Reference number(s)
1947-A

Specialty Guideline Management Novoseven RT

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
NOVOSEVEN RT	coagulation factor VIIa [recombinant]

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

- Hemophilia A or hemophilia B with inhibitors
- Congenital factor VII deficiency
- Glanzmann's thrombasthenia
- Acquired hemophilia

Compendial Uses[2-6,12]

- Acquired von Willebrand syndrome
- Inhibitors to factor XI

All other indications are considered experimental/investigational and not medically necessary.

Reference number(s)
1947-A

Prescriber Specialties

Must be prescribed by or in consultation with a hematologist.

Coverage Criteria

Congenital Factor VII Deficiency[1,8]

Authorization of 12 months may be granted for treatment of congenital factor VII deficiency.

Hemophilia A with Inhibitors[1,7,8]

Authorization of 12 months may be granted for 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[1,7,8]

Authorization of 12 months may be granted for 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[1,9-11]

Authorization of 12 months may be granted for treatment of Glanzmann's thrombasthenia.

Acquired Hemophilia[1]

Authorization of 12 months may be granted for treatment of acquired hemophilia.

Acquired von Willebrand Syndrome[2-4]

Authorization of 12 months may be granted for 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[5-6,12]

Authorization of 12 months may be granted for treatment of inhibitors to factor XI.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when the member is experiencing benefit from therapy (e.g., reduced frequency or severity of bleeds).

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. NovoSeven RT [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; July 2020.
2. 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
3. Tiede A, Rand J, Budde U, et al. How I treat the acquired von Willebrand syndrome. Blood. 2011;117(25):6777-85.
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.
5. O'Connell NM. Factor XI deficiency – from molecular genetics to clinical management. Blood Coagul Fibrinolysis. 2003;14(Suppl 1):S59-S64.
6. 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.
7. Srivastava A, Santagostino E, Dougall A, et al. WFH Guidelines for the Management of Hemophilia, 3rd edition. Haemophilia. 2020;26 Suppl 6:1-158. doi:10.1111/hae.14046.
8. National Hemophilia Foundation. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. Revised October 2024. MASAC Document #290. https://www.hemophilia.org/sites/default/files/document/files/MASAC-Products-Licensed.pdf. Accessed December 3, 2024.

9. World Federation of Hemophilia. What are inherited platelet function disorders? http://www1.wfh.org/publication/files/pdf-1336.pdf. 2010. Accessed December 3, 2024.
10. World Federation of Hemophilia. Platelet function disorders. http://www1.wfh.org/publication/files/pdf-1147.pdf. 2008. Accessed December 3, 2024.
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.