

SPECIALTY GUIDELINE MANAGEMENT

FIRAZYR (icatibant)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

Treatment of acute attacks of hereditary angioedema in adults 18 years of age and older

B. Compendial Uses

Treatment of angiotensin-converting enzyme (ACE) inhibitor-induced angioedema

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. **Hereditary angioedema (HAE)**

Indefinite authorization may be granted for the treatment of acute HAE attacks in members 18 years of age or older when either of the following criteria is met:

1. Member has C1 inhibitor deficiency as confirmed by laboratory testing.
2. Member has normal C1 inhibitor as confirmed by laboratory testing and meets one of the following criteria:
 - a. Member has an F12 gene mutation as confirmed by genetic testing.
 - b. Member has a family history of angioedema and the angioedema was refractory to a trial of antihistamine (e.g., cetirizine) for at least one month.

B. **ACE inhibitor-induced angioedema**

Authorization of 3 days may be granted for acute management of ACE inhibitor-induced angioedema.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Firazyr [package insert]. Lexington, MA: Shire Orphan Therapies, Inc.; December 2015.
2. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed April 15, 2016.
3. Bowen T, Cicardi M, Farkas H, et al. 2010 International consensus algorithm for the diagnosis, therapy, and management of hereditary angioedema. *Allergy Asthma Clin Immunol.* 2010;6(1):24.
4. Bas M, Greve J, Stelter K, et al. A Randomized Trial of Icatibant in ACE-Inhibitor–Induced Angioedema. *N Engl J Med.* 2015;372:418-25.
5. Cicardi M, Bork K, Caballero T, et al. Hereditary Angioedema International Working Group. Evidence-based recommendations for the therapeutic management of angioedema owing to hereditary C1 inhibitor deficiency: consensus report of an International Working Group. *Allergy.* 2012;67:147-157.

6. 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(5): 458-467.
7. Zuraw BL, Bork K, Binkley KE, et al. Hereditary angioedema with normal C1 inhibitor function: consensus of an international expert panel. *Allergy Asthma Proc*. 2012; 33(6):S145-S156.
8. Craig T, Pursun EA, Bork K, et al. WAO guideline for the management of hereditary angioedema. *WAO Journal*. 2012; 5:182-199.
9. Lang DM, Aberer W, Bernstein JA, et al. International consensus on hereditary and acquired angioedema. *Ann Allergy Asthma Immunol*. 2012; 109:395-202.
10. Cicardi M, Aberer W, Banerji A, et al. Classification, diagnosis, and approach to treatment for angioedema: consensus report from the Hereditary Angioedema International Working Group. *Allergy*. 2014;69: 602-616.
11. Bowen T. Hereditary angioedema: beyond international consensus – circa December 2010 – The Canadian Society of Allergy and Clinical Immunology Dr. David McCourtie Lecture. *Allergy Asthma Clin Immunol*. 2011;7(1):1.
12. Bernstein J. Update on angioedema: Evaluation, diagnosis, and treatment. *Allergy and Asthma Proceedings*. 2011;32(6):408-412.
13. Longhurst H, Cicardi M. Hereditary angio-edema. *Lancet*. 2012;379:474-481.