CareSource

PHARMACY POLICY STATEMENT **Indiana Medicaid**	
DRUG NAME	Kalbitor (ecallantide)
BILLING CODE	J1290
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office
COVERAGE REQUIREMENTS	Prior-Authorization Required (Non-Preferred Product) Alternative preferred products include Berinert and Firazyr QUANTITY LIMIT—12 vials (4 cartons) per fill
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Kalbitor (ecallantide) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

HEREDITARY ANGIOEDEMA (HAE)

For **initial** authorization:

1. Member must be 12 years of age or older; AND
2. Medication must be prescribed by or in consultation with an allergist or immunologist; AND
3. Member has a diagnosis of 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. Member has documented trial and failure of or contraindication to both Firazyr and Berinert (Chart notes required); AND
6. Medication is not being used in combination with another on-demand therapy (e.g. Berinert, Firazyr, Ruconest).
7. **Dosage allowed:** 30mg subQ (as three 10mg (1 mL) injections); may repeat once within 24-hour period if the attack persists.

If member meets all the requirements listed above, 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 member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Kalbitor (ecallantide) not medically necessary for the treatment of diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
08/28/2017	New policy for Kalbitor created. Criteria for each type of HAE specified. Criteria of documentation of attacks, discontinuation of meds that can cause HAE, and restriction on combinations with other meds for acute attacks added.
01/20/2021	Updated references. Removed hematology as a specialist. Simplified the diagnostic criteria. Removed log book requirement. Reworded the renewal criteria. Extended initial auth duration to 6 mo and renewal to 12 mo. Removed statement about causative meds. Clarified the dosing. Adjusted quantity limit to allow for repeat doses per label.

References:

1. Kalbitor [package insert]. Burlington, MA; Dyax Corp.; September 2014.
2. Frank MM, Zuraw B, Banerji A, et al. Management of children with hereditary angioedema due to C1 inhibitor deficiency. Pediatrics. 2016 Nov;138(5). pii: e20160575.
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, Ansotegui I, et al. The international WAO/EAACI guideline for the management of hereditary angioedema-The 2017 revision and update. *Allergy*. 2018;73(8):1575-1596. doi:10.1111/all.13384
5. Cicardi M, Levy RJ, McNeil DL, et al. Ecallantide for the treatment of acute attacks in hereditary angioedema. *N Engl J Med*. 2010;363(6):523-531. doi:10.1056/NEJMoa0905079

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