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Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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 prescription for a non-preferred Bile Salt, regardless of the quantity prescribed. See Preferred Drug List (PDL) for the list of preferred Bile Salts at: https://papdl.com/preferred-drug-list.

2. 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

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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

OR

4. 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

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

FOR RENEWALS OF PRESCRIPITONS 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.

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CHOLBAM (cholic acid) PRIOR AUTHORIZATION FORM

PRIOR AUTHORIZATION REQUEST INFORMATION			PRESCRIBER INFORMATION	
☐New request ☐Renewal request	☐Additional info PA#:_____	# of pages in request: _____	Prescriber name:	
Name of office contact:			Specialty:	
Contact's phone number:			State license #:	
LTC facility contact/phone:			NPI:	MA Provider ID#:
RECIPIENT INFORMATION			Street address:	
Recipient name:			Suite #:	City/state/zip:
Recipient ID#:	DOB:		Phone:	Fax:
Medication will be billed via: ☐ Pharmacy ☐ Medical (Jcode:)			Place of Service: ☐ Hospital ☐ Provider's Office ☐ Home ☐ Other	

CLINICAL INFORMATION

Drug requested: Cholbam capsule	Strength:	Quantity:
Directions:		Refills:
Diagnosis:		Dx code *(required)*:

Section A: Initial Cholbam requests	
1. If prescriber is NOT a hepatologist or pediatric gastroenterologist, is the requested medication being prescribed in consultation with one of the above specialists?	☐Yes – *submit documentation of consultation* ☐No or not applicable
2. Does the Recipient have one of the following diagnoses? ☐bile acid synthesis disorder (BASD) due to a single enzyme defect (SED) ☐peroxisomal disorder (PD) (including Zellweger spectrum disorder)	☐Yes – *submit results and dates of mass spectrometry or other biochemical or genetic testing* ☐No – *submit documentation supporting the use of Cholbam for Recipient's diagnosis*
3. *For a diagnosis of peroxisomal disorder*, will Cholbam be used in addition to other therapy/treatment?	☐Yes – *submit documentation of concurrent therapy or treatment* ☐No
4. Does the Recipient have results of the following baseline (before starting Cholbam) lab tests? ☐AST ☐GGTP ☐bilirubin ☐ALT ☐alkaline phosphatase ☐INR	☐Yes – *submit results and dates of all lab monitoring for all requested values* ☐No
Section B: Renewal Cholbam requests	
1. Does the recipient have documentation of the following lab results since starting Cholbam and within the past 6 months? ☐AST ☐GGT ☐bilirubin ☐ALT ☐alkaline phosphatase ☐INR	☐Yes – *submit results and dates of all lab monitoring for all requested values* ☐No
2. Has the Recipient shown clinical signs or symptoms or lab indicators of any of the following since starting Cholbam? ☐complete biliary obstruction ☐persistent or ongoing worsening of liver function ☐persistent or ongoing cholestasis	☐Yes ☐No *Submit medical record documentation of clinical monitoring*
3. *For the FIRST RENEWAL REQUEST after starting or restarting Cholbam*, has the Recipient experienced an improvement in liver function within the first 3 months of treatment?	☐Yes – *submit results and dates of baseline LFTs and LFTs drawn 3 months after starting/restarting Cholbam* ☐No

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Prescriber Signature:	Date:

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OCALIVA (obeticholic acid) PRIOR AUTHORIZATION FORM

PRIOR AUTHORIZATION REQUEST INFORMATION		PRESCRIBER INFORMATION	
☐New request ☐Renewal request	Total # of pages: _____	Prescriber name:	
Name of office contact:		Specialty:	
Contact's phone number:		State license #:	
LTC facility contact/phone:		NPI:	MA Provider ID#:
BENEFICIARY INFORMATION		Street address:	
Beneficiary name:		Suite #:	City/state/zip:
Beneficiary ID#:	DOB:	Phone:	Fax:
Medication will be billed via: ☐ Pharmacy ☐ Medical (Jcode:)		Place of Service: ☐ Hospital ☐ Provider's Office ☐ Home ☐ Other	

CLINICAL INFORMATION

Drug requested: Ocaliva tablet	Strength:	Quantity:
Directions:		Refills:
Diagnosis:		Dx code *(required)*:

Specialty Pharmacy Drug Program: Ocaliva is part of the DHS Specialty Pharmacy Drug Program and is only available from one of the two DHS specialty pharmacies – **Walgreen's Specialty Pharmacy**.

Initial Ocaliva requests	
5. If prescriber is NOT a hepatologist or gastroenterologist, is the requested medication being prescribed in consultation with one of the above specialists?	☐Yes – *Submit documentation of consultation.* ☐No or not applicable
6. Does the beneficiary have a diagnosis of primary biliary cholangitis (PBC)?	☐Yes – *Submit documentation of lab results and medical history supporting diagnosis.* ☐No – *Submit documentation supporting the use of Ocaliva for beneficiary's diagnosis.*
7. Does the beneficiary have results of the following baseline (before starting Ocaliva) lab results? ☐AST ☐GGTP ☐bilirubin ☐HDL-C ☐ALT ☐alkaline phosphatase ☐INR	☐Yes – *Submit results and dates of all lab monitoring for all requested values.* ☐No
8. Does the beneficiary have a history of trial and failure, contraindication, or intolerance of ursodiol (ursodeoxycholic acid or UDCA)?	☐Yes – *Submit all supporting documentation of trial and failure (including doses tried), contraindications, or intolerances with ursodiol.* ☐No
9. Will the beneficiary be taking Ocaliva in combination with ursodiol?	☐Yes *Submit documentation of planned* ☐No *treatment regimen.*
Renewal Ocaliva requests	
10. Does the beneficiary have documentation of the following lab results since starting Ocaliva and within the past 6 months? ☐AST ☐GGT ☐bilirubin ☐HDL-C ☐ALT ☐alkaline phosphatase ☐INR	☐Yes – *Submit results and dates of all lab monitoring for all requested values.* ☐No
11. Has the beneficiary shown clinical signs or symptoms or lab indicators of complete biliary obstruction since starting Ocaliva?	☐Yes *Submit documentation of clinical* ☐No *monitoring.*

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Prescriber Signature:	Date: