UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 2209-8
Program	Prior Authorization/Medical Necessity
Medication	Firazyr® (icatibant)*, icatibant, Sajazir™ (icatibant)*
P&T Approval Date	6/2020, 4/2021, 4/2022, 4/2023, 2/2024, 4/2024, 4/2025, 2/2026
Effective Date	5/1/2026

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. Sajazir (icatibant)* injection is a bradykinin B2 receptor antagonist indicated for treatment of acute attacks of HAE in adults 18 years of age and older.

2. Coverage Criteria [a]:

A. Initial Authorization

1. **Firazyr*, icatibant,** or **Sajazir*** 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 variant(s) in the gene(s) for factor XII, angiopoietin-1, plasminogen-1, kininogen-1, myoferlin, or heparan sulfate-glucosamine 3-O-sulfotransferase 6
         (b) Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema
         (c) Recurring angioedema attacks that are refractory to high-dose antihistamines with unknown background de-novo mutation(s) (i.e., no family history) (HAE-unknown)

-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, Ekterly, Kalbitor, or 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*, icatibant,** or **Sajazir*** will be approved based on **all** of the following criteria:

a. Documentation of positive clinical response to icatibant therapy

-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, Ekterly, Kalbitor, or Ruconest)

-AND-

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

(1) Immunologist
(2) Allergist

Authorization of therapy will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

* Firazyr (brand) and Sajazir are typically excluded from coverage. Coverage reviews may be in place if required by law or the benefit plan.

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, LLC; June 2025.
2. Wu, E. Hereditary angioedema with normal C1 inhibitor. In: UpToDate, Saini, S (Ed), UpToDate, Waltham, MA, 2025.
3. Busse, P., Christiansen, S., Riedl., M., et. al. "US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema." *The Journal of Allergy and Clinical Immunology.* 2020 September 05.
4. Maurer M, Magerl M, Betschel S, et al. The international WAO/EAACI guideline for the management of hereditary angioedema-The 2021 revision and update. Allergy. 2022;77(7):1961-1990. doi:10.1111/all.15214
5. Sajazir [package insert]. Cambridge, CB3 0FA, United Kingdom: Cycle Pharmaceuticals Ltd; February 2024.

Program	Prior Authorization/Medical Necessity - Firazyr (icatibant), Sajazir (icatibant)
Change Control	
6/2020	New program.
4/2021	Added diagnosis criteria. Updated references.
4/2022	Updated references.
4/2023	Annual review. Added Sajazir, updated background, and updated references.
2/2024	Added coverage exclusion statement for brand Firazyr and Sajazir. Added Kalbitor to list of other products indicated for the acute treatment of HAE attacks.
4/2024	Update to examples of genetic variant(s) and diagnostic criteria with normal C1 inhibitor levels. Updated language for reauthorization criteria. Updated references.
4/2025	Annual review. No changes to coverage criteria. Updated reference.
2/2026	Annual review. Updated examples of acute treatments for HAE attacks. No changes to coverage criteria. Updated references.