



PRIOR AUTHORIZATION CONSIDERATIONS CHECKLIST

Prescribers and office staff can use this checklist of considerations when submitting a prior authorization (PA) to a health plan for patients prescribed IQIRVO

This checklist is for informational purposes only and lists coverage criteria that may be required or helpful for PA submissions. Provision of this information does not constitute medical or legal advice and the information may be incomplete or inapplicable for some health plans. Including the below information in a PA submission does not guarantee approval by a health plan and is not intended to be a substitute for or an influence on the independent clinical decision of the prescribing healthcare professional. Ipsen cannot guarantee that these are the criteria used by health plans or pharmacy benefit managers when making PA decisions. It is recommended that the prescribing healthcare professional or staff check the plan's specific coverage criteria and PA requirements, as these can vary by health plan and with time.

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IPSEN CARES serves as a central point of contact dedicated to assisting patients, providers, and staff.

Call (866) 435-5677, Monday-Friday, 8 AM - 8 PM EST, fax (855) 465-3820, or visit our website IPSENCARES.com.

IPSEN CARES can help provide information on how to submit a PA to the patient's specific health plan. Please consider enrolling your patient into IPSEN CARES should you require PA support.

Please note that IPSEN CARES will not submit a PA on behalf of the prescriber or office. IPSEN CARES can help provide information and templates to support the submission of a PA to the patient's health plan.

INDICATION

IQIRVO® 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.

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).

Limitations of Use

Use of IQIRVO is not recommended in patients who have or develop decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy).

IMPORTANT SAFETY INFORMATION

Myalgia, Myopathy, and Rhabdomyolysis: Rhabdomyolysis resulting in acute kidney injury occurred in one IQIRVO-treated patient who had cirrhosis at baseline and was also taking a stable dose of an HMG-CoA reductase inhibitor (statin). Myalgia or myopathy, with or without CPK elevations, occurred in patients treated with IQIRVO alone or treated concomitantly with a stable dose of an HMG-CoA reductase inhibitor. Assess for myalgia and myopathy prior to IQIRVO initiation. Consider periodic assessment (clinical exam, CPK measurement) during treatment with IQIRVO, especially in those who have signs and symptoms of new onset or worsening of muscle pain or myopathy. Interrupt IQIRVO treatment if there is new onset or worsening of muscle pain, or myopathy, or rhabdomyolysis.

Please see Important Safety Information throughout and full [Prescribing Information](#).

Examples of Common Coverage Policy Criteria for IQIRVO



When preparing the PA, confirm the health plan's specific coverage policy criteria requirements



Diagnostic Criteria

Some health plans may require that a PBC diagnosis¹ is confirmed by the presence of at least 2 of the following 3 criteria:

- History of elevated ALP levels¹⁻⁷
 - ALP is elevated for ≥ 6 months above the upper limit of normal (ULN) as defined by normal laboratory reference values $\geq 1.67 \times \text{ULN}$ [174 U/L in females, 215 U/L in males] or reference appropriate guideline
- Positive anti-mitochondrial antibody (AMA) titers²⁻⁴
 - Titers $>1:40$ on immunofluorescence or immuno-enzymatic reactivity, OR
 - Positive PBC-specific antinuclear antibody (ANA)
- Histologic evidence of PBC on liver biopsy²⁻⁴



Medical Criteria

- UDCA treatment²⁻⁵
 - UDCA for ≥ 12 months or documented inability to tolerate UDCA at therapeutic dose
- IQIRVO is prescribed by or in consultation with 1 of the following²⁻⁵:
 - Gastroenterologist
 - Hepatologist
 - Liver transplant physician
- The patient is not receiving IQIRVO in combination with Livdelzi[®] (seladelpar)⁵



Confirmation of No Evidence of Other Liver Diseases

- No history or evidence of other concomitant liver disease²⁻⁵
 - Confirmation via chart notes
 - No clinically significant hepatic decompensation

IMPORTANT SAFETY INFORMATION (continued)

Fractures: Fractures occurred in 6% of IQIRVO-treated patients compared to no placebo-treated patients. Consider the risk of fracture in the care of patients treated with IQIRVO and monitor bone health according to current standards of care.

Adverse Effects on Fetal and Newborn Development: IQIRVO may cause fetal harm when administered during pregnancy. For females of reproductive potential, verify that the patient is not pregnant prior to initiation of therapy. Advise females of reproductive potential to use effective non-hormonal contraceptives or add a barrier method when using systemic hormonal contraceptives during treatment with IQIRVO and for 3 weeks following the last dose of IQIRVO.

Drug-Induced Liver Injury: Drug-induced liver injury occurred in one patient who took IQIRVO 80 mg once daily and two patients who took IQIRVO at 1.5-times the recommended dosage, of which one presented with autoimmune-like hepatitis. The median time to onset of elevation in liver tests was 85 days. Obtain baseline clinical and laboratory assessments at treatment initiation with IQIRVO and monitor thereafter according to routine patient management.

Please see Important Safety Information throughout and full Prescribing Information.

IQIRVO[®]
elafibranor 80 mg tablets

Examples of Common Coverage Policy Criteria for IQIRVO



When preparing the PA, confirm the health plan's specific coverage policy criteria requirements



Additional Information That May Be Required for Continuation of Therapy

- ALP²⁻⁵
 - Submission of medical records (eg, laboratory values) documenting a reduction in ALP level ($\geq 15\%$ reduction in ALP level, ALP level < 1.67 times ULN, total bilirubin \leq to ULN) with IQIRVO therapy from pretreatment baseline
- No evidence of decompensated cirrhosis²⁻⁵
- The patient is not receiving IQIRVO in combination with Livdelzi⁵
- IQIRVO is prescribed by or in conjunction with a hepatologist, gastroenterologist, or liver transplant physician ²⁻⁵



Always be mindful of following each health plan's specific criteria and processes for submitting PAs for patients prescribed IQIRVO. Consider including the following literature as supporting documentation for IQIRVO PA submissions:

- IQIRVO (elafibranor) Prescribing Information. Ipsen Biopharmaceuticals, Inc.; 2024.
- Kowdley KV, et al; for the ELATIVE Study Investigators' Group; ELATIVE Study Investigators' Group. Efficacy and safety of elafibranor in primary biliary cholangitis. *N Engl J Med.* 2024;390(9):795-805. Available at: <https://www.nejm.org/doi/10.1056/NEJMoa2306185>

IMPORTANT SAFETY INFORMATION (continued)

Drug-Induced Liver Injury (continued): Interrupt IQIRVO treatment if liver tests (ALT, AST, total bilirubin [TB], and/or alkaline phosphatase [ALP]) worsen, or the patient develops signs and symptoms consistent with clinical hepatitis (e.g., jaundice, right upper quadrant pain, eosinophilia). Consider permanent discontinuation if liver tests worsen after restarting IQIRVO.

Hypersensitivity Reactions: Hypersensitivity reactions have occurred in a clinical trial with IQIRVO at 1.5-times the recommended dosage. Three patients (0.2%) had rash or unspecified allergic reaction that occurred 2 to 30 days after IQIRVO initiation. Hypersensitivity reactions resolved after discontinuation of IQIRVO and treatment with steroids and/or antihistamines. If a severe hypersensitivity reaction occurs, permanently discontinue IQIRVO. If a mild or moderate hypersensitivity reaction occurs, interrupt IQIRVO and treat promptly. Monitor the patient until signs and symptoms resolve. If a hypersensitivity reaction recurs after IQIRVO rechallenge, then permanently discontinue IQIRVO.

Biliary Obstruction: Avoid use of IQIRVO in patients with complete biliary obstruction. If biliary obstruction is suspected, interrupt IQIRVO and treat as clinically indicated.

Please see Important Safety Information throughout and full Prescribing Information.

IQIRVO[®]
elafibranor 80 mg tablets

IMPORTANT SAFETY INFORMATION (continued)

Drug-Drug Interactions

IQIRVO may reduce the systemic exposure of progestin and ethinyl estradiol (CYP3A4 substrates), which may lead to contraceptive failure and/or an increase in breakthrough bleeding. Switch to effective non-hormonal contraceptives or add a barrier method when using hormonal contraceptives during treatment with IQIRVO and for at least 3 weeks after last dose.

CPK elevation and/or myalgia occurred in patients on IQIRVO monotherapy. Co-administration of IQIRVO and HMG-CoA reductase inhibitors can increase the risk of myopathy. Monitor for signs and symptoms of muscle injury. Consider periodic assessment (clinical exam, CPK) during treatment. Interrupt IQIRVO treatment if there is new onset or worsening of muscle pain or myopathy.

Co-administration of IQIRVO with rifampin, an inducer of metabolizing enzymes, may reduce the systemic exposure of elafibranor resulting in delayed or suboptimal biochemical response. Monitor the biochemical response (e.g., ALP and bilirubin) when patients initiate rifampin during treatment with IQIRVO.

Bile acid sequestrants may interfere with IQIRVO absorption and systemic exposure, which may reduce efficacy. Administer IQIRVO at least 4 hours before or after a bile acid sequestrant, or at as great an interval as possible.

Use in Special Populations

Pregnancy: Based on data from animal reproduction studies, IQIRVO may cause fetal harm when administered during pregnancy. There are insufficient data from human pregnancies exposed to IQIRVO to allow an assessment of a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Report pregnancies to Ipsen Biopharmaceuticals, Inc. adverse event reporting line at 1-855-463-5127 or <https://www.ipsen.com/contact-us/>.

Lactation: There are no data available on the presence of IQIRVO or its metabolites in human milk, or on effects of the drug on the breastfed infant or the effects on milk production. IQIRVO is not recommended during breastfeeding and for at least 3 weeks following last dose of IQIRVO because the risk to breastfed child cannot be excluded.

Females and Males of Reproductive Potential: IQIRVO may cause fetal harm when administered to pregnant women. Verify the pregnancy status of females of reproductive potential prior to initiating IQIRVO. Advise females of reproductive potential to use effective contraception during treatment with IQIRVO and for 3 weeks after the final dose.

The most common adverse events occurring in $\geq 10\%$ of patients were weight gain (23%), abdominal pain (11%), nausea (11%), vomiting (11%), and diarrhea (11%).

You are encouraged to report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Ipsen Biopharmaceuticals, Inc. at 1-855-463-5127.

Please see full [Prescribing Information](#).

References: 1. IQIRVO (elafibranor) Prescribing Information. Ipsen Biopharmaceuticals, Inc.; 2024. 2. CVS Caremark. Specialty Guideline Management. IQIRVO® (elafibranor) Policy 2025. Accessed July 25, 2025. https://info.caremark.com/content/dam/enterprise/caremark/microsites/dig/pdfs/pa_forms_default/6531-A_Iqirvo.pdf 3. Aetna Better Health®. Coverage Policy/Guideline. IQIRVO. 2025. Accessed July 25, 2025. <https://fr.aetnabetterhealth.com/content/dam/aetna/medicaid/pdfs/formulary/guidelines/Iqirvo-Aetna-Medicaid-Policy-ua.pdf> 4. Cigna Healthcare. Drug Coverage Policy. Hepatology – IQIRVO. 2025. Accessed July 25, 2025. https://static.cigna.com/assets/chcp/pdf/coveragePolicies/pharmacy/ip_0710_coveragepositioncriteria_hepatology_iqirvo.pdf 5. UnitedHealthcare Pharmacy. Clinical Pharmacy Programs. Prior Authorization/Medical Necessity. IQIRVO® (elafibranor). 2024. 6. Lindor KD, et al. Primary Biliary Cholangitis: 2018 Practice Guidance from the American Association for the Study of Liver Diseases. *Hepatology*. 2019;69(1):394-419. 7. Mayo Clinic. Alkaline phosphatase blood (ALP) test. August 5, 2025. Accessed September 2, 2025. <https://www.mayoclinic.org/tests-procedures/alkaline-phosphatase-alp-blood-test/about/pac-20587036>

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