Clinical Policy: Factor VIIa (Recombinant - NovoSeven RT)

Reference Number: PA.CP.PHAR.220
Effective Date: 01/18
Last Review Date: 07/18

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for factor VIIa (NovoSeven® RT).

FDA Approved Indication(s)
NovoSeven RT is a recombinant factor VIIa concentrate/intravenous injection 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;
- Treatment of bleeding episodes and perioperative management in 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. Congenital Hemophilia A and B (must meet all):
1. Prescribed by or in consultation with a hematologist;
2. Diagnosis of congenital hemophilia A (factor VIII deficiency) or B (factor IX deficiency) with inhibitors (factor VIII or IX antibodies);
3. Request is for one of the following:
   a. Control and prevention of bleeding episodes;
4. b. Perioperative management.Dose does not exceed 90 mcg/kg every two hours.

Approval duration: 3 months

B. Congenital Factor VII Deficiency (must meet all):
1. Prescribed by or in consultation with a hematologist;
2. Diagnosis of congenital factor VII deficiency;
3. Request is for one of the following:
   a. Control and prevention of bleeding episodes;
   b. Perioperative management.
4. Dose does not exceed 30 mcg/kg every four hours.

Approval duration: 3 months

C. 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:
   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

D. Acquired Hemophilia (must meet all):
1. Prescribed by or in consultation with a hematologist;
2. Diagnosis of acquired hemophilia as evidenced by the presence of coagulation factor VIII inhibitors (autoantibodies);
3. Request is for one of the following:
   a. Control and prevention of bleeding episodes;
   b. Perioperative management.
4. Dose does not exceed 90 mcg/kg every two hours.

Approval duration: 3 months

E. 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 90 mcg/kg every two hours (30 mcg/kg every four hours for congenital factor VII deficiency).

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.

Formulations (recombinant human):
Solution Reconstituted, Intravenous:
NovoSeven RT: 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	

References
1. NovoSeven RT Prescribing Information. Plainsboro, NJ: Novo Nordisk, Inc.; October 2017. Available at http://www.novo-pi.com/novosevenrt.pdf. Accessed November 29, 2017.
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 November 29, 2017.