

# Specialty Guideline Management

## Fibryga

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Fibryga	fibrinogen [human]

### Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

#### FDA-approved Indications<sup>1</sup>

Fibryga is indicated for:

- Fibrinogen supplementation in bleeding patients with acquired fibrinogen deficiency.
- The treatment of acute bleeding episodes in adults and children with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia.

#### Limitation of use

Fibryga is not indicated for dysfibrinogenemia.

All other indications are considered experimental/investigational and not medically necessary.

## Coverage Criteria

### Congenital Fibrinogen Deficiency<sup>1,2</sup>

Authorization of 1 month may be granted for treatment of acute bleeding episodes in members with a diagnosis of congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia.

### Acquired Fibrinogen Deficiency<sup>1</sup>

Authorization of 1 month may be granted for treatment of bleeding episodes in members with a diagnosis of acquired fibrinogen deficiency.

## Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria section.

## References

1. Fibryga [package insert]. Paramus, NJ: Octapharma USA, Inc.; July 2024.
2. National Hemophilia Foundation. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. Revised April 2024. MASAC Document #284. <https://www.bleeding.org/sites/default/files/document/files/MASAC-Products-Licensed.pdf>. Accessed October 15, 2024.