Ruconest (recombinant C1 esterase inhibitor)

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

B. REQUIRED DOCUMENTATION
The following information is necessary to initiate the prior authorization review:
- Laboratory report with C4 level, and C1 inhibitor antigenic protein level and/or C1 inhibitor functional activity and antigenic protein levels
- For the diagnosis of HAE with normal C1 inhibitor, F12 gene mutation testing results (if applicable)

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

D. INITIAL CRITERIA FOR APPROVAL
Hereditary Angioedema (HAE)
Authorization of 12 months may be granted to members who meet ALL of the following criteria:
1. Member is at least 13 years of age
2. Ruconest is being requested for the treatment of acute HAE attacks
3. The diagnosis of HAE has been confirmed by laboratory testing. Diagnostic laboratory testing for HAE has been performed (including eg, C4 levels, C1 inhibitor antigenic protein level and/or C1 inhibitor functional and antigenic protein levels)activity
   Ruconest is being requested for the treatment of acute HAE attacks.
4. For members with HAE with C1 inhibitor deficiency (HAE type I or type II):
   a. Low C4 level, and
b. Low C1 inhibitor antigenic protein level and/or C1 inhibitor functional activity (level is below the lower limit of normal as defined by the laboratory performing the test)

5. For members with HAE with normal C1 inhibitor (HAE type III):
   a. Normal C4 level, normal C1 inhibitor antigenic protein level and normal C1 inhibitor functional activity
   b. Member meets EITHER of the following criteria:
      i. Member tested positive for the F12 gene mutation
      ii. Member has a family history of angioedema
   c. Other causes of angioedema have been ruled out (e.g., 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. CONTINUATION OF THERAPY

E. Authorization of 12 months may be granted to members requesting authorization for continuation of therapy if Ruconest was previously authorized by HMSA and will be used for the treatment of acute HAE attacks. CONTINUATION OF THERAPY
   • No previous authorization/precertification:
     o All members (including members currently receiving treatment without prior authorization) must meet criteria for initial approval in section D.
   • Reauthorization:
     o Authorization of 12 months may be granted to members requesting authorization for continuation of therapy if Ruconest was previously authorized HMSA/CVS and member demonstrated a clinical response to therapy.

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.

G. ADMINISTRATIVE GUIDELINES

Precertification is required. Please refer to the HMSA medical policy web site for the fax form.

G.H. IMPORTANT REMINDER

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.
This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

H.I. REFERENCES


Revised: August 2016  Document History

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