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**Primary Biliary Cholangitis: 2021 Practice Guidance Update from the American Association for the Study of Liver Diseases**

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**Changes from the Prior AASLD Practice Guidance on Primary Biliary Cholangitis (PBC)**

Guidance Statements 9 and 10 that were published in the 2018 Practice Guidance on PBC have been revised.

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## **Purpose and Scope of This Practice Guidance**

This American Association for the Study of Liver Diseases 2021 Practice Guidance on Primary Biliary Cholangitis (PBC) is a focused update of the PBC guidance published in 2018. The major changes from the last guidance to this guidance include information about obeticholic acid (OCA).

## **Obeticholic Acid**

In May 2021, the FDA issued a new warning restricting the use of obeticholic acid in patients with advanced cirrhosis<sup>1</sup>. This is defined as cirrhosis with current or prior evidence of liver decompensation (e.g., encephalopathy, coagulopathy) or portal hypertension (e.g., ascites, gastroesophageal varices, or persistent thrombocytopenia).

## **Revised Guidance Statements**

Two Guidance Statements that were published in the 2018 Practice Guidance on PBC have been revised as follows:

9. Fibrates can be considered as off-label alternatives for patients with PBC and inadequate response to Ursodeoxycholic Acid (UDCA) although fibrates are discouraged in patients with decompensated liver disease.

10. OCA is contraindicated in patients with advanced cirrhosis. This is defined as cirrhosis with current or prior evidence of liver decompensation (e.g., encephalopathy, coagulopathy) or portal hypertension (e.g., ascites, gastroesophageal varices or persistent thrombocytopenia). Furthermore, we would recommend careful monitoring of any patient with cirrhosis, even if not advanced, receiving OCA.

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**References:**

<sup>1</sup>Due to risk of serious liver injury, FDA restricts use of Ocaliva (obeticholic acid) in primary biliary cholangitis (PBC) patients with advanced cirrhosis | FDA, <https://www.fda.gov/drugs/drug-safety-and-availability/due-risk-serious-liver-injury-fda-restricts-use-ocaliva-obeticholic-acid-primary-biliary-cholangitis> Accessed May 2021.

<sup>2</sup>Lindor, K.D., Bowlus, C.L., Boyer, J., Levy, C. and Mayo, M. (2019), Primary Biliary Cholangitis: 2018 Practice Guidance from the American Association for the Study of Liver Diseases. *Hepatology*, 69: 394-419. <https://doi.org/10.1002/hep.30145>