

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)

O 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

Please see <u>Important Safety Information</u> throughout and accompanying full <u>Prescribing</u> <u>Information</u>, including <u>Instructions for Use</u>.



What Is IPSEN CARES®?

Starting a new treatment can be a time filled with questions and uncertainty. IPSEN CARES® is here to help along the way.

IPSEN CARES is a patient support program that is designed to help patients and families during treatment with Bylvay® (odevixibat).

When you enroll in IPSEN CARES, you will be connected with a dedicated Patient Access Manager and Patient Education Liaison.

IMPORTANT SAFETY INFORMATION

· Speak with your healthcare provider if you experience abdominal pain, vomiting, diarrhea, hematoma, decreased weight, or dehydration as these have been reported with the use of Bylvay. Patients should contact their healthcare provider if they experience new onset or worsening of diarrhea

Meet Your IPSEN CARES® Team

Patient Access Manager

When you enroll in IPSEN CARES®, you will be connected with a dedicated Patient Access Manager (PAM). PAMs are experienced in navigating the world of health insurance and can help you understand what is needed to get access to, and afford, your prescribed treatment.

Your PAM:



Can provide information and support to help you prepare to talk to your healthcare provider, specialty pharmacy, and insurance company



Will work with you to understand your specific situation and healthcare coverage needs



Will help to identify possible financial support programs for which you may qualify

Patient Education Liaison

You will be connected with a Patient Education Liaison (PEL). PELs are healthcare educators and are experienced in working with individuals living with certain conditions.

Your PEL:



Can provide educational information to help you, your family, and caregivers better understand your condition, access needs, and prescribed treatment expectations



Will help you to understand your specific situation and healthcare needs in alignment with the direction and advice provided by your healthcare provider



Will work in connection with your healthcare providers to support you and your caregivers through some of the many challenges of living with your condition

Personalized Support Services



Financial & Insurance Assistance

- Initiate benefits investigation to help you understand your health insurance coverage
- Provide financial assistance for eligible patients*
- Coordinate treatment logistics related to prior authorization



Dedicated, Individualized Support

- Provide information and support to help interactions between the healthcare provider, the patient and family, insurance company, and specialty pharmacy
- Provide an understanding of your specific situation and healthcare needs



Continuity of Care

- Coordinate the details associated with patient transitions (including relocation, vacations, transitions from pediatric to adult clinics, insurance changes, and other events affecting continuity of care)
- Work with your healthcare provider and specialty pharmacy to help you get your prescribed treatment when and where you need it



Educational Materials and Programs

- Provide educational information related to your condition and treatment expectations
- Provide information about advocacy groups that support your condition, as well as advocacy groups for the broader community who are impacted by the condition
- Provide information about testing (Some insurance plans may require testing before providing coverage—the IPSEN CARES® team can provide information regarding the different places where testing may be available)

IMPORTANT SAFETY INFORMATION (Continued)

· Elevations in liver tests (for example, AST, ALT, TB) have been observed with use of Bylvay (odevixibat). The patient's healthcare provider will obtain liver tests before starting Bylvay and periodically during treatment with Bylvay. Patients should report to their healthcare provider any symptoms of liver problems (for example, nausea, vomiting, skin or the whites of eyes turn yellow, dark or brown urine, pain on the right side of the abdomen, loss of appetite)

^{*}While many support resources are available to everyone enrolled in IPSEN CARES, certain offerings will be tailored to your financial need and other eligibility criteria must also be met to qualify for certain offerings. Remember to always talk to your healthcare provider about your treatment experience. Terms and conditions apply. Visit IPSENCARES.com to learn more.

Getting Started With IPSEN CARES®

For you to enroll in IPSEN CARES®, your doctor must complete the IPSEN CARES Enrollment Form and you must review and sign the patient authorization section. You can also sign the patient authorization online at IPSENCARES.com.

• You can also print the Patient Authorization Form and send it back to IPSEN CARES by fax: (888) 525-2416 or email: support@IPSENCARES.com.





IMPORTANT SAFETY INFORMATION (Continued)

- · Bylvay (odevixibat) may impair absorption of fat-soluble vitamins (FSV), which include vitamins A, D, E and K (vitamin K is assessed by measuring INR). The patient's healthcare provider will obtain serum levels of vitamins A, D, E, and INR (for vitamin K) at baseline and periodically during treatment to assess for worsening of FSV deficiency
- Do not swallow the 200 mcg or 600 mcg capsule(s) containing Oral Pellets whole. These are intended to be opened and the contents mixed into soft food. Take Bylvay in the morning with a meal

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

Please see accompanying full <u>Prescribing Information</u>, including <u>Instructions for Use</u>.

We're here to help.

IPSENCARES.com · (866) 435-5677 · 8:00 AM - 8:00 PM ET

Helping patients get access to their prescribed medications with the information and support they need.

Our IPSEN CARES® patient support program provides patients and families with resources to help them better understand and manage their condition.

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