

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

When requesting Sevenfact, the individual requiring treatment must be diagnosed with an FDA-approved indication 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.

Coverage Guidelines

- The request is for treatment of bleeding episodes in individuals with hemophilia A or B with inhibitors
- 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. April 2020.
2. National Hemophilia Foundation. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Other Bleeding Disorders. MASAC Document #263. Revised August 2020.