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# PROACTIVE PRURITUS MANAGEMENT

## Setting expectations and reviewing strategies to help patients start and stay on OCALIVA

### 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.

### SELECT 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 throughout and on pages 10 and 11 and accompanying **Full Prescribing Information**, including **Boxed WARNING**, for OCALIVA 5 mg and 10 mg tablets.

# PRURITUS IS A COMMON SYMPTOM OF PRIMARY BILIARY CHOLANGITIS (PBC)[1]

Pruritus affects most patients with PBC and can precede a PBC diagnosis for years.[1] It is also an adverse event of OCALIVA.[2] Complicating matters, in some cases, itch sensations can fluctuate, making them difficult to objectify.[3]

As a prescriber, how can you help set patients up for success when starting on OCALIVA? **Setting treatment expectations and reviewing pruritus management strategies early on can go a long way.**

**Keeping treatment goals top of mind is an important reminder for patients when discussing a pruritus management plan**

## Pruritus Management Kit for Your Patients Taking OCALIVA

This evidence-based kit gets ahead of pruritus management for your patients starting their OCALIVA journey. It contains, but is not limited to, samples to soothe itching, such as Biofreeze® gel, moisturizing cream, an oatmeal bath packet, and hydrocortisone ointment.


### Order kits today

Contact your Intercept® sales representative for kits to be provided to your practice so you can distribute them to your patients taking OCALIVA.

## SELECT IMPORTANT SAFETY INFORMATION (cont'd)

### 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.



# PROACTIVE LIFESTYLE MODIFICATIONS FOR PATIENTS

**Patients can incorporate the following into their daily routine to help manage pruritus, ideally, prior to experiencing any issues:**

### Sleep

- **Practice good sleep habits:** Pruritus can cause sleep deprivation.[3] Patients also report that itching can become worse at night.[4] Practicing good sleep habits and strategies can help improve sleep duration and quality.[5]
- **Play "white noise"** in the bedroom[5]
- **Use aromatherapy and massage**[5]
- **Maintain a cooler room temperature** at night[1]
- **Consider wearing gloves to bed**[6]

### Hygiene

- **Take cool showers**[7]
- **Apply a daily moisturizer,** such as Eucerin®[1,7]
- **Keep fingernails trimmed**[1,3]
- **Switch to mild or clear/unscented soaps** and laundry detergents[7]

### OTC Treatments

- **Apply topical corticosteroids,** such as hydrocortisone[1]
- **Add an antihistamine**[2,a]
- **Try capsaicin (hot pepper) cream** for localized forms of chronic pruritus[1]

### General

- **Stay hydrated** by drinking enough water[6]
- **Wear loose-fitting clothes**[7]
- **Engage in relaxation techniques,** such as meditation or aromatherapy[1,5,7]
- **Use cold packs** or fabric strips soaked in cold water[1,7]

**Avoiding the following can help manage itching:**

### Diet

**Avoid:**

- Hot and spicy foods[1]

### General

**Avoid:**

- Contact with allergenic and irritant substances (e.g., fragrances)[1]
- Activities and situations that contribute to dry skin (e.g., saunas, dry climate)[1]
- Overexcitement and stress[1]
- Clothing made from materials that can irritate the skin (e.g., wool)[7]
- Smoking tobacco[7]

[a]Recommended per the Full Prescribing Information for OCALIVA.
OTC, over-the-counter.

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# MONITOR PATIENTS FOR TREATMENT SUCCESS ON OCALIVA

| Monitoring schedule | |
|---|---|
| **START** OF TREATMENT | **INITIATE** OCALIVA at 5 mg once daily[2]<br>**MANAGE** patient expectations regarding the possibility of pruritus and time to treatment response (ie, some patients may see reductions in ALP as early as the first 2 weeks)<br>**IMPLEMENT** proactive pruritus management and patient lifestyle modifications<br>**DISTRIBUTE** Intercept Pruritus Management Kit[a] (See page 2) |
| **2** WEEKS | **CALL** patient and assess for pruritus (may present within first 2 weeks of treatment with OCALIVA)<br>**REMIND** patients of the importance of staying on OCALIVA<br>**REINFORCE** proactive pruritus management and patient lifestyle modifications |
| **1** MONTH | **EVALUATE** for pruritus and other side effects and review management strategies[7,b]<br>**CONTINUE TO ENCOURAGE** adherence to OCALIVA[7] |
| **3** MONTHS | **EVALUATE** pruritus and other side effects to determine if the patient is appropriate for up-titration to 10 mg[2,7,b] |
| **3-6** MONTHS | **PERFORM** liver monitoring every 3 to 6 months[8]<br>**CONTINUE** monitoring for pruritus and other side effects[7] |

[a]The Pruritus Management Kit is available in the US only and is not provided outside of the US.
[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 a maximum of 10 mg once daily.[2]
ALP, alkaline phosphatase.

## SELECT IMPORTANT SAFETY INFORMATION (cont'd)

### 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.



# HELPING PATIENTS REACH THEIR TREATMENT GOALS[2,7]

In order for patients to achieve their treatment goals, adherence is critical. If lifestyle modifications alone aren't sufficiently managing your patient's pruritus, consider titrating the OCALIVA dosage and re-evaluating as needed.

**OCALIVA titration schedule for patients with pruritus[2,7,c]**

| | IF AT 5 MG ONCE DAILY | IF AT 10 MG ONCE DAILY |
|---|---|---|
| None or Mild | Up-titrate to 10 mg[b] once daily after the first 3 months | Stay at 10 mg |
| Moderate | Stay at 5 mg[d] | Stay at 10 mg<br>OR<br>Down-titrate per clinical judgment[d] |
| Severe | Reduce to 5 mg[d] every other day<br>OR<br>Temporarily pause treatment up to 2 weeks,[e] then restart at a reduced dosage | Reduce to 5 mg once daily[d] |

Adapted from Pate J, et al. *BMJ Open Gastroenterol.* 2019;6(1):e000256.

- **Add an antihistamine or bile acid binding resin**
- **Consider discontinuing OCALIVA treatment in patients who continue to experience persistent, intolerable pruritus despite management strategies**

### Facilitating adherence for patients new to OCALIVA

- Remind patients to **focus on the long-term treatment goal**
- Encourage patients to **download the PBC Living® app** to help track symptoms
- Share lifestyle tips to help patients manage pruritus. **See page 3**
- Encourage patients to access patient support through **Interconnect®.** **See page 9**

[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]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.[7]
[d]Based on clinical judgment and patient feedback, which may include factors other than pruritus severity and should reflect patient choice and comfort.[7]
[e]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.[7]

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# ESTABLISHED SAFETY PROFILE IN 12-MONTH PIVOTAL TRIAL[2]

OCALIVA was studied in 216 patients with PBC in a 12-month, double-blind, placebo-controlled trial.

**Most common adverse reactions[a,b] (N=216)**

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

[a]A total of 16 patients (7%) who were intolerant 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.[2]
[b]Occurring in ≥5% of patients in either OCALIVA treatment arm and at an incidence ≥1% higher than in the placebo treatment arm.[2]
[c]Patients randomized to OCALIVA titration received OCALIVA 5 mg 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.[2]
[d]Includes skin eruptions, prurigo, pruritus, generalized pruritus, eye pruritus, ear pruritus, anal pruritus, vulvovaginal pruritus, and rash pruritic.[2]
[e]Includes fatigue, tiredness, and asthenia.[2]
[f]Includes upper abdominal pain, abdominal pain, abdominal discomfort, lower abdominal pain, abdominal tenderness, and gastrointestinal pain.[2]
[g]Includes urticaria, rash, rash macular, rash papular, rash maculo-papular, heat rash, and urticaria cholinergic.[2]
[h]Includes dizziness, syncope, and presyncope.[2]
[i]Includes decreased free thyroxine, increased thyroid stimulating hormone (blood), and hypothyroidism.[2]
UDCA, ursodeoxycholic acid.

## SELECT IMPORTANT SAFETY INFORMATION (cont'd)

### Warnings and Precautions

**Hepatic Decompensation and Failure in PBC Patients with Cirrhosis (cont'd)**

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.



# OBSERVATIONS OF 1-YEAR TRIAL (n=198)

**1%**
**OF PATIENTS**
who started on 5 mg discontinued due to pruritus vs 10% who started on 10 mg[2]

**97%**
**OF PATIENTS**
who completed the double-blind phase chose to continue OCALIVA treatment in the long-term open-label extension (OLE)[9]

**~60%**
**OF PATIENTS**
in the study had a baseline history of pruritus prior to adding on OCALIVA[2]

Treatment-emergent pruritus generally started within
**1**
**MONTH**
of treatment with OCALIVA[2]

# OBSERVATIONS OF OLE (n=193)

- 63% of patients who entered the OLE had a history of PBC-related pruritus (at baseline, 56% had pruritus)[10]
- 70% of patients experienced pruritus **during the OLE**[11]
  - Throughout treatment, more pruritus days were mild than moderate or severe[11]

**OLE study limitations:** A maximum dose of OCALIVA 10 mg is presented, excluding data points as subjects titrated to greater than 10 mg daily. As this was a post hoc analysis, these results are exploratory and no clinical conclusions should be made[10,11]

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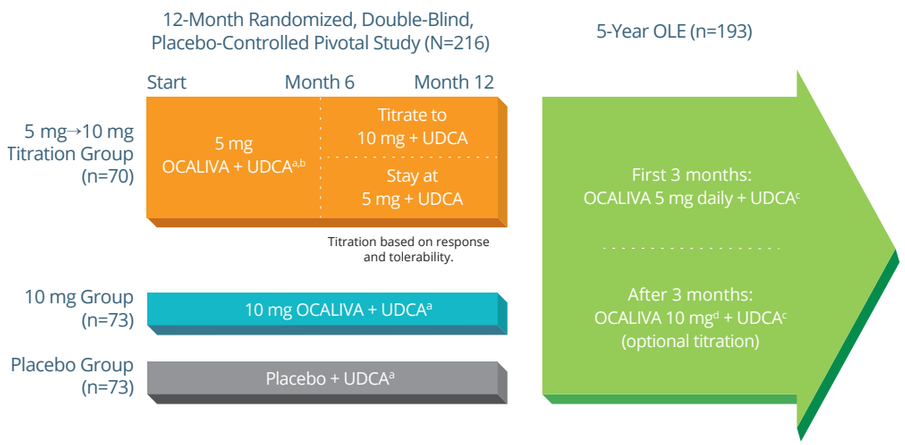
# POISE CLINICAL STUDY DESIGN

## 12-Month Clinical Study and 5-Year OLE[2,10,12]




**Primary composite endpoint is defined as[2,9,11]:**

- ALP <1.67x ULN
- ALP decrease of ≥15%
- Total bilirubin ≤ULN

**Baseline characteristics:**

Adults with PBC (ages 29 to 86, mean 56) who are intolerant to UDCA or have had an inadequate response to UDCA after at least 12 months, defined as (1) ALP: ≥1.67x ULN and/or (2) total bilirubin: >1x ULN, but <2x ULN. If intolerant to UDCA, no UDCA use for ≥3 months (n=16).[2,a]

**Study limitations:** In this open-label extension, no placebo or other comparators were included, and therefore no clinical conclusions should be made.[12]

[a]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.
[b]In the 5 mg→10 mg titration group, 36 patients stayed at 5 mg, and 33 were titrated to 10 mg after 6 months.
[c]Among patients who entered the OLE, 13 (7%) were intolerant and did not receive concomitant UDCA during double-blind or open-label treatment with OCALIVA.
[d]Protocol initially allowed doses up to 25 mg but was later amended to a maximum daily dose of OCALIVA 10 mg to ensure dosing per the approved label.
ULN, upper limit of normal.

## SELECT IMPORTANT SAFETY INFORMATION (cont'd)

### Warnings and Precautions

**Hepatic Decompensation and Failure in PBC Patients with Cirrhosis (cont'd)**

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



# INTERCONNECT CAN HELP YOUR PBC PATIENTS START AND STAY ON THERAPY

Ensure your patients have access to comprehensive and personalized support right from the start by enrolling them in Interconnect. After your patients are enrolled, you will be assigned a designated Care Coordinator to provide continuous tailored support and help keep treatment plans on track.

### High patient satisfaction[13]

**86% patient satisfaction.** Patients enrolled in Interconnect enjoy access, ongoing support, and an array of services.[e]

### Strong starts[14]

**Patients enrolled in Interconnect had a 20% higher success rate** in receipt of their initial OCALIVA shipment, compared to patients working with a specialty pharmacy alone.[f]

### Ongoing adherence[15]

**50% more patients who enrolled in Interconnect stayed on OCALIVA over a 12-month period,** compared to those working with a specialty pharmacy alone.[g]

Interconnect® SUPPORT SERVICES

**Get your patients support**

1-844-622-ICPT | interconnectsupport.com

[e]This pertains to Interconnect patient support services only.[13]
[f]Interconnect conversion rate is 81% and Specialty Pharmacy is 67%. 81%/67%=20% difference in favor of Interconnect.[14]
[g]Interconnect persistence rate is 67.3% and Specialty Pharmacy is 44.7%. 67.3%/44.7%=50% difference in favor of Interconnect.[15]

## SELECT IMPORTANT SAFETY INFORMATION (cont'd)

### Warnings and Precautions

**Hepatic Decompensation and Failure in PBC Patients with Cirrhosis (cont'd)**

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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### Contraindications

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- 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

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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.

**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 accompanying **Full Prescribing Information,** including **Boxed WARNING** or visit OCALIVAhcp.com.

***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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# PRURITUS CONSIDERATIONS FOR YOUR PATIENTS STARTING AND STAYING ON OCALIVA

## Observations of 1-year trial (n=198)

- **1% of patients who started on 5 mg discontinued due to pruritus** vs 10% who started on 10 mg[2]
- **97% of patients who completed the double-blind phase chose to continue OCALIVA** treatment in the long-term OLE[9]
- **~60% of patients in the study had a baseline history of pruritus** prior to adding on OCALIVA[2]
- **Treatment-emergent pruritus generally started within 1 month** of treatment with OCALIVA[2]

## Observations of OLE (n=193)

- **Among patients who entered the OLE, 63% had a history of PBC-related pruritus** (at baseline, 56% had pruritus)[10]
  - Throughout treatment, more pruritus days were mild than moderate or severe[11]

**Keeping treatment goals top of mind is an important reminder for patients when discussing a pruritus management plan**

**See Study Design details on page 8.**

**References: 1.** Weisshaar E, Szepietowski JC, Dalgard FJ, et al. European S2k Guideline on Chronic Pruritus. *Acta Derm Venereol*. 2019;99(5):469-506. doi:10.2340/00015555-3164 **2.** OCALIVA full prescribing information. Morristown, NJ: Intercept Pharmaceuticals, Inc; 2022. **3.** Düll MM, Kremer AE. Newer approaches to the management of pruritus in cholestatic liver disease. *Curr Hepatology Rep*. 2020;19:86-95. doi:10.1007/s11901-020-00517-x **4.** Rishe E, Azarm A, Bergasa NV. Itch in primary biliary cirrhosis: a patients' perspective. *Acta Derm Venereol*. 2008;88(1):34-37. **5.** Albakri U, Drotos E, Meertens R. Sleep health promotion interventions and their effectiveness: an umbrella review. *Int J Environ Res Public Health*. 2021;18(11):1-39. **6.** Pullen R. A clinical review of primary biliary cholangitis. *Gastroenterol Nurs*. 2020;43(2):E48-E55. doi:10.1097/SGA.0000000000000480 **7.** 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 **8.** 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. **9.** 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. doi:10.1056/NEJMoa1509840 **10.** Trauner M, Nevens F, Shiffman ML, et al. Long-term efficacy and safety of obeticholic acid for patients with primary biliary cholangitis: 3-year results of an international open-label extension study. *Lancet Gastroenterol Hepatol*. 2019;4(6):445-453. **11.** Data on file: INT-PB-MED-00009. **12.** Data on file: US-PB-MED-00899. **13.** Data on file: US-PB-MED-00936. **14.** Data on file: US-PB-MED-00268. **15.** Data on file: US-PB-MED-00267.

Intercept