Enroll in Interconnect®

Enrollment Form Checklist

In this packet, you will find all of the necessary forms to enroll your patients in Interconnect and give them access to a full suite of support services for OCALIVA® (obeticholic acid).[a]

Please complete these forms and submit them to Interconnect:

By mail	By fax	By email
Interconnect P.O. Box 580 Somerville, NJ 08876	1-855-686-8730	info@interconnectsupport.com

- ☐ Enrollment Form (Statement of Medical Necessity)
- ☐ Patient Authorization Form
- ☐ Copies of both sides of patient's pharmacy benefit card(s)
- ☐ Copies of both sides of patient's insurance card(s)
- ☐ Patient Assistance Application (if needed)

[a]Not all patients will qualify for every service offering.

Enrollment Form
(Statement of Medical Necessity)

Please fax this completed form to Interconnect at 1-855-686-8730.
Contact your Care Coordinator at 1-844-622-4278.

A. Prescriber information

First name _____ Last name _____

Address _____

City _____ State _____ ZIP _____

Phone _____ Ext. _____ Fax _____

Primary contact email _____

Primary contact name _____ Clinic/facility name office _____

NPI no. _____ State license no. _____ Prescriber tax ID _____

Preferred contact: ☐ Email ☐ Phone ☐ Fax

B. Patient information

☐ Male ☐ Female Date of birth: ____/____/____

First name _____ Last name _____

Address _____

City _____ State _____ ZIP _____

Email _____ Phone number _____

Preferred contact: ☐ Email ☐ Phone ☐ OK to leave message

Preferred language: ☐ English ☐ Spanish ☐ Other _____

Prescription drug information
Attach copies of both sides of patient's pharmacy benefit card(s).

☐ Check if no coverage (If there is no coverage, please complete the Patient Assistance Application form)

Patient insurance information
Attach copies of both sides of patient's insurance card(s).

☐ Check if no coverage ☐ Check if patient has secondary insurance

Primary insurance name _____ Policy no. _____

Group no. _____ Insurance company phone no. _____

Policy holder name _____ Last 4 digits of SSN _____

C. Prescription and medical information

Prescription for OCALIVA® (obeticholic acid): **# of refills:**

☐ 5 mg, PO once daily x 30 days, #30 tablets _____

☐ 10 mg, PO once daily x 30 days, #30 tablets _____

☐ Child-Pugh B/C: 5 mg, PO 1x/wk, #4 tablets _____

☐ Child-Pugh B/C: 5 mg, PO 2x/wk, at least 3 days apart, #8 tablets _____

☐ Child-Pugh B/C: 10 mg, PO 2x/wk, at least 3 days apart, #8 tablets _____

Prior authorization number (if known) _____

Prior authorization effective dates _____

Additional considerations: _____

Allergies: _____

Concurrent medications: _____

(Please note that Interconnect's limited specialty pharmacy network includes CVS Specialty, Accredo, and Walgreens.)

C. Prescription and medical information (cont'd)

Prescriber authorization
I authorize Intercept Pharmaceuticals, Inc. as my designated agent and on behalf of my patient to (1) forward this statement of medical necessity to furnish any information on this form to and recruit necessary patient information from the insurer of above-named patient and (2) forward this prescription, by fax or other mode of delivery, to the pharmacy. I certify that the rationale for prescribing OCALIVA is for a primary diagnosis of ICD-10: K74.3, and I will be supervising the patient's treatment accordingly.

Please select 1 option and sign only once below.

Prescriber's signature
(no stamps; substitution permitted) _____

Date _____

OR

Prescriber's signature
(no stamps; dispense as written) _____

Date _____

Special note: The physician is to comply with their state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Non-compliance of state-specific requirements could result in outreach to the prescriber.

Statement of Medical Necessity
Primary diagnosis: ICD-10: K74.3

1. When was the patient first diagnosed with PBC (month/year)? ____/____
2. Is the patient currently taking UDCA (ursodeoxycholic acid)?
   ☐ Yes ☐ No
   a. If yes, list UDCA start date (month/year) ____/____
   b. If no, has the patient been on UDCA previously? ☐ Yes ☐ No
   c. Reason for discontinuation? _____
3. Antimitochondrial antibody test (AMA): ☐ Positive ☐ Negative
4. Patient biopsy: ☐ Positive ☐ Negative ☐ Not applicable
5. Patient's current alkaline phosphatase (ALP) level: _____ units/L
6. Patient's total bilirubin level: _____ mg/dL; Lab reference range: _____
7. Is patient cirrhotic? ☐ Yes ☐ No
   If yes, ☐ Compensated ☐ Decompensated (eg, ascites, variceal bleed, encephalopathy, jaundice)
8. Child-Pugh score: ☐ A (5-6) ☐ B (7-9) ☐ C (10-15) ☐ Unknown

Interim Access Program (IAP) Rx for OCALIVA
Optional, at no cost; patient must be commercially insured, new to therapy, a US resident, and have a pre-defined access barrier greater than 15 days. IAP requests will be reviewed by Interconnect® on a case by case basis. Patient authorization signatures on the second page of the Patient Consent Information form are needed to enroll in the IAP.

☐ I authorize the use of IAP where applicable

Please sign and fax the completed form and required documentation to 1-855-686-8730

The form may also be sent by

Mail: Interconnect, P.O. Box 580, Somerville, NJ 08876

Email: info@interconnectsupport.com

☐ Additional documentation attached

ICPT SMN v0.2

For Office Use Only

Interconnect Patient ID # _____

Please see Important Safety Information for OCALIVA on page 4 and Full Prescribing Information, including Boxed WARNING for OCALIVA or visit ocalivahcp.com. Rx only.

Interconnect SUPPORT SERVICES

Recommended Dose and Dosage Adjustment for OCALIVA® (obeticholic acid)

Starting Dosage

The recommended starting dosage of OCALIVA is 5 mg orally once daily in adults who have not achieved an adequate response to an appropriate dosage of UDCA for at least 1 year or are intolerant to UDCA.

Dosage Titration

If an adequate reduction in ALP and/or total bilirubin has not been achieved after 3 months of OCALIVA 5 mg once daily, and the patient is tolerating OCALIVA, increase the dosage of OCALIVA to 10 mg once daily to improve response. Initiation of therapy with a starting dosage of OCALIVA 10 mg once daily is not recommended due to an increased risk of pruritus.

Maximum Dosage

The maximum recommended dosage of OCALIVA is 10 mg once daily.

Dosage Adjustment in Hepatic Impairment

Treatment with OCALIVA in patients with moderate and severe hepatic impairment should be initiated and monitored by a healthcare provider with experience managing PBC. The recommended starting dosage of OCALIVA for moderate (Child-Pugh Class B) and severe (Child-Pugh Class C) hepatic impairment is 5 mg once weekly.

If an adequate reduction in ALP and/or total bilirubin has not been achieved after 3 months of OCALIVA 5 mg once weekly, and the patient is tolerating the drug, increase the dosage of OCALIVA to 5 mg twice weekly (at least three days apart) and subsequently to 10 mg twice weekly (at least three days apart) depending on response and tolerability.

Monitor patients during treatment with OCALIVA for the occurrence of liver-related adverse reactions. Weigh the potential risks against the benefits of continuing treatment with OCALIVA in patients who have experienced clinically significant liver-related adverse reactions.

For complete prescribing information please refer to the OCALIVA Package Insert.

The Child-Pugh score[1,2]

Factor	1 point	2 points	3 points
Bilirubin (mg/dL)	<2	2-3	>3
Albumin (g/dL)	>3.5	2.8-3.5	<2.8
Prothrombin Time OR International Normalized Ratio	<4 <1.7	4-6 1.7-2.3	>6 >2.3
Ascites	None	Mild/Moderate (diuretic responsive)	Severe (diuretic refractory)
Encephalopathy Grade	None	Grade 1-2	Grade 3-4

	Class A	Class B	Class C
Total points	5-6	7-9	10-15

1. Lucey M et al. Minimal criteria for placement of adults on the liver transplant waiting list: A report of a national conference organized by the American Society of Transplant Physicians and the American Association for the Study of Liver Diseases. *Liver Transplantation and Surgery*. 1997;3(6):628-637.
2. Food and Drug Administration. Guidance for Industry: Pharmacokinetics in patients with impaired hepatic function: study, design, data analysis, and impact on dosing and labeling. 2003.

IMPORTANT SAFETY INFORMATION

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.**

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 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 ≥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 Full Prescribing Information, including Boxed WARNING for OCALIVA 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.

Interconnect® Support Services Patient Authorization for OCALIVA® (obeticholic acid)

Please fax this completed form to Interconnect at 1-855-686-8730.
Contact your Care Coordinator at 1-844-622-4278.

Patient name | Date of birth | Patient email | Phone number

I. HIPAA authorization

The Interconnect Support Services program (the "Program") provides services which vary from patient to patient, and may include prescription management, support in securing reimbursement, referrals to patient financial support programs, drug shipment and refills outreach, compliance and persistency messaging to the patient and the patient's physician, and no-cost medication to qualified patients prescribed OCALIVA. This Authorization will allow the patient's healthcare provider(s) and health insurer(s) to share information with Intercept Pharmaceuticals, Inc. and companies working on its behalf and their employees, including their field representatives and agents (collectively, "Intercept"), so that Intercept can provide the patient with the services described above for which the patient is eligible.

AUTHORIZATION: By signing this Authorization, I (the patient or the patient's personal representative) authorize each of my physicians, pharmacists, and other healthcare providers (collectively, "Healthcare Providers") and each of my health insurers (collectively, "Insurers") to use and/or disclose the protected health information described below to Intercept solely for the use of delivering Program services specific to me. My health information may be disclosed orally or in writing, or through data transfer, facsimile, or email.

My Healthcare Providers and Insurers may use or disclose my protected health information as requested by Intercept. This information may include: **(1)** my name, birth date, address, or telephone number; **(2)** medical records and treatment information as necessary; **(3)** information about my health benefits or health insurance coverage; **(4)** and financial information about me. Intercept may receive and use this information to administer the Program as well as determine my eligibility for specific services such as financial assistance.

I understand that, once my protected health information has been disclosed to Intercept, federal privacy laws may no longer protect the information from further disclosure, but Intercept has agreed to use and disclose my information only for purposes of providing Program services or as I have indicated in section II. I also understand that:

- I do not have to sign this Authorization. My treatment, payment for treatment, insurance enrollment, or eligibility for insurance benefits will not be affected. If I do not sign, however, I will not be eligible to receive Program services.
- This Authorization will remain in effect until I am no longer participating in the Program, at which time it will expire.
- I may revoke (cancel) this Authorization at any time by mailing a letter requesting such cancellation to Interconnect at P.O. Box 580, Somerville, NJ, 08876 or by emailing Intercept at privacyprotection@interceptpharma.com. If I cancel, my Healthcare Providers and Insurers will not make further disclosures of my protected health information to Intercept, except for disclosures made in reliance on this Authorization. The cancellation will not affect Intercept's ability to use or disclose information it has received. If I cancel, I will no longer be able to receive Program services.
- I am entitled to a copy of this signed Authorization.

Patient/personal representative signature | Date

Patient/personal representative printed name | Relationship (personal representative), if applicable (parent, power of attorney, etc)

II. Patient consent and program services opt-in

By signing below, I agree to let the Program contact me by phone, mail, or email to provide more information about taking part in the Program, which provides services including prescription management, support in securing reimbursement, referrals to financial patient support programs, drug shipment and refill outreach, and no-cost medication to qualified patients.

I further agree to allow Intercept and its employees and agents (collectively, "Intercept") to receive, use, and disclose information provided about me to deliver Program services requested by me or my physician. My information may be used and disclosed to administer the Program services described above. I authorize the Program to send, via mail or fax, prescription information to a pharmacy. I also understand and agree that:

- Intercept may verify the accuracy of the information on this form and request additional financial and insurance information.
- Intercept's privacy practices may change over time. Significant changes will be communicated in a timely manner to all participants of the Program.
- Intercept may change or discontinue the Program at any time. Significant changes will be communicated in a timely manner to all participants of the Program.
- This consent will be in effect for as long as I participate in the Program.
- I do not have to sign this consent, and I may cancel this Authorization at any time by mailing a letter requesting such cancellation to Interconnect at P.O. Box 580, Somerville, NJ, 08876 or by emailing Intercept at privacyprotection@interceptpharma.com. If I revoke or do not sign the consent, I will not be eligible to receive Program services. Revoking or not signing the consent will not otherwise affect my treatment or insurance eligibility or benefits.
- I have given a signed HIPAA authorization form to my Healthcare Provider.
- I will contact the Program if my financial status or insurance coverage changes.

☐ **Additional opt-in:** I further authorize Intercept to contact me by mail, email, telephone, or text message for marketing purposes, or otherwise provide me with information about its products, services, and programs or other topics of interest, or to conduct market research. Any information I provide may be used by Intercept to help develop new products, services, and programs. I understand I do not need to agree to this additional opt-in to be eligible to receive the Program services outlined above.

Patient/personal representative signature | Date

Patient/personal representative printed name | Relationship (personal representative), if applicable (parent, power of attorney, etc)

Please sign and fax the completed form and required documentation to:

1-855-686-8730

The form may also be sent by

Mail: Interconnect, P.O. Box 580, Somerville, NJ 08876 or **Email:** info@interconnectsupport.com

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Please see Important Safety Information for OCALIVA on page 7 and Medication Guide and full Prescribing Information, including Boxed Warning, for OCALIVA 5 mg and 10 mg tablets or visit ocaliva.com. Rx only.

Interconnect® SUPPORT SERVICES

Patient Assistance Application

You are eligible for this program if:

- You do not have any prescription drug coverage for OCALIVA® (obeticholic acid)
- You are diagnosed with primary biliary cholangitis
- You are a legal resident of the United States
- Your annual gross household income is at or below 400% of the Federal Poverty Level for all family sizes. Please visit the US Department of Health & Human Services, Office of the Assistant Secretary for Planning and Evaluation, to view the current Federal Poverty Guidelines at https://aspe.hhs.gov/poverty-guidelines

Patient information (to be completed by the patient)

First name _____ Last name _____ ___/___/___ Date of birth ☐ Male ☐ Female

Address _____ City _____

State _____ ZIP _____ Preferred contact: ☐ Email ☐ Home phone ☐ Cell phone

Email address _____ Home phone _____ Cell phone (optional) _____

Are you a US citizen? ☐ YES ☐ NO If no, are you a permanent resident of the United States? ☐ YES ☐ NO

Total household income: $ _____ No. of people in household: _____

Do you have private prescription insurance coverage? ☐ YES ☐ NO

Are you enrolled in Medicaid? ☐ YES ☐ NO

Are you enrolled in Medicare Part A and/or Part B? ☐ YES ☐ NO Medicare ID no. (if applicable): _____

Ship OCALIVA to: ☐ Patient's home ☐ Prescribing HCP

Patient declaration

I know that to qualify for free medicine my household gross income must be at or below 400% of the Federal Poverty Level, and I certify that the patient financial information I have provided is correct. I certify I have no health plan coverage for OCALIVA; this includes Medicare, Medicaid, or other public programs. I do not have the resources to pay for OCALIVA. I agree to provide Interconnect® proof of my income, if requested. I agree that if my certification about my income is false, I will reimburse Intercept Pharmaceuticals, Inc.

_____ _____

Patient's signature Date

Statement of Medical Necessity

To the best of my knowledge, this patient has no coverage (including Medicare, Medicaid, or other Federal healthcare programs) for OCALIVA. I certify that, in my medical judgment, OCALIVA is medically necessary for this patient, and that I will be supervising this patient's treatment.

_____ _____

Prescriber's signature Date

Please sign and fax the completed form and required documentation to:

1-855-686-8730

The form may also be sent by

Mail: Interconnect, P.O. Box 580, Somerville, NJ 08876

Email: info@interconnectsupport.com

☐ **Additional documentation attached**

ICPT SMN v0.2

Please see Important Safety Information for OCALIVA on page 7 and Medication Guide and full Prescribing Information, including Boxed Warning, for OCALIVA 5 mg and 10 mg tablets or visit ocaliva.com.

IMPORTANT SAFETY INFORMATION

What is OCALIVA® (obeticholic acid)?

OCALIVA is a prescription medicine used to treat primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have not responded well enough to UDCA, or alone for adults who cannot tolerate UDCA. It is not known if taking OCALIVA will improve your chance of survival or improve your symptoms of PBC. There are ongoing studies to find out how OCALIVA works over a longer period of time.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about OCALIVA?

OCALIVA may cause serious side effects including:

Worsening of liver problems, liver failure, in some cases leading to death, have happened in people with PBC with advanced liver cirrhosis when OCALIVA was taken more often than recommended.

If you have primary biliary cholangitis (PBC) with advanced cirrhosis, you may need a lower dose of OCALIVA. Before you start OCALIVA, and during your treatment with OCALIVA, your healthcare provider will do tests to check your liver. These tests will help your healthcare provider decide how much OCALIVA you should take and how often you should take it. If you have worsening liver problems, your dose of OCALIVA may be changed, stopped for a period of time, or stopped completely by your healthcare provider.

Tell your healthcare provider right away if you have any of the following symptoms of worsening liver problems during treatment with OCALIVA:

- Swelling of your stomach area from a build-up of fluid; yellowing of your skin or the whites of your eyes; black, tarry, or bloody stools; coughing up or vomiting blood, or your vomit looks like "coffee grounds"; or mental changes (such as confusion, sleepier than usual or harder to wake up, slurred speech, mood swings, or changes in personality)

Tell your healthcare provider right away if you have any of the following symptoms during treatment with OCALIVA and **they are severe or do not go away:**

- Stomach-area pain, nausea, vomiting, or diarrhea; loss of appetite or weight loss; new or worsening fatigue, weakness, fever, or chills; light-headedness; less frequent urination

Who should not take OCALIVA?

Do not take OCALIVA if you have or had a complete blockage in the bile ducts in your liver or gallbladder.

What are the possible side effects of OCALIVA?

OCALIVA may cause serious side effects including:

- See **"What is the most important information I should know about OCALIVA?"**
- **Severe Itching.** Itching (pruritus) is a common side effect and can sometimes become severe (intense itching or itching all over your body). Severe itching can cause discomfort, problems sleeping, and problems doing daily activities, and usually needs to be treated. Tell your healthcare provider if you get severe itching or if your itching gets worse.
- **Decreases in Good Cholesterol.** Decreases in HDL-C ("good cholesterol") have been observed in patients taking OCALIVA. Your healthcare provider will check your cholesterol levels during treatment to see if you should continue taking OCALIVA.

The most common side effects of OCALIVA include: pruritus (itching of the skin), tiredness, stomach pain and discomfort, rash, joint pain, mouth and throat pain, dizziness, constipation, swelling in your hands, ankles or feet, fast or irregular heartbeat, fever, changes in how your thyroid gland works, and eczema (skin dryness, irritation, redness, crusting, or drainage).

These are not all the possible side effects associated with OCALIVA. Call your healthcare provider for medical advice about side effects.

What should I tell my healthcare provider before taking OCALIVA?

Before taking OCALIVA, tell your healthcare provider about all of your medical conditions, including if you:

- **are pregnant or plan to become pregnant.** It is not known if OCALIVA will harm your unborn baby.
- **are breastfeeding or plan to breastfeed.** It is not known if OCALIVA passes into your breastmilk. Talk with your healthcare provider about the best way to feed your baby if you take OCALIVA.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. OCALIVA can affect the way certain medicines work. Certain other medicines may affect the way OCALIVA works.

Please see Medication Guide and full Prescribing Information for OCALIVA 5 mg and 10 mg tablets or visit ocaliva.com.

Available by prescription only.

To report negative side effects of OCALIVA, please contact Intercept Pharmaceuticals, Inc. at 1-844-782-ICPT or you may report to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.