Kalbitor (ecallantide) is a plasma kallikrein inhibitor indicated for treatment of acute attacks of hereditary angioedema (HAE) in patients 12 years of age and older. It must be administered by a healthcare professional because of the risk for anaphylaxis, which is a black box warning for the product. HAE is a rare autosomal dominant disease characterized by episodic unpredictable swelling, which can occur in a variety of anatomic locations. The swelling results from excess production of the vasodilator bradykinin. Attacks may be painful and cause functional impairment but are not associated with pruritis. The most common types of HAE are caused by deficiency (type 1) or dysfunction (type 2) of C1 inhibitor (C1-INH). Type 1 is the most prevalent.

Kalbitor (ecallantide) will be considered for coverage when the following criteria are met:

**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 icatibant (if 18 years of age or older) and Berinert; AND
6. Medication is not being used in combination with another acute HAE therapy (e.g., Berinert, Firazyr, Ruconest).
7. Dosage allowed/Quantity limit: 30mg subQ (as three 10mg (1 mL) injections); may repeat once within 24-hour period if the attack persists.
   QL: 12 vials (4 cartons) per fill

*If all the above requirements are met, 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 all the above requirements are met, the medication will be approved for an additional 12 months.*
CareSource considers Kalbitor (ecallantide) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>08/28/2017</td>
<td>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.</td>
</tr>
<tr>
<td>01/20/2021</td>
<td>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.</td>
</tr>
<tr>
<td>07/05/2022</td>
<td>Transferred to new template, updated references, put “icatibant” instead of “Firazyr.”</td>
</tr>
</tbody>
</table>

References:


Effective date: 01/01/2023
Revised date: 07/05/2022