

Clinical Policy: Linerixibat (Lynavoy)

Reference Number: PA.CP.PHAR.784

Effective Date: 08/2026

Last Review Date: 07/2026

Description

Linerixibat (Lynavoy™) is an ileal bile acid transporter (IBAT) inhibitor.

FDA Approved Indication(s)

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

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

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Lynavoy is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Cholestatic Pruritus (must meet all):

1. Diagnosis of cholestatic pruritus associated with PBC;
2. Prescribed by or in consultation with a hepatologist or gastroenterologist;
3. Age $\geq$ 18 years;
4. Failure of cholestyramine at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Lynavoy is not prescribed concurrently with other IBAT inhibitors (e.g., Livmarli®, Bylvay®);
6. Dose does not exceed 80 mg (2 tablets) per day.

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Cholestatic Pruritus (must meet all):

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy;

3. Lynavoy is not prescribed concurrently with other IBAT inhibitors (e.g., Livmarli, Bylvay);
4. If request is for a dose increase, new dose does not exceed 80 mg (2 tablets) per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ALP: alkaline phosphatase

AMA: anti-mitochondrial antibodies

FDA: Food and Drug Administration

IBAT: ileal bile acid transporter

PBC: primary biliary cholangitis

UDCA: ursodeoxycholic acid

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
cholestyramine	4 g to 8 g PO BID	24 g/day

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

None reported

Appendix D: General Information

- A diagnosis of PBC can be established when two of the following three criteria are met:
 - ALP is elevated above the upper limit of normal as defined by normal laboratory references values;
 - Positive anti-mitochondrial antibodies (AMA) or other PBC-specific auto-antibodies, including sp100 or gp210, if AMA is negative;
 - Histologic evidence of PBC from a liver biopsy.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Cholestatic pruritus associated with PBC	40 mg PO BID	80 mg/day

VI. Product Availability

Tablet: 40 mg

VII. References

1. Lynavoy Prescribing Information. Durham, NC: GlaxoSmithKline; March 2026. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/220295Orig1s000lbl.pdf. Accessed March 25, 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 Jan;69(1):394-419. doi: 10.1002/hep.30145.
3. Lindor KD, Bowlus CL, Boyer J, et al. Primary biliary cholangitis: 2021 practice guidance update from the American Association for the study of liver diseases. Hepatology. 2022 April;75(4):1012-1013.
4. European Association for the Study of the Liver (EASL). EASL clinical practice guidelines: the diagnosis and management of patients with primary biliary cholangitis. J Hepatology. 2017;67:145-72.

Reviews, Revisions, and Approvals	Date
Policy created	07/2026