Ruconest (recombinant C1 esterase inhibitor)

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

Effective Date: 10/01/2015

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

B. REQUIRED DOCUMENTATION
The following information is necessary to initiate the prior authorization review:
• C4 level 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 (e.g., Cinryze, Berinert)

D. INITIAL CRITERIA FOR APPROVAL
1. Hereditary Angioedema (HAE)
   Authorization of 12 months may be granted to members who meet ALL of the following criteria:
   a. The diagnosis of HAE has been confirmed by laboratory testing.
   b. Ruconest is being requested for the treatment of acute HAE attacks.

E. CONTINUATION OF THERAPY
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.

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. **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. **REFERENCES**