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: Kalbitor® (ecallantide) **(J1290) (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:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

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

Diagnosis: _____ **ICD Code**: _____

Weight (if applicable): _____**Date weight obtained:** _____

☐ 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.

Dosing Limit:

- **Quantity Limit: 6 vials per 28 days**
- **1 mL = 10 billable units; 3 vials = 30 billable units**
- **NDC (47783-101-01): 3 single-dose vials in 1 carton**
- **Coverage is provided for 12 months and will be eligible for renewal**

Recommended Dosing: 30 mg (3 mL), administered subcutaneously in three 10 mg (1 mL) injections. If an attack persists, an additional dose of 30 mg may be administered within a 24-hour period

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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.

❑ **Treatment of acute attacks of Hereditary Angioedema (HAE)**

Initial Authorization: 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).

- ❑ Member must be at least 18 years of age

AND

- ❑ Prescribed by or in consultation with a specialist in allergy, immunology, hematology, pulmonology or medical genetics

AND

- ❑ Provider attests the member is avoiding **BOTH** of the following possible triggers for HAE attacks:
  - ❑ Estrogen-containing oral contraceptive agents **AND** hormone replacement therapy
  - ❑ Antihypertensive agents containing ACE inhibitors

AND

- ❑ Member has a history of **ONE** of the following:
  - ❑ **Three (3) or more** severe HAE attacks per month **(select all that apply)**:
    - ❑ Moderate to severe cutaneous attacks (without concomitant hives)
    - ❑ Abdominal attacks (pain and swelling)
    - ❑ Mild to severe airway swelling attacks of HAE (i.e. laryngeal/pharyngeal/tongue swelling)
  - ❑ Disablement for more than 5 days per month by HAE

AND

- ❑ Member must have trial and failure of icatibant *requires prior authorization* **(submit documentation)**

AND

Member 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) **in addition to <u>ONE</u>** 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])

<u>OR</u>

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) **in addition to <u>ONE</u>** 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])

<u>OR</u>

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 member does **<u>NOT</u>** have abnormal lab values indicative of HAE I or HAE II
- ❑ Member 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 members only)

<u>AND</u>

- ❑ **ONE of the following:**

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- ❑ 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 kininogen-1)
- ❑ Member 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

Reauthorization: 12 months. 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.

- ❑ Member must continue to meet initial authorization criteria

AND

- ❑ Significant improvement in severity and duration of attacks has been achieved and sustained

AND

- ❑ Member has experienced an 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 – Proprium Rx**

For urgent reviews: Practitioner should call Sentara Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara'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.