

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	everolimus
Brand Name	Afinitor®
Dosage Form(s)	2.5 mg, 5 mg and 10 mg oral tablets
Manufacturer	Novartis Pharmaceuticals Canada Inc.
Submission Review	New Submission
Use Reviewed	For the treatment of adult patients (>18 years of age) with renal angiomyolipoma (AML) associated with tuberous sclerosis complex (TSC), who do not require immediate surgery.
Common Drug Review (CDR)	CDR recommended Do not list http://www.cadth.ca/media/cdr/complete/cdr_compete_Afinitor_September_27_13.pdf
Drug Benefit Council (DBC)	DBC met on April 14, 2014. DBC considered various inputs including the following: the final review completed by the Common drug Review (CDR) which included clinical and pharmacoeconomic evidence review material and the recommendation from the Canadian Drug Expert Committee (CDEC); a Clinical Practice Reviews from two specialists; Manufacturer comments; responses to Patient Input Questionnaires for one patient group; and a Budget Impact Analysis.
Drug Coverage Decision	Non-Benefit
Date	August 12, 2014
Reason(s)	<p>Drug coverage decision is consistent with DBC recommendation.</p> <ul style="list-style-type: none"> In one randomized, double-blind controlled trial (RCT), EXIST-2, everolimus was shown to reduce the size of AML in everolimus-treated patients versus placebo. However, a reduction of AML size has not been definitely linked to a reduction in bleeding complications, avoidance of surgery, or long-term preservation of kidney function. Therefore, the clinical relevance of the trial outcome on reduction in AML tumour size is not certain. Based on economic considerations, the submitted product price, and uncertain efficacy of the drug, cost-effectiveness is uncertain.
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](#) gives advice to the Ministry. The Council 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. and the drugs cost
- 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 Council
- drugs used to treat similar medical conditions that B.C. PharmaCare already covers
- the overall cost of covering the drug

For more information about the B.C. Drug Review Process, please visit
<http://www.health.gov.bc.ca/pharmacare/outgoing/drugrevproc2.pdf>.

To find out more about the Pharmaceutical Services Division and the PharmaCare program, visit
www.health.gov.bc.ca/pharmacare.

This document is intended for information only.

It does not take the place of advice from a physician or other qualified health care provider.