



5.85.07

Section:	Prescription Drugs	Effective Date:	April 1, 2021
Subsection:	Hematological Agents	Original Policy Date:	December 7, 2011
Subject:	Kalbitor	Page:	1 of 4

Last Review Date: March 12, 2021

Kalbitor

Description

Kalbitor (ecallantide)

Background

Kalbitor (ecallantide) 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 pediatric patients less than 12 years of age have not been established (1).

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Related policies

Berinert, Cinryze, Firazyf, Haegarda, Orladeyo, Ruconest, Takhzyro

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

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Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Kalbitor (ecallantide) 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 pediatric patients 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

1. Kalbitor [package insert]. Burlington, MA : Dyax Corp.; March 2015.

Policy History

Date	Action
December 2011	New Policy
September 2012	Annual editorial and reference update
March 2013	Annual editorial and reference update Addition to criteria that Kalbitor must be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and hereditary angioedema.
June 2014	Annual review Revision of age to 12
December 2014	Annual editorial review and reference update

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	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
November 2018	Annual review
September 2019	Annual review
September 2020	Annual review
March 2021	Annual editorial review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.