

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: Kalbitor® (ecallantide) (J1290) (Medical)

DRUG INFORMATION: Complete all information below. Authorization process will be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code: _____

Dosing Limit: (see below)

A. **Quantity Limit (max daily dose) - Pharmacy Benefit:** Kalbitor 10mg vial: 6 vials per 28 days

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

- J1290 10mg injection: 1 billable unit=1mg **AND** NDC 47783-0101-xx 10mg
- 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 12 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)

PA Kalbitor_OH (Medical)

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 sections 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; 9/15/2017; 10/4/2017**