

ALASKA MEDICAID
Prior Authorization Criteria

**Cholbam™
(cholic acid)**

FDA INDICATIONS AND USAGE¹

Cholbam™ (cholic acid) is a bile acid indicated for the treatment of bile acid synthesis disorders (BASDs) due to single enzyme defects (SEDs) and as an adjunctive treatment of peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption.

APPROVAL CRITERIA¹

1. Prescribed by a specialist gastroenterologist or hepatologist; **AND**
2. The diagnosis of Bile Acid Synthesis Disorders due to Single Enzyme Defects confirmed by:
 - a. An abnormal urinary bile acid as confirmed by Fast Atom Bombardment ionization – Mass Spectrometry (FAB-MS) analysis; **OR**
 - b. Molecular genetic testing consistent with the diagnosis; **OR**
3. The diagnosis of peroxisomal disorders, including Zellweger spectrum disorders; **AND**
 - a. The patient exhibits symptoms of liver disease, steatorrhea, or complications due to reduced fat-soluble vitamin absorption; **AND**
 - b. Cholbam™ will be used as adjunctive therapy.
3. Baseline liver function labs (e.g., AST, ALT, GGT, ALP, bilirubin, INR) (updated labs required for renewal).

DENIAL CRITERIA

1. Failure to meet approval criteria; **OR**
2. Complete biliary obstruction develops

CAUTIONS¹

1. Monitor AST, ALT, GGT, alkaline phosphatase, bilirubin and INR every month for the first 3 months, every 3 months for the next 9 months, every 6 months during the next three years and annually thereafter.
2. Administer the lowest dose that effectively maintains liver function.

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DURATION OF APPROVAL

1. Initial Approval: 3 months
 - a. Reauthorization 12 months with chart notes documenting the patient is showing improvements in liver function labs.

QUANTITY LIMIT¹

The recommended dosage of CholbamTM is 10 to 15mg/kg/day administered in one to two doses daily.

- a. In patients with concomitant familial hypertriglyceridemia a dose of 11 to 17mg/kg/day, adjusted based on clinical response, may be needed.

REFERENCES / FOOTNOTES:

1. CholbamTM[prescribing information]. San Diego, CA: Manchester Pharmaceuticals, Inc. Revised 05/2021