Reference number(s)
2983-A

SPECIALTY GUIDELINE 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 are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: 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

A. Prophylaxis to reduce the frequency of bleeding episodes in afibrinogenemia

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for prophylaxis to reduce the frequency of bleeding episodes in afibrinogenemia when the member is experiencing 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. 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 October 4, 2023.
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 October 4, 2023.
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.