Effective date: 02/01/2026
Review date: 11/2025 Scope: Medicaid

Ekterly (sebetralstat) tablets

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Treatment of acute attacks of hereditary angioedema (HAE) in adult and pediatric patients aged 12 years of age and older.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Hereditary angioedema (HAE)
Authorization of 6 months may be granted for treatment of acute hereditary angioedema attacks when all of the following criteria are met:

A. Medication is prescribed by, or in consultation with allergist/immunologist or a physician who specializes in the management of HAE
B. Member must be 12 years of age or older
C. Documentation that the member has history of moderate to severe cutaneous attacks (without concomitant hives) OR abdominal attacks OR mild to severe airway swelling attacks of HAE (i.e., debilitating cutaneous/gastrointestinal symptoms OR laryngeal/pharyngeal/tongue swelling)
D. Documentation that member does not have a history of severe laryngeal attacks, as Ekterly (sebetralstat) tablets need to be swallowed whole
E. Member has documented diagnosis of HAE type I or type II and meets one of the following (a or b):
    a. Documentation that the member has C1 inhibitor deficiency or dysfunction as confirmed by laboratory testing; and meets one of the following criteria:
        i. C1 inhibitor (C1-INH) antigenic level below the lower limit of normal as defined by the laboratory performing the test, or
        ii. Normal C1-INH antigenic level and a low C1-INH functional level (functional C1-INH less than 50% or C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test); OR
    b. Documentation that the member has normal C1 inhibitor as confirmed by laboratory testing and meets one of the following criteria:
        i. Member has an F12, angiopoietin-1, plasminogen, or kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) pathogenic variant as confirmed by genetic testing, or

ii. Member has a documented family history of angioedema and the member's angioedema was refractory to a trial of high-dose antihistamine therapy (e.g., cetirizine 40mg per day or the equivalent) for at least one month.

F. Member will not use Ekterly (sebetralstat) concomitantly with other medications used for the treatment of acute HAE attacks (e.g., Icatibant, Kalbitor (ecallantide), Ruconest (C1 esterase inhibitor), Berinert (C1 esterase inhibitor), etc.)
G. Other causes of angioedema have been ruled out (e.g., angiotensin-converting enzyme inhibitor [ACE-I] induced angioedema, angioedema related to an estrogen containing drug, allergic angioedema).
H. Documentation that the member does not require sustained use of strong CYP3A4 inhibitors (i.e., clarithromycin, erythromycin, itraconazole, ketoconazole, voriconazole, ritonavir, cobicistat, atazanavir, etc.) OR moderate or strong CYP3A4 inducers(i.e., bosentan, dexamethasone, efavirenz, modafinil, nafcillin, rifampin, carbamazepine, phenytoin, phenobarbital, mitotane, cenobamate, etc.)
I. Documentation that the member does not have severe hepatic impairment (Child-Pugh Class C)
J. For members 18 years of age and older, they have documentation that they have had an inadequate response, intolerance, or contraindication to icatibant

III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continuation of therapy when all of the following criteria are met:

A. Documentation that the member meets the criteria for initial approval.
B. Documentation that the member has experienced a reduction in severity and/or duration of attacks when the requested medication is used to treat an acute attack.
C. Prophylaxis treatment should be considered based on the attack frequency, attack severity, comorbid conditions, and member's quality of life

IV. QUANTITY LIMIT

Ekterly 300mg: 1200mg or 4 tablets per 30 days

V. REFERENCES

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17. Sharma J, Jindal AK, Banday AZ, et al. Pathophysiology of Hereditary Angioedema (HAE) Beyond the SERPING1 Gene [published online ahead of print, 2021 Jan 14] [published correction appears in Clin Rev Allergy Immunol. 2021 Feb 17]. Clin Rev Allergy Immunol. 2021;10.1007/s12016-021-08835-8. Doi:10.1007/s12016-021-08835-8.
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