

AvMed

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 1-305-671-0200.** 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

<input type="checkbox"/> Iqirvo [®] (elafibranor)	<input type="checkbox"/> Livdelzi [®] (seladelpar)	<input type="checkbox"/> Ocaliva [®] (obeticholic acid)
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MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ 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**)

- 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.****