

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)	lumacaftor-ivacaftor
Brand name	Orkambi™
Manufacturer	Vertex Pharmaceuticals (Canada) Inc.
Indication	Orkambi™ is used for the chronic treatment of cystic fibrosis (CF). It is used for patients aged 12 and older who have two copies of the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.
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 lumacaftor-ivacaftor (Orkambi™), you can Search the CDR Reports .
Public input start date	Wednesday May 18, 2016
Public input closing date	Wednesday June 15, 2016 AT MIDNIGHT
How is the drug taken?	Orkambi™ is taken orally (by mouth).
How often is the drug is taken?	Orkambi™ is taken twice daily.

Information about the drug	
General drug and/or drug study information	<p>Cystic fibrosis is a disease that causes thick, sticky mucus to build up in the lungs, digestive tract, and other areas of the body.</p> <p>The CFTR protein helps bring chloride ions out of the cells in many organs. People who have two copies of the F508del mutation in the CFTR gene have a lower amount of CFTR protein at the surface of their cells.</p> <p>Orkambi™ is a type of medicine called a “cystic fibrosis transmembrane conductance regulator corrector and potentiator”. The two ingredients in Orkambi™ help bring more chloride ions out of the cells in many organs:</p> <ul style="list-style-type: none"> • <i>lumacaftor</i>, a CFTR corrector, increases the number of the CFTR proteins at the cell surface. • <i>ivacaftor</i>, a CFTR potentiator, makes the CFTR proteins at the cell surface work better. <p>Studies looked at the following factors to assess if Orkambi™ is helpful and safe for the treatment of cystic fibrosis:</p> <ul style="list-style-type: none"> • Lung function • Number of times the condition worsens • Change in weight • Symptoms related to breathing • Levels of sweat chloride levels • Side effects (mild to serious) of the medication • Patients leaving the trial due to bad reactions • Liver function • Deaths
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
lumacaftor-ivacaftor (Orkambi™)	Under Review	Two tablets every 12 hours	\$261,431
<i>Treatments Indicated for the Management of Cystic Fibrosis</i>			
aztreonam (Cayston®)	Limited Coverage	75 mg inhaled 3 times daily for 28 days, followed by 28 days off therapy	\$27,684
dornase alfa (Pulmozyme®)	Non-Benefit	2.5 mg inhaled once or twice daily	\$14,856– \$29,711
ivacaftor (Kalydeco®)	Under Review	150 mg twice daily by mouth	\$321,930
tobramycin (TOBI®) solution for inhalation	Limited Coverage	300 mg inhaled twice daily every other month	\$21,480
tobramycin (TOBI® Podhaler®)	Limited Coverage	4 capsules inhaled 2 times per day for 28 days, followed by 28 days off therapy	\$20,279
<i>Treatments used for the Management of Cystic Fibrosis– Not Indicated</i>			
colistimethate (Coly-mycin™)	Regular Benefit	75 mg twice daily	\$11,658
tobramycin injectable	Regular Benefit	300 mg inhaled twice daily every other month	\$6,552

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 Council
- 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.