Effective Date: 11/01/2026
Reviewed: 8/2026 Scope: Medicaid

Lynavoy (linerixibat)

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
Lynavoy is indicated for the treatment of cholestatic pruritus associated with primary biliary cholangitis (PBC) in adult patients.

Limitations of use: Avoid use of Lynavoy in patients with decompensated cirrhosis or those with prior or active hepatic decompensated events (e.g., variceal hemorrhage, ascites, hepatic encephalopathy).

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

II. CRITERIA FOR INITIAL APPROVAL

Cholestatic Pruritus in Primary Biliary Cholangitis (PBC)
Authorization of 6 months may be granted for treatment of cholestatic pruritus in 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. This medication must be prescribed by or in consultation with a hepatologist or gastroenterologist.
D. Member does not have decompensated cirrhosis or prior or active hepatic decompensated events (e.g., variceal hemorrhage, ascites, hepatic encephalopathy).
E. Member has been evaluated for any other concomitant liver disease (e.g., chronic viral hepatitis, alcoholic liver disease, liver cancer).
F. Documentation that member has moderate to severe pruritus associated with PBC impacting daily life and sleep
G. Documentation that member experienced an inadequate treatment response to one of the following:
    a. Cholestyramine/colestipol 4 g/dose up to 16 g/day
    b. Naltrexone 50 mg daily
    c. Rifampin 150 mg to 300 mg twice daily
    d. Sertraline 75 mg to 100 mg once daily

Contraindications, adverse effects and/or intolerance must be documented.

H. Documentation of serum ALP level prior to initiation of therapy with the requested drug.
I. If member has documented elevated serum ALP level, documentation that member experienced an inadequate treatment response to Livdelzi. Contraindications, adverse effects and/or intolerance must be documented.
J. If the request is for Lynavoy to be used in combination with Iqirvo (elafibranor) or Livdelzi (seladelpar) to treat PBC, the member has a documented inadequate response, intolerance, or contraindication to monotherapy Livdelzi for the treatment of PBC and cholestatic pruritus associated with PBC.
K. Member will not be using Lynavoy concomitantly with any other ileal bile acid transporter (IBAT) inhibitor [e.g., Bylvay (odevixibat), Livmarli (maralixibat)].

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. If member has not been approved for this drug by Neighborhood in the past, clinician must submit documentation that initial criteria is met.
B. Documentation that member has achieved or maintained a clinical benefit from Lynavoy (e.g., improvement in pruritus).
C. This medication must be prescribed by or in consultation with a hepatologist or gastroenterologist.
D. Member has not developed decompensated cirrhosis or experienced a hepatic decompensated event (e.g., variceal hemorrhage, ascites, hepatic encephalopathy).
E. If the request is for Lynavoy to be used in combination with Iqirvo (elafibranor) or Livdelzi (seladelpar) to treat PBC, the member has a documented inadequate response, intolerance, or contraindication to monotherapy Livdelzi for the treatment of PBC and cholestatic pruritus associated with PBC.
F. Member will not be using Lynavoy concomitantly with any other ileal bile acid transporter (IBAT) inhibitor [e.g., Bylvay (odevixibat), Livmarli (maralixibat)].

IV. QUANTITY LIMIT

Lynavoy 40mg tablets have a quantity limit of 2 tablets per day.

V. REFERENCES

1. Lynavoy [package insert]. Durham, NC: GlaxoSmithKline; March 2026.
2. 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.
3. 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.