Medical Policy:
RiaSTAP (fibrinogen)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.145	January 10, 2024	July 15th 2019

Definitions

RiaSTAP (coagulation factor I) is a soluble plasma glycoprotein and a physiological substrate of 3 enzymes: thrombin, factor XIIIa, and plasmin. Thrombin converts fibrinogen into fibrin. Fibrin is stabilized in the presence of calcium ions and by activated Factor XIII. Factor XIIIa induces cross-linking of fibrin polymers which result in the fibrin clot being more elastic and more resistant to fibrinolysis. The cross-linked fibrin is the end result of the coagulation cascade.

RiaSTAP is FDA-labeled for the treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia

Length of Authorization

Coverage will be provided for 12 months and may be renewed.

Guideline

I. Initial Approval Criteria

RiaSTAP *may be considered medically necessary if the below condition is met* ***AND*** *use is consistent with the medical necessity criteria that follows:*

1. **Fibrinogen Deficiency** (Factor I deficiency)
    a. Diagnosis of congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia; **AND**
    b. One of the following:
        i. Routine prophylactic treatment; **OR**
        ii. Peri-operative management of surgical bleeding; **OR**
        iii. Treatment of bleeding episodes.

Limitations/Exclusions

1. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

II. Renewal Criteria

1. Patient continues to meet INITIAL APPROVAL CRITERIA.

Dosage/Administration

Indication	Dose
Fibrinogen Deficiency	**Baseline fibrinogen level known**: dose = (target level (mg/dL) - measured level (mg/dL)) divided by 1.7 (mg/dL per mg/kg body weight) IV not exceeding 5 mL/min. **Baseline fibrinogen level unknown:** 70 mg/kg IV not exceeding 5 mL/min. *Maintain fibrinogen level of 100 mg/dL until hemostasis is obtained.*

Applicable Procedure Codes

Code	Description
J7178	Injection, human fibrinogen concentrate (RiaSTAP), 1 mg, 1 billable unit = 1 mg

Applicable NDCs

Code	Description
63833-0891-51	RiaSTAP single use vial; powder for injection

ICD-10 Diagnoses

Code	Description
D68.2	Hereditary deficiency of other clotting factors [congenital fibrinogen deficiency]

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/10/2024	Annual Review: No Criteria Changes
EmblemHealth & ConnectiCare	5/9/2023	Annual Review: no criteria changes
EmblemHealth & ConnectiCare	1/11/2023	Transfer to New Template
EmblemHealth & ConnectiCare	7/15/2019	New Policy

References

1. RiaSTAP® [package insert]. Kankakee, IL: CSL Behring LLC, October 2017.