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.**

Primary Biliary Cholangitis (PBC) Drugs

Drug Requested: select one drug below

❑ **Iqirvo®** (elafibranor)	❑ **Livdelzi®** (seladelpar)	❑ **Ocaliva®** (obeticholic acid)

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 and Quantity Limits:

- Iqirvo® - 1 tablet (80 mg) once daily
- Livdelzi® - 1 capsule (10 mg) once daily
- Ocaliva® - Initial: 1 tablet (5 mg) once daily; if an adequate reduction in alkaline phosphatase and/or total bilirubin has not been achieved after 3 months, increase to 1 tablet (10 mg) once daily (maximum: 10 mg/day)

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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
- ❑ Medication is prescribed by or in consultation with a hepatologist or gastroenterologist
- ❑ Member must have a confirmed diagnosis of Primary Biliary Cholangitis (PBC) with documentation of at least **ONE** of the following **(must submit medical chart notes and lab test results for documentation):**
  - ❑ 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 has taken UDCA (ursodiol tablets or capsules) for at least 12 months consecutively with insufficient response to therapy and will continue taking UDCA, or has had life-threatening or clinically significant adverse reaction to UDCA **(must submit documentation of therapy failure or intolerance)**
- ❑ Baseline alkaline phosphatase (ALP) level is ≥ 1.67 times the upper limit of normal despite compliance with UDCA treatment for 12 months (if tolerated) or without UDCA if not tolerated **(must submit test results from within the last 60 days)**
- ❑ Baseline total bilirubin level must be submitted **(must submit test results from within the last 60 days)**
- ❑ Member will **NOT** use any of the following concomitantly while taking the prescribed medication: Iqirvo® (elafibranor), Livdelzi® (seladelpar), Ocaliva® (obeticholic acid), Bylvay® (odevixibat) or Livmarli® (maralixibat)
- ❑ Member does **NOT** have any of the following: complete biliary obstruction, decompensated cirrhosis (e.g., evidence of portal hypertension, ascites, variceal bleeding, hepatic encephalopathy), autoimmune hepatitis, primary sclerosing cholangitis, alcoholic liver disease, or non-alcoholic steatohepatitis
- ❑ Member has **NOT** received a liver transplant

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 **ALL** initial authorization criteria
- ❑ Member continues to take ursodeoxycholic acid (UDCA) in combination with the requested medication unless member has had life-threatening or clinically significant adverse reaction to UDCA **(must submit documentation of therapy failure or intolerance)**

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- ❑ Member has experienced a decrease in ALP level of at least 15% as compared to pre-treatment level **(must submit current lab test results)**
- ❑ Member has experienced a normalization of total bilirubin levels **(must submit current lab test results)**
- ❑ Member has experienced disease response to treatment defined by improved or stabilized clinical signs/symptoms of PBC

Medication being provided by Specialty Pharmacy – Proprium Rx

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.*