Mass General Brigham
Health Plan

RiaSTAP (fibrinogen concentrate [human])
Effective 01/01/2024

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications**		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	N/A		

Overview

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.

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.

Coverage Guidelines

Authorization may be granted for members new to the plan who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted when one of the following criteria is met:

1. Authorization may be granted for treatment of acute bleeding episodes in members with a diagnosis of congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia.
2. Authorization may be granted for perioperative management of bleeding in members with a diagnosis of afibrinogenemia.
3. Authorization may be granted for prophylaxis to reduce the frequency of bleeding episodes in members with afibrinogenemia (with justification from the medical records).

Continuation of Therapy

1. **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).
2. **All other indications**
   All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

Limitations

1. Initial approvals for treatment of acute bleeding episodes in members with a diagnosis of congenital fibrinogen deficiency and perioperative management of bleeding in members with a diagnosis of afibrinogenemia will be granted for 1 month.
2. Initial approvals and reauthorizations for prophylaxis to reduce the frequency of bleeding episodes in members with afibrinogenemia will be granted for 12 months.

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 other bleeding disorders. Revised March 2022. MASAC Document #272. https://www.hemophilia.org/sites/default/files/document/files/272_Treatment.pdf. Accessed October 4, 2022.
3. American Hospital Formulary Service Drug Information. American Society of Health-System Pharmacists. Bethesda, Maryland. Wolters Kluwer Clinical Drug Information, Inc., Last Updated March 28, 2022. URL: https://online.lexi.com/lco/action/home. Accessed October 4, 2022.
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.

Review History

12/13/2023: Reviewed at Dec P&T, switched from SGM to Custom. Effective 1/1/2024