

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 capsules
Manufacturer	Novartis Pharmaceuticals Canada Inc.
Submission	New Submission
Review	
Use Reviewed	For the treatment of subependymal giant cell astrocytoma (SEGA), a brain tumour associated with a genetic condition called tuberous sclerosis complex (TSC)
Common Drug	Yes. CDR recommended to: Do not list .
Review (CDR)	Visit the CDR website for more details: www.cadth.ca/node/88649 .
Drug Benefit	Everolimus was not reviewed by the DBC as the CDR recommended not to list everolimus for
Council (DBC)	this indication.
Drug Coverage	Non-Benefit
Decision	
Date	July 28, 2015
Reason(s)	 Everolimus was not reviewed by the DBC because it received a "Do not list" recommendation from the CDR. The Ministry of Health reviewed clinical evidence and pharmacoeconomic reports prepared by the CDR, the Final Canadian Drug Expert Committee (CDEC) Recommendation and Reasons, and patient input received from one patient and one caregiver. One randomized controlled trial and one open-label uncontrolled trial demonstrated treatment with everolimus reduces the size of the SEGA lesions; however the clinical significance of this finding is uncertain, as reducing lesion size has not been shown to improve outcomes of importance to patients, including quality of life, seizure frequency, hydrocephalus, or the need for neurosurgery. Although the trials were not designed to evaluate differences in harms between everolimus and placebo, serious adverse events were more commonly reported in the everolimus group compared with placebo group. The cost-effectiveness of everolimus as a treatment option for SEGA associated with TSC is uncertain.
Other	None
Information	

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

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

For more information about the Medical Beneficiary and 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.