



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Icatibant-Sajazir Page: 1 of 4

Effective Date: 2/2/2026 Last Review Date: 10/2025

Applies to: Illinois Maryland Florida Kids
 Pennsylvania Kids Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Sajazir and Icatibant under the patient's prescription drug benefit.

Description:

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 Indications

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.

Applicable Drug List:

Sajazir

Icatibant

Policy/Guideline:

Documentation for all indications:

The patient is unable to take Berinert, when available and where indicated, for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- For initial authorization, the following should be documented:
 - C1 inhibitor functional and antigenic protein levels
 - F12, angiopoietin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) gene mutation testing, if applicable
 - Chart notes confirming family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine therapy, if applicable
- For continuation of therapy, chart notes demonstrating a reduction in severity and/or duration of attacks.



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Prescriber Specialties

This medication must be prescribed by or in consultation with a prescriber who specializes in the management of HAE.

Coverage Criteria

Hereditary Angioedema (HAE)

Authorization of 12 months may be granted for treatment of acute HAE attacks when the requested medication will not be used in combination with any other medication used for the treatment of acute HAE attacks and EITHER of the following criteria is met at the time of diagnosis:

- Member meets EITHER of the following criteria:
 - Member has C1 inhibitor deficiency or dysfunction as confirmed by laboratory testing and meets one of the following criteria:
 - C1 inhibitor (C1-INH) antigenic level below the lower limit of normal as defined by the laboratory performing the test, or
 - 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).
 - Member has normal C1 inhibitor as confirmed by laboratory testing and meets one of the following criteria:
 - 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
 - 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.
- Other causes of angioedema have been ruled out (e.g., angiotensin-converting enzyme inhibitor [ACE-I] induced angioedema, angioedema related to an estrogen-containing drug, allergic angioedema).

Continuation of Therapy

Authorization of 12 months may be granted for continuation of therapy when ALL of the following criteria are met:

- Member meets the criteria for initial approval.
- Member has experienced a reduction in severity and/or duration of acute attacks.
- Prophylaxis should be considered based on the attack frequency, attack severity, comorbid conditions, and member's quality of life.

Approval Duration and Quantity Restrictions:

Approval: 12 months



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Quantity Level Limit:

- Icatibant 30 mg/3 mL (10 mg/mL) prefilled syringe: 15 syringes per 30 days
- Sajazir (icatibant) 30 mg/3 mL (10 mg/mL) prefilled syringe: 15 syringes per 30 days

References:

1. Firazyr [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; January 2024.
2. icatibant [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals; April 2024.
3. 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.
4. 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.
5. 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.
6. Zuraw BL, Bork K, Bouillet L, et al. Hereditary Angioedema with Normal C1 Inhibitor: an Updated International Consensus Paper on Diagnosis, Pathophysiology, and Treatment. *Clin Rev Allergy Immunol.* 2025;68(1):24. Published 2025 Mar 7. doi:10.1007/s12016-025-09027
7. Maurer M, Magerl M, Ansotegui I, et al. The international WAO/EAACI guideline for the management of hereditary angioedema – the 2021 revision and update. *Allergy.* 2022 Jan 10. doi: 10.1111/all. 15214. Online ahead of print.
8. Lang DM, Aberer W, Bernstein JA, et al. International consensus on hereditary and acquired angioedema. *Ann Allergy Asthma Immunol.* 2012;109:395-402.
9. 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.
10. 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.
11. Bernstein JA. Update on angioedema: Evaluation, diagnosis, and treatment. *Allergy and Asthma Proceedings.* 2011;32(6):408-412.
12. Longhurst H, Cicardi M. Hereditary angio-edema. *Lancet.* 2012;379:474-481.
13. 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.
14. 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.
15. Bernstein J. Severity of hereditary angioedema, prevalence, and diagnostic considerations. *Am J Med.* 2018;24:292-298.
16. Bork K, Aygören-Pürsün E, Bas M, et al. Guideline: Hereditary angioedema due to C1 inhibitor deficiency. *Allergo J Int.* 2019;28:16-29.
17. 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.



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18. 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.
19. Kanani, A., Schellenberg, R. & Warrington, R. Urticaria and angioedema. All Asth Clin Immun 7, S9 (2011), Table 2.
20. Sajazir [package insert]. Cambridge, United Kingdom: Cycle Pharmaceuticals Ltd; February 2024.
21. Veronez CL, Csuka D, Sheik FR, et al. The expanding spectrum of mutations in hereditary angioedema. J Allergy Clin Immunol Pract. 2021;S2213-2198(21)00312-3.