

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 in patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia, for the treatment of acute bleeding episodes.

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 are 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).

Reference number(s)
2983-A

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; July 2020.
2. National Hemophilia Foundation. MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders. Revised August 2020. MASAC Document #263. https://www.hemophilia.org/sites/default/files/document/files/263_treatment.pdf. Accessed October 14, 2020.
3. American Hospital Formulary Service Drug Information. American Society of Health-System Pharmacists. Bethesda, Maryland. Wolters Kluwer Clinical Drug Information, Inc., Last Updated March 2, 2020. URL: <https://online.lexi.com/lco/action/home>. Accessed January 6, 2021.
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.