UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Firazyr

Program	Prior Authorization
Medication	Firazyr® (icatibant)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	3/2013
Pharmacy and Therapeutics Approval Date	7/2020
Effective Date	9/2020

1. Background:

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.[1]

2. Coverage Criteria:

A. Initial Authorization

1. Firazyr will be approved based on **all** of the following criteria:

a. Diagnosis of hereditary angioedema (HAE) as confirmed by **one** of the following:

(1) C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by **one** of the following (per laboratory standard):
(a) C1-INH antigenic level below the lower limit of normal
(b) C1-INH functional level below the lower limit of normal

-OR-

(2) HAE with normal C1 inhibitor levels and **one** of the following:
(a) Confirmed presence of a FXII, angiopoietin-1 or plasminogen gene mutation
(b) Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema

-AND-

b. **Both** of the following:

(1) Prescribed for the acute treatment of HAE attacks

-AND-

(2) Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Berinert, Ruconest)

-AND-

c. Prescribed by **one** of the following:

(1) Immunologist
(2) Allergist

Authorization of therapy will be issued for 12 months.

B. Reauthorization

1. **Firazyr** will be approved based on **all** of the following criteria:

a. Documentation of positive clinical response

-AND-

b. **Both** of the following:

(1) Prescribed for the acute treatment of HAE attacks

-AND-

(2) Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Berinert, Ruconest)

-AND-

c. Prescribed by **one** of the following:

(1) Immunologist
(2) Allergist

Authorization of therapy will be issued for 12 months.

3. **Additional Clinical Programs:**
   - Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
   - Supply limits may be in place.

4. References:

1. Firazyr [package insert]. Lexington, MA: Shire Orphan Therapies, Inc.; December 2015.
2. Maurer M, Magerl M, Ansotegui I, et al. The international WAO/EAACI guideline for the management of hereditary angioedema-The 2017 revision and update. Allergy. 2018 Jan 10.
3. Wu, E. Hereditary angioedema with normal C1 inhibitor. In: UpToDate, Saini, S (Ed), UpToDate, Waltham, MA, 2020.

Program	Prior Authorization –Firazyr (icatibant)
Change Control	
Date	Change
3/2013	New pharmacy/medical guideline.
9/2014	Added "Not used in combination with other approved treatments for acute HAE attacks (eg, Berinert, Kalbitor or Ruconest)."
7/2016	Updated clinical criteria to align with Employer and Individual notification policy. Updated policy template.
7/2017	Annual review. No changes.
7/2018	Annual review. No changes to the program.
7/2019	Annual review. No changes to the program.
7/2020	Annual review. Updated clinical criteria: Added that diagnosis must be confirmed by certain tests; added prescriber requirement. Added reauthorization criteria Added Additional Clinical Rules Section. Updated references.