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

Reference Number: CP.PHAR.526
Effective Date: 06.01.21
Last Review Date: 05.25
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) products requiring prior authorization: fibrinogen concentrate [human] (Fibryga®, RiaSTAP®) and fibrinogen, human-chmt (Fesilty™).

FDA Approved Indication(s)

Fesilty, Fibryga, and RiaSTAP are indicated for the treatment of acute bleeding episodes in 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: Fesilty, 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 health plans affiliated with Centene Corporation® that Fesilty, 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 (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 one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
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: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
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 one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
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: 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):
  - Fesilty: severe hypersensitivity reactions, including anaphylaxis, to Fesility or its components (arginine hydrochloride, polysorbate 80, sodium citrate dihydrate, trehalose dihydrate)
  - 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, human-chmt (Fesilty)	**Congenital fibrinogen deficiency:** The recommended target plasma fibrinogen level is 100 mg/dL for minor bleeding and 150 mg/dL for major bleeding. When baseline fibrinogen level is known • Age ≥ 6 years: [Target fibrinogen level (mg/dL) – measured fibrinogen level (mg/dL)]/1.8 (mg/dL per mg/kg body weight) by IV infusion • Age < 6 years: [Target fibrinogen level (mg/dL) – measured fibrinogen level (mg/dL)]/1.6 (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, plasma fibrinogen level, and the clinical condition of the patient
Fibrinogen concentrate [human] (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 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	**Congenital fibrinogen deficiency** When baseline fibrinogen level is known	Individualized based

Drug Name	Dosing Regimen	Maximum Dose
[human] (RiaSTAP)	[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	on the extent of bleeding, laboratory values, and the clinical condition of the patient

VI. Product Availability

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

VII. References

1. Fesilty Prescribing Information. Research Triangle Park, NC: Grifols Therapeutics; December 2025. Available at: https://grifolsug-pi.com/inserts/Fesilty.pdf. Accessed January 5, 2026.
2. Fibryga Prescribing Information. Paramus, NJ: Octapharma USA, Inc.; November 2024. Available at: https://www.fibrygausa.com. Accessed March 6, 2025.
3. RiaSTAP Prescribing Information. Kankakee, IL: CSL Behring LLC; June 2021. Available at: https://www.riastap.com. Accessed January 16, 2025.
4. De Moerloose P, Casini A, Neerman-Arbez M. Congenital fibrinogen disorders: an update. Semin Thromb Hemost 2013;39:585-95.
5. 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 January 5, 2026.
6. 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.
7. 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 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	P&T Approval Date
Policy created	02.03.21	05.21
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.	03.04.22	05.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.04.22	
2Q 2023 annual review: no significant changes; references reviewed and updated.	02.04.23	05.23
2Q 2024 annual review: no significant changes; references reviewed and updated.	01.11.24	05.24
RT4: updated Fibryga with new FDA indication for acquired fibrinogen deficiency.	08.14.24	
2Q 2025 annual review: no significant changes; references reviewed and updated.	03.05.25	05.25
RT4: added newly approved Fesilty.	01.05.26	

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.