

YOUR VISIT

PRIMARY BILIARY CHOLANGITIS

WORKBOOK

Tools for today's
appointment

SUMMER 2025



COMPLIMENTARY COPY
TAKE ONE HOME

ASK THE EXPERT: COMMON QUESTIONS ANSWERED

page 4

SCAN ME

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DAILY DIARY: TRACK YOUR SYMPTOMS page 6

QUESTIONS TO ASK

USE THIS WORKBOOK TO HELP MAKE THE MOST OF YOUR TIME WITH YOUR DOCTOR.

► How severe is my liver damage?

► What treatments do you recommend?

► What side effects are common with these treatments?

► Am I a candidate for liver transplant?

► When should I call you?

► Treatments I've tried:

	WHAT TYPE AND DOSE/AMOUNT?	HOW WELL DID IT WORK?	DID YOU HAVE SIDE EFFECTS OR PROBLEMS?
MEDICATION			
OTHER TREATMENTS/ LIFESTYLE CHANGES			

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STATS & FACTS

By Sonya Collins | Reviewed by Brunilda Nazario, MD, WebMD Chief Physician Editor, Medical Affairs

10x



HOW MANY MORE WOMEN GET
PRIMARY BILIARY CHOLANGITIS
(PBC) THAN MEN.

MOST COMMON AGES
at which PBC is diagnosed.

40 TO 60



3 in 10

**NUMBER OF PEOPLE WITH PBC
WHO DEVELOP OSTEOPOROSIS.**

Regular exercise can help prevent it.



1 in 2

**NUMBER OF PEOPLE WITH UNTREATED PBC WHO PROGRESS
TO CIRRHOSIS WITHIN FOUR YEARS OF DIAGNOSIS.**

Medical treatment and lifestyle changes can help prevent this.

UP TO 3 in 4

**NUMBER OF PEOPLE WITH PBC
WHO HAVE A NON-LIVER-RELATED**

autoimmune condition, too.

15 in 100,000

NUMBER OF PEOPLE WHO HAVE PBC worldwide.



SOURCES: National Library of Medicine, Cleveland Clinic, *Scientific Reports*

COMMON QUESTIONS ANSWERED

TWO LIVER EXPERTS WEIGH IN ON THE AUTOIMMUNE DISEASE PRIMARY BILIARY CHOLANGITIS

By Sonya Collins | Reviewed Brunilda Nazario, MD, WebMD Chief Physician Editor, Medical Affairs



MONIKA SARKAR, MD

Before you got diagnosed with primary biliary cholangitis (PBC), you'd probably never even heard of this autoimmune disease of the liver. Now you may have a lot of questions and feel like you have a lot to learn. Here, two experts answer some of patients' most common questions about this rare liver condition. Monika Sarkar, MD, is a transplant hepatologist specializing in women's liver health at UCSF Health in California, and Dian Chiang, MD, is section head of hepatology at Cleveland Clinic in Ohio.

Q: What is PBC?

Monika Sarkar, MD: PBC is a rare disease that involves inflammation and damage of the bile ducts (small tubes that carry digestive fluids) in the liver. Over time, the inflammation can cause scarring of the liver, called fibrosis; cirrhosis of the liver, which is severe, irreversible scarring; and even liver failure. PBC causes itching and decreased bone density and is associated with thyroid disease, dry eyes, dry mouth, and joint pain.

Q: What causes PBC?

Dian Chiang, MD: PBC is an autoimmune disease, so it's caused by the immune system mistakenly attacking the bile duct cells in the liver. But we don't know what triggers this autoimmune reaction, though several gene variants have been identified as risk factors.

Q: Who gets PBC?

Sarkar: PBC can develop in anyone, but it's most common in middle-age women, and it's also more common in people who have other autoimmune conditions, such as rheumatoid arthritis and autoimmune thyroid disease.

Q: How is PBC treated?

Chiang: There are several different FDA-approved treatment options available for this disease. The first option is a medicine you take by mouth to slow the progress of liver disease. It has also shown to improve

liver enzymes, which are proteins that the liver produces and which aid in many important chemical reactions in the body. It may also reduce the risk of developing cirrhosis of the liver and reduce your risk of one day needing a liver transplant.

Several medications have been approved by the FDA as second-line treatments for people with PBC who don't respond to the first-line treatment. These second-line medications are effective in helping people achieve biochemical remission, which is when the liver enzymes go back to normal in your blood tests.

Studies are ongoing to collect real-world data to confirm the long-term benefits of the newer second-line medications in reducing the risk of fibrosis progression and cirrhosis and increasing transplant-free survival.

Q: Does weight play a role in PBC?

Sarkar: Fat in the liver can worsen PBC, so people who are overweight or have obesity, have type 2 diabetes, or have high cholesterol should focus on healthy nutrition and regular exercise to help keep their liver healthy.

Q: Can lifestyle changes help with PBC?

Chiang: Lifestyle changes are essential in the treatment of PBC. First, minimizing or avoiding alcohol and eating a Mediterranean diet may reduce the risk of developing fatty liver disease. Second, regular exercise may reduce the risk of muscle mass loss, also called sarcopenia, and bone loss, also called osteoporosis, which are two common complications of PBC.

Q: What's going on in PBC research?

Sarkar: New PBC treatments are under investigation, and some of them should be available in the near future. They will include options to better treat PBC symptoms such as itching.



DIAN CHIANG, MD

KEEP A RECORD

LOG YOUR PBC SYMPTOMS SO YOU CAN GIVE YOUR DOCTOR A MORE COMPLETE PICTURE OF YOUR CONDITION.

“There are a variety of symptoms that can be associated with PBC,” says Carmen Stanca, MD, a transplant hepatologist at Baylor Scott & White Health in Plano, TX. “Alongside the pruritus, or itching, fatigue is a very common one, as is dry eyes and dry mouth and bone issues. If the condition advances, that’s when you see signs of liver dysfunction or failure—jaundice, swelling in your legs and abdomen, and blood in your stool.”

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
DATE							
SYMPTOMS							
MEDICATIONS TAKEN							
RESPONSE							

SCAN OR COPY THIS PAGE BEFORE YOU FILL IT IN TO USE FOR TWO OR THREE MONTHS

LET'S GET GOING

ACTIONABLE TIPS FOR PRIMARY BILIARY CHOLANGITIS MANAGEMENT

By Rachel Reiff Ellis | Reviewed by Brunilda Nazario, MD, WebMD Chief Physician Editor, Medical Affairs

"If you're feeling overwhelmed about food changes to help manage your PBC, try sticking to a Mediterranean diet," says Tammy K. Lee, a liver disease/hepatology nurse practitioner at Sutter Health in Oakland, CA. "Focus on whole grains, healthy fats, lean proteins, nuts, seeds, beans, and lots of fruits and veggies."

Reduce your sodium.

Lots of foods—especially processed foods—have high sodium. Sodium increases swelling in your tissues and can make fluid build up in your abdomen. Choose low-sodium or no-sodium options.

Follow the plan.

Take medications and supplements as your doctor directs. Your treatments work best when you use them the way they're meant to be used.

Don't drink or smoke.

Both habits harm your already-damaged liver. Your liver processes alcohol, adding stress to it. If you have cirrhosis, you shouldn't drink alcohol at all.

Cut back on bothersome fat.

When you're dealing with yellowish skin (jaundice), fatty foods may give you diarrhea or bloating. Pay attention to how fatty foods make you feel, and cut out foods that upset your system.

Avoid raw shellfish.

These foods put you at higher risk of infection than other choices because they often carry harmful bacteria. This puts your liver in danger.



Prioritize exercise.

Regular physical activity lowers your risk of bone loss. Walking is ideal—it helps your heart while boosting bone and muscle health.

Track your symptoms.

This information is helpful for both you and your doctor. Use our diary on page 6 to keep a daily record.

“I didn’t feel like other PBC treatments were an option for me. **IQIRVO** is helping me meet my treatment goal of decreasing my ALP levels.*”

– **Christine** mom and avid hiker living with PBC

Christine is living with primary biliary cholangitis (PBC) and taking IQIRVO. She was compensated for her time. Individual results may vary. Talk with your doctor about a treatment plan that fits your needs.

*ALP lowering of IQIRVO was studied in a 52 week trial of 161 patients and lowered ALP in as quickly as 4 weeks, and the effects were sustained over 52 weeks. Some people (15%) achieved a normal ALP level compared to people who took ursodiol alone.

INDICATION

What is IQIRVO® used for?

IQIRVO is a prescription medicine used to treat primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have not responded well to UDCA, or used alone in patients unable to tolerate UDCA. IQIRVO was approved under accelerated approval based on 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). IQIRVO is not recommended for use in people who have symptoms or signs of advanced liver disease. It is not known if taking IQIRVO will improve your chance of survival or prevent liver decompensation. It is not known if IQIRVO is safe and effective in children under 18 years of age.

IMPORTANT SAFETY INFORMATION

What Warnings should I know about IQIRVO?

IQIRVO can cause muscle problems (myalgia, myopathy, rhabdomyolysis) and muscle pain that can be severe. Treatment with IQIRVO may cause muscle pain or worsen existing pain and can increase the level of an enzyme in your blood called creatine phosphokinase (CPK); both can be a sign of muscle damage. If there is new or worsening muscle pain, your healthcare provider may examine you and perform a blood test. Stop taking IQIRVO and call your healthcare provider right away if you have any of the following signs or symptoms: severe muscle pain, unexplained soreness, unexplained muscle weakness, or dark, reddish urine.

IQIRVO may increase the risk of bone fractures. Tell your healthcare provider about any bone fractures, or if you develop pain, or have changes in your ability to move around.

Please see additional Important Safety Information for IQIRVO on the following pages.



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IQV-US-001898 April 2025

“When I was first diagnosed with PBC, I struggled with **symptoms like itch that impacted my daily life.** For me, with IQIRVO I feel my PBC symptoms are being controlled.*”

– **Jared** animal lover and chef living with PBC

Jared is living with PBC and taking IQIRVO. He was compensated for his time. Individual results may vary. Talk with your doctor about a treatment plan that fits your needs.

*In the clinical trial, Iqirvo was studied in people who had moderate-severe levels of itch defined as a PBC Worst Itch Numeric Rating Scale (WI-NRS) score greater than or equal to 4. People taking Iqirvo reported on average reduction of 1.93 points in the WI-NRS score, compared to people taking ursodiol alone (average reduction of 1.15 points). People taking IQIRVO reported an average reduction of 2.5 points in the PBC-40 itch score and 4.2 point reduction in the 5-D itch total score compared to people taking ursodiol alone (average reduction of 0.1 points and 1.2 with ursodiol, respectively). Itch was a secondary outcome of the study and **results did not reach statistical significance**. Data should be reviewed with caution. If you have questions about this limitation, your doctor can help explain it further.

IMPORTANT SAFETY INFORMATION (continued)

What Warnings should I know about IQIRVO?

IQIRVO may cause harm to an unborn baby when taken during pregnancy. Women taking IQIRVO who can become pregnant should use effective birth control during treatment and for 3 weeks after the last dose of IQIRVO. Talk to your healthcare provider about birth control methods that may be right for you. Tell your healthcare provider right away if you become pregnant or think you may be pregnant.

IQIRVO can cause liver problems and abnormal liver blood test results. Your healthcare provider should do tests before starting and during treatment with IQIRVO to check your liver function. Tell your healthcare provider right away if you experience any of the following during treatment with IQIRVO: swelling of your stomach-area (abdomen), yellowing of your skin or whites of your eyes, black, tarry, or bloody stools, mental changes such as confusion, being sleepier than usual or harder to wake up, slurred speech, mood swings, or changes in personality, or coughing up or vomiting blood, or your vomit looks like coffee grounds. If you have severe stomach-area (abdomen) pain, nausea, vomiting, diarrhea, loss of appetite or weight loss, new or worsening fatigue, weakness, fever and chills, light-headedness, or less frequent urination, tell your healthcare provider right away.

Some people taking IQIRVO had allergic reactions, which may include rash, trouble breathing, itching, or swelling of your face, lips, tongue, or throat. If you experience any of these, stop taking IQIRVO, call your healthcare provider right away or go to the nearest hospital emergency room.

IQIRVO can cause blockage of the bile duct and may increase your risk of gallstones. Call your healthcare provider right away if you develop pain in the upper right stomach area or yellowing of the skin.

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- Are breastfeeding or plan to breastfeed. It is not known if IQIRVO passes into your breast milk. Talk with your healthcare provider about the best way to feed your baby if you take IQIRVO.

What are the side effects of IQIRVO?

The most common side effects of IQIRVO include weight gain, diarrhea, stomach pain, nausea, vomiting, joint pain, constipation, muscle pain, bone fractures, gastroesophageal reflux disease (GERD), dry mouth, weight loss, and rash. These are not all of the possible side effects of IQIRVO. Call your doctor for medical advice about side effects.

What other medications might interact with IQIRVO?

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. IQIRVO can affect the way certain medicines work. Certain medicines may affect the way IQIRVO works. If you take a bile acid binding resin, take IQIRVO at least 4 hours before or after you take your bile acid resin.

You are encouraged to report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch. You may also report side effects to Ipsen Biopharmaceuticals, Inc. at 1-855-463-5127. Please see accompanying full Prescribing Information.

The risk information provided here is not comprehensive. To learn more, talk with your health care provider or pharmacist. The FDA-approved product labeling can be found at www.IQIRVO.com.



– **Cecilia** mom, psychologist & advocate living with PBC

“I’ve been on IQIRVO for 10 months and find **treatment fits my routine** – I take the pill once-daily at a time that **works best for my life**. I also find I am able to manage side effects with my doctor.”



Hear the impact IQIRVO is making in the lives of people with PBC

IQIRVO
elafibranor 80 mg tablets

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Cecilia is living with PBC and taking IQIRVO. She was compensated for her time. Individual results may vary. Talk to your doctor about a treatment plan that fits your needs.

Indication and Important Safety Information

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elafibranor 80 mg tablets

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NEXT STEPS

Treatment plan:

► MEDICATIONS

DRUG			
DOSE			
WHEN TO TAKE IT			
HOW TO TAKE IT			

► LIFESTYLE CHANGES

TYPE	RESULT
DIET	
EXERCISE PLAN	
STRESS RELIEF	
SKIN CARE	

My next appointment is:

I should call between visits if:

“The outcomes of people with PBC have improved significantly over the past three decades and continue to improve.
**NEW THERAPIES GIVE PEOPLE HOPE THAT THIS
CONDITION CAN BE BETTER MANAGED.”**

DAVID E. BERNSTEIN, MD,
DIRECTOR OF GASTROENTEROLOGY AND HEPATOLOGY AMBULATORY SERVICES AT NYU LANGONE HEALTH IN BETHPAGE, NY