

BILE SALTS

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 non-preferred Bile Salt. See the Preferred Drug List (PDL) for the list of preferred Bile Salts at: <https://papdl.com/preferred-drug-list>.
2. A prescription for cholic acid.
3. A prescription for obeticholic acid.

B. 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;**AND**
5. 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 a 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 an intolerance to UDCA;**AND**

6. 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

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 PRIOR AUTHORIZATION FOR BILE SALTS: The determination of medical necessity of a request 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

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 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 beneficiary.

BILE SALTS – CHOLBAM (cholic acid) & OCALIVA (obeticholic acid) PRIOR AUTHORIZATION FORM

<input type="checkbox"/> New request <input type="checkbox"/> Renewal request		Total pages: _____	Prescriber name:	
Name of office contact:			Specialty:	
Contact's phone number:			NPI:	State license #:
LTC facility contact/phone:			Street address:	
Beneficiary name:			City/state/zip:	
Beneficiary ID#:	DOB:	Phone:	Fax:	

CLINICAL INFORMATION

Drug requested:	Strength:	
Dose/directions:	Quantity:	Refills:
Diagnosis (<i>submit documentation</i>):	Dx code (<i>required</i>):	

Complete all sections that apply to the beneficiary and this request. Check all that apply and submit documentation for each item.

INITIAL requests

- For Cholbam (cholic acid):**
 - ☐ Cholbam (cholic acid) is prescribed by or in consultation with a hepatologist or pediatric gastroenterologist
 - ☐ Medical history and lab test results support the beneficiary's diagnosis (eg, serum or urinary bile acid levels using mass spectrometry, neurologic exam)
- For Ocaliva (obeticholic acid):**
 - ☐ Ocaliva (obeticholic acid) is prescribed by or in consultation with a hepatologist or gastroenterologist
 - ☐ Medical history and lab test results support the beneficiary's diagnosis (eg, alkaline phosphatase, antimitochondrial antibodies, histologic evaluation, imaging)
 - ☐ The beneficiary does NOT have any of the following contraindications to Ocaliva (obeticholic acid): decompensated cirrhosis (Child-Pugh Class B or C) or a prior decompensation event, compensated cirrhosis with evidence of portal hypertension (eg, ascites, gastroesophageal varices, persistent thrombocytopenia), or complete biliary obstruction
 - ☐ The beneficiary tried and failed optimally titrated doses of ursodeoxycholic acid (UDCA, ursodiol)
 - ☐ The beneficiary will take Ocaliva (obeticholic acid) in combination with ursodeoxycholic acid (UDCA, ursodiol)
 - ☐ The beneficiary has a contraindication or history of intolerance to ursodeoxycholic acid (UDCA, ursodiol)

RENEWAL requests

- For Cholbam (cholic acid):**
 - ☐ Cholbam (cholic acid) is prescribed by or in consultation with a hepatologist or pediatric gastroenterologist
 - ☐ The beneficiary experienced improvement in liver function within the first 3 months of treatment with Cholbam (cholic acid)
 - ☐ The beneficiary does NOT have complete biliary obstruction, persistent clinical or lab indicators of worsening liver function, or cholestasis
- For Ocaliva (obeticholic acid):**
 - ☐ Ocaliva (obeticholic acid) is prescribed by or in consultation with a hepatologist or gastroenterologist
 - ☐ The beneficiary has results of recent LFTs showing a positive clinical response to Ocaliva (obeticholic acid)
 - ☐ The beneficiary does NOT have any of the following contraindications to Ocaliva (obeticholic acid): decompensated cirrhosis (Child-Pugh Class B or C) or a prior decompensation event, compensated cirrhosis with evidence of portal hypertension (eg, ascites, gastroesophageal varices, persistent thrombocytopenia), or complete biliary obstruction

PLEASE FAX COMPLETED FORM TO HIGHMARK WHOLECARE – PHARMACY DIVISION

Prescriber Signature:	Date:
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