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

Reference Number: ERX.SPA.186
Effective Date: 01.11.17
Last Review Date: 05.22
Line of Business: Commercial, Medicaid

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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: 3 months (bleeding episodes/surgery) or 6 months (prophylaxis)

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
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: 3 months (bleeding episodes/surgery) or 6 months (prophylaxis)

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – ERX.PA.01 or evidence of coverage documents.

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

Appendix D: General Information
- Life-threatening bleeding episodes include, but are not limited to, bleeds in the following sites: intracranial, neck/throat, or gastrointestinal.
- Serious bleeding episodes include bleeds in the following site: joints (hemarthrosis).
- Spontaneous bleed is defined as a bleeding episode that occurs without apparent cause and is not the result of trauma.

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: 100 units/kg IV every 6-12 hours	200 units/kg/day
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, 1,000, 2,500 units

VII. References

1. Feiba Prescribing Information. Westlake Village, CA: Baxalta US Inc.; February 2020. Available at: www.feiba.com. Accessed November 23, 2021.
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 Hemophilia Foundation (NHF): Database of treatment guidelines. Available at https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-Scientific-Advisory-Council-MASAC/MASAC-Recommendations. Accessed December 1, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q18 annual review: Added efficacy statement to renewal criteria.	11.28.17	02.18
1Q 2019 annual review: no significant changes; references reviewed and updated.	09.26.18	02.19
1Q 2020 annual review: no significant changes; references reviewed and updated.	11.27.19	02.20
Added routine prophylaxis-specific requirement for severe hemophilia classification or at least one life-threatening or serious spontaneous bleed for classification of non-severe hemophilia; added requirement for prescriber attestation of not partaking in contact sports.	05.28.20	08.20
Removed requirement for prescriber attestation of not partaking in contact sports.	10.01.20	11.20
1Q 2021 annual review: added requirement for documentation of member's current body weight for calculation of appropriate dosage; 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 present after previous use of factor VIII products, and substantiation of severe disease is not necessary.	03.08.22	05.22

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.