DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Hereditary Angioedema – Ekterly Drug Quantity Management Policy – Per Days
- Ekterly® (sebetralstat tablets – KalVista)

REVIEW DATE: 07/16/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

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

Dosing

The recommended dose for Ekterly is 600 mg (two 300 mg tablets) at the earliest recognition of an acute HAE attack.[1] A second dose of Ekterly may be taken at least 3 hours after the first dose if response is inadequate, or if symptoms worsen or recur. The maximum recommended dosage is 1,200 mg (four 300 mg tablets) in any 24-hour period. Of note, in the clinical trial, patients had the option to be administered a second dose of Ekterly 3 hours after the first dose. The second rescue dose was given for 39.8% of Ekterly-treated attacks.

Availability
Ekterly is supplied as 300 mg tablets in packets containing 4 tablets each.[1]

Guidelines
US HAE Medical Advisory Board guidelines (2020) recommend that all patients with laboratory confirmed HAE should have access to at least two standard doses of an approved on-demand medication for treatment of acute attacks.[2] On-demand treatment of attacks is most effective when administered early after attack onset.

The quantity limits outlined below provide for the patient to treat 4 attacks (at the maximum Ekterly dose) per 28 days, with an override provided to treat an additional 4 attacks (at the maximum Ekterly dose) each month.

POLICY STATEMENT
This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Ekterly. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. "One-time" approvals are provided for 30 days in duration.

Drug Quantity Limits

Product	Strength/Dosage Form	Retail Maximum Quantity per 28 Days	Home Delivery Maximum Quantity per 84 Days
Ekterly® (sebetralstat tablets)	300 mg tablets (packets of 4 tablets each)	16 tablets*	48 tablets*

* This is a quantity sufficient to treat four acute hereditary angioedema attacks in each 28-day period, assuming that the patient requires two 600 mg doses in a 24-hour period to treat the attack. If a patient requires additional Ekterly doses for an additional attack, exceptions will be provided based on the criteria below.

Exceptions to the quantity limits listed above are covered as medically necessary when the following criteria are met. Any other exception is considered not medically necessary.

CRITERIA
1. If the patient requires additional doses of Ekterly to treat a subsequent attack of hereditary angioedema (HAE), approve a one-time override for 16 additional tablets at retail or home delivery.
   Note: At retail, the approval quantity should be the number of Ekterly tablets the patient has received in the past 28 days plus 16 tablets. At home delivery, the approval quantity should be the number of Ekterly tablets the patient has received in the past 84 days plus 16 tablets. ONE override may be approved ONCE every 30 days.

REFERENCES

1. Ekterly® tablets [prescribing information]. Cambridge, MA: KalVista; 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.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	07/16/2025