

ITCHING IN PFIC

Progressive Familial
Intrahepatic Cholestasis

Relief You've Been Waiting For

A GUIDE FOR
PATIENTS AND CAREGIVERS

All images are actor portrayals.

Indication and Usage

Bylvay is indicated for the treatment of pruritus in patients 3 months of age and older with progressive familial intrahepatic cholestasis (PFIC).

Limitation of Use:

- Bylvay may not be effective in PFIC type 2 patients with ABCB11 variants resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3).

Please see Important Safety Information on page 7 and accompanying full Prescribing Information with Instructions for Use.



 **Bylvay**[™]
(odevixibat)

200 | 400 | 600 | 1200 mcg capsules

[Bylvay.com](https://www.bylvay.com)

About PFIC

Progressive familial intrahepatic cholestasis (PFIC) is a spectrum of rare, inherited, liver diseases. It causes itching that, until now, no medicine could effectively relieve.

The itching (pruritus) can be so severe that infants and children may scratch through their skin.¹ Many patients turn to surgery, including transplant, to relieve the itching.^{2,3}



What Happens in PFIC?

The body naturally makes bile acids that help with digestion, including absorbing fats and some vitamins. In people with PFIC, the normal flow of bile acids is disrupted. Bile acids build up in the body, damaging the liver.^{4,5}

The itching PFIC causes may be so severe that children may scratch through their skin.¹



Relief from Pruritus in PFIC: Bylvay is Here to Help

Until recently, there have been no medical treatments approved for pruritus in PFIC. Patients often have been treated with surgeries, such as biliary diversion and liver transplantation, which all have significant risks.^{2,6-8}

Bylvay (odevixibat) may change that. Bylvay is the first FDA-approved medicine to treat pruritus in PFIC. Bylvay is an oral medicine that is taken once a day.

Learn more about Bylvay on the following pages.

Important Safety Information

Speak with your healthcare provider if you experience: abdominal pain, vomiting, diarrhea, and dehydration as these have been reported with the use of Bylvay. Contact your healthcare provider if you experience new or worsening diarrhea, or dehydration.

Please see Important Safety Information on page 7 and accompanying full Prescribing Information with Instructions for Use.

A Chance for Relief from the Itch

Because of the severe itching it causes, PFIC can disrupt activities like going for a swim or relaxing at home. Bylvay gives patients a chance for relief from the itch.

Bylvay, the first non-surgical treatment approved for pruritus in PFIC, is proven effective in patients as young as 3 months old. Many patients had little or no scratching after 4 weeks on Bylvay.



Bylvay may provide **itch relief** without surgery.

How Does Bylvay Work?

While it is not known exactly how Bylvay works, it is thought that by reducing bile acids in the blood, Bylvay may reduce the amount of itching PFIC patients experience.

Bylvay was studied in the largest clinical trial completed in PFIC patients. In the clinical trial, 83% of Bylvay patients and 85% of placebo patients experienced side effects. The most common side effects during the trial were diarrhea, liver test changes, vomiting, stomach pain and fat-soluble vitamin problems.



Bylvay is approved for patients as young as 3 months old.



Everyday Help with Bylvay



Bylvay is an oral capsule that is taken once a day in the morning with a meal. Your doctor will prescribe the right dose based on your child's weight.



It can be swallowed as a capsule or opened and mixed in a small amount (up to 30mL or 2 tablespoons) of apple sauce, oatmeal, banana or carrot puree, chocolate pudding, or rice pudding in a bowl. Food should be at or below room temperature. **Bylvay should not be mixed with liquid. Patients who only take liquid food should not use Bylvay.**



Patients taking bile acid binding resins should take Bylvay at least 4 hours before or 4 hours after the bile acid binding resins.



Bylvay does not need to be refrigerated.



For complete instructions on taking Bylvay, see the Instructions for Use included with this brochure.

For more information about Bylvay, visit Bylvay.com.

Remember, it's important to take Bylvay every morning, as prescribed by your doctor.



Important Safety Information

Increases in the amounts of some liver enzymes (for example, AST, ALT, TB) have been seen with use of Bylvay. Your healthcare provider will run liver tests before and during treatment with Bylvay. You should report to your 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).

Please see Important Safety Information on page 7 and accompanying full Prescribing Information with Instructions for Use.

Albireo Assist: Helping Navigate the Way

Albireo Assist is a comprehensive support program for people taking Bylvay and their caregivers.*

People enrolled in Albireo Assist are assigned a dedicated Care Coordinator who is available throughout their treatment journey. Care Coordinators can provide:



Financial & Insurance Assistance

- Help understanding your health insurance coverage, including benefits, deductibles, and copay or coinsurance
- Help getting a prior authorization if your insurance requires it
- Information on financial assistance programs for eligible patients; the types of programs available to you will depend on the type of insurance you have
- Information on copay assistance for eligible patients

\$0 Copay Assistance Program**

**The maximum amount of Copay assistance under the Program is \$20,000.00 per calendar year.



Dedicated, Live Support

- Access to your dedicated Care Coordinator who is just a phone call away
- Personalized support from an experienced professional who knows you and wants to help



Care Logistics

- Connecting you with the right specialty pharmacy based on your benefits
- Helping ensure you get your refills on time



Educational Materials & Programs

- Offering resources to help you and others in your life better understand your/your child's condition and treatment
- Providing information about community resources and patient meetings

*See albireoassist.com/copayterms.pdf for full terms and conditions.

**Call 855-ALBIREO (855-252-4736), option 1, 8am-6pm ET
or go to www.albireoassist.com for more information.**

Important Safety Information

- Speak with your healthcare provider if you experience: abdominal pain, vomiting, diarrhea, and dehydration as these have been reported with the use of Bylvay. Contact your healthcare provider if you experience new or worsening diarrhea, or dehydration.
- Increases in the amounts of some liver enzymes (for example, AST, ALT, TB) have been seen with use of Bylvay. Your healthcare provider will run liver tests before and during treatment with Bylvay. You should report to your 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).
- Bylvay may reduce the body's ability to absorb fat-soluble vitamins (FSV), which include vitamins A, D, E and K. Your healthcare provider will measure blood levels of these vitamins before and during treatment with Bylvay.

- **Do not mix Bylvay with liquids.**
- 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 Prescribing Information with Instructions for Use.



With Bylvay, a Chance for Relief from the Itch

- Bylvay can reduce itching caused by PFIC
- Bylvay reduces bile acids in the blood
- Bylvay is an oral medicine that is taken once a day, and does not need to be refrigerated
- Albireo Assist provides personal support for patients and families

About Albireo

Committed to Making a Meaningful Difference

Albireo is committed to working with physicians and families to help advance the care of people with cholestatic liver diseases through the development and commercialization of novel treatments.

[Bylvay.com](https://www.bylvay.com)

[AlbireoAssist.com](https://www.albireoassist.com)

855-ALBIREO (855-252-4736)

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