

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

When requesting Sevenfact, the individual requiring treatment must be diagnosed with one of the following FDA-approved indication or approve compendial uses 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 patient with hemophilia A or B with inhibitors

Coverage Guidelines

Hemophilia A or B with inhibitors

- The request is for treatment or prevention of bleeding episodes
- Individual is 12 years of age and older

Approval duration (initial): 3 months

Approval duration (renewal): 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 Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. MASAC Document #284. Revised April 2024.
3. Factor VIIa recombinant (Sevenfact®). Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. [Updated; January 24, 2024; Accessed August 2, 2024].
4. 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.
5. 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.
6. World Federation of Hemophilia. WFH Guidelines for the Management of Hemophilia. 3rd edition. Haemophilia.2020;00:1-158.

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