UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1456-2
Program	Prior Authorization/Notification
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 not achieved an adequate response to an appropriate dosage of ursodeoxycholic acid (e.g., Urso, ursodiol) after at least 12 consecutive months of therapy

      -OR-

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

Initial authorization will be issued for 12 months

B. Reauthorization

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

   a. Documentation of positive clinical response to Iqirvo therapy

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.

3. Additional Clinical Rules:

- 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.
- Supply limits may be in place
- Medical necessity may be in place
- Step Therapy may be in place

4. References:

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

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