

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	ledipasvir-sofosbuvir
Brand Name	Harvoni™
Dosage Form(s)	400 mg/90 mg mg single fixed-dose oral tablet
Manufacturer	Gilead Sciences Canada Inc.
Submission Review	New Submission
Use Reviewed	For the treatment of chronic hepatitis C (CHC) infection genotype 1 infection
Common Drug Review (CDR)	CDR recommended to: List with criteria. Visit the CDR website for criteria details: www.cadth.ca/media/cdr/complete/cdr_complete_SR0395_Harvoni_Mar_20-15.pdf
Drug Benefit Council (DBC)	In an effort to streamline the drug review process whenever possible, the Ministry of Health (Ministry) pre-consulted with the DBC on February 2, 2015 for this drug product. The DBC advised that because sofosbuvir-ledipasvir is similar to sofosbuvir (which was reviewed by the DBC on September 14, 2014), the Ministry may accept CDEC's sofosbuvir-ledipasvir recommendation. The DBC also advised that another review from DBC was not needed unless the CDEC recommendation was substantially different from sofosbuvir for genotype 1 or unless the Ministry sought additional advice from the DBC.
Drug Coverage Decision	Limited Coverage benefit Access the ledipasvir-sofosbuvir criteria from www.gov.bc.ca/pharmacarespecialauthority
Date	March 24, 2015
Reason(s)	Drug coverage decision is consistent with CDEC recommendation. <ul style="list-style-type: none"> • Sofosbuvir-ledipasvir has reported high cure rates (based upon sustained viral response), is dosed once-daily, is generally well-tolerated (compared to interferon-containing regimens) and offers a shorter duration of therapy for most patients. • Based on the CDR pharmacoeconomic report, sofosbuvir-ledipasvir is cost-effective compared to other therapies in treatment-naïve patients and treatment-experienced patients without cirrhosis. • The Ministry also considered input from clinical experts and patient input received from the sofosbuvir review.
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.