

# Specialty Guideline Management

## Sevenfact

### 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
Sevenfact	coagulation factor VIIa [recombinant]-jncw

### 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<sup>1</sup>

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.

#### Limitations 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.

### Exclusions

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

# Coverage Criteria

## Hemophilia A with Inhibitors<sup>1,2</sup>

Authorization of 12 months may be granted for treatment of hemophilia A with inhibitors (see Appendix) when the inhibitor titer is  $\geq 5$  Bethesda units per milliliter (BU/mL) or the member has a history of an inhibitor titer  $\geq 5$  BU.

## Hemophilia B with Inhibitors<sup>1,2</sup>

Authorization of 12 months may be granted for treatment of hemophilia B with inhibitors (see Appendix) when the inhibitor titer is  $\geq 5$  Bethesda units per milliliter (BU/mL) or the member has a history of an inhibitor titer  $\geq 5$  BU.

# 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)<sup>2</sup>

The presence of inhibitors is confirmed by a specific blood test called the Bethesda inhibitor assay.

- High-titer inhibitors:
  - $\geq 5$  BU/mL
  - Inhibitors act strongly and quickly neutralize factor
- Low-titer inhibitors:
  - $< 5$  BU/mL
  - Inhibitors act weakly and slowly neutralize factor

# References

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

Reference number(s)
3760-A

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.