

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 3141-4
Program	Step Therapy
Medication	Berinert® (C1 esterase inhibitor [human])
P&T Approval Date	6/2020, 6/2021, 6/2022, 6/2023
Effective Date	9/1/2023; Oxford only: N/A

1. Background:

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try Ruconest® before coverage of Berinert for the acute treatment of hereditary angioedema (HAE) attacks.

Berinert (C1 esterase inhibitor [human]) is indicated for the treatment of acute abdominal, facial, or laryngeal hereditary angioedema (HAE) attacks in adult and pediatric patients.

Ruconest (C1 esterase inhibitor [recombinant]) is indicated for the treatment of acute attacks in adult and adolescent patients with hereditary angioedema (HAE)

2. Coverage Criteria ^a:

A. Hereditary Angioedema

1. **Berinert** will be approved based on the following criterion:

- a. History of failure, contraindication, or intolerance to Ruconest (C1 esterase inhibitor [recombinant])

Authorization will be issued for 12 months.

B. Other Indications

1. **Berinert** will be approved

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 Rules:

- 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.
- Medical necessity, supply limits and/or Notification may be in place.

4. References:

1. Berinert [package insert]. King of Prussia, PA: CSL Behring LLC.; September 2021.
2. Ruconest [package insert]. Warren, NJ: Pharming Healthcare Inc.; April 2020.

Program	Step Therapy - Berinert (C1 esterase inhibitor [human])
Change Control	
6/2020	New program.
6/2021	Annual review with no changes to criteria. References updated.
6/2022	Annual review with no changes to criteria. Reference updated.
6/2023	Annual review with no changes to criteria.