

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

Reference Number: LA.PHAR.217

Effective Date:

Last Review Date: 06.21

Line of Business: 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

Prior authorization is required. 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 Louisiana Healthcare Connections 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. **For routine prophylaxis requests, member meets one of the following (a or b):**
 - a. **Member has severe hemophilia (defined as factor level of < 1%);**
 - b. **Member has experienced at least one life-threatening or serious spontaneous bleed (see Appendix D);**
5. **Documentation of member's current body weight (in kg);**

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6. 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 the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Louisiana Healthcare Connections benefit 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 Louisiana Healthcare Connections benefit and documentation supports positive response to therapy.
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.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 – LA.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)

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- 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

<u>Indication</u>	<u>Dosing Regimen</u>	<u>Maximum Dose</u>
<u>Control and prevention of bleeding episodes</u>	<u>Joint hemorrhage: 50-100 units/kg IV every 12 hours</u> <u>Mucous membrane bleeding: 50-100 units/kg IV every 6 hours</u> <u>Soft tissue hemorrhage (e.g., retroperitoneal bleeding): 100 units/kg IV every 12 hours</u> <u>Other severe hemorrhage: 100 units/kg IV every 6-12 hours</u>	<u>200 units/kg/day</u>
<u>Perioperative management</u>	<u>Pre-operative: 50-100 units/kg IV as a single dose</u> <u>Post-operative: 50-100 units/kg IV every 6-12 hours</u>	<u>200 units/kg/day</u>
<u>Routine prophylaxis</u>	<u>85 units/kg IV every other day</u>	<u>85 units/kg/2 days</u>

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; February 2020. Available at http://www.shirecontent.com/PI/PDFs/FEIBA_USA_ENG.pdf. Accessed December 1, 2020.
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 December 1, 2020.

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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.

<u>HCPCS Codes</u>	<u>Description</u>
J7198	Anti-inhibitor, per IU

<u>Reviews, Revisions, and Approvals</u>	<u>Date</u>
<u>Converted corporate to local policy</u>	<u>06.2021</u>

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. LHCC 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.

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 LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. 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. LHCC

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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.

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