

# BC PharmaCare Drug Information

The drug below is being considered for coverage under the BC PharmaCare program. PharmaCare is a government-funded drug plan that helps B.C. residents with the cost of eligible prescription drugs and medical supplies. For more information about PharmaCare, visit the [PharmaCare website](#).

PharmaCare reviews each drug for treating a specific illness or medical condition (also called an “indication”). If PharmaCare decides to cover a drug, that coverage applies only to the indication(s) specified. In some cases, PharmaCare covers a drug only for people who have not responded to other drugs that treat the same indication.

More information about the PharmaCare drug review process is provided on the last page of this document.

Drug information	
Generic name (scientific name)	<b>seladelpar</b>
Brand name	<b>Lyvdelzi®</b>
Manufacturer	Gilead Sciences Canada, Inc.
Indication	For the treatment of primary biliary cholangitis (PBC), in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA alone, or as monotherapy in adults unable to tolerate UDCA.
Has the drug been reviewed by CDA-AMC, or will CDA-AMC be reviewing it? (See note below.)	Yes For more information about the CDA-AMC Reimbursement Review (CRR) of seladelpar, <a href="#">Search the CDA-AMC Reports</a> .
Public input start date	<b>Wednesday, December 31, 2025</b>
Public input closing date	<b>Tuesday, January 27, 2026, at 11:59 pm</b>
How is the drug taken?	Seladelpar is taken orally (by the mouth).
How often is the drug taken?	Seladelpar is taken once daily.

## General drug and/or drug study information

The Ministry of Health is reviewing seladelpar for the treatment of primary biliary cholangitis (PBC), in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA alone, or as monotherapy (on its own) in adults unable to tolerate UDCA.

PBC is a chronic disease that gradually damages the bile ducts in the liver. Bile ducts are small tubes that transport bile, a fluid produced by the liver that helps with digestion, especially of fats. This damage leads to a build-up of bile in the liver, causing inflammation and eventually liver scarring (cirrhosis). Symptoms can include itching, fatigue, and jaundice (yellowing of the skin and whites of the eyes), but some people may have no symptoms for years. If left untreated, PBC can cause liver failure and death.

Seladelpar works by activating a protein inside liver cells called peroxisome proliferator-activated receptor (PPAR)-delta, which helps regulate genes involved in bile acid production and inflammation. By turning on this receptor, seladelpar reduces the amount of bile acids made in the liver and improves their flow, which helps prevent the buildup that causes liver damage in primary biliary cholangitis. Seladelpar also has anti-inflammatory effects that may lessen liver irritation and scarring.

Studies looked at the following:

- Biochemical response to treatment at 12 months defined by:
  - Alkaline phosphatase (ALP) levels of less than 1.67× the upper limit of normal (ULN). High levels of ALP can indicate liver or bile duct issues.
  - A greater than or equal to 15% decrease in ALP from baseline, and
  - Total bilirubin of less than or equal to 1.0× ULN. Bilirubin is a substance produced when the liver breaks down red blood cells. Elevated levels of bilirubin can indicate liver dysfunction or bile duct obstruction.
- ALP normalization at 12 months, defined as ALP of less than or equal to 1.0× ULN
- Changes from baseline in weekly averaged Pruritus (itching) Numerical Rating Scale (NRS) scores with baseline NRS scores greater than or equal to 4, at 6 months<sup>a</sup>
- Changes from baseline in weekly averaged Pruritus NRS scores with baseline NRS scores greater than or equal to 4, at 12 months<sup>a</sup>

Drug information	
	<ul style="list-style-type: none"> <li>Quality of life (QoL) as measured by changes from baseline in PBC-40<sup>b</sup> QoL total scores at 12 months</li> <li>Bad reactions</li> <li>Serious bad reactions</li> <li>Patients leaving the trial due to bad reactions</li> <li>Bad reactions of special interest: liver-related toxicity, muscle-related toxicity, renal (kidney)-related toxicity, pancreatic-related toxicity</li> </ul>
Other considerations	None

Note:

CDA-AMC ([Canada's Drug Agency-L'Agence des Médicaments du Canada](#)) is a national organization that reviews drugs on behalf of Canadian public sector plans when drug manufacturers want those plans to provide coverage for the drug. For detailed information about the PharmaCare drug review process, including the role of the CDA-AMC Reimbursement Review (CRR) in that process, visit [How PharmaCare Decides Which Drugs to Cover](#).

Table of Comparators Used to Treat the Same Indication		
Generic Name (Brand Name) of Drug Comparator	Dosage Form	PharmaCare Status (if and how the drug is already covered)
seladelpar (Lyvdelzi) (as monotherapy and in combination with UDCA)	10 mg capsule	Under Review
<b><i>Peroxisome Proliferator-Activated Receptor Agonist</i></b>		
elafibranor (Iqirvo®) (as monotherapy and in combination with UDCA)	80 mg tablet	Under Review
<b><i>Farnesoid X receptor</i></b>		
obeticholic acid (Ocaliva®) (as monotherapy and in combination with UDCA)	5 mg, 10 mg tablet	<a href="#">Limited Coverage</a>

<sup>a</sup> The "pruritus NRS" is an abbreviation for Pruritus Numerical Rating Scale, a tool used to measure the severity of itch, or pruritus. The most common version is the Peak Pruritus Numerical Rating Scale (PP-NRS), a single-item, self-reported scale where patients rate their "worst" itch on a 0–10 scale over the past 24 hours.

<sup>b</sup> The PBC-40 is a 40-item, disease-specific quality of life questionnaire for patients with PBC. It assesses the impact of the disease across six domains: fatigue, symptoms, itch, cognitive function, emotional well-being, and social functioning. Scores are calculated so that higher scores indicate a worse quality of life.

Table of Comparators Used to Treat the Same Indication		
Generic Name (Brand Name) of Drug Comparator	Dosage Form	PharmaCare Status (if and how the drug is already covered)
<b><i>Bile Acid</i></b>		
ursodeoxycholic acid (Ursodiol generics)	250 mg, 500 mg tablet	Regular Benefit, <a href="#">Subject to LCA</a>
<b><i>Peroxisome proliferator-activated receptors (Not indicated for Primary Biliary Cholangitis)</i></b>		
bezafibrate (generic)	400 mg sustained-release tablet	Non-benefit

### The Drug Review Process in B.C.

A manufacturer submits a request to the Ministry of Health (Ministry).

An independent group called the [Drug Benefit Council \(DBC\)](#) gives advice to the Ministry. The DBC looks at:

- whether the drug is safe and effective
- advice from a national group called [Canada's Drug Agency-L'Agence des médicaments du Canada \(CDA-AMC\)](#)
- what the drug costs and whether it is a good value to the citizens of B.C.
- ethical considerations related to covering or not covering the drug
- input from physicians, patients, caregivers, patient groups and drug submission sponsors

The Ministry makes PharmaCare coverage decisions by taking into account:

- existing PharmaCare policies, programs and resources
- the evidence-informed advice of the DBC
- the drugs already covered by PharmaCare to treat similar medical conditions
- the overall cost of covering the drug

For more information about the drug review process in B.C., visit: the [How PharmaCare decides which drugs to cover](#).

#### **This document provides information only.**

It does not take the place of advice from a physician or other qualified health care provider.