IPSEN CARES® Bylvay® (odevixibat) capsules Enrollment Form

IPSEN CARES® Coverage, Access, Reimbursement & Education Support

Questions? Call IPSEN CARES at 1-866-435-5677, Monday–Friday 8 AM–8 PM ET

Please submit all completed pages to IPSEN CARES for processing by faxing to 1-855-465-3820

PATIENT INFORMATION

First Name _____ Address _____

Last Name _____ City _____ State _____ ZIP _____

Date of Birth (MM/DD/YYYY) ____ / ____ / ____ Home Phone # _____ Cell Phone # _____

Sex Assigned at Birth ◯ Male ◯ Female Best Time to Contact ☐ Morning ☐ Afternoon ☐ Evening

Caregiver/Legal Guardian Name (First & Last) Email _____

_____ Caregiver/Legal Guardian Phone # _____

Preferred Language _____ Relationship to Patient _____

INSURANCE INFORMATION

☐ Patient does not have insurance

Complete the chart below or attach copies of the front and back of the patient's primary insurance card for both pharmacy and medical benefits. If applicable, please also attach the patient's secondary insurance card for pharmacy and medical benefits.

	Primary Medical Benefit	Primary Pharmacy Benefit
Policy Holder Name		
Primary Insurance Co.		
Insurance Co. Phone #		
Subscriber Policy ID #		
Policy/Employer/Group #		
RxBIN		
RxPCN		

TEMPORARY PATIENT ASSISTANCE PROGRAM (TPAP)

☐ By checking this box, I have determined there is an immediate and urgent medical need for Bylvay. My patient should be evaluated for TPAP due to insurance delays. If approved, eligible patients may receive a temporary free supply of Bylvay.

DIAGNOSIS

◯ Alagille syndrome (ALGS): primary diagnosis

◯ Progressive familial intrahepatic cholestasis (PFIC): primary diagnosis

◯ ICD-10: _____

SPECIALTY PHARMACY

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

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.

PRESCRIBER INFORMATION

Prescriber Name (First & Last) _____ Office Contact and Title _____

Office/Institution _____ Phone # _____ Fax # _____

Specialty _____ NPI _____ Tax ID _____ Email _____

Address _____ Preferred Method of Contact ☐ Phone ☐ Fax ☐ Email

City _____ State _____ ZIP _____

PRESCRIPTION: Bylvay® (odevixibat) (SEE PAGE 3 FOR WEIGHT-BASED DOSING TABLES)

Patient's Current Weight _____ kg Date Measured (MM/DD/YYYY) ____ / ____ / ____

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

*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

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. I authorize Ipsen and its agents or contractors to forward a prescription 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, and that non-compliance could result in outreach to me. Medications received by me or on my behalf in connection with any IPSEN CARES program will be used only for the 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.

Prescriber Signature _____ **Prescriber Signature** _____ **Date** _____

(stamp signature not allowed) (dispense as written) (substitution permissible)

We are collecting your personal information to fulfill your request. Please see Ipsen's privacy policy at https://www.ipsen.com/us/privacy-policy/ and Consumer Health Data Privacy Policy at https://www.ipsen.com/us/consumer-health-data-privacy/. Residents of certain states have additional rights regarding the collection, use, and disclosure of their personal information, and more information about those rights is available at Ipsen's Supplemental State Privacy Notice at https://www.ipsen.com/us/Supplement-Website-Privacy-Notice. US residents who are unable to review or access this notice may call 1-844-975-1739 to access this notice in an alternative format.

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PATIENT AUTHORIZATION FOR DISCLOSURE AND USE OF HEALTH INFORMATION

(Required for IPSEN CARES participation)

By signing below, I am providing my authorization for disclosure and use of my health information on the terms set forth on pages 3 and 4 of this Enrollment Form. If I am a legal representative signing on behalf of the patient, I certify that I am authorized to do so.

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

Printed Name of Signing Party _____ **Date** _____

If Legal Representative, indicate relationship to patient _____

REQUIRED FOR IPSEN CARES ENROLLMENT:

☐ **PATIENT CONFIRMATION AND CONSENT TO TERMS OF IPSEN CARES ENROLLMENT**
(Required for IPSEN CARES participation)
By checking this box, I confirm I would like to enroll in IPSEN CARES and that any information, including insurance, US residency, and financial information, I provide is complete and accurate. I agree to immediately notify IPSEN CARES if my health insurance coverage changes. I understand that Ipsen may revise, change, or terminate this program at any time without notice.

☐ **PATIENT ATTESTATION REQUIRED FOR COPAY ASSISTANCE**
(Only required for copay assistance)
By checking this box, 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 I would like to be enrolled into the IPSEN CARES Copay Assistance Program.

THE FOLLOWING TWO CONSENTS ARE OPTIONAL FOR ALL PROGRAMS:

☐ **MARKETING, MARKET RESEARCH, AND CLINICAL STUDY COMMUNICATIONS CONSENT**
By checking this box, I agree to the use of my personal health information for marketing, market research, and clinical study outreach purposes, as described on page 4.

☐ **TEXT MESSAGING CONSENT**
By checking this box, I agree to receive text messages as described on page 4 that may involve the use of my personal health information and for which data rates may apply.

Scan the QR code to learn more about IPSEN CARES.

WEIGHT-BASED DOSING TABLES

See dosing tables below to determine dosage by patient weight in kg.

Recommended Dosage for PFIC in Patients (40 mcg/kg/day) Aged 3 Months and Older

Pruritus in PFIC	
Body Weight (kg)	**Once Daily Dosage (mcg)**
7.4 and below	200
7.5 to 12.4	400
12.5 to 17.4	600
17.5 to 25.4	800
25.5 to 35.4	1,200
35.5 to 45.4	1,600
45.5 to 55.4	2,000
55.5 and above	2,400

Recommended Dosage for ALGS in Patients (120 mcg/kg/day) Aged 12 Months and Older

Cholestatic Pruritus in ALGS	
Body Weight (kg)	**Once Daily Dosage (mcg)**
7.4 and below	600
7.5 to 12.4	1,200
12.5 to 17.4	1,800
17.5 to 25.4	2,400
25.5 to 35.4	3,600
35.5 to 45.4	4,800
45.5 to 55.4	6,000
55.5 and above	7,200

1. Patient Authorization for Disclosure and Use of Health Information

(Required for IPSEN CARES participation)

By signing this Authorization via the signature block on page 2, I authorize my doctor(s) and their staff, other healthcare providers, pharmacies that may receive my prescription for Bylvay, and my insurance company (collectively, my "Providers") to disclose my personal information, including information about my insurance, prescription(s), care management, medical condition(s), and related information (collectively, "Health Information") to Ipsen Biopharmaceuticals, Inc., its affiliates, agents, and/or vendors that support administration of the IPSEN CARES program (collectively, "Ipsen") so that I may participate in IPSEN CARES, including, if applicable, the IPSEN CARES Patient Assistance Program (the "PAP"). I agree that Ipsen may collect my Health Information from me, my legal representative, and my Providers for Ipsen's use and disclosure solely for the following purposes: (1) enroll me in IPSEN CARES and facilitate my participation in other patient programs for which I am eligible at my request (including PAP); (2) establish my benefit eligibility and potential out-of-pocket costs for Bylvay; (3) communicate with my Providers; (4) provide me support services, including patient education and financial assistance for Bylvay; (5) help get Bylvay shipped to me or my Providers; (6) support Ipsen internal program operations, analytics, and improvement, which may include live, automated, or artificial intelligence monitoring and analytics; and (7) as required or allowed by law or as I may otherwise agree. I understand that once my Health Information has been disclosed to Ipsen, it may no longer be protected by certain privacy laws and may be redisclosed, but I also understand that Ipsen intends to use and disclose my Health Information only for the purposes described in this Authorization.

1. Patient Authorization for Disclosure and Use of Health Information (continued)
(Required for IPSEN CARES participation)

I understand that I may refuse to sign this Authorization. If I do so, I will not be able to participate in IPSEN CARES or the PAP, but my decision will not affect my eligibility for medical treatment, my ability to seek payment for this treatment, my insurance enrollment, or my eligibility for insurance coverage. I understand that my healthcare providers may receive remuneration from Ipsen in connection with my Health Information and/or for any therapy support services provided to me. This Authorization expires 3 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 and that I can obtain additional copies by contacting IPSEN CARES at 1-866-435-5677.

I understand that I can revoke this Authorization by contacting IPSEN CARES at 1-866-435-5677 or writing to IPSEN CARES, 2250 Perimeter Park Dr., Suite 300, Morrisville, NC 27560. Revocation of this Authorization will end further uses and disclosures of my Health Information by the parties identified in this form, but it will not change any actions taken before my revocation is received by Ipsen.

2. Patient Consent to Process Health Information for Marketing, Market Research, and Clinical Study Communications Purposes (Optional)

By checking the box for this consent on page 2, I agree that Ipsen may process my personal information, including the information I provide on this form and my Health Information, for marketing and market research purposes, including to communicate with me via mail and email about IPSEN CARES, Ipsen products and services, and medical conditions. I also agree that Ipsen may contact me about clinical studies for which I may be eligible to participate, and I understand that I am not required to participate in such studies. I agree that Ipsen may disclose my Information to Ipsen's vendors for such purposes. If I consent, I understand that I may withdraw my consent at any time by calling 1-844-975-1739, or by sending my request in writing to: IPSEN CARES, 2250 Perimeter Park Dr. Suite 300 Morrisville, NC 27560.

3. Patient Consent to Receive SMS Text Messages (Optional)

By checking the box for this consent on page 2, I agree that Ipsen (directly or through its vendors) may send me text messages ("texts") at the mobile phone number I have provided on this form about Ipsen CARES and Ipsen's products or services, which may include promotional messages. I understand that I do not need to agree to receive any such text messages in order to purchase or use any Ipsen products or services. I understand that I may opt out from receiving text messages from Ipsen by calling 1-866-435-5677 or replying "STOP" by text to any text from Ipsen. Message and data rates may apply.

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