



# TREATMENT MANAGEMENT GUIDE

## INDICATION

OCALIVA is indicated 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.

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.

## IMPORTANT SAFETY INFORMATION

### **WARNING: HEPATIC DECOMPENSATION AND FAILURE IN INCORRECTLY DOSED PBC PATIENTS WITH CHILD-PUGH CLASS B OR C OR DECOMPENSATED CIRRHOSIS**

- In postmarketing reports, hepatic decompensation and failure, in some cases fatal, have been reported in patients with Primary Biliary Cholangitis (PBC) with decompensated cirrhosis or Child-Pugh Class B or C hepatic impairment when OCALIVA was dosed more frequently than recommended.
- The recommended starting dosage of OCALIVA is 5 mg once weekly for patients with Child-Pugh Class B or C hepatic impairment or a prior decompensation event.

Please see additional Important Safety Information throughout 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.

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Please see Important Safety Information throughout and [Full Prescribing Information, including Boxed WARNING](#), for OCALIVA.

## Important Safety Information

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- The recommended starting dosage of OCALIVA is 5 mg once weekly for patients with Child-Pugh Class B or C hepatic impairment or a prior decompensation event.

#### **Contraindications**

OCALIVA is contraindicated in patients with complete biliary obstruction.

#### **Warnings and Precautions**

##### **Hepatic Decompensation and Failure in Incorrectly Dosed PBC Patients with Child-Pugh Class B or C or Decompensated Cirrhosis**

In postmarketing reports, hepatic decompensation and failure, in some cases fatal, have been reported in patients with decompensated cirrhosis or Child-Pugh B or C hepatic impairment when OCALIVA was dosed more frequently than the recommended starting dosage of 5 mg once weekly. Reported cases typically occurred within 2 to 5 weeks after starting OCALIVA and were characterized by an acute increase in total bilirubin and/or ALP concentrations in association with clinical signs and symptoms of hepatic decompensation (e.g., ascites, jaundice, gastrointestinal bleeding, worsening of hepatic encephalopathy). Patients who died due to liver-related complications generally had decompensated cirrhosis prior to treatment and were started on OCALIVA 5 mg once daily, which is 7-fold greater than the once-weekly starting regimen in this population.

Routinely monitor patients for progression of PBC disease, including liver-related complications, with laboratory and clinical assessments. Dosage adjustment, interruption or discontinuation may be required. Close monitoring is recommended for patients at an increased risk of hepatic decompensation. Severe intercurrent illnesses that may worsen renal function or cause dehydration (e.g., gastroenteritis), may exacerbate the risk of hepatic decompensation. Interrupt treatment with OCALIVA in patients with laboratory or clinical evidence of worsening liver function indicating risk of decompensation, and monitor the patient's liver function. Consider discontinuing OCALIVA in patients who have experienced clinically significant liver-related adverse reactions. Discontinue OCALIVA in patients who develop complete biliary obstruction.

#### **Liver-Related Adverse Reactions**

Dose-related, liver-related adverse reactions including jaundice, worsening ascites and primary biliary cholangitis flare have been observed in clinical trials, as early as one month after starting treatment with OCALIVA 10 mg once daily up to 50 mg once daily (up to 5-times the highest recommended dosage). Monitor patients during treatment with OCALIVA for elevations in liver biochemical tests and for the development of liver-related adverse reactions.

#### **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

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randomized controlled 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 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 occurring in  $\geq 5\%$  of subjects taking OCALIVA were 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 coadministering OCALIVA and warfarin.

- **CYP1A2 Substrates with Narrow Therapeutic Index**

Obeticholic acid, the active ingredient in OCALIVA, 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 coadministered 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 throughout and [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](http://www.fda.gov/medwatch)**



## About OCALIVA

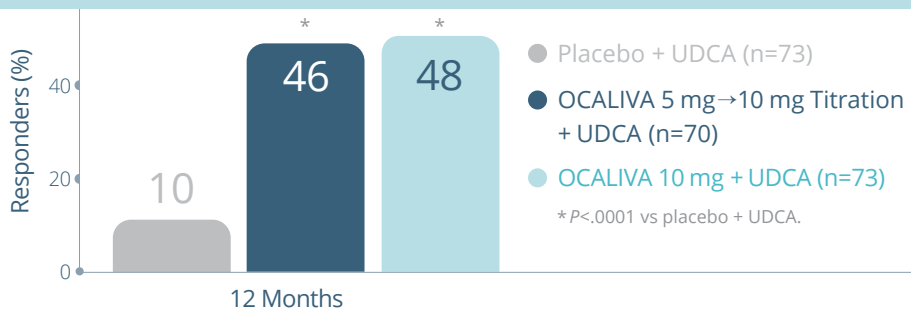
### OCALIVA is the first approved treatment for PBC in nearly 20 years<sup>1,2</sup>

- FXR agonist<sup>a</sup> with demonstrated efficacy in patients with an inadequate response to UDCA<sup>2</sup>
  - Efficacy demonstrated in combination with UDCA and as monotherapy in adults unable to tolerate UDCA<sup>2</sup>

### Primary composite endpoint was composed of<sup>2</sup>:

- ✓ 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<sup>2,b,c</sup>



### Percentage of patients achieving the components of the primary composite endpoint at Month 12<sup>2,c</sup>

	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<sup>2</sup>
- 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<sup>2,3</sup>

<sup>a</sup>A key regulator of bile acid, inflammatory, fibrotic, and metabolic pathways.

<sup>b</sup>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.

<sup>c</sup>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.

Please see Important Safety Information throughout and [Full Prescribing Information, including Boxed WARNING](#), for OCALIVA.

## OCALIVA Tolerability

### Most Common Adverse Reactions (N=216)<sup>2,a,b</sup>

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

<sup>a</sup>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.

<sup>b</sup>Occurring in ≥5% of patients in either OCALIVA treatment group and at an incidence ≥1% higher than placebo.

<sup>c</sup>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.

<sup>d</sup>Includes skin eruptions, prurigo, pruritus, pruritus generalized, eye pruritus, ear pruritus, anal pruritus, vulvovaginal pruritus, and rash pruritic.

<sup>e</sup>Includes fatigue, tiredness, and asthenia.

<sup>f</sup>Includes abdominal pain upper, abdominal pain, abdominal discomfort, abdominal pain lower, abdominal tenderness, and gastrointestinal pain.

<sup>g</sup>Includes urticaria, rash, rash macular, rash papular, rash maculo-papular, heat rash, and urticaria cholinergic.

<sup>h</sup>Includes dizziness, syncope, and presyncope.

<sup>i</sup>Includes thyroxine free decreased, blood thyroid stimulating hormone increased, and hypothyroidism.

Please see Important Safety Information throughout and [Full Prescribing Information, including Boxed WARNING](#), for OCALIVA.



## Safety

### **WARNING: Hepatic Decompensation and Failure in Incorrectly Dosed PBC Patients with Child-Pugh Class B or C or Decompensated Cirrhosis**

- In postmarketing reports, hepatic decompensation and failure, in some cases fatal, have been reported in patients with decompensated cirrhosis or Child-Pugh Class B or C hepatic impairment when OCALIVA was dosed more frequently than the recommended starting dosage of 5 mg once weekly
- Reported cases typically occurred within 2 to 5 weeks after starting OCALIVA and were characterized by an acute increase in total bilirubin and/or ALP concentrations in association with clinical signs and symptoms of hepatic decompensation (eg, ascites, jaundice, gastrointestinal bleeding, worsening of hepatic encephalopathy)
- Patients who died due to liver-related complications generally had decompensated cirrhosis prior to treatment and were started on OCALIVA 5 mg once daily, which is 7-fold greater than the once-weekly starting regimen in this population

### **Patient management**

- Routinely monitor patients for progression of PBC disease, including liver-related complications, with laboratory and clinical assessments. Dosage adjustment, interruption or discontinuation may be required
- Close monitoring is recommended for patients at an increased risk of hepatic decompensation. Severe intercurrent illnesses that may worsen renal function or cause dehydration (eg, gastroenteritis), may exacerbate the risk of hepatic injury or decompensation
- Interrupt treatment with OCALIVA in patients with laboratory or clinical evidence of worsening liver function indicating risk of decompensation, and monitor the patient's liver function. Consider discontinuing OCALIVA in patients who have experienced clinically significant liver-related adverse reactions
- Discontinue OCALIVA in patients who develop complete biliary obstruction

### **Liver-related adverse reactions**

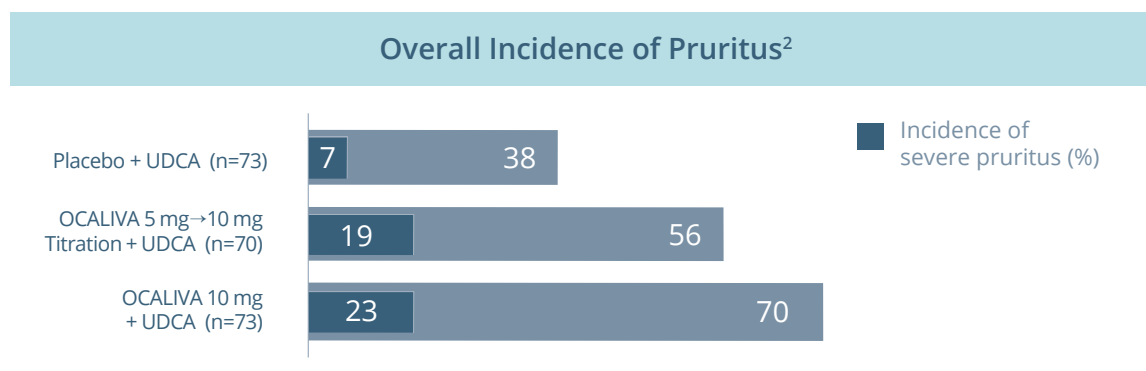
- Dose-related, liver-related adverse reactions including jaundice, worsening ascites and primary biliary cholangitis flare have been observed in clinical trials, as early as one month after starting treatment with OCALIVA 10 mg once daily up to 50 mg once daily (up to 5-times the highest recommended dosage)
- Monitor patients during treatment with OCALIVA for elevations in liver biochemical tests and for the development of liver-related adverse reactions

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## Adverse Reactions and Discontinuation

### Pruritus, a common symptom of PBC<sup>4</sup>

- Approximately 60% of patients in the study had a baseline history of pruritus<sup>2</sup>
- Treatment-emergent pruritus generally started within the first month of treatment<sup>2</sup>



### Overall discontinuation rates<sup>2</sup>

- 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<sup>5</sup>

### Discontinuation due to pruritus: 1% with OCALIVA 5 mg starting dose<sup>2</sup>



- 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<sup>2,a</sup>



<sup>a</sup>Eg, dosage adjustment, treatment interruption, or initiation of a bile acid binding resin or an antihistamine.

### Reduction in HDL-C<sup>2</sup>

- Reduction from baseline in HDL-C was observed at 2 weeks in 20% of patients in the OCALIVA 10 mg group, 9% of patients in the OCALIVA 5 mg→10 mg titration group, and in 2% of patients in the placebo group
  - At 1 year, HDL-C reductions in the above groups were 19%, 12%, and 2%, respectively

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## Dosing

### Up-titrate for optimal efficacy, if tolerated<sup>2</sup>



- The recommended starting dose for OCALIVA is **5 mg orally once daily** for non-cirrhotic or compensated Child-Pugh Class A patients<sup>2</sup>
  - For patients with moderate to severe hepatic impairment (Child-Pugh Class B or C), or a prior decompensation event,<sup>a</sup> the recommended starting dose is **5 mg once weekly**
- If an adequate reduction in alkaline phosphatase and/or total bilirubin has not been achieved after 3 months, and the patient is tolerating OCALIVA, increase the dosage as recommended below<sup>2</sup>

### Dosage adjustment for hepatic impairment<sup>2</sup>

	NON-CIRRHOTIC OR COMPENSATED CHILD-PUGH CLASS A	CHILD-PUGH CLASS B OR C OR WITH A PRIOR DECOMPENSATION EVENT <sup>a</sup>
<b>Starting OCALIVA Dosage for first 3 months</b>	5 mg once daily	5 mg once weekly
<b>OCALIVA Dosage Titration after first 3 months, for patients who have not achieved an adequate reduction in ALP and/or total bilirubin and who are tolerating OCALIVA<sup>b</sup></b>	10 mg once daily	5 mg twice weekly (at least 3 days apart) Titrate to 10 mg twice weekly (at least 3 days apart) based on response and tolerability
<b>Maximum OCALIVA Dosage</b>	10 mg once daily	10 mg twice weekly (at least 3 days apart)

<sup>a</sup>Eg, gastroesophageal variceal bleeding, new or worsening jaundice, spontaneous bacterial peritonitis.

<sup>b</sup>Prior to dosage adjustment, re-calculate the Child-Pugh classification.

- **Routinely monitor patients during treatment with OCALIVA for disease progression and the occurrence of liver-related adverse reactions<sup>2</sup>**
- OCALIVA dosing may be further modified to help manage moderate to severe pruritus, as described in the Full Prescribing Information<sup>2</sup>

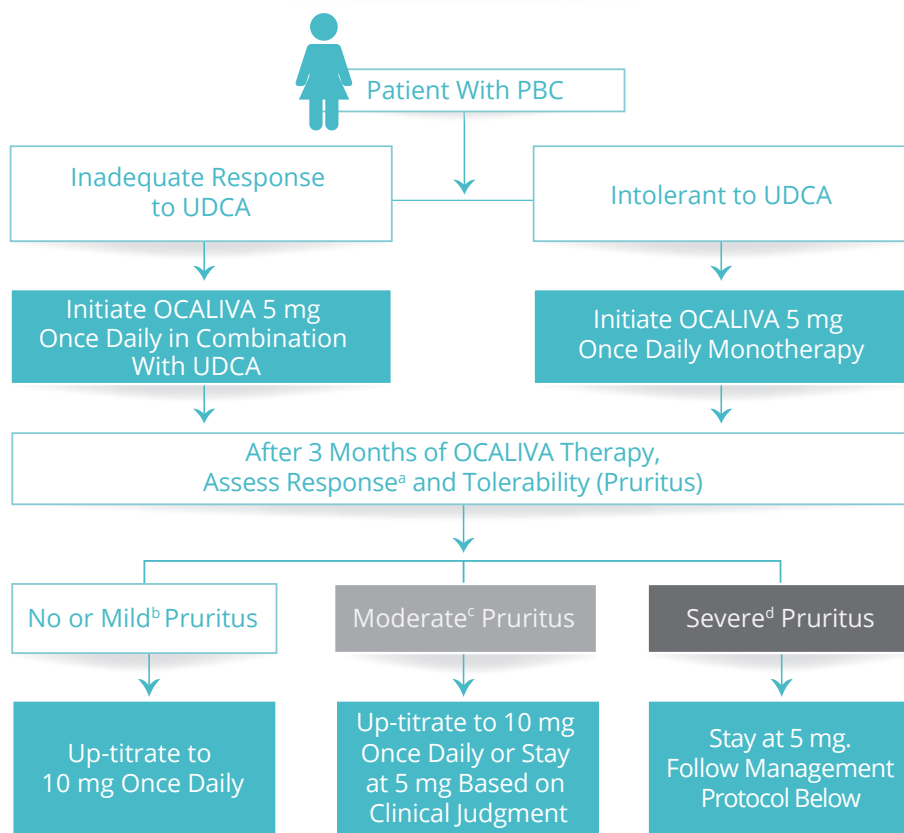
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#### WARNING: HEPATIC DECOMPENSATION AND FAILURE IN INCORRECTLY DOSED PBC PATIENTS WITH CHILD-PUGH CLASS B OR C OR DECOMPENSATED CIRRHOSIS

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## Treatment Guidance for Non-Cirrhotic or Compensated Child-Pugh Class A Patients<sup>2,6</sup>



### For patients with severe/intolerable pruritus on OCALIVA, consider one or more of the following<sup>2</sup>:

- +** Add an antihistamine or bile acid binding resin
- ↓** Reduce the dosage of OCALIVA (*only if patient is non-cirrhotic or compensated Child-Pugh Class A*)
  - 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 if applicable
  - Up-titrate based on biochemical response, tolerability, and Child-Pugh classification

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

<sup>a</sup>If an adequate reduction in alkaline phosphatase has not been achieved after 3 months, and the patient is tolerating the drug, increase to 10 mg once daily. In the clinical study, an adequate reduction in alkaline phosphatase is defined as achievement of the primary composite endpoint (percentage of subjects achieving alkaline phosphatase <1.67x ULN, total bilirubin ≤ ULN, and alkaline phosphatase decrease of ≥15%).<sup>2</sup>

<sup>b</sup>Generally localized; causing no limitation of usual activities or minimal sleep disturbance; the subject may experience slight discomfort. Medicinal intervention is not indicated.<sup>6</sup>

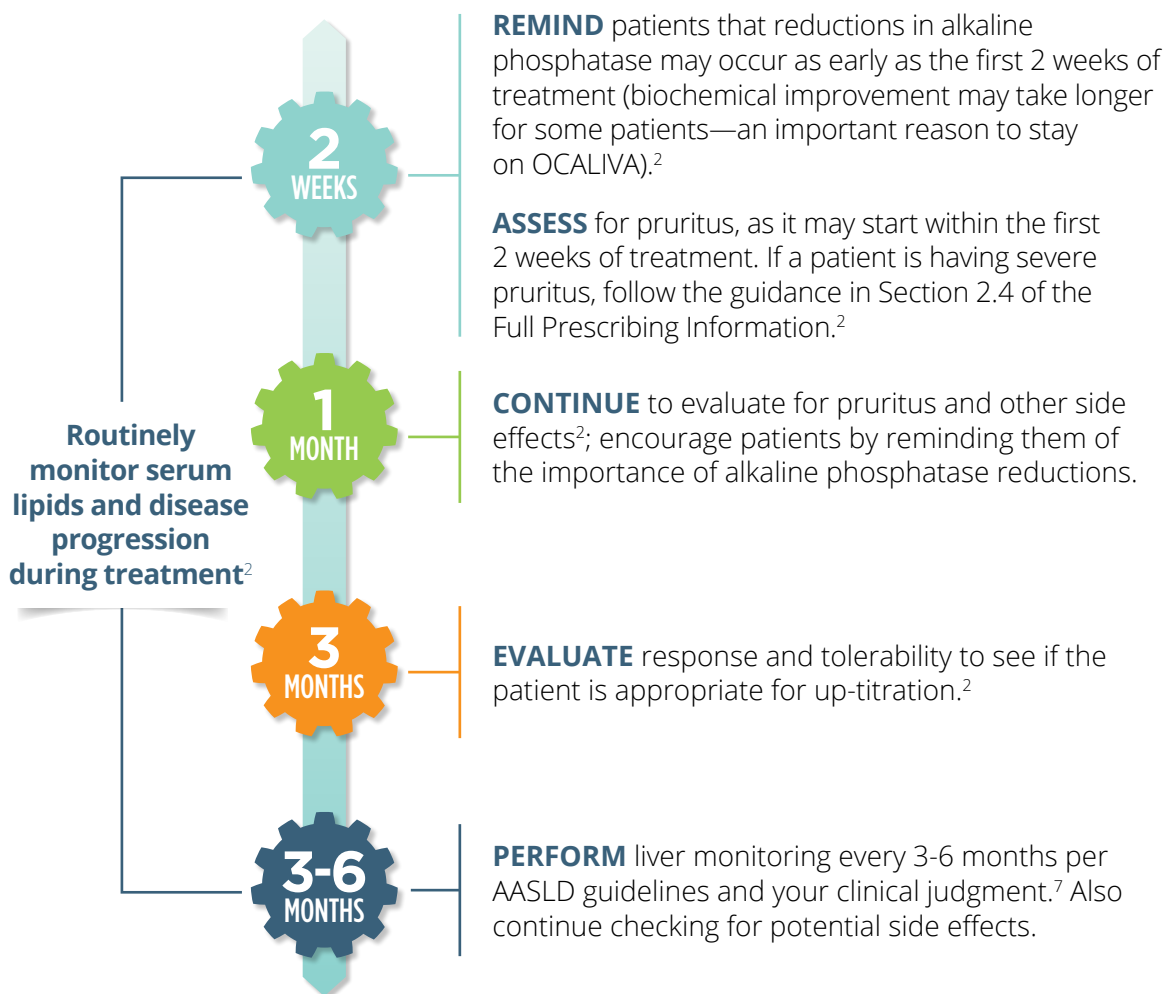
<sup>c</sup>Intense or widespread; causing some limitation of usual activities or sleep disturbance; the subject may experience annoying discomfort. Medicinal intervention may be indicated.<sup>6</sup>

<sup>d</sup>Intense or widespread and interfering with activities of daily living or severe sleep disturbance; patient may experience intolerable discomfort. Medicinal intervention is typically indicated.<sup>6</sup>

Please see Important Safety Information throughout and [Full Prescribing Information, including Boxed WARNING](#), for OCALIVA.

## Monitoring Treatment

Tolerability and treatment response should be monitored throughout treatment<sup>2</sup>



AASLD, American Association for the Study of Liver Diseases.

### Additional monitoring recommendations<sup>2</sup>

- Monitor patients during treatment for elevations in liver biochemical tests and for the development of liver-related adverse reactions
- Monitor HDL-C levels at baseline and throughout treatment

Please see Important Safety Information throughout and [Full Prescribing Information, including Boxed WARNING](#), for OCALIVA.

**OCALIVA**<sup>®</sup>  
obeticholic acid

## Interconnect® Patient Support



### Your Patients. Our Commitment.

When you choose OCALIVA for your patients, Interconnect® provides comprehensive, personalized support to assist your office and 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 a full suite of 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<sup>a</sup>



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



**Education**  
Supplying resources and answers to questions about OCALIVA

<sup>a</sup>For qualified patients with commercial insurance.

### For more information:



1-844-622-ICPT



[interconnectsupport.com](http://interconnectsupport.com)

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



1-855-686-8730



For additional information on OCALIVA, please visit [ocalivahcp.com](http://ocalivahcp.com)

To learn more about Intercept Pharmaceuticals, Inc., please visit [interceptpharma.com](http://interceptpharma.com)

For medical inquiries, contact [medinfo@interceptpharma.com](mailto:medinfo@interceptpharma.com)

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### References:

1. URSO [package insert]. Bridgewater, NJ: Aptalis Pharma US, Inc.; 2013. 2. OCALIVA [package insert]. New York, NY: Intercept Pharmaceuticals, Inc; 2020. 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; for 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. Data on file: GL-PB-MED-00068. 7. Lindor KD, Gershwin ME, Poupon R, Kaplan M, Bergasa NV, Heathcote EJ. Primary biliary cirrhosis. *Hepatology*. 2009;50(1):291-308.

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