DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Hereditary Angioedema – Kalbitor Drug Quantity Management Policy – Per Days
- Kalbitor® (ecallantide subcutaneous injection – Shire)

REVIEW DATE: 02/19/2025

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 AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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

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

Potentially serious hypersensitivity reactions, including anaphylaxis, have occurred in patients treated with Kalbitor.[1] Kalbitor should only be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and HAE.

Dosing

The recommended dose of Kalbitor is 30 mg (3 mL) administered subcutaneously (SC) in three 10 mg injections.[1] If the attack persists, an additional dose of 30 mg SC may be administered within a 24-hour period.

Availability

Kalbitor is supplied as three 10 mg/mL single-use vials packaged in a carton.[1] Each vial contains 10 mg of ecallantide.

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.

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Kalbitor. 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. All approvals are provided for the duration noted below. "One-time" approvals are provided for 30 days in duration.

Drug Quantity Limits

Product	Package Size	Retail Maximum Quantity per 28 Days	Home Delivery Maximum Quantity per 84 Days
Kalbitor® (ecallantide SC injection)	3 single-use vials (10 mg/mL each) per carton	4 cartons (12 single-use vials)*	12 cartons (36 single-use vials)*

SC – Subcutaneous; * This is a quantity sufficient to treat two acute hereditary angioedema attacks in each 28-day period, assuming that the patient requires two doses in a 24-hour period to treat each attack. If a patient requires additional Kalbitor doses for a subsequent attack, exceptions will be provided based on the criteria below.

Hereditary Angioedema – Kalbitor Drug Quantity Management Policy – Per Days product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

1. If the patient requires additional doses of Kalbitor to treat a subsequent attack of hereditary angioedema, approve a one-time override for the requested quantity, not to exceed 12 additional single-use vials (4 cartons of 3 vials each) at retail or home delivery.
Note: At retail, the approval quantity should be the number of vials of Kalbitor the patient has received in the past 28 days plus 12 vials. At home delivery, the approval quantity should be the number of vials of Kalbitor the patient has received in the past 84 days plus 12 vials. ONE override may be approved ONCE every 30 days.

REFERENCES

1. Kalbitor® subcutaneous injection [prescribing information]. Lexington, MA: Takeda; December 2020.
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	--	01/18/2023
Annual Revision	No criteria changes.	02/09/2024
Annual Revision	Policy statement was updated to note that "one-time" approvals are provided for 30 days in duration. **Kalbitor SC injection:** Override was updated to approve a one-time override for 12 additional vials if the patient requires additional doses of Kalbitor to treat a subsequent attack of hereditary angioedema. Previously, criteria approved 6 additional vials. Criteria Note was updated to clarify "At retail, the approval quantity should be the number of vials of Kalbitor the patient has received in the past 28 days plus 12 vials. At home delivery, the approval quantity should be the number of vials of Kalbitor the patient has received in the past 84 days plus 12 vials. ONE override may be approved ONCE every 30 days."	02/19/2025