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

Reference Number: PA.CP.PHAR.217
Effective Date: 01/18
Last Review Date: 01/19

Coding Implications
Revision Log

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
It is the policy of Pennsylvania Health and Wellness 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. Prescribed by or in consultation with a hematologist;
2. Diagnosis of hemophilia A or B with inhibitors;
3. Request is for any 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. 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: Refer to PA.CP.PMN.53

II. Continued Approval

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy.
3. 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)
6 months (routine prophylaxis)

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to PA.CP.PMN.53

Background

Description/Mechanism of Action:
Feiba (anti-inhibitor coagulant complex) is a freeze-dried sterile human plasma fraction with factor VIII inhibitor bypassing activity. One unit of activity is defined as that amount of Feiba that shortens the activated partial thromboplastin time (aPTT) of high titer factor VIII inhibitor reference plasma to 50% of the blank value. Multiple interactions of the components in Feiba restore the impaired thrombin generation of hemophilia patients with inhibitors.

III. 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

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Control and prevention of	Joint hemorrhage: 50-100 units/kg IV every 12 hours	200 units/kg/day

Indication	Dosing Regimen	Maximum Dose
bleeding episodes	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	
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

V. Product Availability

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

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	Antiinhibitor, per IU

Reviews, Revisions, and Approvals	Date	Approval Date
Dose guidelines delineated. References reviewed and updated.	02/18	
1Q 2019 annual review: removed “congenital” as this is not specified in the FDA-approved indication and patients with acquired disease were included in clinical trials; references reviewed and updated.	01/19	

References

1. Feiba Prescribing Information. Westlake Village, CA: Baxter Healthcare Corporation; April 2018. Available at http://www.shirecontent.com/PI/PDFs/FEIBA_USA_ENG.pdf. Accessed November 7, 2018.
2. Srivastava A, Brewer AK, Mauser-Bunschoten EP, et al. Guidelines for the management of hemophilia. Haemophilia. Jan 2013; 19(1): e1-47.
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 September 26, 2018.