UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Ruconest

Program	Prior Authorization
Medication	Ruconest® (C1 esterase inhibitor [recombinant])
Markets in Scope	Arizona, California, Hawaii, Nevada, Maryland, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	3/2013
Pharmacy and Therapeutics Approval Date	7/2020
Effective Date	9/2020

1. Background:

Ruconest® (C1 esterase inhibitor [recombinant]) is indicated for the treatment of acute attacks in adult and adolescent patients with hereditary angioedema (HAE). Effectiveness was not established in HAE patients with laryngeal attacks.[1]

2. Coverage Criteria:

A. Initial Authorization

1. Ruconest will be approved based on **all** of the following criteria:

a. Diagnosis of hereditary angioedema (HAE) as confirmed by **one** of the following:

(1) C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by **one** of the following (per laboratory standard):
(a) C1-INH antigenic level below the lower limit of normal
(b) C1-INH functional level below the lower limit of normal

-OR-

(2) HAE with normal C1 inhibitor levels and **one** of the following:
(a) Confirmed presence of a FXII, angiopoietin-1 or plasminogen gene mutation
(b) Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema

-AND-

b. **Both** of the following:

(1) Prescribed for the acute treatment of HAE attacks

-AND-

(2) Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Berinert, Firazyr)

-AND-

c. Prescribed by **one** of the following:

(1) Immunologist
(2) Allergist

Authorization of therapy will be issued for 12 months.

B. Reauthorization

1. **Ruconest** will be approved based on **all** of the following criteria:

a. Documentation of positive clinical response

-AND-

b. **Both** of the following:

(1) Prescribed for the acute treatment of HAE attacks

-AND-

(2) Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Berinert, Firazyr)

-AND-

c. Prescribed by **one** of the following:

(1) Immunologist
(2) Allergist

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Authorization of therapy will be issued for 12 months.

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Ruconest [package insert]. Bridgewater, NJ: Pharming Healthcare, Inc.; December 2019.
2. Maurer M, Magerl M, Ansotegui I, et al. The international WAO/EAACI guideline for the management of hereditary angioedema-The 2017 revision and update. Allergy. 2018 Jan 10.
3. Wu, E. Hereditary angioedema with normal C1 inhibitor. In: UpToDate, Saini, S (Ed), UpToDate, Waltham, MA, 2020.

Program	Prior Authorization –Ruconest (C1 esterase inhibitor [recombinant])
Change Control	
Date	Change
3/2013	New pharmacy/medical guideline.
9/2014	HAE attacks, changed history of failure, contraindication, or intolerance of “alkylated androgen (eg, danazol)” to “17-alpha alkylated androgen (eg, danazol, oxandrolone) or Antifibrinolytics (eg, aminocaproic acid, tranexamic acid)”, and added continuation of prior therapy for patients who are being treated prophylactically. For the off-label treatment indication, added “Not used in combination with other approved treatments for acute HAE attacks (eg, Berinert, Firazyr, Kalbitor or Ruconest).” Berinert: Added “Not used in combination with other approved treatments for acute HAE attacks (e.g. Firzayr, Kalbitor or Ruconest).” Added new criteria for Ruconest, a newly approved

	C1 esterase inhibitor (recombinant), mirroring Firazyr and Berinert, with an authorization duration of 12 months: • Diagnosis of HAE • For the treatment of acute HAE attacks • Not used in combination with other approved treatments for acute HAE attacks (eg, Berinert, Firzayr, or Kalbitor) • Prescribed by an immunologist, allergist, or rheumatologist
7/2016	Updated clinical criteria to align with E&I. Cinryze, Berinert, Ruconest separated into individual policies to align with E&I. Updated policy to new template.
7/2017	Annual review. No changes.
7/2018	Annual review. Updated reference.
4/2019	Added step through preferred products.
7/2020	Annual review. Updated clinical criteria: Added that diagnosis must be confirmed by certain tests. Added prescriber requirement. Added reauthorization criteria. Removed step thru preferred products. Added Additional Clinical Rules Section. Updated references.