

Hemophilia Products – Anti-Inhibitor Coagulant Complex:

Feiba

(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, 09/17/2025

Scope: Medicaid*, Commercial*, Medicare

*(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. 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, musculoskeletal 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

- Medicare 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**

- Member has inhibitors to Factor VIII with a current or historical titer of ≥ 5 Bethesda Units (BU)**;
AND
- Will NOT be used in combination with another agent used as prophylactic therapy for Hemophilia A*** See chart below; **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 members with severe factor VIII deficiency (factor VIII level of $<1\%$); **OR**
 - Used as secondary prophylaxis in members with at least TWO documented episodes of spontaneous bleeding into joints; **OR**
 - Member has a documented trial and failure of Immune Tolerance Induction (ITI); **AND**
 - Member 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**
- Member has inhibitors to Factor IX with a current or historical titer of ≥ 5 Bethesda Units (BU)**; **AND**
- Will NOT be used in combination with another agent used as prophylactic therapy for Hemophilia B***
***see chart below; **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 members with severe factor IX deficiency (factor VIII level of $<1\%$); **OR**
 - Used as secondary prophylaxis in members with at least TWO documented episodes of spontaneous bleeding into joints; **OR**
 - Member has documented trial and failure of Immune Tolerance Induction (ITI)

****Note:** Members 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.

***** Drugs to treat Hemophilia A or B**

Hemophilia A & B Drug Chart	
Factor VIIa (Hemophilia A or B)	
Novoseven RT	J7189
Sevenfact	J7212
Anti-Inhibitor Coagulant Complex (Hemophilia A or B)	
Feiba	J7198
Factor VIII (Hemophilia A)	
Advate	J7192
Kogenate FS	J7192
Helixate FS	J7192
Recombinate	J7192
Kovaltry	J7211
Eloctate	J7205
Koate / Koate-DVI	J7190
Hemofil M	J7190
Novoeight	J7182
Nuwiq	J7209
Obizur	J7188
Xyntha / Xyntha Solofuse	J7185
Afstyla	J7210
Adynovate	J7207
Jivi	J7208
Esperoct	J7204

Altuviiiio	J7214
Factor IX (Hemophilia B)	
AlphaNine SD	J7193
Mononine	J7193
Alprolix	J7201
Profilnine	J7194
BeneFIX	J7194
Ixinity	J7213
Rixubis	J7200
Idelvion	J7202
Rebinyn	J7203

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

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

- Prescriptions cannot be filled without an expressed need from the member, 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 member clinical history (including member 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 member has on-hand should be taken into account when dispensing factor product. Members 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:

- Member 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 member is fully adherent to therapy, etc.); **AND**
- The cumulative amount of medication(s) the member 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**
- Member 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 acute bleeding for Congenital Hemophilia A / Hemophilia B with inhibitors	<u>Joint hemorrhage</u> 50-100 units/kg IV every 12 hours until pain and acute disabilities are improved
	<u>Mucous Membrane Bleeding</u> 50-100 units/kg IV every 6 hours for at least 1 day or until bleeding is resolved
	<u>Soft tissue hemorrhage</u> 100 units/kg IV every 12 hours until resolution of bleeding
	<u>Other severe hemorrhage</u> 100 units/kg IV every 6-12 hours until resolution of bleed
Routine Prophylaxis for Congenital Hemophilia A/	85 units/kg IV every other day

Indication	Dose
Hemophilia B with inhibitors	
Perioperative management for Congenital 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	Takeda Pharmaceuticals U.S.A., Inc	J7198	1 IU	500 units	64193-0426-xx
				1000 units	64193-0424- xx
				2500 units	64193-0425- xx

VIII. References

1. Feiba [package insert]. Takeda Pharmaceuticals U.S.A., Inc.. December 2024. Accessed May 2024.
2. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. Revised April 11, 2024. National Hemophilia Foundation. MASAC Document #284, April 2024. Available at: <https://www.bleeding.org>. Accessed April 2024.
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
10. First Coast Service Options, Inc. Local Coverage Article: Billing and Coding: Hemophilia Clotting Factors (A56482). Centers for Medicare & Medicaid Services Inc. Updated on 09/29/2023 with effective date 10/01/2023. Accessed April 2024.
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.

Medicare Part B Covered Diagnosis Codes		
Jurisdiction	NCD/LCA/LCD Document (s)	Contractor
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
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 Medicare 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.