



STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES



Office of Pharmacy Service
Prior Authorization Criteria

Ruconest®
Effective 06/01/2020

[Prior Authorization Request Form](#)

RUCONEST is a C1 esterase inhibitor (recombinant) indicated for the treatment of acute attacks in adult and adolescent patients with hereditary angioedema (HAE).

CRITERIA FOR APPROVAL:

- 1) Diagnosis of hereditary angioedema (HAE) must be clinically established by, or in consultation with, an allergist, immunologist, hematologist or dermatologist; **AND**
- 2) Patient must be 13 years of age or older; **AND**
- 3) Diagnosis of HAE is documented based on laboratory evidence of one of the following:
 - a. Low C4 level and a low C1 inhibitor (C1-INH) antigenic level; or
 - b. Low C4 level, normal C1-INH antigenic level and low C1-INH functional level; or
 - c. Normal C4, normal C1-INH antigenic level, normal C1-INH AND documentation of family history of hereditary angioedema or HAE causing mutation; **AND**
- 4) Patient must be experiencing at least one symptom of a moderate or severe attack (non-laryngeal) (i.e. swelling of the face or abdomen); **AND**
- 5) Baseline frequency of HAE attacks must be documented; **AND**
- 6) Patient is not concurrently taking an angiotensin converting enzyme (ACE) inhibitor, estrogen replacement therapy or any other medication known to potentially cause angioedema; **AND**
- 7) Patient is NOT concurrently on, or using in combination with, other approved treatments for acute HAE attacks (e.g. Firazyr, Berinert, and Kalbitor); **AND**
- 8) Patient does not have known or suspected allergies to rabbits or rabbit derived products.

Initial prior authorization approval will be for 6 months.

Continuation of therapy Criteria:

Medical records documenting improvement (reduction in the number, duration and/or severity of attacks prior to treatment) are provided.

Continuation of therapy approval will be for 12 months.



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References:

- 1.) Ruconest package insert 7/2014
- 2.) Lexi-Comp Clinical Application 4/21/2020
- 3.) US Hereditary Angioedema Association Medical Advisory Board 2013 Recommendations for the Management of Hereditary Angioedema Due to C1 Inhibitor Deficiency; J ALLERGY CLIN IMMUNOL: IN PRACTICE VOLUME 1, NUMBER 5