UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1168-10
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, 3/2022, 5/2022, 5/2023
Effective Date	8/1/2023; Oxford only: 8/1/2023

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.

Cholbam should be discontinued if liver function does not improve within 3 months of starting treatment, if complete biliary obstruction develops, or if there are persistent clinical or laboratory indicators of worsening liver function or cholestasis.

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]:

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) Bile acid synthesis disorder is due to single enzyme defects (SEDs)

      -OR-

   b. **All** of the following:

      (1) Diagnosis of a peroxisomal disorder including Zellweger spectrum disorders

      -AND-

      (2) Patient exhibits manifestations of liver disease, steatorrhea or complications from decreased fat-soluble vitamin absorption

      -AND-

(3) Cholbam is being used as adjunctive treatment

Authorization will be issued for 3 months.

B. Reauthorization

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

   a. Documentation of positive clinical response to Cholbam therapy as evidenced by **both** of the following:

      (1) Improvement in liver function (e.g., aspartate aminotransferase [AST], alanine aminotransferase [ALT])

      -AND-

      (2) Absence of complete biliary obstruction

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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 Travere Therapeutics, Inc. May 2021.

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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.
3/2022	Annual review. No changes to coverage criteria. Updated reference.
5/2022	Changed initial authorization length to 3 months to align with package insert. Added "as evidenced by improvement in liver function" with examples to reauthorization criteria.

5/2023	Annual review. Added “absence of complete biliary obstruction” to reauthorization criteria. Updated background and reference. Added state mandate footnote.