

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	macitentan
Brand Name	Opsumit™
Dosage Form(s)	10 mg
Manufacturer	Actelion Pharmaceuticals Canada Inc.
Submission Review	New Submission
Use Reviewed	For the treatment of pulmonary arterial hypertension (PAH) (World Health Organization (WHO) Group 1)
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/cdr_complete_SR0364_Opsumit_Jan-30-15.pdf
Drug Benefit Council (DBC)	DBC met on March 2, 2015. DBC considered various inputs including: the final review completed by the CDR, which included clinical and pharmacoeconomic evidence review material and the recommendation from the Canadian Drug Expert Committee (CDEC); Patient Input Questionnaire responses from three Patient Groups; a Clinical Practice Review report from one specialist; and a Budget Impact Analysis.
Drug Coverage Decision	Non-Benefit
Date	January 26, 2016
Reason(s)	<p>Drug coverage decision is consistent with the DBC recommendation.</p> <ul style="list-style-type: none"> The DBC recommended that macitentan be listed for the treatment of PAH with certain clinical criteria as long as the cost of macitentan does not exceed cost of generic bosentan. One randomized controlled trial (RCT), reviewed by the DBC, demonstrated that treatment with macitentan resulted in reduced morbidity and mortality (as a composite end point) compared with placebo in patients with PAH. However, there are no comparative head-to-head trials with any other drugs for the treatment of PAH. Therefore, there is no evidence that macitentan is more effective or safer than other drugs for the treatment of PAH. At the submitted price, macitentan costs similar to brand-name bosentan but is more expensive than generic bosentan, ambrisentansildenafil and tadalafil. The Ministry participated in the pan-Canadian Pharmaceutical Alliance (pCPA) negotiations with Actelion Pharmaceuticals Canada Inc. for macitentan, but the participating jurisdictions did not reach an agreement with the manufacturer.
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.