CareSource Rx Innovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Ekterly (sebetralstat)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Ekterly, approved by the FDA in 2025, 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. It is the first oral option for treatment of acute HAE attacks.
HAE is a rare autosomal dominant disease characterized by episodic unpredictable swelling, which can occur in a variety of anatomic locations. The swelling results from excess production of the vasodilator bradykinin. Attacks may be painful and cause functional impairment but are not associated with pruritis. The most common types of HAE are caused by deficiency (type 1) or dysfunction (type 2) of C1 inhibitor (C1-INH). Type 1 is the most prevalent.

Ekterly (sebetralstat) will be considered for coverage when the following criteria are met:

Hereditary Angioedema

For **initial** authorization:
1. Member is at least 12 years of age; AND
2. Medication must be prescribed by or in consultation with an allergist or immunologist; AND
3. HAE type I or type II confirmed by both of the following:
   a) Low C4 level;
   b) Low (<50% of normal) C1 inhibitor antigenic and/or functional level; AND
4. Medication is being prescribed for the treatment of acute HAE attacks; AND
5. Medication is not being used in combination with another acute HAE therapy; AND
6. If 18 years of age or older, member has had a trial and failure of icatibant.
7. **Dosage allowed/Quantity limit:** 600 mg (two tablets) orally at the earliest recognition of an acute HAE attack. A second dose may be taken at least 3 hours after the first dose if response is inadequate, or if symptoms worsen or recur. Max 1,200 mg (four tablets) in any 24-hour period. QL: 8 tablets per fill

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must document improvement such as faster time to symptom relief or resolution of attack.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Ekterly (sebetralstat) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
07/10/2025	New policy for Ekterly created.

References:

1. Ekterly [prescribing information]. KalVista Pharmaceuticals, Inc.; 2025.
2. Cohn DM, Aygören-Pürsün E, Bernstein JA, et al. Evaluation of patient-reported outcome measures for on-demand treatment of hereditary angioedema attacks and design of KONFIDENT, a phase 3 trial of sebetralstat. *Clin Transl Allergy*. 2023;13(9):e12288. doi:10.1002/clt2.12288
3. Busse PJ, Christiansen SC, Riedl MA, et al. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema [published online ahead of print, 2020 Sep 6]. *J Allergy Clin Immunol Pract*. 2020;S2213-2198(20)30878-3. doi:10.1016/j.jaip.2020.08.046
4. Maurer M, Magerl M, Betschel S, et al. The international WAO/EAACI guideline for the management of hereditary angioedema - The 2021 revision and update. *World Allergy Organ J.* 2022;15(3):100627. Published 2022 Apr 7. doi:10.1016/j.waojou.2022.100627
5. Betschel S, Badiou J, Binkley K, et al. The International/Canadian Hereditary Angioedema Guideline [published correction appears in Allergy Asthma Clin Immunol. 2020 May 6;16:33]. *Allergy Asthma Clin Immunol*. 2019;15:72. Published 2019 Nov 25. doi:10.1186/s13223-019-0376-8
6. Bork K, Bernstein JA, Machnig T, Craig TJ. Efficacy of Different Medical Therapies for the Treatment of Acute Laryngeal Attacks of Hereditary Angioedema due to C1-esterase Inhibitor Deficiency. *J Emerg Med*. 2016;50(4):567-80.e1. doi:10.1016/j.jemermed.2015.11.008
7. Li HH, Aygören-Pürsün E, Magerl M, et al. Indirect treatment comparison of oral sebetralstat and intravenous recombinant human C1 esterase inhibitor for on-demand treatment of hereditary angioedema attacks. *Allergy Asthma Clin Immunol.* 2025;21(1):10. Published 2025 Mar 15. doi:10.1186/s13223-025-00955-6

Effective date: 01/01/2026
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