ecallantide (Kalbitor)

Commercial Medical Benefit Drug Policy

Place of Service
Home Health Administration
Infusion Center Administration
Office Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: IMMUNOLOGICAL AGENTS
Mechanism of Action: Ecallantide is recombinant protein that acts as a kallikrein inhibitor
HCPCS:
J1290:Injection, ecallantide, 1 mg
How Supplied:
10 mg/mL solution for injection (single-use glass vial)

Condition(s) listed in policy *(see coverage criteria for details)*

- Hereditary Angioedema, Treatment

The following conditions do not meet the safety and efficacy criteria established by Blue Shield of California's Pharmacy & Therapeutics committee and are not covered:

- Prophylaxis of HAE

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Hereditary Angioedema, Treatment
Meets medical necessity if all the following are met:

1. Being used for treatment of acute HAE attack
2. Inadequate response, intolerable side effect, or contraindication to generic icatibant

Covered Doses:
Up to 2 injections of a 30 mg subcutaneous injection within a 24-hour period

Coverage Period:
Cover up to 3 treatments per request (6 doses)

ICD-10:
D84.1

Additional Information

Kalbitor warning: Anaphylaxis
Anaphylaxis has been reported after administration of Kalbitor. Because of the risk of anaphylaxis, KALBITOR should only be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and hereditary angioedema. Healthcare professionals should be aware of the similarity of symptoms between hypersensitivity reactions and hereditary angioedema and patients should be monitored closely

HAE Diagnosis:

- Suspicion of HAE-1/2 should prompt laboratory investigations to support a diagnosis
  - Measurements of serum/plasma levels of C1-INH function, C1- INH protein, and C4 are used to diagnose HAE-1/2
  - HAE-1: Both concentration and function of C1-INH are low (<50% of normal).
  - HAE-2:
    - C1-INH concentrations are normal or elevated
    - C1-INH function is low (<50% of normal)
  - C4 levels are usually low in HAE-1/2 patients, but the sensitivity and specificity of C4 as a marker for HAE are limited.
  - Sequencing of the SERPING1 gene can be supportive in the diagnostic workup of some HAE-1/2 patients (including prenatal diagnosis); however, bio-chemical C1-INH testing is effective and less expensive than genetic testing

- HAE with normal C1 inhibitor (HAE-nC1-INH)
  - The different forms of HAE share some clinical features and, possibly, therapeutic options with HAE-1/2
  - Can only be diagnosed by genetic testing, which is becoming increasingly available
  - Genetic testing should be performed and include testing for the 6 recognized HAE types:
    - HAE with mutation in the factor XII gene (HAE-FXII)
    - HAE with mutation in the angiopoietin-1 gene (HAE-ANGPT1)
    - HAE with mutation in the plasminogen gene (HAE-PLG)
    - HAE with mutation in the kininogen 1 gene (HAE-KNG1)
    - HAE with mutation in the myoferlin gene (HAE-MYOF)
    - HAE with mutation in the heparan sulfate 3-O- sulfotransferase 6 gene (HAE-HS3ST6).
  - Additional mutations are likely to be identified in the future and should be included in the genetic diagnostic workup for HAE.

Type of Angioedema	Laboratory Findings		
	C4 Level	Antigenic C1 INH Level	Functional C1 INH Level
HAE – Type I	↓	↓	↓
HAE – Type II	↓	↔ or ↑	↓

Key: ↓ - decreased, ↑ - increased, ↔ - normal
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: 1961–

1990.

References

1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Kalbitor (ecallantide) [prescribing information]. Cambridge, MA: Takeda Pharmaceuticals USA Inc; June 2025.
4. Maurer, et al. The international WAO/EAACI guideline for the management of hereditary angioedema—The 2021 revision and update. Allergy. 2022; 77: 1961– 1990.
5. Zuraw BL, Bernstein JA, Lang DM, et al. A focused parameter update: Hereditary angioedema, acquired C1 inhibitor deficiency, and angiotensin-converting enzyme inhibitor–associated angioedema. J Allergy Clin Immunol. 2013 Jun;131(6):1491 - 3. DOI: https://doi.org/10.1016/j.jaci.2013.03.034

Review History

Date of Last Annual Review: 1Q2025

Changes from previous policy version:

- No clinical change following revision.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee