

Clinical Pharmacy Program Guidelines for Cholbam

Program	Prior Authorization
Medication	Cholbam [®] (cholic acid)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	9/2015
Pharmacy and Therapeutics Approval Date	3/2020
Effective Date	5/2020

1. Background:

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.

2. Coverage Criteria:

<p>A. <u>Initial Authorization</u></p> <p>1. Cholbam will be approved based on <u>one</u> of the following criteria:</p> <p>a. <u>All</u> of the following:</p> <p style="padding-left: 40px;">(1) Diagnosis of a bile acid synthesis disorder</p> <p style="text-align: center;">-AND-</p> <p style="padding-left: 40px;">(2) It is due to single enzyme defects</p> <p style="text-align: center;">-OR-</p> <p>b. <u>All</u> of the following:</p> <p style="padding-left: 40px;">(1) Diagnosis of peroxisomal disorders including Zellweger spectrum disorders</p> <p style="text-align: center;">-AND-</p> <p style="padding-left: 40px;">(2) Patient exhibits manifestations of liver disease, steatorrhea, or</p>

complications from decreased fat soluble vitamin absorption

-AND-

(3) It is being used as adjunctive treatment

Authorization will be issued for 12 months.

B. Reauthorization

1. Cholbam will be approved based on the following criterion:

a. Documentation of positive clinical response to Cholbam therapy

Authorization will be issued for 12 months.

3. References:

1. Cholbam [package insert]. Manchester Pharmaceuticals, Inc., San Diego, CA. March 2015.

Program	Prior Authorization - Cholbam® (cholic acid)
Change Control	
Date	Change
9/2015	New policy; new FDA-approved drug
9/2016	Updated policy template and removed prescriber check to align with E&I criteria
9/2017	Annual Review. Updated background. No changes to criteria.
9/2018	Annual review. No changes.
9/2019	Annual review. Minor updates to the background. No changes to clinical criteria.
3/2020	Annual review. Updated reference.