

Bylvay (odevixibat) FDA Approval Patient Advocacy FAQ

1. What is Bylvay and what is it approved to treat?

- Bylvay (odevixibat) has been approved by the U.S. Food & Drug Administration (FDA) as the first drug approved for the treatment of pruritus in patients with all sub-types of progressive familial intrahepatic cholestasis (PFIC).
- It is a once-daily, non-systemic ileal bile acid transport inhibitor (IBATi). It can be taken as a once-daily capsule, or it can also be opened and sprinkled onto soft food to help with adherence for young children. It does not require refrigeration and is easily administered.

2. What is PFIC?

- Progressive familial intrahepatic cholestasis, or PFIC, is a rare and devastating disorder affecting young children that causes progressive, life-threatening liver disease in which children are unable to drain bile from the liver.
- In many cases, PFIC leads to cirrhosis and liver failure within the first 10 years of life.
- The most prominent and problematic ongoing manifestation of PFIC is pruritus, or intense itching, which often results in a severely diminished quality of life.
- Up until now, there have been no approved drugs for PFIC, only surgical options that include biliary diversion surgery (BDS) and liver transplantation, and without them most PFIC patients do not survive past the age of 30.

3. How does the approval of Bylvay change the standard of care for patients with PFIC?

- Before Bylvay, there were no medicines approved for PFIC—only invasive surgical options, including a procedure known as biliary diversion surgery (BDS) and liver transplantation.
- Under the care and recommendation by their physician, patients may now be able to take an oral once-daily medication.

4. How will Albireo support patients in accessing Bylvay?

- Albireo has launched Albireo Assist™, a company-run program of customized, patient services with dedicated Care Coordinators (CC) to support every U.S. patient needing Bylvay.
- Care Coordinators will guide patients and their families through available financial and non-financial services.
- Some of the specific patient access programs Albireo Assist offers include:
 - Patient Assistance Program: Free drug program for qualifying patients based on income (gross household income below 500% of Federal Poverty Level) and other financial factors.
 - Copay assistance program: Qualifying commercial patients will pay as little as \$0 in copay costs. There will be a \$20,000 annual maximum, after patients will transition to the patient assistance or the bridge programs.
 - Bridge program: Families receive up to 60-days of treatment, bridging the gap for families who may be experiencing a temporary barrier to access.
 - Good faith replacement policy: 15-day supply of medication to qualifying patients if their medication is damaged or lost.
- Full program details and eligibility requirements can be assessed at www.albireoassist.com

5. What should I do next? How can I find out more?

- Talk to your doctor to determine if you should be treated with Bylvay.
- Learn more about Bylvay at www.albireopharma.com/programs/bylvay
- Join an educational patient town hall event, date TBD but more to come soon.