



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Sevenfact

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Effective Date: 4/7/2024

Last Review Date: 4/2024

Applies to:	<input checked="" type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input checked="" type="checkbox"/> Florida Kids
	<input checked="" type="checkbox"/> New Jersey	<input checked="" type="checkbox"/> Maryland	<input type="checkbox"/> Michigan
	<input checked="" type="checkbox"/> Pennsylvania Kids	<input type="checkbox"/> Virginia	<input type="checkbox"/> Texas

**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.



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## 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  $\geq 5$  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 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:
  - $\geq 5$  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.); November 2022.
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 August 2023. MASAC Document #280.  
<https://www.hemophilia.org/sites/default/files/document/files/MASAC-Products-Licensed.pdf>. Accessed December 8, 2023.