Ruconest (recombinant C1 esterase inhibitor)

Line(s) of Business: HMO; PPO; QUEST Integration
Medicare Advantage

Original Effective Date: 10/01/2015
Current Effective Date: 05/01/2019

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
Treatment of acute attacks in adult and adolescent patients with hereditary angioedema (HAE)

B. REQUIRED DOCUMENTATION

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

- Initial therapy
  - Laboratory report with C4 level, C1 inhibitor antigenic protein level and/or C1 inhibitor functional activity
  - For the diagnosis of HAE with normal C1 inhibitor, F12 gene mutation testing results (if applicable)
- Continuation of therapy
  - Documentation supporting a positive clinical response to therapy with Ruconest (e.g., chart notes, medical records)

C. CRITERIA FOR APPROVAL

Authorization of 12 months may be granted for treatment of acute hereditary angioedema attacks when either of the following criteria is met:
1. Member has C1 inhibitor deficiency or dysfunction as confirmed by laboratory testing.
2. Member has normal C1 inhibitor as confirmed by laboratory testing and meets one of the following criteria:
   a. Member has an F12, angiopoietin-1, or plasminogen gene mutation as confirmed by genetic testing, or
   b. Member has a family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine (e.g., cetirizine) for at least one month.

D. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continuation of therapy when all of the following criteria are met:
1. Member meets all initial authorization criteria.
2. Member has experienced reduction in severity and duration of attacks since starting treatment.
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.

F. ADMINISTRATIVE GUIDELINES
Pre-certification is required. Please refer to the HMSA medical policy web site for the fax form.

G. 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/CVS’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

H. REFERENCES

Document History

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