Neighborhood Health Plan OF RHODE ISLAND™
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Hemophilia Products – Anti-Inhibitor Coagulant Complex: Feiba NF/Feiba VF
(Intravenous)

Effective date: 01/01/2020

Review date: 10/02/2019, 12/18/19, 1/22/20, 06/24/2021, 06/16/2022, 6/22/2023, 12/07/2023, 01/04/2024, 08/14/2024

Scope: Medicaid*, Commercial*, Medicare-Medicaid Plan (MMP)
***(Medication only available on the Medical Benefit)**

I. Length of Authorization

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

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):

- Feiba 500 IU (Orange) vial: 274vials per 28-day supply
- Feiba 1000 IU (Green) vial: 137 vials per 28-day supply
- Feiba 2500 IU (Purple) vial: 55 vials per 28-day supply

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

136.850 billable units per 28 day supply

III. Summary of Evidence

Feiba is an anti-inhibitor coagulant complex indicated for use in hemophilia A and B with inhibitors for control and prevention of bleeding episodes, perioperative management and routine prophylaxis to prevent/reduce bleeding episode frequency. Efficacy was demonstrated through a multicenter, randomized prospective trial which enrolled 44 subjects with Hemophilia A with inhibitors, 3 hemophilia B subjects with inhibitors and 2 acquired factor VIII inhibitor subjects. It was designed to evaluate the efficacy of Feiba in the treatment of joint, mucous membrane, musculocutaneous and emergency bleeding episodes such as central nervous system hemorrhages and surgical bleedings. Subjects were treated with 50 units/kg at 12-hour intervals. Bleeds were controlled in 93% of episodes with 78% of the episodes having hemostasis achieved with one or more infusions within 36 hours. The most common adverse reactions observed in >5% of subjects were anemia, diarrhea, hemarthrosis, hepatitis B surface antibody positive, nausea, and vomiting. The serious adverse drug reactions are hypersensitivity and thromboembolic events, including stroke, pulmonary embolism, and deep vein thrombosis.

IV. Initial Approval Criteria

- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Hemophilia A (congenital factor VIII deficiency) † Φ

- Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing; **AND**
- Patient has inhibitors to Factor VIII with a current or historical titer of ≥ 5 Bethesda Units (BU)****; 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**
    - Used as primary prophylaxis in patients with severe factor VIII deficiency (factor VIII level of <1%); **OR**
    - Used as secondary prophylaxis in patients with 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 Hemlibra (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**
- Patient has inhibitors to Factor IX with a current or historical titer of ≥ 5 Bethesda Units (BU)****; 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**
    - Used as primary prophylaxis in patients with severe factor IX deficiency (factor VIII level of <1%); **OR**
    - Used as secondary prophylaxis in patients with at least TWO documented episodes of spontaneous bleeding into joints; **OR**
  - Patient has documented trial and failure of Immune Tolerance Induction (ITI)

*****Note:** Patients with inhibitor titer levels >0.6 BU to <5 BU who are not responding to or are not a candidate for standard factor replacement, will be evaluated on a case-by-case basis.*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

V. 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.

VI. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria identified in section IV; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hypersensitivity reactions (severe anaphylactoid reactions, urticaria, angioedema, gastrointestinal manifestations, bronchospasm, etc.), embolic and thromboembolic events (venous thrombosis, pulmonary embolism, myocardial infarction, stroke, 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 episode

- 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

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 for Congenital Hemophilia A/ Hemophilia B with inhibitors	85 units/kg IV every other day
Perioperative management ofCongenital Hemophilia A / Hemophilia B with inhibitors	50-100 units/kg IV administered as a onetime dose immediately prior to surgery OR 50 - 100 units/kg IV administered every 6 – 12 hours postoperatively until resolution of bleed and healing is achieved

VII. Billing Code/Availability Information

HCPCS Code & NDC:

Drug	Manufacturer	J-Code	1 Billable Unit Equiv.	Vial Size	NDC
Feiba NF		J7198	1 IU	500 units	64193-0426-xx
				1000 units	64193-0424- xx

	Takeda Pharmaceuticals U.S.A., Inc			2500 units	64193-0425- xx

VIII. References

1. Feiba [package insert]. Takeda Pharmaceuticals U.S.A., Inc.. March 2024. AccessedApril 2024.
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3. Guidelines for the Management of Hemophilia. 3rd Edition. World Federation of Hemophilia. 2020. Available at: https://www1.wfh.org/publications/files/pdf-1863.pdf Accessed April 2024.
4. Annual Review of Factor Replacement Products. Oklahoma Health Care Authority Review Board. Updated April 2016. Access June 2016.
5. Graham A1, Jaworski K. Pharmacokinetic analysis of anti-hemophilic factor in the obese patient. Haemophilia. 2014 Mar;20(2):226-9.
6. Croteau SE1, Neufeld EJ. Transition considerations for extended half-life factor products. Haemophilia. 2015 May;21(3):285-8.
7. 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).
8. MASAC Recommendation Concerning Prophylaxis for Hemophilia A and B with and without Inhibitors. Revised April 27, 2022. National Hemophilia Foundation. MASAC Document #267; April 2022. Available at: https://www.bleeding.org/healthcare-professionals/guidelines-on-care/masac-documents/masac-document-267-masac-recommendation-concerning-prophylaxis-for-hemophilia-a-and-b-with-and-without-inhibitors. Accessed April
9. Hoots, WK. (2024). Hemophilia A and B: Routine management including prophylaxis. In Leung LLK, Tirnauer JS (Eds.), *UptoDate*. Last updated: April 16, 2024. Accessed May 13, 2024. Available from https://www.uptodate.com/contents/hemophilia-a-and-b-routine-management-including-prophylaxis?search=hemophilia%20a&source=search_result&selectedTitle=2~150&usage_type=default&display_rank=2#H978189854
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11. 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 April 2024.
12. Novitas Solutions, Inc. Local Coverage Article: Billing and Coding: Hemophilia Factor Products (A56433). Centers for Medicare & Medicaid Services Inc. Updated on 09/29/2023 with effective date 10/01/2023. Accessed April 2024.

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)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes		
Jurisdiction	**NCD/LCA/LCD Document (s)**	**Contractor**
J, M	A56065	Palmetto GBA
H, L	A56433	Novitas Solutions, Inc.
N	A56482	First Coast Service Options, Inc.

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

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Policy Rationale:

Feiba NF/VF were reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Feiba NF/VF according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.