OPTIMA HEALTH COMMUNITY CARE
AND
OPTIMA FAMILY CARE
(MEDICAID)

PHARMACY/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 1-844-348-3720**. 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) **(J1290) (Medical)**

DRUG INFORMATION: Complete the information below or authorization 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 to ensure authorization will **NOT** be delayed.

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**

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- ❑ 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**

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 - PropriumRx**

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 #: _____

REVISED/UPDATED: ~~8/1/2017; 8/29/2018;~~ **10/8/2018**