Commercial PA Criteria

Effective: July 31, 2024

Prior Authorization: Iqirvo

Products Affected: Iqirvo (elafibranor) oral tablets

Medication Description: Iqirvo, a peroxisome proliferator-activated receptor (PPAR) agonist, is indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA.

Covered Uses: Primary biliary cholangitis

Exclusion Criteria:

1. **Alcoholic Liver Disease.** There are no data available to support the use of Iqirvo in patients with alcoholic hepatitis.
2. **Metabolic Dysfunction-Associated Steatotic Liver Disease (MASLD)/Nonalcoholic Fatty Liver Disease (NAFLD), including Metabolic Dysfunction-Associated Steatohepatitis (MASH)/Non-Alcoholic Steatohepatitis (NASH).** In a Phase III trial (RESOLVE-IT) of Iqirvo in adults with MASH and fibrosis, Iqirvo did not demonstrate a statistically significant effect on the primary endpoint of NASH resolution without worsening of fibrosis. The response rate in the 717 patients enrolled was 19.2% for patients who received Iqirvo compared to 14.7% for patients in the placebo arm. Additionally, no significant differences as compared to placebo were achieved in the key secondary endpoints, including fibrosis improvement of at least one stage and changes in metabolic parameters.

Required Medical Information:

1. Diagnosis
2. Medication history

Prescriber Restriction: The medication is prescribed by, or in consultation with, a gastroenterologist, hepatologist, or liver transplant physician.

Age Restriction: Patient is ≥ 18 years of age and older

Coverage Duration:

Initial: 6 months

Renewal: 12 months

Other Criteria:

Initial Approval Criteria

1. **Primary Biliary Cholangitis.** Approve Iqirvo for the duration noted if the patient meets ONE of the following (A **OR** B):
   Note: Primary Biliary Cholangitis is also known as Primary Biliary Cirrhosis.
   A. Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, **and** v):
      i. Patient is ≥ 18 years of age; **AND**

ii. According to the prescriber, the patient has a diagnosis of primary biliary cholangitis as defined by TWO of the following (a, b, **OR** c):
   a. Alkaline phosphatase is elevated above the upper limit of normal as defined by normal laboratory reference values; **OR**
   b. Positive anti-mitochondrial antibodies or other primary biliary cholangitis-specific auto-antibodies, including sp100 or gp210, if anti-mitochondrial antibodies are negative; **OR**
   c. Histologic evidence of primary biliary cholangitis from a liver biopsy; **AND**

iii. Patient meets ONE of the following (a **or** b):
   a. Patient has been receiving ursodiol therapy for ≥ 1 year and has had an inadequate response according to the prescriber; **OR**
   b. According to the prescriber the patient is unable to tolerate ursodiol therapy; **AND**
   Note: Examples of ursodiol therapy include ursodiol generic tablets and capsules, Urso 250, Urso Forte, and Actigall.

iv. Patient does not currently have, or have a history of, a hepatic decompensation event **AND**
Note: Examples of hepatic decompensation include ascites, gastroesophageal varices, variceal bleeding, hepatic encephalopathy, and coagulopathy.

v. The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician.

B. Patient is Currently Receiving Therapy. Approve for 1 year if the patient meets BOTH of the following (i **and** ii):
   i. Patient does not currently have, or have a history of, a hepatic decompensation event.
   Note: Examples of hepatic decompensation include ascites, gastroesophageal varices, variceal bleeding, hepatic encephalopathy, and coagulopathy.
   ii. Patient has demonstrated a response to therapy as determined by the prescriber.
   Note: Examples of a response to therapy are improved biochemical markers of primary biliary cholangitis (e.g., alkaline phosphatase [ALP], bilirubin, gamma-glutamyl transpeptidase [GGT], aspartate aminotransferase [AST], alanine aminotransferase [ALT]).

References:

1. Iqirvo® tablets [prescribing information]. Cambridge, MA: Ipsen; June 2024.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	07/31/2024