Highmark Wholecare
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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 prescription for cholic acid.

3. 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 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

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;

   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 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

5. 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;

   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

Highmark Wholecare
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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.

Highmark Wholecare
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

HEPATIC AND BILIARY AGENTS PRIOR AUTHORIZATION FORM *(form effective 1/5/2026)*

☐New request ☐Renewal request	Total pages: _____	Prescriber name:	
Name of office contact:		Specialty:	
Contact's phone number:		NPI:	State license #:
LTC facility contact/phone:		Street address:	
Beneficiary name:		City/state/zip:	
Beneficiary ID#:	DOB:	Phone:	Fax:

CLINICAL INFORMATION

Drug requested:	Strength:	
Dose/directions:	Quantity:	Refills:
Diagnosis *(submit documentation)*:	Dx code (*required*):	

Complete all sections that apply to the beneficiary and this request.
Check all that apply and submit documentation for each item.

INITIAL requests

1. For CHOLBAM (cholic acid):

☐Cholbam (cholic acid) is prescribed by or in consultation with a hepatologist or pediatric gastroenterologist
☐Medical history and lab test results support the beneficiary's diagnosis (eg, serum or urinary bile acid levels using mass spectrometry, neurologic exam)

2. For a PPAR AGONIST (e.g., Iqirvo [elafibranor], Livdelzi [seladelpar lysine]):

☐The requested drug is prescribed by or in consultation with a hepatologist or gastroenterologist
☐Medical history and lab test results support the beneficiary's diagnosis (eg, alkaline phosphatase, antimitochondrial antibodies, histologic evaluation, imaging)
☐The beneficiary tried and failed optimally titrated doses of ursodeoxycholic acid (UDCA, ursodiol)
☐The beneficiary will take the requested drug in combination with ursodeoxycholic acid (UDCA, ursodiol)
☐The beneficiary has a contraindication or history of an intolerance to ursodeoxycholic acid (UDCA, ursodiol)

3. For all other NON-PREFERRED Hepatic and Biliary Agents:

☐Tried and failed or has a contraindication or an intolerance to the preferred Hepatic and Biliary Agents *(Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.)*

Highmark Wholecare
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

RENEWAL requests

1. For CHOLBAM (cholic acid):

☐ Cholbam (cholic acid) is prescribed by or in consultation with a hepatologist or pediatric gastroenterologist
☐ The beneficiary experienced improvement in liver function within the first 3 months of treatment with Cholbam (cholic acid)
☐ The beneficiary does NOT have complete biliary obstruction, persistent clinical or lab indicators of worsening liver function, or cholestasis

2. For a PPAR AGONIST (e.g., Iqirvo [elafibranor], Livdelzi [seladelpar lysine]):

☐ The requested drug is prescribed by or in consultation with a hepatologist or gastroenterologist
☐ The beneficiary has results of recent LFTs showing a positive clinical response to the requested drug

3. For all other NON-PREFERRED Hepatic and Biliary Agents:

☐ Tried and failed or has a contraindication or an intolerance to the preferred Hepatic and Biliary Agents *(Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.)*

PLEASE FAX COMPLETED FORM WITH REQUIRED CLINICAL DOCUMENTATION

Prescriber Signature:	**Date**: