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: **Ruconest®** (C1 Inhibitor Recombinant) **(J0596)** ***(Medical)***

DRUG INFORMATION: Complete the 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: Ruconest 2100mg vial: 2 vials per 28 days

B. Max Units (per dose and over time) - Medical Benefit: 60 billable units per 28 days

<84 kg = Max 420 billable per 28 days

≥84 kg= 420 billable per 28 days

- J0596 2100 IU vial: 10 unit=1billable ***AND*** NDC 68012-0350-xx 2100mg
- **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 authorization process.

Initial Approval Criteria:

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

- ❑ Patient must be at least 13 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~~; ~~9/16/2017~~; ~~9/29/2017~~; **10/4/2017**