Firazyr® (icatibant)

Humana

Pharmacy Coverage Policy

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Line of Business: Medicare, Commercial, Medicaid - Humana, Medicaid - Ohio
Policy Type: Prior Authorization

Disclaimer

Description

Firazyr (icatibant) is a potent and selective antagonist of the B2 receptor, and can alleviate the symptoms of an acute release of bradykinin. Acute attacks of hereditary angioedema (HAE), resulting vascular leakage and edema are the most recognizable symptom of HAE and are directly attributable to increases in bradykinin formation. Icatibant has an affinity for the B2 receptor that is equal to that of bradykinin and is a competitive antagonist of the human B2 receptor.

Firazyr (icatibant) is indicated for the treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older.

Icatibant is available as Firazyr and as a generic product in 30mg/3mL, single-use, prefilled syringes for subcutaneous administration.

Coverage Determination

Please note the following regarding medically accepted indications:

All reasonable efforts have been made to ensure consideration of medically accepted indications in this policy. Medically accepted indications are defined by CMS as those uses of a covered Part D drug that are approved under the federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of the Act. These compendia guide review of off-label and off-evidence prescribing and are subject to minimum evidence standards for each compendium. Currently, this review includes the following references when applicable and may be subject to change per CMS:

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
- Truven Health Analytics Micromedex DrugDEX
- Elsevier/Gold Standard Clinical Pharmacology
- Wolters Kluwer Lexi-Drugs

Firazyr (icatibant) will require prior authorization. This agent may be considered medically necessary when the following criteria are met:

Hereditary Angioedema

- The member must have a diagnosis of hereditary angioedema (HAE) type 1 or type 2
- The member must have documentation of:
  - Known HAE-causing C1INH mutation **OR**
  - Evidence of low C4 level (i.e. C4 level below lower limit of normal laboratory reference range) **AND**
    - Low C1 inhibitor (C1INH) antigenic level (i.e. C1INH level below lower limit of normal laboratory reference range) **OR**
    - Low C1INH functional level (i.e. functional C1INH less than 50% or below lower limit of normal laboratory reference range)
- Must provide lab report or medical record documentation which include lab values as required by policy
- Lab values must include C1q level
- The member is being treated by a specialist in hereditary angioedema (i.e. allergist and/or immunologist)
- The member must be 18 years of age or older
- The member is using icatibant for treatment of acute attacks of HAE
- For brand Firazyr, the member has had previous treatment or intolerance to generic icatibant*

**For Medicare part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days*

Note: Policy criteria apply to both brand and generic products containing icatibant

Firazyr (icatibant) will be approved in plan year durations or as determined through clinical review.

Coverage Limitations

Firazyr (icatibant) therapy is not considered medically necessary for members with the following concomitant conditions:

- Use for prophylaxis of HAE attack
- Evidence of autoantibodies against the C1INH protein
- Evidence of underlying lymphoproliferative, malignant, or autoimmune disorder that causes angioedema attacks
- Use in combination with other agents approved for acute treatment of HAE attack (e.g. Berinert, Kalbitor, Ruconest)

- Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

Background

This is a prior authorization policy about Firazyr (icatibant).

Hereditary angioedema (HAE) is a rare autosomal dominant disorder characterized by episodes of well-demacrated angioedema without urticaria. The most common forms of HAE are caused by deficiency or dysfunction in C1 inhibitor (C1INH). HAE affects skin or mucosal tissues of upper respiratory and gastrointestinal tracts most often. Laryngeal edema may cause fatal asphyxiation.

Firazyr Drug Interactions

- ACE inhibitors - Firazyr is a bradykinin B2 receptor antagonist and thereby has the potential to have a pharmacodynamic interaction with ACE inhibitors where Firazyr may attenuate the antihypertensive effect of ACE inhibitors. Clinical trials to date have excluded subjects taking ACE inhibitors.

Warnings and Precautions

- Laryngeal attacks - 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.

Firazyr (icatibant) is not indicated for the treatment of acute acquired angioedema attack, or for the prophylaxis of acquired angioedema attack. Of importance, this therapy will likely not be effective for patients with autoantibody-mediated acquired C1 inhibitor deficiency and high titer monoclonal anti-C1 inhibitor antibody concentrations.

Patients may self-administer icatibant containing products upon recognition of symptoms of an HAE attack after training under the guidance of a healthcare professional.

Provider Claims Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

Firazyr; Sajazir; icatibant; Hereditary Angioedema; HAE; subcutaneous injection; pharmacy

References

1. Bowen et al. 2010 International consensus algorithm for the diagnosis, therapy and management of hereditary angioedema. Allergy, Asthma & Clinical Immunology. 2010. 6:24, pg 1-13.
2. Busse PJ, Christiansen SC. Hereditary Angioedema. N Engl J Med 2020;382:1136-48. DOI:10.1056/NEJMra1808012.
3. 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. [DOI: 10.1016/j.jaip.2020.08.046].
4. Cicardi M. Algorithm: Acquired C1 inhibitor deficiency: Clinical manifestations, epidemiology, pathogenesis, and diagnosis. Post TW, Ed. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com/contents/image?imageKey=ALLRG%2F64553&topicKey=ALLRG%2F8112&search=C1INH%20deficiency%20diagnostic%20algorithm&source=outline_link&selectedTitle=1~150 (Accessed on July 7, 2019).
5. Cicardi M, Banerji A, et al. Icatibant, a new bradykinin-receptor antagonist, in hereditary angioedema. N Engl J Med 2010;363:532-41.
6. Cicardi M, Bork K. et al. Evidence-based recommendations for the therapeutic management of angioedema owing to hereditary C1 inhibitor deficiency: consensus report of an International Working Group. Allergy. 2012;67(2):147.
7. Cicardi M, Zuraw B. Table: Comparison of complement studies in angioedema disorders. Post TW, Ed. UpToDate. Waltham, MA: UpToDate Inc.

https://www.uptodate.com/contents/image?imageKey=ALLRG%2F83098&topicKey=ALLRG%2F8098&search=hereditary%20angioedema&source=outline_link&selectedTitle=1~150 (Accessed on July 7, 2019).

8. Clinical Pharmacology Web site. http://www.clinicalpharmacology.com. Updated periodically.
9. Craig T, Pürsün EA, Bork K, et al. WAO Guideline for the Management of Hereditary Angioedema. The World Allergy Organization Journal. 2012;5(12):182-199.
10. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: http://www.micromedexsolutions.com/. Updated periodically.
11. David C. Dugdale, III, MD and Stuart I. Henochowicz, MD, FACP. Hereditary Angioedema. Medline Plus. US National Library of Medicine and National Institutes of Health. Last updated March 20, 2016. http://www.nlm.nih.gov/medlineplus/ency/article/001456.htm. Accessed August 2017.
12. Firazyr [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; October 2021.
13. Frank MM, Jiang H. New therapies for hereditary angioedema: Disease outlook changes dramatically. J Allergy Clin Immunol. Jan 2008; 121 (1): 272-80.
14. Lexicomp Online Web site. http://online.lexi.com/lco/action/home. Updated periodically.
15. 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; 73(8):1575-1596.
16. Sajazir [prescribing information]. Cambridge, United Kingdom: Cycle Pharmaceuticals Ltd; June 2021.