CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Orladeyo (berotralstat)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Orladeyo is a plasma kallikrein inhibitor approved in December 2020 for the prevention of hereditary angioedema (HAE) attacks. It is the first FDA approved oral drug for HAE attack prophylaxis, taken once daily for long term use. It is not for on-demand use to manage acute attacks. Approval was based on clinical trials showing that Orladeyo reduced the frequency of HAE attacks compared to placebo. Although it may not have the same level of effectiveness as competitor products, the advantage of oral administration may compensate for this difference, depending on patient specific factors such as disease severity. Patients with type 1 or type 2 HAE have deficient or dysfunctional C1 esterase inhibitor, respectively. This leads to an uncontrolled increase in plasma kallikrein activity, which generates excess bradykinin, causing greater vascular permeability that results in angioedema attacks. Type I HAE is the most common.

Orladeyo (berotralstat) will be considered for coverage when the following criteria are met:

Hereditary Angioedema (HAE)

For **initial** authorization:

1. Member is at least 12 years of age; AND
2. Medication must be prescribed by or in consultation with an allergist or immunologist; AND
3. Member has a diagnosis of HAE type I or type II confirmed by both of the following:
   a) Low C4 level;
   b) Low (<50% of normal) C1 inhibitor antigenic and/or functional level; AND
4. Chart notes must document the member's baseline frequency of HAE attacks; AND
5. Member is inadequately controlled with on-demand treatment alone; AND
6. Orladeyo is being prescribed for ongoing prophylaxis and will not be used to treat acute attacks; AND
7. Member has a trial and failure of or contraindication to Haegarda.
8. **Dosage allowed/Quantity limit:** 150mg once daily (28 capsules per 28 days).

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must document a reduced rate of HAE attacks compared to baseline.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Orladeyo (berotralstat) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
01/05/2021	New policy for Orladeyo created.
11/19/2021	Annual review, no changes

References:

1. Orladeyo (berotralstat) [package insert]. Durham, NC: BioCryst Pharmaceuticals, Inc; 2020.
2. Busse PJ, Christiansen SC, Riedl MA, et al. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema [published online ahead of print, 2020 Sep 6]. *J Allergy Clin Immunol Pract*. 2020;S2213-2198(20)30878-3. doi:10.1016/j.jaip.2020.08.046
3. Maurer M, Magerl M, Ansotegui I, et al. The international WAO/EAACI guideline for the management of hereditary angioedema-The 2017 revision and update. *Allergy*. 2018;73(8):1575-1596. doi:10.1111/all.13384
4. Zuraw B, Lumry WR, Johnston DT, et al. Oral once-daily berotralstat for the prevention of hereditary angioedema attacks: A randomized, double-blind, placebo-controlled phase 3 trial [published online ahead of print, 2020 Oct 21]. *J Allergy Clin Immunol*. 2020;S0091-6749(20)31484-6. doi:10.1016/j.jaci.2020.10.015

Effective date: 01/01/2022
Revised date: 11/19/2021