

ALASKA MEDICAID
Prior Authorization Criteria

Ekterly[®]
(sebetralstat)

FDA INDICATIONS AND USAGE¹

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

APPROVAL CRITERIA^{1,2,3}

1. Patient meets FDA labeled age **AND**;
2. Prescribed by or in consultation with an immunologist **AND**;
3. Patient has the confirmed diagnosis of hereditary angioedema **AND**;
4. Medications with an established link to angioedema (e.g. angiotensin converting enzyme inhibitors, estrogen replacement therapy, etc.) have been evaluated and discontinued where appropriate **AND**;
5. Ekterly will only be used for treatment of acute HAE attacks.

DENIAL CRITERIA¹

1. Failure to meet approval criteria **OR**;
2. Patient will take in combination with another treatment indicated for acute HAE attacks **OR**;
3. Patient has severe hepatic impairment (Child-Pugh Class C)

CAUTIONS¹

- Ekterly[®] should not be used with moderate or strong CYP3A4 inducers or strong CYP3A4 inhibitors. Dose adjustment may be required when taken with moderate CYP3A4 inhibitors.
- Dose adjustment may be necessary in patients with moderate hepatic impairment (Child-Pugh Class B).
- The safety of Ekterly[®] in pregnancy or breast feeding has not been determined.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to one year

QUANTITY LIMIT

- 8 tablets per 30 days
 - Not to exceed 4 tablets in any 24 hour period

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REFERENCES / FOOTNOTES:

1. Ekterly (sebetralstat) [prescribing information]. Cambridge, MA: KalVista; July 2025
2. 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.
3. Riedl MA, Farkas H, Aygoren-Pursun E, et al. Oral sebetralstat for on-demand treatment of hereditary angioedema attacks. N Engl J Med. 2024;391(1):32-43.