UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 2421-1
Program	Prior Authorization/Medical Necessity
Medication	Lynavoy (linerixibat)
P&T Approval Date	5/2026
Effective Date	8/1/2026

1. Background:

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

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Lynavoy** will be approved based on **all** of the following criteria:

   a. Diagnosis of primary biliary cholangitis (PBC)

   -AND-

   b. Patient is experiencing moderate-to-severe pruritis associated with PBC (e.g., pruritis causing sleep disruption, fatigue, or impaired quality of life)

   -AND-

   c. Patient has had an inadequate response to at least two other conventional treatments for the symptomatic relief of pruritus (e.g., cholestyramine, rifampin, naltrexone, and sertraline).

   -AND-

   d. Patient does not have any of the following:

      (1) Decompensated cirrhosis
      (2) Prior or active hepatic decompensation events (e.g. variceal hemorrhage, ascites, hepatic encephalopathy)

   -AND-

   e. Prescribed by a gastroenterologist or hepatologist

Initial authorization will be issued for 12 months

B. Reauthorization

1. **Lynavoy** will be approved based on **all** the following criteria:

   a. Documentation of positive clinical response to Lynavoy therapy (e.g., improved pruritis, less sleep disturbance)

   -AND-

   b. Patient does not have any of the following:
      (1) Decompensated cirrhosis
      (2) Prior or active hepatic decompensation events (e.g. variceal hemorrhage, ascites, hepatic encephalopathy)

   -AND-

   c. Prescribed by a gastroenterologist or hepatologist

Reauthorization will be issued for 12 months

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Supply limits may be in place.
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References:

1. Livdelzi [package insert]. Foster City, CA: Gilead Sciences, Inc.; October 2025.
2. Hirschfield GM, Bowlus CL, Jones DEJ, et al. Linerixibat in patients with primary biliary cholangitis and cholestatic pruritus (GLISTEN): a randomised, multicentre, double-blind, placebo-controlled, phase 3 trial. Lancet Gastroenterol Hepatol. 2026;11(1):22-33.
3. 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.
4. Lindor KD, Bowlus CL, Boyer J, Levy C, Mayo M. Primary biliary cholangitis: 2021 practice guidance update from the American Association for the Study of Liver Diseases. *Hepatology*. 2022;75(4):1012-1013.

Program	Prior Authorization/Medical Necessity – Lynavoy (linerixibat)
Change Control	
Date	Change
5/2026	New program.