



## Prior Authorization Approval Criteria

### *Kalbitor (Ecallantide)*

<b>Generic name:</b>	Ecallantide
<b>Brand name:</b>	Kalbitor
<b>Medication class:</b>	Plasma kallikrein inhibitor
<b>FDA-approved uses:</b>	treatment of acute attacks of hereditary angioedema (HAE) in patients 16 years of age or older.
<b>Available dosage forms:</b>	10mg/ml single use vial
<b>Usual dose:</b>	30mg administered subcutaneously in three 10mg injections. If attack persists, an additional dose of 30mg may be administered within a 24 hour period.
<b>Approximate cost:</b> (based on AWP 2010)	\$9,540.00 per 30 mg treatment. (\$3,180.00/10mg vial)
<b>Duration of therapy:</b>	one time administration per attack which may be repeated within a 24 hour period if attack persists.

**Criteria for use** (*bullet points below are all inclusive unless otherwise noted*):

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Patient must have clinically diagnosed HAE and is having an acute attack.
- Patient must be 16 years of age or older.
- Must be prescribed by a specialist.
- Must be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and hereditary angioedema.

**Caution:**

- Anaphylaxis has been reported after administration of Kalbitor

**Contraindication:**

- Hypersensitivity to Kalbitor

**Not approved if:**

- Patient does not meet the above stated criteria
- Patient has any contraindications to the use of Kalbitor

**Special considerations:**

- Vials should be kept refrigerated. Vials removed from refrigerator should be stored at room temperature and used within 14 days or returned to refrigeration until use.
- The product approval required a risk evaluation and mitigation strategy (REMS) program to communicate the risk of anaphylaxis and the importance of distinguishing between a hypersensitivity reaction and HAE attack symptoms.
- This is a medical benefit. Must be administered by a health care professional.

FCHP Pharmacy and Therapeutics Committee approval: \_\_\_\_\_

Date: \_\_\_\_\_

Adopted: 06/09/10