Clarivate™

Lynavoy is the first FDA-approved therapy for cholestatic pruritus in PBC

Market Event Summary

Kanika Ujla | April 2026

Lynavoy's FDA approval fills a critical unmet need in PBC treatment

Background

- Primary biliary cholangitis (PBC) is a rare, chronic autoimmune cholestatic liver disease that can progress to cirrhosis and liver failure. Cholestatic pruritus is one of the most common and debilitating symptoms of PBC and significantly impairs quality of life.
- Currently approved treatments for PBC, including UDCA and newer second-line agents such as PPAR agonists—Iqirvo (elafibranor) and Livdelzi (seladelpar)—are primarily indicated to slow disease progression and improve biochemical markers, with limited and inconsistent effects on pruritus.
- Management of cholestatic pruritus has historically relied on off-label therapies (including bile acid sequestrants, rifampicin, opioid antagonists, and antihistamines), which show variable efficacy and are often limited by tolerability issues.
- As a result, cholestatic pruritus remains a major unmet need in PBC, with many patients experiencing persistent or refractory symptoms despite optimized disease-modifying therapy.

Event

- On March 19, 2026, the FDA approved GSK's Lynavoy (linerixibat), the first therapy approved in the U.S. for the treatment of cholestatic pruritus in adult patients with PBC.
- Lynavoy is an oral IBAT inhibitor that inhibits ileal bile acid reuptake, thereby reducing systemic bile acid levels and other pruritogenic mediators.
- The approval was based on results from the Phase 3 GLISTEN trial, demonstrating statistically significant improvements in cholestatic pruritus and itch-related sleep interference versus placebo, with rapid onset (by week 2) and sustained effects over 24 weeks.

Clarivate™

Clarivate's takeaways

Treatment dynamics

- Lynavoy is unlikely to compete directly with UDCA or approved PPAR agonists (elafibranor and seladelpar), as its FDA label is focused on the treatment of cholestatic pruritus rather than slowing liver disease progression. Owing to its first-in-class status, targeted IBAT inhibitor mechanism of action, oral administration, and demonstrated efficacy in reducing itch severity and sleep disturbance, Lynavoy will expand the PBC treatment armamentarium by addressing a major symptomatic gap that remains inadequately managed with existing therapies. As a result, Lynavoy is likely to be positioned as an add-on in patients with cholestatic pruritus.

Commercial

- Given the high prevalence of cholestatic pruritus in PBC and the limited effectiveness of off-label options, Lynavoy has the potential to achieve meaningful uptake as a broadly applicable adjunctive therapy, positioning it for sustained commercial opportunity despite the relatively small overall PBC population.

About the author

Kanika Ujla

Senior Healthcare Research & Data Analyst

DRG Commercial Solutions

Kanika Ujla, M.Sc., is a senior healthcare research and data analyst on the Infectious, Niche, and Rare Diseases team at Clarivate. She has experience in R&D, consulting, and business research with healthcare and life science companies. Kanika obtained her master's degree in biotechnology from the University of Jammu and her bachelor's degree in biotechnology from Chaudhary Charan Singh University.

Clarivate coverage of Primary biliary cholangitis

- Primary Biliary Cholangitis | Niche & Rare Disease Landscape & Forecast | US/EU5 (published September 2025)
- Primary Biliary Cholangitis | Treatment Algorithms: Claims Data Analysis | US | published October 2025
- Primary Biliary Cholangitis | Unmet Need | US/EU | published April 2025

About Clarivate

Clarivate is a leading global provider of transformative intelligence. We offer enriched data, insights & analytics, workflow solutions and expert services in the areas of Academia & Government, Intellectual Property and Life Sciences & Healthcare. For more information, please visit clarivate.com.