CareSource Rx Innovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Firazyr or Sajazir (icatibant)
BENEFIT TYPE	Medical or Pharmacy
STATUS	Prior Authorization Required

Firazyr, approved by the FDA in 2011, is a bradykinin B2 receptor antagonist indicated for treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older.
HAE is a rare autosomal dominant disease characterized by episodic unpredictable swelling, which can occur in a variety of anatomic locations. The swelling results from excess production of the vasodilator bradykinin. Attacks may be painful and cause functional impairment but are not associated with pruritis. The most common types of HAE are caused by deficiency (type 1) or dysfunction (type 2) of C1 inhibitor (C1-INH). Type 1 is the most prevalent.
Firazyr is available as generic icatibant. Another brand name of icatibant is Sajazir.

Icatibant will be considered for coverage when the following criteria are met:

Hereditary Angioedema (HAE)

For **initial** authorization:
1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with an allergist or immunologist; AND
3. Member has a diagnosis of HAE type I or type II confirmed by both of the following:
   a) Low C4 level;
   b) Low (<50% of normal) C1 inhibitor antigenic and/or functional level; AND
4. Medication is being prescribed for the treatment of acute HAE attacks; AND
5. Medication is not being used in combination with another on-demand therapy (e.g., Kalbitor, Berinert, Ruconest); AND
6. If the request is for brand name Firazyr or Sajazir, documentation of medical necessity must be provided to justify inability to use generic icatibant.
7. **Dosage allowed/Quantity limit:** 30 mg subQ; may repeat at 6-hour intervals if response is inadequate. Max of 3 doses in 24 hours.
   QL: 6 syringes per fill (18 mL)

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must document improvement such as faster time to symptom relief or resolution of attack.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers icatibant not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
08/25/2017	New policy for Firazyr created. Criteria for each type of HAE specified. Criteria of documentation of attacks, discontinuation of meds that can cause HAE, and restriction on combinations with other meds for acute attacks added.
01/20/2021	Updated references. Removed hematology as a specialist. Simplified the diagnostic criteria. Removed log book requirement. Removed statement about causative meds. Added ACE inhibitor interaction. Reworded renewal criteria. Extended initial auth duration to 6 mo and renewal to12 mo. Amended the quantity limit to say 6 syringes instead of 6 mL.
07/05/2022	Transferred to new template. Updated references. Added Sajazir. Added pharmacy benefit as option. Added statement about using generic icatibant.
06/19/2025	Removed “member is not taking an ACE inhibitor.”

References:

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2. Sajazir (prescribing information). Cycle Pharmaceuticals Ltd; 2024.
3. Frank MM, Zuraw B, Banerji A, et al. Management of children with hereditary angioedema due to C1 inhibitor deficiency. Pediatrics. 2016 Nov;138(5). pii: e20160575.
4. Busse PJ, Christiansen SC, Riedl MA, et al. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema [published online ahead of print, 2020 Sep 6]. *J Allergy Clin Immunol Pract*. 2020;S2213-2198(20)30878-3. doi:10.1016/j.jaip.2020.08.046
5. Lumry WR, Farkas H, Moldovan D, et al. Icatibant for Multiple Hereditary Angioedema Attacks across the Controlled and Open-Label Extension Phases of FAST-3. *Int Arch Allergy Immunol*. 2015;168(1):44-55. doi:10.1159/000441060
6. Betschel S, Badiou J, Binkley K, et al. The International/Canadian Hereditary Angioedema Guideline [published correction appears in Allergy Asthma Clin Immunol. 2020 May 6;16:33]. *Allergy Asthma Clin Immunol*. 2019;15:72. Published 2019 Nov 25. doi:10.1186/s13223-019-0376-8
7. Bork K, Bernstein JA, Machnig T, Craig TJ. Efficacy of Different Medical Therapies for the Treatment of Acute Laryngeal Attacks of Hereditary Angioedema due to C1-esterase Inhibitor Deficiency. *J Emerg Med*. 2016;50(4):567-80.e1. doi:10.1016/j.jemermed.2015.11.008
8. Maurer M, Magerl M, Betschel S, et al. The international WAO/EAACI guideline for the management of hereditary angioedema - The 2021 revision and update. *World Allergy Organ J*. 2022;15(3):100627. Published 2022 Apr 7. doi:10.1016/j.waojou.2022.100627

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