



## **Hemophilia Products – Factor VIIa:**

### **NovoSeven RT<sup>®</sup>; Sevenfact<sup>®</sup>**

**(Intravenous)**

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#### **I. Length of Authorization**

Coverage is provided for 3 months and may be renewed thereafter, unless otherwise specified\*.

*Note: The cumulative amount of medication the patient has on-hand will be taken into account for authorizations. Up to 5 'on-hand' doses for the treatment of acute bleeding episodes will be permitted at the time of the authorization request.*

*\*Initial and renewal authorization periods may vary by specific covered indication*

#### **II. Dosing Limits**

##### **A. Quantity Limit (max daily dose) [NDC Unit]:**

- NovoSeven RT 1000 mcg vial = 12 vials per 30 days
- NovoSeven RT 2000 mcg vial = 12 vials per 30 days
- NovoSeven RT 5000 mcg vial = 24 vials per 30 days
- NovoSeven RT 8000 mcg vial = 15 vials per 30 days
- Sevenfact 1 mg vial = 48 vials per 30 days
- Sevenfact 5 mg vial = 24 vials per 30 days

##### **B. Max Units (per dose and over time) [HCPCS Unit]:**

- 120,000 billable units per 30-day supply

#### **III. Initial Approval Criteria<sup>1-4,9</sup>**

Coverage is provided in the following conditions:

##### **NovoSeven RT ONLY<sup>1</sup>**

**Hemophilia A (congenital factor VIII deficiency) † Φ**

- Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing; **AND**

- Confirmation patient has acquired inhibitors to Factor VIII; **AND**
- Used as treatment in at least one of the following:
  - Treatment and control of acute bleeding episodes (episodic treatment of acute hemorrhage); **OR**
  - Perioperative management (*\*Authorizations valid for 1 month*); **OR**
  - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes when the following criteria are also met:
    - Patient has at least two documented episodes of spontaneous bleeding into joints; **OR**
    - Patient has documented trial and failure of Immune Tolerance Induction (ITI); **AND**
      - Patient has documented trial and failure or contraindication to Hemlibra

### **Acquired Hemophilia †**

- Diagnosis of acquired hemophilia has been confirmed by blood coagulation testing; **AND**
- Used as treatment for one of the following:
  - Treatment and control of acute bleeding episodes (episodic treatment of acute hemorrhage); **OR**
  - Perioperative management (*\*Authorizations valid for 1 month*)

### **Hemophilia B (congenital factor IX deficiency aka Christmas disease) † Φ**

- Diagnosis of congenital factor IX deficiency has been confirmed by blood coagulation testing; **AND**
- Confirmation patient has acquired inhibitors to Factor IX; **AND**
- Used as treatment for one of the following:
  - Treatment and control of acute bleeding episodes (episodic treatment of acute hemorrhage); **OR**
  - Perioperative management (*\*Authorizations valid for 1 month*); **OR**
  - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes when the following criteria are also met:
    - Patient has at least two documented episodes of spontaneous bleeding into joints; **OR**
    - Patient has documented trial and failure of Immune Tolerance Induction (ITI)

### **Congenital Factor VII Deficiency † Φ**

- Diagnosis of congenital factor VII deficiency has been confirmed by blood coagulation testing; **AND**
- Used as treatment for one of the following:

- Treatment and control of acute bleeding episodes (episodic treatment of acute hemorrhage); **OR**
- Perioperative management (*\*Authorizations valid for 1 month*)

#### **Glanzmann's Thrombasthenia † Φ**

- Diagnosis of Glanzmann Thrombasthenia has been confirmed by blood coagulation testing; **AND**
- Used as treatment for one of the following:
  - Treatment and control of acute bleeding episodes (episodic treatment of acute hemorrhage); **OR**
  - Perioperative management (*\*Authorizations valid for 1 month*); **AND**
- The use of platelet transfusions is known or suspected to be ineffective or contraindicated

#### **Sevenfact ONLY<sup>2</sup>**

#### **Hemophilia A (Congenital Factor VIII Deficiency)/Hemophilia B (Congenital Factor IX Deficiency) † Φ**

- Patient is at least 12 years of age; **AND**
- Diagnosis of congenital factor VIII or IX deficiency has been confirmed by blood coagulation testing; **AND**
- Confirmation patient has Hemophilia A (Factor VIII) inhibitors or Hemophilia B (Factor IX) inhibitors; **AND**
- Used as treatment and control of acute bleeding episodes (episodic treatment of acute hemorrhage); **AND**
- Will not be used for the treatment of Congenital Factor VII Deficiency

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

### **IV. Dispensing Requirements for Rendering Providers (Hemophilia Management Program)**

- Prescriptions cannot be filled without an expressed need from the patient, caregiver or prescribing practitioner. Auto-filling is not allowed.
- Monthly, rendering provider must submit for authorization of dispensing quantity before delivering factor product. Information submitted must include:
  - Original prescription information, requested amount to be dispensed, vial sizes available to be ordered from the manufacturer, and patient clinical history (including patient product inventory and bleed history)
  - Factor dose should not exceed +1% of the prescribed dose and a maximum of three vials may be dispensed per dose. If unable to provide factor dosing within the required threshold, below the required threshold, the lowest possible dose able to be

achieved above +1% should be dispensed. Prescribed dose should not be increased to meet assay management requirements.

- The cumulative amount of medication(s) the patient has on-hand should be taken into account when dispensing factor product. Patients should not have more than 5 extra doses on-hand for the treatment of acute bleeding episodes.
- Dispensing requirements for renderings providers are a part of the hemophilia management program. This information is not meant to replace clinical decision making when initiating or modifying medication therapy and should only be used as a guide.

## V. Renewal Criteria <sup>1-4,9-10</sup>

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hypersensitivity reactions including anaphylaxis (e.g., hives, itching, rash, difficulty breathing, swelling around the mouth/throat, chest tightness, wheezing, dizziness/fainting, low blood pressure, etc.), serious arterial and venous thrombotic events, development of neutralizing antibodies (inhibitors), etc.; **AND**
- Any increases in dose must be supported by an acceptable clinical rationale (i.e., weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy, etc.); **AND**
- The cumulative amount of medication(s) the patient has on-hand will be taken into account when authorizing. The authorization will allow up to 5 doses on-hand for the treatment of acute bleeding episodes as needed for the duration of the authorization; **AND**

### **Treatment and control of acute bleeding episodes (NovoSeven RT/Sevenfact)**

- Renewals will be approved for a 6-month authorization period

### **Perioperative management of bleeding (NovoSeven RT Only)**

- Coverage may NOT be renewed

### **Routine prophylaxis to prevent or reduce the frequency of bleeding episodes (NovoSeven RT Only)**

- Renewals will be approved for a 12-month authorization period; **AND**
- Patient has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline)

## VI. Dosage/Administration <sup>1-4</sup>

Indication	Dose
<b>NovoSeven RT</b>	
Control and prevention of bleeding: Congenital Hemophilia A or B with inhibitors	<u>Hemostatic</u> Administer 90 mcg/kg intravenously every 2 hours, adjustable based on severity of bleeding until hemostasis is achieved, or until the treatment has been judged to be inadequate. <u>Post-Hemostatic</u> Administer 90 mcg/kg intravenously every 3-6 hours after hemostasis is achieved for severe bleeds
Control and prevention of bleeding: Acquired Hemophilia	Administer 70-90 mcg/kg intravenously every 2-3 hours until hemostasis is achieved
Control and prevention of bleeding: Congenital Factor VII deficiency	Administer 15-30 mcg/kg intravenously every 4-6 hours until hemostasis is achieved
Control and prevention of bleeding: Glanzmann's Thrombasthenia	Administer 90 mcg/kg intravenously every 2-6 hours in severe bleeding episodes requiring systemic hemostatic therapy until hemostasis is achieved
Perioperative management Congenital Hemophilia A or B with inhibitors	<u>Minor</u> <ul style="list-style-type: none"> <li><u>Initial</u>: Administer 90 mcg/kg intravenously immediately before surgery, repeat every 2 hours during surgery.</li> <li><u>Post-Op</u>: Administer 90 mcg/kg intravenously every 2 hours after surgery for 48 hours, then every 2-6 hours until healing has occurred.</li> </ul> <u>Major</u> <ul style="list-style-type: none"> <li><u>Initial</u>: Administer 90 mcg/kg intravenously immediately before surgery, repeat every 2 hours during surgery.</li> <li><u>Post-Op</u>: Administer 90 mcg/kg intravenously every 2 hours after surgery for 5 days, then every 4 hours or by continuous infusion, via pump, at 50 mcg/kg/hr until healing occurs.</li> </ul>
Perioperative management Acquired Hemophilia	Administer 70-90 mcg/kg intravenously immediately before surgery and every 2-3 hours for the duration of surgery and until hemostasis is achieved
Perioperative management Congenital Factor VII deficiency	Administer 15-30 mcg/kg intravenously immediately before surgery and every 4-6 hours for the duration of surgery and until hemostasis is achieved
Perioperative management Glanzmann's Thrombasthenia	<u>Initial</u> : Administer 90 mcg/kg intravenously immediately before surgery and repeat every 2 hours for the duration of the procedure. <u>Post-Op</u> : Administer 90 mcg/kg intravenously every 2-6 hours to prevent post-operative bleeding
<b>Sevenfact</b>	

Indication	Dose
Control and treatment of bleeding: Congenital Hemophilia A or B with inhibitors	<p><u>For Mild or Moderate Bleeds:</u></p> <ul style="list-style-type: none"> <li>Administer 75 mcg/kg intravenously repeated every 3 hours until hemostasis is achieved</li> </ul> <p>or</p> <ul style="list-style-type: none"> <li>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</li> </ul> <p><u>For Severe Bleeds:</u></p> <ul style="list-style-type: none"> <li>Administer 225 mcg/kg intravenously initially, followed if necessary 6 hours later with 75 mcg/kg every 2 hours until hemostasis is achieved.</li> </ul>

## VII. Billing Code/Availability Information

### HCPCS Code & NDC:

Drug	Manufacturer	HCPCS Code	1 Billable Unit Equiv.	Vial Size	NDC
NovoSeven RT	Novo Nordisk	J7189	1 mcg	1 mg	00169-7010-xx
				2 mg	00169-7020-xx
				5 mg	00169-7050-xx
				8 mg	00169-7040-xx
NovoSeven RT with MixPro package				1 mg	00169-7201-xx
				2 mg	00169-7202-xx
				5 mg	00169-7205-xx
				8 mg	00169-7208-xx
Sevenfact	LFB S.A.	J7212	1 mcg	1 mg	71127-1000-xx
				5 mg	71127-5000-xx

## VIII. References

- NovoSeven RT [package insert]. Bagsvaerd, Denmark; Novo Nordisk; July 2020. Accessed May 2023.
- Sevenfact [package insert]. Puteaux, France; LFB S.A., November 2022. Accessed May 2023.
- MASAC RECOMMENDATIONS CONCERNING PRODUCTS LICENSED FOR THE TREATMENT OF HEMOPHILIA AND OTHER BLEEDING DISORDERS. Revised August 2020 National Hemophilia Foundation. MASAC Document #263; August 2020. Available at: <https://www.hemophilia.org/>. Accessed May 2023.
- Guidelines for the Management of Hemophilia. 3<sup>rd</sup> Edition. World Federation of Hemophilia. 2020. Available at: <https://www1.wfh.org/publications/files/pdf-1863.pdf>. Accessed April 2022.
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- Graham A1, Jaworski K. Pharmacokinetic analysis of anti-hemophilic factor in the obese patient. Haemophilia. 2014 Mar;20(2):226-9.

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8. Mingot-Castellano, et al. Application of Pharmacokinetics Programs in Optimization of Haemostatic Treatment in Severe Hemophilia a Patients: Changes in Consumption, Clinical Outcomes and Quality of Life. Blood. 2014 December; 124 (21).
9. MASAC RECOMMENDATION CONCERNING PROPHYLAXIS. 2016 National Hemophilia Foundation. MASAC Document #241; February 2016. Available at: <http://www.hemophilia.org/>. Accessed May 2023.
10. Rayment R, Chalmers E, Forsyth K, et al. Guidelines on the use of prophylactic factor replacement for children and adults with Haemophilia A and B. B J Haem:190;5, Sep2020. <https://onlinelibrary.wiley.com/doi/10.1111/bjh.16704>. Accessed April 2022.
11. First Coast Service Options, Inc. Local Coverage Article: Billing and Coding: Hemophilia Clotting Factors (A56482). Centers for Medicare & Medicaid Services Inc. Updated on 10/28/2022 with effective date 10/01/2022. Accessed May 2023.
12. Palmetto GBA. Local Coverage Article: Billing and Coding: Guidance for Anti-Inhibitor Coagulant Complex (AICC) National Coverage Determination (NCD) 110.3 (A56065). Centers for Medicare & Medicaid Services Inc. Updated on 11/14/2022 with effective date 11/24/2022. Accessed May 2023.
13. Novitas Solutions, Inc. Local Coverage Article: Billing and Coding: Hemophilia Factor Products (A56433). Centers for Medicare & Medicaid Services Inc. Updated on 10/14/2022 with effective date 10/01/2022. Accessed May 2023.

## Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D66	Hereditary factor VIII deficiency
D67	Hereditary factor IX deficiency
D68.0	Von Willebrand's disease
D68.2	Hereditary deficiency of other clotting factors
D68.311	Acquired hemophilia
D69.1	Qualitative platelet defects



## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx> . Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA):

<b>Jurisdiction(s): N</b>	<b>NCD/LCD Document (s): A56482</b>
<a href="https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a56482&amp;areaId=all&amp;docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP">https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a56482&amp;areaId=all&amp;docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP</a>	

<b>Jurisdiction(s): J,M</b>	<b>NCD/LCD Document (s): A56065</b>
<a href="https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a56065&amp;areaId=all&amp;docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP">https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a56065&amp;areaId=all&amp;docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP</a>	

<b>Jurisdiction(s): H,L</b>	<b>NCD/LCD Document (s): A56433</b>
<a href="https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a56433&amp;areaId=all&amp;docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP">https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a56433&amp;areaId=all&amp;docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP</a>	

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC



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Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
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Grievance Specialist  
PreferredOne Community Health Plan  
PO Box 59052  
Minneapolis, MN 55459-0052  
Phone: 1.800.940.5049 (TTY: 763.847.4013)  
Fax: 763.847.4010  
[customerservice@preferredone.com](mailto:customerservice@preferredone.com)

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Room 509F, HHH Building  
Washington, D.C. 20201  
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

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XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

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1.800.940.5049 (TTY: 763.847.4013).

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- Qualified interpreters
- Information written in other languages

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Fax: 763.847.4010  
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You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Room 509F, HHH Building  
Washington, D.C. 20201  
1-800-368-1019, 800-537-7697 (TDD)

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ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).

XIYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.800.940.5049 (TTY: 763.847.4013).

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1.800.940.5049 (TTY: 763.847.4013)。

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.800.940.5049 (телетайп: 763.847.4013).

បំពេញ: ប្រសិនបើ អ្នកនិយាយភាសាខ្មែរ, សេវាជំនួយភាសា ដោយមិនគិតថ្លៃ គឺអាចមានសំរាប់អ្នក។ ហៅ 1.800.940.5049 (TTY: 763.847.4013).

ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፡ በነጻ ሊያገኙበት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049 (ማስማት ለተሳናቸው: 763.847.4013) .

ဟံသာဝတီ: နမူနာတို့ ကညီ ကျိအသိ, နမူနာ ကျိအတိအကျတို့ တလက်ကွက်လက်စွာ နှိတ်ခံဘက်သို့လွှဲလိ။ ကိ: 1.800.940.5049 (TTY: 763.847.4013).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY: 763.847.4013).

ប្រយ័ត្ន: បើសិនជាអ្នកនិយាយភាសាខ្មែរ, សេវាជំនួយភាសា ដោយមិនគិតថ្លៃ គឺអាចមានសំរាប់អ្នក។ ហៅ 1.800.940.5049 (TTY: 763.847.4013).

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013). 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1.800.940.5049 (TTY: 763.847.4013).