Reference number(s)
4695-A

Standard Medicare Part B 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[1]

Sevenfact [coagulation factor VIIa (recombinant)-jncw] 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 will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

Hemophilia A with Inhibitors[1,3]

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Authorization of 12 months may be granted for members 12 years of age or older 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.

Hemophilia B with Inhibitors[1,3]

Authorization of 12 months may be granted for members 12 years of age or older 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

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Hemophilia A or B with Inhibitors

Authorization for 12 months may be granted for members 12 years of age or older when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat Hemophilia A or B with inhibitors.
- The member is receiving benefit from therapy (e.g., reduced frequency or severity of bleeds).

Appendix

Inhibitors - Bethesda Units (BU)[3]

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

Summary of Evidence

The contents of this policy were created after examining the following resources:

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- The prescribing information for Sevenfact.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- WFH Guidelines for the Management of Hemophilia, 3rd edition.
- MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System.

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Sevenfact are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

References

1. Sevenfact [package insert]. Puteaux , France: Laboratoire Francais du Fractionnement et des Biotechnologies S.A. (LFB S.A.); November 2025.
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 4, 2025.

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