Clinical Policy: Anti-Inhibitor Coagulant Complex, Human (Feiba)

Reference Number: CP.PHAR.217
Effective Date: 05.01.16
Last Review Date: 02.25
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Anti-inhibitor coagulant complex, human (Feiba®) is a human plasma fraction with factor VIII inhibitor bypassing activity. It contains mainly non-activated factors II, IX, and X and activated factor VII.

FDA Approved Indication(s)

Feiba is indicated for use in hemophilia A and B patients with inhibitors for:

- Control and prevention of bleeding episodes;
- Perioperative management;
- Routine prophylaxis to prevent or reduce the frequency of bleeding episodes.

Limitation(s) of use: Feiba is not indicated for the treatment of bleeding episodes resulting from coagulation factor deficiencies in the absence of inhibitors to coagulation factor VIII or coagulation factor IX.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Feiba is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Hemophilia A or B with Inhibitors (must meet all)**:**

1. Diagnosis of hemophilia A or B with inhibitors;
2. Prescribed by or in consultation with a hematologist;
3. Request is for one of the following uses (a, b, or c):
   a. Control and prevention of bleeding episodes;
   b. Perioperative management;
   c. Routine prophylaxis to prevent or reduce the frequency of bleeding episodes;
4. Documentation of member's current body weight (in kg);
5. Dose does not exceed the FDA approved maximum recommended dose for the relevant indication.

Approval duration:
Surgical/acute bleeding: 3 months
Prophylaxis:
Medicaid/HIM – 6 months (*12 months for HIM Texas*)

Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Hemophilia A or B with Inhibitors (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. Documentation of member's current body weight (in kg);
4. If request is for a dose increase, new dose does not exceed the FDA approved maximum recommended dose for the relevant indication.

Approval duration:
Surgical/acute bleeding: 3 months
Prophylaxis:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business:

CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): history of anaphylactic or severe hypersensitivity reactions to Feiba or any of its components, including factors of the kinin generating system; disseminated intravascular coagulation; acute thrombosis or embolism (including myocardial infarction)
- Boxed warning(s): thromboembolic events

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Control and prevention of bleeding episodes	Joint hemorrhage: 50-100 units/kg IV every 12 hours Mucous membrane bleeding: 50-100 units/kg IV every 6 hours Soft tissue hemorrhage (e.g., retroperitoneal bleeding): 100 units/kg IV every 12 hours Other severe hemorrhage (e.g., central nervous system bleeds): 100 units/kg IV every 6-12 hours	200 units/kg/day

Indication	Dosing Regimen	Maximum Dose
Perioperative management	Pre-operative: 50-100 units/kg IV as a single dose Post-operative: 50-100 units/kg IV every 6-12 hours	200 units/kg/day
Routine prophylaxis	85 units/kg IV every other day	85 units/kg/2 days

VI. Product Availability

Powder for reconstitution in single-use vial: 500 units, 1,000 units, 2,500 units

VII. References

1. Feiba Prescribing Information. Westlake Village, CA: Baxter Healthcare Corporation; March 2024. Available at http://www.shirecontent.com/PI/PDFs/FEIBA_USA_ENG.pdf. Accessed November 1, 2024.
2. Srivastava A, Santagostino E, Dougall A, et al. WFH guidelines for the management of hemophilia. *Haemophilia.* 2020;26(suppl 6):1-158.
3. Medical and Scientific Advisory Council (MASAC) of the National Bleeding Disorders Foundation (formerly National Hemophilia Foundation): Database of treatment guidelines. Available at https://www.hemophilia.org/healthcare-professionals/guidelines-on-care/masac-documents. Accessed November 18, 2024.
4. Rezende SM, Neumann I, Angchaisuksiri P, et al. International Society on Thrombosis and Haemostasis clinical practice guideline for treatment of congenital hemophilia A and B based on the Grading of Recommendations Assessment, Development, and Evaluation methodology. J Thromb Haemost. 2024;22(9):2629-2652.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J7198	Anti-inhibitor, per IU

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2021 annual review: added requirement for documentation of member's current body weight for calculation of appropriate dosage; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	12.01.20	02.21
1Q 2022 annual review: no significant changes; references reviewed and updated.	11.23.21	02.22
Removed the requirement for factor VIII activity level or documentation of bleed history since inhibitors would only be	03.08.22	05.22

Reviews, Revisions, and Approvals	Date	P&T Approval Date
present after previous use of factor VIII products, and substantiation of severe disease is not necessary.		
Template changes applied to other diagnoses/indications and continued therapy section.	10.05.22	
1Q 2023 annual review: no significant changes; references reviewed and updated.	11.09.22	02.23
Extended initial and continued authorization durations for hemophilia prophylaxis from 6 months to 12 months for HIM Texas.	08.28.23	
1Q 2024 annual review: no significant changes; references reviewed and updated.	10.29.23	02.24
1Q 2025 annual review: for Medicaid and HIM lines of business, continued approval duration revised from 6 months to 12 months for prophylaxis; for Commercial line of business, all prophylaxis approval durations revised to "6 months or to the member's renewal date, whichever is longer;" references reviewed and updated.	11.01.24	02.25

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan

retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.