

Drug Coverage Decision for B.C. PharmaCare

About PharmaCare

B.C. PharmaCare is a government-funded drug plan. It helps British Columbians with the cost of eligible prescription drugs and specific medical supplies.

Details of Drug Reviewed

Drug	Lumacaftor/ivacaftor
Brand Name	Orkambi™
Dosage Form(s)	200/125 mg tablet
Manufacturer	Vertex Pharmaceuticals (Canada) Inc.
Submission Type	New Submission
Use Reviewed	For the treatment of cystic fibrosis (CF) in patients with F508del mutation
Common Drug Review (CDR)	CDR recommended: Do Not Reimburse . Visit the CDR website for more details: https://www.cadth.ca/about-cadth/what-we-do/products-services/cdr/reports
Drug Benefit Council (DBC)	DBC met on December 5, 2016. DBC considered various inputs including: clinical and pharmacoeconomic evidence review material and the recommendation from the CDR; Clinical Practice Reviews from two Specialists; Manufacturer comments; responses to Patient Input Questionnaires from one patient, three caregivers, and one patient group; and a Budget Impact Analysis.
Drug Coverage Decision	Non-Benefit – No Exceptional Ministry Funding
Date	March 21, 2017
Reason(s)	Drug coverage decision is consistent with the DBC recommendation In clinical studies, lumacaftor/ivacaftor does not appear to improve survival and failed to show any statistically significant or reliable improvements in weight gain, lung exacerbations, or quality of life. The modest improvement in lung function was of uncertain clinical significance, and the majority of patients failed to achieve an improvement of 5%. Given the high price of over \$260,000 per patient per year, lumacaftor/ivacaftor is not cost-effective.
Other Information	None

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

Visit the [The Drug Review Process in B.C. - Overview](#) and [Ministry of Health - PharmaCare](#) for more information.

This document is intended for information only.

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