

Novartis Canada's statement on CADTH draft recommendations for LEQVIO® (inclisiran)

Mar 21, 2024

Montréal, QC, March 21, 2024 – Novartis Pharmaceuticals Canada Inc. (Novartis Canada) is deeply disappointed with the draft recommendations of the Canadian Drug Expert Committee (CDEC) issued by the Canadian Agency for Drugs and Technologies in Health (CADTH) for LEQVIO® (inclisiran).

These draft recommendations advise to not reimburse LEQVIO for the treatment of hypercholesterolemia for both the heterozygous familial hypercholesterolemia (HeFH) and non-familial hypercholesterolemia with atherosclerotic cardiovascular disease (ASCVD) populations.

As an organization, Novartis respects the process conducted by CADTH but at the same time holds a firm belief in the value that LEQVIO brings to patients, clinicians, and the healthcare system. Globally, LEQVIO is widely accessible in 94 countries,¹ with public reimbursement in 31 countries,² and has positively impacted over 178,000 patients.²

LEQVIO was first approved by Health Canada in 2021 based on clinical trials that demonstrated its efficacy to safely lower LDL cholesterol^{3,4,5} and received a positive funding recommendation from the Institut national d'excellence en santé et en services sociaux (INESSS) in 2021 for adults with heterozygous familial hypercholesterolemia (HeFH). Since its commercialization in 2022, LEQVIO has made a difference in the lives of more than 2,000 Canadian patients.

The draft recommendations are open for feedback from eligible stakeholders until April 5th, 2024. This feedback opportunity can be accessed through the CADTH website^{6,7} at [Open Calls for Input and Feedback | CADTH](#).

Novartis Canada stands behind the potential of this innovative therapy and remains committed to dedicating efforts and striving for a positive outcome that benefits Canadians living with cardiovascular diseases.

About Cardiovascular Disease (CVD)

Cardiovascular diseases (CVD), including heart disease, stroke and vascular cognitive impairment, are responsible for the loss of one life every five minutes,⁸ and is the second leading cause of death in Canada after cancer.⁹ In Canada, heart disease is the leading cause of hospitalization among Canadian women, aside from giving birth,¹⁰ and within the Canadian healthcare system, CVD accounts for \$22 billion annually.⁸ The five-year prevalence of ASCVD in Canada ranges between 6.91%- 8.55% in adults.^{9,10} HeFH has an estimated prevalence of 1 in 250 to 311 individuals.^{11,12,13}

About Novartis

Novartis is a focused innovative medicines company. Every day, we work to reimagine medicine to improve and extend people's lives so that patients, healthcare professionals and societies are empowered in the face of serious disease. Our medicines reach more than 250 million people worldwide. Reimagine medicine with us: Visit us at <https://www.novartis.com> and connect with us on [LinkedIn](#), [Facebook](#), [X/Twitter](#) and [Instagram](#).

In Canada, Novartis Pharmaceuticals Canada Inc. employs approximately 600 people to serve the evolving needs of patients and the healthcare system and invests over \$30 million in R&D yearly in the country. For more information visit www.novartis.ca.

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List of links present in page

1. <https://prod1.novartis.ca/ca-fr/ca-fr/en/news/media-releases/novartis-canadas-statement-cadth-draft-recommendations-leqvio-inclisiran>
2. <https://www.cadth.ca/open-calls-input-and-feedback-0>
3. <https://www.novartis.com/>
4. <https://www.linkedin.com/company/novartis/mycompany/verification/>
5. <https://www.facebook.com/novartis/>
6. <https://twitter.com/Novartis>
7. <https://www.instagram.com/accounts/login/?next=https%3A//www.instagram.com/novartis/%3Fhl%3Dde>
8. [https://urldefense.com/v3/__http://www.novartis.ca__;!!N3hqHg43uw!v-lbHt-KA6bR9t5vGKE2Kpqpgl4HMK9-V-mMZ1Z_9LKcqcvcvBhHLIYPNSUW2eUqQl-HzEOkOWjPNR2168dDUCWNXk4-t2oJqE_w\\$](https://urldefense.com/v3/__http://www.novartis.ca__;!!N3hqHg43uw!v-lbHt-KA6bR9t5vGKE2Kpqpgl4HMK9-V-mMZ1Z_9LKcqcvcvBhHLIYPNSUW2eUqQl-HzEOkOWjPNR2168dDUCWNXk4-t2oJqE_w$)
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12. <https://classic.clinicaltrials.gov/ct2/show/NCT03399370>
13. <https://classic.clinicaltrials.gov/ct2/show/NCT03400800>
14. <https://www.cadth.ca/inclisiran-1>
15. <https://www.cadth.ca/inclisiran-0>
16. <https://www.heartandstroke.ca/articles/connected-by-the-numbers>
17. <https://www.canada.ca/content/dam/phac-aspc/documents/services/publications/diseases-conditions/heart-disease-fact-sheet/heart-disease-factsheet-eng.pdf>