Effective Date: 02/01/2025
Reviewed: 11/2024 Scope: Medicaid

Primary Biliary Cholangitis (PBC)

IQIRVO (elafibranor)
LIVDELZI (seladelpar)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Iqirvo

Iqirvo is indicated for the 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.

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 trial(s).

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

Livdelzi

Livdelzi is indicated for the 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.

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 trial(s).

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

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Primary biliary cholangitis (PBC) (previously known as primary biliary cirrhosis)
Authorization of 6 months may be granted for treatment of PBC in adult members when all of the following criteria are met:

A. Member is 18 years of age or older
B. Documentation that diagnosis of PBC is confirmed by at least two of the following criteria:
    1. Biochemical evidence of cholestasis with elevation of alkaline phosphatase (ALP) level for at least 6 months duration.
    2. Presence of antimitochondrial antibodies (AMA) (titer >1:40 by immunofluorescence or immunoenzymatic reactivity) or PBC-specific antinuclear antibodies (ANA) (e.g., anti-gp210, anti-sp100).
    3. Histologic evidence of PBC on liver biopsy (e.g., non-suppurative inflammation and destruction of interlobular and septal bile ducts).
C. Documentation that member has an elevated serum ALP level prior to initiation of therapy with the requested drug.
D. This medication must be prescribed by or in consultation with a hepatologist or gastroenterologist.
E. Member does not have decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy).
F. Documentation that member meets either of the following criteria:
    1. Member has had an inadequate response to at least 12 months of prior therapy with ursodeoxycholic acid (UDCA)/ursodiol at the recommended dose of 13-15 mg/kg/day and the member will continue concomitant therapy with UDCA/ursodiol.
    2. Member has an intolerance to UDCA/ursodiol.
G. Member will not be using Iqirvo, Livdelzi and/or Ocaliva concomitantly.

III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for members requesting continuation of therapy when all of the following criteria are met:

A. Documentation that members have achieved or maintained a clinical benefit from Iqirvo or Livdelzi therapy as evidenced by any of the following with an ALP level within the last 6 months:
    1. At least a 15% reduction in serum ALP level
    2. Serum ALP level less than 1.67 times upper limit of normal (ULN)
    3. Nomalization of ALP
B. This medication must be prescribed by or in consultation with a hepatologist or gastroenterologist.
C. Member has not developed decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy).
D. Member will not be using Iqirvo, Livdelzi and/or Ocaliva concomitantly.

IV. REFERENCES

1. Iqirvo [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; June 2024.
2. Livdelzi [package insert]. Foster City, CA: Gilead Sciences, Inc.; August 2024.
3. Lindor KD, Bowlus CL, Boyer J, et al. Primary biliary cholangitis: 2018 Practice guidance from the American Association for the study of liver diseases. *Hepatology.* 2019;69(1):394-419.

4. European Association for the Study of the Liver. EASL clinical practice guidelines: The diagnosis and management of patients with primary biliary cholangitis. *J Hepatol.* 2017;67(1):145-172.