Clinical Policy: Factor VIIa (Recombinant - NovoSeven RT)

Reference Number: PA.CP.PHAR.220
Effective Date: 01/18
Last Review Date: 01/19

Coding Implications
Revision Log

Description
Factor VIIa, recombinant (NovoSeven® RT) is a coagulation factor.

FDA Approved Indication(s)
NovoSeven RT is indicated for treatment of bleeding episodes and perioperative management in:

- Adults and children with hemophilia A or B with inhibitors, congenital FVII deficiency, and Glanzmann's thrombasthenia with refractoriness to platelet transfusions, with or without antibodies to platelets;
- Adults with acquired hemophilia.

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness that NovoSeven RT is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Hemophilia A and B with Inhibitors, Congenital Factor VII Deficiency (must meet all):

1. Diagnosis of one of the following (a or b):
   a. Congenital or acquired hemophilia A or B with inhibitors;
   b. Congenital factor VII deficiency;
2. Prescribed by or in consultation with a hematologist;
3. Request is for one of the following uses (a or b):
   a. Control and prevention of bleeding episodes;
   b. Perioperative management.
4. Dose does not exceed one of the following (a or b):
   a. Hemophilia: 90 mcg/kg every two hours;
   b. Congenital factor VII deficiency: 30 mcg/kg every four hours.

Approval duration: 3 months

B. Glanzmann's Thrombasthenia (must meet all):

1. Prescribed by or in consultation with a hematologist;
2. Diagnosis of Glanzmann's thromboasthenia;
3. Condition is refractory to platelet transfusions;
4. Request is for one of the following use (a or b):
   a. Control and prevention of bleeding episodes;
   b. Perioperative management.
5. Dose does not exceed 90 mcg/kg every two hours.

Approval duration: 3 months

C. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy applies (*see PA.LTSS.PHAR.01*);
2. Member is responding positively to therapy.
3. If request is for a dose increase, new dose does not exceed one fo the following (a or b):
   a. Congenital factor VII deficiency: 30 mcg/kg every four hours;
   b. All other indications: 90 mcg/kg every two hours.

Approval duration: 3 months

B. Other diagnoses/indications (1 or 2)

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy, or the Continuity of Care policy applies (*see PA.LTSS.PHAR.01*);
   Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to PA.CP.PMN.53

Background

Description/Mechanism of Action:
Recombinant factor VIIa is a vitamin K-dependent glycoprotein that promotes hemostasis by activating the extrinsic pathway of the coagulation cascade. It replaces deficient activated coagulation FVII, which complexes with tissue factor and may activate coagulation factor X to Xa and factor IX to IXa. When complexed with other factors, coagulation factor Xa converts prothrombin to thrombin, a key step in the formation of a fibrin-platelet hemostatic plug.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s): thrombosis

Appendix D: General Information

- Congenital hemophilia A is a deficiency of factor VIII.
- Congenital hemophilia B is a deficiency of factor IX.

- Acquired hemophilia is evidenced by presence of coagulation factor inhibitors (autoantibodies).

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Treatment of bleeding episodes	Congenital hemophilia A or B with inhibitors: • 90 mcg/kg IV every 2 hours, adjustable based on severity of bleeding until hemostasis is achieved • 90 mcg/kg IV every 3-6 hours after hemostasis is achieved for severe bleeds Congenital factor VII deficiency: 15-30 mcg/kg IV every 4-6 hours until hemostasis is achieved Glanzmann's thrombasthenia: 90 mcg/kg IV every 2-6 hours until hemostasis is achieved Acquired hemophilia: 70-90 mcg/kg IV every 2-3 hours until hemostasis is achieved	Congenital factor VII deficiency: 30 mcg/kg every 4 hours All other indications: 90 mcg/kg every 2 hours
Peri-operative management	Congenital hemophilia A or B with inhibitors: *Minor surgery:* • 90 mcg/kg IV immediately before surgery, repeat every 2 hours during surgery • 90 mcg/kg IV every 2 hours after surgery for 48 hours, then every 2-6 hours until healing has occurred *Major surgery:* • 90 mcg/kg IV immediately before surgery, repeat every 2 hours during surgery • 90 mcg/kg IV every 2 hours after surgery for 5 days, then every 4 hours or by continuous infusion at 50 mcg/kg/hour until healing has occurred • Additional boluses can be given Congenital factor VII deficiency: 15-30 mcg/kg IV immediately before surgery and every 4-6 hours for the duration of surgery and until hemostasis is achieved Note: doses as low as 10 mcg/kg can be effective	Congenital factor VII deficiency: 30 mcg/kg every 4 hours Glanzmann's thrombasthenia: 140 mcg/kg every 2 hours All other indications: 90 mcg/kg every 2 hours

Indication	Dosing Regimen	Maximum Dose
	Glanzmann's thrombasthenia: • 90 mcg/kg IV immediately before surgery and repeat every 2 hours for the duration of the procedure • 90 mcg/kg IV every 2-6 hours to prevent postoperative bleeding • Higher doses of 100-140 mcg/kg can be used for surgical patients who have clinical refractoriness with or without platelet-specific antibodies Acquired hemophilia: 70-90 mcg/kg immediately before surgery and every 2-3 hours for the duration of surgery and until hemostasis is achieved	

V. Product Availability

Powder for reconstitution in single-use vial: 1, 2, 5, 8 mg

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J7189	Factor VIIa (antihemophilic factor, recombinant), per 1 mcg

Reviews, Revisions, and Approvals	Date	Approval Date
Dose guidelines delineated. References reviewed and updated.	02/18	
1Q 2019 annual review: references reviewed and updated.	01/19	

References

1. NovoSeven RT Prescribing Information. Plainsboro, NJ: Novo Nordisk, Inc.; October 2018. Available at http://www.novosevenrt.com. Accessed November 8, 2018.
2. Srivastava A, Brewer AK, Mauser-Bunschoten EP, et al. Guidelines for the management of hemophilia. Haemophilia. Jan 2013; 19(1): e1-47.
3. Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation (NHF): Database of treatment guidelines. Available at

https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-Scientific-Advisory-Council-MASAC/MASAC-Recommendations. Accessed September 26, 2018.