CVS/caremark™

SPECIALTY GUIDELINE MANAGEMENT

FEIBA (anti-inhibitor coagulant complex [human])

POLICY

A. 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.

FDA-Approved Indication

- Hemophilia A and hemophilia B with inhibitors

Compendial Use

- Acquired hemophilia A

All other indications are considered experimental/investigational and are not a covered benefit.

B. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:

- Laboratory documentation of highest Bethesda titer in members with hemophilia A or hemophilia B with inhibitors

C. CRITERIA FOR APPROVAL

1. Hemophilia A With Inhibitors

Authorization for 12 months may be granted to members who are prescribed FEIBA for hemophilia A with inhibitors (see Appendix) when the inhibitor titer is ≥ 5 Bethesda units per milliliter (BU/mL).

2. Hemophilia B With Inhibitors

Authorization for 12 months may be granted to members who are prescribed FEIBA for hemophilia B with inhibitors (see Appendix) when the inhibitor titer is ≥ 5 BU/mL.

3. Acquired Hemophilia A

Authorization for 12 months may be granted for members who are prescribed FEIBA for acquired hemophilia A.

D. CONTINUATION OF THERAPY

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

E. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

F. 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

REFERENCES

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