Seladelpar capsule (LIVDELZI) in Primary Biliary Cholangitis
Criteria for Use
January 2025

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 seladelpar.

- ☐ Decompensated cirrhosis (e.g., Child-Pugh Class B or C) or a prior decompensation event, including hepatorenal syndrome, MELD ≥ 12, hepatocellular carcinoma, hepatic encephalopathy, international normalized ratio (INR) > 1.3, platelet count < 150 x 10^3/microL. ^1
- ☐ 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) > 3 times ULN
- ☐ Other chronic liver conditions, such as primary sclerosing cholangitis, autoimmune hepatitis, metabolic dysfunction-associated steatohepatitis (MASH), and alpha-1 antitrypsin deficiency
- ☐ Concomitant OAT3 inhibitors or strong CYP2C9 inhibitors

Inclusion Criteria

All 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 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 13–15 mg/kg/day)
- ☐ Tried elafibranor (unless medically inadvisable) and had intolerance or inadequate response after 13 weeks

Additional Inclusion Criteria – Select If Applicable

- ☐ For patients who are pregnant or plan to become pregnant: Counseling provided on potential risks vs benefits of treatment.
- ☐ For patients who are lactating / providing breastmilk to an infant or plan to do so: Counseling provided on potential risks vs benefits of treatment.

Other Justification

- ☐ _____

Footnotes

1 MELD, model for end-stage liver disease

Prepared: January 2025.

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