OCALIVA®
obeticholic acid

TREATMENT MANAGEMENT GUIDE

INDICATION

OCALIVA, a farnesoid X receptor (FXR) agonist, 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 patients 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.

SELECTED IMPORTANT SAFETY INFORMATION

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.**

Please see additional Important Safety Information on pages 3 and 4 and **Full Prescribing Information, including Boxed WARNING,** for OCALIVA. **Rx only**.

TREATMENT MANAGEMENT GUIDE

The adverse reactions discussed in this guide are not inclusive of all possible adverse reactions that may occur with OCALIVA. Please consult the Full Prescribing Information for further guidance.

Contents of the OCALIVA Treatment Management Guide:

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IMPORTANT SAFETY INFORMATION

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

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- **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

OCALIVA is contraindicated in patients with:

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

Warnings and Precautions

Hepatic Decompensation and Failure in PBC Patients with Cirrhosis

Hepatic decompensation and failure, sometimes fatal or resulting in liver transplant, have been reported with OCALIVA 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.

Hepatotoxicity was observed in the OCALIVA clinical trials. A dose-response relationship was observed for the occurrence of hepatic adverse reactions including jaundice, worsening ascites, and primary biliary cholangitis flare with dosages of OCALIVA of 10 mg once daily to 50 mg once daily (up to 5-times the highest recommended dosage), as early as one month after starting treatment with OCALIVA in two 3-month, placebo-controlled clinical trials in patients with primarily early stage PBC.

Routinely monitor patients for progression of PBC, including hepatic adverse reactions, with laboratory and clinical assessments to determine whether drug discontinuation is needed. Closely monitor patients with compensated cirrhosis, concomitant hepatic disease (e.g., autoimmune hepatitis, alcoholic liver disease), and/or with 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 to determine whether drug discontinuation is needed. Permanently discontinue OCALIVA 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. If severe intercurrent illness occurs, interrupt treatment with OCALIVA and monitor the patient's liver function. After resolution of the intercurrent illness, consider the potential risks and benefits of restarting OCALIVA treatment.

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Severe Pruritus

Severe pruritus was reported in 23% of patients in the OCALIVA 10 mg arm, 19% of patients in the OCALIVA titration arm, and 7% of patients in the placebo arm in a 12-month double-blind randomized controlled clinical trial of 216 patients. Severe pruritus was defined as intense or widespread itching, interfering with activities of daily living, or causing severe sleep disturbance, or intolerable discomfort, and typically requiring medical interventions. Consider clinical evaluation of patients with new onset or worsening severe pruritus. Management strategies include the addition of bile acid binding resins or antihistamines, OCALIVA dosage reduction, and/or temporary interruption of OCALIVA dosing.

Reduction in HDL-C

Patients with PBC generally exhibit hyperlipidemia characterized by a significant elevation in total cholesterol primarily due to increased levels of high-density lipoprotein-cholesterol (HDL-C). Dose-dependent reductions from baseline in mean HDL-C levels were observed at 2 weeks in OCALIVA-treated patients, 20% and 9% in the 10 mg and titration arms, respectively, compared to 2% in the placebo arm. Monitor patients for changes in serum lipid levels during treatment. For patients who do not respond to OCALIVA after 1 year at the highest recommended dosage that can be tolerated (maximum of 10 mg once daily), and who experience a reduction in HDL-C, weigh the potential risks against the benefits of continuing treatment.

Adverse Reactions

The most common adverse reactions (≥5%) are: pruritus, fatigue, abdominal pain and discomfort, rash, oropharyngeal pain, dizziness, constipation, arthralgia, thyroid function abnormality, and eczema.

Drug Interactions

- Bile Acid Binding Resins
  Bile acid binding resins such as cholestyramine, colestipol, or colesevelam adsorb and reduce bile acid absorption and may reduce the absorption, systemic exposure, and efficacy of OCALIVA. If taking a bile acid binding resin, take OCALIVA at least 4 hours before or 4 hours after taking the bile acid binding resin, or at as great an interval as possible.

- Warfarin
  The International Normalized Ratio (INR) decreased following coadministration of warfarin and OCALIVA. Monitor INR and adjust the dose of warfarin, as needed, to maintain the target INR range when co-administering OCALIVA and warfarin.

- CYP1A2 Substrates with Narrow Therapeutic Index
  Obeticholic acid may increase the exposure to concomitant drugs that are CYP1A2 substrates. Therapeutic monitoring of CYP1A2 substrates with a narrow therapeutic index (e.g., theophylline and tizanidine) is recommended when co-administered with OCALIVA.

- Inhibitors of Bile Salt Efflux Pump
  Avoid concomitant use of inhibitors of the bile salt efflux pump (BSEP) such as cyclosporine. Concomitant medications that inhibit canalicular membrane bile acid transporters such as the BSEP may exacerbate accumulation of conjugated bile salts including taurine conjugate of obeticholic acid in the liver and result in clinical symptoms. If concomitant use is deemed necessary, monitor serum transaminases and bilirubin.

Please see additional Important Safety Information on pages 1 and 3 and click here for **Full Prescribing Information, including Boxed WARNING,** for OCALIVA.

To report SUSPECTED ADVERSE REACTIONS, contact Intercept Pharmaceuticals, Inc. at 1-844-782-ICPT or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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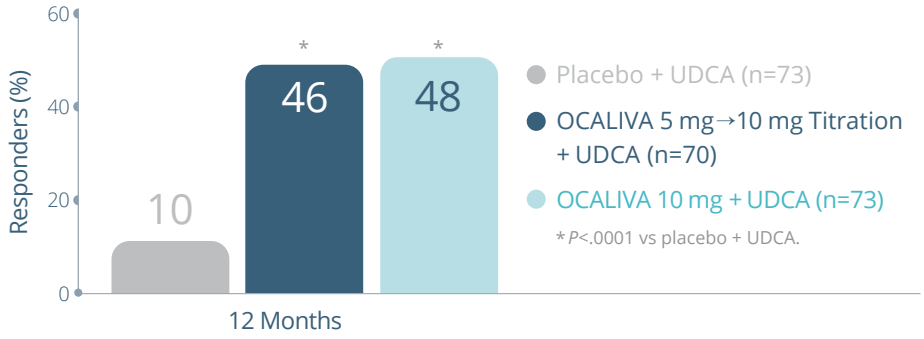
OCALIVA is the first approved treatment for PBC in nearly 20 years[1,2]

- FXR agonist[a] with demonstrated efficacy in patients with an inadequate response to UDCA[2]
  - Efficacy demonstrated in combination with UDCA and as monotherapy in adults unable to tolerate UDCA[2]

Primary composite endpoint was composed of[2]:

- ☑ Alkaline phosphatase <1.67x ULN
- ☑ Alkaline phosphatase decrease of ≥15%
- ☑ Total bilirubin ≤ ULN

46% of Patients Met the Primary Endpoint vs 10% of Patients Taking UDCA Alone[2,b,c]



Percentage of patients achieving the components of the primary composite endpoint at Month 12[2,c]

	OCALIVA 5 mg→10 mg Titration + UDCA (n=70)	OCALIVA 10 mg + UDCA (n=73)	Placebo + UDCA (n=73)
ALP <1.67x ULN	47%	55%	16%
ALP decrease of ≥15%	77%	78%	29%
Total bilirubin ≤ ULN	89%	82%	78%

- 92% of patients had normal bilirubin at baseline[2]
- Among patients who completed treatment in the titration group (n=64), 10 mg group (n=63), and placebo group (n=70), ≥95% of patients receiving OCALIVA had bilirubin ≤ ULN vs 81% of patients in the placebo group[2,3]

[a]A key regulator of bile acid, inflammatory, fibrotic, and metabolic pathways.
[b]A phase 3, randomized, double-blind, placebo-controlled, parallel-group, 12-month study of 216 patients with PBC having an inadequate response to UDCA, defined as alkaline phosphatase ≥1.67x ULN or total bilirubin > ULN but <2x ULN. Patients had to have been on UDCA for ≥1 year or, if intolerant to UDCA, ≥3 months without UDCA. Patients received either UDCA + OCALIVA 5 mg (titrated to 10 mg at Month 6 if needed for greater response and if tolerability allowed; called the titration group), UDCA + OCALIVA 10 mg, or UDCA + placebo.
[c]16 patients (7%) were intolerant and did not receive concomitant UDCA: 6 patients (8%) in the OCALIVA 10 mg arm, 5 patients (7%) in the OCALIVA 5 mg→10 mg titration arm, and 5 patients (7%) in the placebo arm.

ALP, alkaline phosphatase; FXR, farnesoid X receptor; PBC, primary biliary cholangitis; UDCA, ursodeoxycholic acid; ULN, upper limit of normal.

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OCALIVA Tolerability

Most Common Adverse Reactions (N=216)[2,a,b]

Adverse Reaction	OCALIVA + UDCA		Placebo + UDCA Group (n=73)
	10 mg Group (n=73)	5 mg→10 mg Titration Group[c] (n=70)	
Pruritus[d]	70%	56%	38%
Fatigue[e]	25%	19%	15%
Abdominal pain and discomfort[f]	10%	19%	14%
Rash[g]	10%	7%	8%
Arthralgia	10%	6%	4%
Oropharyngeal pain	8%	7%	1%
Dizziness[h]	7%	7%	5%
Constipation	7%	7%	5%
Peripheral edema	7%	3%	3%
Palpitations	7%	3%	1%
Pyrexia	7%	0%	1%
Thyroid function abnormality[i]	4%	6%	3%
Eczema	3%	6%	0%

[a]Occurring in ≥5% of patients in either OCALIVA treatment group and at an incidence ≥1% higher than placebo.
[b]16 patients (7%) were intolerant and did not receive concomitant UDCA: 6 patients (8%) in the OCALIVA 10 mg arm, 5 patients (7%) in the OCALIVA 5 mg→10 mg titration arm, and 5 patients (7%) in the placebo arm.
[c]Patients randomized to OCALIVA titration received OCALIVA 5 mg once daily for the initial 6-month period. At Month 6, patients who did not achieve the composite endpoint and did not have evidence of tolerability issues were titrated from 5 mg to 10 mg for the final 6 months of the trial.
[d]Includes skin eruptions, prurigo, pruritus, pruritus generalized, eye pruritus, ear pruritus, anal pruritus, vulvovaginal pruritus, and rash pruritic.
[e]Includes fatigue, tiredness, and asthenia.
[f]Includes abdominal pain upper, abdominal pain, abdominal discomfort, abdominal pain lower, abdominal tenderness, and gastrointestinal pain.
[g]Includes urticaria, rash, rash macular, rash papular, rash maculo-papular, heat rash, and urticaria cholinergic.
[h]Includes dizziness, syncope, and presyncope.
[i]Includes thyroxine free decreased, blood thyroid stimulating hormone increased, and hypothyroidism.

UDCA, ursodeoxycholic acid.

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WARNING: Hepatic Decompensation and Failure in PBC Patients with Cirrhosis[2]

- Hepatic decompensation and failure, sometimes fatal or resulting in liver transplant, have been reported with OCALIVA® (obeticholic acid) treatment in PBC patients with cirrhosis, either compensated or decompensated
- Among postmarketing cases reporting it, median time to hepatic decompensation (eg, new onset ascites) was 4 months for patients with compensated cirrhosis; median time to a new decompensation event (eg, 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
- Hepatotoxicity was observed in the OCALIVA clinical trials. A dose-response relationship was observed for the occurrence of hepatic adverse reactions including jaundice, worsening ascites, and primary biliary cholangitis flare with dosages of OCALIVA of 10 mg once daily to 50 mg once daily (up to 5-times the highest recommended dosage), as early as one month after starting treatment with OCALIVA in two 3-month, placebo-controlled clinical trials in patients with primarily early stage PBC

Patient management[2]

- Routinely monitor patients for progression of PBC, including hepatic adverse reactions, with laboratory and clinical assessments to determine whether drug discontinuation is needed
- Closely monitor patients with compensated cirrhosis, concomitant hepatic disease (eg, autoimmune hepatitis, alcoholic liver disease), and/or with severe intercurrent illness for new evidence of portal hypertension (eg, ascites, gastroesophageal varices, persistent thrombocytopenia) or increases above the upper limit of normal in total bilirubin, direct bilirubin, or prothrombin time to determine whether drug discontinuation is needed
- Permanently discontinue OCALIVA in patients who develop laboratory or clinical evidence of hepatic decompensation (eg, ascites, jaundice, variceal bleeding, hepatic encephalopathy), have compensated cirrhosis and develop evidence of portal hypertension (eg, ascites, gastroesophageal varices, persistent thrombocytopenia), experience clinically significant hepatic adverse reactions, or develop complete biliary obstruction
- If severe intercurrent illness occurs, interrupt treatment with OCALIVA and monitor the patient's liver function. After resolution of the intercurrent illness, consider the potential risks and benefits of restarting OCALIVA treatment

PBC, primary biliary cholangitis.

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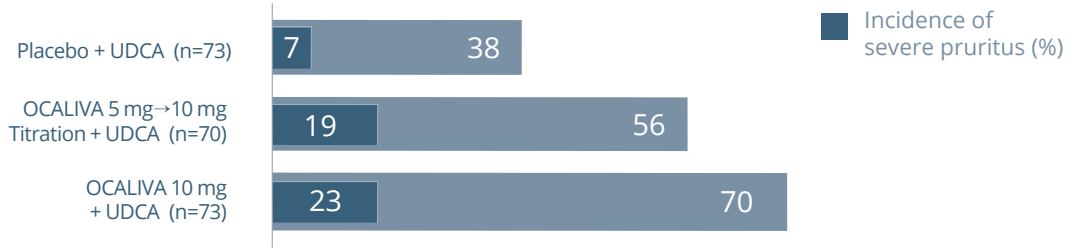
Adverse Reactions and Discontinuation

Pruritus, a common symptom of PBC[4]

- Approximately 60% of patients in the study had a baseline history of pruritus[2]
- Treatment-emergent pruritus generally started within the first month of treatment[2]

Overall Incidence of Pruritus[2]



Overall discontinuation rates[2]

- During the clinical trial, treatment was discontinued for 4% of patients in the placebo group, 10% of patients in the OCALIVA titration group, and 12% in the OCALIVA 10 mg group
- 97% of patients who completed the 12-month trial chose to continue in the long-term extension[5]

Discontinuation due to pruritus: 1% with OCALIVA 5 mg starting dose[2]

1% OCALIVA 5 mg→10 mg Titration + UDCA

10% OCALIVA 10 mg + UDCA

- Lower rate in the OCALIVA 5 mg→10 mg titration group vs the 10 mg once-daily group (1% vs 10%)

Patients requiring intervention to help manage pruritus[2,a]

50% Placebo + UDCA

62% OCALIVA 5 mg→10 mg Titration + UDCA

59% OCALIVA 10 mg + UDCA

[a]Eg, dosage adjustment, treatment interruption, or initiation of a bile acid binding resin or an antihistamine.

PBC, primary biliary cholangitis; UDCA, ursodeoxycholic acid.

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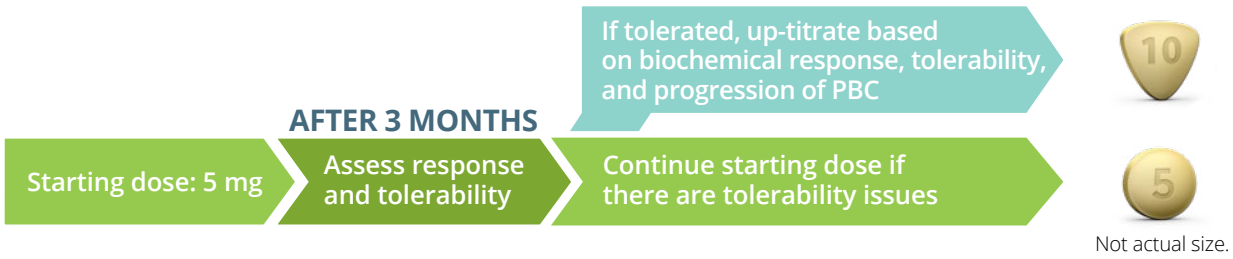
OCALIVA® obeticholic acid

For patients without cirrhosis or with compensated cirrhosis who do not have evidence of portal hypertension[2]

Prior to the initiation of OCALIVA® (obeticholic acid), healthcare providers should determine whether the patient has decompensated cirrhosis (eg, Child-Pugh Class B or C), has had a prior decompensation event, or has compensated cirrhosis with evidence of portal hypertension (eg, ascites, gastroesophageal varices, persistent thrombocytopenia) because OCALIVA is contraindicated in these patients.

- Starting dose: **5 mg once daily**
- Titration dose: **10 mg once daily**
  - — After the first 3 months, for patients who have not achieved an adequate reduction in ALP and/or total bilirubin and who are tolerating OCALIVA, increase to a maximum dosage of 10 mg once daily



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Patient management[2]

- Continue to closely monitor patients with compensated cirrhosis, concomitant hepatic disease (eg, autoimmune hepatitis, alcoholic liver disease), and/or severe intercurrent illness for new evidence of portal hypertension[a] or increases above the upper limit of normal in total bilirubin, direct bilirubin, or prothrombin time to determine whether drug discontinuation is needed
- Permanently discontinue OCALIVA in patients who:
  - — develop laboratory or clinical evidence of hepatic decompensation (eg, ascites, jaundice, variceal bleeding, hepatic encephalopathy)
  - — have compensated cirrhosis and develop evidence of portal hypertension[a]
  - — experience clinically significant hepatic adverse reactions, or
  - — develop complete biliary obstruction

[a]Eg, ascites, gastroesophageal varices, persistent thrombocytopenia.

ALP, alkaline phosphatase; PBC, primary biliary cholangitis.

SELECTED IMPORTANT SAFETY INFORMATION

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

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In a roundtable of 11 leading experts in the fields of gastroenterology, hepatology, and psychiatry, recommendations related to pruritus management were suggested.[6]

When administering OCALIVA, ask your patients about pruritus and re-evaluate 2–4 weeks after the initial dose to ensure that pruritus symptoms are managed and not left untreated.[6]

Consider titrating OCALIVA dosage to help patients experiencing pruritus due to treatment.

Assess pruritus[a] at current daily OCALIVA dosage[2,6]

	IF AT 5 MG ONCE DAILY	IF AT 10 MG ONCE DAILY
NONE OR MILD	Up-titrate to 10 mg[b] once daily	Stay at 10 mg
MODERATE	Up-titrate to 10 mg[b] once daily OR stay at 5 mg[c]	Stay at 10 mg
SEVERE	Reduce to 5 mg every other day[c] OR temporarily pause treatment for up to 2 weeks[d]	Reduce to 5 mg once daily[c]

Consider the following management strategies when evaluating patients with new onset or worsening severe pruritus[2]:

- Add an antihistamine or bile acid binding resin
- Reduce the dosage of OCALIVA to:
  - 5 mg every other day, for patients intolerant to 5 mg once daily
  - 5 mg once daily, for patients intolerant to 10 mg once daily
- Temporarily interrupt OCALIVA dosing for up to 2 weeks. Restart at a reduced dosage and titrate the dosage based on biochemical response and tolerability
- Consider discontinuing OCALIVA treatment in patients who continue to experience persistent, intolerable pruritus despite management strategies

[a]Pruritus severity can be assessed using objective measurement tools, such as the Visual Analogue Scale (VAS), 5-D Itch Scale, PBC-40 tool, or PBC-27 tool.[6]
[b]After the first 3 months, for patients who have not achieved an adequate reduction in ALP and/or total bilirubin and who are tolerating OCALIVA, increase to maximum of 10 mg once daily.[2]
[c]Based on clinical judgment and patient feedback, which may include factors other than pruritus severity and should reflect patient choice and comfort.[6]
[d]If treatment is paused for 2 weeks, restart at 5 mg every other day, then gradually up-titrate to 5 mg daily and, if tolerated, to 10 mg daily.[6]

ALP, alkaline phosphatase; PBC, primary biliary cholangitis.

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Evaluate response and tolerability throughout PBC treatment

Routinely monitor patients for biochemical response, tolerability, and progression of PBC, including hepatic adverse reactions, during treatment[2,b]

START of treatment

- **INITIATE** OCALIVA at 5 mg once daily[2]
- **MANAGE** patient expectations regarding when they may see a response to treatment[a] and the possibility of pruritus[2]
- **DISCUSS** the importance of preventative pruritus management[2]

2 WEEKS

- **ASSESS** for pruritus, as it may present within the first 2 weeks of treatment[2]

1 MONTH

- **EVALUATE** for pruritus and other side effects; review management strategies[2]
- **ENCOURAGE** adherence to OCALIVA by reminding patients of the importance of ALP reductions[7]

3 MONTHS

- **CONTINUE** to evaluate response and tolerability, including pruritus, to determine if the patient is appropriate for titration to maximum of 10 mg once daily[2]

3-6 MONTHS

- **PERFORM** liver monitoring every 3-6 months per AASLD guidelines and your clinical judgment[7]; continue monitoring for pruritus and other side effects

Consider discontinuing OCALIVA treatment in patients who continue to experience persistent, intolerable pruritus despite management strategies[2]

[a]Some patients may see reductions in ALP as early as the first 2 weeks.
[b]Closely monitor patients with compensated cirrhosis, concomitant hepatic disease (eg, autoimmune hepatitis, alcoholic liver disease), and/or severe intercurrent illness for new evidence of portal hypertension (eg, ascites, gastroesophageal varices, persistent thrombocytopenia) or increases above the upper limit of normal in total bilirubin, direct bilirubin, or prothrombin time. Permanently discontinue OCALIVA in patients who develop laboratory or clinical evidence of hepatic decompensation (eg, ascites, jaundice, variceal bleeding, hepatic encephalopathy), have compensated cirrhosis and develop evidence of portal hypertension, experience clinically significant hepatic adverse reactions, or develop complete biliary obstruction.

AASLD, American Association for the Study of Liver Diseases; ALP, alkaline phosphatase; PBC, primary biliary cholangitis.

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Interconnect® Patient Support

Interconnect®
SUPPORT SERVICES

Your Patients. Our Commitment.

When you choose OCALIVA for your patients, Interconnect® provides comprehensive, personalized support to help your patients start and stay on therapy.

Treatment begins with a single enrollment form. Once your patients are enrolled in Interconnect®, they will have access to personalized support services to help them throughout their OCALIVA treatment.

One dedicated Care Coordinator will help guide your office and patients through

Financial assistance
Helping to improve treatment access, including a $0 co-pay program[a]

Personalized support
Providing ongoing proactive support to encourage treatment compliance and persistence

Education
Supplying resources and answers to questions about OCALIVA

[a] For qualified patients with commercial insurance.

For more information:

interconnectsupport.com

1-844-622-ICPT

To get started on OCALIVA, fax the enrollment form to:

1-855-686-8730

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For additional information on OCALIVA, please visit **ocalivahcp.com**

To learn more about Intercept Pharmaceuticals, Inc., please visit **interceptpharma.com**

For medical inquiries, contact **medinfo@interceptpharma.com**

Please see Important Safety Information on pages 1, 3 and 4 and **Full Prescribing Information, including Boxed WARNING,** for OCALIVA.

References: 1. URSO [package insert]. Bridgewater, NJ: Aptalis Pharma US, Inc; 2013. **2.** OCALIVA full prescribing information. New York, NY: Intercept Pharmaceuticals, Inc; 2021. **3.** Data on file: US-PB-MED-00129. **4.** Carey EJ, Ali AH, Lindor KD. Primary biliary cirrhosis. *Lancet*. 2015;386(10003):1565-1575. **5.** Nevens F, Andreone P, Mazzella G, et al; the POISE Study Group. A placebo-controlled trial of obeticholic acid in primary biliary cholangitis. *N Engl J Med*. 2016;375(7):631-643. **6.** Pate J, Gutierrez JA, Frenette CT, et al. Practical strategies for pruritus management in the obeticholic acid-treated patient with PBC: proceedings from the 2018 expert panel. *BMJ Open Gastroenterol*. 2019;6(1):e000256. doi:10.1136/bmjgast-2018-000256 **7.** Lindor KD, Bowlus CL, Boyer J, Levy C, Mayo M. Primary biliary cholangitis: 2018 practice guidance from the American Association for the Study of Liver Diseases. *Hepatology*. 2019;69(1):394-419.

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