

Commercial & HealthCare Exchange PA Criteria Effective: February 2, 2021

Prior Authorization: Orladeyo

Products Affected: Orladeyo (berotralstat) Capsules

Medication Description: Orladeyo is a plasma kallikrein inhibitor that binds plasma kallikrein and inhibits its proteolytic activity, controlling excess bradykinin generation in patients with hereditary angioedema.

Covered Uses: Indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years of age and older.

Exclusion Criteria: N/A

Required Medical Information:

1. Diagnosis
2. Laboratory values

Age Restrictions: 12 years of age or older

Prescriber Restrictions: Prescribed by, or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders.

Coverage Duration: 1 year

Other Criteria:

Initial

Hereditary Angioedema

- A. Patient has HAE type I or type II as confirmed by the following diagnostic criteria (i and ii):
 - i. Patient has low levels of functional C1-INH protein (less than 50% of normal) at baseline, as defined by the laboratory reference values; **AND**
 - ii. Patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values

Continuation

- A. Documentation that the patient has had a favorable clinical response since initiating Orladeyo prophylactic therapy compared with baseline

References:

1. Orladeyo [package insert]. BioCryst Pharmaceuticals, Inc. Durham, NC 27703. December 2020.
2. Berotralstat. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. January 2021.
3. Berotralstat. IBM Micromedex® DRUGDEX®. IBM Watson Health, Greenwood Village, Colorado, USA. December 2020.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	02/02/2021

