Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCGAS025.0226	**GASTROINTESTINAL AGENTS** **PRIMARY BILIARY CHOLANGITIS AGENTS** See Table 1 for Applicable Medications
Effective Date: 4/1/2026	**Review/Revised Date**: 07/16, 10/17, 09/18, 10/18, 11/19, 10/20, 07/21, 11/21, 10/22, 10/23, 10/24, 01/26 (NN)
Original Effective Date: 10/16	**P&T Committee Meeting Date**: 08/16, 12/17, 09/18,12/18, 12/19, 12/20, 08/21, 12/21, 12/22, 12/23. 10/24, 12/24, 02/26
Approved by: Oregon Region Pharmacy and Therapeutics Committee	

SCOPE:
Providence Health Plan and Providence Health Assurance as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:
Commercial
Medicaid

POLICY CRITERIA:

COVERED USES:
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

REQUIRED MEDICAL INFORMATION:
For initial authorization, all the following criteria must be met:
1. Confirmed diagnosis of primary biliary cholangitis as evidenced by two (2) of the following criteria:
    a. Elevated alkaline phosphatase (ALP) [above the upper limit of normal (ULN) as defined by laboratory reference values]
    b. Presence of antimitochondrial antibody (AMA)
    c. Histologic evidence of primary biliary cholangitis from liver biopsy
2. Both a and b must be met:
    a. Use of ursodiol for a minimum of 12 months and has had an inadequate response according to prescribing physician, unless patient is unable to tolerate ursodiol
    b. Documentation that the medication will be used in combination with ursodiol, unless patient is unable to tolerate ursodiol

For reauthorization, all the following criteria must be met:
1. Maintenance of biochemical response, defined as all the following:
    a. Alkaline phosphatase (ALP) less than or equal to 1.67 times the upper limit of normal (ULN)
    b. Total bilirubin (tBili) less than or equal to ULN

c. ALP decrease of at least 15%
2. Documentation that ursodiol will be continued, if tolerated
3. Hepatic function is assessed at least annually

EXCLUSION CRITERIA:
- Non-alcoholic steatohepatitis (NASH)
- Decompensated cirrhosis (such as Child-Pugh Class B or C) or a prior decompensated event
- Use in combination with Iqirvo or Livdelzi

AGE RESTRICTIONS: N/A

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with, a gastroenterologist or hepatologist.

COVERAGE DURATION:
Initial authorization will be approved for six months. Reauthorization will be approved for one year.

QUANTITY LIMIT:
One tablet/capsule per day

Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.

Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.

Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services.

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

INTRODUCTION:
Primary biliary cholangitis (PBC), previously called primary biliary cirrhosis, is an autoimmune disease in which the bile ducts are inflamed and slowly destroyed. The etiology of PBC is thought to be due to a combination of genetic risk factors and environmental triggers. PBC is a chronic disease that may extend over many

decades and the rate of progression varies greatly among individual patients. The major symptoms of PBC are fatigue and itching.

FDA APPROVED INDICATIONS:
Elafibranor (Iqirvo)

- Treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA. Elafibranor is not recommended in patients with decompensated cirrhosis.

Seladelpar (Livdelzi)

- Treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA

Both drugs were approved by the FDA under accelerated approval based on reduction of ALP. Improvement in survival or prevention of liver decompensation events have not been demonstrated.

POSITION STATEMENT:
Primary biliary cholangitis (PBC) is a condition where small and medium sized bile ducts of the liver are damaged. PBC is associated with progressive liver failure. A lab test for autoantibodies called antimitochondrial antibodies (AMA) is positive for 90%-95% of people with PBC and for <1% of people without the disease. If PBC progresses to liver failure complications, a liver transplantation is the treatment of choice. Common symptoms of PBC are fatigue and itching.

The diagnosis of PBC should be suspected in the setting of chronic cholestasis after exclusion of other causes of liver disease, particularly in a middle-aged female with an unexplained elevation of serum ALP. The diagnosis is largely confirmed with tests for AMA. A liver biopsy can be used to further substantiate the diagnosis but is rarely needed.

Ursodeoxycholic acid (UDCA, ursodiol)
Ursodeoxycholic acid (UDCA), at a dose of 13 to 15 mg/kg/day, is the first-line therapy for PBC based on the recommendation of the 2018 Practice Guidance from the American Association for the Study of Liver diseases (AASLD) for Primary Biliary Cholangitis. Several randomized trials, combined analyses, and long-term observational studies have shown that UDCA not only improves biochemical indices but also delays histologic progression and improves survival without transplantation. and have shown to improve overall survival in PBC. Treatment response is monitored using serum alkaline phosphatase (ALP) and total bilirubin.

Based on the practice guidelines, biochemical response should be assessed after 1 year of treatment with UDCA.

An updated guidance was released in 2021 by AASLD which recommends the use of fibrates as an off-label alternatives for patients with PBC and inadequate response to ursodeoxycholic acid, although fibrates are discouraged in patients with decompensated liver disease.

Obeticholic acid (Ocaliva)
On September 11, 2025, Intercept Pharmaceuticals announced the voluntary withdrawal of Ocaliva (obeticholic acid) from the US market due to safety concerns raised by the FDA. Following a transition period for patients to consult with their healthcare providers about other treatment options, Ocaliva was officially withdrawn from the US commercial market on November 14, 2025.

Elafibranor (Iqirvo)
The approval is based on data from the Phase 3 ELATIVE trial (NCT04526665) in 161 adults with PBC with an inadequate response or intolerance to UDCA. In the trial, the composite primary endpoint of biochemical response (alkaline phosphatase [ALP] <1.67 times upper limit of normal [ULN], total bilirubin [TB] ≤ULN, and ALP decrease ≥15% from baseline) was achieved in 51% of patients treated with elafibranor (with or without UDCA) versus 4% of patients who received placebo (with or without UDCA), for a 47% treatment difference. Secondary endpoints showed normalization in ALP levels in only elafibranor-treated patients (15% for elafibranor with or without UDCA versus 0% for placebo with or without UDCA). Most patients (95%) received study treatment (elafibranor or placebo) in combination with UDCA.

Elafibranor is dosed 80 mg orally once daily with or without food. The most common adverse reactions with elafibranor reported in ≥10% of study participants were weight gain, abdominal pain, diarrhea, nausea, and vomiting. The label for elafibranor includes warnings regarding myalgia, myopathy, and rhabdomyolysis; fractures.

Seladelpar (Livdelzi)
The efficacy of seladelpar was evaluated in a phase 3 (NCT04620733), 12-month, randomized, double-blind, placebo-controlled trial that included 193 adult patients with PBC who had an inadequate response or intolerance to UDCA. Patients with decompensated liver disease were excluded. The primary endpoint was a composite biochemical response at month 12, defined as achieving an alkaline phosphatase (ALP) level less than 1.67 times the upper limit of normal (ULN), an ALP decrease of ≥15% from baseline, and total bilirubin ≤ULN.

More patients who received seladelpar (62%) demonstrated a biochemical response versus patients who received placebo (20%). Additionally, more patients who received seladelpar achieved normal ALP levels compared with those who received placebo (25% vs. 0%). Patients who received seladelpar also experienced a greater reduction in the score on the pruritus numerical rating scale than placebo (least-squares mean change from baseline, −3.2 vs. −1.7). Seladelpar or placebo was administered in combination with UDCA in 94% of patients and as monotherapy in the 6% of patients who were unable to tolerate UDCA.

Seladelpar is dosed 10 mg orally once daily with or without food. The most common adverse reactions (reported in ≥ 5% and higher compared to placebo) are headache, abdominal pain, nausea, abdominal distension, and dizziness.

REFERENCE/RESOURCES:

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TABLE 1.

Brand Name	Generic Name
Iqirvo	elafibranor tablet
Livdelzi	seladelpar capsule