UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2024 P 1188-9 |
| Program | Prior Authorization/Notification |
| Medication | Ocaliva® (obeticholic acid) |
| P&T Approval Date | 5/2016, 6/2017, 6/2018, 6/2019, 6/2020, 6/2021, 6/2022, 6/2023, 6/2024 |
| Effective Date | 9/1/2024 |

**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 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)

**Initial authorization will be issued for 12 months**

**B. Reauthorization**

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

   a. Documentation of positive clinical response to Ocaliva therapy

**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.

## 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 may be in place
- Medical necessity may be in place
- Step Therapy may be in place

## 4. References:

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

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| **Change Control** | |
| Date | Change |
| 5/2016 | New program. |
| 6/2016 | Changed clinical criteria based on FDA approved label. |
| 6/2017 | Annual review with no changes to clinical criteria. Updated Clinical Rules to include that Step Therapy may be in place. |
| 6/2018 | Annual review with no changes to clinical criteria. Updated references. |
| 6/2019 | Annual review with no changes. |
| 6/2020 | Annual review. Added black box warning information. |
| 6/2021 | Annual review. No changes to clinical criteria. |
| 6/2022 | Annual review. Changed clinical criteria based on changes to prescribing information. Revised order of listing of two criteria to better align with prescribing information. Background and reference updated. |
| 6/2023 | Annual review with no changes to coverage criteria. Added state mandate and updated reference. |

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| 6/2024 | Annual review. Updated initial authorization to 12 months. |