

FEIBA® (anti-inhibitor coagulant complex)

When requesting Feiba, the individual requiring treatment must be diagnosed with one of the following FDA-approved indications or approved off-label compendial use and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-Approved Indications

Feiba is an anti-inhibitor coagulant complex 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.

Approved Off-label Compendial Use

Treatment of bleeding episodes in individuals with acquired hemophilia A

Coverage Guidelines

Hemophilia A with Inhibitors

The individual must meet the following criteria for authorization:

1. Meets **one** of the following:
 - a. Has a positive inhibitor titer of greater than or equal to 5 Bethesda Units; OR
 - b. Has a history of an inhibitor with anamnestic response to Factor VIII replacement therapy, which precludes the use of Factor VIII replacement to treat bleeding episodes; OR
 - c. Has a history of an inhibitor with refractory hemostatic response to increased Factor VIII dosing, which precludes the use of Factor VIII replacement to treat bleeding episodes;
2. FEIBA is prescribed by or in consultation with a hemophilia specialist.

Hemophilia B with inhibitors

The individual must meet the following criteria for authorization:

1. Meets **one** of the following:
 - a. Has a positive inhibitor titer of greater than or equal to 5 Bethesda Units; OR
 - b. Has a history of an inhibitor with anamnestic response to Factor IX replacement therapy, which precludes the use of Factor IX replacement to treat bleeding episodes; OR

- c. Has a history of an inhibitor with refractory hemostatic response to increased Factor IX dosing, which precludes the use of Factor IX replacement to treat bleeding episodes;
2. FEIBA is prescribed by or in consultation with a hemophilia specialist.

Acquired Hemophilia A

The individual must meet **BOTH** of the following criteria for authorization:

1. The request is for treatment of bleeding episodes;
2. FEIBA is prescribed by or in consultation with a hemophilia specialist.

Approval duration: 12 months

Dosing Recommendations

For intravenous use only

Type of Bleeding	Dose (unit/kg)	Frequency/Duration
Control and prevention of bleeding	50-100	Determined by the type of bleeding episode
Perioperative management	50-100	Determined by the type of surgical intervention
Routine prophylaxis	85	Every other day

References

1. FEIBA® intravenous infusion [prescribing information]. Lexington, MA: Baxalta/Takeda; December 2024.
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 #290. Available at: <https://www.hemophilia.org/sites/default/files/document/files/MASAC-Products-Licensed.pdf>. Accessed on December 7, 2025.
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 December 7, 2025.