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

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I. Length of Authorization

Coverage is provided for 3 months and may be renewed thereafter, unless otherwise specified*

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) [NDC unit]:

- Feiba 500 IU (Orange) single-dose vial: 293 vials per 30-day supply
- Feiba 1000 IU (Green) single-dose vial: 147 vials per 30-day supply
- Feiba 2500 IU (Purple) single-dose vial: 59 vials per 30-day supply

B. Max Units (per dose and over time) [HCPCS Unit]:

- 146,625 billable units per 30 day supply

III. Initial Approval Criteria [1-3,7-10]

Coverage is provided in the following conditions:

Hemophilia A (congenital factor VIII deficiency) † Φ

- 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) † Φ

- 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); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

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 [1-3,7]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash, etc.), thromboembolic events (venous thrombosis, pulmonary embolism, myocardial infarction, stroke, etc.), 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**

Control and prevention of acute bleeding episodes

- Renewals will be approved for a 6 month authorization period

Perioperative management of surgical bleeding

- Coverage may NOT be renewed

Routine prophylaxis to prevent or reduce the frequency of bleeding episodes

- Renewals will be approved for a 12 month authorization period; **AND**
- Patient has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline)

Dosage/Administration[1-3]

Indication	Dose
Control and prevention of bleeding Congenital Hemophilia A / Hemophilia B with inhibitors	Joint hemorrhage Administer 50—100 units/kg IV every 12 hours until pain and acute disabilities are improved Mucous Membrane Bleeding Administer 50—100 units/kg IV every 6 hours for at least 1 day or until bleeding is resolved Soft tissue hemorrhage Administer 100 units/kg IV every 12 hours until resolution of bleed

Indication	Dose
	Other severe hemorrhage Administer 100 units/kg IV every 6—12 hours until resolution of bleed
Routine Prophylaxis Congenital Hemophilia A/ Hemophilia B with inhibitors	Administer 85 units/kg IV every other day
Perioperative management Congenital Hemophilia A / Hemophilia B with inhibitors	Preoperative Administer 50—100 units/kg IV administered as a 1 time dose immediately prior to surgery Postoperative Administer 50 – 100 units/kg IV administered every 6 – 12 hours postoperatively until resolution of bleed and healing is achieved

VI. Billing Code/Availability Information

HCPCS Code & NDC:

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

VII. References

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12. Palmetto GBA. Local Coverage Article: Billing and Coding: Guidance for Anti-Inhibitor Coagulant Complex (AICC) National Coverage Determination (NCD) 110.3 (A56065). Centers for Medicare & Medicaid Services Inc. Updated on 11/14/2022 with effective date 11/24/2022. Accessed May 2023.
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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), Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/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/LCA):

Jurisdiction(s): J,M	NCD/LCD Document (s): A56065
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a56065&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

Jurisdiction(s): H,L	NCD/LCD Document (s): A56433
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a56433&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

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.
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