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	**inclisiran**
Brand name	Leqvio®
Dosage form(s)	284 mg in 1.5 mL single-dose pre-filled syringe
Manufacturer	Novartis Pharmaceuticals Canada Inc.
Submission type	**Resubmission**
Indication reviewed	For the treatment of primary hypercholesterolemia, to further reduce low-density lipoprotein cholesterol (LDL-C) levels in adults with the following conditions who are on maximally tolerated dose of a statin, with or without other LDL-C -lowering therapies: • Heterozygous familial hypercholesterolemia (HeFH), or • Non-familial hypercholesterolemia (nFH) with atherosclerotic cardiovascular disease (ASCVD)
Canada's Drug Agency (CDA-AMC) Clinical Reimbursement Reviews (CRR)	**For HeFH Indication:** The Canadian Drug Expert Committee (CDEC) recommended: **to Reimburse with clinical criteria and/or conditions**. Visit the CDA-AMC website for more details. **For nFH with ASCVD indication:** The Canadian Drug Expert Committee (CDEC) recommended: **Do Not Reimburse**. Visit the CDA-AMC website for more details.
Ministry of Health (the Ministry) Review	The Ministry reviewed clinical and pharmacoeconomic reports prepared by the CDA-AMC's CRR, including clinical and pharmacoeconomic evidence review material and the recommendations of the CDEC. The Ministry also considered patient input provided to CDEC and a budget impact assessment for the HeFH indication. The Ministry received Patient Input Questionnaire responses from 22

	patients and 3 caregivers for the nFH with ASCVD indication, and 57 patients for the HeFH indication.
Drug Coverage Decision	**Non-benefit**
Date	June 4, 2026
Reason(s)	**Drug coverage decision is consistent with the CDEC recommendation that Leqvio <u>not</u> be reimbursed an adjunct to lifestyle changes, including diet, to further reduce LDL-C levels in adults who are on a maximally tolerated dose (MTD) of a statin, with or without other LDL-C–lowering therapies, and who have <u>nFH with ASCVD</u>.** • Evidence from 2 clinical trials showed that treatment with Leqvio lowered bad cholesterol (LDL-C) in adults with nFH with ASCVD who were already being treated with the highest possible dose of statins and in those who cannot tolerate treatment with statins. • A post hoc pooled analysis of major adverse cardiovascular events (MACEs) from the ORION-10 and ORION-11 trials precluded the CDEC from determining whether inclisiran reduces the risk of cardiovascular morbidity and death in adults with nFH with ASCVD. • The pan-Canadian Pharmaceutical Alliance (pCPA) negotiations were not pursued for the nFH with ASCVD indication because of the CDEC's recommendation not to reimburse. **Drug coverage decision is consistent with the CDEC recommendation that Leqvio be reimbursed by public drug plans as an adjunct to lifestyle changes, including diet, to further reduce LDL-C levels in adults who are on a maximally tolerated dose (MTD) of a statin, with or without other LDL-C–lowering therapies, and who have <u>HeFH</u>, if certain conditions are met including price reduction.** • Evidence from a clinical trial showed that treatment with Leqvio lowered LDL-C (also known as "bad cholesterol") in adults with HeFH who were already being treated with the highest possible dose of statins and in those who could not tolerate treatment with statins. • CDEC determined that there was not enough evidence to show that Leqvio would reduce cardiovascular (CV) morbidity and death or improve health-related quality of life (HRQoL). • Based on CDA-AMC's assessment of the health economic evidence, Leqvio does not represent good value to the health care system at the public list price. The CDEC determined that there is not enough evidence to justify a greater cost for Leqvio compared with PCSK9 monoclonal antibodies (i.e., alirocumab and evolocumab). • The Ministry did not participate in the pCPA negotiations for HeFH indication, as BC's cost mandate was not reached, and the listing would not

	provide additional value to British Columbians in terms of cost-effectiveness and clinical benefit.

The drug review process in B.C.

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

An independent national organization called Canada's Drug Agency (CDA-AMC) provides evidence-based recommendations to public drug plans across Canada through its reimbursement review process. As part of the CDA-AMC's Clinical Reimbursement Review process, the Canadian Drug Expert Committee (CDEC) makes reimbursement recommendations for non-oncology pharmaceuticals to the participating federal, provincial, and territorial publicly funded drug plans. In developing its recommendations, the CDEC considers:

- whether the drug is safe and effective
- what the drug costs and whether funding it provides good value
- ethical considerations of covering or not covering the drug
- input from physicians, patients, caregivers, patient groups and drug submission sponsors

The Ministry makes a BC PharmaCare coverage decision by considering:

- existing BC PharmaCare policies, programs and resources
- the evidence-informed advice of the CDA-AMC
- the recommendations and reimbursement conditions of the CDEC
- if a Ministry Initiated review, the advice of an independent expert group called the Drug Benefit Council (DBC)
- BC-specific patient input collected through the Your Voice website
- drugs already covered by BC PharmaCare that treat similar medical conditions
- the overall cost of covering the drug
- the outcomes of pan-Canadian Pharmaceutical Alliance (pCPA) negotiations with manufacturers

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.