UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2019 P 3074-6
Program	Step Therapy
Medication	Ocaliva (obeticholic acid)
P&T Approval Date	5/2016, 6/2017, 6/2018, 6/2019
Effective Date	9/1/2019; 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[a]:

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.

[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.

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 2018.

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.