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

Reference Number: LA.PHAR.526
Effective Date: 09.29.23
Last Review Date: 10.09.24 ~~03.25.24~~
Line of Business: Medicaid

Coding Implications
Revision Log

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

****Please note: This policy is for medical benefit****

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 ~~adults and children~~patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia.

Fibryga is additionally indicated for fibrinogen supplementation in bleeding patients with acquired fibrinogen deficiency.

Limitation(s) of use: Fibryga and RiaSTAP are 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 Louisiana Healthcare Connections® 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. For members who have not previously used fibrinogen concentrate (samples do not count), 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.

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Approval duration: 3 months

B. Acquired Fibrinogen Deficiency (must meet all):
1. Diagnosis of acquired fibrinogen deficiency;
2. Request is for Fibryga;
3. Prescribed by or in consultation with a hematologist;
4. Request is for fibrinogen supplementation for bleeding;
5. Member meets one of the following (a or b):
   a. Plasma fibrinogen level < 200 mg/dL;
   b. Thromboelastometry FIBTEM A10 ≤ 10 mm;
6. Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication.

Approval duration: 3 months

~~B.~~C. **Other diagnoses/indications** (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy ~~for the relevant line of business:~~ LA.PMN.53 for Medicaid.

II. Continued Therapy

A. ~~Congenital Fibrinogen Deficiency~~All Indications in Section I (must meet all)**:**
1. Currently receiving medication via Louisiana Healthcare Connections 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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy ~~for the relevant line of business:~~ LA.PMN.53 for Medicaid.

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

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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 – LA.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):
  - Fibryga: 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)~~
  - RiaSTAP: known anaphylactic or severe systemic reactions to human plasma-derived products;
- Boxed warning(s): none reported

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V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Fibrinogen concentrate (Fibryga)	**Congenital fibrinogen deficiency:** 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 **Acquired fibrinogen deficiency** Age ≥ 18 years: 4 g IV	Individualized based on the extent of bleeding, laboratory values, and the clinical condition of the patient

Drug Name	Dosing Regimen	Maximum Dose
	Age ≥ 12 and < 18 years: 50 mg/kg body weight IV Age < 12 years: 70 mg/kg body weight IV Administer additional doses as needed to bleeding patients when plasma fibrinogen level is ≤ 200 mg/dL or thromboelastometry FIBTEM A10 is ≤ 10 mm (or equivalent values generated by other viscoelastic testing methods)	
Fibrinogen concentrate (RiaSTAP)	**Congenital fibrinogen deficiency** 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

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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.~~July 2024. Available at: https://www.fibrygausa.com~~/wp-content/uploads/2021/03/20201222_pil_347_11.07_US_en.pdf.~~. Accessed ~~February 5, 2023~~August 7, 2024.
2. RiaSTAP Prescribing Information. Kankakee, IL: CSL Behring LLC; June 2021. Available at: https://www.riastap.com. Accessed ~~February 5, 2023~~January 11, 2024.
3. De Moerloose P, Casini A, Neerman-Arbez M. Congenital fibrinogen disorders: an update. Semin Thromb Hemost 2013;39:585-95.
4. Medical and Scientific Advisory Council (MASAC) of the National Bleeding Disorders Foundation (formerly National Hemophilia Foundation~~. MASAC recommendations concerning products licensed for the ~~): Database of treatment ~~of hemophilia and other bleeding disorders (revised March 2022).~~guidelines. Available at~~:~~ https://www.hemophilia.org/~~sites/default/files/document/files/272_Treatment.pdf.~~healthcare-professionals/guidelines-on-care/masac-documents. Accessed ~~February 5, 2023~~January 28, 2024.

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5. Casini A, Undas A, Palla R, et al; Diagnosis and classification of congenital fibrinogen disorders: communication from the SSC of the ISTH. J Thromb Haemost. 2018;16(9):1887-1890.
~~4.~~6. National Advisory Committee (NAC) on Blood and Blood Products; NAC Statement on Fibrinogen Concentrate Use in Acquired Hypofibrinogenemia. Available at: https://nacblood.ca/en/resource/nac-statement-fibrinogen-concentrate-use-acquired-hypofibrinogenemia. Accessed August 7, 2024.

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	LDH Approval Date
Policy created	05.01.23	08.28.23
Annual review: no significant changes; references reviewed and updated.	03.25.24	05.23.24
Updated Fibryga with new FDA indication for acquired fibrinogen deficiency	10.09.24	

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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. LHCC 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.

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 LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. 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. LHCC 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 LHCC has no control or right of control. Providers are not agents or employees of LHCC.

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