

ISSUE DATE January 6, 2016	EFFECTIVE DATE January 20, 2016	NUMBER *See below
SUBJECT Prior Authorization of Bile Salts - Pharmacy Service		BY  Leesa M. Allen, Deputy Secretary Office of Medical Assistance Programs

IMPORTANT REMINDER: All providers (including all associated service locations - 13 digits) who enrolled on or before **March 25, 2011** must revalidate their enrollment information no later than **March 24, 2016**. New enrollment application including all revalidation requirements may be found at http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994. Please send in your application(s) as soon as possible.

PURPOSE:

The purpose of this bulletin is to:

1. Inform providers that the Department of Human Services (Department) will require prior authorization of Cholbam (cholic acid).
2. Issue updated handbook pages that include instructions on how to request prior authorization of prescriptions for 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 (MA) Program and providing services in the fee-for-service (FFS) delivery system, including pharmacy services to residents of long term care facilities.

BACKGROUND:

The Department's Pharmacy and Therapeutics (P&T) Committee meets semi-annually to review published peer-reviewed clinical literature and make recommendations relating to new drugs in therapeutic classes already included in the Preferred Drug List (PDL), changes in the status of drugs on the PDL from preferred to non-preferred and non-preferred to preferred,

*01-16-02	09-16-02	27-16-02	
02-16-02	11-16-02	30-16-02	
03-16-02	14-16-02	31-16-02	
08-16-02	24-16-02	32-16-02	33-16-02

<p>COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:</p> <p>The appropriate toll free number for your provider type</p> <p>Visit the Office of Medical Assistance Programs Web site at http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm</p>
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new quantity limits, and classes of drugs to be added to or deleted from the PDL. The P&T Committee also recommends new guidelines or modifications to existing guidelines to evaluate requests for prior authorization of prescriptions for medical necessity.

DISCUSSION:

During the November 3, 2015 meeting, the P&T Committee recommended that the Department require a clinical prior authorization of Cholbam (cholic acid) and proposed guidelines to determine medical necessity of Cholbam (cholic acid). The recommended guidelines were subject to public review and comment, and subsequently approved for implementation by the Department. The revised 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:
http://www.providersynergies.com/services/documents/PAM_PDL_20100223.pdf
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/document/s/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. 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

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 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.

C .Clinical Review Process

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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