UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3074-12
Program	Step Therapy
Medication	Ocaliva® (obeticholic acid)
P&T Approval Date	5/2016, 6/2017, 6/2018, 6/2019, 6/2020, 11/2021,6/2022, 6/2023, 6/2024, 12/2024
Effective Date	3/1/2025

1. Background:

Step therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try and fail ursodeoxycholic acid (e.g., Urso, ursodiol) before providing coverage for Ocaliva® (obeticholic acid).

2. Coverage Criteria[a]:

A. Primary biliary cholangitis

1. **Ocaliva** will be approved based on **all** of the following criteria:

   a Diagnosis of primary biliary cholangitis

   -AND-

   b. **One** of the following^:

      (1) Patient has not achieved an adequate response to an appropriate dosage of ursodeoxycholic acid (e.g., Urso, ursodiol) after at least 12 consecutive months of therapy

      -OR-

      (2) History of contraindication or intolerance to ursodeoxycholic acid (e.g., Urso, ursodiol)

      -OR-

      (3) **Both** of the following:

         (a) As continuation of therapy

         -AND-

         (b) Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Intercept sponsored Ocaliva Interconnect® support program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Ocaliva

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Authorization will be issued for 12 months.

B. <u>Other Indications</u>

1. **Ocaliva** will be approved

Authorization will be issued for 12 months.

[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.
^Tried/failed alternative(s) are supported by FDA labeling.

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 and/or Notification may be in place.

4. References:

1. Ocaliva [package insert]. Morristown, NJ: Intercept Pharmaceuticals, Inc.; May 2022.

Program	Step Therapy – Ocaliva (obeticholic acid)
Change Control	
5/2016	New program
6/2016	Changed clinical criteria based on FDA approved label.
7/2016	Added Indiana and West Virginia coverage information.
11/2016	Administrative change. Added California coverage information.
6/2017	Annual review. Changed criterion to criteria in A.1 of clinical criteria. Updated coverage criteria to include manufacturer sample language (i.e. Ocaliva support program). State mandate reference language updated.
6/2018	Annual review. Updated references.
6/2019	Annual review with no changes.
6/2020	Annual review with no changes.
11/2021	No changes to coverage criteria.
6/2022	Changed clinical criteria based on changes to prescribing information. Added footnote that tried/failed alternative(s) are supported by FDA labeling. Background and reference updated.
6/2023	Annual review with no changes to coverage criteria. Background and reference updated.
6/2024	Annual review with no changes to coverage criteria.
12/2024	Revised outline of coverage criteria without change to clinical intent.

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