PreferredOne®

PRIOR AUTHORIZATION POLICY

POLICY: Hemophilia – FEIBA® (anti-inhibitor coagulant complex for intravenous use – Takeda)

REVIEW DATE: 10/02/2019

OVERVIEW

FEIBA, a human plasma fraction with Factor VIII bypassing activity, is indicated for use in hemophilia A and B patients with inhibitors for control and prevention of bleeding episodes, perioperative management, and routine prophylaxis to prevent or reduce the frequency of bleeding episodes.[1] It contains both activated and inactivated forms of Factors II, VII, IX, and X and is thus referred to as activated prothrombin complex concentrate.[1,2] FEIBA is produced from pooled human plasma.[1]

FEIBA is the only commercially available activated prothrombin complex concentrate. Prothrombin complex concentrates are commercially available, and each product has unique pharmacology and labeled use. Profilnine® SD (Factor IX complex for intravenous use) is a three-factor prothrombin complex concentrate containing Factors II, IX, and X, with minimal levels of Factor VII.[3] It is indicated only in hemophilia B. Kcentra® (prothrombin complex concentrate [human] for intravenous use) is a four-factor prothrombin complex concentrate containing inactivated forms of Factors II, VII, IX, and X.[4] Kcentra is labeled for urgent reversal of acquired coagulation factor deficiency induced by vitamin K antagonist (e.g, warfarin) therapy in adults with acute major bleeding or need for an urgent surgery or invasive procedure.

Disease Overview

Hemophilia A is an X-linked bleeding disorder caused by a deficiency in coagulation Factor VIII.[5] The birth prevalence of hemophilia A in the US is approximately 1:6,500 live male births. **Hemophilia B**, caused by deficiency in coagulation Factor IX, is clinically indistinguishable from hemophilia A and is also inherited in an X-linked manner.[6] The birth prevalence is approximately 1:30,000 live male births. Bleeding episodes are treated with plasma-derived or recombinant Factor VIII or Factor IX concentrates. These agents are also given prophylactically for individuals with severe disease.

Approximately 30% of patients with severe hemophilia A and 1 to 3% of patients with severe hemophilia B develop alloimmune inhibitors (antibodies) to Factor VIII or Factor IX concentrate.[5,6] Presence of inhibitors at high titers makes the factor replacement ineffective, and alternative "bypassing" agents are needed to promote hemostasis. FEIBA acts as a bypassing agent by multiple mechanisms which are not fully understood; one major mechanism is supplying activated Factor X, which is normally produced by activated Factors VIII and IX in healthy individuals.[7] Other bypassing agents include NovoSeven RT® (coagulation Factor VIIa [recombinant] for intravenous use) and Hemlibra® (emiczumab-kxwh for subcutaneous use). Hemlibra is a monoclonal antibody that mimics the action of Factor VIII and therefore is only indicated in hemophilia A.[8]

Guidelines

The National Hemophilia Foundation (NHF) Medical and Scientific Advisory Council (MASAC) has recommendations concerning products used for the treatment of hemophilia, as well as guidelines specific to treatment of hemophilia patients with inhibitors (2018 and 2013, respectively).[2,9] FEIBA is supported in these guidelines and noted to be indicated for use in hemophilia patients only when an inhibitor is present.

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POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of FEIBA. Approval is recommended for those who meet the Criteria and Dosing for the listed indication(s). Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by an Express Scripts clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below.

Because of the specialized skills required for evaluation and diagnosis of patients treated with FEIBA as well as the monitoring required for adverse events and long-term efficacy, approval requires these agents to be prescribed by or in consultation with a physician who specializes in the condition being treated.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of FEIBA is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Hemophilia A with Inhibitors.** Approve for 1 year if FEIBA is prescribed by or in consultation with a hemophilia specialist.

2. **Hemophilia B with Inhibitors.** Approve for 1 year if FEIBA is prescribed by or in consultation with a hemophilia specialist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

FEIBA has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. FEIBA® for intravenous use [prescribing information]. Lexington, MA: Shire/Takeda; December 2018.
2. MASAC (Medical and Scientific Advisory Council) recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders (Revised April 2018). MASAC Document #253. Adopted on April 23, 2018. Available at: https://www.hemophilia.org/sites/default/files/document/files/masac253.pdf. Accessed on July 8, 2019.
3. Profilnine® SD for intravenous use [prescribing information]. Los Angeles, CA: Grifols Biologicals; August 2010.
4. Kcentra® for intravenous use [prescribing information]. Kankakee, IL: CSL Behring LLC; October 2018.
5. Adam MP, Ardinger HH, Pagon RA, et al. GeneReviews®: Hemophilia A [Internet]. Updated June 22, 2017. Available at: https://www.ncbi.nlm.nih.gov/books/NBK1404/. Accessed on June 6, 2019.
6. Konkle BA, Hutson J, Fletcher SN. GeneReviews®: Hemophilia B [Internet]. Updated June 15, 2017. Available at: https://www.ncbi.nlm.nih.gov/books/NBK1495/. Accessed on June 6, 2019.
7. Hoffman M, Dargaud Y. Mechanisms and monitoring of bypassing agent therapy. *J Thromb Haemost.* 2012;10(8):1478-85.
8. Hemlibra® for subcutaneous use [prescribing information]. South San Francisco, CA: Genentech, Inc.: October 2018.
9. MASAC (Medical and Scientific Advisory Council) recommendation regarding prophylaxis with bypassing agents in patients with hemophilia and high titer inhibitors. MASAC Document #220. Adopted on October 6, 2013. Available at: https://www.hemophilia.org/sites/default/files/document/files/masac220.pdf. Accessed on June 6, 2019.

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PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
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Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

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