PRIOR AUTHORIZATION POLICY

POLICY: Hepatology – Lynavoy Prior Authorization Policy
- Lynavoy™ (linerixibat tablets – GlaxoSmithKline)

REVIEW DATE: 04/15/2026

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Lynavoy, an ileal bile acid transporter (IBAT) inhibitor, is indicated for the treatment of **cholestatic pruritus associated with primary biliary cholangitis (PBC)** in adults.[1]

Limitation of use: Avoid Lynavoy in patients with decompensated cirrhosis or those with prior or active hepatic decompensation events (e.g., variceal hemorrhage, ascites, hepatic encephalopathy).[1]

Guidelines

The American Association for the Study of Liver Diseases (AASLD) guidelines for primary biliary cholangitis (2018) state that the diagnosis can be confirmed when patients meet two of the following criteria: 1) there is cholestasis as evidenced by alkaline phosphatase elevation; 2) anti-mitochondrial antibodies are present, or if negative for anti-mitochondrial antibodies, other primary biliary cholangitis-specific

autoantibodies, including sp100 or gp210, are present; 3) there is histologic evidence of nonsuppurative destructive cholangitis and destruction of interlobular bile ducts. It is specifically noted that diagnosis in a patient who is negative for anti-mitochondrial antibodies does not require a liver biopsy if other diagnostic criteria are met.[2] Treatment with UDCA (available in the US as ursodiol) is the recommended treatment for patients with PBC who have abnormal liver enzyme values regardless of histologic stage. Although UDCA is the standard of care, it is not effective for the most prominent symptoms of PBC, which are pruritus and fatigue. Fatigue can affect up to 80% of patients and pruritus can affect up to 70% of patients. Guidelines from the AASLD recommend anion-exchange resins (e.g., cholestyramine, colesevelam, colestipol) as first-line therapy for managing cholestatic pruritus. In patients with pruritus refractory to first-line therapy, rifampicin is recommended as second-line therapy, followed by naltrexone and then sertraline.

Safety

The safety and efficacy of Lynavoy in patients with moderate to severe hepatic impairment (Child-Pugh B or C) with decompensated cirrhosis or those with decompensation events have not been established.[1] Use of Lynavoy should be avoided.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Lynavoy. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Lynavoy as well as the monitoring required for adverse events and long-term efficacy, approval requires Lynavoy to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Lynavoy™ (linerixibat tablets – GlaxoSmithKline) is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Cholestatic Pruritus Associated with Primary Biliary Cholangitis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   Note: Primary Biliary Cholangitis is also known as Primary Biliary Cirrhosis.
   A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, v, vi and vii):
      i. Patient is ≥ 18 years of age; AND
      ii. Patient has a diagnosis of primary biliary cholangitis as defined by TWO of the following (a, b, or c):

a) Alkaline phosphatase is elevated above the upper limit of normal as defined by normal laboratory reference values; OR

b) Positive anti-mitochondrial antibodies or other primary biliary cholangitis-specific auto-antibodies, including sp100 or gp210, if anti-mitochondrial antibodies are negative; OR

c) Histologic evidence of primary biliary cholangitis from a liver biopsy; AND

iii. According to the prescriber, the patient is receiving ursodiol therapy, unless intolerant; AND

iv. According to the prescriber, the patients has moderate to severe pruritus; AND

v. Patient has tried at least one systemic medication for cholestatic pruritus, unless contraindicated; AND
Note: Systemic medications for cholestatic pruritus include cholestyramine, rifampicin, naltrexone, sertraline, and fenofibrate.

vi. Patient does not currently have, or have a history of, a hepatic decompensation event; AND
Note: Examples of hepatic decompensation include ascites, gastroesophageal varices, variceal bleeding, hepatic encephalopathy, and coagulopathy.

vii. The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician; OR

B) Patient is Currently Receiving Therapy. Approve for 1 year if the patient meets BOTH of the following (i and ii):

i. Patient does not currently have, or have a history of, a hepatic decompensation event; AND
Note: Examples of hepatic decompensation include ascites, gastroesophageal varices, variceal bleeding, hepatic encephalopathy, and coagulopathy.

ii. According to the prescriber, the patient has demonstrated a response to therapy.
Note: Examples of a response to therapy include decrease in pruritus, reduced pruritus-related sleep interference, and improved biochemical markers of primary biliary cholangitis (e.g., alkaline phosphatase [ALP], bilirubin).

CONDITIONS NOT COVERED

Lynavoy™ (linerixibat tablets – GlaxoSmithKline) is(are) considered not medically necessary for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Concomitant use with Iqirvo (elafibranor tablets) or Livdelzi (seladelpar capsules)**. There are no data available to support the use of Lynavoy in combination with Iqirvo or Livdelzi in patients with PBC.

REFERENCES

1. Lynavoy™ tablets [prescribing information]. 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 (AASLD). *Hepatology*. 2019;69(1):394-419.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	04/15/2026