

# Specialty Guideline Management

## Lynavoy

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Lynavoy	linerixibat

### 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 Indications<sup>1</sup>

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 decompensation events (e.g., variceal hemorrhage, ascites, hepatic encephalopathy).

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

### Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Reference number(s)
7424-A

- Initial requests: Chart notes, medical record documentation, or laboratory results confirming diagnosis.
- Continuation requests: Chart notes or medical record documentation showing benefit from therapy (e.g., improvement in pruritus).

## Exclusions

Coverage will not be provided for members with decompensated cirrhosis or those with prior or active hepatic decompensation events (e.g., variceal hemorrhage, ascites, hepatic encephalopathy).

## Prescriber Specialties

This medication must be prescribed by or in consultation with a hepatologist or gastroenterologist.

## Coverage Criteria

### Cholestatic Pruritus in Primary Biliary Cholangitis (PBC)<sup>1-3</sup>

Authorization of 12 months may be granted for treatment of cholestatic pruritus in PBC in adult members when all of the following criteria are met:

- Diagnosis of PBC is confirmed by at least two of the following criteria:
  - Biochemical evidence of cholestasis with elevation of alkaline phosphatase (ALP) level for at least 6 months duration.
  - Presence of antimitochondrial antibodies (AMA) or PBC-specific antinuclear antibodies (ANA) (e.g., anti-gp210, anti-sp100).
  - Histologic evidence of PBC on liver biopsy (e.g., non-suppurative inflammation and destruction of interlobular and septal bile ducts).
- Member has been evaluated for any other concomitant liver disease (e.g., chronic viral hepatitis, alcoholic liver disease, liver cancer).

## Continuation of Therapy

Authorization of 12 months may be granted for all members (including new members) requesting continuation of therapy when the member is experiencing benefit from therapy (e.g., improvement in pruritus).

Reference number(s)
7424-A

## Other

The requested medication will not be used concomitantly with any other ileal bile acid transporter (IBAT) inhibitor (e.g., Bylvay, Livmarli).

## References

1. Lynavoy [package insert]. Durham, NC: GlaxoSmithKline; March 2026.
2. Lindor KD, Bowlus CL, Boyer J, Levy C, Mayo M. Primary biliary cholangitis: 2018 Practice guidance from the American Association for the Study of Liver Diseases. *Hepatology*. 2019;69(1):394-419. doi: 10.1002/hep.30145.
3. European Association for the Study of the Liver (EASL). EASL clinical practice guidelines: The diagnosis and management of patients with primary biliary cholangitis. *J Hepatol*. 2017;67(1):145-172. doi: 10.1016/j.jhep.2017.03.022.