Effective date: 12/12/2018
Review date: 6/2019, 5/2020, 7/2020, 6/2021, 4/2022, 3/2023, 3/2024 7/2025, 11/2025 Scope: Medicaid

Icatibant subcutaneous injection

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Hereditary angioedema (HAE)
Authorization of 6 months may be granted for treatment of acute hereditary angioedema attacks when all of the following criteria are met:

A. Medication is prescribed by, or in consultation with allergist/immunologist or a physician who specializes in the management of HAE
B. Member must be 18 years of age or older
C. Documentation that the member has history of moderate to severe cutaneous attacks (without concomitant hives) OR abdominal attacks OR mild to severe airway swelling attacks of HAE (i.e., debilitating cutaneous/gastrointestinal symptoms OR laryngeal/pharyngeal/tongue swelling)
D. Documentation that the cumulative amount of medications the member has on hand, indicated for the acute treatment of HAE, will not exceed maximum recommended dose of 30mg every 6 hours, for a maximum of 90mg (3 doses) in 24 hours.
E. Member has documented diagnosis of HAE type I or type II and meets one of the following (a or b):
    a. Documentation that the member has C1 inhibitor deficiency or dysfunction as confirmed by laboratory testing; and 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, or
        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); OR
    b. 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, or kininogen-1 (KNG1) gene, heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) pathogenic variant as confirmed by genetic testing; or

ii. Member has a documented family history of angioedema and the member's angioedema was refractory to a trial of high-dose antihistamine therapy (e.g., cetirizine 40 mg per day or the equivalent) for at least one month.

F. Member will not use icatibant concomitantly with other medications used for the treatment of acute HAE attacks (e.g., Ekterly (sebetralstat), Kalbitor (ecallantide), Ruconest (C1 esterase inhibitor), or Berinert (C1 esterase inhibitor), etc.)
G. Other causes of angioedema have been ruled out (e.g., angiotensin-converting enzyme inhibitor [ACE-I] induced an angioedema, angioedema related to an estrogen containing drug, allergic angioedema).

III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continuation of therapy when all of the following criteria are met:

A. Documentation that the member meets the criteria for initial approval.
B. Documentation 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.
C. Prophylaxis treatment should be considered based on the attack frequency, attack severity, comorbid conditions, and member's quality of life

IV. QUANTITY LIMIT

Icatibant injection 9ml per 30 days

V. REFERENCES

1. icatibant [package insert]. Carlsbad, CA: Leucadia Pharmaceuticals; February 2024. Accessed October 2025.
2. 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.
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. 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(5):458-467.
5. 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.
6. 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.
7. Lang DM, Aberer W, Bernstein JA, et al. International consensus on hereditary and acquired angioedema. *Ann Allergy Asthma Immunol*. 2012;109:395-402.
8. 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.
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.

10. Bernstein JA. Update on angioedema: Evaluation, diagnosis, and treatment. *Allergy and Asthma Proceedings*. 2011;32(6):408-412.
11. Longhurst H, Cicardi M. Hereditary angio-edema. *Lancet*. 2012;379:474-481.
12. 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.
13. 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.
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.