

Reimbursement Recommendation

Evolocumab

Reimbursement request: For the treatment of adult and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia who require additional lowering of low-density lipoprotein cholesterol

Requester: Public drug programs

Recommendation: Reimburse with conditions

Summary

What Is the Reimbursement Recommendation for Evolocumab?

The Formulary Management Expert Committee (FMEC) recommends that evolocumab be reimbursed for the treatment of adult and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of low-density lipoprotein cholesterol (LDL-C), provided certain conditions are met.

What Are the Conditions for Reimbursement?

Evolocumab may be initiated for the treatment of adult and pediatric patients aged 10 years and older with HoFH who require additional lowering of LDL-C. Evolocumab may be renewed if all of the following conditions are met: an assessment of response at 12 weeks after initiation and a clinically relevant reduction in LDL-C. Initiation of evolocumab should be limited to clinicians with expertise in the diagnosis and management of dyslipidemia. Evolocumab should be priced no higher than the least costly comparator for this population.

Why Did Canada's Drug Agency Make This Recommendation?

FMEC reviewed clinical evidence from 1 randomized controlled trial and a cost comparison of evolocumab versus other treatments used in Canada. Evolocumab likely provides clinically meaningful reductions in LDL-C and apolipoprotein B in patients with HoFH.

FMEC concluded that evolocumab demonstrates acceptable clinical value; the reimbursement recommendation also considered unmet clinical need, distinct social and ethical considerations, economic considerations, and impacts on health systems.

Review Background

What Is Homozygous Familial Hypercholesterolemia?

HoFH is a rare and life-threatening genetic disorder characterized by defects in the LDL receptor-mediated clearance of LDL-C. HoFH manifests as extreme elevations in LDL-C. Untreated levels typically exceed 10 mmol/L, which predisposes patients to accelerated atherosclerotic cardiovascular disease, often as early as childhood or young adulthood, and to premature mortality. HoFH is generally estimated to occur in approximately 1 in 300,000 to 1 in 400,000 individuals worldwide. In Canada, 38 to 100 cases are estimated based on the overall population of 38,000,000. Quebec was reported to have a higher prevalence of HoFH due to founder effects.

What Are the Current Treatment Options?

Standard therapy includes high-intensity statins and ezetimibe, but these are often insufficient to achieve target LDL-C levels in almost all patients with HoFH. Lipoprotein apheresis, which is often considered when LDL-C remains uncontrolled despite drug therapy, is effective but burdensome, requiring frequent procedures and vascular access, and is limited to a few specialized centres. Additional lipid-lowering therapies may be used. Alirocumab does not have a Health Canada indication but can be effective in patients with HoFH and residual LDL receptor activity. Evinacumab, lomitapide, and mipomersen are potent lipid-lowering therapies specifically indicated for the treatment of HoFH, but their use may be limited by variable efficacy (i.e., mutation-dependent), safety concerns, high cost, and restricted availability. In clinical practice, maximally tolerated doses of statins, ezetimibe, and proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor are considered components of standard medical therapy for HoFH.

What Is the Treatment Under Review?

Evolocumab is a PCSK9 inhibitor that is administered by subcutaneous injection. Health Canada has approved evolocumab, 140 mg in 1.0 mL (140 mg/mL) and 420 mg in 3.5 mL (120 mg/mL), solution for subcutaneous injection, as an adjunct to diet and other LDL-C-lowering therapies (e.g., statins, ezetimibe) in patients aged 10 years and older with HoFH who require additional LDL-C lowering. The Health Canada indication aligns with the request for the reimbursement review of evolocumab in adult and pediatric patients aged 10 years and older with HoFH who require additional lowering of LDL-C (i.e., in addition to diet and other LDL-lowering therapies, such as statins, ezetimibe, or LDL apheresis).

Why Did We Conduct This Review?

At the request of the Formulary Working Group, Canada's Drug Agency (CDA-AMC) reviewed the available evidence for evolocumab to inform a recommendation on whether it should be reimbursed for the treatment of adult and pediatric patients aged 10 years and older with HoFH who require additional lowering of LDL-C. Public drug programs identified an unmet need for a reimbursement recommendation for evolocumab because there is no public funding in place for PCSK9 inhibitors. The data protection for evolocumab expired in 2024, so this drug is eligible for a nonsponsored reimbursement review as per the [Procedures for Reimbursement Reviews](#).

Summary of Input From Interested Parties

- We did not receive input from patient groups.
- One clinician group, **Canadian Cardiovascular Society**, indicated that the goals of treatment for patients with HoFH are to prolong life, delay atherosclerotic cardiovascular disease and early cardiovascular events, and reduce invasive procedures.
- **Amgen Canada Inc.**, a manufacturer of evolocumab, provided input on the population, appropriate active comparators, outcomes, relevant published studies, severe unmet need, heterogeneity of response to treatment in HoFH, system impact, and economic considerations.
- **Public drug plans** inquired about the evidence for evolocumab to inform a recommendation on whether it should be reimbursed for the treatment of adult and pediatric patients aged 10 years and older with HoFH who require additional lowering of LDL-C. The public drug plans outlined implementation questions related to considerations for the initiation of therapy and continuation or renewal of therapy.

► Refer to the Main Report and the Supplemental Material document for [this review](#).



Person With Lived Experience

A person with lived experience from Ontario living with HoFH shared her 14-year treatment journey with FMEC. She first stressed that the treatment journey for HoFH is variable across individuals and that her experience is just one of many, noting her presentation was not as severe as other patients. She shared that she was diagnosed with HoFH at the age of 13 years after presenting with xanthoma on her knee and LDL-C of approximately 17 mmol/L. Her age of diagnosis is considered late for this condition. Despite the late diagnosis, she did not present with any obvious cardiac manifestation at the time of diagnosis, although she has been diagnosed with supra-aortic stenosis. Each step in her treatment journey reflected escalation due to inadequate LDL-C control. Her first line of therapy consisted of statins, which was later escalated and combined with ezetimibe. There was minimal LDL-C reduction with the escalated therapy due to underlying biology; namely, the lack of functional LDL-C receptors. Despite a minimal response to combination statin and ezetimibe therapy, she continued these therapies for potential long-term cardiovascular protection. She described her experience with transitioning to specialized care and new therapies. She was provided with an early referral to an adult lipidologist at the Ottawa Heart Institute. She was initially treated with PCSK9 inhibitor therapy. She noted that the biweekly injections were easy to administer, well tolerated, and provided modest LDL-C reduction (approximately 9 mmol/L to 10 mmol/L). However, treatment was eventually discontinued due to insufficient clinical benefits. In 2019, she was started on apheresis due to inadequate control and disease progression including aortic stenosis. The biweekly LDL-C apheresis sessions consisted of filtering blood via extracorporeal circuit and were 2 to 3 hours long. Immediately after treatment, her LDL-C would be reduced to approximately 5 mmol/L to 6 mmol/L. However, before the next session, her LDL-C levels rebounded to approximately 9 mmol/L to 10 mmol/L. She described how treatment with apheresis was both invasive and time-consuming, requiring time off school and work. She experienced more side effects while undergoing apheresis, notably hypotension during and after treatment sessions. She described how she preferred peripheral access over a central line, which impacted how she was able to access care across multiple centres. She described how she learned to advocate for herself across multiple care centres in order to receive apheresis through peripheral access instead of a central line. When she moved to a new city to pursue her education, she travelled 6 hours one-way to receive her treatment in her hometown until eventually the other hospital could perform it using peripheral access. Currently, her therapy has been advanced to taking evinacumab. She has been able to maintain optimal lipid control since starting treatment with evinacumab. The person with lived experience described that her treatment journey was quite smooth and perhaps unique due to the following supportive and contextual factors: strong family support, access to specialized centres and adaptive health care teams, access to compassionate funding, and private health care insurance. She managed the treatment burden by advocating to receive scheduling accommodations and preferred treatment administration and maintained good social functioning with minimal lifestyle disruption.

Disclaimer: The perspectives shared by people with lived experiences who present to the committee reflect their individual experiences and are not necessarily representative of all people with the same condition or course of treatment. Their insights provide valuable context about what a patient, support person, or caregiver might go through when facing this condition or treatment, helping to inform the committee's deliberations. These narratives complement other forms of evidence and input and should be considered as part of a broader understanding of the condition and treatment under review. When gender or gendered pronouns are used in these narratives, they are included with the permission of the individual.

Recommendation

With a vote of 9 to 0, FMEC recommends that evolocumab, for the treatment of adult and pediatric patients aged 10 years and older with HoFH who require additional lowering of LDL-C, be reimbursed if the conditions presented in [Table 1](#) are met.

Table 1: Conditions, Reasons, and Guidance

Reimbursement condition	Reason	Implementation guidance
Initiation		
1. Evolocumab may be initiated for the treatment of adult and pediatric patients aged 10 years and older with HoFH who require additional lowering of LDL-C.	The TESLA B trial enrolled patients older than 12 years; 10 of 49 (20%) were adolescents (aged 13 to 17 years) and 7 received evolocumab. The response to treatment in adolescents was consistent with that seen in the overall population. The pooled post hoc analysis by Raal et al. (2024) assessed clinical effectiveness and safety of evolocumab in pediatric patients aged 10 to 17 years. It reported supportive evidence on the use of evolocumab, with sustained LDL-C reductions and mostly mild adverse events over 4 years.	FMEC heard from the guest specialists that evolocumab is being used off label to treat patients with HoFH younger than 10 years in clinical practice in Canada.
Renewal		
2. Evolocumab should be renewed if all of the following conditions are met: 2.1. an assessment of response at 12 weeks after initiation 2.2. a clinically relevant reduction in LDL-C.	Responsiveness to evolocumab may be influenced by the underlying <i>LDLR</i> mutation status because the efficacy of PCSK9 inhibition depends on the presence of functional LDL receptors.	FMEC heard from the guest specialists that 12 weeks is generally sufficient to assess response based on therapy, clinical trial data, and standard clinical practice.
Prescribing		
3. Prescribing should be limited to clinicians with expertise in the diagnosis and management of dyslipidemia.	This will ensure that treatment is prescribed for appropriate patients and adverse events are optimally managed.	Treatment initiation and guidance are often provided by specialists. Follow-up and routine monitoring can be undertaken by primary care clinicians, if they receive appropriate instructions from the treating specialist.

Reimbursement condition	Reason	Implementation guidance
Pricing		
4. Evolocumab should be priced no higher than the least costly comparator for this population.	FMEC concluded that reimbursement of evolocumab will be associated with lower drug acquisition costs than most relevant comparators based on publicly available list prices. Based on the available clinical evidence, the effectiveness of evolocumab against its relevant comparators is unknown. Evolocumab should be priced no higher than the least costly comparator for this population.	—

FMEC = Formulary Management Executive Committee; HoFH = homozygous familial hypercholesterolemia; LDL = low-density lipoprotein; LDL-C = low-density lipoprotein cholesterol; PSK9 = proprotein convertase subtilisin/kexin type 9.

Summary of Deliberation

FMEC deliberated on all domains of value of the deliberative framework before developing its recommendation: clinical value, unmet clinical need, distinct social and ethical considerations, economic considerations, and impacts on health systems. For further information on the domains of value, please refer to the [Expert Committee Deliberation at Canada's Drug Agency](#) document.

FMEC considered the following key discussion points, organized by the 5 domains of value.



Clinical Value

- **FMEC concluded that evolocumab demonstrates acceptable clinical value versus appropriate comparators in Canada.**
- Through reflection on the insights shared by the person with lived experience and the patient lead on the committee, FMEC members noted that patients value less invasive treatments that achieve clinically meaningful improvements in LDL-C levels and daily functioning while minimizing adverse events, the need for hospitalization, and disruptions to quality of life.
- **FMEC** members highlighted the following discussion points:
 - **Appropriate comparators.** The committee agreed that evinacumab and lomitapide as comparators in the assessment of evolocumab in HoFH are aligned with both the Canadian Cardiovascular Society Dyslipidemia Guidelines and the European Society of Cardiology / European Atherosclerosis Guidelines for the Management of Dyslipidemias. The 2 comparators align with current practice and the approach to dyslipidemia management in Canada.
 - **Outcomes assessed.** Ultimately, patients with HoFH seek to reduce the risk of cardiovascular events while minimizing the adverse effects associated with drug therapy.
 - As lipid-lowering therapies are preventive in nature, their efficacy is primarily assessed through reductions in LDL-C and other lipid parameters. Clinicians and patients with cholesterol disorders

commonly use LDL-C as a surrogate marker of treatment efficacy and a strong predictor of cardiovascular outcomes. A 2018 meta-analysis conducted by the Cholesterol Treatment Trialists Collaboration demonstrated that each 1 mmol/L reduction in LDL-C was associated with an approximately 20% to 22% reduction in major cardiovascular events. However, these findings were derived from populations with baseline LDL-C levels averaging 1.8 mmol/L (70 mg/dL) or lower and may not be directly generalizable to patients with HoFH.

- **Efficacy of evolocumab.** PCSK9 inhibitors have demonstrated substantial reductions in LDL-C levels in patients with HoFH, with treatment effects that are comparable to or greater than those typically observed with statin therapy in this population.
- **Harms of evolocumab.** PCSK9 inhibitors are generally associated with an acceptable safety profile and have been shown to cause fewer adverse effects than statins. The most frequently reported adverse events are injection-site reactions, including redness, swelling, and pain. Hypersensitivity reactions have been reported but are rare.
- **Level of certainty in clinical value.** The committee agreed that there is an acceptable level of certainty in clinical value.
- FMEC heard from the guest specialists that, although there are no clinical trial data in HoFH demonstrating cardiovascular event reduction, it is plausible that meaningful LDL-C lowering with pharmacologic therapy will translate into reduced cardiovascular risk over time, given the highly atherogenic nature of the disease and the early onset of cardiovascular complications.
- FMEC heard from the guest specialists that the typical treatment approach for HoFH involves initiating therapy with statins and ezetimibe, followed by assessment of treatment response after approximately 6 to 8 weeks. If LDL-C levels remain inadequately controlled, doses are escalated and arrangements made for PCSK9 inhibitors, which involves paperwork and approval, coordination of medication access, and patient education regarding self-administration by injection. If evolocumab were available, clinicians would consider immediate initiation of triple therapy (statin plus ezetimibe plus evolocumab) only in patients with manifestations of severe cardiovascular disease, but not routinely otherwise.



Unmet Clinical Need

- **FMEC concluded that there is a significant clinical need arising from HoFH despite available treatments.**
- Through reflection on the insights shared by the person with lived experience and the patient lead on the committee, FMEC members noted that:
 - HoFH is typically treated using a stepwise approach, starting with statins and then adding ezetimibe. However, standard therapy may not result in sufficient reduction in LDL-C levels.
 - Patients with HoFH who have little to no residual LDL receptor activity may derive limited benefit from therapies whose mechanism of action relies on functional LDL receptors. Therefore, additional treatment options are necessary.

- Nonpharmacological interventions, including dietary modifications and lifestyle changes, are recommended but have limited impact on LDL-C levels. They may also impose a substantial burden on patients and can be challenging to maintain over the long term.
- **FMEC** members highlighted the following discussion points:
 - **Availability of treatment options.** Although alternative agents can safely and effectively reduce LDL-C, the magnitude of LDL-C reduction required in HoFH is considerable and is typically not achievable with standard therapy consisting of maximally tolerated statins plus ezetimibe. Consequently, most patients require additional lipid-lowering agents beyond dual therapy and, in many cases, lipid aphaeresis is needed.
 - **Severity of the disease.** HoFH is a rare and serious condition associated with markedly elevated LDL-C levels and a high risk of premature cardiovascular disease. Individuals who are affected commonly experience significant early-onset morbidity and increased premature mortality.
 - **Significant unmet clinical need.** The committee recognized that patients and caregivers value effective therapies that provide consistent reductions in LDL-C and demonstrate cardiovascular benefit with fewer significant adverse effects.
 - FMEC felt that evolocumab addresses the key unmet clinical needs in HoFH, having demonstrated significant reductions in LDL-C with an acceptable harms profile in the studied patient populations.
 - **Evidence generation.** The committee acknowledged that evidence generation is challenging given the rarity of the condition, particularly in the pediatric population, which is typically identified through cascade screening.
 - FMEC heard from the guest specialist that the underlying genetic defect in HoFH results in severely elevated LDL-C levels from birth, leading to cumulative LDL-C exposure and progressive cardiovascular risk over time. Consequently, management focuses on identifying the optimal combination of lipid-lowering therapies that can achieve meaningful LDL-C reductions and complement more intensive interventions, such as lipid apheresis. Although treatment intensification is ideally initiated before complications develop, patients who experience worsening cardiovascular risk — such as the development of severe aortic valve stenosis or other manifestations of atherosclerotic cardiovascular disease — often require a renewed emphasis on LDL-C lowering, including the addition of more intensive therapies. Another guest specialist shared that most patients will inevitably require apheresis, even those receiving triple therapy.
 - FMEC heard from the drug plan lead that, of the 2 PCSK9 inhibitors (evinacumab and evolocumab) marketed in Canada, evolocumab is the only drug with a Health Canada indication for the treatment of HoFH that includes pediatric patients aged 10 years and older. FMEC noted that recent European guidance emphasizes early diagnosis and initiation of lipid-lowering therapy in children with HoFH, often younger than 10 years, and as soon as possible after diagnosis. The guest specialists confirmed that aggressive management (including a trial of evolocumab) of HoFH in patients younger than 10 years is undertaken on a case-by-case basis.

- The committee heard from the guest specialists that liver transplantation may be considered in rare cases of severe HoFH, but it is not a cure and generally considered a last-resort intervention rather than standard therapy. Further, it was highlighted that gene therapy is currently under development for this condition.



Distinct Social and Ethical Considerations

- **FMEC concluded that evolocumab would potentially address a significant nonclinical need arising from HoFH despite available treatments.**
- **FMEC did not identify any important measures that should be implemented to ensure that the use of evolocumab addresses relevant social and ethical implications.**
- Through reflection on the insights shared by the person with lived experience during the meeting testimony and from the patient lead on the committee, FMEC members noted that:
 - PCSK9 inhibitors were considered relatively easy to manage; evolocumab was administered by subcutaneous injections of 420 mg once monthly (and then titrated to 420 mg every 2 weeks if a clinically meaningful response is not achieved after 12 weeks). However, apheresis was associated with a substantially greater treatment burden due to its invasive nature, side effects, time requirements (e.g., 2 to 3 hours in hospital, time away from school or work to attend specialized clinics), and availability in limited sites.
 - HoFH can lead to the development of tendon and cutaneous xanthomas, as well as xanthelasma around the eyes. These cholesterol deposits may cause physical discomfort and serve as visible manifestations of the disease, potentially contributing to social stigma.
 - Parents and caregivers emphasized the importance of early screening and timely diagnosis of HoFH in children.
- **FMEC** members highlighted the following discussion points:
- **Unmet nonclinical needs.** Before the availability of PCSK9 inhibitors, lipid apheresis was often considered a next-line option following maximally tolerated statins and ezetimibe. However, access to apheresis is limited, it requires repeated procedures, and it is commonly administered in acute care settings. In contrast, more readily accessible therapies that can be self-administered at home offer important advantages in convenience and care delivery.
- **Social and ethical considerations.** The committee agreed that providing education and supporting treatment initiation at an early age may require assistance from caregivers or health care professionals. However, evolocumab is easy to administer, and patients can be trained by health care professionals or caregivers to self-inject. Multiple training resources are also available to support appropriate use.



Economic Considerations

- **FMEC concluded that there are economic considerations that are important to address when implementing evolocumab**
- **FMEC** members highlighted the following discussion points:
 - Reimbursement of evolocumab will be associated with lower drug acquisition costs than most relevant comparators based on publicly available list prices.
 - The effectiveness of evolocumab against its relevant comparators is unknown.
 - According to the clinical experts, there might be some cost advantage to subcutaneous administration compared to IV (at publicly available list prices), and some disadvantage compared to oral drugs.
 - Evolocumab should be priced no higher than the least costly comparator for this population.



Impacts on Health Systems

- **FMEC did not identify any impacts on health systems that are important to address when implementing evolocumab.**
- **FMEC** members highlighted the following discussion points:
 - **Impacts on health systems.** The committee agreed there was no impact on health systems.
 - **Considerations for health system sustainability.** FMEC agreed that, given the rarity of the condition, it was unlikely that implementing evolocumab would meaningfully alleviate broader health system sustainability challenges.
 - **Equity implementation.** The committee agreed that there were no factors to be addressed to support equitable implementation because evolocumab is easily available through multiple avenues.
 - **Testing procedure considerations.** The committee considered that genetic confirmation of HoFH before initiation of evolocumab would not be required. Therefore, it was not anticipated to be an implementation or access barrier.
 - FMEC heard from the guest specialist that the goal of treatment for HoFH is to reduce LDL levels across the lifespan to prevent cardiovascular disease events. Therefore, the need for lipid apheresis is dependent on age, LDL responsiveness or responsiveness to treatment, risk profile, and baseline LDL levels. Need for lipid apheresis is not solely binary (i.e., need or do not need), but includes the frequency. For patients with response to treatment, the addition of more intensive lipid-lowering therapies, such as PCSK9 inhibitors, may either improve LDL levels before and after apheresis or may decrease the need or frequency of lipid apheresis.
 - FMEC heard from the drug plan lead that access to LDL apheresis is very limited. According to the guest specialist, LDL apheresis requires additional expertise and experience. Therefore, there is a significant inequity for patients who have HoFH.

Sources of Information Used by the Committee

To make its recommendation, the committee considered the following information (links to the full documents for the review can be found on the [project web page](#)):

- the CDA-AMC review of the clinical and pharmacoeconomic evidence related to evolocumab (refer to the Main Report and the Supplemental Material document)
- patients' perspectives gathered by 1 clinician group, Canadian Cardiovascular Society (refer to the Patient and Clinician Group Input document)
- industries' perspectives gathered by 1 industry group, Amgen Canada Inc. (refer to the Industry Group input)
- input from a person with lived experience who delivered a brief presentation and answered questions from the committee (refer to the Person with Lived Experience section earlier in this document)
- input from 1 clinician group, the Canadian Cardiovascular Society (refer to the Patient and Clinician Group Input document)
- input from public drug programs that participate in the reimbursement review process (refer to the FMEC Responses to Questions From the Drug Program document)
- input from 3 guest specialists with expertise in the management of HoFH consulted by CDA-AMC.

Feedback on Draft Recommendation

CDA-AMC received feedback from 1 industry group (Amgen Canada Inc.) and the public drug programs. Both groups agreed with the recommendation. The public drug plan programs had no requested revisions. The feedback from Amgen Canada Inc. was reviewed and editorial revisions were made.

Amgen Canada Inc. disagreed with the inclusion of alirocumab as a comparator within the clinical and pharmacoeconomic review for HoFH and highlighted that alirocumab is currently not indicated for HoFH by Health Canada. Although the clinical experts engaged in this review and FMEC noted that alirocumab is part of recommended treatment for HoFH in European clinical practice guidelines, public drug plans acknowledged it is not currently reimbursed for this indication.

Amgen Canada Inc. also noted that the dosage of evolocumab for HoFH in the product monograph is 420 mg once monthly and can be uptitrated to 420 mg once every 2 weeks. The conclusions in the Reimbursement Review report, the economic considerations in the reimbursement consideration, and the pricing conditions remain the same regardless of the dosage of evolocumab used in the cost comparison.

All feedback received in response to the draft recommendation is available on the CDA-AMC [project web page](#).

FMEC Information

Members of the Committee

Dr. Emily Reynen (Chair), Dr. Zaina Albalawi, Ms. Marilyn Barrett, Dr. Hardit Khuman, Ms. Valerie McDonald, Dr. Bill Semchuk, Dr. Jim Silvius, Dr. Marianne Taylor, Dr. Maureen Trudeau, Dr. Dominika Wranik. Three guest specialists from Ontario and the Prairies participated in this review.

Meeting date: June 5, 2026

Conflicts of interest: None

Special thanks: CDA-AMC extends special thanks to Zobaida Al-Baldawi who presented directly to FMEC and to patient organizations representing and supporting the community of people living with HoFH.

Note: CDA-AMC makes every attempt to engage with people with lived experiences as closely to the indication and treatments under review as possible; however, at times, CDA-AMC is unable to do so and instead engages with individuals with similar treatment journeys or experience with comparators under review to ensure lived experience perspectives are included and considered in Reimbursement Reviews. CDA-AMC is fortunate to be able to engage with individuals who are willing to share their treatment journeys with FMEC.



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