IPSEN CARES® ENROLLMENT FORM

Questions? Call IPSEN CARES at 1-866-435-5677

IQIRVO® elafibranor 80 mg tablets

Please print the form, fill it out completely, sign it, and fax to: 1-855-465-3820

IPSEN CARES must receive all pages in order for the Enrollment Form to be complete.

Note: Page 3 can be left blank if the patient is not seeking to participate in the Patient Assistance Program.

Completed by the prescriber

STEP 1

PRESCRIBER INFORMATION

Prescriber Name (First & Last) _____

State License # _____ Tax ID # _____ NPI # _____

Medicaid Provider # (Required if Medicaid Patient) _____

Provider Transaction Access # (PTAN) _____

Office/Institution _____ Specialty _____

Preferred Method of Contact ☐ Phone ☐ Fax ☐ Email

Address _____

City _____ State _____ Zip _____

Office Contact and Title _____

Phone # _____ Fax # _____

Email _____

Best Time to Contact ☐ Morning ☐ Afternoon ☐ Evening

STEP 2

SPECIALTY PHARMACY

If you would like IPSEN CARES to triage the prescription to the Iqirvo limited specialty pharmacy network, complete the prescription information in Step 4.

Preferred Specialty Pharmacy* - Please indicate below if you have a preferred specialty pharmacy within the Iqirvo network

☐ AcariaHealth™ ☐ Accredo Health Group, Inc.

☐ AllianceRx Walgreens Pharmacy ☐ CenterWell Specialty Pharmacy

☐ CVS Specialty® ☐ Optum® Specialty Pharmacy ☐ No preference

Was Rx Sent to a Specialty Pharmacy Already? ☐ Yes ☐ No

If Yes, Please Provide the Name of the Specialty Pharmacy

_____

Selection will be honored if permitted by patient's insurance.

STEP 3

DIAGNOSIS

K74.3 Primary Biliary Cholangitis (PBC)

Iqirvo is indicated for the treatment of adult patients with PBC in combination with ursodeoxycholic acid (UDCA) for adults with inadequate response to UDCA or as monotherapy for adults with an intolerance to 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). Iqirvo is not recommended for people who have or develop decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy).

STEP 4

PRESCRIPTION AND PRESCRIBER ATTESTATION

Complete this section if you would like IPSEN CARES to triage the prescription to a specialty pharmacy or if the patient is seeking enrollment in the PAP.

PRESCRIPTION: Iqirvo® (elafibranor)

Patient Name (First & Last) _____ Date of Birth (MM/DD/YY) ____/____/____

Patient Address _____ Gender Assigned at Birth ☐ Male ☐ Female

Medication	Strength	Quantity	Days Supply	Refills	Directions
Iqirvo	80 mg tablet				80 mg taken orally once daily

Prior Authorization #, if known: _____ Prior Authorization Effective Dates: _____

Additional Considerations: _____

PRESCRIBER ATTESTATION

(The Prescriber must sign if this form is to be used as a prescription to be triaged to a specialty pharmacy to enroll the patient for free goods as part of the Patient Assistance Program (PAP), or to enroll a patient for free goods as part of the Temporary Patient Assistance Program (TPAP). If the request is limited to Benefit Verification or Copay Assistance Program support, the Prescriber, or an individual acting at the direction of the Prescriber and involved in the patient's care may sign this form.)

By signing below, I certify that the therapy referenced in this form is medically necessary. If this form is to be used to enroll a patient in free goods as part of the PAP or Temporary PAP, I certify that the therapy referenced in this form is prescribed consistent with an FDA-approved indication. I certify that a prescription signed by a licensed prescriber is on file for the referenced therapy and that I have received the necessary authorization from the patient and/or the patient's guardian to release the information herein and medical and/or patient information relating to Iqirvo therapy to Ipsen and its agents or contractors for the purpose of seeking reimbursement for Iqirvo therapy, assisting in initiating or continuing Iqirvo therapy, and/or evaluating the patient's eligibility for Ipsen's patient support programs administered by IPSEN CARES. I authorize Ipsen and its agents or contractors to forward a prescription by fax or other delivery mode to the designated pharmacy. I understand that I must comply with applicable state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Non-compliance with state-specific requirements could result in outreach to me. I certify that any medications received by me or on my behalf from Ipsen in connection with any IPSEN CARES program will be used only for the named patient. These medications will not be offered for sale, transfer, or otherwise diverted. Additionally, no claim for reimbursement will be submitted concerning these medications, or any services provided by IPSEN CARES, to any payor, including Medicare, Medicaid, or any other federal or state health insurance program, nor will any medications be returned for credit. If the named patient does not return for therapy, product will be returned to Ipsen. I acknowledge that I have assisted the named patient in enrolling in IPSEN CARES exclusively for purposes of patient care and not in consideration for, expectation of, or actual receipt of remuneration of any sort.

Name (First & Last) _____ **Title** _____

PRESCRIBER SIGNATURE (stamp signature not allowed)

Prescriber Signature (dispense as written) _____ **Date** _____

Prescriber Signature (substitution permissible) _____ **Date** _____

Please see Indication and Important Safety Information on pages 6-7 and accompanying full Prescribing Information, including Medication Guide.

IPSENCARES® Coverage, Access, Reimbursement & Education Support

IPSEN CARES® ENROLLMENT FORM

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IQIRVO® elafibranor 80 mg tablets

Completed by the patient/legal guardian

STEP 5

PATIENT INFORMATION

Patient Name (First & Last) _____

Address _____

City _____

State _____ Zip _____

Date of Birth (MM/DD/YY) ____ / ____ / ____

Gender Assigned at Birth ☐ Male ☐ Female

Email _____

Home Phone # _____

Cell Phone # _____

Caregiver/Legal Guardian Name (First & Last)

_____

Caregiver/Legal Guardian Phone # _____

Relationship to Patient _____

Best Time to Contact ☐ Morning ☐ Afternoon ☐ Evening

Would you like to receive text messages from Ipsen for the purposes of helping you/the patient participate in IPSEN CARES patient support programs and/or stay on therapy, as described in Step 9 on Page 5, under *Additional Product and Support Information*? I give permission to Ipsen to contact me by text message for the purposes described in Step 9 on Page 5. Carrier, text, and data rates may apply.

☐ Yes ☐ No If Yes, please initial here: _____

Would you like to receive marketing information from Ipsen as described in Step 9 on Page 5 under *Additional Product and Support Information*? I give permission to Ipsen to contact me with information via mail, email, phone, or text message, all of which may include marketing, advertisements, disease state awareness materials, and educational material about Iqirvo and programs that support patients. I understand and agree that any information I provide may be used by Ipsen to conduct data analysis and market research, and to develop new programs and resources. Automatic dialing may be used. Carrier, text, and data rates may apply. I understand that I am not required to provide this consent as a condition of purchasing any goods or services. ☐ Yes ☐ No If Yes, please initial here: _____

STEP 6

INSURANCE INFORMATION

Complete or attach front and back copy of patient's primary and secondary insurance cards for pharmacy and medical benefits.

Is Patient Insured? ☐ Yes ☐ No

Policy Holder Name _____

Primary Insurance Co. _____

Insurance Co. Phone # _____

Subscriber Policy ID # _____

Policy/Employer/Group # _____

Is Physician a Participating Provider? ☐ Participating ☐ Non-Participating

Does Patient Have Secondary Insurance? ☐ Yes ☐ No

Secondary Insurance Co. _____

Insurance Co. Phone # _____

Subscriber Policy ID # _____

Policy/Employer/Group # _____

Pharmacy Benefit Manager _____

RxBIN _____ RxPCN _____

RxGroup _____ RxID _____

STEP 7

IPSEN CARES COPAY PROGRAM (Required for patients seeking to participate in the Iqirvo Copay Assistance Program)

Eligible patients using commercial insurance can save on out-of-pocket Ipsen medication costs. Please see Patient Eligibility & Terms and Conditions.

I attest that I am not enrolled in any health insurance plan from any state or federally funded programs (including, but not limited to, Medicare or Medicaid, VA, DOD, or TRICARE) and agree to the Terms and Conditions of the Copay Program. ☐ Yes ☐ No

☐ I would like IPSEN CARES to check my eligibility for, and enroll me into, the Iqirvo Copay Assistance Program if the results of this benefit verification determine that I have commercial or private health insurance.

☐ **I confirm that any information, including financial and insurance information, that I provide to IPSEN CARES is complete and true, and I will immediately notify IPSEN CARES in the event my health insurance coverage changes. I also understand that Ipsen may revise, change, or terminate this program at any time without notice.**

Please print the form, fill it out completely, sign it, and fax to: 1-855-465-3820
IPSEN CARES must receive all pages in order for the Enrollment Form to be complete.
Note: Page 3 can be left blank if the patient is not seeking to participate in the Patient Assistance Program.

IQIRVO® elafibranor 80 mg tablets

Completed by the patient/legal guardian

IPSEN CARES PATIENT ASSISTANCE PROGRAM APPLICATION

(Required for patients seeking to participate in the Patient Assistance Program)

The Patient Assistance Program (PAP) is designed to provide Iqirvo at no cost to eligible patients. Patients may be eligible to receive free drug if they are experiencing financial hardship and meet financial eligibility criteria, are uninsured or functionally uninsured, residents of the U.S., and received a valid prescription for an on-label use of Iqirvo as supported by information provided in the program application. Eligibility does not guarantee approval for participation in the program. Free Iqirvo provided by the PAP is intended only for the patient named in the application and must not be sold, transferred, or otherwise diverted. Patients must not seek reimbursement for the free drug provided by the PAP. The PAP provides Iqirvo product only, and does not cover the cost of previously purchased product or medical services. The PAP is not insurance. By submitting an application for the PAP, patient agrees to abide by these program terms.

STEP 8

PROOF OF INCOME*

My estimated annual household income currently is $ _____ Number of people in household _____

***IPSEN CARES will conduct a soft credit check as part of the process of confirming income and determining eligibility for the program.**

THIRD PARTY VERIFICATION AUTHORIZATION

I understand that I am providing "written instructions" under the Fair Credit Reporting Act ("FCRA") authorizing the IPSEN CARES Patient Assistance Program (the "Program"), Ipsen Biopharmaceuticals, Inc. ("Ipsen"), and its vendor, on an ongoing basis as needed for the duration of my participation in Program, under the FCRA, to obtain information from my credit profile or other information from a credit reporting agency (including, without limitation, Experian Health), for the purpose of determining financial qualifications and eligibility for programs administered by Ipsen and the Program.
I understand that I am affirmatively agreeing to these terms in order to proceed in this financial screening process. I promise that any information, including financial and insurance information that I provide, are complete and true and, unless I have indicated otherwise, I have no drug insurance coverage, which includes Medicaid, Medicare or any public or private assistance program or any other form of insurance. If my income or health coverage changes, I will call the Program at 1-866-435-5677.

Patient/Legal Guardian Signature _____ **Date** _____

Please print the form, fill it out completely, sign it, and fax to: 1-855-465-3820
IPSEN CARES must receive all pages in order for the Enrollment Form to be complete.
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IQIRVO® elafibranor 80 mg tablets

Completed by the patient/legal guardian

STEP 9

PATIENT AUTHORIZATION TO USE/DISCLOSE HEALTH INFORMATION: IPSEN CARES® PROGRAM

I authorize my doctor(s) and their staff (including those pharmacies that may receive my prescription for Iqirvo) to disclose my protected health information ("PHI"), including health information about insurance, prescription, care management, and medical condition to Ipsen Biopharmaceuticals, Inc., and/or its affiliates, and/or its agents or third-party vendors that have been hired to administer the Ipsen Coverage, Access, Reimbursement & Education Support (IPSEN CARES) program (collectively, "Ipsen") in order for Ipsen to (1) enroll me in IPSEN CARES; (2) establish my benefit eligibility and potential out of pocket costs for Iqirvo; (3) communicate with my doctors and health plans about my treatment plan; (4) provide support services, including patient education and financial assistance for Iqirvo; (5) help get Iqirvo shipped to me or my healthcare provider; and (6) facilitate my participation in Iqirvo patient programs as I have requested or may request, including the IPSEN CARES Patient Assistance Program (the "PAP") if applicable. I agree that, using the contact information I provide, Ipsen may contact me by phone, mail, and/or email for reasons related to the IPSEN CARES program and support services, including (1) determining I am eligible for assistance and related support services, (2) leaving messages for me that disclose that I am on Iqirvo therapy and/or applied for IPSEN CARES support services and am or am not eligible for assistance; (3) operating Ipsen Cares patient programs that might help me pay for or access my medicines; and (4) confirming receipt of medications. I consent to being contacted by an IPSEN CARES program representative in order for the program to obtain further information or clarification regarding any adverse event I may experience. I also give Ipsen permission to share my PHI and other information with people and companies that work with IPSEN CARES, including; government agencies, including insurance providers; my doctor(s) and other people, or institutions who are involved in my healthcare, such as pharmacies and hospitals; and/or other organizations that might help me pay for my medication. All information that I provide may be used by Ipsen or any third party working on behalf of Ipsen in connection with IPSEN CARES. I understand that my healthcare providers may receive remuneration from Ipsen in connection with my PHI and/or for any therapy support services provided to me.

I understand that once my PHI has been disclosed to Ipsen, it is no longer protected by federal privacy laws, and Ipsen may re-disclose it; however, Ipsen has agreed to make reasonable efforts to protect my PHI by using and disclosing it only for the purposes described above or as required by law. I can withdraw this authorization by contacting IPSEN CARES at 1-866-435-5677 or mailing a letter requesting such revocation to IPSEN CARES, 2250 Perimeter Park Dr. Suite 300 Morrisville, NC 27560, but it will not change any actions taken before I withdraw this authorization. Withdrawal of this authorization will end further uses and disclosures of PHI by the parties identified in this form except to the extent those uses and disclosures have been made in reliance upon this authorization. I understand that I may refuse to sign this form and, if I do so, I will not be able to participate in IPSEN CARES, but it will not affect my eligibility to obtain medical treatment, my ability to seek payment for this treatment, or affect my insurance enrollment or eligibility for insurance coverage. This authorization expires three years from the date signed unless a shorter time is required by law or unless I revoke my authorization before that time. I understand that I will receive a copy of the signed authorization.

PATIENT AUTHORIZATION

I have read and understand the IPSEN CARES Patient Authorization on this page and agree to the terms.

Patient/Legal Guardian Signature _____ **Date** _____

Please print the form, fill it out completely, sign it, and fax to: 1-855-465-3820
IPSEN CARES must receive all pages in order for the Enrollment Form to be complete.
Note: Page 3 can be left blank if the patient is not seeking to participate in the Patient Assistance Program.

IQIRVO® elafibranor 80 mg tablets

Completed by the patient/legal guardian

STEP 9 (continued)

ADDITIONAL PRODUCT AND SUPPORT INFORMATION

Text Communications

To the extent that I have opted in under Step 5 of this form, I agree to be contacted by autodialed text messages ("texts") at the mobile phone number I have provided for the purpose of helping me stay on therapy, which may promote or advertise the Ipsen products included in the therapy plan, and/or which may include provision of educational materials and information about programs that support patients. I certify that the number I am providing belongs to me and not a family member or third party. I understand that I may opt out of individual communications or all text communications entirely at any time by calling 1-866-435-5677 or replying "STOP" by text to any text from Ipsen. Ipsen will not sell or rent this information and will use it only in accordance with this authorization and consent. Consent to being contacted by text messages is not a condition of participation in the IPSEN CARES programs or the purchase of any products or services. I understand that my cellular service carrier's data and text messaging rates may apply. This authorization expires three years from the date signed unless a shorter time is required by law or unless I revoke my authorization before that time. If I am providing this consent on behalf of another person, I certify that I am authorized to agree to every element of this consent on behalf of such other person, and I agree that I will be liable and will hold Ipsen harmless in the event that such other person alleges that they did not give consent.

Marketing Information

To the extent that I have opted in under Step 5 of this form, I would like to receive information from Ipsen via mail, email, phone or text message, all of which may include marketing content, advertisements, disease state awareness materials and educational material about Iqirvo, and programs that support patients. These text messages and voice calls may be made via the use of automatic telephone dialing systems. I certify that the number I am providing belongs to me and not to a family member or other third party. I understand that I do not have to sign this section of the form in order to participate in the IPSEN CARES program and that I may revoke this authorization to receive additional product information at any time. I agree that Ipsen and its agents may use and disclose my personal information (including name, address, phone number, and/or email) to provide this information and Ipsen may also contact me to solicit my opinions regarding Iqirvo and Ipsen's products and services. I understand and agree that any information I provide may be used by Ipsen to conduct data analysis and market research, and to develop new programs and resources. I understand that my cell phone carrier's standard rates may apply for calls and texts to my cell phone. This authorization expires three years from the date signed unless a shorter time is required by law or unless I revoke my authorization before that time. I may revoke this authorization, by calling 1-866-435-5677 or sending a request in writing to: IPSEN CARES, 2250 Perimeter Park Dr. Suite 300 Morrisville, NC 27560. If I am providing this consent on behalf of another person, I certify that I am authorized to agree to every element of this consent on behalf of such other person, and I agree that I will be liable and will hold Ipsen harmless in the event that such other person alleges that they did not give consent.

We are collecting personal information in order to fulfill your request. Please see Ipsen's privacy policy at https://www.ipsen.com/us/privacy-policy/. Residents of certain states have additional rights regarding the collection, use, and disclosure of their personal information. For more information, please see Ipsen's Supplemental State Privacy Notice at https://www.ipsen.com/us/Supplement-Website-Privacy-Notice/.

INDICATION and IMPORTANT SAFETY INFORMATION

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. 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/.

Use in Special Populations (continued)

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 see accompanying full Prescribing Information, including Medication Guide.

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IPSEN CARES is a registered trademark of Ipsen S.A.
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