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

Reference Number: CP.PHAR.217
Effective Date: 05.01.16
Last Review Date: 02.18
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 an anti-inhibitor coagulant complex/intravenous formulation 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.

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Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) 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. Congenital Hemophilia A and B (must meet all):

1. Diagnosis of congenital hemophilia A (factor VIII deficiency) or B (factor IX deficiency) with inhibitors (antibodies to factor VIII or IX);
2. Prescribed by or in consultation with a hematologist;
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;
4. Dose does not exceed the FDA approved maximum recommended dose for the relevant indications.

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

B. Other diagnoses/indications

1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Congenital Hemophilia A and B (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
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 indications.

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

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to CP.PMN.53 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 – CP.PMN.53 or evidence of coverage.

IV. Appendices/General Information

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

Appendix B: Therapeutic Alternatives
Not Applicable

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	400 units/kg/day

Indication	Dosing Regimen	Maximum Dose
	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	400 units/kg/day
Routine prophylaxis	85 units/kg IV every other day	85 units/kg/dose

VI. Product Availability

Vial: 500, 1000, 2500 units

VII. References

1. Feiba Prescribing Information. Westlake Village, CA: Baxter Healthcare Corporation; April 2017. Available at http://www.shirecontent.com/PI/PDFs/FEIBA_USA_ENG.pdf. Accessed November 28, 2017
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 November 28, 2017.

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	P&T Approval Date
Policy split from CP.PHAR.12.Blood Factors and converted to new template. Removed requests for documentation. Dosing details removed. Approval period for non-prophylactic use is edited to provide 3 months on initial approval and one 3-month re-auth; approval period for prophylactic use is added at 6 months initial/6 months continuing therapy. Reviewed by specialist.	04.01.16	05.16

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Safety information removed. Wording for uses made consistent across all blood factor policies. Approval periods across all blood factor policies are worded as follows: 3 months (bleeding episodes/surgery); 6 months (routine prophylaxis). Efficacy statement added to renewal criteria. Hemophilias are specified as "congenital" versus "acquired" across blood factor policies where indicated. Reviewed by specialist-hematology/internal medicine.	04.01.17	05.17
1Q18 annual review: - No significant changes - Converted to new template - References reviewed and updated.	11.28.17	02.18

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.