Kalbitor

**Description**

Kalbitor (ecallantide)

**Background**

Kalbitor is a human plasma kallikrein inhibitor for the treatment of acute attacks in adult and adolescent patients with hereditary angioedema (HAE). Hereditary angioedema, which is caused by having insufficient amounts of a plasma protein called C1-esterase inhibitor. People with HAE can develop rapid swelling of the hands, feet, limbs, face, intestinal tract, or airway. These acute attacks of swelling can occur spontaneously, or can be triggered by stress, surgery or infection. Swelling of the airway is potentially fatal without immediate treatment. Kalbitor is intended to restore the level of functional C1-esterase inhibitor in a patient’s plasma, thereby treating the acute attack of swelling (1).

**Regulatory Status**

FDA-approved indication: Kalbitor is a plasma kallikrein inhibitor indicated for treatment of acute attacks of hereditary angioedema (HAE) in patients 12 years of age and older (1).

Kalbitor includes a boxed warning of serious hypersensitivity reactions, including anaphylaxis. Anaphylaxis has occurred in 4% of treated patients. Kalbitor should only be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and hereditary angioedema (1).

The safety and efficacy of Kalbitor in patients less than 12 years of age have not been established (1).
Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Kalbitor may be considered medically necessary in patients 12 years of age or older for the treatment of acute attacks of hereditary angioedema (HAE) and if the conditions indicated below are met.

Kalbitor may be considered investigational in patients less than 12 years of age and for all other indications.

Prior-Approval Requirements

Age 12 years of age and older

Diagnosis

Patient must have the following:

1. Acute attacks of Hereditary Angioedema (HAE)
   a. Only administered by a healthcare professional with appropriate medical support to manage anaphylaxis and hereditary angioedema.

   AND NONE of the following:
   1. Prophylactic therapy
   2. Dual therapy with another agent for treating acute attacks of HAE

Prior – Approval Renewal Requirements

Same as above

Policy Guidelines
Pre - PA Allowance
None

Prior - Approval Limits
Duration 12 months

Prior – Approval Renewal Limits
Duration 12 months

Rationale

Summary
Kalbitor is a plasma kallikrein inhibitor indicated for the treatment of acute attacks in adult and adolescent patients with hereditary angioedema (HAE). HAE symptoms include episodes of edema (swelling) in various body parts including the hands, feet, face, and airway. HAE is caused by mutations to C1-esterase-inhibitor (C1-INH). The safety and efficacy of Kalbitor in children less than 12 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Kalbitor while maintaining optimal therapeutic outcomes.

References

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2011</td>
<td>New Policy</td>
</tr>
<tr>
<td>September 2012</td>
<td>Annual editorial and reference update</td>
</tr>
<tr>
<td>March 2013</td>
<td>Annual editorial and reference update</td>
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<tr>
<td></td>
<td>Addition to criteria that Kalbitor must be administered by a healthcare</td>
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<td></td>
<td>professional with appropriate medical support to manage anaphylaxis and</td>
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<td></td>
<td>hereditary angioedema.</td>
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<tr>
<td>June 2014</td>
<td>Annual review</td>
</tr>
<tr>
<td></td>
<td>Revision of age to 12</td>
</tr>
<tr>
<td>December 2014</td>
<td>Annual editorial review and reference update</td>
</tr>
</tbody>
</table>
Section: Prescription Drugs
Subsection: Hematological Agents
Subject: Kalbitor

Effective Date: October 1, 2019
Original Policy Date: December 7, 2011
Page: 4 of 4

Addition of the no dual therapy with another agent for treating acute attacks of HAE

December 2015 Annual review and reference update
December 2016 Annual editorial review and reference update.
               Changed Policy Code from 5.10.07 to 5.85.07
September 2017 Annual review
December 2017 Annual review
September 2018 Annual review
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September 2019 Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 13, 2019 and is effective on October 1, 2019.