Clinical Policy: Factor VIIa (Recombinant - NovoSeven RT)
Reference Number: CP.PHAR.220
Effective Date: 05/16
Last Review Date: 05/17

See Important Reminder at the end of this policy for important regulatory and legal information.

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

Policy/Criteria
It is the policy of health plans affiliated with Centene Corporation® 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;
         b. Perioperative management.

      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.

      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 thrombosthenia;
      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.

      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.

**Approval duration: 3 months**

E. **Other diagnoses/indications:** Refer to CP.PHAR.57 - Global Biopharm Policy.

II. **Continued Approval**
   A. **All Indications in Section I** (must meet all):
      1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
      2. Member is responding positively to therapy.

   **Approval duration: 3 months**

   B. **Other diagnoses/indications** (1 or 2)
      1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy;
      
      **Approval duration: Duration of request or 6 months (whichever is less); or**
      
      2. Refer to CP.PHAR.57 - Global Biopharm Policy

**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)

*FDA Approved Indications:*
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.
CLINICAL POLICY
Coagulation Factor VIIa

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.

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tr>
<td>J7189</td>
<td>Factor VIIa (antihemophilic factor, recombinant), per 1 mcg</td>
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Reviews, Revisions, and Approvals

<table>
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<th>Date</th>
<th>Approval Date</th>
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<tbody>
<tr>
<td>Policy split from CP.PHAR.12.Blood Factors and converted to new template. Removed specific titer levels and factor VIII dose increases. Approval period for non-prophylactic use is edited to provide 3 months on initial approval and one 3-month re-auth. Added criteria for Glanzmann’s thrombasthenia. Reviewed by specialist.</td>
<td>04/16</td>
<td>05/16</td>
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<td>Safety information removed. Wording for uses and approval periods for all blood factor products made consistent across all policies. Efficacy statement added to renewal criteria. Hemophiliacs are specified as “congenital” versus “acquired” across blood factor policies where indicated. Added requirement that acquired hemophilia be evidenced by the presence of factor VIII inhibitors. Reviewed by specialist- hematology/internal medicine.</td>
<td>04/17</td>
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References

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of
physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical
information. The Health Plan makes no representations and accepts no liability with respect to the content
of any external information used or relied upon in developing this clinical policy. This clinical policy is
consistent with standards of medical practice current at the time that this clinical policy was approved.
“Health Plan” means a health plan that has adopted this clinical policy and that is operated or
administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s
affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the
guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a
contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits
are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence
of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal
requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not
be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and
regulatory requirements relating to provider notification. If there is a discrepancy between the effective
date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and
regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical
policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not
intended to dictate to providers how to practice medicine. Providers are expected to exercise professional
medical judgment in providing the most appropriate care, and are solely responsible for the medical
dvice and treatment of members. This clinical policy is not intended to recommend treatment for
members. Members should consult with their treating physician in connection with diagnosis and
treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent
judgment and over whom the Health Plan has no control or right of control. Providers are not agents or
employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this
clinical policy or any information contained herein are strictly prohibited. Providers, members and their
representatives are bound to the terms and conditions expressed herein through the terms of their
contracts. Where no such contract exists, providers, members and their representatives agree to be bound
by such terms and conditions by providing services to members and/or submitting claims for payment for
such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage
provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the
state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage
Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs and LCDs and
Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical