

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

Reference Number: PA.CP.PHAR.217

Effective Date: 01/18

Last Review Date: 05/17

Coding Implications
Revision Log

Description

The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness[®] clinical policy for anti-inhibitor coagulant complex (Feiba[®]).

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. Congenital Hemophilia A and B (must meet all):
 - 1. Prescribed by or in consultation with a hematologist;
 - 2. Diagnosis of congenital hemophilia A (factor VIII deficiency) or B (factor IX deficiency) with inhibitors (antibodies to factor VIII or IX);
 - 3. Request is for any of the following:
 - a. Control and prevention of bleeding episodes;
 - b. Perioperative management;
 - c. Routine prophylaxis to prevent or reduce the frequency of bleeding episodes.

Approval duration: 3 months (bleeding episodes/surgery) 6 months (routine prophylaxis)

B. Other diagnoses/indications: Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

II. Continued Approval

- A. Congenital Hemophilia A and B (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.

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.PHAR.57 - Global Biopharm Policy.

CLINICAL POLICY Anti-Inhibitor Coagulant Complex



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.

Formulations (from human plasma):

Solution Reconstituted, Intravenous

• Feiba: 500; 1000; 2500 (units)

FDA Approved Indications:

Feiba is an anti-inhibitor coagulant complex/intravenous formulation indicated for:

- Use in hemophilia A and B patients with inhibitors for:
 - o Control and prevention of bleeding episodes;
 - o Perioperative management;
 - o Routine prophylaxis to prevent or reduce the frequency of bleeding episodes.

Limitations 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.

Appendices

Appendix A: Abbreviation Key

aPTT: activated partial thromboplastin time

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

References

 Feiba Prescribing Information. Westlake Village, CA: Baxter Healthcare Corporation; November 2013. Accessed April 4, 2017. Available at http://www.shirecontent.com/PI/PDFs/FEIBA_USA_ENG.pdf. Accessed April 26, 2017

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- 2. Prothrombin complex concentrate, activated, from human plasma (factor eight inhibitor bypassing activity [FEIBA]): Drug Information (Lexicomp). In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Available at uptodate.com. Accessed April 26, 2017.
- 3. Srivastava A, Brewer AK, Mauser-Bunschoten EP, et al. Guidelines for the management of hemophilia. Haemophilia. Jan 2013; 19(1): e1-47.
- 4. 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 April 28, 2017.