



**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.

Completed by the patient/legal guardian

**STEP 5**

**PATIENT INFORMATION**

Patient Name (First & Last) \_\_\_\_\_ Home Phone # \_\_\_\_\_  
 Address \_\_\_\_\_ Cell Phone # \_\_\_\_\_  
 City \_\_\_\_\_ Caregiver/Legal Guardian Name (First & Last) \_\_\_\_\_  
 State \_\_\_\_\_ Zip \_\_\_\_\_  
 Date of Birth (MM/DD/YY) \_\_\_\_ / \_\_\_\_ / \_\_\_\_ Caregiver/Legal Guardian Phone # \_\_\_\_\_  
 Sex Male Female Relationship to Patient \_\_\_\_\_  
 Email \_\_\_\_\_

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 Does Patient Have Secondary Insurance? Yes No  
 Policy Holder Name \_\_\_\_\_ Secondary Insurance Co. \_\_\_\_\_  
 Primary Insurance Co. \_\_\_\_\_ Insurance Co. Phone # \_\_\_\_\_  
 Insurance Co. Phone # \_\_\_\_\_ Subscriber Policy ID # \_\_\_\_\_  
 Subscriber Policy ID # \_\_\_\_\_ Policy/Employer/Group # \_\_\_\_\_  
 Policy/Employer/Group # \_\_\_\_\_ RxBIN \_\_\_\_\_ RxPCN \_\_\_\_\_  
 Pharmacy Benefit Manager \_\_\_\_\_ 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.**

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**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)**

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## 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.

STEP 8 (Patient/legal guardian)

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 AND USAGE

Bylvay is an ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of cholestatic pruritus in:

- Patients 12 months of age and older with Alagille syndrome (ALGS)
- Patients 3 months of age and older with progressive familial intrahepatic cholestasis (PFIC)
  - **Limitation of Use:** Bylvay may not be 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

## IMPORTANT SAFETY INFORMATION

### Warnings and Precautions:

#### Liver Test Abnormalities

Patients enrolled in PFIC and ALGS clinical trials had abnormal liver tests at baseline. In clinical trials, treatment-emergent elevations of liver tests or worsening of liver tests relative to baseline values were observed during the clinical trials.

In a clinical trial with PFIC patients, treatment-emergent elevations of liver tests or worsening of liver tests relative to baseline values were observed during the clinical trial. Most abnormalities included elevations in AST, ALT, or total and direct bilirubin. Treatment interruption days ranged from 3 days to 124 days; no PFIC patients permanently discontinued treatment due to liver test abnormalities.

In a clinical trial with ALGS patients, treatment-emergent elevations or worsening in liver tests relative to baseline values were observed during the trial. Most abnormalities included elevations in ALT or AST. One ALGS patient interrupted treatment for 40 days; no ALGS patients permanently discontinued treatment due to liver test abnormalities.

**Please see accompanying full Prescribing Information, including Instructions For Use.**

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## **IMPORTANT SAFETY INFORMATION (continued)**

### **Warnings and Precautions (continued):**

#### **Liver Test Abnormalities (continued)**

Obtain baseline liver tests and monitor during treatment. Dose reduction or treatment interruption may be required if abnormalities occur. For persistent or recurrent liver test abnormalities, consider treatment discontinuation.

Bylvay was not evaluated in PFIC or ALGS patients with cirrhosis. Closely monitor for liver test abnormalities; permanently discontinue Bylvay if a patient progresses to portal hypertension or experiences a hepatic decompensation event.

#### **Diarrhea**

In a PFIC clinical trial, diarrhea was reported in 2 (10%) placebo-treated patients, 9 (39%) Bylvay-treated 40 mcg/kg/day patients, and 4 (21%) Bylvay-treated 120 mcg/kg/day patients. Treatment interruption due to diarrhea occurred in 2 patients with 3 events during treatment with Bylvay 120 mcg/kg/day. Treatment interruption due to diarrhea ranged between 3 to 7 days. One patient treated with Bylvay 120 mcg/kg/day withdrew from the pivotal clinical trial due to persistent diarrhea.

In an ALGS clinical trial, diarrhea in ALGS patients was reported in 1 (6%) placebo-treated patient and in 10 (29%) Bylvay-treated patients. No patients interrupted or permanently discontinued Bylvay due to diarrhea.

If diarrhea occurs, monitor for dehydration and treat promptly. Interrupt Bylvay 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 Bylvay treatment.

#### **Fat-Soluble Vitamin (FSV) Deficiency**

Fat-soluble vitamins (FSV) include vitamin A, D, E, and K (measured using INR levels). PFIC patients can have FSV deficiency at baseline. Bylvay may affect absorption of fat-soluble vitamins. In a clinical trial, new onset or worsening of existing FSV deficiency was reported in 1 (5%) placebo-treated patient and 3 (16%) Bylvay-treated 120 mcg/kg/day patients; none of the Bylvay-treated 40 mcg/kg/day patients had new onset or worsening of existing FSV deficiency. In an ALGS clinical trial, new or worsening of existing FSV deficiency was reported in 3 (17.6%) placebo-treated patients and 3 (8.6%) Bylvay-treated patients.

Obtain serum FSV levels at baseline and monitor during treatment, along with any clinical manifestations. If FSV deficiency is diagnosed, supplement with FSV. Discontinue Bylvay if FSV deficiency persists or worsens despite adequate FSV supplementation.

#### **Adverse Reactions**

The most common adverse reactions for Bylvay in patients with PFIC are diarrhea, liver test abnormalities, vomiting, abdominal pain, and fat-soluble vitamin 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**

There are no human data on Bylvay use in pregnant persons 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. For more information, please call 1-855-252-4736.

**Please see accompanying full Prescribing Information, including Instructions For Use.**