

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

(form effective 1/9/2023)

Prior authorization guidelines for **Bile Salts** and **Quantity Limits/Daily Dose Limits** are available on the DHS Pharmacy Services website at <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/default.aspx>.

<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

1. 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)

2. 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

1. 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

2. 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 WITH REQUIRED CLINICAL DOCUMENTATION TO DHS – PHARMACY DIVISION

Prescriber Signature:

Date:

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