IPSEN CARES® ENROLLMENT FORM

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

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.

Bylvay® (odevixibat)
200 | 400 | 600 | 1200 mcg capsules

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 _____

Address _____

City _____ State _____ Zip _____

Office Contact and Title _____

Phone # _____ Fax # _____

Email _____

STEP 2

SPECIALTY PHARMACY

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

Preferred Specialty Pharmacy: ☐ Accredo Health Group, Inc. ☐ Optum Frontier Therapies ☐ PANTHERx

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

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

If Yes, Please Provide the Name of the Specialty Pharmacy

_____

STEP 3

DIAGNOSIS

ICD-10 _____ Pruritus ☐ Yes ☐ No

☐ Diagnosis: Progressive familial intrahepatic cholestasis (PFIC)

☐ Diagnosis: Alagille syndrome (ALGS)

Bylvay is indicated for the treatment of cholestatic pruritus in patients 3 months of age and older with PFIC and for patients 12 months of age and older with ALGS.

Limitations of Use: Bylvay is not effective in a subgroup of PFIC type 2 patients with specific *ABCB11* variants resulting in non-functional or complete absence of the bile salt export pump protein.

STEP 4

PRESCRIPTION AND PRESCRIBER ATTESTATION

Complete and sign 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: Bylvay® (odevixibat)

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

Sex ☐ Male ☐ Female Current Weight ____ kg Date Measured ____ / ____ / ____

See Dosing Tables in Prescribing Information to determine dosage by patient weight in kg.

Medication	Strength (check box of requested dose)	Quantity	Days Supply	Refills	Directions‡
Bylvay	☐ 200 mcg oral pellets for sprinkle only*				☐ Sprinkle over/mix with food _____mcg total once daily
	☐ 600 mcg oral pellets for sprinkle only*				☐ Take _____mcg total swallowed whole once daily
	☐ 400 mcg capsule†				**Supplies**
	☐ 1200 mcg capsule†				☐ Ancillary supplies for patients unable to take soft foods (includes 5 mL syringe and medicine cup for mixing in liquid)

*200 mcg and 600 mcg strengths must be opened and sprinkled, NOT swallowed whole

†400 mcg and 1200 mcg strengths can be opened and sprinkled OR swallowed whole

‡Daily dose must be a multiple of the listed strengths

PRESCRIBER ATTESTATION

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. 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 Bylvay therapy to Ipsen and its agents or contractors for the purpose of seeking reimbursement for Bylvay therapy, assisting in initiating or continuing Bylvay 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. 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. 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 _____ **Date** _____

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200 | 400 | 600 | 1200 mcg capsules

Completed by the patient/legal guardian

STEP 5

PATIENT INFORMATION

Patient Name (First & Last) _____

Address _____

City _____

State _____ Zip _____

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

Sex ☐ Male ☐ Female

Email _____

Home Phone # _____

Cell Phone # _____

Caregiver/Legal Guardian Name (First & Last)

_____

Caregiver/Legal Guardian Phone # _____

Relationship to Patient _____

I give permission to Ipsen to contact me by text message for the purposes described in Step 8 on Pages 3-4. ☐ Yes ☐ No
If Yes, please initial here: _____

I give permission to Ipsen to contact me as described in Step 8 on Page 4 with information via mail, email, phone, or text message, all of which may include marketing, advertisements, disease state awareness materials, and educational material about Bylvay 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. 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 # _____

Pharmacy Benefit Manager _____

Does Patient Have Secondary Insurance? ☐ Yes ☐ No

Secondary Insurance Co. _____

Insurance Co. Phone # _____

Subscriber Policy ID # _____

Policy/Employer/Group # _____

RxBIN _____ RxPCN _____

RxGroup _____ RxID _____

STEP 7

IPSEN CARES COPAY PROGRAM (Required for patients seeking to participate in the Bylvay 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 Bylvay 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.

Bylvay® (odevixibat)
200 | 400 | 600 | 1200 mcg capsules

STEP 8 (Patient/legal guardian)

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 Bylvay) 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 Bylvay; (3) communicate with my doctors and health plans about my treatment plan; (4) provide support services, including patient education and financial assistance for Bylvay; (5) help get Bylvay shipped to me or my healthcare provider; and (6) facilitate my participation in Bylvay 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 if I am eligible for assistance and related support services, (2) leaving messages for me that disclose that I am on Bylvay 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** _____

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. (continued on next page)

STEP 8 (Patient/legal guardian)

ADDITIONAL PRODUCT AND SUPPORT INFORMATION (continued)

Text Communications (continued)

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 Bylvay, 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 Bylvay 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/.

INDICATIONS

BYLVAY is an ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of:

- cholestatic pruritus in patients ≥12 months of age with Alagille syndrome (ALGS)
- pruritus in patients ≥3 months of age with progressive familial intrahepatic cholestasis (PFIC)

Limitation of Use:

BYLVAY is not recommended in a subgroup of PFIC type 2 patients with specific *ABCB11* variants resulting in non-functional or complete absence of the bile salt export pump protein.

IMPORTANT SAFETY INFORMATION

Contraindications

IBAT inhibitors, including BYLVAY, are contraindicated in patients with prior or active hepatic decompensation events (e.g., variceal hemorrhage, ascites, hepatic encephalopathy).

WARNINGS AND PRECAUTIONS

Hepatotoxicity

BYLVAY treatment is associated with a potential for drug-induced liver injury (DILI). In the PFIC and ALGS trials, treatment-emergent elevations or worsening of liver tests occurred. Of the six patients who experienced DILI, two underwent liver transplant.

Obtain baseline liver tests because some ALGS and PFIC patients have abnormal liver tests at baseline and monitor patients frequently for the first 6 to 8 months, and as clinically needed thereafter, for elevations in liver tests, for the development

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Hepatotoxicity (continued)

of liver-related adverse reactions, and for physical signs of hepatic decompensation. If liver test abnormalities or signs of clinical hepatitis occur in the absence of other causes, consider dose reduction or treatment interruption. Permanently discontinue BYLVAY if a patient experiences the following: persistent or recurrent liver test abnormalities, or upon rechallenge, signs and symptoms consistent with clinical hepatitis, or a hepatic decompensation event.

The safety and effectiveness of BYLVAY have not been established in patients with decompensated cirrhosis. Monitor patients with compensated cirrhosis or portal hypertension more frequently and discontinue if hepatic decompensation occurs. IBAT inhibitors, including BYLVAY, are contraindicated in patients with prior or active hepatic decompensation events.

Diarrhea

In the PFIC and ALGS clinical trials, diarrhea was reported more frequently in BYLVAY-treated patients compared to placebo. In the PFIC clinical trials, treatment interruption due to diarrhea occurred in 2 patients with 3 events.

Treatment interruption due to diarrhea ranged between 3 to 7 days. One patient withdrew from the trial. In the ALGS clinical trial, no patients interrupted or discontinued treatment due to diarrhea.

If diarrhea occurs, monitor for dehydration and treat promptly. Interrupt dosing if a patient experiences persistent diarrhea. Restart BYLVAY at 40 mcg/kg/day when diarrhea resolves and increase the dose as tolerated if appropriate. If diarrhea persists and no alternate etiology is identified, stop treatment.

Fat-Soluble Vitamin (FSV) Deficiency

Fat-soluble vitamins (FSV) include vitamin A, D, E, and K. PFIC and ALGS patients can have FSV deficiency at baseline. BYLVAY may adversely affect absorption of FSVs. In clinical trials, new onset or worsening of existing FSV deficiency was reported more frequently in BYLVAY-treated patients compared to placebo.

Obtain baseline INR (International Normalized Ratio) and FSV levels and monitor during treatment along with any clinical manifestations. If FSV deficiency is diagnosed, supplement with FSV. Discontinue BYLVAY if FSV deficiency persists, worsens, or complications occur despite adequate FSV supplementation.

If bone fracture occurs, consider interrupting BYLVAY treatment and supplement with FSV if indicated.

If bleeding occurs, interrupt treatment with BYLVAY. Optimize treatment of FSV deficiency and consider restarting BYLVAY once the patient is clinically stable.

Adverse Reactions

The most common adverse reactions for BYLVAY in patients with PFIC are diarrhea, liver test abnormalities, vomiting, abdominal pain, and FSV deficiency.

The most common adverse reactions for BYLVAY patients with ALGS are diarrhea, abdominal pain, hematoma, and decreased weight.

Drug Interactions

For patients taking bile acid binding resins, take BYLVAY at least 4 hours before or 4 hours after taking a bile acid binding resin.

Use in Specific Populations

Limited human data on BYLVAY use in pregnant persons are insufficient to establish a drug-associated risk of major birth defects, miscarriage, or adverse developmental outcomes. Based on findings from animal reproduction studies, BYLVAY may cause cardiac malformations when a fetus is exposed during pregnancy. As BYLVAY may inhibit the absorption of fat-soluble vitamins, which are essential for normal fetal growth and development, monitor pregnant patients for FSV deficiency and increase supplementation as needed. Consider the woman's need for BYLVAY, the potential drug-related risks to the fetus, and the potential adverse outcomes from untreated maternal PFIC and ALGS.

There is a pregnancy exposure registry that monitors pregnancy outcomes in persons exposed to BYLVAY during pregnancy. Pregnant women exposed to BYLVAY, or their healthcare providers, should report BYLVAY exposure by calling 1-855-463-5127.

To report SUSPECTED ADVERSE REACTIONS, contact Ipsen Biopharmaceuticals, Inc. at 1-855-463-5127 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information, including Instructions For Use.