Humana. CareSource™

PHARMACY POLICY STATEMENT
Kentucky Medicaid

DRUG NAME	Kalbitor (Ecallantide)
BILLING CODE	J1290
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Home/Office
COVERAGE REQUIREMENTS	Prior-Authorization Required (Non-Preferred Product) Alternative preferred products include Berinert and Firazyr QUANTITY LIMIT— 6 mL per fill (18 mL per 30 days)
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 medication is being used **for the treatment of acute HAE attacks** (NOT for treatment of acquired angioedema); AND
2. Medication must be prescribed by or in consultation with a provider specializing in allergy, immunology, or hematology; AND
3. Member has documented trial and failure of or contraindication to **both** Firazyr and Berinert (Chart notes required); AND
4. Member must have a confirmed diagnosis of HAE as **one** of the following:
   a) Type 1 HAE documented in chart notes with ALL of the following (Note: tests listed below must be repeated for confirmation of diagnosis):
      i) Low levels (below the limits of the laboratory's normal reference range) of C4, C1-INH antigenic protein and C1-INH functional level; AND
      ii) Positive family history of angioedema OR earlier age of onset (before age 30) with normal C1q antigenic protein level;
   b) Type 2 HAE documented in chart notes with ALL of the following (Note: tests listed below must be repeated for confirmation of diagnosis):
      i) Normal or elevated level of C1-INH antigenic protein (as defined by performing lab); AND
      ii) Low level (below the limits of the laboratory's normal reference range) C4 and C1-INH functional; AND
5. Medication is **not** being used in combination with Berinert, Firazyr, or Ruconest; AND
6. Medications known to cause angioedema (i.e. ACE-Inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate.
7. **Dosage allowed:** Three 10 mg (1mL) injection at onset; repeat within 24 hours if the attack persists.

Note: Personal documentation (log book, journal, etc.) of medication use will be necessary for reauthorization. Prescribers should be aware and make their patients aware of this requirement for reauthorization.

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease; AND
3. Log of medication use supported by medical chart or by claims data has been provided.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.

CareSource considers Kalbitor (Ecallantide) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Acquired angioedema (AAE)
- HAE prophylactic therapy

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.

References:

1. Kalbitor [package insert]. Burlington, MA; Dyax Corp.; September 2014.
2. Cicardi M, Zuraw B, Saini S, et al. Hereditary angioedema: pathogenesis and diagnosis. UpToDate. Updated November 15, 2016.
3. Craig, T., Pürsün, E. A., Bork, K., Bowen, et al. (2012). WAO Guideline for the Management of Hereditary Angioedema. The World Allergy Organization Journal, 5(12), 182–199. http://doi.org/10.1097/WOX.0b013e318279affa.
4. 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.
5. Bowen T, Cicardi M, Farkas H, et al. 2010 International consensus algorithm for the diagnosis, therapy, and management of hereditary angioedema. Allergy Asthma Clin Immunol. 2010;6(1):24.
6. Kalbitor. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: http://www.micromedexsolutions.com. Accessed August 8, 2017.

Effective date: 09/08/2017
Revised date: 08/28/2017