09-J2000-65
Original Effective Date: 09/15/16

Reviewed: 07/09/25

Revised: 08/15/25

Subject: Obeticholic Acid (Ocaliva®) Tablet

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Obeticholic acid (Ocaliva) is a semi-synthetic bile acid analogue and farnesoid X receptor (FXR) agonist. FXR is expressed in the liver and intestine, and is responsible for regulating bile acid, inflammatory, fibrotic, and metabolic pathways. When obeticholic acid activates FXR, bile acid synthesis by the liver is suppressed and transport of bile acids out of hepatocytes is increased, thereby decreasing intracellular bile acid concentrations in hepatocytes. Obeticholic acid was approved by the FDA in May 2016 for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA. Obeticholic acid was previously granted orphan drug designation by the FDA for the treatment of PBC in April 2008. In May 2021, the FDA issued a Drug Safety Communication stating that they are restricting the use of obeticholic acid in PBC patients with advanced liver cirrhosis because it can cause serious harm. The Ocaliva product labeling was updated to include a revised indication and new contraindications regarding use in patients with decompensated cirrhosis (e.g., Child-Pugh Class B or C) or a prior decompensation event and patients with compensated cirrhosis who have evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia). The label's Boxed Warning was also updated with this information along with related warnings about this risk.

Primary biliary cholangitis (PBC), previously referred to as primary biliary cirrhosis, is a chronic, progressive autoimmune cholestatic liver disease that slowly destroys the intrahepatic bile ducts within the liver. This causes bile to accumulate in the liver resulting in gradual injury to liver cells and ultimately cirrhosis. Women account for about 90% of PBC cases. It is most commonly diagnosed in patients between the age of 35 and 60. Since cirrhosis occurs only in the late stage, the name primary biliary cirrhosis is now considered a misnomer for patients in the earlier stages of disease. Patients are often initially asymptomatic, and the first sign of disease is often abnormal liver tests [e.g., alkaline

phosphatase (ALP), alanine aminotransferase (ALT), and aspartate aminotransferase (AST)]. Fatigue, pruritus, and dry eyes/mouth are the most common symptoms of PBC if symptoms are present prior to the onset of cirrhosis. Once symptoms develop, the mediation duration of survival is 5 to 8 years. The serological hallmark of PBC is the presence of anti-mitochondrial antibody (AMA), a highly disease-specific antibody identified in about 95% of patients with PBC. There is no cure for PBC; however, the use of ursodiol (a.k.a., ursodeoxycholic acid, UDCA) can help improve liver function and may help slow disease progression/onset of cirrhosis. However, up to 30 to 40% of UDCA-treated patients have an inadequate biochemical response, which is associated with significantly worse transplant-free survival rates than UDCA-responsive patients. Prior to the approval of obeticholic acid, UDCA was the only FDA-approved treatment for PBC. In September 2017, the FDA issued a Drug Safety Communication that obeticholic acid is being incorrectly dosed in some patients with moderate to severe decreases in liver function resulting in an increased risk of serious liver injury and death. In January 2018, the FDA required that this information be added as a Boxed Warning in the prescribing information (along with additional dosage information), and that a Medication Guide be provided to patients to inform them about this issue.

The safety and efficacy of obeticholic acid leading to FDA approval for PBC assessed in a randomized, double-blind, placebo-controlled, 12-month trial (PBC OCA International Study of Efficacy or POISE) of 216 patients with PBC who were taking UDCA for at least 12 months (on a stable dosage for at least 3 months), or who were unable to tolerate UDCA and did not receive UDCA for at least 3 months. Patients were included in the trial if the ALP was 1.67-times upper limit of normal (ULN) or greater and/or if total bilirubin was greater than 1-times ULN but less than 2-times ULN. Patients were excluded from the trial if they had other liver disease, presence of clinically significant hepatic decompensation events, severe pruritus, or Model for End Stage Liver Disease (MELD) score of 15 or greater. Patients were randomized (1:1:1) to receive either obeticholic acid 10 mg once daily for the entire 12 months of the trial, (n=73); obeticholic acid titration (5 mg once daily for the initial 6 months, with the option to increase to 10 mg once daily for the last 6 months if the patient was tolerating but had ALP 1.67-times ULN or greater, and/or total bilirubin greater than ULN, or less than 15% ALP reduction) (n=70); or placebo (n=73). Obeticholic acid or placebo was given in combination with UDCA in 93% of patients and as monotherapy in 7% of patients who were unable to tolerate UDCA. The primary endpoint was response at month 12. Response was defined as a composite of three criteria: ALP less than 1.67-times the ULN, total bilirubin less than or equal to ULN, and an ALP decrease of at least 15%.

The study population was 91% female and 94% white. The mean age was 56 years (range 29 to 86 years). The mean baseline ALP concentration was 323.2 U/L, corresponding to 2.74-times ULN. Approximately 29% of the patients had ALP concentration levels greater than 3-times the ULN. The mean baseline total bilirubin concentration was 0.65 mg/dL and was less than or equal to the ULN in 92% of the enrolled patients. The primary efficacy results at month 12 can be seen in the table below. Changes in noninvasive measures of liver fibrosis (e.g., elastography and enhanced liver fibrosis scores) did not differ significantly between either treatment group and the placebo group at 12 months. Pruritus was more common with obeticholic acid than with placebo (56% of patients in the 5-10-mg group and 68% of those in the 10-mg group vs. 38% in the placebo group). The rate of serious adverse events was 16% in the 5-10-mg group, 11% in the 10-mg group, and 4% in the placebo group. A multi-year study to assess the effects of obeticholic acid on clinical outcomes in patients with PBC who have

more advanced liver disease [Clinical Outcomes with Obeticholic Acid in Liver Treatment (COBALT)] is being conducted with an expected completion date of late 2024 or early 2025.

Table 1: Results of POISE trial at Month 12

	Obeticholic acid 10 mg (n=73)	Obeticholic acid titration (n=70)	Placebo (n=73)
Primary composite endpoint			
Responder rate	47%	46%	10%
Components of primary endpoint			
ALP <1.67-times ULN	55%	47%	16%
Decrease in ALP of at least 15%	77%	77%	29%
Total bilirubin ≤ULN	82%	89%	78%

POSITION STATEMENT:

The Food and Drug Administration has deemed the drug(s) or biological product(s) in this coverage policy to be appropriate for self-administration or administration by a caregiver (i.e., not a healthcare professional). Therefore, coverage (i.e., administration) in a provider-administered setting such as an outpatient hospital, ambulatory surgical suite, physician office, or emergency facility is not considered medically necessary.

Initiation of obeticholic acid (Ocaliva) **meets the definition of medical necessity** for members meeting **ALL** of the following criteria ("1" to "7"):

1. Obeticholic acid is prescribed by, or in consultation with, a gastroenterologist or hepatologist
2. The member has a diagnosis of primary biliary cholangitis (PBC, a.k.a., primary biliary cirrhosis)
3. The member does **NOT** have **ANY** of the following contraindications for use:
    - Decompensated cirrhosis (e.g., Child-Pugh Class B or C)
    - A prior decompensation event (e.g., ascites, jaundice, variceal bleeding, hepatic encephalopathy)
    - Compensated cirrhosis with evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia)
    - Complete biliary obstruction
4. The member's baseline ALP level is elevated
5. **EITHER** of the following ("a" or "b"):
    a. Obeticholic acid (Ocaliva) will be used in combination with ursodiol treatment
    b. Obeticholic acid (Ocaliva) will be used as monotherapy because of ONE of the following ("i" or "ii"):
        i. The member has not achieved an adequate biochemical response to ursodiol

ii. The member has experienced persistent and intolerable adverse effects with the use of ursodiol, despite dosage reduction and other management interventions, that necessitates the complete discontinuation of ursodiol treatment

6. **NOT** being administered in combination with elafibranor (Iqirvo) or seladelpar (Livdelzi)
7. The dosage does not exceed 5 mg once daily for the first 3 months, followed by 10 mg daily thereafter - the dose must be achieved using the fewest number of tablets possible

Duration of approval: 6 months

Continuation of obeticholic acid (Ocaliva) **meets the definition of medical necessity** for members meeting **ALL** of the following criteria ("1" to "7"):

1. Authorization or reauthorization for obeticholic acid has been previously approved by Florida Blue or another health plan in the past 2 years for the treatment of PBC (if another health plan, documentation of a health plan-paid claim for Ocaliva during the 90 days immediately before the authorization request must be submitted); **OR** the member previously met **ALL** indication-specific initiation criteria (with the exception of the baseline ALP requirement).
2. The member has had a positive biochemical response to treatment (e.g., by a reduction in ALP level as compared to baseline)
3. Member is taking obeticholic acid in combination with ursodiol treatment, unless obeticholic acid was initiated as monotherapy due to prior intolerance to or ineffectiveness of ursodiol
4. The member does **NOT** have **ANY** of the following contraindications for use:
    - Decompensated cirrhosis (e.g., Child-Pugh Class B or C)
    - A prior decompensation event (e.g., ascites, jaundice, variceal bleeding, hepatic encephalopathy)
    - Compensated cirrhosis with evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia)
    - Complete biliary obstruction
5. **NOT** being administered in combination with elafibranor (Iqirvo) or seladelpar (Livdelzi)
6. Obeticholic acid is prescribed by, or in consultation with, a gastroenterologist or hepatologist
7. The dosage does not exceed 10 mg once daily - the dose must be achieved using the fewest number of tablets possible

Duration of approval: 1 year

Ocaliva is considered **experimental or investigational** for the treatment of nonalcoholic steatohepatitis (NASH), nonalcoholic fatty liver disease (NAFLD), and all other off-label indications. There is insufficient evidence in the peer-reviewed medical literature to support safety, efficacy, and net health outcomes.

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL

PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved

- 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) 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.
- Prior to initiation, healthcare providers should determine whether the patient has decompensated cirrhosis (e.g., Child-Pugh Class B or C), has had a prior decompensation event, or has compensated cirrhosis with evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia) because use is contraindicated in these patients.
- The recommended dosage is to start at 5 mg once daily for the first 3 months. After the first 3 months, for patients who have not achieved an adequate reduction in ALP and/or total bilirubin and who are tolerating, increase to a maximum dosage of 10 mg once daily.
- Take with or without food. For patients taking bile acid binding resins, take obeticholic acid at least 4 hours before or 4 hours after taking a bile acid binding resin, or at as great an interval as possible.
- Routinely monitor patients during treatment for biochemical response, tolerability, and progression of PBC. Closely monitor patients with compensated cirrhosis, concomitant hepatic disease (e.g., autoimmune hepatitis, alcoholic liver disease), and/or severe intercurrent illness for new evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia) or increases above the upper limit of normal in total bilirubin, direct bilirubin, or prothrombin time. Permanently discontinue in patients who develop laboratory or clinical evidence of hepatic decompensation, have compensated cirrhosis and develop evidence of portal hypertension, experience clinically significant hepatic adverse reactions, or develop complete biliary obstruction.

Dose Adjustments

- Intolerable Pruritus: consider one or more of the following:
    - Add an antihistamine or bile acid binding resin
    - Reduce the dosage to 5 mg every other day, for patients intolerant to 5 mg once daily, or 5 mg once daily, for patients intolerant to 10 mg once daily
    - Temporarily interrupt dosing for up to 2 weeks, followed by restarting at a reduced dosage. Titrate the dosage based on biochemical response and tolerability.
    - Consider discontinuing obeticholic acid treatment in patients who continue to experience persistent, intolerance pruritus despite management strategies.

- Hepatic Impairment:
    - Mild impairment (Child-Pugh A): No adjustment necessary; however, use is contraindicated in patients with compensated cirrhosis who have evidence of portal hypertension
    - Moderate (Child-Pugh B) to severe (Child-Pugh C) impairment: Use is contraindicated
- Renal Impairment: Obeticholic acid has not been studied in patients with moderate and severe renal impairment; dosage adjustment is likely not needed

Drug Availability

- 5 and 10 mg tablets

PRECAUTIONS:

Boxed Warning

WARNING: HEPATIC DECOMPENSATION AND FAILURE IN PRIMARY BILIARY CHOLANGITIS PATIENTS WITH CIRRHOSIS

- Hepatic decompensation and failure, sometimes fatal or resulting in liver transplant, have been reported with Ocaliva treatment in primary biliary cholangitis (PBC) patients with either compensated or decompensated cirrhosis.
- Ocaliva is contraindicated in PBC patients with decompensated cirrhosis, a prior decompensation event, or with compensated cirrhosis who have evidence of portal hypertension.
- Permanently discontinue Ocaliva in patients who develop laboratory or clinical evidence of hepatic decompensation; have compensated cirrhosis and develop evidence of portal hypertension; or experience clinically significant hepatic adverse reactions while on treatment.

Contraindications

- Patients with decompensated cirrhosis (e.g., Child-Pugh Class B or C) or a prior decompensation event
- Patients with compensated cirrhosis who have evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia)
- Patients with complete biliary obstruction

Precautions/Warnings

- **Hepatic Decompensation and Failure in PBC Patients with Cirrhosis**: Hepatic decompensation and failure, sometimes fatal or resulting in liver transplant, have been reported with treatment in PBC patients with cirrhosis, either compensated or decompensated. Among postmarketing cases reporting it, median time to hepatic decompensation (e.g., new onset ascites) was 4 months for patients with compensated cirrhosis; median time to a new decompensation event (e.g., hepatic encephalopathy) was 2.5 months for patients with decompensated cirrhosis. Some of these cases occurred in patients with decompensated cirrhosis when they were treated with higher than the recommended dosage for that patient population; however, cases of hepatic decompensation and failure have continued to be reported in patients with decompensated cirrhosis even when they

received the recommended dosage. Routinely monitor patients for progression of PBC, including hepatic adverse reactions, with laboratory and clinical assessments. Closely monitor patients at risk of hepatic decompensation. Permanently discontinue in patients who develop laboratory or clinical evidence of hepatic decompensation (e.g., ascites, jaundice, variceal bleeding, hepatic encephalopathy); have compensated cirrhosis and develop evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia); experience clinically significant hepatic adverse reactions; or develop complete biliary obstruction. Interrupt treatment in patients with severe intercurrent illness.

- **Severe Pruritus**: In the major clinical trial, severe pruritus was reported in 23% of patients in the obeticholic acid10 mg arm, 19% of patients in the titration arm, and 7% of patients in the placebo arm. Management strategies include the addition of bile acid binding resins or antihistamines, and dosage reduction and/or temporary dosing interruption of obeticholic acid.
- **Reduction in HDL-C**: Monitor for changes in serum lipid levels during treatment. For patients with minimal or no response and who experience a reduction in HDL-C, weigh the potential risks against the benefits of continuing treatment.
- **Drug Interactions**:
    - Warfarin: Potential for decreased INR; monitor INR and adjust the dosage of warfarin, as needed, to maintain the target INR range
    - CYP1A2 Substrates with Narrow Therapeutic Index (e.g., theophylline and tizanidine): Potential for increased exposure to CYP1A2 substrates; monitor drug concentrations of CYP1A2 substrates with narrow therapeutic index.
- **Pregnancy**: The limited available human data on the use of obeticholic acid during pregnancy are not sufficient to inform a drug-associated risk. In animal reproduction studies, no developmental abnormalities or fetal harm was observed when pregnant rats or rabbits were administered obeticholic acid during the period of organogenesis.

BILLING/CODING INFORMATION:

The following codes may be used to describe:

HCPCS Coding

J8499	Prescription drug, oral, non-chemotherapeutic, Not Otherwise Specified

ICD-10 Diagnosis Codes That Support Medical Necessity

K74.3	Primary biliary cirrhosis

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of guideline creation.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

None

RELATED GUIDELINES:

None

OTHER:

Child-Pugh Nomogram

Parameter	Points Scored for Observed Findings		
	1 point	2 points	3 points
Encephalopathy grade	None	1 or 2	3 or 4
Ascites	Absent	Slight	Moderate
Serum bilirubin (mg/dL)	<2	2 to 3	>3
Serum albumin (g/dL)	>3.5	2.8 to 3.5	<2.8
International Normalized Ratio (INR)	<1.7	1.7 to 2.2	>2.2
Child-Pugh Class is obtained by adding the points from all 5 parameters to derive a total score, which can range from 5 to 15 points. Child-Pugh Class A: 5 to 6 points Child-Pugh Class B: 7 to 9 points Child-Pugh Class C: 10 to 15 points			

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 07/09/25.

GUIDELINE UPDATE INFORMATION:

09/15/16	New Medical Coverage Guideline.
08/15/17	Review and revision to guideline consisting of updating the description section, position statement, and references.
03/15/18	Revision to guidelines consisting of updating the description section, position statement, other section, and references based on a revised product label including a new Boxed Warning and dosage recommendations.
05/15/18	Revision to guidelines consisting of updating the position statement.
08/15/18	Review and revision to guideline consisting of updating references.
08/15/19	Review and revision to guideline consisting of updating the references.
08/15/20	Review and revision to guideline consisting of updating the position statement and references.
07/15/21	Review and revision to guideline consisting of updating the description, position statement, dosage/administration, warnings/precautions, and references.
08/15/22	Review and revision to guideline consisting of updating the references.
08/15/23	Review and revision to guideline consisting of updating the references.
08/15/24	Review and revision to guideline consisting of revising the position statement to not allow combination therapy with elafibranor (Iqirvo) and updating the references.
01/01/25	Review and revision to the guideline consisting of updating the position statement to not allow for concomitant use with seladelpar (Livdelzi).
03/15/25	Review and revision to the guideline consisting of updating the position statement to remove documentation requirements and allow prescribing in consultation with a gastroenterologist or hepatologist.
08/15/25	Review and revision to guideline consisting of updating the references.