

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Berotralstat (Orladeyo)

Notes:

- Quantity Limits: Yes
- At this time, berotralstat (Orladeyo) is only dispensed from Optime Care Specialty pharmacy.

Initiation (new start) criteria: Non-formulary **berotralstat (Orladeyo)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescriber is an Allergist or Immunologist
- Patient is at least 12 years of age
- Diagnosis of hereditary angioedema (HAE) type I or type II confirmed by either:
 - A complement 4 (C4) level below the lower limit of normal AND a C1 inhibitor (C1-INH) protein level below the lower limit of normal
 - A mutation known to cause HAE in either the SERPING1 or F12 gene
- Patient has either:
 - History of one or more attack(s) every 4 weeks that significantly interrupts daily activities despite short-term treatment.
 - History of attacks involving the face, throat, or gastrointestinal tract that interrupt daily activity despite short-term treatment.
- Patient has a contraindication, intolerance, therapeutic failure, or is unable to receive treatment with either Takhzyro (lanadelumab-flyo) or Haegarda (C1 Esterase Inhibitor subcutaneous [human]) for HAE prophylaxis.
- Berotralstat is not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Takhzyro, Cinryze, Haegarda, danazol).

Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary **berotralstat (Orladeyo)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescriber is an Allergist or Immunologist
- Patient is at least 12 years of age
- Diagnosis of hereditary angioedema (HAE) type I or type II.
- Berotralstat is not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Takhzyro, Cinryze, Haegarda, danazol).

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Continued use criteria (12 months after initiation): Non-formulary **berotralstat (Orladeyo)** will continue to be covered on the prescription drug benefit when the following criteria are met:

- Berotralstat is continued to be prescribed by an Allergist or Immunologist.
- The patient has a documented improvement in HAE attack frequency, or HAE attack severity compared to when berotralstat (Orladeyo) was stated.
- Berotralstat continues not to be used in combination with other products indicated for prevention of HAE attacks (e.g., Takhzyro, Cinryze, Haegarda, danazol)

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