SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: icatibant or sajazir (Firazyr®) **(J1744) (Medical)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

Dosing Limit: **(see below)**

A. Quantity Limit (max daily dose):

Pharmacy Benefit: icatibant or sajazir (Firazyr) 30mg/3ml vial: 3 subcutaneous pen per 28 days

B. Max Units (per dose and over time):

Medical Benefit: 90 billable units per 28 days; 1mg = 1billable

- **J1744 30mg/3mL vial: 1mg=1billable AND NDC 54092-0702-xx 30mg**
- **Coverage is provided for 12 months and will be eligible for renewal**

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- ❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Approval Criteria - 12 months: The cumulative amount of medication(s) the patient 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 patient to have a cumulative amount of HAE medication(s) on-hand in order to treat acute attacks for the duration of the authorization (unless otherwise specified).

Treatment of acute attacks of Hereditary Angioedema Criteria:

- ❑ Member must be at least 18 years of age

AND

- ❑ Must be prescribed by or in consultation with a specialist in: allergy, immunology, hematology, pulmonology or medical genetics

AND

- ❑ Provider attests the patient is avoiding **ALL** of the following possible triggers for HAE attacks:
  - ❑ Helicobacter pylori infections **(confirmed by lab test)**
  - ❑ Estrogen-containing oral contraceptive agents AND hormone replacement therapy
  - ❑ Antihypertensive agents containing ACE inhibitors

AND

- ❑ Member has a history of one of the following criteria:
  - ❑ **Three (3) or more** severe HAE attacks per month (i.e., airway swelling, debilitating cutaneous or gastrointestinal episodes)
  - ❑ Disablement for more than 5 days per month by HAE
  - ❑ Recurrent laryngeal attacks caused by HAE

AND

Patient has one of the following clinical presentations that is consistent with a HAE subtype, confirmed by repeat blood testing (please submit chart notes for symptoms and lab values to confirm the HAE subtype):

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II.A. ❑ HAE I: (all bullet points must apply)

- ❑ 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)
- ❑ Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test)
- ❑ Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test) **AND** one of the following:
  - ❑ Member has a family history of HAE
  - ❑ Acquired angioedema has been ruled out (i.e., patient onset of symptoms occur prior to 30 years old, normal C1q levels, patient does not have underlying disease such as lymphoma or benign monoclonal gammopathy [MGUS])

OR

II.B. ❑ HAE II (C1-Inhibitor dysfunction): (all bullet points must apply)

- ❑ Normal to elevated C1-INH antigenic level
- ❑ Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test)
- ❑ Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test) **AND** one of the following:
  - ❑ Member has a family history of HAE
  - ❑ Acquired angioedema has been ruled out (i.e., patient onset of symptoms occur prior to 30 years old, normal C1q levels, patient does not have underlying disease such as lymphoma or benign monoclonal gammopathy [MGUS])

OR

II.C. ❑ HAE III with normal C1-INH: (all bullet points must apply)

- ❑ Normal C1-INH antigenic level
- ❑ Normal C4 level
- ❑ Normal C1-INH functional level
- ❑ Repeat blood testing during an attack has confirmed the patient does not have abnormal lab values indicative of HAE I or HAE II
- ❑ Patient had an inadequate response or intolerance to an adequate trial of prophylactic therapy with one of following:
  - ❑ antifibrinolytic agent: (❑ tranexamic acid (TXA) **OR** ❑ aminocaproic acid)
  - ❑ 17α- alkylated androgen: danazol
  - ❑ progestins (female patients only)

AND

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- ❑ **One of the following:**
  - ❑ Patient 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 kininogen-1)
  - ❑ Patient has a family history of HAE and documented evidence of lack of efficacy of chronic high-dose antihistamine therapy (e.g. cetirizine standard dosing at up to four times daily or an alternative equivalent, given for at least one month or an interval long enough to expect three or more angioedema attacks) **AND** corticosteroids

Renewal Criteria. All criteria must be checked for approval. To support each line checked, all documentation (lab results, diagnostics, and/or chart notes) must be provided or request may be denied.

- ❑ Member must continue to meet initial criteria

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)

Medication being provided by (check box below that applies):

❑ **Physician's office** **OR** ❑ **Specialty Pharmacy- PropriumRx**

For urgent reviews: Practitioner should call Optima Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Optima's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee**: 9/19/2013
REVISED/UPDATED: ~~11/20/2013; 10/31/2014; 4/3/2015; 5/22/2015; 12/30/2015; 1/29/2016; 8/17/2016; 9/22/2016; 12/11/2016; 7/30/2017; 9/13/2017; 11/16/2017; 3/31/2018; 5/18/2018; 12/11/2018; (Reformatted) 3/16/2019; 7/6/2019; 9/20/2019; 4/1/2021;~~ **7/21/2021**