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| | TTER HEALTH® | | | | |
| Coverage Policy/Guideline | | | | | |
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| A | ⊠Illinois | □Florida | ⊠Florida Kids | | |
| Applies to: | ⊠New Jersey | ⊠Maryland | □Michigan | | |
| | ⊠Pennsylvania Kids | □Virginia | □Texas | | |

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. 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.

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

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

Continuation of Therapy:

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

Approval Duration and Quantity Restrictions:

Approval: 12 months

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