

# 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 1-844-723-2094. 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** (select applicable drug below): **Medical**

**Cinryze®** (C1 Esterase Inhibitor Human) (**J0598**)     **Haegarda®** (C1 Esterase Inhibitor Human) (**J3590**)

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

Drug Name: \_\_\_\_\_

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:
- 1,000units every 3-4 days=7,000 units every 30 days (14 vials)  
Cinryze 7,000 IU vial: 700 billable units per 30 days  
10 units=1billable
- **J0598** 500 unit: 10 unit=1billable **AND** NDC 42227-0081-xx 500unit

- Coverage is provided for **12 months** and will be eligible for renewal

**CLINICAL CRITERIA:** Check boxes below to qualify. If **not** checked, authorization process will be delayed.

### Initial Approval Criteria:

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

- Patient must be at least 9 years of age; **AND**
- Patient has a history of one of the following criteria for long-term HAE prophylaxis:
  - History of **four (4) or more** severe HAE attacks per month (i.e., airway swelling, debilitating cutaneous or gastrointestinal episodes); **OR**
  - Patient is disabled more than 5 days per month by HAE; **OR**
  - History of recurrent laryngeal attacks caused by HAE; **AND**
- Treatment of patient with “on-demand” therapy (i.e., Kalbitor, Firazyr, Ruconest, or Berinert) did not provide satisfactory control or access to “on-demand therapy” is limited (**defined as more than 5 attacks/month for 4 months consecutively within the same year**); **AND**
- Patient has tried and failed, is intolerant, or has a contraindication to attenuated (17 alpha-alkylated) androgens (i.e., Danazol) for HAE prophylaxis; **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; **AND**

**II.A.  Patient has the following clinical presentation consistent with HAE I:**

- Treatment of patient with “on-demand” therapy (i.e., Kalbitor, Firazyr, Ruconest, or Berinert) did not provide satisfactory control or access to “on-demand therapy” is limited (**defined as more than 5 attacks/month for 4 months consecutively within the same year**); **AND**
- 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**

(continued on next page)

- Patient has a family history of HAE; **OR**
- Normal C1q level; **OR**

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

- Treatment of patient with “on-demand” therapy (i.e., Kalbitor, Firazyr, Ruconest, or Berinert) did not provide satisfactory control or access to “on-demand therapy” is limited (*defined as more than 5 attacks/month for 4 months consecutively within the same year*); **AND**
- 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:**

- Treatment of patient with “on-demand” therapy (i.e., Kalbitor, Firazyr, Ruconest, or Berinert) did not provide satisfactory control or access to “on-demand therapy” is limited (*defined as more than 5 attacks/month for 4 months consecutively within the same year*); **AND**
- 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):**

- Location/site of drug administration:** \_\_\_\_\_  
**NPI or DEA # of administering location:** \_\_\_\_\_

**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 #:** \_\_\_\_\_

**\*Approved by Pharmacy and Therapeutics Committee: 9/19/2013**

**REVISED/UPDATED:** 11/20/2013; 10/31/2014; 4/3/2015; 5/22/2015; 12/30/2015; 1/29/2016; 8/17/2016; 9/22/2016; 12/11/2016; 7/30/2017; 9/13/2017; 11/16/2017; 3/31/2018; 5/18/2018