SENTARA HEALTH PLAN

PHARMACY 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 will 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: Berinert® IV (C1 Esterase Inhibitor Human) **(J0597)**

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: None**

B. **Max Units (per dose and over time):** **Medical Benefit:**
20 IU/kg = 80kg = 1600units
Berinert (80kg) 1600 IU vial: 160 billable units per 28 days
10 units = 1billable

- **J0597- 500IU vial: 10 unit = 1billable AND NDC 63833-0825-xx 500mg**
- **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:

I. Treatment of acute attacks of Hereditary Angioedema (HAE):

- ❑ Member must be at least 18 years of age;

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

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

II.A.❑ Member has the following clinical presentation consistent with HAE I:

- ❑ 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

- ❑ Member has a family history of HAE

OR

- ❑ Normal C1q level

OR

II.B.❑ Member has the following clinical presentation consistent with HAE II:

- ❑ Normal to elevated C1-INH antigenic level

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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).

OR

II.C.❑ Member has the following clinical presentation consistent with HAE III:

❑ Normal C1-INH antigenic level)

AND

❑ Normal C4 level

AND

❑ Normal C1-INH functional level

AND

❑ Member has a known HAE causing C1-INH mutation (i.e., mutation of coagulation factor XII gene);

OR

❑ Member has a family history of HAE

AND

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 the criteria in section I & II (A-C);

AND

❑ Significant improvement in severity and duration of attacks have been achieved and sustained;

AND

❑ Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include hypersensitivity reactions.

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Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____
  NPI or DEA # of administering location: _____

OR

- ❑ **Specialty Pharmacy – PropriumRx**

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.

***Approved by Pharmacy and Therapeutics Committee:** 12/12/2016
REVISED/UPDATED: ~~3/28/2017~~; ~~7/24/2017~~; ~~5/18/2018~~; **(Reformatted)** ~~3/14/2019~~; ~~7/6/2019~~; **9/16/2019**