MEDICAL MUTUAL®

Drug Policy

Policy:	Ekterly (sebetralstat)	Annual Review Date: 04/16/2026 Last Revised Date: 04/16/2026

OVERVIEW

Ekterly, a plasma kallikrein inhibitor, is indicated for the **treatment of acute attacks of hereditary angioedema (HAE)** in adult and pediatric patients ≥ 12 years of age.[1]

POLICY STATEMENT

This policy involves the use of Ekterly. Prior authorization is recommended for pharmacy benefit coverage of Ekterly. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Ekterly as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Ekterly be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Ekterly is recommended in those who meet the following criteria:

1. **Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency – Treatment of Acute Attacks.** Approve for 1 year if the patient meets ONE of the following (A or B):
   - **A)** Initial therapy. Approve if the patient meets ALL of the following (i, ii, iii and iv):
     - **i.** Patient is ≥ 12 years of age; AND
     - **ii.** Patient has HAE type I or type II as confirmed by the following diagnostic criteria (a and b):
       Note: A diagnosis of HAE with normal C1-INH (also known as HAE type III) does NOT satisfy this requirement.
       - **a)** Patient has low levels of functional C1-INH protein (< 50% of normal) **at baseline**, as defined by the laboratory reference values* **;**AND
       - **b)** Patient has lower than normal serum C4 levels **at baseline**, as defined by the laboratory reference values* AND
     - **iii.** The medication is prescribed by or in consultation with an allergist/immunologist or a physician who specializes in the treatment of HAE or related disorders.

iv. If the patient is 18 years or older, they have tried generic icatibant with inadequate response, intolerance or contraindication to icatibant therapy.*

B) Patient who has treated previous HAE attacks with Ekterly. Approve if the patient meets ALL of the following (i, ii, iii and iv):
Note: If the patient is currently receiving the requested therapy but has not previously received approval of Ekterly for this indication through the Coverage Review Department, review under criteria for Initial Therapy.

i. Patient has a diagnosis of HAE type I or type II*; AND
Note: A diagnosis of HAE with normal C1-INH (also known as HAE type III) does NOT satisfy this requirement.

ii. According to the prescriber, the patient has had a favorable clinical response with Ekterly treatment*; AND
Note: Examples of a favorable clinical response include decrease in the duration of HAE attacks, quick onset of symptom relief, complete resolution of symptoms, or decrease in HAE acute attack frequency or severity.

iii. The medication is prescribed by or in consultation with an allergist/immunologist or a physician who specializes in the treatment of HAE or related disorders.

iv. If the patient is 18 years or older, they have tried generic icatibant with inadequate response, intolerance or contraindication to icatibant therapy.*

Initial Approval/ Extended Approval.
A) *Initial Approval:12 months*
B) *Extended Approval: 12 months*

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Ekterly has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Hereditary Angioedema (HAE) Prophylaxis**. Data are not available and Ekterly is not indicated for prophylaxis of HAE attacks.
2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

***Documentation Requirements:**

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or

performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Ekterly® tablets [prescribing information]. Cambridge, MA: KalVista Pharmaceuticals; July 2025.
2. Busse PJ, Christiansen SC, Riedl MA, et al. US HAEA Medical Advisory Board 2020 guidelines for the management of hereditary angioedema. *J Allergy Clin Immunol Pract*. 2021;9(1):132-150.e3.
3. Maurer M, Magerl M, Betschel S, et al. The international WAO/EAACI guideline for the management of hereditary angioedema: the 2021 revision and update. *Allergy*. 2022;77(7):1961-1990.