UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1011-12
Program	Prior Authorization/Notification
Medication	Berinert® (C1 esterase inhibitor, human)
P&T Approval Date	11/2012, 11/2013, 8/2014, 8/2015, 7/2016, 7/2017, 7/2018, 7/2019, 7/2020, 7/2021, 7/2022, 7/2023, 7/2024
Effective Date	10/1/2024

1. Background:

Berinert is a plasma-derived C1 esterase inhibitor (human) indicated for the treatment of acute abdominal, facial, or laryngeal attacks of hereditary angioedema (HAE) in adult and pediatric patients. The safety and efficacy of Berinert for prophylactic therapy has not been established.[1]

2. Coverage Criteria[a]:

A. Berinert 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., Firazyr, Kalbitor or Ruconest)

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 limits may be in place.

3. References:

1. Berinert [package insert]. Kankakee, IL: CSL Behring LLC; September 2021.

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Change Control	
11/2013	Annual review. Removed requirement for Type I or II HAE. Changed authorization duration from 12 months to 60 months.
8/2014	Annual review. Added an additional criterion that does not allow combination use with other HAE acute treatments. Decreased authorization from 60 months to 12 months. Updated Background and References.
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 with no changes to the coverage criteria. Updated background and references.
7/2018	Annual review with no changes to the coverage criteria. Updated references.
7/2019	Annual review with no changes to coverage criteria. Updated references.
7/2020	Annual review with no changes to coverage criteria.
7/2021	Annual review with no changes to coverage criteria. Updated references.
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.
7/2024	Annual review with no changes to coverage criteria.