

## Clinical Policy: Bile Salts

Reference Number: PHW.PDL.198

Effective Date: 01/01/2020

Last Review Date: 11/2023

[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 PA Health & Wellness<sup>®</sup> 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 Bile Salt with a prescribed quantity that exceeds the quantity limit.
3. A prescription for cholic acid.
4. A prescription for obeticholic acid.

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

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

1. Is prescribed the Bile Salt for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Does not have a contraindication to the requested medication; **AND**
4. For cholic acid, both of the following:

- a. Is prescribed cholic acid by or in consultation with a hepatologist or pediatric gastroenterologist,
  - b. Has documentation of a medical history and lab test results that support the beneficiary's diagnosis;
3. For obeticholic acid, all of the following:
- a. Is prescribed obeticholic acid by or in consultation with a hepatologist or gastroenterologist,
  - b. Has documentation of medical history and lab test results that support the beneficiary's diagnosis,
  - c. Has a history of therapeutic failure of or a contraindication or an intolerance to optimally-titrated doses of ursodeoxycholic acid (UDCA),
  - d. One of the following:
    - i. Will be prescribed obeticholic acid in combination with UDCA,
    - ii. Has a contraindication or intolerance of UDCA;
4. For all other non-preferred Bile Salts, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Bile Salts approved or medically accepted for the beneficiary's diagnosis; **AND**
5. If a prescription for a 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

NOTE: If the beneficiary 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 beneficiary, the request for prior authorization will be approved.

**FOR RENEWALS OF PRESCRIPTIONS FOR BILE SALTS:** The determination of medical necessity of requests for renewal of a prior authorization for a Bile Salt that was previously approved will take into account whether the beneficiary:

1. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
2. Does not have a contraindication to the requested medication; **AND**
3. For cholic acid, all of the following:
  - a. Is prescribed cholic acid by or in consultation with a hepatologist or pediatric gastroenterologist,
  - b. Has documented improvement in liver function within the first 3 months of treatment,

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

**AND**

4. For obeticholic acid, both of the following:
  - a. Is prescribed obeticholic acid by or in consultation with a hepatologist or gastroenterologist,
  - b. Has documentation of a positive response to obeticholic acid as evidenced by liver function tests;

**AND**

5. For all other non-preferred Bile Salts, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Bile Salts approved or medically accepted for the beneficiary's diagnosis; **AND**
6. If a prescription for a Bile Salts is for 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.

NOTE: If the beneficiary 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 beneficiary, the request for prior authorization will be approved.

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 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. Ocaliva [package insert]. New York, NY: Intercept Pharmaceuticals, Inc; May 2021 February 2022.
3. Hirschfield G, Mason A, Luketic V, et al. Efficacy of obeticholic acid in patients with primary biliary cirrhosis and inadequate response to ursodeoxycholic acid. *Gastroenterology*. 2015;148:751-761. doi: 10.1053/j.gastro.2014.12.005.
4. Nevens F, Andreone G, Mazzella G, et al. A placebo-controlled trial of obeticholic acid in primary biliary cholangitis. *N Engl J Med*. 2016;375:631-643. doi: 10.1056/NEJMoa1509840.
5. Erlichman J, Loomes KM. Causes of cholestasis in neonates and young children. In: UpToDate [internet database]. Abrams SA, Rand EB, Hoppin AG, eds. Waltham, MA: UpToDate Inc. Updated January 19, 2022. Accessed April 21, 2022.
6. Wanders RJA. Peroxisomal disorders. In: UpToDate [internet database]. Patterson MC, Firth HV, Armsby C, eds. Waltham, MA: UpToDate Inc. Updated March 3, 2020. Accessed April 21, 2022.
7. Poupon R. Overview of the management of primary biliary cholangitis. In: UpToDate [internet database]. Lindor KD, Robson KM, eds. Waltham, MA: UpToDate Inc. Updated October 27, 2021. Accessed April 21, 2022.

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
Q1 2023: policy revised according to DHS revisions effective 01/09/2023.	10/2022
Q1 2024 annual review: no changes.	11/2023