

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	lixisenatide
Brand Name	Adlyxine™
Dosage Form(s)	0.05 mg/mL and 0.10 mg/mL solution for injection in a 3 mL pre-filled pen
Manufacturer	Sanofi-Aventis Canada Inc.
Submission Type	New Submission
Use Reviewed	Treatment for type 2 diabetes mellitus (T2DM)
Common Drug Review (CDR)	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/SR0520_Adlyxine_complete_Nov-23-17.pdf
Provincial Review	DBC now screens drug submissions under review by the CDR 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 Adlyxine on November 6, 2017. The DBC advised that because lixisenatide is similar to some of the other drugs used for the treatment of T2DM, the Ministry may accept the CDEC's recommendation.
Drug Coverage Decision	Non-Benefit
Date	June 12, 2018
Reason(s)	Drug coverage decision is consistent with CDR recommendation. <ul style="list-style-type: none"> The CDR recommended that lixisenatide be reimbursed with a condition that the price of lixisenatide does not exceed the drug plan costs of the least costly pharmacotherapy reimbursed for the treatment of type 2 diabetes mellitus in combination with a basal insulin (with or without metformin). However, less costly treatment options exist. Adlyxine in combination with basal insulin (with or without metformin) was similar to rapid-acting insulin glulisine (Apidra™) or demonstrated some advantage over placebo with respect to efficacy not safety or quality of life. However, more hypoglycemic (low sugar) side effects were reported in patients treated with Apidra. Adlyxine was found to be similar to placebo in terms of the cardiovascular outcome benefit. Based on economic considerations and the submitted product price, Adlyxine was not cost effective and/or did not offer optimal value for money. The CDR also noted that there was no evidence to suggest that lixisenatide meets a need

	<p>that is not currently met by existing treatment options.</p> <ul style="list-style-type: none"> There are three indications approved for lixisenatide, but the manufacturer only requested reimbursement for one indication (in combination with a basal insulin, with or without metformin). The place in therapy for this indication is unclear in comparison to the other glucagon-like peptide-1 receptor (GLP-1) drugs, which are being reviewed for use in combination with metformin and a sulfonylurea. The Ministry decided to opt-out of the pCPA negotiation as the place in therapy for lixisenatide was unclear and the Canadian Agency for Drugs and Technologies (CADTH) Therapeutic Review for third-line treatment is not yet completed.
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.