

**Kalbitor (ecallantide)**  
**Effective 01/01/2024**

<b>Plan</b>	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Medical and Specialty Medications</b>		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	<b>Non-Specialty Medications</b>		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
<b>Exceptions</b>	N/A		

### Overview

Kalbitor is indicated for the treatment of acute hereditary angioedema (HAE) attacks in patients 12 years or age or older

### Coverage Guidelines

Authorization may be granted for members new to the plan who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

**OR**

Authorization may be granted for treatment of Hereditary Angioedema (HAE) when all the following criteria are met:

1. The member is using requested medication for the treatment of acute HAE attacks
2. The requested medication will not be used in combination with any other medication used for the treatment of acute HAE attacks and ONE of the following criteria is met at the time of diagnosis:
  - a. Documentation that the member has C1 inhibitor deficiency or dysfunction as confirmed by laboratory testing and meets BOTH of the following criteria:
    - i. Member has a C4 level below the lower limit of normal as defined by the laboratory performing the test
    - ii. Member meets ONE of the following criteria:
      - I. C1 inhibitor (C1-INH) antigenic level below the lower limit of normal as defined by the laboratory performing the test
      - II. Normal C1-INH antigenic level and a low C1-INH functional level (functional C1-INH less than 50% or C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test).
  - a. Documentation that the member has normal C1 inhibitor as confirmed by laboratory testing and meets ONE of the following criteria:

- i. Member has an F12, angiotensin-converting enzyme 1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosaminase 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) gene mutation as confirmed by genetic testing, or
  - ii. Member has a documented family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine therapy (i.e., cetirizine at 40 mg per day or the equivalent) for at least one month.
- 3. Member has had inadequate response, adverse reaction or contraindication to generic Firazyr (icatibant)
- 4. This medication is prescribed by or in consultation with a prescriber who specializes in the management of HAE.

### **Continuation of Therapy**

Reauthorization will be granted for HAE when provider submits the following:

- a. Physician attestation that the member has experienced a reduction in severity and/or duration of attacks when the requested medication is used to treat an acute attack
- b. Prophylaxis should be considered based on the attack frequency, attack severity, comorbid conditions, and member's quality of life.

### **Limitations**

- 1. Initial approvals and reauthorizations will be granted for 6 months

### **References**

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3. Cicardi M, Bork K, Caballero T, et al. Evidence-based recommendations for the therapeutic management of angioedema owing to hereditary C1 inhibitor deficiency: consensus report of an International Working Group. *Allergy*. 2012;67:147-157.
4. 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: In Practice*. 2021 Jan;9(1):132-150.e3.
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9. Bowen T. Hereditary angioedema: beyond international consensus – circa December 2010 – The Canadian Society of Allergy and Clinical Immunology Dr. David McCourtie Lecture. *Allergy Asthma Clin Immunol*. 2011;7(1):1.
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14. Bernstein J. Severity of hereditary angioedema, prevalence, and diagnostic considerations. *Am J Med*. 2018;24:292-298.
15. Bork K, Aygören-Pürsün E, Bas M, et al. Guideline: Hereditary angioedema due to C1 inhibitor deficiency. *Allergo J Int*. 2019;28:16–29.
16. Craig T, Busse P, Gower RG, et al. Long-term prophylaxis therapy in patients with hereditary angioedema with C1 inhibitor deficiency. *Ann Allergy Asthma Immunol*. 2018;121(6):673-679.
17. Sharma J, Jindal AK, Banday AZ, et al. Pathophysiology of Hereditary Angioedema (HAE) Beyond the SERPING1 Gene [published online ahead of print, 2021 Jan 14] [published correction appears in Clin Rev Allergy Immunol. 2021 Feb 17]. *Clin Rev Allergy Immunol*. 2021;10.1007/s12016-021-08835-8. Doi:10.1007/s12016-021-08835-8.
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### **Review History**

05/10/2023 – Created for May P&T; switched from CVS SGM to custom. Effective 7/1/23

11/15/2023 – Reviewed and Updated for Nov P&T; Removed ‘Member must meet all initial criteria’ for Reauthorization. Effective 1/1/2024

