

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 1351-6
Program	Prior Authorization/Notification
Medication	Orladeyo® (berotralstat)*
P&T Approval Date	3/2021, 3/2022, 3/2023, 3/2024, 3/2025, 3/2026
Effective Date	6/1/2026

1. Background:

Orladeyo is a plasma kallikrein inhibitor indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 2 years and older. Orladeyo should not be used for the treatment of acute HAE attacks.

2. Coverage Criteria^a:

<p>A. Orladeyo* will be approved based on all of the following criteria:</p> <ol style="list-style-type: none"> 1. Diagnosis of hereditary angioedema (HAE) <p style="text-align: center;">-AND-</p> <ol style="list-style-type: none"> 2. Both of the following: <ol style="list-style-type: none"> a. For prophylaxis against HAE attacks <p style="text-align: center;">-AND-</p> <ol style="list-style-type: none"> b. Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Andembry, Cinryze, Dawnzera, Haegarda, Takhzyro) <p style="text-align: center;">Authorization will be issued for 12 months.</p> <p>^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.</p>

* Orladeyo is typically excluded from coverage. Coverage reviews may be in place if required by law or the benefit plan.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Orladeyo [package insert]. Durham, NC: BioCryst Pharmaceuticals, Inc.; December 2025.

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Change Control	
3/2021	New program.
3/2022	Annual review. Aligned combination use language with prophylactic therapies without change to clinical intent.
3/2023	Annual review. Added state mandate and updated reference.
3/2024	Annual review with no changes to clinical criteria.
3/2025	Annual review with no changes to clinical criteria.
3/2026	Annual review. Updated program by notating that Orladeyo is typically excluded from coverage. Updated list of examples of prophylactic HAE treatments. Updated background and references by updating FDA labeled indication.