

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

When requesting Sevenfact, the individual requiring treatment must be diagnosed with one of the following FDA-approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-Approved Indications

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

Hemophilia A with Inhibitors

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

1. Is 12 years of age and older;
2. Meets **one** of the following;
 - a. Has a positive inhibitor titer greater than or equal to 5 Bethesda Units; OR
 - b. Has a history of anamnestic response to Factor VIII replacement therapy, which precludes the use of Factor VIII replacement to treat bleeding episodes; OR
 - c. Has a history of refractory response to increased Factor VIII dosing, which precludes the use of Factor VIII replacement to treat bleeding episodes;
3. Sevenfact is prescribed by or in consultation with a hemophilia specialist.

Hemophilia B with Inhibitors

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

1. Is 12 years of age and older;
2. Meets **one** of the following;
 - a. Has a positive inhibitor titer greater than or equal to 5 Bethesda Units; OR
 - b. Has a history of anamnestic response to Factor IX replacement therapy, which precludes the use of Factor IX replacement to treat bleeding episodes; OR
 - c. Has a history of refractory response to increased Factor IX dosing, which precludes the use of Factor IX replacement to treat bleeding episodes;
3. Sevenfact is prescribed by or in consultation with a 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. November 2025.
2. Meeks SL, Leissinger CA. The evolution of factor VIIa in the treatment of bleeding in haemophilia with inhibitors. *Haemophilia*. 2019;25(6):911-918.
3. 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.
4. 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 December 7, 2025.
5. 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 December 7, 2025.