

Medical Policy:

RiaSTAP (fibrinogen) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.145	February 21, 2025	July 15 th 2019

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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	<p>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.</p> <p>Baseline fibrinogen level unknown: 70 mg/kg IV not exceeding 5 mL/min.</p> <p><i>Maintain fibrinogen level of 100 mg/dL until hemostasis is obtained.</i></p>

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
63833-0891-90	RiaSTAP single use vial; powder for injection

ICD-10 Diagnoses

Code	Description
D68.2	Hereditary deficiency of other clotting factors [congenital fibrinogen deficiency]
D68.8	Other specified coagulation defects

Revision History

Company(ies)	DATE	REVISION
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EmblemHealth & ConnectiCare	2/21/2025	Annual Review: added D68.8 and 63833-0891-90
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.