

berotralstat capsule (ORLADEYO)

Diagnosis Considered for Coverage:

- Prevention of Hereditary Angioedema (HAE) acute attacks – type 1 or 2

Coverage Criteria:

For diagnosis of prevention of Hereditary Angioedema (HAE) attacks:

- Lab documentation shows serum C4 and C1-INH (antigenic and functional) levels consistent with HAE type I or II, **and**
- Not being used in the combination with other HAE preventative therapies (e.g. Haegarda, Takhzyro), **and**
- Dose does not exceed 150 mg daily, **and**
- Meets one of the following:
 - a. Patient has history of frequent attacks (i.e. at least one HAE episode per month), **or**
 - b. Patient has history of serious attacks with laryngeal/ upper airway involvement, **or**
 - c. Patient has a history of attacks resulting in impaired daily living.

Coverage Duration: one year

Effective Date: 5/31/2023