

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2024 P 3141-5
Program	Step Therapy
Medication	Berinert® (C1 esterase inhibitor [human])
P&T Approval Date	6/2020, 6/2021, 6/2022, 6/2023, 6/2024
Effective Date	9/1/2024

**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 <sup>a</sup>:**

<p><b>A. <u>Hereditary Angioedema</u></b></p> <p>1. <b>Berinert</b> will be approved based on the following criterion:</p> <p style="padding-left: 40px;">a. History of failure, contraindication, or intolerance to Ruconest (C1 esterase inhibitor [recombinant])</p> <p style="text-align: center;"><b>Authorization will be issued for 12 months.</b></p> <p><b>B. <u>Other Indications</u></b></p> <p>1. <b>Berinert</b> will be approved</p> <p style="text-align: center;"><b>Authorization will be issued for 12 months.</b></p> <p><sup>a</sup> 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.</p>
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**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.

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<b>Change Control</b>	
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.
6/2024	Annual review with no changes to criteria.