# Market Withdrawal: Ocaliva

**Intercept Pharmaceuticals, Inc., announced its decision to voluntarily withdraw Ocaliva (obeticholic acid) from the US market for the treatment of primary biliary cholangitis (PBC), a rare, progressive liver disease.** This decision follows a request from the US Food and Drug Administration (FDA). In addition, FDA has placed a clinical hold on all Intercept clinical trials conducted under a US IND involving obeticholic acid.

Ocaliva received FDA accelerated approval in 2016 for the treatment of PBC in adults with an inadequate response to or intolerance of ursodeoxycholic acid (UDCA). On December 12, 2024, the FDA issued a Drug Safety Communication after identifying cases of serious liver injury among patients being treated for PBC with Ocaliva who did not have cirrhosis of the liver. The FDA evaluated liver safety in the postmarket clinical trial in patients who were appropriate for Ocaliva treatment based on the approved indication and found that some cases of liver injury in patients without cirrhosis resulted in liver transplant. Among these patients, the risk of both liver transplant and death were higher in patients receiving Ocaliva compared with those receiving placebo.

The withdrawn NDCs are included in the table below.

| Product | NDC |
|---|---|
| **Ocaliva (obeticholic acid)** | 69516-0010-30<br>69516-0005-30 |

Patients currently prescribed Ocaliva for PBC treatment should consult their healthcare professionals before making any changes. Intercept will provide additional information to support healthcare professionals and patients as it works with FDA on the transition process. **There will be a transitional period of 60 days during which Ocaliva will remain available to allow time for patients to be transitioned to an alternative therapy. After this transition period ends on November 14, Ocaliva will no longer be commercially available in the US.**

Healthcare professionals who have questions about Ocaliva can contact Intercept Medical Information at medinfo@interceptpharma.com or call 1-844-782-4278. Patients should speak with their healthcare professionals and also may contact Intercept's Patient Support Services (Interconnect) at 1-844-622-4278.

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Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax:

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

**MedImpact is taking the following actions in response to this recall:**

- Effective 09/18/25, **a SOFT POS alert message** has been set to fire for the NDCs above as follows: “DRUG WITHDRAWN FROM THE MARKET EFFECTIVE 11-14-25 DUE TO SAFETY CONCERNS. CONTACT PHYSICIAN.”
- An affected member report has been run to identify members who have claims for these NDCs within the past 120 days (i.e., since 05/21/25). Clients should retrieve the report from their subscription folder in MedOptimize (see below or attached job aid).
    - Log in to MedOptimize
    - Click on “Team Content,” and then the “Subscription Reports” folder
    - Go to the “Drug Recalls” folder
    - Click on “…” then “view versions”
    - Click on the “XLS” icon to download the report associated with date for recall
    - If no members are impacted (zero claims for report run dates), the “XLS Drug Recall-Detail” report will say “No data available”
    - Clients should contact their client team directly for assistance
    - Sample physician and member template letters concerning this recall are attached

**For additional information regarding the drug’s safety, please refer to the FDA drug safety notification at:**

https://www.fda.gov/drugs/drug-safety-and-availability

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**For additional information regarding the withdrawal, please refer to Intercept's press release at:**

https://www.interceptpharma.com/about-us/news