

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 3074-13
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, 12/2025
Effective Date	3/1/2026

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).

On September 11, 2025, Intercept Pharmaceuticals announced the voluntary market withdrawal of Ocaliva following a request from the US Food and Drug Administration.

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

Authorization will be issued for 12 months.

B. Other Indications

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.
2. Intercept Pharmaceuticals, Inc. Intercept announces voluntary withdrawal of Ocaliva[®] for primary biliary cholangitis (PBC) from the US market; US clinical trials involving obeticholic acid placed on clinical hold. Intercept Pharmaceuticals. Published September 11, 2025. Accessed November 3, 2025. <https://www.interceptpharma.com/about-us/news/?id=3148535>.

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.
12/2025	Annual review with no changes to coverage criteria. Updated background and references to reflect withdrawal of drug from market.