

## Fibrinogen Products (RiaSTAP®, Fibryga®, Fesilty®)

When requesting RiaSTAP®, Fibryga® or Fesilty® 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.

Fesilty is a human fibrinogen concentrate indicated for the 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:
  - Fibrinogen supplementation in bleeding individuals with acquired fibrinogen deficiency (applies to Fibryga only);
  - 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:

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

### **Fesilty for Congenital Fibrinogen Deficiency:**

For adults and adolescents 6 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 6 years of age:

$$\frac{\text{Target fibrinogen level (mg/dL)} - \text{measured fibrinogen level (mg/dL)}}{1.6 \text{ (mg/dL per mg/kg body weight)}}$$

- Dose when fibrinogen level is unknown: 70mg/kg body weight for RiaSTAP®, Fibryga® and Fesilty®
- **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**

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3. May JE, Wolberg AS, Lim MY. Disorders of fibrinogen and fibrinolysis. Hematol Oncol Clin North Am. 2021;35(6):1197-1217.
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