

Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	January 7, 2022 March 19, 2025

Bile Salts Agents

Preferred: Ursodiol

Non-Preferred: Actigall[®] /Urso[®] /Urso Forte[®] (ursodiol), Chenodal[®] (chenodiol), Cholbam[®] (cholic acid), and Ocaliva[®] (obeticholic acid)

LENGTH OF AUTHORIZATION: Up to 6 months

INITIAL REVIEW CRITERIA:

Chenodal[®]

- Patient must be ≥ 18 years of age.
- Patient must have a diagnosis of cholelithiasis who have small radiolucent (non-calcified) cholesterol gallstones, have a normally functioning gallbladder, are not eligible for surgery due to disease or age and have experienced an inadequate response or contraindication with ursodiol.
- Current labs (within 30 days of request) have been submitted for the following:
 - AST/ALT
 - ALP (alkaline phosphatase)
 - Bilirubin
 - INR
 - Lipids

Cholbam[®]

- Patient must have a diagnosis of bile acid synthesis disorders due to single enzyme defects (SEDs) **including Smith-Lemli-Opitz Syndrome (SLOS) OR** peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea or complications from decreased fat-soluble vitamin absorption.
- Current labs (within 30 days of request) have been submitted for the following:
 - AST/ALT
 - ALP
 - Bilirubin
 - INR
 - GGT (Gamma-glutamyltransferase)

Ocaliva[®]

- Patient must be ≥ 18 years of age.
- Patient must have a diagnosis of primary biliary cholangitis (PBC) without cirrhosis or with compensated cirrhosis who do not have evidence of portal hypertension.
- Medication is used in combination with ursodiol with inadequate response or as monotherapy in patients with a contraindication to ursodiol.
- Patient does not have decompensated cirrhosis (e.g., Child-Pugh Class B or C), prior decompensation event, compensated cirrhosis with evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia), or complete biliary obstruction.
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DOSING AND ADMINISTRATION:

- Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>