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5.85.023

Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Hematological Agents	**Original Policy Date:**	January 1, 2012
Subject:	Icatibant	**Page:**	1 of 5

Last Review Date: June 13, 2024

Icatibant

Description

Firazyr (**icatibant**)

Sajazir (**icatibant**)

Preferred products: generic icatibant, Sajazir

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. Patient **MUST** have tried at least **ONE** preferred product (generic Firazyr: icatibant or Sajazir) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

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. Patient **MUST** have tried at least **ONE** preferred product (generic Firazyr: icatibant or Sajazir) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

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 ; May 2022.

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 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 Policy code changed from 5.11.07 to 5.85.23
September 2017	Annual editorial review and reference update
December 2017	Annual review
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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.