UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1142-10
Program	Prior Authorization/Notification
Medications	Ruconest® (C1 esterase inhibitor [recombinant])
P&T Approval Date	8/2014, 8/2015, 7/2016, 7/2017, 7/2018, 7/2019, 7/2020, 7/2021, 7/2022, 7/2023
Effective Date	10/1/2023; Oxford only: N/A

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]:

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

1. Diagnosis of hereditary angioedema (HAE)

-AND-

2. For the treatment of acute HAE attacks

-AND-

3. Not used in combination with other products indicated for acute HAE attacks (e.g., Berinert, Firazyr, or Kalbitor)

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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 limitations may be in place.

4. References:

1. Ruconest [package insert]. Bridgewater, NJ: Pharming Healthcare, Inc.; April 2020

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Change Control	
8/2014	New program.
8/2015	Annual review. Updated references.
7/2016	Annual review with no changes to the coverage criteria. Updated background and references.
7/2017	Annual review. No changes.
7/2018	Annual review. No changes to the coverage criteria. Updated references.
7/2019	Annual review. No changes to the program.
7/2020	Annual review. No changes to coverage criteria.
7/2021	Annual review. No changes to coverage criteria.
7/2022	Annual review with no changes to coverage criteria. Added state mandate footnote. Updated reference.
7/2023	Annual review. Revised wording of criteria without change to clinical intent.