Clinical Policy: Hepatic and Biliary Agents

Reference Number: PHW.PDL.198
Effective Date: 01/01/2020
Last Review Date: 11/2024

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Hepatic and Biliary Agents are **medically necessary** when the following criteria are met:

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 prescription for a non-preferred Hepatic and Biliary Agents, regardless of the quantity prescribed.

2. A prescription for a Hepatic and Biliary Agents with a prescribed quantity that exceeds the quantity limit.

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. Clinical Review Guidelines and 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 member:

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 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 member's diagnosis;

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 medical history and lab test results that support the member's diagnosis,

6. For a PPAR agonist Hepatic and Biliary Agent, both of the following:
    a. Is prescribed the requested medication by or in consultation with a hepatologist or gastroenterologist
    b. Has documentation of a medical history and lab test results that support the member's diagnosis;

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 member's diagnosis; **AND**

8. If a prescription for a Hepatic and Biliary Agents 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 PA.CP.PMN.59 Quantity Limit Override

NOTE: If the member 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 member, the request for prior authorization will be approved.

FOR RENEWALS OF PRESCRIPITONS FOR HEPATIC AND BILIARY AGENTS:
The determination of medical necessity of requests for renewal of a prior authorization for a Hepatic and Biliary Agent that was previously approved will take into account whether the member:

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;

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 medication by or in consultation with a hepatologist or gastroenterologist
    b. Has documentation of a positive response to the requested medication as evidenced by liver function tests;
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 member'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 PA.CP.PMN.59 Quantity Limit Override.

NOTE: If the member 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 member, 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 the request for a prescription for a Hepatic and Biliary Agents. 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. **Approval Duration:**
   - **New request: 6 months**
   - **Renewal request: 12 months**

E. References:

1. Cholbam (cholic acid) Prescribing Information. Manchester Pharmaceuticals, Inc. March 2015
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; May 2021 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.

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021 annual review: no changes.	01/2021
Q1 2023: policy revised according to DHS revisions effective 01/09/2023.	10/2022
Q1 2024 annual review: no changes.	11/2023
Q1 2025: policy revised according to DHS revisions effective 01/06/2025.	11/2024