

Fibrinogen Products (RiaSTAP®, Fibryga®)

When requesting RiaSTAP® or Fibryga®, the individual requiring treatment must be diagnosed with one of the following FDA-approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

RiaSTAP is a human blood coagulation factor indicated for the treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia.

Fibryga is a human fibrinogen concentrate indicated for fibrinogen supplementation in bleeding patients with acquired fibrinogen deficiency and treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia.

Coverage Guidelines

- The request is for one of the following:
 - o Fibrinogen supplementation in bleeding individuals with acquired fibrinogen deficiency (applies to Fibryga only);
 - o Treatment of acute bleeding episodes in individuals with congenital fibrinogen deficiency, including afibrinogenemia or hypofibrinogenemia;
- The medication is prescribed by or in consultation with a hematologist.

Approval duration: 1 month

Dosing Recommendations

For intravenous use only.

- Dose when fibrinogen level is known:

RiaSTAP for Congenital Fibrinogen Deficiency:

$$\frac{\text{Target fibrinogen level (mg/dL)} - \text{measured fibrinogen level (mg/dL)}}{1.7 \text{ (mg/dL per mg/kg body weight)}}$$

Fibryga for Congenital Fibrinogen Deficiency:

For adults and adolescents 12 years of age and above:

$$\frac{\text{Target fibrinogen level (mg/dL)} - \text{measured fibrinogen level (mg/dL)}}{1.8 \text{ (mg/dL per mg/kg body weight)}}$$

For children less than 12 years of age:

$$\frac{\text{Target fibrinogen level (mg/dL)} - \text{measured fibrinogen level (mg/dL)}}{1.4 \text{ (mg/dL per mg/kg body weight)}}$$

- Dose when fibrinogen level is unknown: 70mg/kg body weight for RiaSTAP® and Fibryga®
- **Fibryga for Acquired Fibrinogen Deficiency:**
 - For adults: 4 grams
 - For adolescents 12 years of age and above: 50 mg/kg body weight
 - For children less than 12 years of age: 70 mg/kg body weight

References

1. RiaSTAP® intravenous infusion [prescribing information]. Kankakee, IL: CSL Behring; June 2021.
2. Fibryga® intravenous infusion [prescribing information]. Paramus, NJ: Octapharma; June 2025.
3. May JE, Wolberg AS, Lim MY. Disorders of fibrinogen and fibrinolysis. *Hematol Oncol Clin North Am.* 2021;35(6):1197-1217.
4. Factor I (Fibrinogen) Deficiency. National Hemophilia Foundation. Available at: <https://www.hemophilia.org/Bleeding-Disorders/Types-of-Bleeding-Disorders/Other-Factor-Deficiencies/Factor-I>. Accessed on August 11, 2025.
5. Casini A, Unda A, Palla R, et al. Diagnosis and classification of congenital fibrinogen disorders: communication from the SSC of the ISTH. *J Thromb Hemost.* 2018;16(9).
6. Congenital afibrinogenemia. National Organization for Rare Disorders. Updated 2018. Available at: <https://rarediseases.org/rare-diseases/afibrinogenemia-congenital/>. Accessed on August 11, 2025.
7. Palla R, Peyvandi F, Shapiro AD. Rare bleeding disorders: diagnosis and treatment. *Blood.* 2015;125(13):2052-2061.
8. Mumford AD, Ackroyd S, Alikhan R, et al.; BCSH Committee. Guideline for the diagnosis and management of the rare coagulation disorders: a United Kingdom Haemophilia Centre Doctors' Organization guideline on behalf of the British Committee for Standards in Haematology. *Br J Haematol.* 2014;167(3):304-26.
9. 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 11, 2025.