Mass General Brigham
Health Plan

Kalbitor (ecallantide)
Effective 01/01/2026

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	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 within the past 90 days 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, angiopoietin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine 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:

1. 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
2. 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

1. Bernstein J. Severity of hereditary angioedema, prevalence, and diagnostic considerations. *Am J Med.* 2018;24:292-298.
2. Bernstein JA. Update on angioedema: Evaluation, diagnosis, and treatment. *Allergy and Asthma Proceedings.* 2011;32(6):408-412.
3. Bork K, Aygören-Pürsün E, Bas M, et al. Guideline: Hereditary angioedema due to C1 inhibitor deficiency. *Allergo J Int*. 2019;28:16–29.
4. Bowen T, Cicardi M, Farkas H, et al. 2010 International consensus algorithm for the diagnosis, therapy, and management of hereditary angioedema. *Allergy Asthma Clin Immunol*. 2010;6(1):24.
5. 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.
6. 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.
7. Cicardi M, Aberer W, Banerji A, et al. Classification, diagnosis, and approach to treatment for angioedema: consensus report from the Hereditary Angioedema International Working Group. *Allergy*. 2014;69:602-616.
8. 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.
9. 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.
10. Farkas H, Martinez-Saguer I, Bork K, et al. International consensus on the diagnosis and management of pediatric patients with hereditary angioedema with C1 inhibitor deficiency. *Allergy*. 2017;72(2):300-313.
11. Henao MP, Kraschnewski J, Kelbel T, Craig T. Diagnosis and screening of patients with hereditary angioedema in primary care. *Therapeutics and Clin Risk Management.* 2016;12:701-711.
12. Kalbitor [package insert]. Cambridge, MA: Takeda Pharmaceuticals; June 2025
13. Kanani, A., Schellenberg, R. & Warrington, R. Urticaria and angioedema. *All Asth Clin Immun* 7, S9 (2011), Table 2.

14. Lang DM, Aberer W, Bernstein JA, et al. International consensus on hereditary and acquired angioedema. *Ann Allergy Asthma Immunol*. 2012;109:395-402.
15. Longhurst H, Cicardi M. Hereditary angio-edema. *Lancet.* 2012;379:474-481.
16. Maurer 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;73:1575-1596.
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.
18. 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(6):S145-S156.

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
10/08/2025- Reviewed and updated for October P&T. Updated the policy to indicate that it no longer applies to the medical benefit. Effective 01/01/2026.