

Reference number(s)
1943-A

SPECIALTY GUIDELINE MANAGEMENT

FEIBA (anti-inhibitor coagulant complex [human])

POLICY

I. INDICATIONS

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. FDA-Approved Indication
Hemophilia A and hemophilia B with inhibitors
- B. Compendial Use
Acquired hemophilia A

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

II. CRITERIA FOR INITIAL APPROVAL

A. Hemophilia A with Inhibitors

Indefinite authorization may be granted for treatment of hemophilia A with inhibitors (see Appendix) when the inhibitor titer is ≥ 5 Bethesda units per milliliter (BU/mL) or if the patient has a history of an inhibitor titer ≥ 5 BU.

B. Hemophilia B with Inhibitors

Indefinite authorization may be granted for treatment of hemophilia B with inhibitors (see Appendix) when the inhibitor titer is ≥ 5 Bethesda units per milliliter (BU/mL) or if the patient has a history of an inhibitor titer ≥ 5 BU.

C. Acquired Hemophilia A

Indefinite authorization may be granted for treatment of acquired hemophilia A.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

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

V. REFERENCES

1. FEIBA [package insert]. Lexington, MA: Baxalta US Inc.; December 2018.
2. 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 15, 2019.
3. *Acquired hemophilia*. World Federation of Hemophilia. <http://www1.wfh.org/publications/files/pdf-1186.pdf>. Accessed December 12, 2019.
4. Huth-Kuhne A, Baudo F, Collins P, et al. International recommendations on the diagnosis and treatment of patients with acquired hemophilia A. *Haematologica*. 2009;94(4):566-75.
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 April 2018. MASAC Document # 253. <https://www.hemophilia.org/sites/default/files/document/files/masac253.pdf>. Accessed December 12, 2019.
7. Srivastava A, Brewer A, Street A, et al. Guidelines for the management of hemophilia. *Haemophilia*. 2013;19(1):e1-e47.
8. 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 14, 2019.
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.