

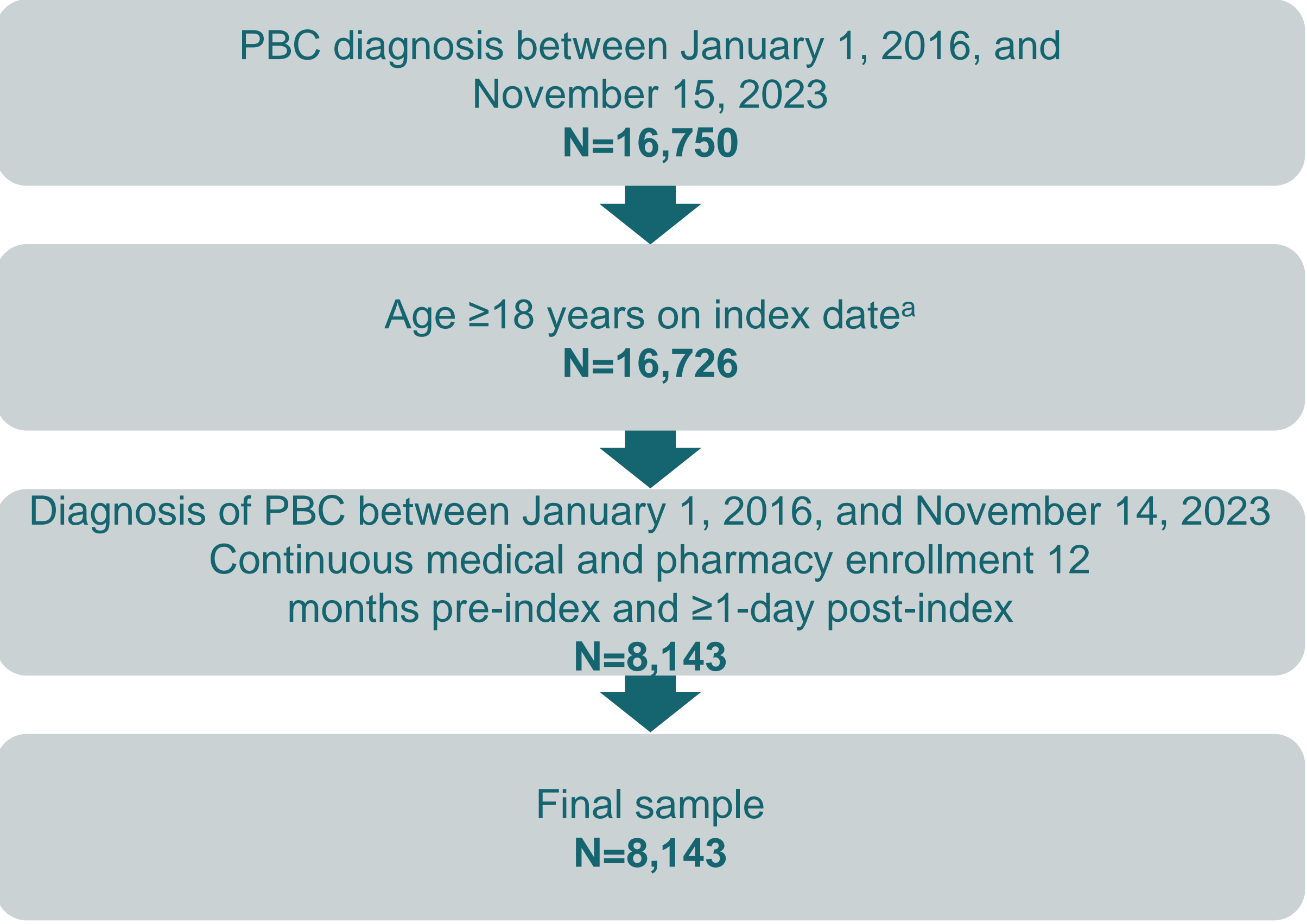
Introduction

- Primary biliary cholangitis (PBC) is a chronic autoimmune liver disease characterized by progressive destruction of intrahepatic bile ducts and may lead to cirrhosis, hepatic decompensation, and death without treatment^{1,2}
- Although PBC progression can be slow, the economic burden of the disease can be high^{3,4}
- The goal of our study was to evaluate the economic burden of healthcare resource utilization (HCRU) in patients with PBC, especially for acute care

Methods

- This study was a retrospective administrative claims analysis using Optum's deidentified Clinformatics® Data Mart Database (**Figure 1**)
- Inclusion criteria
 - ≥18 years of age at index date (date of the first claim with a diagnosis of PBC)
 - Diagnosis of PBC (≥1 inpatient claim or ≥2 outpatient claims on separate days) between January 1, 2016, and November 14, 2023
 - Patients were required to be enrolled in a medical and pharmacy plan for 12 months pre-index (baseline) and ≥1-day post-index
- Patients were followed until the end of the study period (November 15, 2023), end of enrollment, or death (whichever occurred first)
- Baseline patient demographics and clinical characteristics (Charlson Comorbidity Index [CCI])⁵ were assessed using descriptive statistics
- During the follow-up period, hospitalizations and emergency department (ED) visits (not leading to hospitalization) were measured
 - All-cause, liver-related, and pancreatobiliary-related events
 - Liver-related and pancreatobiliary-related events were identified based on diagnosis codes (International Classification of Diseases [ICD] 9 or 10) present at any diagnostic position (e.g., primary, secondary). Sensitivity analysis was conducted to identify these events based on diagnosis codes present in the primary diagnostic position
 - Liver-related: alcohol-associated liver disease, toxic/inflammatory liver disease, chronic/viral hepatitis, hepatic failure, fibrosis, cirrhosis, hepatic decompensation, liver neoplasms, liver infections, liver complications, liver injury, other liver diseases)
 - Pancreatobiliary-related (a subset of liver-related): PBC, cholelithiasis, cholecystitis, pancreatic diseases, biliary duct and gallbladder–related injury and diseases
- Annualized number of hospitalizations/ED visits was calculated by dividing the total number of hospitalizations/ED visits during the follow-up period by the length of the follow-up period
- Annualized overall and acute care (hospitalization and ED visits) medical costs were also assessed

Figure 1. Sample selection from Optum's deidentified Clinformatics® Data Mart Database



^aIndex date defined as date of first claim with a diagnosis for PBC (≥1 inpatient claim or ≥2 outpatient claims on separate days). Abbreviations: PBC, primary biliary cholangitis.

Results

Patient Demographics (Table 1)

- The 8,143 patients identified with PBC were mostly White (69.4%) and female (80.8%) with a mean (SD) age of 67 (12.7) years
- The majority of patients were enrolled in Medicare (69.7%)

Table 1. Baseline demographics of the study population

Demographic	N=8,143
Female, n (%)	6,578 (80.8)
Age at index, y	
Mean (SD)	67.0 (12.7)
Median (IQR)	69.0 (60.0, 76.0)
Race/ethnicity, n (%)	
White	5,651 (69.4)
Hispanic	1,097 (13.5)
Black	693 (8.5)
Asian	222 (2.7)
Unknown	98 (1.2)
Missing	382 (4.7)
Insurance type at index, n (%)	
Commercial	2,461 (30.2)
Medicare	5,678 (69.7)
Multiple ^a	4 (<0.1)

^aThe patient had multiple types of coverage and types of service during their continuous enrollment around the index date. Abbreviation: IQR, interquartile range.

Clinical Characteristics (Table 2)

- The mean (SD) CCI was 3 (2.79), and the most frequent comorbidities were diabetes without chronic complications (n=2,301; 28.3%) followed by chronic pulmonary disease (n=2,057; 25.3%)

Table 2. Baseline clinical characteristics of the study population

Charlson Comorbidity Index (CCI)	N=8,143
CCI score	
Mean (SD)	3.0 (2.79)
Median (IQR)	3.0 (1.0, 5.0)
Range	1.0, 18.0
CCI components occurring in >10% of patients, n (%)	
Diabetes without chronic complication	2,301 (28.3)
Chronic pulmonary disease	2,057 (25.3)
Renal disease	1,621 (19.9)
Peripheral vascular disease	1,596 (19.6)
Moderate or severe liver disease ^a	1,510 (18.5)
Diabetes with chronic complication	1,245 (15.3)
Congestive heart failure	1,113 (13.7)
Cerebrovascular disease	1,029 (12.6)
Rheumatic disease	978 (12.0)

^aIncludes esophageal varices with or without bleeding, portal hypertension, hepatic encephalopathy, hepatorenal syndrome, gastric varices, alcoholic liver failure, hepatic failure, chronic liver failure, toxic liver disease with hepatic necrosis, and hepatic veno-occlusive disease. Abbreviations: CCI, Charlson Comorbidity Index; IQR, interquartile range.

Healthcare Resource Utilization (Table 3)

- Annually, 19.8% of patients had ≥1 all-cause hospitalization, and among these patients, 62.4% had additional hospitalizations
- 11.5% of patients had ≥1 liver-related hospitalization annually, identified based on liver-related diagnosis codes in any position
 - Among these patients, 61.9% had additional hospitalizations
- 5.2% had ≥1 liver-related hospitalization annually, identified based on liver-related diagnosis codes in the first position
 - Among these patients, 59.5% had additional hospitalizations

- 19.6% of patients had ≥1 all-cause ED visit annually, and among these patients, 50.6% had additional all-cause ED visits (median [interquartile range]: 2.02 [1.39, 3.39])
- 3.2% of patients had ≥1 liver-related ED visit annually, identified based on liver-related diagnosis codes in any position
 - Among these patients, 50.8% had additional liver-related ED visits
- 1.8% of patients had ≥1 liver-related ED visit annually, identified based on liver-related diagnosis codes in the first position
 - Among these patients, 52.4% had additional liver-related ED visits

Table 3. Annualized health care resource utilization during follow-up

N=8,143	All-cause	Liver-related (diagnosis codes in any position)	Pancreatobiliary-related (diagnosis codes in any position) ^a	Liver-related (diagnosis codes in the first position)	Pancreatobiliary-related (diagnosis codes in the first position) ^a
Patients with ≥1 hospitalization, n (%)	1,612 (19.8)	938 (11.5)	326 (4.0)	422 (5.2)	109 (1.3)
Patients with additional hospitalizations (among those with ≥1 hospitalization)	1,006 (62.4)	581 (61.9)	173 (53.1)	251 (59.5)	57 (52.3)
Hospitalizations, mean (SD), per patient per year	0.98 (2.82)	0.56 (2.12)	0.16 (0.88)	0.25 (1.49)	0.06 (0.51)
Number of hospitalizations (among patients with ≥1 hospitalization)	4.42 (5.01)	4.29 (4.78)	3.18 (3.09)	4.31 (5.04)	3.19 (2.97)
Patients with ≥1 ED visit, ^b n (%)	1,594 (19.6)	262 (3.2)	69 (0.8)	143 (1.8)	23 (0.3)
Patients with additional ED visits (among those with ≥1 ED visit)	806 (50.6)	133 (50.8)	27 (39.1)	75 (52.4)	9 (39.1)
ED visits, mean (SD), per patient per year	0.78 (2.61)	0.14 (1.35)	0.03 (0.29)	0.08 (1.27)	0.01 (0.20)
Number of ED visits (among patients with ≥1 ED visit)	3.33 (5.13)	3.30 (6.79)	2.28 (2.00)	3.67 (8.87)	2.41 (2.79)

^aA subset of liver-related care was reported as pancreatobiliary-related care including PBC, cholelithiasis, cholecystitis, pancreatic diseases, biliary duct and gallbladder–related injury and diseases. ^bVisits that did not lead to hospitalization. Abbreviations: ED, emergency department; PBC, primary biliary cholangitis.

Annualized Medical Costs (Table 4)

- The mean (SD) annual total overall and liver-related (diagnosis codes in any position) medical costs per patient were \$60,040.72 (166,770.15) and \$36,456.65 (142,385.39), respectively
- For patients with acute-care events, the overall and liver-related (diagnosis codes in any position) mean (SD) acute-care costs (hospitalizations and/or ED visits annually) were \$64,332.63 (176,322.49) and \$67,306.24 (187,176.49), respectively
- The annualized liver-related mean (SD) medical costs per patient for diagnosis codes categorized in the first position was \$14,580.14 (105,751.34)
- The liver-related mean (SD) acute-care costs (hospitalizations and/or ED visits annually) for diagnosis codes categorized in the first position were \$72,887.91 (244,615.61) for patients with acute-care events

Table 4. Annualized medical costs during follow-up

N=8,143	Total	Liver-related (diagnosis codes in any position)	Pancreatobiliary-related (diagnosis codes in any position) ^a	Liver-related (diagnosis codes in the first position)	Pancreatobiliary-related (diagnosis codes in the first position) ^a
Annualized medical costs, mean (SD)	\$60,040.72 (166,770.15)	\$36,456.65 (142,385.39)	\$15,522.68 (74,205.44)	\$14,580.14 (105,751.34)	\$3,680.63 (47,572.62)
Annualized medical costs in acute care (among those with ≥1 acute-care event), mean (SD)	\$64,332.63 (176,322.49)	\$67,306.24 (187,176.49)	\$45,274.50 (133,929.12)	\$72,887.91 (244,615.61)	\$46,006.10 (215,050.53)

^aA subset of liver-related care was reported as pancreatobiliary-related care including PBC, cholelithiasis, cholecystitis, pancreatic diseases, biliary duct and gallbladder–related injury and diseases.

Conclusions

- Patients with PBC with at least one episode of acute care tend to have additional acute-care episodes
- Among patients with ≥1 acute-care event, the average overall and liver-related medical costs per year were similar, suggesting that most of the acute-care costs were attributable to liver-related events
- The high utilization of acute-care services contributes to an increased economic burden for patients with PBC

References

- Murillo Perez CF, Fisher H, Hiu S, et al. Greater transplant-free survival in patients receiving obeticholic acid for primary biliary cholangitis in a clinical trial setting compared to real-world external controls. *Gastroenterology*. 2022;163(6):1630-1642 e3. doi:10.1053/j.gastro.2022.08.054
- Trivella J, John BV, Levy C. Primary biliary cholangitis: epidemiology, prognosis, and treatment. *Hepatol Commun*. 2023;7(6):e0179. doi:10.1097/HC9.0000000000000179
- Shahab O, Sayiner M, Paik J, Felix S, Golabi P, Younossi ZM. Burden of primary biliary cholangitis among inpatient population in the United States. *Hepatol Commun*. 2019;3(3):356-364. doi:10.1002/hep4.1314
- Primary biliary cholangitis: patient characteristics and the health care economic burden in the United States. *Gastroenterol Hepatol*. 2021;17(2):suppl 3.
- Glasheen WP, Cordier T, Gumpina R, Haugh G, Davis J, Renda A. Charlson Comorbidity Index: ICD-9 update and ICD-10 translation. *Am Health Drug Benefits*. 2019;12(4):188-197.

Acknowledgment and Funding

This study was funded by Intercept Pharmaceuticals, Inc. Medical writing support was provided by Diane Kim, PhD, and was funded by Intercept Pharmaceuticals, Inc.

Author Disclosures

RGG: Grant/research support: Gilead. Consultant and/or advisor: Abbott, AbbVie, Altimmune, Arrowhead, Eiger, Genentech, Genantis, Gerson Lehrman Group, Gilead Sciences, Helios, HepaTx, HepQuant, Intercept, Janssen, Pfizer, Topography Health, and Venatorx. Current activity with scientific or clinical advisory boards: AbbVie, Genantis, Gilead, Helios, HepaTx, HepQuant, Intercept, Janssen, Pfizer, and Prodigy. Current clinical trials alliance: Topography Health. Chair of clinical advisory board: Prodigy. Advisory consultant, diagnostic companies: Fujifilm/Wako, Perspectrum, and Quest. Data safety monitoring board: CymaBay Therapeutics, Durect, and Takeda. Speakers' bureau: Activities focused on hepatitis B, C, and D virus, and liver cancer, specifically, epidemiology, diagnosis, and treatment. In addition, there were program presentations on vaccination for hepatitis B virus and the management of complications of cirrhosis. Speaker's contract for promotional talks: AbbVie, BMS, Eisai, Genentech, Gilead Sciences, and Intercept. Minor stock shareholder (liver space noted only): RiboSciences and CoCrystal. Stock options: AngioCrine, Eiger, Genantis, HepQuant, and HepaTx. **JPM** and **DL:** Employees of Genesis Research Group. **RN, DW, JL,** and **LB:** Employees of Intercept.

Corresponding Author

Radhika Nair
radhika.nair@interceptpharma.com



Copies of this poster obtained through the QR code are for personal use only and cannot be reproduced without permission of the corresponding author of this poster.