

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	nintedanib
Brand Name	Ofev®
Dosage Form(s)	100 mg and 150 mg capsules
Manufacturer	Boehringer Ingelheim Canada Ltd.
Submission Type	New Submission
Use Reviewed	Idiopathic pulmonary fibrosis (IPF)
Common Drug Review (CDR)	Yes, CDR recommended: to Reimburse with clinical criteria and/or conditions . Visit the CDR website for more details: www.cadth.ca/sites/default/files/cdr/complete/SR0426_Ofev_Oct-19-15.pdf
Drug Benefit Council (DBC)	DBC met on November 2, 2015. In their review, the DBC considered the following: final review completed by the CDR, which included clinical and pharmacoeconomic evidence review material and the recommendation from the Canadian Drug Expert Committee (CDEC). The DBC also considered Patient Input Questionnaire responses from one patient and two Patient Groups, Clinical Practice Reviews from one specialist and one general physician, as well as a Budget Impact Assessment.
Drug Coverage Decision	Limited Coverage Benefit. Access the nintedanib criteria from www.gov.bc.ca/pharmacarespecialauthority
Date	February 6, 2018
Reason(s)	<p>Drug coverage decision is consistent with the CDEC recommendation but is inconsistent with the DBC recommendation.</p> <ul style="list-style-type: none"> • Two double-blind, randomized controlled trial (RCTs) demonstrated that nintedanib resulted in statistically significant improvements on a pulmonary function outcome compared with placebo. Based on this CDEC recommended covering the medication with criteria but on the condition that the cost not exceed a competing product. The trials showed no statistically significant differences between nintedanib and placebo in mortality outcomes and inconsistent results on quality of life related outcomes were observed. Therefore, the DBC recommended that this drug not be listed. • Based on economic considerations and the submitted product price, the drug was not cost-effective and did not offer optimal value for money. • The Ministry participated in the pan-Canadian Pharmaceutical Alliance (pCPA) negotiations with the manufacturer of nintedanib and the participating jurisdictions were able to reach an agreement with the manufacturer. • Considering the improvements observed on pulmonary function outcomes in clinical studies, the severity of the disease, the unmet clinical need and the agreement that was reached between the manufacturer and the pCPA, the decision was made to list nintedanib as a

	Limited Coverage benefit for the treatment of IPF.
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.