

# Elafibranor (IQIRVO) in Primary Biliary Cholangitis

## Criteria for Use

### November 2024

VA Pharmacy Benefits Management Services and National Formulary Committee

*The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.*

The Product Information should be consulted for detailed prescribing information.

#### Exclusion Criteria

If ANY of the following are selected, the patient will NOT meet criteria for elafibranor.

- Decompensated cirrhosis (e.g., Child-Pugh Class B or C) or a prior decompensation event, including hepatorenal syndrome, MELD  $\geq$  12, hepatocellular carcinoma, hepatic encephalopathy, international normalized ratio (INR)  $>$  1.3, platelet count  $<$  150. <sup>1</sup>
- Compensated cirrhosis with evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia)
- Complete biliary obstruction
- Severely advanced primary biliary cholangitis (PBC) defined as total bilirubin greater than upper limit of normal (ULN) and albumin less than the lower limit of normal
- Alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST)  $>$  5 times the ULN
- Creatine phosphokinase (CPK)  $>$  2 times the ULN
- Other chronic liver conditions, such as primary sclerosing cholangitis, autoimmune hepatitis, metabolic dysfunction-associated steatohepatitis (MASH), and alpha-1 antitrypsin deficiency
- Myopathy or rhabdomyolysis
- Pregnancy
- Lactating

#### Inclusion Criteria

All of the following criteria must be selected to meet criteria.

- Prescribed and monitored by a VA or VA Community Care hepatologist or locally designated expert in primary biliary cholangitis (PBC)
- Documented diagnosis of PBC without cirrhosis or PBC with compensated cirrhosis and no evidence of portal hypertension
- Tried ursodiol monotherapy (unless medically inadvisable) and had intolerance or inadequate response after 12 months (stable dose for at least 3 months at 13 to 15 mg/kg/day)

#### Additional Inclusion Criteria: Select if applicable

- Pregnancy has been excluded prior to receiving elafibranor
- For patients who can become pregnant: Counseling provided on potential risks vs benefits of treatment.
- Counseling provided on the use of effective non-hormonal contraception or addition of a barrier method to hormonal contraceptives during therapy and for 3 weeks after the last dose

#### Other Justification

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#### Footnotes

1 MELD: Model for End-stage Liver Disease

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Prepared: November 2024.

Contact: Francine Goodman, PharmD, BCPS, National Program Manager, VA Pharmacy Benefits Management Services – Formulary Management (12PBM)

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