UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2351-2
Program	Prior Authorization/Medical Necessity
Medication	Iqirvo® (elafibranor)
P&T Approval Date	9/2024, 9/2025
Effective Date	12/1/2025

1. Background:

Iqirvo (elafibranor) is a 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.

This indication is approved under accelerated approval based on reduction of alkaline phosphatase (ALP). Improvement in survival or prevention of liver decompensation events have not been demonstrated. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s). Use of Iqirvo is not recommended in patients who have or develop decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy).

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Iqirvo** will be approved based on **all** of the following criteria:

   a. Diagnosis of primary biliary cholangitis

   -AND-

   b. Patient does not have decompensated cirrhosis

   -AND-

   c. **One** of the following^:

      (1) **Both** of the following:

         (a) Used in combination with ursodeoxycholic acid (e.g., Urso, ursodiol)
         (b) Patient has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal after at least 12 consecutive months of treatment with ursodeoxycholic acid (e.g., Urso, ursodiol)

      -OR-

      (2) History of contraindication or intolerance to ursodeoxycholic acid (e.g., Urso, ursodiol)

-AND-

d. Patient is not receiving Iqirvo in combination with Livdelzi (seladelpar) or Ocaliva (obeticholic acid)

-AND-

e. Prescribed by one of the following:

(1) Hepatologist
(2) Gastroenterologist

Initial authorization will be issued for 12 months

B. Reauthorization

1. **Iqirvo** will be approved based on **all** the following criteria:

a. Submission of medical records (e.g., laboratory values) documenting a reduction in ALP level from pre-treatment baseline (i.e., prior to Iqirvo therapy)

-AND-

b. Patient does not have decompensated cirrhosis

-AND-

c. Patient is not receiving Iqirvo in combination with Livdelzi (seladelpar) or Ocaliva (obeticholic acid)

-AND-

d. Prescribed by one of the following:

(1) Hepatologist
(2) Gastroenterologist

Reauthorization will be issued for 12 months

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
^Tried/failed alternative(s) are supported by FDA labeling.

3. Additional Clinical Rules:

- Supply limits may be in place.
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References:

1. Iqirvo [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; June 2024.

Program	Prior Authorization/Medical Necessity – Iqirvo (elafibranor)
Change Control	
Date	Change
9/2024	New program.
9/2025	Annual review with no changes to coverage criteria.