SENTARA HEALTH PLANS

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-800-750-9692**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Lynavoy® (linerixibat)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

Recommended Dosing: Oral: 40 mg twice daily.

Quantity Limit: 2 tablets per day

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

- ❑ Member is 18 years of age or older
- ❑ Prescribed by or in consultation with a hepatologist, gastroenterologist or liver transplant specialist

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- ❑ Member must have a confirmed diagnosis of Primary Biliary Cholangitis (PBC) with documentation of at least **TWO** of the following **(must submit medical chart notes and diagnostics/lab test results for documentation)**:
  - ❑ Alkaline phosphatase is elevated above the upper limit of normal as defined by normal laboratory reference values
  - ❑ Anti-mitochondrial antibodies (AMA) titer of 1:40 or higher or a level that is above the laboratory upper limit of normal range, or other primary biliary cholangitis-specific auto-antibodies, including sp100 or gp210, if AMA is negative
  - ❑ Histologic evidence of primary biliary cholangitis from a liver biopsy (i.e., nonsuppurative destructive cholangitis and destruction of interlobular bile ducts)
- ❑ Member is currently established on therapy with ursodiol **(must be documented in pharmacy claims and/or medical chart notes)**
- ❑ Member has had trial and failure of bile acid resins (i.e., cholestyramine, colesevelam, colestipol) **AND** at least **TWO** of the following therapies for treatment of cholestatic pruritus **(must submit documentation of therapy failures)**:
  - ❑ rifampicin
  - ❑ naltrexone
  - ❑ sertraline
  - ❑ fenofibrate
  - ❑ Livdelzi* (*requires prior authorization)
- ❑ Member has moderate to severe cholestatic pruritus with a current Worst Itch Numerical Rating Scale [WI-NRS] score of ≥ 4 **(must submit baseline WI-NRS assessment with score)**
- ❑ Provider attests that baseline liver tests (e.g., alanine aminotransferase [ALT] and aspartate aminotransferase [AST], total bilirubin) will be obtained prior to starting Lynavoy and levels will be monitored per standard clinical practice
- ❑ Member does **NOT** have decompensated cirrhosis or prior or active hepatic decompensation events (e.g. variceal hemorrhage, ascites, hepatic encephalopathy)
- ❑ Member will **NOT** use any of the following concomitantly while taking the prescribed medication: Iqirvo® (elafibranor), Livdelzi® (seladelpar), Bylvay® (odevixibat) or Livmarli® (maralixibat)

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member continues to meet diagnostic criteria for PBC in initial authorization section above

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- ❑ Member has a documented positive response to therapy as evidenced by **ONE** of the following **(please provide current supporting test results)**
  - ❑ Improvement in Worst Itch Numerical Rating Scale [WI-NRS] score from baseline **(must submit current WI-NRS assessment with score)**
  - ❑ Stabilization of score below baseline level **(must submit current WI-NRS assessment with score)**
- ❑ Member is currently established on therapy with ursodiol **(must be documented in pharmacy claims and/or medical chart notes)**
- ❑ Member does **NOT** have decompensated cirrhosis or prior or active hepatic decompensation events (e.g. variceal hemorrhage, ascites, hepatic encephalopathy)
- ❑ Member will **NOT** use any of the following concomitantly while taking the prescribed medication: Iqirvo® (elafibranor), Livdelzi® (seladelpar), Bylvay® (odevixibat) or Livmarli® (maralixibat)

Medication being provided by Specialty Pharmacy – Proprium Rx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.****

*Previous therapies will be verified through pharmacy paid claims or submitted chart notes.**

***Approved by Pharmacy and Therapeutics Committee**: 7/23/2026
REVISED/UPDATED/REFORMATTED: 8/28/2026