 Bethesda units per milliliter (BU/mL) or the member has a history of an inhibitor titer ≥ 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 ≥ 5 Bethesda units per milliliter (BU/mL) or the member has a history of an inhibitor titer ≥ 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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4. 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.
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8. 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.
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11. 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.
12. Duga S, Salomon O. Congenital factor XI deficiency: an update. *Semin Thromb Hemost*. 2013;39(6):621-631.
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Review History

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