MEDICATION POLICY:
Primary Biliary Cholangitis Agents

Applicable Drugs: Iqirvo (elafibranor), Livdelzi (seladelpar), Ocaliva (obeticholic acid)

Preferred: N/A

Non-preferred: N/A

VSI-Excluded Drugs: Iqirvo, Ocaliva, Livdelzi

Date of Origin: 11/18/2024

Date Last Reviewed / Revised: 12/12/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

I. Documented diagnosis of Primary Biliary Cholangitis (PBC) AND meets ALL criteria A through E:
   A. Diagnosis of PBC confirmed by two of three features:
      i. Biochemical evidence of cholestasis based on alkaline phosphatase (ALP) elevation (as defined by the performing laboratory's reference values).
      ii. Presence of antimitochondrial antibodies (AMA), or other PBC-specific autoantibodies, including sp100 or gp210, if AMA is negative.
      iii. Histologic evidence of PBC (e.g., nonsuppurative destructive cholangitis and destruction of interlobular bile ducts) seen on biopsy.
   B. Minimum age requirement: 18 years old
   C. Documented trial and failure, or contraindication to, treatment with ursodiol at a dose of 13-15 mg/kg/day for at least 12 months.
   D. ALP levels are at least 1.67 times the upper limit of normal (i.e. greater than 174 U/L for women and 215 U/L for men).
   E. Total bilirubin level no more than 2 times the upper limit of normal (ULN) (e.g, less than 41 µmol/L).

II. Treatment must be prescribed by or in consultation with a hepatologist or gastroenterologist.

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

IV. Refer to plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Use of more than one agent from this policy concomitantly
- Previous or planned liver transplantation

- Hepatitis B or C virus infection
- Alcohol-related liver disease
- Autoimmune hepatitis
- Complete biliary obstruction
- Primary biliary cirrhosis-autoimmune hepatitis overlap
- Evidence of clinically significant hepatic decompensation (such as esophageal varices, poorly controlled ascites, hepatic encephalopathy, coagulopathy, etc.)

OTHER CRITERIA

- Obeticholic acid (Ocaliva) is contraindicated in PBC patients with decompensated cirrhosis, a prior decompensation event, or with compensated cirrhosis who have evidence of portal hypertension.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Iqirvo, Livdelzi, Ocaliva: 30 tablets per 30 days
- Iqirvo: 80 mg tablets
- Livdelzi: 10 mg capsules
- Ocaliva: 5 mg and 10 mg tablets
- Refer to Table 1 for FDA-approved dosing regimen

APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** 12 months, with documented clinically significant improvement (such as a reduction of ALP level to less than 1.67x ULN, with at least a 15% reduction from baseline, and normal total bilirubin levels).

APPENDIX

Table 1: FDA-Approved Dosing Regimen

Medication	Dosing Regimen
Iqirvo	80 mg orally once daily
Livdelzi	10 mg once daily
Ocaliva	Start with 5 mg once daily for the first 3 months. If after 3 months the patient has not achieved an adequate reduction in ALP and/or total bilirubin and is tolerating therapy, increase to 10 mg once daily.

REFERENCES

1. Iqirvo. Prescribing information. Ipsen Pharmaceuticals, Inc; 2024. Accessed 12/12/2025 . https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/218860s000lbl.pdf
2. Livdelzi Prescribing information. Gilead Sciences, Inc; 2024. Accessed 12/12/25. https://www.gilead.com/-/media/files/pdfs/medicines/pbc/livdelzi/livdelzi_pi.pdf
3. Ocaliva Prescribing information. Intercept Pharmaceuticals, Inc; 2022. Accessed 12/12/25. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/207999s008lbl.pdf
4. Lindor KD, Bowlus CL, Boyer J, Levy C, Mayo M. Primary biliary cholangitis: 2018 practice guidance from the American Association for the Study of Liver Diseases. Hepatology. 2019;69(1):394-419. doi:10.1002/hep.30145
5. Lindor KD, Bowlus CL, Boyer J, Levy C, Mayo M. Primary biliary cholangitis: 2021 practice guidance update from the American Association for the Study of Liver Diseases. Hepatology. 2022;75(4):1012-1013. doi:10.1002/hep.32117

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.