



UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2020 P 3074-7
Program	Step Therapy
Medication	Ocaliva (obeticholic acid)
P&T Approval Date	5/2016, 6/2017, 6/2018, 6/2019, 6/2020
Effective Date	9/1/2020; Oxford only: N/A

**1. Background:**

Step therapy programs are utilized to encourage use of lower cost, preferred 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<sup>a</sup>:**

**A. Primary biliary cholangitis (aka primary biliary cirrhosis)**

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

**a.** Diagnosis of primary biliary cholangitis (aka primary biliary cirrhosis)

**-AND-**

**b. One** of the following:

(a) 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-**

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

**-OR-**

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

(1) As continuation of therapy

**-AND-**

(2) **One** of the following:

- (a) 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

**-OR-**

(b) **One** of the following:

- i. 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-**

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

**Authorization will be issued for 12 months.**

## **B. Other Indications**

**1. Ocaliva** will be approved based on the following criterion:

- a.** Indication other than primary biliary cholangitis (aka primary biliary cirrhosis)

**Authorization will be issued for 12 months.**

<sup>a</sup> 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.

## **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]. New York, NY: Intercept Pharmaceuticals, Inc.; February 2020.

Program	Step Therapy - Ocaliva (obeticholic acid)
<b>Change Control</b>	
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.