Drug Coverage Policy

Effective Date 5/15/2024
Coverage Policy Number.....IP0354
Policy Title.....FEIBA

Hemophilia – FEIBA

- Hemophilia – FEIBA® (anti-inhibitor coagulant complex intravenous infusion – Baxalta/Takeda)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Medical Necessity Criteria

FEIBA is considered medically necessary when the following criteria are met:

1. **Hemophilia A with inhibitors.** Individual meets **ALL** of the following criteria:
   A. **ONE** of the following:
      i. Positive inhibitor titer at least 5 Bethesda Units or greater
      ii. History of an inhibitor with anamnestic response to Factor VIII replacement therapy, which, according to the prescriber, precludes the use of Factor VIII replacement to treat bleeding episodes

iii. History of an inhibitor with refractory hemostatic response to increased Factor VIII dosing, which, according to the prescriber, precludes the use of Factor VIII replacement to treat bleeding episodes

B. Medication is prescribed by or in consultation with a hematologist

Dosing. Up to a maximum of 2,390 units/kg intravenously per 28 days

2. **Hemophilia B with inhibitors** Individual meets **ALL** of the following criteria:
   A. **ONE** of the following:
      i. Positive inhibitor titer at least 5 Bethesda Units or greater
      ii. History of an inhibitor with anamnestic response to Factor IX replacement therapy, which, according to the prescriber, precludes the use of Factor IX replacement to treat bleeding episodes
      iii. History of an inhibitor with refractory hemostatic response to increased Factor IX dosing, which, according to the prescriber, precludes the use of Factor IX replacement to treat bleeding episodes
   B. Medication is prescribed by or in consultation with a hematologist

Dosing. Up to a maximum of 2,390 units/kg intravenously per 28 days

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Reauthorization Criteria

Continuation of FEIBA (anti-inhibitor coagulant complex intravenous infusion) is considered medically necessary for **ALL** covered diagnoses when initial criteria are met AND there is demonstration of beneficial response

Authorization Duration

Initial and reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Coding Information

1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J7198	Antiinhibitor, per IU

Background

OVERVIEW
FEIBA, a human plasma fraction with Factor VIII bypassing activity, is indicated for use in **hemophilia A and B patients with inhibitors** for control and prevention of bleeding episodes, perioperative management, and routine prophylaxis to prevent or reduce the frequency of bleeding episodes.[1] It contains both activated and inactivated forms of Factors II, VII, IX, and X and is thus referred to as activated prothrombin complex concentrate (aPCC).[1,2] FEIBA is produced from pooled human plasma.[1]

Guidelines
Regarding **hemophilia A with inhibitors** and **hemophilia B with inhibitors** (without history of anaphylaxis/allergy to Factor IX), World Federation of Hemophilia guidelines (2020) support aPCC for patients with high-titer inhibitors who require acute treatment or around surgery/invasive procedures.[3] For low-titer inhibitors, Factor VIII or IX replacement may be used. These products may also be used for patients with a history of a high-titer inhibitor whose titer has fallen to low or undetectable levels. However, once an anamnestic response occurs, further treatment with Factor replacement is typically no longer effective, and bypass agent therapy (e.g., aPCC) is needed. National Bleeding Disorders Foundation Medical and Scientific Advisory Council (MASAC) guidelines (updated August 2023) have similar recommendations: treatment for patients with inhibitors depends on multiple factors, including type of inhibitor (high- or low-responding), current titer, location of bleed, and previous response.[2]

Dosing Information
Dosing of clotting factor concentrates is highly individualized. MASAC provides recommendations regarding doses of clotting factor concentrate in the home (2016).[4] The number of required doses varies greatly and is dependent on the severity of the disorder and the prescribed regimen. Per MASAC guidance, patients on prophylaxis should also have a minimum of one major dose and two minor doses on hand for breakthrough episodes in addition to the prophylactic doses used monthly. The guidance also notes that an adequate supply of clotting factor concentrate is needed to accommodate weekends and holidays. Therefore, maximum doses in this policy allow for prophylactic dosing plus three days of acute episodes or perioperative management per 28 days. Doses exceeding this quantity will be reviewed on a case-by-case basis by a clinician.

Dosing considerations for individual indications are as follows:

- **Hemophilia A with Inhibitors** and **Hemophilia B with Inhibitors:** For routine prophylaxis, a dose of 85 units/kg every other day is recommended.[1] Dosing for acute episodes and perioperative management can range up to 100 units/kg every 6 hours (400 units/kg daily dose).

References

1. FEIBA® intravenous infusion [prescribing information]. Lexington, MA: Baxalta/Takeda; March 2023.
2. National Bleeding Disorders Foundation. MASAC (Medical and Scientific Advisory Council) recommendations concerning products licensed for the treatment of hemophilia and selected disorders of the coagulation system (August 2023). MASAC Document #280. Available at:

https://www.hemophilia.org/sites/default/files/document/files/MASAC-Products-Licensed.pdf. Accessed on November 5, 2023.
3. Srivastava A, Santagostino E, Dougall A, et al. WFH guidelines for the management of hemophilia, 3rd edition. *Haemophilia*. 2020;26 Suppl 6:1-158.
4. MASAC (Medical and Scientific Advisory Council) recommendations regarding doses of clotting factor concentrate in the home. MASAC Document #242. Adopted on June 7, 2016. Available at: https://www.hemophilia.org/sites/default/files/document/files/242.pdf. Accessed on November 8, 2023.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	No criteria changes	5/15/2024

The policy effective date is in force until updated or retired.