

**Clinical Policy: Linerixibat (Lynavoy)**

Reference Number: CP.PHAR.784

Effective Date: 09.01.26

Last Review Date: 08.26

Line of Business: Commercial, HIM/ICHRA, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

**Description**

Linerixibat (Lynavoy<sup>™</sup>) 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 health plans affiliated with Centene Corporation<sup>®</sup> 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 ≥ 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<sup>®</sup>, Bylvay<sup>®</sup>);
6. Dose does not exceed 80 mg (2 tablets) per day.

**Approval duration: 12 months**

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of

- business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
- b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

## II. Continued Therapy

### A. Cholestatic Pruritus (must meet all):

1. Member meets one of the following (a or b):
  - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
  - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

### 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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid or evidence of coverage documents.

### IV. Appendices/General Information

#### *Appendix A: Abbreviation/Acronym Key*

|                                    |                                   |
|------------------------------------|-----------------------------------|
| ALP: alkaline phosphatase          | IBAT: ileal bile acid transporter |
| AMA: anti-mitochondrial antibodies | PBC: primary biliary cholangitis  |
| FDA: Food and Drug Administration  | 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/<br>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/2026/220295Orig1s0001bl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/220295Orig1s0001bl.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     | P&T Approval Date |
|-----------------------------------|----------|-------------------|
| Policy created                    | 03.25.26 | 08.26             |

### **Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to

recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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