UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2091-12
Program	Prior Authorization/Medical Necessity
Medication	Ocaliva® (obeticholic acid)
P&T Approval Date	5/2016, 6/2016, 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:

Ocaliva (obeticholic acid), a farnesoid X receptor (FXR) agonist, is indicated for the treatment of primary biliary cholangitis (PBC), without cirrhosis or with compensated cirrhosis without evidence of portal hypertension, in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA. This indication is approved under accelerated approval based on a reduction in alkaline phosphatase (ALP). An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.[1]

2. Coverage Criteria[a]:

A. Initial Authorization

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 does not have cirrhosis

      -OR-

      (2) Patient has compensated cirrhosis without evidence of portal hypertension

   -AND-

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

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

         (a) Used in combination with ursodeoxycholic acid (e.g., Urso, ursodiol)
         (b) Patient has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal after at least 12 consecutive months of treatment with ursodeoxycholic acid (e.g., Urso, ursodiol)

-OR-

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

-AND-

d. Patient is not receiving Ocaliva in combination with Iqirvo (elafibranor) or Livdelzi (seladelpar)

-AND-

e. Prescribed by one of the following:

(1) Hepatologist
(2) Gastroenterologist

Initial authorization will be issued for 12 months

B. Reauthorization

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

a. Submission of medical records (e.g., laboratory values) documenting a reduction in ALP level from pre-treatment baseline (i.e., prior to Ocaliva therapy)

-AND-

b. **One** of the following:

(1) Patient does not have cirrhosis

-OR-

(2) Patient has compensated cirrhosis without evidence of portal hypertension

-AND-

c. Patient is not receiving Ocaliva in combination with Iqirvo (elafibranor) or Livdelzi (seladelpar)

-AND-

d. Prescribed by one of the following:

(1) Hepatologist
(2) Gastroenterologist

Reauthorization 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:

- Supply limits may be in place.
- 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.

4. References:

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

Program	Prior Authorization/Medical Necessity – Ocaliva (obeticholic acid)
Change Control	
Date	Change
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. Added prescriber requirement to reauthorization criteria. 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. Revised order of listing of two criteria to better align with 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. Updated reference.
6/2024	Annual review. Updated initial authorization to 12 months.
12/2024	Added not receiving in combination language to criteria.