Reference number(s)
4034-A

JURISDICTION SPECIFIC MEDICARE PART B

NOVOSEVEN RT (coagulation factor VIIa [recombinant])

POLICY

I. COVERED USES

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

The list of covered ICD-10 codes is prohibitively long to include within this policy. A complete list can be found at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. The FDA-labeled indications uses are listed below:

A. Treatment of bleeding episodes and peri-operative management in adults and children with hemophilia A or B with inhibitors, congenital factor VII deficiency, and Glanzmann's thrombasthenia with refractoriness to platelet transfusions, with or without antibodies
B. Treatment of bleeding episodes and peri-operative management in adults with acquired hemophilia

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available in a legible format with patient identification information (e.g., complete name and dates of service and signature of physician or non-physician practitioner responsible for and providing care to the member, upon request, for all submissions:

A. The submitted medical record must support the use of the selected ICD-10-CM codes. The submitted CPT/HCPCS code must describe the service performed.
B. The medical record documentation must support the medical necessity of the services as stated in this policy.
C. For hereditary factor VIII deficiency (D66) and hereditary factor IX deficiency (D67), the medical record must demonstrate the patient has ongoing bleeding.

III. PRESCRIBER SPECIALTIES

This medication must be initiated by a provider experienced in the treatment of bleeding disorders.

IV. CRITERIA FOR APPROVAL

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A. Congenital Factor VII Deficiency
Authorization of 12 months may be granted for treatment of bleeding episodes and perioperative management of congenital factor VII deficiency when the member will be monitored by hemostasis evaluations while on therapy.

B. Hemophilia A with Inhibitors
Authorization of 12 months may be granted for treatment of bleeding episodes and perioperative management of hemophilia A with inhibitors when both of the following criteria are met:
1. The member has documentation of ongoing bleeding.
2. The member will be monitored by hemostasis evaluations while on therapy.

C. Hemophilia B with Inhibitors
Authorization of 12 months may be granted for treatment of bleeding episodes and perioperative management of hemophilia B with inhibitors when both of the following criteria are met:
1. The member has documentation of ongoing bleeding.
2. The member will be monitored by hemostasis evaluations while on therapy.

D. Glanzmann's Thrombasthenia
Authorization of 12 months may be granted for treatment of Glanzmann's thrombasthenia when all of the following criteria are met:
1. Novoseven RT will be requested for the treatment of bleeding episodes and perioperative management.
2. The member will be monitored by hemostasis evaluations while on therapy.
3. The member is refractory to platelet transfusions.

E. Acquired Hemophilia
Authorization of 12 months may be granted for treatment of bleeding episodes and perioperative management of acquired hemophilia when the member will be monitored by hemostasis evaluations while on therapy.

V. REFERENCES

1. Hemophilia Factor Products LCD (L35111) Version R16. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed December 15, 2021.
2. Billing and Coding: Hemophilia Factor Products (A56433) Version R7. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed December 15, 2021.
3. Novoseven RT [package insert]. Plainsboro, NJ: Novo Nordisk, Inc.; July 2020.

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