Drug Coverage Policy

Effective Date.....3/1/2026
Coverage Policy Number.....IP0355
Policy Title.....Sevenfact

Hemophilia – Eptacog Products - Sevenfact

- **Sevenfact® (Factor VIIa [recombinant]-jncw intravenous infusion – LFB S.A./Hema Biologics)**

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW
Sevenfact, a recombinant Factor VIIa product, is indicated for the treatment and control of bleeding episodes occurring with **hemophilia A or B with inhibitors** in adults and adolescents

(≥ 12 years of age).[1] As a limitation of use, Sevenfact is not indicated for the treatment of patients with congenital Factor VII deficiency.

Disease Overview
In hemophilia A and B, antibodies to exogenous clotting factor, known as "inhibitors", may develop. Approximately 30% of patients with severe hemophilia A and up to 5% of patients with severe hemophilia B develop inhibitors to Factor VIII or Factor IX during their lifetime.[2] A high-responding inhibitor (≥ 5 Bethesda Units [BU]) tends to persist, whereas low-responding inhibitors of < 5 BU may wane without changes to the treatment regimen. Presence of inhibitors is associated with higher disease burden, increased risk of musculoskeletal complications, pain, physical limitations, and treatment challenges.[2,3]

Dosing Information
In the prescribing information, it is noted that maximum tolerated doses have not been determined for Sevenfact.[1] Cumulative daily doses greater than 900 mcg/kg, which may be associated with greater risk of thromboembolic complications, have not been studied.[1] The National Hemophilia Foundation Medical and Scientific Advisory Council (MASAC) provides recommendations regarding doses of clotting factor concentrate in the home (2016).[4] Per MASAC guidance, patients on prophylaxis should also have a minimum of one major dose and two minor doses on hand for breakthrough episodes. The guidance also notes that an adequate supply of clotting factor concentrate is needed to accommodate weekends and holidays. Therefore, maximum doses in this policy allow for three days of acute bleeding per 28 days. Doses exceeding this quantity will be reviewed on a case-by-case basis by a clinician.

Guidelines
National Bleeding Disorders Foundation MASAC guidelines (revised October 2024) recognize both Sevenfact and NovoSeven RT® (coagulation Factor VIIa [recombinant] intravenous infusion) as treatments for **hemophilia A or B with inhibitors**.[5] No preference is stated for one agent over the other. It is noted that choice of product depends on multiple factors, including type of inhibitor (low- or high-responding), current titer, location of bleed, and previous response. Of note, NovoSeven RT, but not Sevenfact, is recognized as a treatment option in other settings, such as acquired hemophilia A and congenital Factor VII deficiency.

World Federation of Hemophilia (WFH) guidelines (2020) support recombinant Factor VIIa for patients with high-titer inhibitors who require acute treatment or around surgery/invasive procedures.[3] For low-titer inhibitors, Factor VIII or IX replacement may be used. These products may also be used for patients with a history of a high-titer inhibitor whose titer has fallen to low or undetectable levels. However, once an anamnestic response occurs, further treatment with Factor replacement is typically no longer effective, and bypass agent therapy (e.g., recombinant Factor VIIa) is needed.

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POLICY STATEMENT
Prior Authorization is required for benefit coverage of Sevenfact. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Sevenfact as well as the monitoring required for adverse events and long-term efficacy,

approval requires Sevenfact to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Documentation: Documentation is required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, laboratory tests, claims records, and/or other information. All documentation must include patient-specific identifying information.

Sevenfact is considered medically necessary when ONE the following is met:

FDA-Approved Indications

1. **Hemophilia A with Inhibitors.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 12 years of age; AND
   - **B) Patient meets ONE** of the following (i, ii, or iii) **[documentation required]**:
     - **i.** Patient has a positive inhibitor titer ≥ 5 Bethesda Units; OR
     - **ii.** Patient has a history of anamnestic response to Factor VIII replacement therapy, which, according to the prescriber, precludes the use of Factor VIII replacement to treat bleeding episodes; OR
     - **iii.** Patient has a history of refractory response to increased Factor VIII dosing, which, according to the prescriber, precludes the use of Factor VIII replacement to treat bleeding episodes; AND
   - **C)** The medication is prescribed by or in consultation with a hemophilia specialist.

   Dosing. Approve up to 2,700 mcg/kg administered intravenously per 28 days.

2. **Hemophilia B with Inhibitors.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 12 years of age; AND
   - **B)** Patient meets **ONE** of the following (i, ii, or iii) **[documentation required]**:
     - **i.** Patient has a positive inhibitor titer ≥ 5 Bethesda Units; OR
     - **ii.** Patient has a history of anamnestic response to Factor IX replacement therapy, which according to the prescriber, precludes the use of Factor IX replacement to treat bleeding episodes; OR
     - **iii.** Patient has a history of refractory response to increased Factor IX dosing, which, according to the prescriber, precludes the use of Factor IX replacement to treat bleeding episodes; AND
   - **C)** The medication is prescribed by or in consultation with a hemophilia specialist.

     Dosing. Approve up to 2,700 mcg/kg administered intravenously per 28 days.

Conditions Not Covered

Sevenfact for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

Coding Information

Note: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J7212	Factor VIIa (antihemophilic factor, recombinant)-jncw (Sevenfact), 1 mcg

References

1. Sevenfact® intravenous infusion [prescribing information]. Les Ulis, France/Louisville, KY: LFB S.A./Hema Biologics; June 2024.
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.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	Updated coverage policy title.	5/1/2024
Annual Revision	No criteria changes.	3/1/2025
Annual Revision	**Hemophilia A with inhibitors.** **Added** documentation requirements. **Hemophilia B with inhibitors.** **Added** documentation requirements.	3/1/2026

The policy effective date is in force until updated or retired.