

Sevenfact® (coagulation factor VIIa [recombinant]-jncw)

When requesting Sevenfact, the individual requiring treatment must be diagnosed with the following FDA-approved indication or approved compendial use and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

Sevenfact is a coagulation factor VIIa concentrate 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.

Approved Off-label Compendial Use

Prevention of bleeding episodes in individuals with hemophilia A or B with inhibitors

Coverage Guidelines

Hemophilia A or B With Inhibitors

The individual must meet **all** of the following criteria for authorization:

- The request is for treatment and control or prevention of a bleeding episode;
- Is 12 years of age and older;
- Sevenfact is prescribed by or in consultation with a hematologist or hemophilia specialist.

Approval duration: 12 months

Dosing Recommendations

For intravenous use only

Type of Bleeding	Dosing Regimen Recommendation
For mild or moderate bleeds	75 mcg/kg repeated every 3 hours until hemostasis is achieved OR Initial dose of 225 mcg/kg. If hemostasis is not achieved within 9 hours, additional 75 mcg/kg doses may be administered every 3 hours as needed to achieve hemostasis
For severe bleeds	225 mcg/kg, followed if necessary 6 hours later with 75 mcg/kg every 2 hours

References

1. Sevenfact prescribing information. Louisville, Kentucky; HEMA Biologics, LLC. June 2024.
2. National Hemophilia Foundation for all bleeding disorders. MASAC Recommendation Concerning Prophylaxis for Hemophilia A and B with and without Inhibitors. MASAC Document #267. Revised April 2022. Available at: <https://www.bleeding.org/healthcare-professionals/guidelines-on-care/masac-documents/masac-document-267-masac-recommendation-concerning-prophylaxis-for-hemophilia-a-and-b-with-and-without-inhibitors>. Accessed on August 11, 2025.
3. National Hemophilia Foundation for all bleeding disorders. MASAC Recommendation on Administration of Inhibitor Bypassing Agents in the Home for Patients with Hemophilia and Inhibitors. MASAC Document #274. Revised September 2022. Available at: <https://www.bleeding.org/healthcare-professionals/guidelines-on-care/masac-documents/masac-document-274-recommendation-on-administration-of-inhibitor-bypassing-agents-in-the-home-for-patients-with-hemophilia-and-inhibitors>. Accessed on August 11, 2025.
4. Meeks SL, Leissinger CA. The evolution of factor VIIa in the treatment of bleeding in haemophilia with inhibitors. *Haemophilia*. 2019;25(6):911-918.
5. Srivastava A, Santagostino E, Dougall A, et al; WFH Guidelines for the Management of Hemophilia panelists and co-authors. WFH Guidelines for the Management of Hemophilia, 3rd edition. *Haemophilia*. 2020 Aug;26 Suppl 6:1-158.
6. MASAC (Medical and Scientific Advisory Council) recommendations regarding doses of clotting factor concentrate in the home. MASAC Document #242. Adopted on June 7, 2016. Available at: <https://www.hemophilia.org/sites/default/files/document/files/242.pdf>. Accessed on August 11, 2025.
7. National Bleeding Disorders Foundation. MASAC (Medical and Scientific Advisory Council) recommendations concerning products licensed for the treatment of hemophilia and selected disorders of the coagulation system (October 2024). MASAC Document #290. Available at: <https://www.hemophilia.org/sites/default/files/document/files/MASAC-Products-Licensed.pdf>. Accessed on August 11, 2025.
8. Konkle BA, Ebbesen LS, Erhardtsen E, et al. Randomized, prospective clinical trial of recombinant factor VIIa for secondary prophylaxis in hemophilia patients with inhibitors. *J Thromb Haemost*. 2007;5(9):1904-1913.