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	tralokinumab
Brand name	Adtralza®
Dosage form(s)	150 mg/mL pre-filled syringe
Manufacturer	LEO Pharma Inc.
Submission type	**New Indication**
Indication reviewed	For the treatment of moderate-to-severe atopic dermatitis (AD) in patients aged 12 years and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable and who had an adequate trial or are ineligible for each of the following therapies: phototherapy (where available) and off-label immunosuppressants.
Canada's Drug Agency (CDA-AMC) Clinical Reimbursement Reviews (CRR)	CDA-AMC recommended: **Do Not Reimburse**. Visit the CDA-AMC website for more details.
Drug Benefit Council (DBC)	Tralokinumb was reviewed internally and was not reviewed by the Drug Benefit Council (DBC) because of the CDA-AMC recommendation not to list.
Drug Coverage Decision	**Non-benefit**
Date	December 17, 2024
Reason(s)	**Drug coverage decision is consistent with the Canadian Drug Expert Committee (CDEC) recommendation that Adtralza not be reimbursed for the treatment of moderate-to-severe AD in adult and adolescent patients 12**

	years and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. • Evidence from 4 clinical trials demonstrated that, in the short-term, Adtralza treatment improved severity of AD, itch symptoms, and health-related quality of life (HRQoL) compared to placebo in adults and adolescents with moderate-to-severe AD; however, it is uncertain if the magnitude of benefit is clinically meaningful to patients and clinicians. Additionally, a clinical trial in adults with severe AD who previously failed or were deemed unsafe to receive a systemic immunosuppressant showed that Adtralza treatment improved severity of AD but not itch, and its effects on other clinical outcomes are unclear. • CDEC acknowledged the potential need for additional treatment options that effectively reduce the severity and symptoms of AD; however, based on the submitted evidence, CDEC could not determine whether Adtralza would adequately meet this need due to the uncertainty around the magnitude of treatment effect, and the benefit of Adtralza versus appropriate comparators and in patients who received prior dupilumab or Janus kinase inhibitors (JAKi) treatment. • The pan-Canadian Pharmaceutical Alliance (pCPA) and the Ministry were not involved in negotiations with the manufacturer for this product because of the CDEC recommendation not to list.

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 and Health Technology Agency (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 BC PharmaCare and Drug reviews for more information.

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It does not take the place of advice from a physician or other qualified health care provider.