AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Sevenfact (coagulation factor VIIa [recombinant]-jncw)	Page:	1 of 2
Effective Date:	4/21/2025	Last Review Date:	3/26/2025
Applies to:	☒Illinois ☒Florida Kids ☒New Jersey ☒Maryland ☒Pennsylvania Kids ☐Virginia		

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Sevenfact 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.

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.

Applicable Drug List:

Sevenfact

Policy/Guideline:

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

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.

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

Approval Duration and Quantity Restrictions:

Approval: 12 months

References:

1. Sevenfact [package insert]. Puteaux, France: Laboratoire Francais du Fractionnement et des Biotechnologies S.A. (LFB S.A.); June 2024.
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 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 11, 2024.