Clinical Policy: Fibrinogen Concentrate [Human] (Fibryga, RiaSTAP)

Reference Number: CP.PHAR.526
Effective Date: 06.01.21
Last Review Date: 05.21
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

The following are fibrinogen (coagulation factor I) concentrates requiring prior authorization: fibrinogen concentrate [human] (Fibryga® and RiaSTAP®).

FDA Approved Indication(s)

Fibryga and RiaSTAP are indicated for the treatment of acute bleeding episodes in patients (specified as adults and children for Fibryga) with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia.

Limitation(s) of use: Fibryga is not indicated for dysfibrinogenemia.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Fibryga and RiaSTAP are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Congenital Fibrinogen Deficiency (must meet all)**:**

1. Diagnosis of congenital fibrinogen deficiency, including afibrinogenemia or hypofibrinogenemia;
2. Confirmation that the member does not have dysfibrinogenemia;
3. Prescribed by or in consultation with a hematologist;
4. Request is for treatment of acute bleeding episodes;
5. Documentation of both of the following (a and b):
   a. Plasma functional and immunoreactive fibrinogen levels are < 150 mg/dL;
   b. Prolonged prothrombin time and activated partial thromboplastin time as determined by laboratory-specific reference values;
6. Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication.

Approval duration: 3 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is

NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Congenital Fibrinogen Deficiency (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed the FDA-approved maximum recommended dose for the relevant indication.

Approval duration: 3 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 3 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents;

B. Dysfibrinogenemia.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): individuals who have manifested severe immediate hypersensitivity reactions, including anaphylaxis, to Fibryga or its components (sodium citrate dihydrate; glycine; L-arginine hydrochloride); known anaphylactic or severe systemic reactions to human plasma-derived products (RiaSTAP)
- Boxed warning(s): none reported

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Fibrinogen concentrate (Fibryga)	The recommended target fibrinogen plasma level is 100 mg/dL for minor bleeding and 150 mg/dL for major bleeding. When baseline fibrinogen level is known • Age ≥ 12 years: [Target fibrinogen level (mg/dL) – measured fibrinogen level (mg/dL)]/1.8 (mg/dL per mg/kg body weight) by IV infusion • Age < 12 years: [Target fibrinogen level (mg/dL) – measured fibrinogen level (mg/dL)]/1.4 (mg/dL per mg/kg body weight) by IV infusion When baseline fibrinogen level is not known 70 mg/kg/dose by IV infusion	Individualized based on the extent of bleeding, laboratory values, and the clinical condition of the patient
Fibrinogen concentrate (RiaSTAP)	When baseline fibrinogen level is known [Target fibrinogen level (mg/dL) – measured fibrinogen level (mg/dL)]/1.7 (mg/dL per mg/kg body weight) by IV infusion When baseline fibrinogen level is not known 70 mg/kg/dose by IV infusion	Individualized based on the extent of bleeding, laboratory values, and the clinical condition of the patient

VI. Product Availability

Drug Name	Availability
Fibrinogen concentrate (Fibryga)	Lyophilized powder for reconstitution in a single-dose bottle: approximately 1 gram
Fibrinogen concentrate (RiaSTAP)	Lyophilized powder for reconstitution in a single-dose vial: 900-1,300 mg

VII. References

1. Fibryga Prescribing Information. Paramus, NJ: Octapharma USA, Inc.; December 2020. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo. Accessed February 3, 2021.
2. RiaSTAP Prescribing Information. Kankakee, IL: CSL Behring LLC; July 2020. Available at: https://www.riastap.com. Accessed February 3, 2021.
3. De Moerloose P, Casini A, Neerman-Arbez M. Congenital fibrinogen disorders: an update. Semin Thromb Hemost 2013;39:585-95.
4. National Hemophilia Foundation. MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders (revised August 2020). Available at: https://www.hemophilia.org/sites/default/files/document/files/263_treatment.pdf. Accessed February 3, 2021.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J7177	Injection, human fibrinogen concentrate (Fibryga), 1 mg
J7178	Injection, human fibrinogen concentrate, not otherwise specified, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	02.03.21	05.21

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise

professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.