

### Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Feiba under the patient's prescription drug benefit.

### **Description:**

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

- A. <u>FDA-Approved Indication</u> Hemophilia A and hemophilia B with inhibitors
- B. <u>Compendial Use</u> Acquired hemophilia A

All other indications are considered experimental/investigational and not medically necessary.

### **Applicable Drug List:**

Feiba

### **Policy/Guideline:**

#### **Prescriber Specialty:**

Must be prescribed by or in consultation with a hematologist.

### **Criteria for Initial Approval:**

### A. Hemophilia A with Inhibitors

Authorization of 12 months may be granted for treatment of hemophilia A with inhibitors (see Appendix) when the inhibitor titer is  $\geq$  5 Bethesda units per milliliter (BU/mL) or if the member has a history of an inhibitor titer  $\geq$  5 BU.

### **B. Hemophilia B with Inhibitors**

Authorization of 12 months may be granted for treatment of hemophilia B with inhibitors (see Appendix) when the inhibitor titer is  $\geq$  5 Bethesda units per milliliter (BU/mL) or if the member has a history of an inhibitor titer  $\geq$  5 BU.

### C. Acquired Hemophilia A

Authorization of 12 months may be granted for treatment of acquired hemophilia A.

### **Continuation of Therapy:**

AETNA BETTER HEALTH® Coverage Policy/Guideline				etna™
Name:	Feiba		Page:	2 of 2
Effective Date: 4/21/2025			Last Review Date:	3/26/2025
Applies to:	⊠Illinois ⊠Maryland	⊠Florida Kids ⊠Pennsylvania Kids	⊠New Jersey □Virginia	

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in criteria for initial approval when the member is experiencing benefit from therapy (e.g., reduced frequency or severity of bleeds).

## Appendix:

## Appendix: Inhibitors - Bethesda Units (BU)

The presence of inhibitors is confirmed by a specific blood test called the Bethesda inhibitor assay.

- High-titer inhibitors:
  - <u>></u>5 BU/mL
  - o Inhibitors act strongly and quickly neutralize factor
- Low-titer inhibitors:
  - **< 5 BU/mL**
  - o Inhibitors act weakly and slowly neutralize factor

# Approval Duration and Quantity Restrictions:

### Approval: 12 months

### **References:**

- 1. FEIBA [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; March 2024.
- AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; https://online.lexi.com/lco/action/doc/retrieve/docid/essential\_ashp/988283 [available with subscription]. Accessed December 2, 2024.
- 3. Acquired hemophilia. World Federation of Hemophilia. http://www1.wfh.org/publications/files/pdf-1186.pdf. Accessed December 5, 2023.
- 4. Tiede A, Collins P, Knoebl P, et al. International recommendations on the diagnosis and treatment of acquired hemophilia A. Haematologica. 2020;105(7):1791-1801. doi:10.3324/haematol.2019.230771.
- 5. Franchini M, Mannucci PM. Acquired haemophilia A: a 2013 update. Thromb Haemost. 2013;110(6):1114-20.
- National Hemophilia Foundation. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. Revised October 2024. MASAC Document #290. https://www.hemophilia.org/sites/default/files/document/files/MASAC-Products-Licensed.pdf. Accessed December 2, 2024.
- 7. Srivastava A, Santagostino E, Dougall A, et al. WFH Guidelines for the Management of Hemophilia, 3rd edition. Haemophilia. 2020;26 Suppl 6:1-158. doi:10.1111/hae.14046.
- National Hemophilia Foundation. MASAC Recommendations Regarding Prophylaxis with Bypassing Agents in Patients with Hemophilia and High Titer Inhibitors. MASAC Document #220. https://www.hemophilia.org/sites/default/files/document/files/masac220.pdf. Accessed December 2, 2024.
- 9. Kruse-Jarres, R, Kempton CL, Baudo, F, et al. Acquired hemophilia A: Updated review of evidence and treatment guidance. Am J Hematol. 2017;92:695-705.