Pharmacy Medical Necessity Guidelines:
Primary Biliary Cholangitis (PBC): Iqirvo® (elafibranor), Livdelzi® (seladelpar), Ocaliva® (obeticholic acid)

Effective: May 12, 2026

Prior Authorization Required		√	Type of Review – Care Management	
Not Covered			Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit		RX	Department to Review	RXUM
	These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0988	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION (FDA)-APPROVED INDICATIONS

Iqirvo (elafibranor), a peroxisome proliferator-activated receptor (PPAR) agonist, indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as a monotherapy in adults unable to tolerate UDCA.

This indication is approved under accelerated approval based on a reduction in alkaline phosphatase (ALP). Improvement in survival or prevention of liver decompensation events have not been demonstrated. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Use of Iqirvo is not recommended in patients who have or develop decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy).

Livdelzi (seladelpar), a PPAR-delta agonist, indicated for the treatment of PBC in combination with UDCA in adults with an inadequate response to UDCA, or as a monotherapy in adults unable to tolerate UDCA.

This indication is approved under accelerated approval based on a reduction in alkaline phosphatase (ALP). Improvement in survival or prevention of liver decompensation events have not been demonstrated. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials

Use of Livdelzi is not recommended in patients who have or develop decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy).

Ocaliva (obeticholic acid), a farnesoid X receptor agonist, is indicated for the treatment of adult patients with PBC without cirrhosis or with compensated cirrhosis who do not have evidence of portal hypertension, either in combination with UDCA with an inadequate response to UDCA or as a monotherapy in patients unable to tolerate UDCA.

This indication is approved under accelerated approval based on a reduction in ALP. An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

COVERAGE GUIDELINES

The plan may authorize coverage of Iqirvo, Livdelzi, or Ocaliva for Members when **ALL** of the following criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of primary biliary cholangitis confirmed by at least two (2) of the following:
    a. Biochemical evidence of cholestasis with an elevated alkaline phosphatase level for at least a duration of six (6) months
    b. Presence of antimitochondrial antibodies (titer ≥1:80 by immunofluorescence or M2 positivity by enzyme immunoassay) or primary biliary cholangitis-specific antibodies (e.g., anti-GP210, anti-SP100)
    c. Histologic evidence of nonsuppurative destructive cholangitis and destruction of interlobular bile ducts on liver biopsy

AND

2. Patient is 18 years of age or older

AND

3. Prescribed by or in consultation with a gastroenterologist or hepatologist

AND

4. Documentation of **one (1)** of the following:
    a. The patient has had an inadequate response to at least one (1) year of therapy with ursodeoxycholic acid/ursodiol and that the requested agent will be administered in combination with ursodeoxycholic acid/ursodiol
    b. The patient is intolerant to ursodeoxycholic acid/ursodiol

Reauthorization Criteria

1. Documented diagnosis of primary biliary cholangitis

AND

2. Patient is 18 years of age or older

AND

3. Prescribed by or in consultation with a gastroenterologist or hepatologist

AND

4. Documentation of **one (1)** of the following:
    a. The patient has had an inadequate response to at last one (1) year of therapy with ursodeoxycholic acid/ursodiol and that the requested agent will be administered in combination with ursodeoxycholic acid/ursodiol
    b. The patient is intolerant to ursodeoxycholic acid/ursodiol

AND

5. Documentation the patient has experienced a therapeutic response as defined by a reduction in alkaline phosphatase of at least 15%

LIMITATIONS

- Iqirvo, Livdelzi, or Ocaliva will not be authorized for the treatment of nonalcoholic steatohepatitis.
- Initial coverage of Iqirvo, Livdelzi, or Ocaliva will be authorized for six (6) months. Reauthorization of Iqirvo, Livdelzi, or Ocaliva will be provided in 12-month intervals.
- Patients new to the plan stable on Ocaliva should be reviewed against Reauthorization Criteria.

CODES

None

REFERENCES

1. European Association for the Study of the Liver. EASL Clinical Practice Guidelines: management of cholestatic liver diseases. J Hepatol. 2009;51:237-67.
2. European Association for the Study of the Liver. EASL Clinical Practice Guidelines on sclerosing cholangitis. Clinical Practice Guidelines. J Hepatol. 2022;77(3):761-806.
3. Hirschfield GM, Mason A, Luketic V, et al. Efficacy of obeticholic acid in patients with primary biliary cirrhosis and inadequate response to ursodeoxycholic acid. Gastroenterology. 2015 Apr;148(4):751- 61.
4. Lindor KD, et al. Primary biliary cholangitis: 2021 practice guidance update from the American Association for the Study of Liver Diseases. Hepatology. 2022 Apr;75(4):1012-13.
5. Lindor KD, et al. Primary biliary cholangitis: 2018 practice guidance from the American Association for the Study of Liver Diseases. Hepatology. 2019;69(1):394-419.
6. Lindor KD, Gershwin E, Poupon R, et al. Primary biliary cirrhosis. Hepatology. 2009;50:291-308.
7. Poupon R. Primary biliary cirrhosis: A 2010 update. J Hepatol. May 2010;52(5):745-58.
8. Ocaliva (obeticholic acid) [prescribing information]. New York, NY: Intercept Pharmaceuticals, Inc.; Feb 2022.
9. Iqirvo (elafibranor) [prescribing information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; June 2024.
10. Livdelzi (seladelpar) [prescribing information]. Foster City, CA: Gilead Sciences, Inc.; August 2024.

APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- August 8, 2023: No changes
- July 9, 2024: No changes (eff 7/9/24)
- February 11, 2025: No changes. Updated title of the Medical Necessity Guideline from Ocaliva (obeticholic acid) to Primary Biliary Cholangitis: Iqirvo (elafibranor), Livdelzi (seladelpar), and Ocaliva (obeticholic acid)." Added Iqirvo (elafibranor) and Livdelzi (seladelpar) to the Medical Necessity Guideline (eff 3/1/25).
- May 12, 2026: No changes (eff 5/12/26).

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services