**Firazyr® (icatibant)**

**Last Review Date:** October 14, 2019  
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**Definition**

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

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**Dosing**

Max dose (per dose and over time):
- 30 billable units per dose up to 3 times in a 24-hour period once per week

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**Guideline**

Firazyr (icatibant) is considered medically necessary for the treatment of acute attacks of hereditary angioedema when the following criteria are met:
- Patient is 18 years of age or older; AND
- Firazyr is prescribed by, or in consultation with, a specialist in: allergy, immunology, hematology, pulmonology, or medical genetics; AND
- Confirmation that member is avoiding medications known to cause angioedema (e.g., ACE inhibitors, oral contraceptives, hormone replacement therapy); AND
- Member has a history of moderate to severe cutaneous or abdominal attacks OR mild to severe airway swelling attacks of HAE (i.e. debilitating cutaneous/gastrointestinal symptoms or laryngeal/pharyngeal/tongue swelling); AND
- Member has one of the following clinical presentations (table below) consistent with HAE subtype:

**HAE I (C1-inhibitor deficiency)**
▪ Low C1 inhibitor- (C1-INH) antigenic level (C1-INH antigenic level below the lower limit of normal as defined by the laboratory performing the test); AND
▪ Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); AND
▪ Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test); AND
  o Member has a family history of HAE; OR
  o Normal C1q level

**HAE II (C1-inhibitor dysfunction)**

▪ Normal to elevated C1-INH antigenic level; AND
▪ Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); AND
▪ Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test)

**HAE with normal C1NH (HAE III)**

▪ Normal C1-INH antigenic level; AND
▪ Normal C4 level; AND
▪ Normal C1-INH functional level; AND
  o Member has a known HAE-causing mutation (e.g., mutation of coagulation factor XII gene [F12 mutation], mutation in the angiopoietin-1 gene, mutation in the plasminogen gene); OR
  o Member has a family history of HAE

Coverage for Firazyr (icatibant) may be renewed when the subsequent criteria are met:

- Member continues to meet the criteria in the initial guideline; AND
- Significant improvement in severity and duration of attacks have been achieved and sustained; AND
- Absence of unacceptable toxicity from the drug (e.g., hypersensitivity reactions, thrombotic events, laryngeal attacks); AND

**Limitations/Exclusions**

- Approval will be granted for 6 months and may be renewed
- The cumulative amount of medication(s) the member has on-hand, indicated for the acute treatment of HAE, will be taken into account when authorizing. The authorization will provide a sufficient quantity in order for the member to have a cumulative amount of HAE medication(s) on-hand in order to treat up to 4 acute attacks per 4 weeks for the duration of the authorization.
- Use of Firazyr (icatibant) is considered experimental or investigational for all other uses.

**Revision History**
7/25/2018 – Increased coverage duration to 6 months, removed confirmation patient is negative for helicobacter pylori infection, updated table describing clinical presentations consistent with HAE

**Applicable Procedure Codes**
J1744  Injection, icatibant, 1mg

Applicable Diagnosis Codes

D84.1  Defects in the complement system

References


7. Specialty-matched clinical peer review.