

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	sofosbuvir
Brand Name	Sovaldi®
Dosage Form(s)	400 mg oral tablet
Manufacturer	Gilead Sciences Canada Inc.
Submission Review	New Submission
Use Reviewed	For the treatment of chronic hepatitis C (CHC) infection
Common Drug Review (CDR)	CDR recommended to: List with criteria. Visit the CDR website for more details: www.cadth.ca/media/cdr/complete/cdr_complete_sovaldi_august_20_2014.pdf
Drug Benefit Council (DBC)	The DBC met on September 14, 2014. DBC considered the following: final review completed by the CDR on August 18, 2014, which included clinical and pharmacoeconomic evidence review material and the recommendation from CDEC. The DBC also considered Patient Input Questionnaire responses from 36 patients, 9 caregivers and 5 patient groups; Clinical Practice Reviews from two specialists; Clinical Practice Reviews on sofosbuvir for the treatment of CHC in hepatitis C virus and human immunodeficiency virus (HCV/HIV) co-infected patients from five specialists; Manufacturer comments to the CDEC recommendation and reasons; an open-label, non-randomized, uncontrolled phase 3 trial of sofosbuvir and RBV in HCV/HIV co-infected patients; as well as a Budget Impact Assessment.
Drug Coverage Decision	Limited Coverage benefit. Access the sofosbuvir drug criteria from www.gov.bc.ca/pharmacarespecialauthority
Date	March 24, 2015
Reason(s)	Drug coverage decision is consistent with the DBC recommendation. <ul style="list-style-type: none"> The available clinical evidence demonstrated that treatment with sofosbuvir plus peginterferon and ribavirin (PR) for genotype 1 and with ribavirin (RBV) for genotype 2 and 3 achieved high rates of sustained virologic response (SVR), which is a measure of successful treatment of CHC. Although the cost per course of treatment is expensive, sofosbuvir is considered “cost effective” in most populations from a pharmacoeconomic perspective because of high cure rates. For genotype 2 and 3, sofosbuvir plus RBV is considerably more expensive than PR treatment. In those patients for whom interferon-based treatment is contraindicated or for those who are treatment-experienced, treatment with sofosbuvir and RBV is reasonable as no other effective therapy options are available. The DBC also recommended that the

	coverage policy not distinguish between patients with HCV/HIV co-infection and HCV mono-infection.
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.