



Drug Coverage Decision for BC PharmaCare

About PharmaCare

BC PharmaCare is a publicly funded drug plan that helps B.C. residents pay for most prescription drugs and pharmacy services, and some medical devices and supplies.

Details of Drug Reviewed

Drug	Estradiol
Brand name	Imvexxy™
Dosage forms	4 mcg and 10 mcg estradiol vaginal inserts
Manufacturer	Knight Therapeutics Inc.
Submission type	New Submission
Indication reviewed	For the treatment of postmenopausal moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy.
Canada's Drug Agency – (CDA-AMC) Reimbursement Reviews (CRR)	CDA-AMC recommended: to Reimburse with clinical criteria and/or conditions. Visit the CRR website for more details .
Drug Benefit Council (DBC)	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 Canadian Drug Expert Committee (CDEC) recommendation and an internal review only. The DBC screened estradiol vaginal inserts (Imvexxy) and advised that because estradiol vaginal inserts (Imvexxy) are similar to some of the other drugs used for the same indication, the Ministry may accept the CDEC's recommendation.
Drug Coverage Decision	Regular benefit
Date	May 14, 2024.
Reasons	<p>Drug coverage decision is consistent with the CDEC recommendation.</p> <ul style="list-style-type: none"> One phase 3, randomized, double-blind, placebo-controlled study (REJOICE) comparing the efficacy and safety of Imvexxy with placebo in postmenopausal women with moderate to severe dyspareunia was reviewed by CDEC. Compared to placebo, Imvexxy decreases severity of the most bothersome symptoms of dyspareunia associated with vulvar and vaginal atrophy.

- The safety was similar between Imvexxy and placebo and was consistent with the expected adverse event profile for an estradiol-containing product.
- The Ministry participated in the pan-Canadian Pharmaceutical Alliance negotiations with the manufacturer which were able to address the concerns identified by the CDEC with respect to the cost-comparison and value for money.

The drug review process in B.C.

A manufacturer submits a request to the Ministry of Health (the Ministry).

An independent group called the [Drug Benefit Council \(DBC\)](#) gives advice to the Ministry by considering:

- whether the drug is safe and effective
- advice from a national group called [Canada's Drug Agency \(CDA\)](#)
- what the drug costs and whether funding it provides good value to the province
- ethical considerations of covering and not covering the drug
- input from physicians, patients, caregivers, patient groups and drug submission sponsors.

The Ministry makes a BC PharmaCare coverage decision by taking into account:

- existing BC PharmaCare policies, programs and resources
- the evidence-informed advice of the DBC
- drugs already covered by BC PharmaCare that treat similar medical conditions.
- the overall cost of covering the drug.

Visit [BC PharmaCare](#) and [Drug reviews](#) 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.