

Clinical Policy: Bile Salts

Reference Number: PHW.PDL.198

Effective Date: 01/01/2020

Last Review Date: 01/2021

[Revision Log](#)

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health and Wellness® that Bile Salts are **medically necessary** when the following criteria are met:

I. Requirements for Prior Authorization of Bile Salts

A. Prescriptions That Require Prior Authorization

Prescriptions for Bile Salts that meet any of the following conditions must be prior authorized:

1. A prescription for a non-preferred Bile Salt, regardless of the quantity prescribed.
2. A prescription for a preferred Bile Salt with a prescribed quantity that exceeds the quantity limit.
3. A prescription for Cholbam (cholic acid).

B. Clinical Review Guidelines and Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Bile Salt, the determination of whether the requested prescription is medically necessary will take into account the following:

1. Whether the recipient has a documented history of therapeutic failure, intolerance, or contraindication of the preferred Bile Salts
2. For Cholbam (cholic acid) whether the recipient:
 - a. Is prescribed Cholbam (cholic acid) by or in consultation with a hepatologist or pediatric gastroenterologist

AND

- b. Is being treated for a condition that is:
 - i. U.S. Food and Drug Administration (FDA) approved, or a medically accepted indication

AND

- ii. Documented by medical history and laboratory results

AND

- c. Will have AST, ALT, GGT, alkaline phosphatase, bilirubin and INR monitored according to prescribing information
3. For Ocaliva (obeticholic acid), whether the recipient:
- a. Is prescribed Ocaliva (obeticholic acid) by or in consultation with a hepatologist or gastroenterologist

AND

- b. Is being treated for a diagnosis that is:
 - i. Indicated in the FDA-approved package insert OR a medically-accepted indication

AND

- ii. Documented by medical history and laboratory results

AND

- c. Has documented baseline liver function tests, including AST, ALT, GGT, alkaline phosphatase, bilirubin, and INR

AND

- d. Has a documented baseline HDL-C

AND

- e. Has a documented history of therapeutic failure of optimally-titrated doses of ursodeoxycholic acid (UDCA)

AND

- f. Will be prescribed Ocaliva (obeticholic acid) in combination with UDCA

OR

- g. Has a contraindication or intolerance of UDCA
- 4. In addition, if a prescription for either a preferred or non-preferred Bile Salt is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override

OR

- 5. Whether the recipient does not meet the clinical review guidelines listed above, but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

FOR RENEWALS OF PRESCRIPTIONS FOR CHOLBAM (CHOLIC ACID): The determination of medical necessity of requests for prior authorization of renewals of prescriptions for Cholbam (cholic acid) that were previously approved will take into account whether the recipient:

- 1. Has documented improvement in liver function within the first 3 months of treatment

AND

- 2. Has documented AST, ALT, GGT, alkaline phosphatase, bilirubin and INR monitoring as recommended per prescribing information

AND

- 3. Does not have complete biliary obstruction, persistent clinical or laboratory indicators of worsening liver function or cholestasis.

FOR RENEWALS OF PRESCRIPTIONS FOR OCALIVA (OBETICHOLIC ACID): The determination of medical necessity of requests for prior authorization of renewals of prescriptions for Ocaliva (obeticholic acid) that were previously approved will take into account whether the recipient:

- 1. Has documented monitoring of liver function tests, including AST, ALT, GGT, alkaline phosphatase, bilirubin, and INR, since starting Ocaliva (obeticholic acid) and within the past six (6) months

AND

- 2. Has documentation of a positive response to Ocaliva (obeticholic acid) as evidenced by liver function tests

AND

3. Has documentation of recent HDL-C monitoring

AND

4. Does not have complete biliary obstruction

OR

5. Does not meet the clinical review guidelines listed above, but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B above, to assess the medical necessity of the request for a prescription for a non-preferred Bile Salt. If the guidelines in Section B are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

D. Approval Duration:

- **New request: 6 months**
- **Renewal request: 12 months**

E. References:

1. Cholbam (cholic acid) Prescribing Information. Manchester Pharmaceuticals, Inc. March 2015
2. Percey, A.K, Peroxisomal disorders. Up To Date, accessed October 15, 2015
3. Abrams, S.H, Causes of neonatal cholestasis. Up To Date, accessed October 15, 2015

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021 annual review: no changes.	01/2021