

<b>ISSUE DATE</b> January 31, 2017	<b>EFFECTIVE DATE</b> January 31, 2017	<b>NUMBER</b> *See below
<b>SUBJECT</b> Prior Authorization of Bile Salts – Pharmacy Service		<b>BY</b>  Leesa M. Allen, Acting Deputy Secretary Office of Medical Assistance Programs

**IMPORTANT REMINDER:** All providers must revalidate their MA enrollment every 5 years. Providers should log into PROMISE to check their revalidation date and submit a revalidation application at least 60 days prior. Enrollment (revalidation) applications may be found at [http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S\\_001994](http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994).

**PURPOSE:**

The purpose of this bulletin is to:

1. Inform providers that the Department of Human Services (Department) will require prior authorization of Ocaliva (obeticholic acid).
2. Issue updated handbook pages that include instructions on how to request prior authorization of Bile Salts, including the type of medical information needed to evaluate requests for medical necessity.

**SCOPE:**

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance Program and providing services in the fee-for-service delivery system, including pharmacy services to residents of long term care facilities.

**BACKGROUND:**

The Department’s Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for efficacy, safety, and

*01-17-08	09-17-07	27-17-06	
02-17-06	11-17-06	30-17-07	
03-17-06	14-17-06	31-17-08	
08-17-07	24-17-06	32-17-06	33-17-07

**COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:**

The appropriate toll free number for your provider type

Visit the Office of Medical Assistance Programs Web site at  
<http://www.dhs.state.pa.us/provider/healthcaremedicalassistance/index.htm>

quality and to recommend interventions for prescribers and pharmacists through the Department's Prospective Drug Use Review and Retrospective Drug Use Review programs.

**DISCUSSION:**

During the September 26, 2016 meeting, the DUR Board recommended revisions to the medical necessity guidelines for Bile Salts to reflect the recent approval of Ocaliva and to ensure appropriate patient selection for this agent. The guidelines to determine medical necessity, as recommended by the DUR Board, were subject to public review and comment, and subsequently approved for implementation by the Department. The requirements for prior authorization and clinical review guidelines to determine the medical necessity of Bile Salts are included in the attached updated provider handbook pages.

**PROCEDURE:**

The procedures for prescribers to request prior authorization of Bile Salts are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapters related to Bile Salts) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

**ATTACHMENTS:**

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

SECTION II  
Bile Salts

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

**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. See Preferred Drug List (PDL) for the list of preferred Bile Salts at: <https://papdl.com/preferred-drug-list>
2. A prescription for a preferred Bile Salt with a prescribed quantity that exceeds the quantity limit. See Quantity Limits for the list of drugs with quantity limits at: [http://www.dhs.pa.gov/cs/groups/webcontent/documents/document/s\\_002077.pdf](http://www.dhs.pa.gov/cs/groups/webcontent/documents/document/s_002077.pdf)
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**

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- 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

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**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 the Quantity Limits Chapter.

**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 PRESCRIPITONS 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 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,

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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. 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