



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	pirfenidone
Brand Name	Esbriet™
Dosage Form(s)	267 mg oral capsule
Manufacturer	InterMune Canada Inc.
Submission Review	New submission
Use Reviewed	The treatment of mild to moderate idiopathic pulmonary fibrosis (IPF) in adult
Common Drug Review (CDR)	Yes, CDR recommended Do not list. Visit CDR website for more details: http://www.cadth.ca/media/cdr/complete/cdr_complete_Esbriet_April-24-13.pdf
Drug Benefit Council (DBC)	DBC met on July 15, 2013. DBC considered various inputs including: the final review completed by the Common Drug Review (CDR) on April 18, 2013, which included clinical and pharmacoeconomic evidence review material and the recommendation from the Canadian Drug Expert Committee (CDEC); a Clinical Practice Reviews from one Specialist and one General Practitioner; Manufacturer comments; responses to Patient Input Questionnaires from 14 patients, 5 caregivers, and 2 patient groups; and a Budget Impact Analysis.
Drug Coverage Decision	Non-benefit
Date	January 14, 2014
Reason(s)	Drug coverage decision is consistent with the DBC recommendation: <ul style="list-style-type: none">• Based from the CDR systematic review, which included two randomized-controlled trials (RCTs) comparing pirfenidone to placebo, there were no significant clinical benefit in mortality and IPF-related mortality.• There were inconsistencies in the results of the two RCTs with respect to clinical benefit improvements in the rate of decline of the percent predicted forced vital lung capacity (FVC), which is a test of lung function, progression-free survival and the six-minute walk test (6MWT).• In addition, there was insufficient evidence to determine if pirfenidone provides clinical benefit on important outcomes such as quality of life, time to worsening IPF, hospitalization due to lung problems, shortness of breath or the need for supplemental oxygen.• Given the uncertain clinical benefit of pirfenidone and the high annual per patient drug cost, the cost-effectiveness of pirfenidone is uncertain. Based on the manufacturer's analysis comparing pirfenidone to placebo, pirfenidone is associated with an incremental cost-utility ratio of \$143,617 per quality adjusted life years (QALY) which is generally not considered cost-effective. In addition, the CDR analysis identified number of limitations in the

	manufacturer's analysis, which would make pirfenidone even less 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.