| Division: Pharmacy Policy | Subject: Prior Authorization Criteria |
|---|---|
| Original Development Date:<br>Original Effective Date:<br>Revision Date: | January 7, 2022 |

# 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) **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.
- Current labs (within 30 days of request) have been submitted for the following:
  - AST/ALT

| Division: Pharmacy Policy | Subject: Prior Authorization Criteria |
|---|---|
| Original Development Date:<br>Original Effective Date:<br>Revision Date: | January 7, 2022 |

- ALP
- Bilirubin
- INR
- Lipids

**DOSING AND ADMINISTRATION:**

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