SPECIALTY GUIDELINE MANAGEMENT

RUCONEST (recombinant C1 esterase inhibitor)

POLICY

A. INDICATIONS

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

FDA-Approved Indication
- Treatment of acute attacks in adults and adolescent patients with hereditary angioedema (HAE)

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

B. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:
- C4 levels and C1 inhibitor functional and antigenic protein levels

C. EXCLUSIONS

- Known or suspected allergy to rabbits or rabbit-derived products
- History of immediate hypersensitivity reactions to C1 esterase inhibitor preparations (eg, Cinryze, Berinert)

D. CRITERIA FOR APPROVAL

1. Hereditary Angioedema (HAE)

Indefinite authorization may be granted to members who meet ALL of the following criteria:
- Diagnostic laboratory testing for HAE has been performed (eg, C4 levels, C1 inhibitor functional and antigenic protein levels).
- Ruconest is being requested for the treatment of acute HAE attacks.
- For members with HAE with C1 inhibitor deficiency, C1 inhibitor antigenic protein level and/or C1 inhibitor functional level is below the lower limit of normal as defined by the laboratory performing the test.
- For members with HAE with normal C1 inhibitor, other causes of angioedema have been ruled out (eg, drug-induced) and the member meets EITHER of the following criteria:
  i. Member tested positive for the F12 gene mutation.
  ii. Member has a family history of angioedema.

E. DOSAGE AND ADMINISTRATION

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

REFERENCE


