

UTILIZATION MANAGEMENT MEDICAL POLICY

- POLICY:** Hematology – Fibrinogen Products Utilization Management Medical Policy
- Fesilty® (fibrinogen-chmt [human] intravenous infusion – Grifols/Biotest)
 - Fibryga® (fibrinogen [human] intravenous infusion – Octapharma)
 - RiaSTAP® (fibrinogen [human] intravenous infusion – CSL Behring)

REVIEW DATE: 08/05/2026

OVERVIEW

Fesilty, Fibryga and RiaSTAP, human fibrinogen concentrates, are indicated for treatment of acute bleeding episodes in patients with **congenital fibrinogen deficiency**, including afibrinogenemia and hypofibrinogenemia.¹⁻³ Fibryga is also FDA-approved for fibrinogen supplementation in bleeding patients with **acquired fibrinogen deficiency**.³ The prescribing information for all products note that these agents are not indicated for dysfibrinogenemia.¹⁻³

Disease Overview

Fibrinogen is a glycoprotein produced in the liver and circulates in blood at concentrations of 150 mg/dL to 450 mg/dL.⁴⁻⁷ Congenital fibrinogen disorders are very rare and caused by mutations in various genes (*FGA*, *FGB*, and *FGG* located on chromosome 4) that result in fibrinogen deficiency and/or dysfunction. Based on fibrinogen plasma levels, these conditions are classified as quantitative (type 1) or qualitative (type 2) deficiencies. Quantitative deficiencies are characterized by the complete lack of fibrinogen (afibrinogenemia) or by a proportional decrease (hypofibrinogenemia) when some fibrinogen is present but below levels necessary for normal clotting. Qualitative deficiencies (dysfibrinogenemia) are when there are normal amounts of fibrinogen but proper clotting does not occur. Patients with congenital fibrinogen deficiency have various bleeding manifestations. There is clinical heterogeneity in disease expression, especially in patients with hypofibrinogenemia and dysfibrinogenemia.

Dosing Information

Dosing is highly individualized. Guidance specific to congenital fibrinogen deficiency is limited. The National Bleeding Disorders Foundation Medical and Scientific Advisory Council (MASAC) provides recommendations regarding doses of clotting factor concentrate in the home (2016).⁸ The number of required doses varies greatly and is dependent on the severity of the disorder and the prescribed regimen. Per MASAC guidance, patients on prophylaxis should also have a minimum of one major dose and two minor doses on hand for breakthrough episodes in addition to the prophylactic doses used monthly. The guidance also notes that an adequate supply of clotting factor concentrate is needed to accommodate weekends and holidays. Therefore, maximum doses in this policy allow for prophylactic dosing plus three days of acute episodes or perioperative management per 28 days. Doses exceeding this quantity will be reviewed on a case-by-case basis by a clinician.

Dosing considerations for individual indications are as follows:

- **Congenital Fibrinogen Deficiency, Including Afibrinogenemia and Hypofibrinogenemia:** Doses of Fesilty, Fibryga and RiaSTAP by intravenous infusion are individualized based on patient-specific characteristics (e.g., extent of bleeding, clinical condition, laboratory values).¹⁻³ Treatment with fibrinogen products is repeated as needed to maintain target levels. The recommended dose when baseline fibrinogen levels is not known is 70 mg/kg body weight for all patient ages.

- **Acquired Fibrinogen Deficiency:** Additional doses of Fibryga may be required after initial administration based on plasma fibrinogen levels or thromboelastometry. Also, doses may need to be adjusted based on the bleeding severity, body weight of the patient, and clinical condition of the patient; multiple doses may be required. Dosing is provided for up to 10 doses per 28 days.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of fibrinogen products (Fesilty, Fibryga, RiaSTAP). Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with fibrinogen products as well as the monitoring required for adverse events and long-term efficacy, approval requires these agents to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

- I.** Coverage of Fesilty, Fibryga and RiaSTAP is recommended in those who meet one of the following criteria:

FDA-Approved Indication

- 1. Congenital Fibrinogen Deficiency (Factor I Deficiency), Including Afibrinogenemia and Hypofibrinogenemia.** Approve for 1 year if the medication is prescribed by or in consultation with a hematologist.

Dosing. Approve up to 700 mg/kg intravenously per 28 days.

- II.** Coverage of Fibryga is recommended in those who meet the following criteria:

FDA-Approved Indication

- 1. Acquired Fibrinogen Deficiency.** Approve for 1 year if the medication is prescribed by or in consultation with a hematologist.

Dosing. Approve ONE of the following doses (A, B, or C):

- A) Patients $\geq$ 18 years of age: Approve up to 40 g per 28 days given intravenously; OR
B) Patients $<$ 18 years of age and $\geq$ 12 years of age: Approve up to 500 mg/kg per 28 days given intravenously; OR
C) Children $<$ 12 years of age: Approve up to 700 mg/kg per 28 days given intravenously.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Fesilty, Fibryga and RiaSTAP is not recommended in the following situations:

1. **Concomitant Use of Fesilty, Fibryga and RiaSTAP.** There are no data to support concomitant use of these products.
2. **Dysfibrinogenemia.** In dysfibrinogenemia, patients have adequate levels of fibrinogen but dysfunctional clotting.^{4,9} It is a limitation of use for Fesilty, Fibryga and RiaSTAP that these agents are not indicated for this condition.¹⁻³
3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Fesilty® intravenous infusion [prescribing information]. Dreieich, Germany: Biotest and Research Triangle Park, NC: Grifols; December 2025.
2. RiaSTAP® intravenous infusion [prescribing information]. Kankakee, IL: CSL Behring; December 2025.
3. Fibryga® intravenous infusion [prescribing information]. Paramus, NJ: Octapharma; August 2025.
4. Factor I (Fibrinogen) Deficiency. National Bleeding Disorders Foundation. Available at: <https://www.hemophilia.org/Bleeding-Disorders/Types-of-Bleeding-Disorders/Other-Factor-Deficiencies/Factor-I>. Accessed on August 1, 2026.
5. Couzens A and Neerman-Arbez M. Congenital fibrinogen deficiencies: not so rare. *Hamostaseologie*. 2025;45:286-296.
6. Mohsenian S, Palla R, Menegatti M, et al. Congenital fibrinogen disorders: a retrospective clinical and genetic analysis of the Prospective Rare Bleeding Disorders Database. *Blood Adv*. 2024;8(6):1392-1404.
7. Casini A, Moerloose P, Meerman-Arbez M. Clinical, laboratory, and molecular aspects of congenital fibrinogen deficiency. *Semin Thromb Hemost*. 2025;51(2):103-110.
8. MASAC (Medical and Scientific Advisory Council) recommendations regarding doses of clotting factor concentrate in the home. MASAC Document #242. Adopted on June 7, 2016. Available at: <https://www.hemophilia.org/sites/default/files/document/files/242.pdf>. Accessed on August 5, 2026.
9. Fujia C and Eby C. An overview of dysfibrinogenemia: pathogenesis, diagnosis, and management. *Clin Lab Med*. 2026;46(2):199-211.

HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	Congenital Fibrinogen Deficiency (Factor I Deficiency), Including Afibrinogenemia and Hypofibrinogenemia: For both Fibryga and RiaSTAP, criteria were removed regarding the diagnosis be confirmed by laboratory testing. This includes the requirement that the patient has a prolonged activated partial thromboplastin time and prothrombin time at baseline (as defined by the laboratory reference values) AND the patient has lower than normal plasma functional and antigenic fibrinogen levels at baseline (as defined by the laboratory reference values). Acquired Fibrinogen Deficiency: This was added as a new approval indication for Fibryga only. Dosing was also added.	08/21/2024
Annual Revision	No criteria changes.	08/20/2025
Selected Revision	Fesilty was added to the policy. Congenital Fibrinogen Deficiency (Factor I Deficiency), Including Afibrinogenemia and Hypofibrinogenemia: Approval of Fesilty was added. Conditions Not Recommended for Approval: Fesilty was added to the fibrinogen products that should not be used concomitantly.	01/14/2026
Annual Revision	No criteria changes.	08/05/2026

08/05/2026

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