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Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Hematological Agents	**Original Policy Date:**	January 1, 2012
Subject:	Firazyr	**Page:**	1 of 4

Last Review Date: March 12, 2021

Firazyr

Description

Firazyr (icatibant)

Background
Firazyr (icatibant) is indicated for the treatment of acute attacks of a rare condition called hereditary angioedema (HAE) in people ages 18 years 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. Firazyr inhibits bradykinin from binding to the receptors and thereby treats the clinical symptoms of an acute, episodic attack of HAE (1).

Regulatory Status
FDA-approved indication: Firazyr 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).

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 Firazyr (1).

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

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.

Firazyr may be considered **medically necessary** in patients 18 years of age or older for the treatment of acute attacks of hereditary angioedema (HAE) and if the conditions indicated below are met.

Firazyr may be considered **investigational** in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following*:*

1. Acute attacks of Hereditary Angioedema (HAE)

AND NONE of the following:
a. Prophylactic therapy
b. Dual therapy with another agent for treating acute attacks of HAE

AND the following for Brand Firazyr **only:**
a. Patient **MUST** have tried the preferred product (generic Firazyr: icatibant) unless the patient has a valid medical exception (e.g. inadequate treatment response, intolerance, contraindication)

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Firazyr (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 Firazyr.

Safety and effectiveness in pediatric patients below the age of 18 years have not been established (1).

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

References

1. Firazyr [package insert]. Lexington, MA: Shire Orphan Therapies LLC; August 2020.

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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.