# Icatibant
# (Firazyr, Sajazir)

| Override(s) | Approval Duration |
|---|---|
| Prior Authorization<br>Quantity Limit | 1 year |

| Medications | Quantity Limit |
|---|---|
| Firazyr (icatibant)<br>Sajazir (icatibant) | Up to 3 syringes (90 mg) per attack (Max: 18 syringes/30 days) |

## APPROVAL CRITERIA

Requests for Firazyr (icatibant) or Sajazir (icatibant) may be approved if the following criteria are met:

I. Individual has a diagnosis of hereditary angioedema; **AND**
II. Individual is using for treatment of acute attacks (not prophylaxis); **AND**
III. Individual is 18 years of age or older; **AND**
IV. Documentation is provided that diagnosis is verified by a C4 level below the lower limit of normal as defined by the laboratory performing the test AND one of the following:
    A. C1 inhibitor (C1-INH) antigenic level below the lower limit of normal as defined by the laboratory performing the test with documentation provided; **OR**
    B. C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test with documentation provided; **AND**
V. Individual has a history of moderate or severe attacks such as airway swelling, severe abdominal pain, facial swelling, nausea and vomiting, or painful facial distortion.

Requests for **brand** Firazyr must also meet the following criteria, in addition to the above Prior Authorization criteria:

I. Documentation is provided that individual has failed an adequate trial of one chemically equivalent generic icatibant agent. Medication samples/coupons/discount cards are excluded from consideration as a trial.; **AND**
    A. Documentation is provided that generic icatibant had inadequate response; **OR**
    B. Documentation is provided that generic icatibant caused adverse outcome; **OR**
    C. Documentation is provided that the individual has a genuine allergic reaction to an inactive ingredient in generic agent. Allergic reaction(s) must be clearly documented in the individual's medical record.

Requests for Firazyr or Sajazir may not be approved for the following:

I. In combination with other Hereditary Angioedema (HAE) agents for acute attacks (including but not limited to Berinert, Icatibant (Firazyr, Sajazir), Kalbitor, or Ruconest); **OR**

II. When the above criteria are not met and for all other indications.

**Key References**:


1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Bork, K., Anderson, J.T., Caballero, T. *et al.* Assessment and management of disease burden and quality of life in patients with hereditary angioedema: a consensus report. *Allergy Asthma Clin Immunol* 17, 40 (2021). https://doi.org/10.1186/s13223-021-00537-2.
5. Busse, PJ, Christiansen SC, Riedl MA et al. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema. J Allergy Clin Immunol Pract. 2021;9:132-50.
6. Efficacy ans Safety Study of DX-2930 to Prevent Acute Angioedema Attacks in Patients with Type I and Type II HAE. NCT02586805 (HELP Study). Available at https://www.clinicaltrials.gov/ct2/show/study/NCT02586805.
7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
8. Riedl MA. Creating a Comprehensive Treatment Plan for Hereditary Angioedema. *Immunol Allergy Clin N Am*. 2013; 33 (4): 471-485. doi:10.1016/j.iac.2013.07.003.
9. Zuraw B, et al. Oral once-daily berotralstat for the prevention of hereditary angioedema attacks: A randomized, double-blind, placebo-controlled phase 3 trial. J Allergy Clin Immunol. 2020.
10. Zuraw BL, Banerji A, Bernstein JA, et al. US Hereditary Angioedema Association Medical Advisory Board 2013 Recommendations for the Management of Hereditary Angioedema Due to C1 Inhibitor Deficiency. *J Allergy Clin Immunol: In Practice*. 2013; 1:458-67. doi:10.1016/j.jaip.2013.07.002.
11. Zuraw BL, Bernstein JA, Lang DM, et al. A focused parameter update: Hereditary angioedema, acquired C1 inhibitor deficiency, and angiotensin-converting enzyme inhibitor–associated angioedema. *J Allergy Clin Immunol*. 2013; 131(6):1491-1493.e1-e25. Available from: http://www.jacionline.org/article/S0091-6749(13)00523-X/pdf.


Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.