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## DRUG POLICY

# Ocaliva (obeticholic acid)

### NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

### BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

### DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

#### FDA-Approved Indication

Ocaliva is indicated for the treatment of adult patients with primary biliary cholangitis (PBC) without cirrhosis or with compensated cirrhosis who do not have evidence of portal hypertension, either in combination with ursodeoxycholic acid (UDCA) 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.

### POLICY

#### Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- A. For initial requests: Pretreatment serum alkaline phosphatase (ALP) level
- B. For continuation of therapy: Current serum alkaline phosphatase (ALP) and/or current total bilirubin level

#### Exclusion

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Coverage will not be provided for patients with either of the following exclusions:

- A. Patient has decompensated cirrhosis (e.g., Child-Pugh Class B or C) or a prior decompensation event.
- B. Patient has compensated cirrhosis with evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia).

#### Prescriber Specialties

The requested medication must be prescribed by or in consultation with one of the following:

- A. Hepatologist
- B. Gastroenterologist

#### Initial Criteria for Approval

##### **A. Primary biliary cholangitis (PBC) (previously known as primary biliary cirrhosis)**

Authorization of 12 months may be granted for treatment of PBC in patients 18 years of age or older when all of the following criteria are met:

1. Diagnosis of PBC is confirmed by at least two of the following three criteria:
  - a. Biochemical evidence of cholestasis with elevation of alkaline phosphatase (ALP) level for at least 6 months duration
  - b. Presence of antimitochondrial antibodies (AMA) (titer > 1:40 by immunofluorescence or immunoenzymatic reactivity) or PBC-specific antinuclear antibodies (ANA) (eg, anti-gp210, anti-sp100)
  - c. Histologic evidence of PBC on liver biopsy (eg, non-suppurative inflammation and destruction of interlobular and septal bile ducts)
2. Patient has an elevated serum ALP level prior to initiation of therapy with the requested drug
3. Patient meets at least one of the following requirements:
  - a. Inadequate response to at least 12 months of prior therapy with ursodeoxycholic acid (UDCA)/ursodiol and the patient will continue concomitant therapy with UDCA/ursodiol, OR
  - b. Intolerance to UDCA/ursodiol

#### Continuation of Therapy

Authorization of 12 months may be granted for patients who have achieved or maintained a clinical benefit from Ocaliva therapy (e.g., at least 15% reduction in serum ALP level, serum ALP level less than 1.67 times upper limit of normal [ULN], total bilirubin less than or equal to ULN).

#### Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

#### Quantity Limits Apply

Ocaliva - 30 tablets per 30 days

### **PROCEDURES AND BILLING CODES**

***To report provider services, use appropriate CPT\* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.***

- Code(s), if applicable

### **REFERENCES**

- Ocaliva [package insert]. New York, NY: Intercept Pharmaceuticals, Inc.; May 2022.
- Lindor KD, Bowlus CL, Boyer J, et al. Primary biliary cholangitis: 2018 Practice guidance from the American Association for the study of liver diseases. *Hepatology*. 2019;69(1):394-419.

- European Association for the Study of the Liver. EASL Clinical Practice Guidelines: management of cholestatic liver diseases. *J Hepatol.* 2017;67:145-172.

## POLICY HISTORY

**Policy #:** 05.02.02

**Policy Creation:** September 2016

**Reviewed:** October 2025

**Revised:** October 2025

**Current Effective Date:** December 18, 2025