

PA DEPARTMENT OF HUMAN SERVICES
MAAC BRIEFING DOCUMENT
HEPATIC AND BILIARY AGENTS

Proposed Effective Date: January 5, 2026

Revisions are noted with a ~~striketrough~~ for deletions and **bold and underline** for additions.

I. Requirements for Prior Authorization of Hepatic and Biliary Agents

A. Revisions to 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. Revisions to 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

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- 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**

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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

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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.
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