Effective date: 12/12/2018
Review date: 6/2019, 5/2020, 7/2020, 6/2021, 4/2022, 3/2023, 3/2024 Scope: Medicaid

SPECIALTY GUIDELINE MANAGEMENT

Icatibant subcutaneous injection

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.

FDA-Approved Indication
Treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older.

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

A. For initial authorization, the following should be documented:
   1. C1 inhibitor functional and antigenic protein levels
   2. F12, angiopoietin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6) or myoferlin (MYOF) gene mutation testing, if applicable
   3. Chart notes confirming family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine therapy, if applicable
B. For continuation of therapy, chart notes demonstrating a reduction in severity and/or duration of attacks

III. CRITERIA FOR INITIAL APPROVAL

Hereditary angioedema (HAE)
Authorization of 6 months may be granted for treatment of acute hereditary angioedema attacks when the requested medication will not be used in combination with other products indicated for acute treatment of HAE attacks (e.g. Berinert, Kalbitor, or Ruconest) and all of the following criteria are met:

A. Medication is prescribed by, or in consultation with allergist/immunologist or a physician who specializes in the treatment of HAE or related disorders
B. Member must be 18 years of age or older
C. Member has history of moderate to severe cutaneous attacks (without concomitant hives) OR abdominal attacks OR mild to severe airway swelling attacks of HAE (i.e., debilitating cutaneous/gastrointestinal symptoms OR laryngeal/pharyngeal/tongue swelling)

D. The cumulative amount of medications the patient has on hand, indicated for the acute treatment of HAE, will not exceed maximum recommended dose of 30mg every 6 hours, for a maximum of 3 doses in 24 hours.
E. Member has C1 inhibitor deficiency or dysfunction as confirmed by laboratory testing and meets one of the following criteria:
    1. C1 inhibitor (C1-INH) antigenic level below the lower limit of normal as defined by the laboratory performing the test, OR
    2. Normal C1-INH antigenic level and a low C1-INH functional level (functional C1-INH less than 50% or C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test), OR
F. Member has normal C1 inhibitor as confirmed by laboratory testing and meets one of the following criteria:
    1. Member has an F12, angiopoietin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6) or myoferlin (MYOF) gene mutation as confirmed by genetic testing, OR
    2. Member has a documented family history of angioedema, and the angioedema was refractory to a trial of high-dose antihistamine (e.g., cetirizine) for at least one month.

IV. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continuation of therapy when all of the following criteria are met:
A. Member meets the criteria for initial approval.
B. Member has experienced a reduction in severity and/or duration of attacks when the requested medication is used to treat an acute attack.
C. For members who have had more than 12 severe attacks or more than 24 days of severe symptoms in the last 12 months, prophylaxis treatment should be considered.

V. QUANTITY LIMIT

Icatibant injection 9ml per 30 days

VI. REFERENCES

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15. Bernstein J. Severity of hereditary angioedema, prevalence, and diagnostic considerations. *Am J Med*. 2018;24:292-298.
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