Pharmacy Medical Necessity Guidelines: Firazyr® (icatibant) for Self-administration

Effective: February 15, 2021

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISRATION-APPROVED INDICATION(S)

Firazyr (icatibant) is a bradykinin B2 receptor antagonist indicated for the treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older.

Hereditary angioedema is a rare, episodic, autosomal dominant, swelling disorder that is characterized by C1 esterase inhibitor (C1-INH) deficiency. C1-INH coordinates the activation of the complement, contact, and fibrinolytic systems. A reduction in the activity of C1-INH may result in an elevated level of bradykinin, which is a key mediator in HAE symptoms. Patients with HAE may experience attacks of swelling and inflammation in the extremities, abdomen, face, urogenital tract, and/or the larynx that are random, recurrent, and potentially life-threatening. The age of onset is variable, ranging from early childhood to adult, with a worsening in frequency occurring around puberty. The age of onset can help to differentiate between HAE and acquired angioedema (AAE), which normally does not present until the fourth decade of life.

There is no clear initiating cause for an HAE attack, but certain triggers have been associated with an increase in attack frequency. These may include physical pressure, emotional stress, anxiety, minor trauma, surgery, oral contraceptives, hormone replacement therapy, menstruation, and illnesses such as colds and influenza. The frequency of HAE attacks ranges from less than one per year to more than 100 per year, and attacks typically last two to five days.

A peripheral attack is defined as swelling that occurs in the hands, feet, arms, legs, face or external genitalia. Peripheral attacks produce disfigurements which are painful and make normal activities difficult or impossible to accomplish. An abdominal attack, which is characterized by edema of the gastrointestinal system and abdomen, is a significant health threat, resulting in severe abdominal pain, nausea and vomiting. Laryngeal edema is the swelling of internal components of the head and neck.

Treatment of HAE is divided into acute treatment, short-term/procedural prophylaxis to prevent an attack, and long-term/routine prophylaxis to minimize the frequency and severity of attacks. Long-term prophylaxis is recommended for patients who experience more than one attack per month, or for those who feel the condition is significantly impacting their lives. Short-term prophylaxis is recommended before dental procedures, minor surgery, endoscopy, or any situation where trauma may precipitate an attack; however, there are no FDA-approved agents currently available for procedural prophylaxis. A multifaceted approach that uses both pharmacologic and supportive therapies is required for optimal prevention and treatment of HAE.

COVERAGE GUIDELINES

The plan may authorize coverage of Firazyr (icatibant) for self-administration for Members when all of the following criteria are met:

1. Documented diagnosis of hereditary angioedema

AND

2. Prescribed by or in consultation with an allergist, hematologist or immunologist

AND

3. The Member is 18 years or older

AND

4. The Member has a history of at least one severe attack within the past 6 months

LIMITATIONS

- Firazyr (icatibant) will not be approved for Members with acquired angioedema.
- Firazyr (icatibant) will be limited to two single-use, prefilled syringe per prescription.
    - For acute laryngeal HAE attacks, Member should be advised to seek medical attention in an appropriate healthcare facility immediately in addition to treatment with Firazyr (icatibant).
    - For all other unresolved HAE attacks, Member should be advised to seek medical attention in an appropriate healthcare facility within 6 hours of self-administration.

CODES

Medical billing codes may not be used for this medication. This medication must be obtained via the Member's pharmacy benefit for self-administration.

Note: Prior Authorization is not required when administered by the physician in the office setting.

REFERENCES

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APPROVAL HISTORY

February 14, 2012: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. June 12, 2012: Changed requirement of history of "at least one severe attack per month" to "at least one severe attack within the past 6 months"
2. May 14, 2013: No changes.
3. April 8, 2014: No changes.
4. April 14, 2015: No changes.
5. January 1, 2016: Administrative change to rebranded template
6. March 8, 2016: Moved Tufts Health Together to Commercial Firazyr (icatibant) for Self-administration Medical Necessity Guidelines.
7. March 14, 2017: No changes.
8. April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
9. March 13, 2018: No changes.
10. February 12, 2019: No changes.
11. January 14, 2020: Updated the quantity limitation of icatibant to two doses per fill.
12. February 9, 2021: Removed requirement for documentation of type I or II hereditary angioedema. Updated the prescriber requirements to "Prescribed by or in consultation with an allergist, hematologist, or immunologist. Removed the Limitation "Firazyr will not be approved for Members concurrently taking an angiotensin converting enzyme (ACE) inhibitor."

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services