Pennsylvania
Department of Human Services

Medical Assistance BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
November 6, 2024	January 6, 2025	*See below

SUBJECT

Prior Authorization of Hepatic and Biliary Agents (formerly Bile Salts) – Pharmacy Services

BY

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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.pa.gov/en/agencies/dhs/resources/for-providers/provider-enrollment-information/provider-enrollment-documents.html.

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 Hepatic and Biliary Agents 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 Hepatic and Biliary Agents 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 Hepatic and Biliary Agents to the appropriate managed care organization.

BACKGROUND:

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 on the Statewide Preferred Drug List (PDL).

*01-25-14	09-25-14	27-25-14	33-25-14
02-25-14	11-25-14	30-25-14	
03-25-14	14-25-14	31-25-14	
08-25-15	24-25-14	32-25-14	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

Fee-for-Service Provider Service Center: 1-800-537-8862

Visit the Office of Medical Assistance Programs website at:
https://www.pa.gov/en/agencies/dhs/departments-offices/omap-info.html

- Changes to the statuses of drugs and products on the Statewide PDL from preferred to non-preferred and non-preferred to preferred.
- Therapeutic classes of drugs and products to be added to or deleted from the Statewide PDL.
- New quantity limits.
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the September 10, 2024, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Hepatic and Biliary Agents:

- Revision of the title of the Bile Salts Statewide PDL therapeutic class to Hepatic and Biliary Agents.
- Addition of a requirement for prior authorization of and corresponding medical necessity guidelines for peroxisome proliferator-activated receptor agonist Hepatic and Biliary Agents.
- Removal of the guidelines for obeticholic acid related to ursodeoxycholic acid.

The revisions to the guidelines to determine medical necessity of prescriptions for Hepatic and Biliary Agents 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 Hepatic and Biliary Agents 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 Hepatic and Biliary Agents) 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.pa.gov/en/agencies/dhs/resources/pharmacy-services/pharmacy-prior-authorization-general-requirements.html

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/clinical-guidelines.html

I. Requirements for Prior Authorization of Hepatic and Biliary Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Hepatic and Biliary Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Hepatic and Biliary Agent. See the Preferred Drug List (PDL) for the list of preferred Hepatic and Biliary Agents at: https://papdl.com/preferred-drug-list.

2. A Hepatic and Biliary Agent 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.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html.

3. A prescription for cholic acid.

4. A prescription for obeticholic acid.

5. A prescription for a peroxisome proliferator-activated receptor (PPAR) agonist (e.g., elafibranor) Hepatic and Biliary Agent.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hepatic and Biliary Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Hepatic and Biliary Agent 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 drug; **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, **both** of the following:

    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;

    AND

6. For a PPAR agonist Hepatic and Biliary Agent, **both** of the following:

    a. Is prescribed the requested drug 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;

    AND

7. For all other non-preferred Hepatic and Biliary Agents, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Hepatic and Biliary Agents approved or medically accepted for the beneficiary's diagnosis; **AND**

8. If a prescription for a Hepatic and Biliary Agent 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 HEPATIC AND BILIARY AGENTS: The determination of medical necessity of a request for renewal of a prior authorization for a Hepatic and Biliary Agent 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 drug; **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;

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 a PPAR agonist Hepatic and Biliary Agent, **both** of the following:

   a. Is prescribed the requested drug by or in consultation with a hepatologist or gastroenterologist
   b. Has documentation of a positive response to the requested drug as evidenced by liver function tests;

   AND

6. For all other non-preferred Hepatic and Biliary Agents, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Hepatic and Biliary Agents approved or medically accepted for the beneficiary's diagnosis; **AND**

7. If a prescription for a Hepatic and Biliary Agent 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 Hepatic and Biliary Agent. 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. Iqirvo [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc. June 2024.
3. Livdelzi [package insert]. Foster City, CA: Gilead Sciences, Inc. August 2024.
4. Ocaliva [package insert]. New York, NY: Intercept Pharmaceuticals, Inc; February 2022.
5. Erlichman J, Loomes KM. Causes of cholestasis in neonates and young children. In: UpToDate [internet database]. Abrams SA, Rand EB, Hoppin AG, eds. Waltham, MA: UpToDate Inc. Updated January 19, 2022. Accessed April 21, 2022.
6. Wanders RJA. Peroxisomal disorders. In: UpToDate [internet database]. Patterson MC, Firth HV, Armsby C, eds. Waltham, MA: UpToDate Inc. Updated March 3, 2020. Accessed April 21, 2022.
7. Poupon R. Overview of the management of primary biliary cholangitis. In: UpToDate [internet database]. Lindor KD, Robson KM, eds. Waltham, MA: UpToDate Inc. Updated July 26, 2024. Accessed August 14, 2024.