

For Immediate Release

AllianceRx Walgreens Prime Studies Use of Ocaliva® in the Treatment of Primary Biliary Cholangitis

Findings to be presented March 31 at AMCP's 2022 annual conference.

ORLANDO, Fla., March 30, 2022 – A recent study evaluating Ocaliva® (obeticholic acid) in patients diagnosed with primary biliary cholangitis (PBC) revealed similar patient-reported adverse effects as in clinical trials while also exploring patient out-of-pocket cost and utilization. The non-comparative longitudinal [study](#) was conducted by [AllianceRx Walgreens Prime](#), a leading specialty and home delivery pharmacy, in conjunction with [Duquesne University School of Pharmacy](#).

PBC is a rare, chronic, autoimmune disease primarily affecting women, in which the bile ducts are destroyed, leading to permanent liver damage. The goal of treatment is to help slow progression of PBC and manage symptoms that reduce quality of life, as there is currently no cure. The U.S. Food and Drug Administration (FDA) has approved two medications for management of PBC: ursodeoxycholic acid (abbreviated UDCA, also known as ursodiol) and obeticholic acid, marketed as Ocaliva.¹

“Ursodiol is first line therapy; however, approximately 40% of patients do not have sufficient improvement in their liver function while on therapy,”¹ says [Kajal Patel, PharmD](#), PGY-1 resident at AllianceRx Walgreens Prime and lead author/analyst of the study. “Obeticholic acid can be used as monotherapy, to patients who are unable to tolerate ursodiol or in combination with ursodiol as second line treatment for these patients.”²

The objective of the study was to evaluate obeticholic acid in patients diagnosed with PBC for patient-reported adverse events, cost and utilization. Dr. Patel says because patients have limited treatment options when ursodiol therapy is intolerable or ineffective, “it is important for providers to understand the costs and outcomes of obeticholic acid, as limited information outside of trials is available.”

For the study, researchers looked into the profiles of patients who filled obeticholic acid from September 1, 2019, to December 31, 2021. A total of 982 patients received a dispensed prescription of obeticholic acid within the study period, and of those, 715 patients met the study inclusion criteria. Patients had to be 18 years of age or older, have an ICD-10 code indicative of PBC, complete two consecutive fills of obeticholic acid, and complete at least one patient care advocate (PCA) initial assessment or at least one PCA refill assessment. They also had to have an index date, which is the date the patient met the inclusion criteria and entered the cohort, of more than 90 days prior to the end of the study period.

Researchers measured adherence by using proportion of days covered (PDC) over a 12-month period, beginning from each patient’s index date. Adverse events (ADE) were defined as side effects reported by the patient to the pharmacy during routine check-in calls completed throughout a patient’s time on therapy during the study period. The researchers used pharmacy dispensing software and clinical patient management applications to collect demographic information, patient-reported ADEs, prescription history, cost and survey response data.

Dr. Patel says that based on the data collected, she was able to evaluate cost, safety, utilization and patient-reported side effects for those taking obeticholic acid for PBC.

“Regarding safety, the most common side effects reported were itching (47%) and fatigue (13%), which were also common in the clinical trials.³ The out-of-pocket copay was lowest for patients with commercial insurance, accompanied with a patient assistance program. Although the average wholesale price of obeticholic acid is costly (\$9,653.41 for a 30-day supply), most patients (94.1%) had an average copay of less than \$50,” she says.⁴ When looking at adherence, most patients (449/715) had a mean PDC greater than 80% with an overall PDC of 77.1%.

[Rick Miller, MSP Pharm, MBA, BSP Pharm, CSP](#), vice president, clinical and professional services, says the greatest takeaway from the research is seeing how obeticholic acid can best be managed based on what patients themselves are reporting. “Knowing the safety and cost trends of patients can help healthcare providers discuss with their patients prior to being prescribed the medication what the benefits and limitations would be for the patient,” he says.

Dr. Patel adds that the hope with these findings is to help providers and other healthcare professionals who care for patients on obeticholic acid for PBC have a better understanding of how to help patients manage their medication appropriately. “Additional research is required as this study did not examine discontinuation rates and reasons. It’s also possible the overall PDC may have been impacted by patient discontinuations as well as changing of insurance and specialty pharmacy provider during the 12-month measurement period from their index date,” she says. “In future studies, it may be important to investigate additional factors to have a better understanding of potential barriers associated with adherence.”

Researchers will present the above findings March 31, 2022, at the [AMCP 2022](#) annual conference in Chicago.

About AllianceRx Walgreens Prime

AllianceRx Walgreens Prime (alliancerxwp.com) is a specialty and home delivery pharmacy that strives to provide exceptional care throughout a patient’s treatment journey with the medications they need every day. Formed in 2017, the company offers tools and resources for patients, providers, and health plans to deliver the optimal health outcomes. The company is headquartered in Orlando, Florida, and its pharmacies are accredited by several national pharmacy accreditation services.

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¹ Lindor K.D., Bowlus C.L., Boyer J., Levy C. and Mayo M. Primary Biliary Cholangitis: 2018 Practice Guidance from the American Association for the Study of Liver Diseases. *Hepatology*. 2018;69(1): 394-419. <https://doi.org/10.1002/hep.30145>

² Ocaliva [package insert]. New York, NY: Intercept Pharmaceuticals, Inc.; 2016.

³ Nevens F, Andreone P, Mazzella G, et al. A Placebo-Controlled Trial of Obeticholic Acid in Primary Biliary Cholangitis. *N Engl J Med*. 2016;375(7):631-643. doi:10.1056/NEJMoa1509840

⁴ IBM Micromedex Red Book. IBM Micromedex. IBM Watson Health; 2021. Accessed March 23, 2022. <https://www.micromedexsolutions.com/>