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# 5.85.023

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| **Section:** | Prescription Drugs | **Effective Date:** | January 1, 2026 |
| **Subsection:** | Hematological Agents | **Original Policy Date:** | January 1, 2012 |
| **Subject:** | Icatibant | **Page:** | 1 of 5 |

***Last Review Date:*** December 12, 2025

# Icatibant

## Description

Firazyr (icatibant)

Sajazir (icatibant)

**Background**
Icatibant is indicated for the treatment of acute attacks of a rare condition called hereditary angioedema (HAE) in adults 18 years of age and older. HAE is caused by low levels or the improper function of a protein called C1 inhibitor, which is involved in regulating how certain immune system and blood clotting pathways function. The absence or dysfunction of the C1 inhibitor leads to bradykinin production. Bradykinin is a vasodilator which is responsible for the characteristic HAE symptoms of localized swelling, inflammation, and pain. Icatibant inhibits bradykinin from binding to the receptors and thereby treats the clinical symptoms of an acute, episodic attack of HAE (1-3).

**Regulatory Status**
FDA-approved indication: Icatibant injection is a bradykinin B2 receptor antagonist indicated for treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older (1-3).

Given the potential for airway obstruction during acute laryngeal HAE attacks, patients should be advised to seek medical attention in an appropriate healthcare facility immediately in addition to treatment with icatibant (1-3).

Safety and effectiveness in pediatric patients less than 18 years of age have not been established (1-3).

**Related policies**
Berinert, Cinryze, Haegarda, Kalbitor, Orladeyo, Ruconest, Takhzyro

## Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Icatibant may be considered **medically necessary** if the conditions indicated below are met.

Icatibant may be considered **investigational** for all other indications.

## Prior-Approval Requirements

**Age** 18 years of age and older

**Diagnosis**

Patient must have the following*:*

1. Hereditary Angioedema (HAE) with **ONE** of the following:
    a. Patient has a C1 inhibitor deficiency or dysfunction as confirmed by laboratory testing **AND ALL** of the following:
        i. C4 level below the lower limit of normal as defined by the laboratory performing the test
        ii. 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)
    b. Patient has normal C1 inhibitor as confirmed by laboratory testing **AND ONE** of the following:
        i. F12, angiopoietin-1, plasminogen, or kininogen-1 (KNG1) gene mutation as confirmed by genetic testing
        ii. Documented family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine (e.g.,

cetirizine) for at least one month

**AND ALL** of the following:
a. Used for acute attacks of hereditary angioedema
b. **NOT** being used for the routine prevention of hereditary angioedema attacks
c. **NO** dual therapy with another agent for treating acute attacks of hereditary angioedema (e.g., Berinert, Kalbitor, Ruconest)

**AND** the following for Brand Firazyr **only:**
a. Inadequate treatment response, intolerance, or contraindication to **BOTH** generic Firazyr: icatibant **AND** Sajazir

## Prior – Approval *Renewal* Requirements

**Age** 18 years of age and older

**Diagnosis**

Patient must have the following:

Hereditary Angioedema (HAE)

**AND ALL** of the following:
a. Used for acute attacks of hereditary angioedema
b. **NOT** being used for the routine prevention of hereditary angioedema attacks
c. Patient has experienced a reduction in severity and/or duration of hereditary angioedema attacks
d. **NO** dual therapy with another agent for treating acute attacks of hereditary angioedema (e.g., Berinert, Kalbitor, Ruconest)

**AND** the following for Brand Firazyr **only:**
a. Inadequate treatment response, intolerance, or contraindication to **BOTH** generic Firazyr: icatibant **AND** Sajazir

## Policy Guidelines

### Pre - PA Allowance

None

## Prior - Approval Limits

**Duration** 12 months

## Prior – Approval *Renewal* Limits

Same as above

## Rationale

**Summary**

Icatibant is a bradykinin B2 receptor antagonist indicated for treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older. Given the potential for airway obstruction during acute laryngeal HAE attacks, patients should be advised to seek medical attention in an appropriate healthcare facility immediately in addition to treatment with icatibant. Safety and effectiveness in patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of icatibant while maintaining optimal therapeutic outcomes.

**References**

1. Firazyr [package insert]. Lexington, MA: Shire Orphan Therapies LLC; January 2024.
2. Icatibant [package insert]. Weston, FL: Apotex Corp; February 2024.
3. Sajazir [package insert]. Cambridge, CBC 0FA, UK : Cycle Pharmaceuticals ; February 2024.

## Policy History

| Date | Action |
|---|---|
| January 2012 | New policy |
| September 2012 | Annual editorial and reference update |
| March 2014 | Annual editorial review and reference update |
| December 2014 | Annual editorial review and reference update<br>Addition of the no dual therapy with another agent for treating acute attacks of HAE |
| December 2015 | Annual editorial review |
| December 2016 | Annual editorial review<br>Policy code changed from 5.11.07 to 5.85.23 |
| September 2017 | Annual editorial review and reference update |
| December 2017 | Annual review |

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| June 2018 | Annual review |
| November 2018 | Annual review |
| September 2019 | Annual review |
| September 2020 | Annual review and reference update |
| December 2020 | Annual review and reference update. Added requirement that brand Firazyr has to t/f the preferred product icatibant |
| March 2021 | Annual editorial review |
| April 2021 | Added initiation requirements including C1 inhibitor testing, C4 testing, C1-INH testing, gene mutation testing, or documented family history of refractory angioedema and continuation requirement for significant reduction in severity and/or duration of HAE attacks since starting therapy per FEP |
| June 2021 | Annual review |
| September 2021 | Changed policy name to Icatibant, added preferred product Sajazir to policy |
| December 2021 | Annual review |
| June 2022 | Annual review |
| June 2023 | Annual review and reference update. Changed policy number to 5.85.023 |
| December 2023 | Annual review |
| June 2024 | Annual review and reference update |
| December 2024 | Annual review and reference update |
| June 2025 | Annual review |
| December 2025 | Annual review. Removed MedEx requirement and switched to t/f |

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.**