Generic Name: elafibranor, obeticholic acid, seladelpar

Therapeutic Class or Brand Name: Primary Biliary Cholangitis Agents

Applicable Drugs: Iqirvo® (elafibranor), Ocaliva® (obeticholic acid), Livdelzi® (seladelpar).

Preferred: N/A

Non-preferred: N/A

VSI-Excluded Drugs: Iqirvo®, Ocaliva®, Livdelzi®

Date of Origin: 11/18/2024

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

I. Documented diagnosis of Primary Biliary Cholangitis (PBC) AND meets ALL criteria A through E:
   A. Diagnosis of PBC confirmed by two of three features:
      i. Biochemical evidence of cholestasis based on alkaline phosphatase (ALP) elevation (as defined by the performing laboratory's reference values)
      ii. Presence of antimitochondrial antibodies (AMA), or other PBC-specific autoantibodies, including sp100 or gp210, if AMA is negative
      iii. Histologic evidence of PBC seen on biopsy
   B. Minimum age requirement: 18 years old
   C. Documented trial and failure, or contraindication to, treatment with ursodiol at a dose of 13-15 mg/kg/day for at least 12 months.
   D. Alkaline phosphatase (ALP) level at least 1.67 times the upper limit of normal (i.e. greater than 174 U/L for women and 215 U/L for men)
   E. Total bilirubin level no more than 2 times the upper limit of normal (ULN). For example, less than 41 µmol/L.

II. Treatment must be prescribed by or in consultation with a hepatologist or gastroenterologist.

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

IV. Refer to plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Use of more than one agent from this policy concomitantly
- Previous or planned liver transplantation

- Hepatitis B or C virus infection
- Alcohol-related liver disease
- Autoimmune hepatitis
- Primary biliary cirrhosis-autoimmune hepatitis overlap
- Evidence of clinically significant hepatic decompensation (such as esophageal varices, poorly controlled ascites, hepatic encephalopathy, coagulopathy, etc.)

OTHER CRITERIA

- Obeticholic acid (Ocaliva®) is contraindicated in PBC patients with decompensated cirrhosis, a prior decompensation event, or with compensated cirrhosis who have evidence of portal hypertension.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Iqirvo®, Livdelzi®, Ocaliva®: 30 tablets per 30 days

APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** 12 months, with documented clinically significant improvement (such as a reduction of ALP level to less than 1.67x ULN, with at least a 15% reduction from baseline, and normal total bilirubin levels).

APPENDIX

N/A

REFERENCES

1. Iqirvo. Prescribing information. Ipsen Pharmaceuticals, Inc; 2024. Accessed 10/25/2024. c91c4c2d-fbd6-4dec-99db-66768cdb2b5c_source__v.pdf
2. Livdelzi Prescribing information. Gilead Sciences, Inc; 2024. Accessed 10/25/2024. https://www.gilead.com/-/media/files/pdfs/medicines/pbc/livdelzi/livdelzi_pi.pdf
3. Ocaliva Prescribing information. Intercept Pharmaceuticals, Inc; 2022. Accessed 10/25/2024. https://www.interceptpharma.com/wp-content/uploads/2023/08/Ocaliva_USPI_Clean_VV-REG-040954.pdf