Overview
Orladeyo (berotralstat) is a plasma kallikrein inhibitor that inhibits plasma kallikrein proteolytic activity, controlling excess bradykinin generation to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years and older.

Coverage Guidelines
Authorization may be granted for members new to AllWays Health Partners who are currently receiving treatment with Orladeyo, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

OR
Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:
1. The member will be using Orladeyo for the prevention of hereditary angioedema attacks
2. Orladeyo will not be used in combination with any medication used for the prophylaxis of HAE attacks.
3. Member meets ONE of the following:
   a. Member has C1 inhibitor deficiency or dysfunction as confirmed by laboratory testing and meets BOTH of the following criteria:
      i. Member has a C4 level below the lower limit of normal as defined by the laboratory performing the test
      ii. Member meets ONE of the following criteria:
         (a) C1 inhibitor (C1-INH) antigenic level below the lower limit of normal as defined by the laboratory performing the test
(b) Normal C1-INH antigenic level and a low C1-INH functional level (functional C1-INH less than 50% or C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test).
   b. Member has normal C1 inhibitor as confirmed by laboratory testing and meets ONE of the following criteria:
      i. Member has an F12, angiopoietin-1, plasminogen, or kininogen-1 (KNG1) gene mutation as confirmed by genetic testing
      ii. Member has a documented family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine (e.g., cetirizine) for at least one month.

Continuation of Therapy
Reauthorization may be granted for members when ALL of the following are met, and documentation is provided:
   1. Member meets all initial approval criteria.
   2. Member has experienced a significant reduction in frequency of attacks (e.g. ≥ 50%) since starting treatment.
   3. Member has reduced the use of medications to treat acute attacks.

Limitations
1. Initial approvals and reauthorizations will be for 6 months.
2. The following quantity limits apply:
   | Oraldeyo capsules | 30 capsules per 30 days |

References

Review History
05/19/2021 – Created and Reviewed May P&T. Effective 07/01/2021.

Disclaimer
AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.