OPTIMA 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 1-844-202-5034. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. Incomplete form will delay authorization process.***

Drug Requested: **Berinert®** (C1 Esterase Inhibitor Human) **(J0597)** ***(Medical)***

DRUG INFORMATON: Complete information below. If incomplete, authorization process will be delayed.

Drug Form/Strength/Quantity: _____

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

Diagnosis: _____ **ICD Code**: _____

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***

CLINICAL CRITERIA: All boxes that apply must be checked. Incomplete information will delay the authorization process.

***Initial Approval Criteria*:**

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

- ❑ Patient must be at least 18 years of age; **AND**
- ❑ Patient 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.❑ Patient 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**
- ❑ Patient has a family history of HAE; **OR**
- ❑ Normal C1q level; **OR**

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

- ❑ 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); **OR**

(continued on next page)

II.C.❑ Patient 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**
- ❑ Patient has a known HAE causing C1-INH mutation (i.e., mutation of coagulation factor XII gene); **OR**
- ❑ Patient has a family history of HAE; **AND**

Renewal Criteria

- ❑ Patient 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.

Medication being provided by (check applicable box below):

- ❑ **Physician's office**

OR

- ❑ **Specialty Pharmacy**: ❑ **Briova SpecialtyRx**

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.

Patient Name: _____

Member Optima #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR NPI #: _____

***Approved by Pharmacy and Therapeutics Committee:** 12/12/2016
REVISED/UPDATED: ~~3/28/2017~~; ~~9/12/2017~~; **10/4/2017**;