Reference number(s)
2989-A

SPECIALTY GUIDELINE MANAGEMENT

FIBRYGA (fibrinogen [human])

POLICY

I. 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 Indication
Fibryga is indicated in adults and adolescents with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia, for the treatment of acute bleeding episodes.

Fibryga is not indicated for dysfibrinogenemia.

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

II. CRITERIA FOR INITIAL APPROVAL

Fibrinogen Deficiency
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.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Fibryga [package insert]. Hoboken, NJ: Octapharma USA, Inc.; September 2017.
2. National Hemophilia Foundation. MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders. Revised August 2020. MASAC Document #263. https://www.hemophilia.org/sites/default/files/document/files/263_treatment.pdf. Accessed October 14, 2020.