

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	macitentan-tadalafil
Brand Name	Opsynvi®
Dosage Form(s)	10 mg/40 mg tablet
Manufacturer	Janssen Inc.
Submission Type	New Submission
Use Reviewed	for the treatment of pulmonary arterial hypertension (PAH), in World Health Organization (WHO) Functional Class (FC) II or III patients.
Common Drug Review (CDR)	Yes, the CDR recommended: to Reimburse with clinical criteria and/or conditions . Visit the CDR website for more details: www.cadth.ca/sites/default/files/DRR/2021/SR0690%20Opsynvi-Rec%20Final.pdf
Provincial Review	The DBC now screens drug submissions under review by the CDR to determine whether a full DBC review is necessary, based on past DBC reviews, recommendations, and existing PharmaCare coverage. If a full DBC review is determined to not be required, the Ministry's drug coverage decision will be based on the Canadian Drug Expert Committee (CDEC) recommendation and an internal review only. The DBC screened macitentan-tadalafil on July 5, 2021. The DBC advised that because macitentan-tadalafil is similar to some of the other drugs used for the treatment of PAH, the Ministry may accept the CDEC's recommendation for macitentan-tadalafil.
Drug Coverage Decision	Non-Benefit
Date	September 14, 2022

Reasons	<p>Drug coverage decision is consistent with the CDEC recommendation.</p> <ul style="list-style-type: none"> • The CDEC recommended that macitentan-tadalafil be listed for the treatment of PAH with certain clinical criteria if the coverage of macitentan-tadalafil should provide cost-savings in comparison with the regimen of macitentan and tadalafil administered as individual components. • The results from three bioequivalence studies in healthy volunteers suggest that the fixed dose combination (FDC) of macitentan-tadalafil is bioequivalent to the individual components administered separately. • One randomized controlled trial (RCT), SERAPHIN, which was previously evaluated as part of the CDR review of macitentan (Opsumit®), demonstrated that treatment with macitentan 10 mg resulted in reduced morbidity and mortality (as a composite end point) compared with placebo in patients with PAH, with WHO FC II or III. • However, there are no comparative head-to-head trials with any other drugs for the treatment of PAH. Therefore, there is no evidence that macitentan is more effective or safer than other drugs for the treatment of PAH. • Macitentan (Opsumit®) is not an eligible PharmaCare benefit, but tadalafil (generics) is a Limited Coverage benefit with criteria. Other Endothelin Receptor Agonist (ERA) comparators, bosentan (generics) and ambrisentan (Volibris®) are Limited Coverage benefits with criteria. Bosentan is also subject to Low-Cost Alternative (LCA) policy. • The Ministry did not participate in the pan-Canadian Pharmaceutical Alliance (pCPA) negotiations with Janssen Inc. for macitentan-tadalafil as the Ministry does not provide coverage for one of the individual components, macitentan. • The pCPA participating jurisdictions and Janssen Inc., were not able to address the concerns identified by the CDEC with respect to the cost savings, and an agreement was not reached at the current time.
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 \(DBC\)](#) 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 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.