Kalbitor® (ecallantide)

When requesting Kalbitor® (ecallantide), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

Kalbitor is indicated for the treatment of acute Hereditary Angioedema (HAE) attacks.

Coverage Guidelines

Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency – Treatment of Acute Attacks

The individual must meet **all** of the following criteria for initial authorization:

- Has HAE type I or type II as confirmed by the following diagnostic criteria:
  - Has low levels of functional C1-INH protein (less than 50% of normal) at baseline, as defined by the laboratory reference values; AND
  - Has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values;
- Medication is prescribed by or in consultation with an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders.

The individual must meet **all** of the following criteria for reauthorization:
Note: An individual who is currently on therapy but has not been previously approved via eviCore coverage determination is reviewed under criteria for initial therapy.

- Has been treated previously for acute HAE type I or type II attacks with Kalbitor;
- Has had a favorable clinical response (e.g., decrease in the duration of HAE attacks, quick onset of symptom relief, complete resolution of symptoms, decrease in HAE acute attack frequency or severity) with Kalbitor treatment;
- Medication is prescribed by or in consultation with an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders.

Approval duration (initial and reauthorization): 12 months

Dosing Recommendation

Administer 30 mg subcutaneously. If the attack persists, an additional dose of 30 mg may be administered within a 24 hour period.

References

1. Kalbitor® [prescribing information]. Lexington, MA: Takeda; June 2025.

2. Busse PJ, Christiansen SC, Riedl MA, et al. US HAEA Medical Advisory Board 2020 guidelines for the management of hereditary angioedema. *J Allergy Clin Immunol Pract*. 2021 Jan;9(1):132-150.e3.
3. Maurer M, Magerl M, Betschel S, et al. The international WAO/EAACI guideline for the management of hereditary angioedema: the 2021 revision and update. *Allergy.* 2022;77(7):1961-1990.

