

BC PharmaCare Drug Information

The drug below is being considered for possible coverage under the B.C. PharmaCare program. PharmaCare is a government-funded drug plan that helps British Columbians with the cost of eligible prescription drugs and specific medical supplies. For more information on PharmaCare, visit [Ministry of Health - PharmaCare](#).

PharmaCare reviews each drug for treating a specific illness or medical condition (known as an “indication”). If a decision is made to cover the drug, it will be only for that illness or condition.

In some cases, PharmaCare may cover a drug only for people who have the illness or condition and have not responded to other drugs used to treat that illness or condition.

For more information on PharmaCare’s drug coverage review process, see the last page of this information sheet.

Information about the drug	
Generic name (scientific name)	obeticholic acid (OCA)
Brand name	Ocaliva®
Manufacturer	Intercept Pharmaceuticals Canada, Inc.
Indication	Primary biliary cholangitis (PBC)
Has the drug been reviewed by the Common Drug Review (CDR)? (see the note below this table.)	Yes For more information about the CDR’s review of obeticholic acid (Ocaliva®), you can Search the CDR Reports .
Public input start date	Friday April 21, 2017
Public input closing date	Friday May 19, 2017 AT MIDNIGHT
How is the drug taken?	Ocaliva is taken by mouth.
How often is the drug is taken?	Ocaliva is taken daily.
General drug and/or drug study information	<p>Primary biliary cholangitis (PBC) is a disease in which the bile ducts in the liver are slowly destroyed. Bile, a fluid produced in the liver, plays a role in digesting food and helps rid your body of worn-out red blood cells, cholesterol and toxins.</p> <p>When bile ducts are damaged, as in PBC, harmful substances can build up in the liver and sometimes lead to irreversible scarring of the liver tissue (cirrhosis).</p> <p>PBC is considered an autoimmune disease, in which the body turns against its own cells. It usually develops slowly and medication can slow its progression, especially if treatment begins early.</p> <p>Ocaliva helps to reduce the concentration of bile acids in the cells of the liver.</p> <p>Studies looked at the following to determine if Ocaliva is safe and effective for the treatment of PBC:</p> <ul style="list-style-type: none"> • Liver enzymes (achieving an ALP¹ < 1.67 x ULN², total bilirubin³ ≤ ULN, and ALP decrease of ≥ 15% from Baseline³ at Month 12) • Percentage of participants with ALP < 1.67 x ULN and total bilirubin ≤ ULN and

Information about the drug	
	<p>ALP decrease of $\geq 15\%$ from Baseline at Month 6</p> <ul style="list-style-type: none"> • Absolute and percentage change in ALP from Baseline at Month 6 and Month 12 • Percentage of participants with ALP \leq ULN • Disease specific quality of life (measured using PBC-40 tool) • Other measures of biochemical treatment response • Liver fibrosis • Mortality • Bad reactions • Patients leaving the trial due to bad reactions • Bad reactions of special interest (itching) <p>¹ ALP = concentration of alkaline phosphatase in the blood ² ULN = upper limit of normal ³ bilirubin = concentration of bilirubin in the blood ⁴ Baseline = measurements taken at at the beginning of a study which is used for comparison with later data</p>
Other considerations	None

Note:

The Common Drug Review (CDR) is a national organization that reviews drugs on behalf of Canadian public sector plans when manufacturers want to have the jurisdictions provide coverage for the drugs. For detailed information on B.C. PharmaCare’s drug review process, including the role of the CDR in that process, see [The Drug Review Process in B.C. - Overview](#).

Cost of the drug under review compared to other drugs used to treat the same indication			
generic name (Brand Name) of Drug Comparator	PharmaCare Status (if and how the drug is already covered)	Usual Dose	Annual Cost of Therapy (\$)*
obeticholic acid (Ocaliva)	Under Review	5 mg once daily, increasing to 10 mg once daily after 6 months based on efficacy and tolerability	36,000
ursodeoxycholic acid (Ursodiol and generics)	Regular Benefit	13 to 15 mg/kg/day in two to four divided doses	1,057 – 1,115

*Based on Common Drug Review Pharmacoeconomic Review Report

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 the [Common Drug Review \(CDR\)](#)
- what the drug costs and whether it is a good value for the people of B.C.
- ethical considerations involved with 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:

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

For more information about the B.C. Drug Review Process, visit: [The Drug Review Process in B.C. - Overview](#).

This document is intended for information only.

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