New Hampshire Medicaid Fee-for-Service Program
Primary Biliary Cholangitis Criteria

Approval Date: November 21, 2024

Medications

Brand Names	Generic Names	Indication
Iqirvo®	**elafibranor**	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
Livdelzi®	**seladelpar**	Treatment of PBC in combination with UDCA in adults who have an inadequate response to UDCA or as monotherapy in patients unable to tolerate UDCA
Ocaliva®	**obeticholic acid**	Treatment of PBC in patients without cirrhosis or compensated cirrhosis without evidence of portal hypertension in combination with UDCA in adults who have an inadequate response to UDCA or as monotherapy in patients unable to tolerate UDCA

Criteria for Approval

1. Patient is 18 years of age or older; **AND**
2. Prescribed by or in consultation with a gastroenterologist or hepatologist; **AND**
3. The patient has a diagnosis of primary biliary cholangitis (PBC) confirmed by at least 2 of the following:
   - Biochemical evidence of cholestasis with an alkaline phosphatase (ALP) elevation
   - Presence of antimitochondrial antibody (AMA) titer > 1:80
   - If AMA is negative or present only in low titer (≤ 1:80), presence of other PBC-specific autoantibodies, including sp100 or gp210
   - Histologic evidence of nonsuppurative destruction cholangitis and destruction of interlobular bile ducts; **AND**
4. Baseline ALP level and total bilirubin level have been measured; **AND**
5. The patient has **one** of the following:
   - Patient has had an inadequate response to treatment with UDCA after 1 year of therapy (ALP > normal and/or total bilirubin greater than the upper limit of normal (ULN) but less 2 times ULN) and the treatment plan includes continued UDCA with the requested drug.
   - Patient has an intolerance or hypersensitivity to UDCA

- Patient has an FDA-labeled contraindication to UDCA; **AND**

6. Patient does not have decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy); **AND**
7. Patient does **not** have complete biliary obstruction; **AND**
8. Prescriber attests that patient will be appropriately monitored according to the product label and monitored for adverse reactions or changes in efficacy with certain concurrently administered drugs as detailed in the prescribing information.

Initial approval period: 12 months

Criteria for Renewal

1. Patient must continue to meet the above criteria; **AND**
2. Patient must demonstrate a biochemical response (e.g., ALP < 1.67 times ULN, with a reduction of ≥ 15% from baseline; total bilirubin levels ≤ ULN); **AND**
3. Patient has not experienced any treatment-restricting adverse effects (e.g., new onset or worsening muscle pain, or myopathy, or rhabdomyolysis; worsening of liver tests [e.g., alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, and/or ALP], or signs and symptoms of clinical hepatitis [e.g., jaundice, upper right quadrant pain, eosinophilia]; severe hypersensitivity reactions, biliary obstruction, and/or severe pruritis).

Renewal period: 12 months

Criteria for Denial

1. Failure to meet approval criteria.

References

Available upon request.

Revision History

Reviewed by	Reason for Review	Date Approved
DUR Board	New	10/15/2024
Commissioner designee	Approval	11/21/2024