

Feiba (anti-inhibitor coagulant complex [human]) Effective 01/01/2024

Plan	 MassHealth UPPL Commercial/Exchange 	Dura anna Tana	Prior Authorization
Benefit	Pharmacy BenefitMedical Benefit	Program Type	Quantity Limit Step Therapy
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	N/A		

Overview

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.

FDA-Approved Indication

1. Hemophilia A and hemophilia B with inhibitors

Compendial Use

1. Acquired hemophilia A

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

Coverage Guidelines

Authorization may be granted for members new to the plan who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Hemophilia A With Inhibitors

Authorization may be granted when the following criteria is met:

- 1. Member has a diagnosis of Hemophilia A with inhibitors (see Appendix).
- 2. The inhibitor titer is ≥ 5 Bethesda units per milliliter (BU/mL) OR the member has a history of an inhibitor titer ≥ 5 BU.
- 3. The requested medication is prescribed by or in consultation with a hematologist.

Hemophilia B With Inhibitors

Authorization may be granted when the following criteria is met:

Mass General Brigham Health Plan includes Mass General Brigham Health Plan, Inc. and Mass General Brigham Health Insurance Company.

- 1. Member has a diagnosis of Hemophilia B with inhibitors (see Appendix).
- 2. The inhibitor titer is ≥ 5 Bethesda units per milliliter (BU/mL) OR the member has a history of an inhibitor titer ≥ 5 BU.
- 3. The requested medication is prescribed by or in consultation with a hematologist.

Acquired Hemophilia A

Authorization may be granted when the following criteria is met:

- 1. Member has a diagnosis of acquired hemophilia A.
- 2. The requested medication is prescribed by or in consultation with a hematologist.

Continuation of Therapy

Reauthorization may be granted for continued treatment in members requesting reauthorization when the member is experiencing benefit from therapy (e.g., reduced frequency or severity of bleeds).

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months.

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

References

- 1. FEIBA [package insert]. Lexington, MA: Baxalta US Inc.; February 2020.
- 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, 2022.
- 3. *Acquired hemophilia*. World Federation of Hemophilia. http://www1.wfh.org/publications/files/pdf-1186.pdf. Accessed December 2, 2022.
- 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.
- 6. National Hemophilia Foundation. MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders. Revised March 2022. MASAC Document



#272. https://www.hemophilia.org/sites/default/files/document/files/272_Treatment.pdf. Accessed December 2, 2022.

- 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, 2022.
- 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.

Review History

12/13/2023: Reviewed at Dec P&T, switched from SGM to Custom. Effective 1/1/2024

