IPSENCARES®
Coverage, Access, Reimbursement & Education Support

IQIRVO® elafibranor 80 mg tablets

Guide to Writing a Letter of Medical Necessity

A **Letter of Medical Necessity** (LMN) explains the prescriber's rationale and clinical decision-making for choosing a specific treatment option.

Health plans often require LMNs as part of a prior authorization or when appealing a coverage determination.

Use of this information **does not guarantee** that a health plan will provide reimbursement for Iqirvo and is not intended to be a substitute for or an influence on your independent medical judgment.

The following pages share tips for writing an effective LMN and a template you can use to write your LMN for individual patients.

Call 1-866-435-5677 Monday – Friday,
8:00 AM – 8:00 PM ET
for additional information or visit us online at IPSENCARES.com

Tips for Writing an Effective Letter of Medical Necessity

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Before you begin an LMN, have the following information ready:

- Patient's full name and date of birth
- Patient's insurance policy/ID number
- Case ID number (for appeals)
- Brief medical history including diagnosis, ICD-10 code, comorbidities, and allergies
- Patient's current and prior therapeutic regimens (include start/stop dates and the reason[s] for discontinuation)
- Background on the patient's current condition and symptoms
- Clinical support for your recommendation

Consider these additional points when writing your letter for Iqirvo:

- **Review the health plan's coverage criteria** for Iqirvo and provide details for the criteria that your patient meets. If applicable, provide your rationale for excluding your patient from criteria they do not meet.
- **Clearly state** why Iqirvo is the appropriate choice for the patient.
- **Provide clinical justification** to support your decision to prescribe Iqirvo and attach relevant clinical data, such as chart notes and relevant laboratory test results and pregnancy status (see full guidance in Section 5 WARNINGS AND PRECAUTIONS of the Iqirvo Prescribing Information).[1]
- **Describe any other patient characteristics** and/or clinical considerations relevant to Iqirvo therapy.
    - Attach clinical documentation that supports your recommendation; this information is in the Iqirvo Prescribing Information (consider Section 12 CLINICAL PHARMACOLOGY and Section 14 CLINICAL STUDIES for efficacy data).

Be mindful of following preferred health plan processes

- **Read the process** for submitting the letter to ensure that you are meeting the requirements of the health plan and state guidelines, including how to submit the request (e.g., fax, phone, email, health plan website).
- **Track the status** of your request and follow up with the health plan if needed.

Reference: 1. Iqirvo (elafibranor) Prescribing Information. Ipsen Biopharmaceuticals, Inc.; 2024.

Sample Letter of Medical Necessity for Iqirvo

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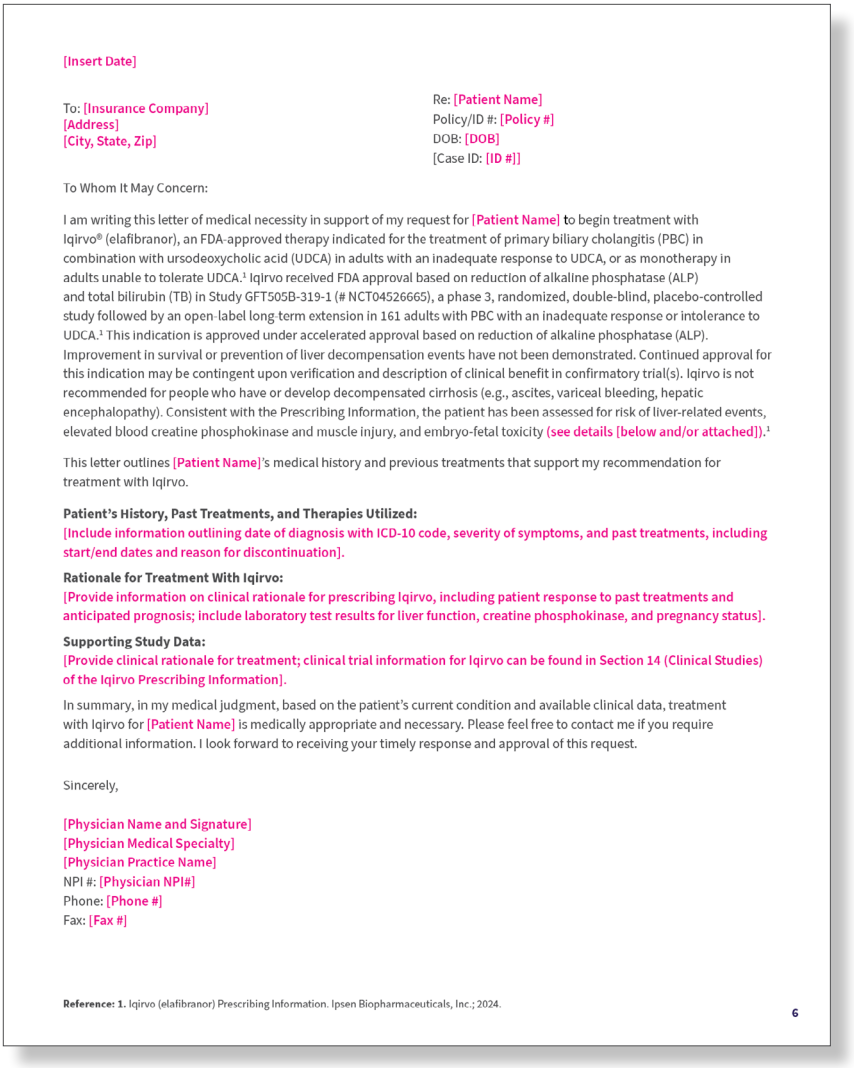
Below is a sample LMN for Iqirvo that uses the editable template provided as the last page of this document. Read through to get a better idea of what a LMN looks like, and then use the template to customize based on your medical opinion and your individual patients' needs.



[Insert Date]

To: [Insurance Company]
[Address]
[City, State, Zip]

Re: [Patient Name]
Policy/ID #: [Policy #]
DOB: [DOB]
[Case ID: [ID #]]

To Whom It May Concern:

I am writing this letter of medical necessity in support of my request for [Patient Name] to begin treatment with Iqirvo® (elafibranor), an FDA-approved therapy 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.[1] Iqirvo received FDA approval based on reduction of alkaline phosphatase (ALP) and total bilirubin (TB) in Study GFT505B-319-1 (# NCT04526665), a phase 3, randomized, double-blind, placebo-controlled study followed by an open-label long-term extension in 161 adults with PBC with an inadequate response or intolerance to UDCA.[1] 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). Iqirvo is not recommended for people who have or develop decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy). Consistent with the Prescribing Information, the patient has been assessed for risk of liver-related events, elevated blood creatine phosphokinase and muscle injury, and embryo-fetal toxicity (see details [below and/or attached]).[1]

This letter outlines [Patient Name]'s medical history and previous treatments that support my recommendation for treatment with Iqirvo.

Patient's History, Past Treatments, and Therapies Utilized:
[Include information outlining date of diagnosis with ICD-10 code, severity of symptoms, and past treatments, including start/end dates and reason for discontinuation].

Rationale for Treatment With Iqirvo:
[Provide information on clinical rationale for prescribing Iqirvo, including patient response to past treatments and anticipated prognosis; include laboratory test results for liver function, creatine phosphokinase, and pregnancy status].

Supporting Study Data:
[Provide clinical rationale for treatment; clinical trial information for Iqirvo can be found in Section 14 (Clinical Studies) of the Iqirvo Prescribing Information].

In summary, in my medical judgment, based on the patient's current condition and available clinical data, treatment with Iqirvo for [Patient Name] is medically appropriate and necessary. Please feel free to contact me if you require additional information. I look forward to receiving your timely response and approval of this request.

Sincerely,

[Physician Name and Signature]
[Physician Medical Specialty]
[Physician Practice Name]
NPI #: [Physician NPI#]
Phone: [Phone #]
Fax: [Fax #]

Reference: 1. Iqirvo (elafibranor) Prescribing Information. Ipsen Biopharmaceuticals, Inc.; 2024.

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This template is for informational purposes only, providing an outline of the types of information that may be required or helpful when responding to a request from a patient's health plan. Use of this information does not constitute medical or legal advice and does not guarantee reimbursement for coverage. It is not intended to be a substitute for, or an influence on, the independent clinical decision of the prescribing healthcare professional. IPSEN makes no representations or warranties about the template or its fitness for any specific use. IPSEN is not responsible for any changes made to the template document. All billing and coding decisions are the responsibility of the relevant physician.

INDICATION AND IMPORTANT SAFETY INFORMATION FOR IQIRVO

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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.

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. 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.

(continued on next page)

Please click here for full Prescribing Information for IQIRVO.

INDICATION AND IMPORTANT SAFETY INFORMATION FOR IQIRVO

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IMPORTANT SAFETY INFORMATION (continued)

Hypersensitivity Reactions (continued): 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.

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 ≥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 click here for full Prescribing Information for IQIRVO.

[Insert Date]

To: **[Insurance Company]**
[Address]
[City, State, Zip]

Re: **[Patient Name]**
Policy/ID #: **[Policy #]**
DOB: **[DOB]**
[Case ID: **[ID #]**]

To Whom It May Concern:

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This letter outlines **[Patient Name]**'s medical history and previous treatments that support my recommendation for treatment with Iqirvo.

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Sincerely,

[Physician Name and Signature]
[Physician Medical Specialty]
[Physician Practice Name]
NPI #: **[Physician NPI#]**
Phone: **[Phone #]**
Fax: **[Fax #]**

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