CVS/caremark™

SPECIALTY GUIDELINE MANAGEMENT

NOVOSEVEN RT (coagulation factor VIIa [recombinant])

POLICY

A. 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

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

Compendial Uses

- Acquired von Willebrand syndrome
- Inhibitors to factor X or XI

All other indications are considered experimental/investigational and are not a covered benefit.

B. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:

- Laboratory documentation of highest Bethesda titer in members with hemophilia A or hemophilia B with inhibitors

C. CRITERIA FOR APPROVAL

1. **Hemophilia A With Inhibitors**
   Authorization of 12 months may be granted to members who are prescribed NovoSeven RT for hemophilia A with inhibitors (see Appendix) when the inhibitor titer is ≥ 5 Bethesda units per milliliter.

2. **Hemophilia B With Inhibitors**
   Authorization of 12 months may be granted to members who are prescribed NovoSeven RT for hemophilia B with inhibitors (see Appendix) when the inhibitor titer is ≥ 5 Bethesda units per milliliter.

3. **Congenital Factor VII Deficiency**
   Authorization of 12 months may be granted to members who are prescribed NovoSeven RT for congenital factor VII deficiency.

4. **Glanzmann's Thrombasthenia**
   Authorization of 12 months may be granted to members who are prescribed NovoSeven RT for Glanzmann's thrombasthenia.

5. **Acquired Hemophilia**
   Authorization of 12 months may be granted to members who are prescribed NovoSeven RT for acquired hemophilia.

6. **Acquired von Willebrand Syndrome**
   Authorization of 12 months may be granted to members who are prescribed NovoSeven RT for acquired von Willebrand syndrome when other therapies failed to control the member's condition (e.g., desmopressin or factor VIII/von Willebrand factor).

7. **Inhibitors to Factor X**
   Authorization of 12 months may be granted to members with inhibitors to factor X.

8. **Inhibitors to Factor XI**
   Authorization of 12 months may be granted to members with inhibitors to factor XI.

D. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

E. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

F. 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

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