

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	tolvaptan
Brand Name	Samsca®
Dosage Form(s)	15 mg and 30 mg tablets
Manufacturer	Otsuka Canada Pharmaceutical Inc.
Submission Review	New Submission
Use Reviewed	Tolvaptan (Samsca®) is indicated for the treatment of clinically important, non-hypovolemic hyponatremia.
Common Drug Review (CDR)	CDR Recommended Do Not List. http://www.cadth.ca/media/cdr/complete/cdr_complete_Samsca_Feb-12-13-e.pdf
Drug Benefit Council (DBC)	DBC met on May 13, 2013. The DBC considered the following: the final review completed by the CDR on February 13, 2013, which included clinical and pharmacoeconomic evidence review material and the recommendation from the Canadian Drug Expert Committee (CDEC). The DBC also considered Clinical Practice Reviews from two Specialists, Manufacturer comments, and a Budget Impact Analysis. Patient input was not available for this review.
Drug Coverage Decision	Non-Benefit
Date	August 15, 2013
Reason(s)	<ul style="list-style-type: none"> • Drug coverage decision is consistent with the DBC recommendation. The drug demonstrated a reduction in sodium levels, compared to placebo but the effect was not sustained after the drug was stopped. • Tolvaptan did not show any benefit compared to placebo when it came to reducing death, frequency of rehospitalization, improvement in mental/physical being or improving the patient's quality of life. • The US Food and Drug Administration (FDA) and Health Canada both released advisories about the potential for this drug to cause irreversible and potentially fatal liver injury, and the FDA has recommended limiting treatment duration to no longer than 30 days. • Based on economic considerations and the submitted product price, the drug was not cost-effective.
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.

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