

Reference number(s)
3760-A

SPECIALTY GUIDELINE MANAGEMENT

SEVENFACT (coagulation factor VIIa [recombinant]-jncw)

POLICY

I. 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

Sevenfact is indicated for the treatment and control of bleeding episodes occurring in adults and adolescents (12 years of age and older) with hemophilia A or B with inhibitors.

Limitation of Use: Sevenfact is not indicated for the treatment of patients with congenital Factor VII deficiency.

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

II. EXCLUSIONS

Coverage will not be provided for members less than 12 years of age.

III. CRITERIA FOR INITIAL APPROVAL

A. Hemophilia A with Inhibitors

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.

B. 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.

IV. CONTINUATION OF THERAPY

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

V. APPENDIX

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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

VI. REFERENCES

1. Sevenfact [package insert]. Les Ulis, France: Laboratoire Francais du Fractionnement et des Biotechnologies S.A. (LFB S.A.); April 2020.
2. 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.
3. National Hemophilia Foundation. MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders. Revised August 2020. MASAC Document #263. https://www.hemophilia.org/sites/default/files/document/files/263_treatment.pdf. Accessed November 20, 2020.