UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 3188-2
Program	Step Therapy
Medication	Iqirvo® (elafibranor)
P&T Approval Date	9/2024, 9/2025
Effective Date	12/1/2025

1. Background:

Step therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try and fail ursodeoxycholic acid (e.g., Urso, ursodiol) before providing coverage for Iqirvo® (elafibranor).

2. Coverage Criteria[a]:

A. Primary biliary cholangitis

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

   a Diagnosis of primary biliary cholangitis

   -AND-

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

      (1) 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)

      -OR-

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

         (a) As continuation of therapy

         -AND-

         (b) Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Ipsen sponsored Ipsen Cares® support program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Iqirvo

Authorization will be issued for 12 months.

B. Other Diagnoses

1. **Iqirvo** will be approved

Authorization 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:

- 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 and/or Notification may be in place.

4. References:

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

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