



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Novoseven RT

Page: 1 of 3

Effective Date: 4/7/2024

Last Review Date: 4/2024

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|-------------|---|--|--|
| Applies to: | <input checked="" type="checkbox"/> Illinois | <input type="checkbox"/> Florida | <input checked="" type="checkbox"/> Florida Kids |
| | <input checked="" type="checkbox"/> New Jersey | <input checked="" type="checkbox"/> Maryland | <input type="checkbox"/> Michigan |
| | <input checked="" type="checkbox"/> Pennsylvania Kids | <input type="checkbox"/> Virginia | <input type="checkbox"/> Texas |

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Novoseven RT under the patient's prescription drug benefit.

Description:

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.

A. FDA-Approved Indications

1. Hemophilia A or hemophilia B with inhibitors
2. Congenital factor VII deficiency
3. Glanzmann's thrombasthenia
4. Acquired hemophilia

B. Compendial Uses

1. Acquired von Willebrand syndrome
2. Inhibitors to factor XI

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

Applicable Drug List:

Novoseven RT

Policy/Guideline:

Prescriber Specialty:

Must be prescribed by or in consultation with a hematologist.

Criteria for Initial Approval:

A. Congenital Factor VII Deficiency

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

B. Hemophilia A with Inhibitors



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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.

C. Hemophilia B with Inhibitors

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.

D. Glanzmann's Thrombasthenia

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

E. Acquired Hemophilia

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

F. Acquired von Willebrand Syndrome

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).

G. Inhibitors to Factor XI

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 criteria for initial approval 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:



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- < 5 BU/mL
- Inhibitors act weakly and slowly neutralize factor

Approval Duration and Quantity Restrictions:

Approval: 12 months

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