Hemophilia Products – Anti-Inhibitor Coagulant Complex: Feiba NF/Feiba VF
(Intravenous)

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I. Length of Authorization

Unless otherwise specified*, the initial authorization will be provided for 3 months and may be renewed every 12 months thereafter.

Note: The cumulative amount of medication the patient has on-hand will be taken into account for authorizations.

** Initial and renewal authorization periods may vary by specific covered indication*

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

N/A

B. Max Units (per dose and over time) [Medical Benefit]:

146,625 billable units per 30 day supply

III. Initial Approval Criteria

Hemophilia A (congenital factor VIII deficiency) †

- Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing; **AND**
- Confirmation the patient has inhibitors to Factor VIII ; **AND**
- Used as treatment in at least one of the following:
  - Control and prevention of acute bleeding episodes (episodic treatment of acute hemorrhage); **OR**
  - Perioperative management *(*Authorizations valid for 1 month)*; **OR**
  - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**

- Patient has at least two documented episodes of spontaneous bleeding into joints; **OR**
- Patient has a documented trial and failure of Immune Tolerance Induction (ITI); **AND**
  - Patient has a documented trial and failure or contraindication to emicizumab-kxwh therapy.

Hemophilia B (congenital factor IX deficiency aka Christmas disease) †

- Diagnosis of congenital factor IX deficiency has been confirmed by blood coagulation testing; **AND**
- Confirmation the patient has inhibitors to Factor IX ; **AND**
- Used as treatment in at least one of the following:
  - Control and prevention of acute bleeding episodes (episodic treatment of acute hemorrhage); **OR**
  - Perioperative management *(*Authorizations valid for 1 month)* ; **OR**
  - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
    - Patient has at least two documented episodes of spontaneous bleeding into joints; **OR**
  - Patient has documented trial and failure of Immune Tolerance Induction (ITI)

† FDA Approved Indication(s)

IV. Dispensing Requirements for Rendering Providers (Hemophilia Management Program)

- Prescriptions cannot be filled without an expressed need from the patient, caregiver or prescribing practitioner. Auto-filling is not allowed.
- Monthly, rendering provider must submit for authorization of dispensing quantity before delivering factor product. Information submitted must include:
  - Original prescription information, requested amount to be dispensed, vial sizes available to be ordered from the manufacturer, and patient clinical history (including patient product inventory and bleed history)
  - Factor dose should not exceed +1% of the prescribed dose and a maximum of three vials may be dispensed per dose. If unable to provide factor dosing within the required threshold, below the required threshold, the lowest possible dose able to be achieved above +1% should be dispensed. Prescribed dose should not be increased to meet assay management requirements.
- The cumulative amount of medication(s) the patient has on-hand should be taken into account when dispensing factor product. Patients should not have more than 5 extra doses on-hand for the treatment of acute bleeding episodes.
- Dispensing requirements for renderings providers are a part of the hemophilia management program. This information is not meant to replace clinical decision making when initiating or modifying medication therapy and should only be used as a guide.

V. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash); thromboembolic events (thromboembolism, pulmonary embolism); development of neutralizing antibodies (inhibitors), etc.; **AND**
- Any increases in dose must be supported by an acceptable clinical rationale (i.e. weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy, etc.); **AND**
- The cumulative amount of medication(s) the patient has on-hand will be taken into account when authorizing. The authorization will allow up to 5 doses on-hand for the treatment of acute bleeding episodes as needed for the duration of the authorization; **AND**

Treatment of acute bleeding episodes/Treatment of Spontaneous and trauma-induced bleeding episodes/On-demand treatment of bleeding episodes

- Renewals will be approved for a 6 month authorization period

Prevention of acute bleeding episodes/Routine prophylaxis to prevent or reduce the frequency of bleeding episode

- Renewals will be approved for a 12 month authorization period

Dosage/Administration

Indication	Dose
Control and prevention of bleeding Congenital Hemophilia A / Hemophilia B with inhibitors	Joint hemorrhage 50—100 units/kg IV every 12 hours until pain and acute disabilities are improved Mucous Membrane Bleeding 50—100 units/kg IV every 6 hours for at least 1 day or until bleeding is resolved Soft tissue hemorrhage 100 units/kg IV every 12 hours until resolution of bleeding Other severe hemorrhage 100 units/kg IV every 6—12 hours until resolution of bleed
Routine Prophylaxis Congenital Hemophilia A/ Hemophilia B with inhibitors	85 units/kg IV every other day
Perioperative management Congenital Hemophilia A /	50—100 units/kg IV administered as a 1 time dose immediately prior to surgery OR

Indication	Dose
Hemophilia B with inhibitors	50 – 100 units/kg IV administered every 6 – 12 hours postoperatively until resolution of bleed and healing is achieved

VI. Billing Code/Availability Information

Jcode & NDC:

Drug	Manufacturer	J-Code	1 Billable Unit Equiv.	Vial Size	NDC
Feiba NF	Baxalta US Inc	J7198	1 IU	500 units	64193-0426-xx
				1000 units	64193-0424- xx
				2500 units	64193-0425- xx
Feiba VH	Baxalta US Inc	J7198	1 IU	500 units	64193-0222- xx
				1000 units	64193-0222- xx
				2500 units	64193-0222- xx

VII. References

1. Fieba [package insert]. Westlake Village, CA; Baxalta US Inc. December 2018. Accessed February 2019.
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3. Guidelines for the Management of Hemophilia. 2nd Edition. World Federation of Hemophilia. 2013. Available at: https://www1.wfh.org/publication/files/pdf-1472.pdf. Accessed June 2017.
4. First Coast Service Options, Inc. Local Coverage Determination (LCD): Hemophilia Clotting Factors (L33684). Centers for Medicare & Medicaid Services, Inc. Updated on 01/03/2017 with effective date 01/01/2017. Accessed June 2017.
5. Novitas Solutions, Inc. Local Coverage Determination (LCD): Hemophilia Clotting Factors (L35111). Centers for Medicare & Medicaid Services, Inc. Updated on 01/06/2017 with effective date 01/01/2017. Accessed June 2017.
6. Annual Review of Factor Replacement Products. Oklahoma Health Care Authority Review Board. Updated April 2016. Access June 2016.
7. Graham A1, Jaworski K. Pharmacokinetic analysis of anti-hemophilic factor in the obese patient. Haemophilia. 2014 Mar;20(2):226-9.
8. Croteau SE1, Neufeld EJ. Transition considerations for extended half-life factor products. Haemophilia. 2015 May;21(3):285-8.
9. Mingot-Castellano, et al. Application of Pharmacokinetics Programs in Optimization of Haemostatic Treatment in Severe Hemophilia a Patients: Changes in Consumption, Clinical Outcomes and Quality of Life. Blood. 2014 December; 124 (21).

10. MASAC RECOMMENDATION CONCERNING PROPHYLAXIS. 2016 National Hemophilia Foundation. MASAC Document #241; February 2016. Available at: http://www.hemophilia.org. Accessed August 2017.
11. First Coast Service Options, Inc. Local Coverage Determination (LCD): Hemophilia Clotting Factors (L33684). Centers for Medicare & Medicaid Services, Inc. Updated on 01/04/2019 with effective date 01/01/2019. Accessed February 2019.
12. Novitas Solutions, Inc. Local Coverage Determination (LCD): Hemophilia Clotting Factors (L35111). Centers for Medicare & Medicaid Services, Inc. Updated on 01/19/2018 with effective date 01/01/2018. Accessed February 2019.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
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):

Jurisdiction(s): H,L	NCD/LCD Document (s): L35111
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L35111&bc=gAAAAAAAAAAAAA==	

Jurisdiction(s): N	NCD/LCD Document (s): L33684
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L33684&bc=gAAAAAAAAAAAAA==	

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 Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, 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