Bypassing Agents: FEIBA and NovoSeven RT

Date of Origin: 01/22/2020 **Last Review Date: 01/22/2020** **Effective Date: 02/01/2020**

Dates Reviewed: 01/22/2020

Developed By: Medical Criteria Committee

I. Length of Authorization

- Initial: 6 months (for on-demand and prophylaxis); 1 month (for perioperative)
- Renewal: 12 months (for prophylaxis); 12 months (for on-demand)

II. Dosing Limits

Product Name	Dosage Form	Indication/ FDA Labeled Dosing	Quantity Limit
FEIBA, anti-inhibitor coagulant complex	500, 1000, 2500 units	**Control and prevention of bleeding – Hemophilia A or B with inhibitors:** Up to 100 units/kg every six to 12 hours until resolution of bleeding **Routine prophylaxis – Hemophilia A or B with inhibitors:** Up to 85 units/kg every other day **Perioperative management – Hemophilia A or B with inhibitors:** Up to 100 units/kg administered as a one-time dose immediately prior to surgery or up to 100 units/kg administered every six to 12 hours postoperatively until resolution of bleed and healing is achieved	**Control and prevention of bleeding – Hemophilia A or B with inhibitors:** Up to the number of doses requested every 28 days **Routine prophylaxis – Hemophilia A or B with inhibitors:** Up to 1,190 units/kg every 28 days **Perioperative management – Hemophilia A or B with inhibitors:** Up to the number of doses requested for 28 days
NovoSeven RT, coagulation factor VIIa (recombinant)	1 mg/vial (1000 mcg/vial) 2 mg/vial (2000 mcg/vial) 5 mg/vial (5000 mcg/vial)	**Control and prevention of bleeding – Hemophilia A or B with inhibitors:** Up to 90 mcg/kg every three to six hours until hemostasis is achieved **Control and prevention of bleeding episodes – Acquired hemophilia:** Up to 90 mcg/kg every two to three hours until hemostasis is achieved	**Control and prevention of bleeding – Hemophilia A or B with inhibitors:** Up to the number of doses requested every 28 days **Control and prevention of bleeding episodes – Acquired hemophilia:** Up to the number of doses requested every 28 days

Product Name	Dosage Form	Indication/ FDA Labeled Dosing	Quantity Limit
	8 mg/vial (8000 mcg/vial)	**Control and prevention of bleeding episodes – Factor VII deficiency:** Up to 30 mcg/kg every four to six hours until hemostasis is achieved	**Control and prevention of bleeding episodes – Factor VII deficiency:** Up to the number of doses requested every 28 days
		Control and prevention of bleeding episodes – Glanzmann's Thrombasthenia: Up to 90 mcg/kg every two to six hours until hemostasis is achieved	**Control and prevention of bleeding episodes – Glanzmann's Thrombasthenia:** Up to the number of doses requested every 28 days
		Perioperative management – hemophilia A or B with inhibitors: Up to 90 mcg/kg immediately before surgery, repeat every two hours during surgery, then up to 90 mcg/kg every two hours after surgery for five days, then every four hours or by continuous infusion, via pump, at 50 mcg/kg/hr until healing occurs	**Perioperative management – hemophilia A or B with inhibitors:** Up to the number of doses requested for 28 days
		Perioperative management – acquired hemophilia: Up to 90 mcg/kg immediately before surgery and every two to three hours for the duration of surgery and until hemostasis is achieved	**Perioperative management – acquired hemophilia:** Up to the number of doses requested for 28 days
		Perioperative management – factor VII deficiency: Up to 30 mcg/kg immediately before surgery and every four to six hours for the duration of surgery and until hemostasis is achieved	**Perioperative management – factor VII deficiency:** Up to the number of doses requested for 28 days
		Perioperative management – Glanzmann's Thrombasthenia: Up to 90 mcg/kg immediately before surgery and repeat every two hours for the duration of the procedure, then up to 90 mcg/kg every two to six hours to prevent post-operative bleeding	**Perioperative management – Glanzmann's Thrombasthenia:** Up to the number of doses requested for 28 days

III. Initial Approval Criteria

Hemophilia A (congenital factor VIII deficiency)

I. **FEIBA** or **NovoSeven RT** may be considered medically necessary when the following criteria below are met:
   A. Treatment is prescribed by or in consultation with a hematologist; **AND**
   B. A diagnosis of hemophilia A has been confirmed by blood coagulation testing; **AND**
   C. Clinical documentation confirming that the member has inhibitors to factor VIII [i.e. high anti-FVIII titer (≥ 5 Bethesda units)]; **AND**
   D. Use is planned for one of the following indications:
      1. On-demand treatment and control of bleeding episodes; **OR**
      2. Perioperative management of bleeding; **OR**
      3. Routine prophylaxis to reduce the frequency of bleeding episodes when one of the following is met:
         i. Member has had more than one documented episode of spontaneous bleeding; **AND**
         ii. Prior therapy with emicizumab-kxwh (Hemlibra) was ineffective, not tolerated, or contraindicated; **OR**
         iii. Member has had an inadequate response to Immune Tolerance Induction (ITI)

Hemophilia B (congenital factor IX deficiency)

I. **FEIBA** or **NovoSeven RT** may be considered medically necessary when the following criteria below are met:
   A. Treatment is prescribed by or in consultation with a hematologist; **AND**
   B. A diagnosis of hemophilia B has been confirmed by blood coagulation testing; **AND**
   C. Clinical documentation confirming that the member has inhibitors to factor VIX [i.e. high anti-IX titer (≥ 5 Bethesda units)]; **AND**
   D. Use is planned for one of the following indications:
      1. On-demand treatment and control of bleeding episodes; **OR**
      2. Perioperative management of bleeding; **OR**
      3. Routine prophylaxis to reduce the frequency of bleeding episodes when one of the following is met:
         i. Member has had more than one documented episode of spontaneous bleeding; **OR**
         ii. Member has had an inadequate response to Immune Tolerance Induction (ITI)

Acquired Hemophilia

I. **NovoSeven RT** may be considered medically necessary when the following criteria below are met:
   A. Treatment is prescribed by or in consultation with a hematologist; **AND**
   B. A diagnosis of acquired hemophilia has been confirmed by blood coagulation testing; **AND**
   C. Use is planned for one of the following indications:
      1. On-demand treatment and control of bleeding episodes; **OR**
      2. Perioperative management of bleeding

Congenital Factor VII Deficiency

I. **NovoSeven RT** may be considered medically necessary when the following criteria below are met:
   A. Treatment is prescribed by or in consultation with a hematologist; **AND**
   B. A diagnosis of congenital factor VII deficiency has been confirmed by blood coagulation testing; **AND**
   C. Use is planned for one of the following indications:
      1. On-demand treatment and control of bleeding episodes; **OR**
      2. Perioperative management of bleeding

Glanzmann's Thrombasthenia

I. **NovoSeven RT** may be considered medically necessary when the following criteria below are met:
   A. Treatment is prescribed by or in consultation with a hematologist; **AND**
   B. A diagnosis of Glanzmann Thrombasthenia has been confirmed by blood coagulation testing; **AND**
   C. Use is planned for one of the following indications:
      1. On-demand treatment and control of bleeding episodes; **OR**
      2. Perioperative management of bleeding; **AND**
   D. The use of platelet transfusions is known or suspected to be ineffective or contraindicated

II. FEIBA and NovoSeven RT are considered investigational when used for all other conditions.

IV. Renewal Criteria

I. Documentation of clinical benefit, including decreased incidence of bleeding episodes or stability of bleeding episodes relative to baseline.

VI. Billing Code/Availability Information

Jcode:

Drug	Manufacturer	J-Code	1 Billable Unit Equiv.	Vial Size	NDC
Novoseven RT	Novo Nordisk	J7189	1 mcg	1 mg	00169-7201
				2 mg	00169-7202
				5 mg	00169-7205
				8 mg	00169-7208
Novoseven RT with MixPro package	Novo Nordisk	J7189	1 mcg	1 mg	00169-7201
				2 mg	00169-7202
				5 mg	00169-7205
				8 mg	00169-7208

Feiba NF	Baxalta US Inc	J7198	1 IU	500 units	64193-0426
				1000 units	64193-0424
				2500 units	64193-0425
Feiba VH	Baxalta US Inc	J7198	1 IU	500 units	64193-0222
				1000 units	64193-0222
				2500 units	64193-0222-

VII. References

1. Fieba [Prescribing information]. Westlake Village, CA; Baxalta US Inc. December 2018.
2. NovoSeven RT [prescribing information]. Bagsvaerd, Denmark; NovoNordisk. January 2019.
3. National Hemophilia Foundation. Hemophilia A. Available from: https://www.hemophilia.org/Bleeding-Disorders/Types-of-Bleeding-Disorders/Hemophilia-A. Accessed July 5, 2019.
4. National Hemophilia Foundation. MASAC Recommendations Concerning products Licensed for the Treatment of Hemophilia and Other Bleeding Disorders. Available from: https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-Scientific-Advisory-Council-MASAC/MASAC-Recommendations. Accessed July 5, 2019.
5. National Hemophilia Foundation. MASAC Recommendation Regarding the Use of Bypassing Agents in Patients with Hemophilia A or B and Inhibitors. Available from: https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-Scientific-Advisory-Council-MASAC/MASAC-Recommendations/MASAC-Recommendation-Regarding-the-Use-of-Bypassing-Agents-in-Patients-with-Hemophilia-A-or-B-and-Inhibitors. Accessed August 21, 2019.
6. Recommendation on the Use and Management of Emicizumab-kxwh (Hemlibra®) for Hemophilia A with and without Inhibitors. Available from: https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-Scientific-Advisory-Council-MASAC/MASAC-Recommendations/Recommendation-on-the-Use-and-Management-of-Emicizumab-kxwh-Hemlibra-for-Hemophilia-A-with-and-without-Inhibitors Accessed August 19, 2019
7. National Hemophilia Foundation. MASAC Recommendation Regarding Prophylaxis with Bypassing Agents in Patients with Hemophilia and High Titer Inhibitors. Available from: https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-Scientific-Advisory-Council-MASAC/MASAC-Recommendations/MASAC-Recommendation-Regarding-Prophylaxis-with-Bypassing-Agents-in-Patients-with-Hemophilia-and-High-Titer-Inhibitors. Accessed August 21, 2019.
8. UpToDate, Inc. Hemophilia A and B: Routine management including prophylaxisHemophilia A and B: Routine management including prophylaxis. UpToDate [database online]. Last updated February 11, 2019.
9. Astermark J, Donfield SM, DiMichele DM, et al. A randomized comparison of bypassing agents in hemophilia complicated by an inhibitor: the FEIBA NovoSeven Comparative (FENOC) Study. Blood. 2007;109(2):546. PMID: 16990605

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
D66	Hereditary factor VIII deficiency
D67	Hereditary factor IX deficiency

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) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-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): N/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 Corporation (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 Corporation (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Cahaba Government Benefit Administrators, 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