Reference number(s)
6328-A

STANDARD MEDICARE PART B MANAGEMENT

RIASTAP (fibrinogen concentrate [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
RiaSTAP is indicated for the treatment of acute bleeding episodes in pediatric and adult patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia.

Limitation of use:
RiaSTAP is not indicated for dysfibrinogenemia.

B. Compendial Uses
1. Perioperative management of bleeding in afibrinogenemia
2. Prophylaxis to reduce the frequency of bleeding episodes in afibrinogenemia

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. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
For prophylaxis to reduce the frequency of bleeding episodes in afibrinogenemia, justification from the medical records.

III. CRITERIA FOR INITIAL APPROVAL

Congenital Fibrinogen Deficiency
A. Authorization of 1 month may be granted for treatment of acute bleeding episodes in members with a diagnosis of congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia.
B. Authorization of 1 month may be granted for perioperative management of bleeding in members with a diagnosis of afibrinogenemia.
C. Authorization of 12 months may be granted for prophylaxis to reduce the frequency of bleeding episodes in members with afibrinogenemia (with justification from the medical records).

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

A. Prophylaxis to reduce the frequency of bleeding episodes in afibrinogenemia
Authorization for 12 months may be granted when all of the following criteria are met:
1. The member is currently receiving therapy with the requested medication
2. The member is receiving benefit from therapy (e.g., reduced frequency of bleeding episodes).

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

V. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for RiaSTAP.
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. MASAC recommendations concerning products licensed for the treatment of hemophilia and selected disorders of the coagulation system.
4. Efficacy and tolerability of a pasteurized human fibrinogen concentrate in patients with congenital fibrinogen deficiency.

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for RiaSTAP are covered in addition to the following:
1. Perioperative management of bleeding in afibrinogenemia
2. Prophylaxis to reduce the frequency of bleeding episodes in afibrinogenemia

VI. EXPLANATION OF RATIONALE

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

Support for perioperative management of bleeding in afibrinogenemia and prophylaxis to reduce the frequency of bleeding episodes in afibrinogenemia can be found in the AHFS-DI compendium. According to the compendium, in a study in individuals with congenital fibrinogen deficiency, clinical efficacy was demonstrated in surgical procedures and bleeding events and when fibrinogen (human) was used for prophylaxis. The compendium references a published, open, multicenter, retrospective study from Kreuz et al., which assessed the efficacy and tolerability of a pasteurized human fibrinogen concentrate in patients with congenital fibrinogen deficiency. Fibrinogen substitution was indicated to stop an ongoing bleed, as prophylaxis before surgery, or for routine prophylaxis to prevent spontaneous bleeding. In total, 151 infusions were recorded in which clinical efficacy was very good in all events with the exception of one surgical procedure, where it was moderate. The investigators concluded that substitution with pasteurized human fibrinogen concentrate in patients with congenital fibrinogen deficiencies is efficient and generally well tolerated.

VII. REFERENCES

1. RiaSTAP [package insert]. Kankakee, IL: CSL Behring LLC; June 2021.

2. National Hemophilia Foundation. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. Revised August 2023. MASAC Document #280. https://www.hemophilia.org/healthcare-professionals/guidelines-on-care/masac-documents/masac-document-280-masac-recommendations-concerning-products-licensed-for-the-treatment-of-hemophilia-and-selected-disorders-of-the-coagulation-system. Accessed January 11, 2024.
3. American Hospital Formulary Service Drug Information. American Society of Health-System Pharmacists. Bethesda, Maryland. Wolters Kluwer Clinical Drug Information, Inc., Last Updated April 21, 2023. URL: https://online.lexi.com/lco/action/home. Accessed January 11, 2024.
4. Kruez W, Meili E, Peter-Salonen K, et al. Efficacy and tolerability of a pasteurized human fibrinogen concentrate in patients with congenital fibrinogen deficiency. *Transfus Apher Sci*. 2005;32(3):247-253.