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

Reference Number: PA.CP.PHAR.526
Effective Date: 04/2021
Last Review Date: 04/2025

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 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 PA Health & Wellness® 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.

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

C. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
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 PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.
   Approval duration: Duration of request or 3 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

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 – PA.CP.PMN.53;

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);
- RiaSTAP: known anaphylactic or severe systemic reactions to human plasma-derived products;

- Boxed warning(s): none reported

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. <u>When baseline fibrinogen level is known</u> • 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 <u>When baseline fibrinogen level is not known</u> 70 mg/kg/dose by IV infusion **Acquired fibrinogen deficiency** Age ≥ 18 years: 4 g IV 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)	Individualized based on the extent of bleeding, laboratory values, and the clinical condition of the patient
Fibrinogen concentrate (RiaSTAP)	**Congenital fibrinogen deficiency** <u>When baseline fibrinogen level is known</u> [Target fibrinogen level (mg/dL) – measured fibrinogen level (mg/dL)]/1.7 (mg/dL per mg/kg body weight) by IV infusion <u>When baseline fibrinogen level is not known</u> 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.; November 2024. Available at: https://www.fibrygausa.com/. Accessed March 6, 2025.
2. RiaSTAP Prescribing Information. Kankakee, IL: CSL Behring LLC; July 2020. Available at: https://www.riastap.com. Accessed January 16, 2025.
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): Database of treatment guidelines. Available at https://www.hemophilia.org/healthcare-professionals/guidelines-on-care/masac-documents. Accessed March 5, 2025.
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.
6. National Hemophilia Foundation. MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders (revised March 2022). Available at: https://www.hemophilia.org/sites/default/files/document/files/263_treatment.pdf. Accessed March 5, 2025.

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
Policy created	04/2021
2Q 2022 annual review: updated RiaSTAP indication to align with FDA-approved language clarifying use in pediatric patients; clarified requirement for documentation of fibrinogen level and prolonged prothrombin time and activated partial thromboplastin time only applies to new starts on Fibryga/Riastap therapy; references reviewed and updated.	04/2022
2Q 2023 annual review: no significant changes; references reviewed and updated.	04/2023
2Q 2024 annual review: no significant changes; references reviewed and updated.	04/2024

Reviews, Revisions, and Approvals	Date
2Q 2025 annual review: RT4: updated Fibryga with new FDA indication for acquired fibrinogen deficiency; references reviewed and updated.	04/2025