

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	duloxetine
Dosage Form(s)	30 mg and 60 mg delayed-release capsules
Manufacturer	Generics
Submission Type	Ministry Initiated
Use Reviewed	Neuropathic pain
Common Drug Review (CDR)	If CDR reviewed, include: Yes, CDR recommended: to Reimburse with clinical criteria and/or conditions. Visit the CDR website for more details: www.cadth.ca/sites/default/files/cdr/complete/cdr_complete_Cymbalta-DPN_August-14-2008.pdf
Drug Benefit Council (DBC)	DBC met on January 12, 2009 and recommended that duloxetine (Cymbalta®) not be listed for the treatment of neuropathic pain associated with diabetic peripheral neuropathy. The current review was initiated by the Ministry and analyzed internally. In their internal review, the Ministry considered various evidence such as the final review completed by the CDR which included the recommendation from the Canadian Drug Expert Committee (CDEC), the DBC recommendation, the Canadian Network for Mood and Anxiety Treatments (CANMAT) guidelines, the Canadian Pain Society recommendations, a Medications for Neuropathic Pain review completed in 2018 by the Provincial Academic Detailing Service (PAD) as well as a Budget Impact Assessment.
Drug Coverage Decision	Limited Coverage Benefit. Access the duloxetine criteria from www.gov.bc.ca/pharmacarespecialauthority
Date	November 27, 2018
Reason(s)	Drug coverage decision is consistent with the CDEC recommendation but is inconsistent with the DBC recommendation. <ul style="list-style-type: none"> At the time the drug was reviewed by the DBC, there was sufficient evidence that duloxetine provides a statistically significant and clinically important reduction in the baseline 24-hour average pain scores compared to placebo. However, studies were of short duration (12 weeks) thus lacking long term safety data. Also, there were no head-to-head comparisons against other commonly used drugs for neuropathic pain and insufficient evidence that duloxetine had any incremental benefits justifying its higher annual cost of therapy. Duloxetine is recommended as a first line therapy for chronic neuropathic pain by the Canadian Pain Society, and is a first line antidepressant in the Canadian Network for

	<p>Mood and Anxiety Treatments (CANMAT) guidelines.</p> <ul style="list-style-type: none"> • The Ministry of Health recognizes the risks associated with prescription opioid misuse and supports appropriate pain management including usage of non opioids as first line therapies. Opioids are useful medications for the treatment of pain. However, their misuse is associated with serious harms, including addiction, overdose, and possibly death, placing a significant burden on individuals and their families, health and social services systems, and public safety systems. • Duloxetine as a PharmaCare limited coverage benefit provides an additional tool to treat chronic pain, and in current climate of the ongoing opioid crisis, is valuable in encouraging appropriate opioid prescribing. • The introduction of generic versions of duloxetine has reduced the budget impact of duloxetine from the original and now compares favourably to alternate treatment options.
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 [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.