Humana

Pharmacy Solutions®

Drug withdrawal notice for Ocaliva (obeticholic acid)

To assist you in the care of your patients, Humana is alerting you to the market withdrawal of Ocaliva® (obeticholic acid) by Intercept Pharmaceuticals, Inc., a wholly owned biopharmaceutical subsidiary of Alfasigma S.p.A., on Sept. 11, 2025.[1] We recommend you review your medical records and contact all patients for whom you have prescribed this medication to warn them about the market withdrawal.

The withdrawal comes after a request from the U.S. Food and Drug Administration (FDA), and the FDA has initiated a clinical hold on all Intercept Pharmaceuticals clinical trials that involve obeticholic acid.[1]

On Dec. 12, 2024, the FDA issued a Drug Safety Communication after identifying cases of serious liver injury in patients treated for primary biliary cholangitis, a rare form of liver disease, with Ocaliva who did not have cirrhosis of the liver.[2]

The FDA evaluated liver safety in the postmarket clinical trial data in patients who were appropriate for Ocaliva treatment based on the approved indication and found that certain cases of liver injury in patients without cirrhosis required a liver transplant. Among these patients, the risk of liver transplant was higher in patients receiving Ocaliva compared with those receiving a placebo.[2]

Medications included in this withdrawal
Visit the Intercept Pharmaceuticals website for specific details on the market withdrawal.

Information for providers:[1]

- We sent a letter to your Humana-covered patients with a claim for Ocaliva and asked them to contact their providers if they have experienced problems that may be related to using this drug product. Providers should stop prescribing Ocaliva and discuss alternative treatment options with their patients.
- Providers with questions can contact:
    - Intercept Medical Information by phone at 844-782-4278, Monday – Friday, 7 a.m. – 7 p.m., Central time, or by email at medinfo@interceptpharma.com.
- Patients can report adverse reactions or quality problems experienced with the use of this product to the FDA's MedWatch Adverse Event Reporting Program online, by phone or by fax.
    - **Online:** Submit the report.
        - Select "FDA 3500."
    - **Phone or fax:** Download the form.
        - Report by phone at 800-FDA-1088 (332-1088) Monday – Friday, 8 a.m. – 4:30 p.m., Eastern time, or by fax to 800-FDA-0178 (332-0178).

Note: A reporting form also can be requested by calling 800-FDA-1088 (332-1088). Complete and return to the address on the pre-addressed form or by fax to 800-FDA-0178 (332-0178).

References

1. “Intercept Announces Voluntary Withdrawal of OCALIVA® for Primary Biliary Cholangitis (PBC) from the US Market; US Clinical Trials Involving Obeticholic Acid Placed on Clinical Hold,” Intercept Pharmaceuticals, Inc., last accessed Oct. 21, 2025, https://www.interceptpharma.com/about-us/news/?id=3148535.
2. “Serious liver injury being observed in patients without cirrhosis taking Ocaliva (obeticholic acid) to treat primary biliary cholangitis,” U.S. Food and Drug Administration, last accessed Oct. 21, 2025, https://www.fda.gov/drugs/drug-safety-and-availability/serious-liver-injury-being-observed-patients-without-cirrhosis-taking-ocaliva-obeticholic-acid-treat.