Livdelzi® seladelpar 10mg Capsules

#1 PRESCRIBED PBC TREATMENT for new second-line starts

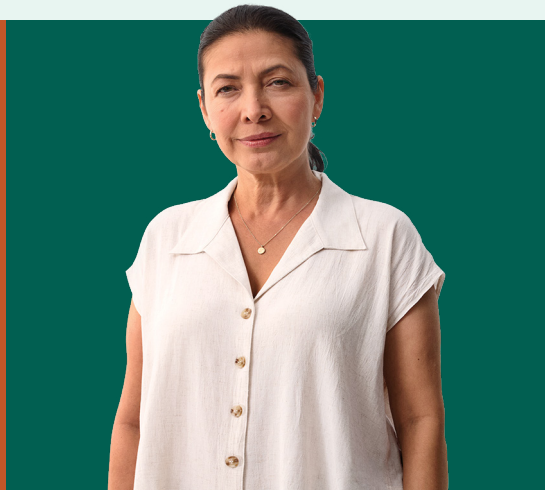
Source: IQVIA® LAAD, 10/2024 through 01/2026.[1,a]

PBC IS *PERSONAL*

Consider these traits when managing patients with PBC:

- AGE
- SEX
- RACE & ETHNICITY
- SYMPTOMS
- PBC HISTORY
- COMORBIDITIES & CONCOMITANT MEDICATIONS

Actor portrayals throughout.



INDICATION

LIVDELZI is indicated for the treatment of primary biliary cholangitis (PBC), in combination with ursodeoxycholic acid (UDCA) in adults who have had an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA.

This indication is approved under accelerated approval based on a reduction of alkaline phosphatase (ALP). Improvement in survival or prevention of liver decompensation events have not been demonstrated. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Limitation of Use: Use of LIVDELZI is not recommended in patients who have or develop decompensated cirrhosis (eg, ascites, variceal bleeding, hepatic encephalopathy).

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- **Fractures:** Fractures occurred in 4% of LIVDELZI-treated patients compared to no placebo-treated patients. Consider the risk of fracture in the care of patients treated with LIVDELZI and monitor bone health according to current standards of care.

Please see additional Important Safety Information throughout and click to see full Prescribing Information for LIVDELZI.

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LAAD=Longitudinal Access and Adjudication Data; PBC=primary biliary cholangitis.

ACCORDING TO A RANGE OF STUDIES

The PBC patient population is more diverse than has been previously understood[2]

1 AGE

Younger patients are less likely to respond to UDCA and may have more aggressive and harder-to-treat PBC[3,a,b]

25% of patients with PBC presented before 50 years of age[3,a]

Patients with PBC

<40 years of age

were symptomatic, with more severe pruritus and fatigue[3,a]

2 SEX

Men with PBC are significantly less likely to respond to UDCA[2,3,a]

The odds of PBC occurring in men were up to

2.5 x greater

than have been previously estimated[2]

A study of US administrative data from 2014-2021 of adults with PBC showed that[6]:

Of 41,426 patients with PBC, **83% were women** (n=34,381) and **17% were men** (n=7045)

Men often presented with more advanced PBC, putting them at risk of end-stage liver disease[2]

Actor portrayals.

[a]Patients (N=2353) from a UK-PBC patient research cohort were analyzed in a cross-sectional study to obtain a better understanding of PBC phenotypes and differences including response to UDCA and impact of symptoms of disease based on age and sex.[3]

[b]AASLD (2018) and EASL (2017) PBC treatment guidelines recommend UDCA as first-line treatment for patients with PBC.[4,5]

AASLD=American Association for the Study of Liver Diseases; EASL=European Association for the Study of the Liver; UDCA=ursodeoxycholic acid.

ACCORDING TO A RANGE OF STUDIES

Many factors can impact PBC severity, prognosis, and treatment response[2]

3 RACE & ETHNICITY

Black, Hispanic, and Indigenous patients with PBC are more likely to have poor or nonresponse to UDCA[2,7,a-c]

Black and Hispanic patients presented with PBC at younger ages and **had more aggressive disease progression**[2,3,7,a,b]

Black patients with PBC had a

47% **increased odds of mortality**

compared with White patients (95% CI, 1.03-2.10)[7,b]

- Black patients with PBC **were significantly less likely to receive UDCA treatment** compared with White patients (50% lower odds; 95% CI, 0.4-0.7)[8,d]

Hispanic patients with PBC had a

12% **higher risk of hospitalization**

compared with White patients[7,b]

[a]Patients (N=2353) from a UK-PBC patient research cohort were analyzed in a cross-sectional study to obtain a better understanding of PBC phenotypes and differences including response to UDCA and impact of symptoms of disease based on age and sex.[3]

[b]The prevalence, characteristics, predictors, outcomes, and trends (among gender and racial categories) of hospitalizations for PBC was explored in a retrospective descriptive epidemiological study using the National Inpatient Sample database from 2007-2014. ICD-9-CM codes were used to identify primary PBC hospitalizations (N=8460).[7]

[c]While Hispanic patients were shown to have poorer responses to UDCA compared with White patients, these results did not translate to poorer outcomes after multivariate adjustment.[7]

[d]To investigate PBC epidemiology and treatment within geographically and racially diverse populations of patients, patient cases (N=4241) from the Fibrotic Liver Disease Consortium during the years 2003-2014 were analyzed to determine the effects of factors associated with PBC prevalence and treatment with UDCA.[8]

4 SYMPTOMS

Symptoms of PBC, including pruritus, are not typically relieved with UDCA[4]

In a cross-sectional study of patients with PBC (N=225)[9,e]:

89% **self-reported pruritus (n=200/225)[9]**

but only **39%** **had pruritus recently documented in their medical records (n=88/225)[9]**

In a retrospective, cross-sectional study of patients with PBC[10,f]:

34% **more patients with PBC-related pruritus reported fatigue vs those who did not have pruritus (26.6% vs 19.9%)**

Fatigue is a complex symptom with multiple potential confounding factors common in patients with PBC (which can include pruritus-induced fatigue, autoimmune diseases, and menopause)[11]

[e]A cross-sectional, noninterventional study (N=225) evaluated the prevalence of patient-reported pruritus vs pruritus documented in medical records. The overlap between individuals with patient-reported and medical record–documented pruritus in relation to pruritus severity was also evaluated.[9]

[f]The prevalence of prespecified comorbidities and medications in a PBC population (n=1963), a PBC-pruritus subpopulation (n=139), and a noncase population (n=10,245,592) was assessed over a 12-month period in a retrospective, cross-sectional study using data from the IBM MarketScan Commercial Claims and Medicare Supplemental Database.[10]

ACCORDING TO A RANGE OF STUDIES

With inadequate treatment, PBC may progress to end-stage liver disease[2,12]

5 PBC HISTORY

1L treatment with UDCA may not achieve biochemical response[4,5]

For patients with PBC taking UDCA:

~50% with early-stage PBC progressed to a moderate stage within 5 years[13]

~40% experienced inadequate biochemical response[4,a]

In a multicenter meta-analysis by the GLOBAL PBC Study Group of patients with PBC taking UDCA (N=4119)[14,b]:

~32% had stage III or IV fibrosis

Suboptimal biochemical response may indicate chronic inflammation, which increases risk of irreversible bile duct damage[15-17]

Actor portrayal.

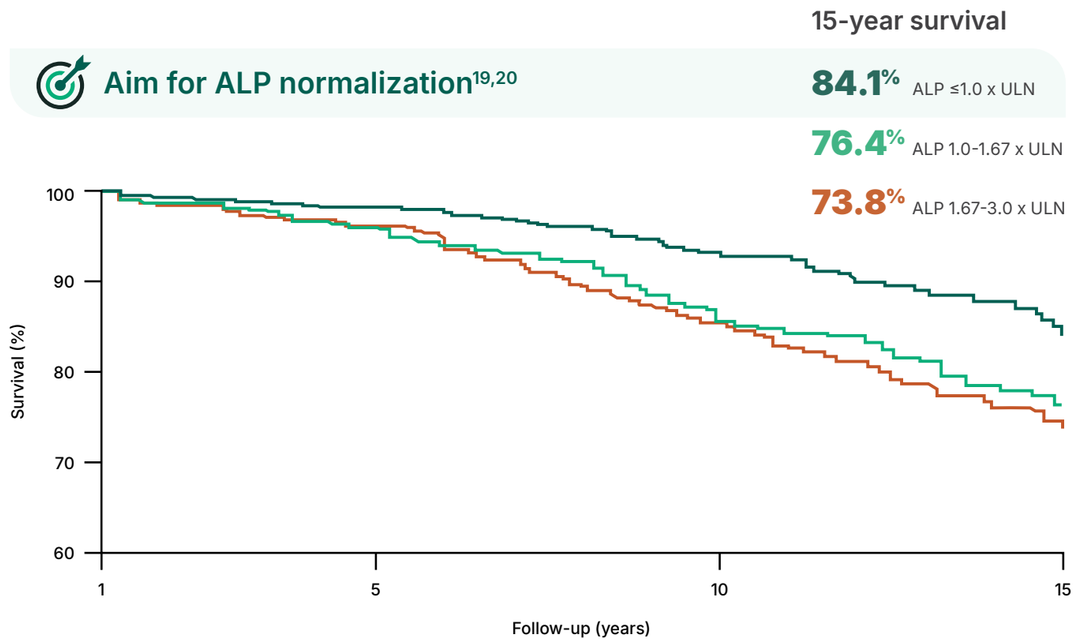
[a]Biochemical response is a prognostic tool for PBC that can be defined by several published criteria. One criterion that has been used in clinical trials defines response to treatment at 12 months as ALP <1.67 x ULN, ≥15% decrease in ALP from baseline, and TB ≤1 x ULN. Conversely, patients who do not meet the criteria thresholds are considered to have an inadequate biochemical response and may remain at risk for disease progression.[4,18]

[b]In an international, multicenter meta-analysis of patients with PBC who were treated with UDCA at liver centers in 8 European and North American countries, histological disease stage was available for 1642 patients using baseline biopsies obtained within 1 year of starting UDCA. Of those patients, 541 (32%) had stage III or IV fibrosis.[14]

1L=first line; ALP=alkaline phosphatase; TB=total bilirubin; ULN=upper limit of normal.

ALP ≤1.0 x ULN (normalization) was associated with improved outcomes and longer transplant-free survival[19,20,c]

Survival estimates stratified by ALP levels in patients with normal bilirubin at 1 year after starting UDCA (n=2005)[19,20,c]



[c]Patients (N=3059) from the GLOBAL PBC Study Group database were analyzed to determine whether bilirubin or ALP levels within the normal range (≤1.0 x ULN) were associated with survival in patients with PBC. The dataset included both untreated patients and patients treated with UDCA. The primary endpoint was a composite of liver transplant and all-cause mortality.[19]

ACCORDING TO A RANGE OF STUDIES

Comorbidities and their concomitant medications can add complexity to PBC treatment decisions[4,5]

6 COMORBIDITIES & CONCOMITANT MEDICATIONS

Consider drug-to-drug interactions when choosing a second-line treatment[4,5]

Patients with PBC may be managing a number of **comorbid conditions** including, but not limited to[4,21]:

Hyperlipidemia
up to **95%**

Autoimmune disorder
up to **55%**

Patients with PBC had high prevalence of comorbidities, particularly other autoimmune disorders such as Sjögren syndrome, thyroid disease, and rheumatoid arthritis.[21]

Portal hypertension
~33%
in patients with stage III or IV fibrosis

Vitamin D deficiency
up to **33%**

Patients with PBC may be taking **concomitant medications** including, but not limited to[10,22]:

~25% of patients with PBC were taking **concomitant statins**[10,a]

~76% of women with PBC reported prior use of **oral contraceptives**[22,b]

~37% of women with PBC reported current use of **hormone replacement therapy**[22,b]

Could patients with PBC with one or more of these key traits reach lower ALP levels and pruritus improvement?

[a]The prevalence of prespecified comorbidities and medications in a PBC population (n=1963), a PBC-pruritus subpopulation (n=139), and a noncase population (n=10,245,592) was assessed over a 12-month period in a retrospective, cross-sectional study using data from the IBM MarketScan Commercial Claims and Medicare Supplemental Database.[10]

[b]In a 2005 US interview-based study of female patients with PBC identified from November 1999 to June 2004 (N=1032), 76% reported prior use of oral contraceptives and 37% reported current use of hormone replacement therapy at the time of the study.[22]

LIVDELZI is the **first and only PBC treatment** that achieved statistically significant reductions across key biomarkers and pruritus vs placebo[23]

In the RESPONSE trial, LIVDELZI helped to:

LOWER
key PBC biomarkers

62% of patients achieved composite biochemical response at 12 months vs 20% of patients in the placebo arm (*P*<0.0001).[23]

LOWER
ALP to normal

25% of patients achieved ALP normalization at 12 months vs 0% of patients in the placebo arm (*P*<0.0001).[23]

LOWER
pruritus

- Rapid improvement as early as 1 month[18]
- **Statistically significant difference at 6 months** vs placebo (NRS -3.2 vs -1.7; *P*=0.0051)[23]
- Reduction in pruritus maintained from months 6 to 12[18]

Study design: RESPONSE was a 12-month, randomized, double-blind, phase 3 pivotal trial that assessed the efficacy and safety of LIVDELZI 10 mg ± UDCA (n=128) vs placebo ± UDCA (n=65), administered once daily. The primary endpoint was composite biochemical response.[a] Key secondary endpoints were ALP normalization at 12 months and change in pruritus NRS at 6 months in patients with baseline average pruritus score ≥4. Baseline average pruritus scores in the pruritus subgroup were 6.1 (LIVDELZI; n=49) and 6.6 (placebo; n=23).[23]

[a]Biochemical response was defined as achieving the following at 12 months: ALP <1.67 x ULN, ≥15% decrease in ALP from baseline, and TB ≤1 x ULN.[23]

IMPORTANT SAFETY INFORMATION (cont'd)
Warnings and Precautions (cont'd)
- **Liver Test Abnormalities:** LIVDELZI has been associated with dose-related increases in serum transaminase (AST and ALT) levels >3x ULN in patients receiving 50 mg and 200 mg once daily (5x and 20x higher than the recommended dosage of 10 mg once daily). Perform baseline clinical and laboratory testing when starting LIVDELZI and monitor thereafter according to routine patient management. Interrupt treatment if the liver tests (ALT, AST, total bilirubin, and/or ALP) worsen, or if the patient develops signs and symptoms of clinical hepatitis (eg, jaundice, right upper quadrant pain, eosinophilia). Consider permanent discontinuation if liver tests worsen after restarting LIVDELZI.
- **Biliary Obstruction:** Avoid use of LIVDELZI in patients with complete biliary obstruction. If biliary obstruction is suspected, interrupt LIVDELZI and treat as clinically indicated.

NRS=Numerical Rating Scale.

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Established safety and tolerability profile, with low discontinuation rates[18,23]

Discontinuation rate[18,24]

LIVDELZI arm
3.1%
of patients discontinued treatment (n=4/128)

vs

Placebo arm
4.6%
of patients discontinued treatment (n=3/65)

Most common adverse reactions (≥5%) in patients with PBC[23,b]

Adverse reaction[c]	LIVDELZI 10 mg ± UDCA (n=128) % (n)	Placebo ± UDCA (n=65) % (n)
Headache	8% (10)	3% (2)
Abdominal pain[d]	7% (9)	2% (1)
Nausea[d]	6% (8)	5% (3)
Abdominal distension[d]	6% (8)	3% (2)
Dizziness	5% (6)	2% (1)

[b]In the trial, 12 patients (6%) were intolerant to UDCA and initiated treatment as monotherapy: 8 patients (6%) in the LIVDELZI 10 mg arm and 4 patients (6%) in the placebo arm.[23]

[c]Adverse reactions occurred in ≥5% of patients in the LIVDELZI arm and at an incidence of ≥1% higher than in the placebo arm.[23]

[d]Gastrointestinal adverse reactions were mild to moderate without the need for discontinuation of LIVDELZI.[23]

In the RESPONSE trial, no drug-induced liver injuries were attributed to LIVDELZI when taken at the recommended 10 mg dose[25]

IMPORTANT SAFETY INFORMATION (cont'd)
Adverse Reactions
- The most common adverse reactions (≥5%) with LIVDELZI were headache (8%), abdominal pain (7%), nausea (6%), abdominal distension (6%), and dizziness (5%).

Pregnancy and Lactation
- **Pregnancy:** There are insufficient data from human pregnancies exposed to LIVDELZI to allow an assessment of a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Report pregnancies to Gilead Sciences, Inc., at 1-800-445-3235.
- **Lactation:** There are no data on the presence of LIVDELZI in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for LIVDELZI and any potential adverse effects on the breastfed infant from LIVDELZI.

Please see additional Important Safety Information throughout and click to see full Prescribing Information for LIVDELZI.

Not all PPARs have the same DDI profile[23,26]

LIVDELZI was evaluated in a broad range of patients with PBC:

- The safety profile in RESPONSE included adverse reactions of patients without cirrhosis and those with compensated cirrhosis in both treatment arms[18,25]
- The patient population also included those taking a wide range of concomitant medications[18,24]

No clinically significant interactions observed with:

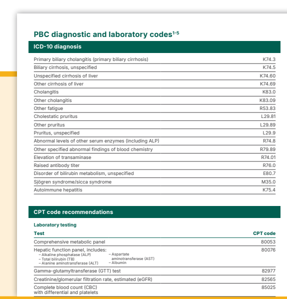
Statins[23,a]
- Simvastatin
- Atorvastatin
- Rosuvastatin

Based on the metabolism of LIVDELZI, there are **no expected interactions with:**

- Estradiol[23,27,b]
- Ibuprofen[23,b]
- Omeprazole[23,28]

[a]No clinically significant differences in the pharmacokinetics of statins were observed when used concomitantly with LIVDELZI.[23]
[b]Coadministration of LIVDELZI with estradiol or ibuprofen has not been formally studied.
DDI=drug-to-drug interaction; PPAR=peroxisome proliferator-activated receptors.

Key PBC diagnostic and procedure codes


PBC diagnostic and laboratory codes
ICD-10 diagnosis
CPT code recommendations

IMPORTANT SAFETY INFORMATION (cont'd)

Drug Interactions

Potential Increased Exposure of LIVDELZI with:

- **Probenecid:** Avoid coadministration with LIVDELZI.
- **Strong CYP2C9 Inhibitors:** Monitor for adverse effects during concomitant use.
- **Dual Moderate CYP2C9 and Moderate or Strong CYP3A4 Inhibitors (eg, fluconazole):** Monitor for adverse effects during concomitant use.
- **CYP2C9 Poor Metabolizers Using Moderate or Strong CYP3A4 Inhibitors:** Monitor for adverse effects during concomitant use of a moderate or strong CYP3A4 inhibitor in patients who are CYP2C9 poor metabolizers.
- **Dual or Multiple Clinical Inhibitors of Drug Transporters OATP1B1, OATP1B3, and BCRP (eg, cyclosporine):** Monitor for adverse effects during concomitant use.

Potential Reduction in LIVDELZI Exposure with:

- **Rifampin:** Concomitant use of LIVDELZI with rifampin, an inducer of metabolizing enzymes, may result in delayed or suboptimal LIVDELZI biochemical response. Monitor biochemical response (eg, ALP and bilirubin) when patients initiate rifampin during LIVDELZI treatment.
- **Bile Acid Sequestrants:** Administer LIVDELZI at least 4 hours before or 4 hours after taking a bile acid sequestrant, or at as great an interval as possible.

Please see additional Important Safety Information throughout and click to see full Prescribing Information for LIVDELZI.

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References

1. Data on file. Gilead Sciences, Inc.; 2025. **2.** Trivella J, John BV, Levy C. Primary biliary cholangitis: epidemiology, prognosis, and treatment. *Hepatol Commun.* 2023;7(6):e0179. doi:10.1097/HC9.0000000000000179 **3.** Carbone M, Mells GF, Pells G, et al. Sex and age are determinants of the clinical phenotype of primary biliary cirrhosis and response to ursodeoxycholic acid. *Gastroenterology.* 2013;144(3):560-569.e7. doi:10.1053/j.gastro.2012.12.005 **4.** Lindor KD, Bowlus CL, Boyer J, Levy C, Mayo M. Primary biliary cholangitis: 2018 practice guidance from the American Association for the Study of Liver Diseases. *Hepatology.* 2019;69(1):394-419. doi:10.1002/hep.30145 **5.** European Association for the Study of the Liver. EASL Clinical Practice Guidelines: the diagnosis and management of patients with primary biliary cholangitis. *J Hepatol.* 2017;67(1):145-172. doi:10.1016/j.jhep.2017.03.022 **6.** Levy C, Buchanan-Peart KA, MacEwan JP, et al. 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How to start your appropriate patients on LIVDELZI

4 simple steps to access LIVDELZI

1

Send the prescription to the selected specialty pharmacy.

2

The specialty pharmacy will:

- Explain insurance coverage
- Submit prior authorization
- Confirm medicine cost and financial assistance options[a]

3

The specialty pharmacy will call the patient to schedule the delivery of the medicine.

4

When it's time for a refill, the specialty pharmacy will call the patient.

LIVDELZI specialty pharmacies

AcariaHealth Specialty Pharmacy
P: (833) 236-9722
F: (833) 494-2747
acariahealth.com

Orsini Rare Disease Pharmacy Solutions
P: (888) 263-8004
F: (877) 846-0402
orsini.com

PANTHERx RARE
P: (888) 685-1482
F: (877) 914-0648
pantherxrare.com

Specialty distributor

CuraScript SD By EVERNORTH
P: (877) 599-7748
curascriptsd.com

SINCE LAUNCH

~95% **of patients** prescribed LIVDELZI have received **insurance approval upon first submission**, streamlining access and minimizing delays in treatment initiation[29,b]

Amanda
Real LIVDELZI patient

99% of eligible patients pay **$0-$10 per month for LIVDELZI** with the Co-pay Savings Program[29,c,d]

Person featured is compensated by Gilead.

Please see Important Safety Information throughout and click to see full Prescribing Information for LIVDELZI.

[a]If additional support is required for your office staff or patient, you can request a Field Reimbursement Manager (FRM) or connect with Support Path®.

[b]Data from 09/2024 through 01/2026.[29]

[c]Data from 09/2024 through 11/2025.[29]

[d]Co-pay savings support is available for commercially insured eligible patients only. Additional restrictions apply. Subject to change; for full terms and conditions, visit www.mysupportpath.com/co-pay. This is not health insurance. Only accepted at participating pharmacies.

GILEAD

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PBC diagnostic and laboratory codes[1-5]

ICD-10 diagnosis

Primary biliary cholangitis (primary biliary cirrhosis)	K74.3
Biliary cirrhosis, unspecified	K74.5
Unspecified cirrhosis of liver	K74.60
Other cirrhosis of liver	K74.69
Cholangitis	K83.0
Other cholangitis	K83.09
Other fatigue	R53.83
Cholestatic pruritus	L29.81
Other pruritus	L29.89
Pruritus, unspecified	L29.9
Abnormal levels of other serum enzymes (including ALP)	R74.8
Other specified abnormal findings of blood chemistry	R79.89
Elevation of transaminase	R74.01
Raised antibody titer	R76.0
Disorder of bilirubin metabolism, unspecified	E80.7
Sjögren syndrome/sicca syndrome	M35.0
Autoimmune hepatitis	K75.4

CPT code recommendations

Laboratory testing

Test	CPT code
Comprehensive metabolic panel	80053
Hepatic function panel, includes: – Alkaline phosphatase (ALP) – Total bilirubin (TB) – Alanine aminotransferase (ALT) – Aspartate aminotransferase (AST) – Albumin	80076
Gamma-glutamyltransferase (GTT) test	82977
Creatinine/glomerular filtration rate, estimated (eGFR)	82565
Complete blood count (CBC) with differential and platelets	85025
Platelet count	85049
Prothrombin time (PT) with substitution of plasma fractions	85611
Prothrombin time (PT)	85610
Pregnancy test (if applicable)	84703

Note: The above lists are not exhaustive and are for informational purposes only. Please consult the latest ICD-10 and CPT codes for a full list. Each provider must make an individualized decision for each patient's needs. Gilead does not guarantee the coverage or reimbursement of any item or service through the use of these codes.

More >

Laboratory testing, specific to antibody test in PBC diagnostic process

Test	CPT code
Mitochondrial antibody, such as M2	86381
PBC-specific anti-nuclear antibodies	83516
Anti-nuclear antibodies (ANA)	86038
Anti-smooth muscle antibodies (ASMA)	86015

Liver assessment, related to PBC diagnostic process

Test	CPT code
Liver biopsy under excision procedures on the biliary tract	47700
Cholecystectomy with cholangiography **OR**	47563
Magnetic resonance cholangiopancreatography	S8037

Liver assessment, monitoring of PBC progression

Test	CPT code
Non-imaging liver elastography (including vibration-controlled transient elastography)	91200
Enhanced liver fibrosis (ELF) testing	81517
Magnetic resonance elastography	76391
Ultrasound elastography	76981
Biopsy	47000

Bone health assessment, noninvasive bone health monitoring

Test	CPT code
Dual-energy X-ray absorptiometry (DXA)	77080

References: 1. The Web's Free 2026 ICD-10-CM/PCS Medical Coding Reference. Updated October 1, 2025. Accessed October 27, 2025. https://www.icd10data.com **2.** Test menu. Labcorp. Accessed June 12, 2025. https://www.labcorp.com/test-menu/search **3.** Moore KJ. Coding & documentation. *Fam Pract Manag.* 2005;12(6):25. **4.** Medical Coding's Best Online Code Search & Lookup Resource. Codify by AAPC. Accessed October 27, 2025. https://www.aapc.com/codes/ **5.** Noninvasive tests for hepatic fibrosis. Humana. Updated April 25, 2024. Accessed October 27, 2025. https://assets.humana.com/is/content/humana/Noninvasive_Tests_Hepatic_Fibrosispdf

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