

SPECIALTY GUIDELINE MANAGEMENT

RIASTAP (fibrinogen concentrate [human])

POLICY

A. 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

- Congenital fibrinogen deficiency
 - RiaSTAP is indicated for the treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia. RiaSTAP is not indicated for dysfibrinogenemia.

Compendial Uses

- Management of surgical bleeding (including prophylaxis) in members with congenital afibrinogenemia or congenital hypofibrinogenemia
- Treatment of acute bleeding episodes and management of surgical bleeding (including prophylaxis) in members with hypodysfibrinogenemia who have a functional (clotting) fibrinogen level < 100 mg/dL

All other indications are considered experimental/investigational and are not a covered benefit.

B. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:

- Laboratory documentation of fibrinogen level

C. EXCLUSIONS

- Dysfibrinogenemia

D. CRITERIA FOR APPROVAL

1. Congenital Fibrinogen Deficiency

1.1. Afibrinogenemia or Hypofibrinogenemia

Authorization of 3 months may be granted to members who meet BOTH of the following criteria:

- a) Diagnosis has been confirmed by low or absent fibrinogen levels.
- b) RiaSTAP is requested for the treatment of an acute bleeding episode OR for the management of surgical bleeding (including prophylaxis to prevent a bleeding episode).

1.2. Hypodysfibrinogenemia^{3,5,6}

Authorization of 3 months may be granted to members who meet BOTH of the following criteria:

- a) Member has a functional (clotting) fibrinogen level < 100 mg/dL.
- b) RiaSTAP is requested for the treatment of an acute bleeding episode OR for the management of surgical bleeding (including prophylaxis to prevent a bleeding episode).

E. CONTINUATION OF THERAPY

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

F. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

RiaSTAP SGM P2015

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