HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Iqirvo (elafibranor)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Iqirvo, approved by the FDA in 2024, is a dual peroxisome proliferator-activated receptor (PPAR) agonist indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA.
PBC is a progressive, autoimmune liver disease that leads to scarring and inflammation of the small bile ducts. It primarily affects women and is characterized by fatigue, pruritis, and jaundice. Antimitochondrial antibody (AMA) is found in 95% of PBC patients. Activation of PPAR-alpha and PPAR-delta inhibits bile acid synthesis.
Ursodiol (ursodeoxycholic acid [UDCA]) is the first-line treatment for PBC. It improves biochemical indices, delays histologic progression, and improves survival.
Accelerated approval of Iqirvo for PBC was based on reduction of alkaline phosphatase (ALP). Improvement in survival or prevention of liver decompensation events have not been demonstrated.

Iqirvo (elafibranor) will be considered for coverage when the following criteria are met:

Primary Biliary Cholangitis (PBC)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a hepatologist or gastroenterologist; AND
3. Member has a diagnosis of PBC confirmed by at least 2 of the following:
   a) Biochemical evidence of cholestasis based on ALP elevation
   b) Presence of AMA or other PBC-specific antibodies, including sp100 or gp210
   c) Histologic evidence of nonsuppurative cholangitis and destruction of small or medium-sized bile ducts on biopsy; AND
4. Member had an inadequate response to UDCA after 1 year of treatment OR the member has documentation of intolerance to UDCA; AND
5. UDCA will be continued in combination with Iqirvo unless the patient has documented intolerance; AND
6. Member does NOT have any of the following:
   a) Decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy)
   b) Complete biliary obstruction.
7. **Dosage allowed/Quantity limit:** 80 mg orally once daily. QL: 30 tablets/30 days.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must show improved (decreased) ALP and/or total bilirubin compared to baseline.

If all the above requirements are met, the medication will be approved for an additional 12 months

HAP CareSource considers Iqirvo (elafibranor) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
06/20/2024	New policy for Iqirvo created.

References:

1. Iqirvo [prescribing information]. Ipsen Biopharmaceuticals, Inc.; 2024.
2. Lindor KD, Bowlus CL, Boyer J, Levy C, Mayo M. Primary Biliary Cholangitis: 2018 Practice Guidance from the American Association for the Study of Liver Diseases. *Hepatology*. 2019;69(1):394-419. doi:10.1002/hep.30145
3. Lindor KD, Bowlus CL, Boyer J, Levy C, Mayo M. Primary biliary cholangitis: 2021 practice guidance update from the American Association for the Study of Liver Diseases. *Hepatology*. 2022;75(4):1012-1013. doi:10.1002/hep.32117
4. Hirschfield GM, Dyson JK, Alexander GJM, et al. The British Society of Gastroenterology/UK-PBC primary biliary cholangitis treatment and management guidelines. *Gut*. 2018;67(9):1568-1594. doi:10.1136/gutjnl-2017-315259
5. European Association for the Study of the Liver. Electronic address: easloffice@easloffice.eu; European Association for the Study of the Liver. EASL Clinical Practice Guidelines: The diagnosis and management of patients with primary biliary cholangitis. *J Hepatol*. 2017;67(1):145-172. doi:10.1016/j.jhep.2017.03.022

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