



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	riociguat
Brand Name	Adempas®
Dosage Form(s)	0.5 mg, 1 mg, 1.5 mg, 2 mg and 2.5 mg oral tablets
Manufacturer	Bayer Inc.
Submission Type	New Indication
Use Reviewed	Pulmonary Arterial Hypertension (PAH)
Common Drug Review (CDR)	Yes, CDR recommended: to Reimburse with clinical criteria and/or conditions . Visit the CDR website for more details: www.cadth.ca/about-cadth/what-we-do/products-services/cdr/reports
Drug Benefit Council (DBC)	DBC met on January 11, 2016. DBC considered various inputs including: final reviews completed by the CDR, which included clinical and pharmacoeconomic evidence review material and the recommendations from the Canadian Drug Expert Committee (CDEC). The DBC also considered Patient Input Questionnaire responses from three patients, two caregivers and one Patient Group, Clinical Practice Reviews from one specialist, a Budget Impact Assessment and a March 2015 Therapeutic Review Report from the Canadian Agency for Drugs and Technologies in Health (CADTH) titled “Drugs for Pulmonary Arterial Hypertension: Comparative Efficacy, Safety, and Cost-Effectiveness”.
Drug Coverage Decision	Non-Benefit
Date	May 2, 2017
Reason(s)	Drug coverage decision is consistent with the DBC recommendation. <ul style="list-style-type: none">• Riociguat was similar to or demonstrated some advantage over placebo with respect to efficacy and safety but not quality of life.• When used as monotherapy, riociguat is more costly than all other oral PAH drugs. When used as add-on combination therapy with endothelin receptor antagonists (ERAs) or prostacyclins, the place in therapy of riociguat is unclear and there is limited clinical evidence supporting the efficacy and cost-effectiveness versus other comparators.• The pan-Canadian Pharmaceutical Alliance (pCPA) decided not to negotiate collectively or individually at the provincial-territorial level with the manufacturer of riociguat. The manufacturers and pCPA jurisdictions have engaged in thorough discussions regarding criteria and conditions as recommended through the CDR review and both recognize that an agreement could not be reached at the current time.
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:

- 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 DBC
- the drugs already covered by PharmaCare that are used to treat similar medical conditions
- the overall cost of covering the drug

Visit the [The Drug Review Process in B.C. - Overview](#) and [Ministry of Health - PharmaCare](#) for more information.

This document is intended for information only.

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