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| ISSUE DATE November 9, 2022 | EFFECTIVE DATE January 9, 2023 | NUMBER *See below |
| SUBJECT Prior Authorization of Bile Salts – Pharmacy Services | | BY  Sally A. Kozak, Deputy Secretary Office of Medical Assistance Programs |

IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMiSe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: <https://www.dhs.pa.gov/providers/Providers/Pages/PROMiSe-Enrollment.aspx>.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Bile Salts submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program. The guidelines to determine the medical necessity of Bile Salts will be utilized in the fee-for-service and managed care delivery systems. Providers rendering services to MA beneficiaries in the managed care delivery system should address any questions related to the prior authorization of Bile Salts to the appropriate managed care organization.

BACKGROUND:

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| *01-22-54 | 09-22-53 | 27-22-41 | 33-22-51 |
| 02-22-38 | 11-22-38 | 30-22-44 | |
| 03-22-37 | 14-22-38 | 31-22-57 | |
| 08-22-62 | 24-22-46 | 32-22-38 | |

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 website at <https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx>.

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed medical literature and recommends the following:

- Preferred or non-preferred status for new drugs and products in therapeutic classes already included in the Preferred Drug List (PDL).
- Changes in the status of drugs and products on the PDL from preferred to non-preferred and non-preferred to preferred.
- New quantity limits.
- Therapeutic classes of drugs and products to be added to or deleted from the PDL.
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the September 13, 2022, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Bile Salts:

- Addition of a requirement for prior authorization of obeticholic acid.
- Addition of a guideline that the Bile Salt is prescribed 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.
- Addition of guidelines that the beneficiary is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.
- Addition of guidelines that the beneficiary does not have a contraindication to the requested medication.
- Removal of the guidelines for cholic acid related to baseline liver function tests.
- Removal of the guidelines for obeticholic acid related to baseline liver function tests and baseline high-density lipoprotein cholesterol.
- Revision of the guideline for obeticholic acid related to a history of therapeutic failure of optimally titrated doses of ursodeoxycholic acid (UDCA) to include a contraindication or an intolerance to UDCA.
- Addition of a guideline to the requests for renewal of prior authorization section for non-preferred Bile Salts that were previously approved.
- Addition of a guideline to the requests for renewal of prior authorization section that cholic acid is prescribed by or in consultation with a hepatologist or pediatric gastroenterologist.
- Addition of a guideline to the requests for renewal of prior authorization section that obeticholic acid is prescribed by or in consultation with a hepatologist or gastroenterologist.
- Addition of a guideline to the requests for renewal of prior authorization section that Bile Salts are subject to the guidelines in the Quantity Limits chapter.

The revisions to the guidelines to determine medical necessity of prescriptions for Bile Salts submitted for prior authorization, as recommended by the P&T Committee, were subject

to public review and comment and subsequently approved for implementation by the Department.

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 chapter 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 and products that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I

Pharmacy Prior Authorization General Requirements

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx>

Prior Authorization of Pharmaceutical Services Handbook – SECTION II

Pharmacy Prior Authorization Guidelines

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx>

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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 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 Bile Salt with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.
3. A prescription for cholic acid.
4. 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:

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- 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; **AND**
7. If a prescription for a Bile Salt is for 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.

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;

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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; **AND**
6. If a prescription for a Bile Salt is for 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.

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.

D. References

1. Cholbam [package insert]. San Diego, CA: Manchester Pharmaceuticals, Inc.; October 2020.
2. Ocaliva [package insert]. New York, NY: Intercept Pharmaceuticals, Inc; February 2022.
3. Hirschfield G, Mason A, Luketic V, et al. Efficacy of obeticholic acid in patients with primary biliary cirrhosis and inadequate response to ursodeoxycholic acid. *Gastroenterology*. 2015;148:751-761. doi: 10.1053/j.gastro.2014.12.005.

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4. Nevens F, Andreone G, Mazzella G, et al. A placebo-controlled trial of obeticholic acid in primary biliary cholangitis. *N Engl J Med*. 2016;375:631-643. doi: 10.1056/NEJMoa1509840.
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