

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	daclatasvir
Brand Name	Daklinza™
Dosage Form(s)	30 mg and 60 mg oral tablets
Manufacturer	Bristol-Myers Squibb Canada
Submission Review	New Submission
Use Reviewed	For the treatment of chronic hepatitis C (CHC) genotype 3 infection, when used in combination with sofosbuvir (Sovaldi™)
Common Drug Review (CDR)	Yes, CDR recommended: List with criteria. Visit the CDR website for more details: www.cadth.ca/sites/default/files/cdr/complete/SR0417_cdr_complete_Daklinza_Sept-23-15_e.pdf .
Drug Benefit Council (DBC)	DBC met on October 5, 2015. DBC considered various inputs including: final review completed by the CDR on September 21, 2015, 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 two patients and three Patient Groups collected through Your Voice; Clinical Practice Reviews from four specialists; three reports from the Canadian Agency for Drugs and Technologies in Health (CADTH), including a July 2015 Clinical Review of Drugs for Chronic Hepatitis C Infection, a July 2015 Cost-Effectiveness Analysis of Drugs for Chronic Hepatitis C Infection, and a September 2015 Therapeutic Review Report on Drugs for Chronic Hepatitis C Infection; as well as a Budget Impact Assessment.
Drug Coverage Decision	Non-Benefit
Date	April 19, 2016
Reason(s)	<p>Drug coverage decision is consistent with the DBC recommendation not to list daclatasvir for the treatment of CHC genotype 3 infection, when used in combination with sofosbuvir.</p> <ul style="list-style-type: none"> The available clinical evidence included only a small number of genotype 3 patients treated, and did not provide sufficient evidence to demonstrate efficacy compared to current sofosbuvir plus ribavirin (RBV) regimen. There are no comparative head-to-head trials with sofosbuvir plus RBV or other combinations. Therefore, there is no evidence that daclatasvir plus sofosbuvir is more effective or safer than sofosbuvir plus RBV. At the submitted confidential price, daclatasvir plus sofosbuvir 12-week regimen is less costly than the transparent price of a 24-week course of sofosbuvir plus RBV.

	<ul style="list-style-type: none"> The Ministry of Health engaged in discussions with the manufacturer for daclatasvir through the pan-Canadian Pharmaceutical Alliance (pCPA), but the pCPA participating jurisdictions agreed that the parameters required for negotiations by both the manufacturer and the participating jurisdictions cannot be achieved through negotiations at this time.
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:

- advice from a national group called the Common Drug Review
- whether the drug is safe and effective
- whether it is a good value for the people of B.C.
- the ethics of covering or not covering the drug
- input from physicians, patients, caregivers, patient groups and drug submission sponsors

The Ministry makes a decision based on many factors, including:

- advice from the DBC
- drugs used to treat similar medical conditions that B.C. PharmaCare already covers
- the overall cost of covering the drug

Visit the B.C. [Drug Review Process](#) and [PharmaCare](#) program 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.