UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1168-7
Program	Prior Authorization/Notification
Medications	Cholbam™ (cholic acid)
P&T Approval Date	11/2015, 9/2016, 9/2017, 9/2018, 9/2019, 3/2020, 3/2021
Effective Date	6/1/2021; Oxford only: 6/1/2021

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.

Limitation of use:
The safety and effectiveness of Cholbam on extrahepatic manifestations of bile acid synthesis disorders due to SEDs or PDs including Zellweger spectrum disorders have not been established.

2. Coverage Criteria:

A. Initial Authorization

1. Cholbam will be approved based on **one** of the following criteria:

a. **Both** of the following:

(1) Diagnosis of a bile acid synthesis disorder

-AND-

(2) It is due to single enzyme defects

-OR-

b. **All** of the following:

(1) Diagnosis of peroxisomal disorders including Zellweger spectrum disorders

-AND-

(2) Patient exhibits manifestations of liver disease, steatorrhea or 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. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program.
- Supply limitations may be in place.

4. References:

1. Cholbam [package Insert].San Diego, CA: Manchester Pharmaceuticals, Inc. A wholly owned subsidiary of Retrophin, Inc.; March 2015.

Program	Prior Authorization/Notification - Cholbam (cholic acid)
Change Control	
11/2015	New program.
9/2016	Annual Review. No changes.
9/2017	Annual Review. Updated background. No changes to criteria.
9/2018	Annual Review. No changes.
9/2019	Annual Review. Updated background. No changes to coverage criteria.
3/2020	Increased initial authorization to 12 months. No changes to coverage criteria.
3/2021	Annual review. No changes to coverage criteria. Updated reference.