

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	difelikefalin
Brand name	Korsuva®
Dosage form(s)	50 mcg/1.0 mL solution in a vial for intravenous injection
Manufacturer	Otsuka Canada Pharmaceutical Inc.
Submission type	New Submission
Indication reviewed	For the treatment of moderate to severe pruritus associated with chronic kidney disease in adult patients on hemodialysis
Canadian Agency for Drugs and Technologies in Health (CADTH) Reimbursement Review (CRR)	CADTH recommendation: Do Not Reimburse . Visit the CADTH website for more details .
Drug Benefit Council (DBC)	The DBC did not review difelikefalin in light of the CADTH recommendation not to list difelikefalin.
Drug Coverage Decision	Non-benefit
Date	April 30, 2024
Reason(s)	<ul style="list-style-type: none"> The drug coverage decision is consistent with the CADTH Canadian Drug Expert Committee (CDEC) recommendation not to reimburse difelikefalin for the treatment of moderate to severe pruritus associated with chronic kidney disease (CKD-aP) in adult patients on hemodialysis (HD). The CDEC could not conclude whether treatment with difelikefalin resulted in clinically meaningful improvements. Evidence from 2 randomized controlled

trials (KALM-1 and KALM-2) demonstrated that treatment with difelikefalin was associated with statistically significant improvements in itch; however, whether the improvement is clinically meaningful to patients is unclear due to a high placebo response, and the trials measuring itch in a way that is inconsistent with clinical practice. As such, it is difficult to determine the actual treatment effect of difelikefalin.

- Patients living with moderate to severe CKD-aP on HD expressed a need for treatments that improve quality of life. Based on the available evidence, it is unclear if difelikefalin is associated with an improvement in quality of life.
- Based on CDEC's economic review, difelikefalin compared to best standard of care is not cost-effective.
- The pan-Canadian Pharmaceutical Alliance (pCPA) notified the manufacturer of difelikefalin that all the pCPA jurisdictions have decided to not engage in discussions/negotiations through the pCPA process.

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 the [Canadian Agency for Drugs and Technologies in Health \(CADTH\)](#)
- 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 [Ministry of Health - PharmaCare](#) and [BC PharmaCare – 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.