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 _____

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)

Prescription 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 _____

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 _____

Prior authorization number (if known) _____

Prior authorization effective dates _____

Additional considerations: _____

Allergies: _____

Concurrent medications: _____

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

C. Prescription and medical information (cont.)

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.

I also certify that I understand OCALIVA is contraindicated in patients with decompensated cirrhosis (e.g., Child-Pugh B or C), a prior decompensation event, with compensated cirrhosis who have evidence of portal hypertension, or with complete biliary obstruction according to the Full Prescribing Information. In addition, I understand that hepatic decompensation and failure, sometimes fatal or resulting in liver transplant, has been reported with OCALIVA treatment in PBC patients with either compensated or decompensated cirrhosis. Understanding this and other information contained in the Full Prescribing Information, I have determined that OCALIVA is appropriate for this patient.

Please select 1 option and sign only once below.

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

OR

Prescriber's signature **(dispense as written)** _____ Date _____

Intercept makes no representation that the information will comply with the requirements of any particular payer/insurer. The use of this information does not guarantee payment or that any payment received will cover your costs.

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.

Interim Access Program (IAP) Rx for OCALIVA

Optional, at no cost; patient must be commercially insured, 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 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

◯ **Additional documentation attached**

For Office Use Only

Interconnect Patient ID # _____

Please see Important Safety Information for OCALIVA on page 3 and Full Prescribing Information, including Boxed WARNING for OCALIVA or visit ocalivahcp.com. Rx only.

INDICATION AND IMPORTANT SAFETY INFORMATION

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.

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.**

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 incurrent 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 click here for Full Prescribing Information, including Boxed WARNING.

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.

Patient Authorization Form

Please fax this completed form to Interconnect at 1-855-686-8730.

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

I. Patient Authorization to Share Personal Health Information

The Interconnect® Support Services program provides services which vary from patient to patient, such as prescription management, support in securing reimbursement, referrals to patient financial support programs, drug shipment and refills outreach, compliance and persistency messaging to patients and the patients' physicians, no-cost medication to qualified patients, and other related services in connection with Intercept products and programs (the "Program"). The Program services may change from time to time.

This Authorization will allow the patient's healthcare provider(s) and health insurer(s) to share information with Intercept Pharmaceuticals, Inc. and its affiliates and their employees, including field representatives (collectively, "Intercept"), as well as third-party companies working on Intercept's behalf, for the purposes described in this Authorization.

AUTHORIZATION: By signing this Authorization, I (the patient or the patient's personal representative on behalf of the patient) 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 personal health information described below to Intercept and third parties administering Program services (including any Intercept service providers), for the purposes described in this Authorization. I understand that my pharmacy providers may receive remuneration for disclosing my protected health information pursuant to this Authorization. My personal health information may be disclosed orally or in writing, including by facsimile, email and/or through other data transfer means.

My Healthcare Providers and Insurers may disclose to Intercept and other third parties helping to administer Program services (including any Intercept service providers), my personal health information such as: (1) my name, birth date, address, or telephone number; (2) medical records and treatment information; (3) information about my health benefits or health insurance coverage; and (4) financial information about me.

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 indicated in this Authorization. Intercept may use, and/or contact me about, my personal health information for the following purposes:

- Contact me by phone, mail, or email to provide information about the Program;
- Verify the accuracy of the information on this form and request additional financial and insurance information;
- Determine my eligibility for the Program and the specific services of the Program, such as financial assistance;
- Facilitate the provision of Program services to me, including delivering Program services such as compliance and persistency messaging and analyzing the impact of the program;
- To send enrollment information to my pharmacy via email, postal mail, or fax;
- For Intercept's medical research and related purposes, including to help develop new products, services, and programs; and/or
- As necessary to comply with applicable laws, including, without limitations, any safety reporting obligations.

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 this Authorization, 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, until the Authorization is required to be terminated pursuant to applicable laws, or until I revoke this Authorization.
- 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 Interconnect at [privacyprotection@interceptpharma.com]. If I revoke this Authorization, my Healthcare Providers and Insurers are not permitted to make further disclosures of my personal health information to Intercept, except for disclosures made in reliance on this Authorization. Revocation of this Authorization will not affect Intercept's ability to use or disclose information it has received. If I revoke this Authorization, I will no longer be able to receive Program services.
- I am entitled to a copy of this signed Authorization.
- Intercept may change or discontinue the Program at any time. Significant changes to the Program will be communicated in a timely manner to all participants of the Program.
- The information disclosed pursuant to this Authorization may be subject to redisclosure by the recipient and may no longer be protected by HIPAA once disclosed.
- I will contact the Program if my financial status or insurance coverage changes.

☐ **Additional opt-in:** By checking this box, I authorize Intercept and third-party companies working on Intercept's behalf, to contact me by mail, email, telephone, or text message for (i) marketing purposes, including to provide me with information about Intercept's products, services, and programs or other topics of interest, and/or (ii) to conduct market research.

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

Email: info@interconnectsupport.com

Patient Assistance Application

You are eligible for this program if:

- You do not have any prescription drug coverage for OCALIVA® (obeticholic acid)
- You are an adult (18 years and older) diagnosed with primary biliary cholangitis
- You are a US citizen or permanent 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 _____

Preferred contact: ◯ Email ◯ Home phone ◯ Cell phone

State _____ ZIP _____

Email address _____ Home phone _____ Cell phone _____

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 your household _____

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

Have 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 ◯ HCP's office

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**

Please see Important Safety Information for OCALIVA on page 6 and Medication Guide and full Prescribing Information, including Boxed Warning for OCALIVA 5 mg and 10 mg tablets or visit ocalivahcp.com.

INDICATION AND IMPORTANT SAFETY INFORMATION

What is OCALIVA?

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. It is not known if OCALIVA is safe and effective in children.

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 or liver failure, in some cases leading to liver transplant or death, has happened in people with primary biliary cholangitis (PBC) with liver cirrhosis when taking 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 if it is safe for you to start taking OCALIVA and safe for you to continue taking OCALIVA.

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"; 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 and chills; light-headedness; less frequent urination

Who should not take OCALIVA?

Do not take OCALIVA if you:

- have PBC with liver cirrhosis with symptoms such as fluid in the stomach-area or confusion (decompensated liver cirrhosis) or with abnormalities in certain tests that check your liver.
- have a complete blockage of 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 (pruritus)**. Itching is a common side effect and can sometimes become severe (intense itching or itching over much of 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.
- **Lower HDL-C** ("good" cholesterol). OCALIVA can lower high levels of HDL-C. Your healthcare provider will check your cholesterol levels during treatment with OCALIVA.

The most common side effects of OCALIVA include: 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; dryness, irritation, redness, crusting or drainage of the skin (eczema).

These are not all the possible side effects of OCALIVA. Call your doctor 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.

The risk information provided here is not complete. To learn more, please talk to your healthcare provider.

Please click here for Full Prescribing Information and Medication Guide for OCALIVA.

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.