Reference number(s)
7351-A

Specialty Guideline Management
Fesilty

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
Fesilty	fibrinogen, human-chmt

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[1]

Fesilty is indicated for the treatment of acute bleeding episodes in pediatric and adult patients with congenital fibrinogen deficiency, including hypo- or afibrinogenemia.

Limitation of use

Fesilty is not indicated for dysfibrinogenemia.

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

Prescriber Specialties

Must be prescribed by or in consultation with a hematologist.

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Coverage Criteria

Congenital Fibrinogen Deficiency[1,2]

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.

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. Fesilty [package insert]. Research Triangle Park, NC: Grifols Therapeutics LLC; December 2025.
2. National Hemophilia Foundation. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. Revised October 2024. MASAC Document #290. https://www.bleeding.org/sites/default/files/document/files/MASAC-Products-Licensed.pdf. Accessed January 8, 2026.

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