

Cholic Acid (Cholbam™)

Goal(s):

- To ensure appropriate use of cholic acid in patients with bile acid synthesis disorders (BASDs) due to a single enzyme defects (SEDs) or as an adjunct to patients with peroxisomal disorders (PD), including Zellweger spectrum disorders, who exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption.

Length of Authorization:

- Up to 12 months

Requires PA:

- Cholic acid

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is this an FDA approved indication?	Yes: Go to #3	No: Pass to RPh. Deny; medical appropriateness
3. Is this a request for continuation of therapy?	Yes: Go to Renewal Criteria	No: Go to #4
4. Is cholic acid prescribed by a hepatologist or pediatric gastroenterologist?	Yes: Go to #5	No: Pass to RPh. Deny; not funded by the OHP.
5. Has baseline hepatic function been assessed? *The manufacturer recommends providers to monitor aspartate transaminase (AST), alanine aminotransferase (ALT), gamma-glutamyl transpeptidase (GGT), alkaline phosphatase (ALP), bilirubin, and international normalized ratio (INR) every month for the first 3 months of therapy, every 3 months for the next 9 months, every 6 months during the next 3 years and annually thereafter. ¹	Yes: Approve for 3 months. Document baseline hepatic function values (AST,ALT, Alk Phos, bilirubin) and date obtained: _____	No: Pass to RPh. Deny; medical appropriateness

Renewal Criteria

1. Is there evidence of improvement of primary biliary cholangitis, defined as: a. ALP <1.67-times the ULN; AND b. Decrease of ALP >15% from baseline: AND c. Normal total bilirubin level?	Yes: Document ALP and total bilirubin level. Go to #2 ALP: _____ units/L Total Bilirubin ____ mg/dL	No: Pass to RPh. Deny; medical appropriateness
2. Has the patient's condition stabilized or improved as assessed by the prescribing provider?	Yes: Approve for 12 months.	No: Pass to RPh. Deny; medical appropriateness

1. Cholbam (cholic acid) capsules [Full Prescribing Information]. San Diego, CA: Retrophin, Inc. March 2015.

P&T/DUR Review: 12/21 (DM); 11/19 (DM)

Implementation: 1/1/22; 1/1/2020