Reference number(s)
4800-A

STANDARD MEDICARE PART B 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 will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. 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 ≥ 5 Bethesda units per milliliter (BU/mL) or if the member has a history of an inhibitor titer ≥ 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 ≥ 5 Bethesda units per milliliter (BU/mL) or if the member has a history of an inhibitor titer ≥ 5 BU.

C. Acquired Hemophilia A
Authorization of 12 months 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 be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

A. The member is currently receiving therapy with the requested medication.
B. The requested medication is being used to treat an indication enumerated in Section II.
C. The member is receiving benefit from therapy (e.g., reduced frequency or severity of bleeds).

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. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for FEIBA.
2. The available compendium
   a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
   b. Micromedex DrugDex
   c. American Hospital Formulary Service- Drug Information (AHFS-DI)
   d. Lexi-Drugs
   e. Clinical Pharmacology
3. International recommendations on the diagnosis and treatment of acquired hemophilia A.
4. Acquired haemophilia A: a 2013 update
5. Medical and Scientific Advisory Council (MASAC) recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders.
6. World Federation of Hemophilia (WFH) Guidelines for the Management of Hemophilia, 3rd edition.
7. MASAC recommendations regarding prophylaxis with bypassing agents in patients with hemophilia and high titer inhibitors.
8. Acquired hemophilia A: Updated review of evidence and treatment guidance.
9. National Coverage Determination: Anti-Inhibitor Coagulant Complex (AICC)

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for FEIBA are covered in addition to acquired hemophilia A.

VI. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using FEIBA to treat acquired hemophilia A can be found in several guidelines.
The World Federation of Hemophilia supports using activated prothrombin complex concentrate (such as FEIBA) to treat bleeding episodes.
The International Recommendations on the Diagnosis and Treatment of Acquired Hemophilia A recommends recombinant activated factor VII (NovoSeven) and activated prothrombin concentrate complex. The guideline does not recommend one drug over another for the treatment for acute bleeds.

Treatment of hemophilia in patients with factor VIII inhibitor antibodies is covered according to the conditions outlined in National Coverage Determination Manual section Anti-Inhibitor Coagulant Complex (110.3).

VII. REFERENCES

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3. *Acquired hemophilia*. World Federation of Hemophilia. http://www1.wfh.org/publications/files/pdf-1186.pdf. Accessed December 3, 2022.
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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.
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 3, 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.
10. National Coverage Determination (NCD) for Anti-Inhibitor Coagulant Complex (AICC) (110.3 – Version 1). https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=150&ncdver=1&bc=0 Accessed September 14, 2023.