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**.

Prophylaxis HAE (Medical)

Drug Requested (select applicable drug below):

PREFERRED	
❑ **Haegarda**® (C1 Esterase Inhibitor Human) **(J3590)**	
Non-Preferred	
❑ **Cinryze**® (C1 Esterase Inhibitor Human) **(J0598)**	❑ **Takhzyro** (lanadelumab) **(J3590)**

DRUG INFORMATION: Complete information below or authorization 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**

(**continued on next page)**

- ❑ 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**
- ❑ 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**

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- ❑ 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;~~ **12/11/2018**