

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 indications.

FDA-approved indication(s)

- Kalbitor® is indicated for treatment of acute Hereditary Angioedema (HAE) attacks

Approved Off-label Compendial use

- None

Coverage Guidelines

Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] – Treatment of Acute Attacks, Initial Therapy

Initial authorization:

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

- The patient has HAE type I or type II as confirmed by the following diagnostic criteria:
 - Patient has low levels of functional C1-INH protein (Less than 50% of normal) at baseline, as defined by the laboratory reference values; AND
 - Patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values; AND
- The 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: 12 months

Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] – Patient who have Treated Previous Acute HAE Attacks with Kalbitor

- The patient has treated previous acute HAE type I or type II attacks with Kalbitor; AND
- According to the prescribing physician, the patient 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; AND
- The medication is prescribed by on in consultation with an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders

Approval duration: 12 months

Dosing Guidelines

- 30 mg by SC injection. Do not administer more than three doses in 24 hours.

References

1. Kalbitor® [prescribing information]. Cambridge, MA: Dyax Corporation; March 2015.
2. Bowen T, Cicardi M, Farkas H, et al. 2010 international consensus algorithm for the diagnosis, therapy and management of hereditary angioedema. *Ann Allergy Asthma Immunol.* 2010;6:24.
3. Mauer M, Magerl M, Ansotegui I, et al. The international WAO/EAACI guideline for the management of hereditary angioedema – the 2017 revision and update. *Allergy.* 2018;73(8):1575-1596. Available at: <https://onlinelibrary.wiley.com/doi/epdf/10.1111/all.13384>. Accessed on September 12, 2018
4. Zuraw BL, Bork K, Binkley KE, et al. Hereditary angioedema with normal C1 inhibitor function: consensus of an international expert panel. *Allergy Asthma Proc.* 2012;33:S145-S156.
5. Magerl M, Germenis AE, Maas C, et al. Hereditary angioedema with normal C1 inhibitor. Update on evaluation and treatment. *Immunol Allergy Clin N Am.* 2017;37:571-584.
6. Zuraw BL, Banerji A, Bernstein JA, et al. US Hereditary Angioedema Association Medical Advisory Board 2013 recommendations for the management of hereditary angioedema due to C1 inhibitor deficiency. *J Allergy Clin Immunol: In Practice.* 2013;1:458-467. Available at: <https://haei.org/wp-content/uploads/2015/04/Zuraw-B-L-US-HAEA-MAB-2013-Recommendations.pdf>. Accessed on September 13, 2018.
7. Zuraw BL, Bernstein JA, Lang DM. A focused parameter update: Hereditary angioedema, acquired C1 inhibitor deficiency, and angiotensin-converting enzyme inhibitor-associated angioedema. *J Allergy Clin Immunol.* 2013;131(6):1491-1493.e25.