

Dedicated Support for Patients and Families

Actor portrayal

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

IPSENCARES[®]
Coverage, Access, Reimbursement & Education Support

USES

Bylvay is indicated for the treatment of itching 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 might not work for some PFIC type 2 patients who have specific *ABCB11* gene changes. Talk with your healthcare provider if you have questions.

Please see [Important Safety Information](#) throughout and accompanying full [Prescribing Information](#), including [Instructions for Use](#).

We're here when you need us.

[IPSENCARES.com](https://www.ipsencares.com) | (866) 435-5677



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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).

IMPORTANT SAFETY INFORMATION

- You should not use Bylvay if you have had or have an advanced stage of liver disease. Talk with your healthcare provider if you have any liver conditions.
- Abnormal liver tests have been observed with use of Bylvay. Liver tests should be obtained before starting and periodically during therapy to monitor for liver injury. Immediately report to your healthcare provider any signs or symptoms of liver injury, such as, nausea, vomiting, skin or the whites of eyes turn yellow, dark or brown urine, pain on the right side of the abdomen, or loss of appetite.
- Notify your healthcare provider if you experience new onset or worsening of diarrhea.
- Bylvay may decrease the absorption of certain vitamins, which include vitamins A, D, E, and K (FSV or fat- soluble vitamins). Your blood levels of these vitamins should be measured before starting and periodically during treatment to assess for FSV deficiency. You may bleed more easily or may bleed longer. Call your healthcare provider if you have any signs or symptoms of bleeding.

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

You should always rely on your healthcare provider for information about your health and the right treatment for you.

Personalized Support Offerings



Financial & Insurance Assistance

- Benefits investigation to help you understand your health insurance coverage
 - Financial assistance through the Copay Assistance Program
 - You may pay as little as \$0 for each Bylvay prescription if you have commercial insurance and meet eligibility criteria*
 - Coordination related to prior authorization and appeals support
 - Assistance program also available for uninsured patients or patients whose insurance does not cover Bylvay
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Dedicated, Individualized Support

- Provide information and support to help interactions between your healthcare provider, you and your family, your insurance company, and your specialty pharmacy
 - Support to help you understand your specific situation and healthcare needs
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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
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Educational Materials and Programs

- Provide educational information related to your condition and treatment expectations
 - 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)
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*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 [IPSECARES.com](https://www.ipsecares.com) to learn more.

IMPORTANT SAFETY INFORMATION (Continued)

- The most common side effects of Bylvay® (odevixibat) treatment in patients with ALGS are diarrhea, abdominal pain, abnormal bleeding, such as bruising, and decreased weight.
- The most common side effects of Bylvay in patients with PFIC are diarrhea, liver test abnormalities, vomiting, abdominal pain, and FSV deficiency.

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: (855) 465-3820 or email: support@IPSENCARES.com.
- If you have any questions about the process, give us a call at (866) 435-5677 Monday - Friday, 8:00 AM - 8:00 PM ET.



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IMPORTANT SAFETY INFORMATION (Continued)

- 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.
- For patients taking bile acid binding resins, take Bylvay® (odevixibat) at least 4 hours before or 4 hours after taking a bile acid binding resin.
- There is a pregnancy safety study that collects outcome data in women taking Bylvay during pregnancy. Pregnant women exposed to Bylvay should report if they have used Bylvay during pregnancy by calling 1-855-463-5127.

You are encouraged to report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch. You may also report side effects to Ipsen Biopharmaceuticals at 1-855-463-5127.

Please see accompanying full [Prescribing Information](#), including [Instructions for Use](#).

We're here to help.

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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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