

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	Pitolisant hydrochloride
Brand Name	Wakix®
Dosage Forms	5 mg and 20 mg tablets
Manufacturer	Paladin Labs Inc.
Submission Type	New Submission
Use Reviewed	The treatment of excessive daytime sleepiness or cataplexy in adult patients with narcolepsy
Canadian Agency for Drugs and Technologies in Health (CADTH) Reimbursement Reviews (CRR)	Yes, CRR recommended: Do Not Reimburse . Visit the CRR website for more details: www.cadth.ca/sites/default/files/DRR/2022/SR0715%20Wakix%20-%20Final%20CADTH%20Recommendation%20for%20publishing-KH_BMc%20-%20KH-meta.pdf
Provincial Review	<p>The DBC now screens drug submissions under review by the CRR to determine whether or not 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 CDEC recommendation and an internal review only. The DBC screened pitolisant on April 4, 2022.</p> <p>Pitolisant was reviewed internally and was not reviewed by the Drug Benefit Council (DBC) because the CRR recommended not to list for the treatment of excessive daytime sleepiness or cataplexy in adult patients with narcolepsy.</p> <p>The Provincial review considered various inputs including: the final reviews completed by the CRR, which included clinical and pharmaco-economic evidence review material and the recommendations from the Canadian Drug Expert Committee (CDEC), and Clinical Practice Reviews (CPRs) from two specialist. Your Voice input resulted in no response from patients, caregivers and patient groups</p>

Drug Coverage Decision	Non-Benefit
Date	August 15, 2023.
Reason(s)	<p>Drug coverage decision is consistent with the CDEC recommendation.</p> <ul style="list-style-type: none"> • Pitolisant did not demonstrate advantage over modafinil with respect to efficacy and safety. • There is a significant uncertainty whether pitolisant offers any therapeutic benefit over other treatments used for excessive daytime sleepiness or cataplexy • Based on economic considerations and the submitted product price, the pitolisant was not cost effective and did not offer optimal value for money.
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 [Canadian Agency for Drugs and Technologies in Health \(CADTH\) Reimbursement Reviews\(CRR\)](#)
- 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.