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)	elexacaftor/tezacaftor/ivacaftor
Brand name	Trikafta®
Manufacturer	Vertex Pharmaceuticals (Canada) Incorporated
Expected Indication	For the treatment of cystic fibrosis (CF) in patients aged 12 years and older who have at least one 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.)	No
Public input start date	Wednesday May 19, 2021
Public input closing date	**Wednesday June 16, 2021, AT MIDNIGHT**
How is the drug taken?	Trikafta is taken orally (by the mouth).
How often is the drug taken?	Trikafta is taken twice daily, two tablets in the morning and one tablet in the evening.

Information about the drug	
General drug and/or drug study information	Trikafta is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 12 years and older who have at least one copy of a genetic mutation that responds to treatment with Trikafta. However, a Notice of Compliance has not yet been issued by Health Canada. CF is an inherited disease that causes thick, sticky mucus to build up in the lungs and digestive tract. Symptoms can include a persistent cough, wheezing, inability to exercise, lung infections, sinus inflammation and infections, poor weight gain and growth, and severe constipation. People with CF are at risk for complications such as diabetes, liver disease, and nutritional deficiencies. CF is caused by mutations in the CF gene. These mutations lead to defects in a specific protein called the cystic fibrosis transmembrane conductance regulator (CFTR) protein. As a result of these defects, the CFTR proteins don't work the way they should. Elexacaftor and tezacaftor are both CFTR correctors, which means they fix the defective proteins, allowing more of the proteins to move to their proper place on the cell surface. Ivacaftor, which is known as a potentiator, then allows CFTR proteins on the surface to stay open longer, which keeps important pathways open. Studies looked at the following: • Changes in lung function • Changes in patients' overall quality of life • Changes in patients' BMI[a] • Changes in the chloride levels in patients' sweat • Worsening of symptoms • Worsening of symptoms requiring hospitalization • Worsening of symptoms requiring intravenous antibiotics • Amount of time until acute symptoms occur • Bad reactions • Serious bad reactions • Patients leaving the trial due to bad reactions • Bad reactions of special interest (For example, rashes and high levels of liver enzymes)
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

[a] The body mass index (BMI) is a measure that uses your height and weight to work out if your weight is healthy.

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)**	**Dosage Form**	**Usual Dose**	**Annual Cost of Therapy**
Elexacaftor/ Tezacaftor/ Ivacaftor (Trikafta)	Under Review	Tablet	Two tablets in the morning and 1 tablet in the evening	$306,600[b]
CFTR modulator therapies				
Ivacaftor (Kalydeco)	Non-Benefit	Tablet	Twice daily	$306,600
Lumacaftor/ Ivacaftor (Orkambi®)	Non-Benefit	Tablet	Two tablets every twelve hours	$249,000

[b] Cost as per CDR Pharmacoeconomic Report for elexacaftor/tezacaftor/ivacaftor (Trikafta®).

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.