

BC PharmaCare Drug Information

The drug below is being considered for possible coverage under the B.C. PharmaCare program. PharmaCare is a government-funded drug plan that helps British Columbians with the cost of eligible prescription drugs and specific medical supplies. For more information on PharmaCare, visit [Ministry of Health - PharmaCare](#).

PharmaCare reviews each drug for treating a specific illness or medical condition (known as an “indication”). If a decision is made to cover the drug, it will be only for that illness or condition.

In some cases, PharmaCare may cover a drug only for people who have the illness or condition and have not responded to other drugs used to treat that illness or condition.

For more information on PharmaCare’s drug coverage review process, see the last page of this information sheet.

Information about the drug	
Generic name (scientific name)	tolvaptan
Brand name	Jinarc™
Manufacturer	Otsuka Canada Pharmaceutical Inc.
Indication	autosomal dominant polycystic kidney disease (ADPKD)
Has the drug been reviewed by the Common Drug Review (CDR)? (see the note below this table.)	Yes. For more information about the CDR’s review of tolvaptan (Jinarc™), you can Search the CDR Reports .
Public input start date	Wednesday September 23, 2015
Public input closing date	Wednesday October 21, 2015 AT MIDNIGHT
How is the drug taken?	Jinarc™ tablets are taken orally (by mouth).
How often is the drug is taken?	Jinarc™ tablets are taken twice daily.

Information about the drug	
General drug and/or drug study information	<p>Jinarc™ is used in adults to treat autosomal dominant polycystic kidney disease (ADPKD).</p> <p>ADPKD is a genetic disorder which leads to the growth of multiple cysts (sacs filled with fluid) on the kidneys. Over time, the cysts grow in size, which can damage the way the kidneys work and may ultimately lead to kidney failure.</p> <p>Jinarc™ works by blocking the effects of a hormone, called vasopressin, which promotes cyst growth in the kidneys in patients with ADPKD. By blocking the effects of vasopressin, Jinarc™ is able to reduce the growth of the cysts in the kidneys and should help protect the kidneys from damage and failure.</p> <p>Studies looked at the following outcomes to assess if Jinarc™ is helpful and safe for the treatment of ADPKD:</p> <ul style="list-style-type: none"> • Disease complications (represented as a combination of outcomes looking at progression of disease including kidney function decline, worsening of kidney pain, blood pressure and loss of proteins thru the urine) • Patient reported outcomes (e.g., kidney pain) • Total kidney volume (size of the kidney and percentage of increase in size of the kidney) • Kidney function measured by blood tests • Fatal and non-fatal cardiovascular events (increased heart beat, irregular heart beat, heart attack and chest pain) • Manifestations not related to kidneys (appearance of liver cysts or other cysts) • Bad reactions • Serious bad reactions • Withdrawals due to bad reactions (patients who stopped taking the drug) • Mortality • Notable harms: worsening of liver function as measured by blood tests
Other considerations	None

Note:

The Common Drug Review (CDR) is a national organization that reviews drugs on behalf of Canadian public sector plans when manufacturers want to have the jurisdictions provide coverage for the drugs. For detailed information on B.C. PharmaCare’s drug review process, including the role of the CDR in that process, see [The Drug Review Process in B.C. - Overview](#).

Cost of the drug under review compared to other drugs used to treat the same indication			
generic name (Brand Name) of Drug Comparator	PharmaCare Status (if and how the drug is already covered)	Usual Dose	Annual Cost of Therapy
tolvaptan (Jinarc™)	Under Review	Taken twice daily in two different doses of 45+15 mg, 60+30 mg, or 90+30 mg	\$34,650

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 \(Council\)](#) gives advice to the Ministry. The Council looks at:

- whether the drug is safe and effective
- advice from a national group called the [Common Drug Review \(CDR\)](#)
- what the drug costs and whether it is a good value for the people of B.C.
- ethical considerations involved with covering or not covering the drug
- input from physicians, patients, caregivers, patient groups and drug submission sponsors

The Ministry makes PharmaCare coverage decisions by taking into account:

- the existing PharmaCare policies, programs and resources
- the evidence-informed advice of the Council
- the drugs already covered by PharmaCare that are used to treat similar medical conditions
- the overall cost of covering the drug

For more information about the B.C. Drug Review Process, visit: [The Drug Review Process in B.C. - Overview](#).

This document is intended for information only.

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