UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 3198-1
Program	Step Therapy
Medication	Ekterly® (sebetralstat)*
P&T Approval Date	11/2025
Effective Date	2/1/2026

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 or Berinert for patients less than 18 years of age and requires a member to try Ruconest or Berinert and icatibant for patients 18 years of age and older before coverage of Ekterly for the acute treatment of hereditary angioedema (HAE) attacks.

Ekterly is a plasma kallikrein inhibitor indicated for the treatment of acute attacks of hereditary angioedema (HAE) in adult and pediatric patients aged 12 years and older.

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.

Icatibant is a bradykinin B2 receptor antagonist indicated for treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older.

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. **Ekterly** will be approved based on **one** of the following criteria:

1. **Both** of the following:

   a. Patient is less than 18 years of age

   -AND-

   b. Submission of medical records documenting a history of failure, contraindication, or intolerance to **one** of the following:

      (1) Berinert [C1 esterase inhibitor (human)]

      (2) Ruconest [C1 esterase inhibitor (recombinant)]

-OR-

2. **Both** of the following:

a. Patient is 18 years of age or older

-AND-

b. Submission of medical records documenting a history of failure, contraindication, or intolerance to **both** of the following:

(1) **One** of the following:

(a) Berinert [C1 esterase inhibitor (human)]

(b) Ruconest [C1 esterase inhibitor (recombinant)]

-AND-

(a) Icatibant (generic Firazyr*)

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.

*Ekterly and brand Firazyr are typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

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. Ekterly [package insert]. Cambridge, MA: KalVista Pharmaceuticals, Inc; July 2025.
2. Berinert [package insert]. King of Prussia, PA: CSL Behring LLC.; September 2021.
3. Icatibant [package insert]. Weston, FL 33326: Apotex Corp.; February 2024.
4. Ruconest [package insert]. Warren, NJ: Pharming Healthcare Inc.; April 2020.

Program	Step Therapy - Ekterly® (sebetralstat)
Change Control	
11/2025	New program.