

CADTH COMMON DRUG REVIEW

Patient Group Input Submissions

EVOLOCUMAB (Repatha)

(Amgen Canada Inc.)

Indication: As an adjunct to diet and maximally tolerated statin therapy in adult patients with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein cholesterol (LDL-C)

evolocumab (Repatha) indicated as an adjunct to diet and maximally tolerated statin therapy in adult patients with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (CVD), who require additional lowering of low density lipoprotein cholesterol (LDL-C). Indicated as an adjunct to diet and other LDL-lowering therapies (eg, statins, ezetimibe, LDL apheresis) in adult patients and adolescent patients aged 12 years and over with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C.

Patient group input submissions were received from the following patient groups. Those with permission to post are included in this document.

Cardiac Health Foundation of Canada — permission granted to post.

CADTH received patient group input for this review on or before March 13, 2017

CADTH posts all patient input submissions to the Common Drug Review received on or after February 1, 2014 for which permission has been given by the submitter.

The views expressed in each submission are those of the submitting organization or individual; not necessarily the views of CADTH or of other organizations. While CADTH formats the patient input submissions for posting, it does not edit the content of the submissions.

CADTH does use reasonable care to prevent disclosure of personal information in posted material; however, it is ultimately the submitter's responsibility to ensure no personal information is included in the submission. The name of the submitting patient group and all conflict of interest information are included in the posted patient group submission; however, the name of the author, including the name of an individual patient or caregiver submitting the patient input, are not posted.

Cardiac Health Foundation of Canada

General Information

Name of the drug CADTH is reviewing and indication(s) of interest	Repatha (evolocumab) for primary hyperlipidemia and mixed dyslipidemia
Name of the patient group	Cardiac Health Foundation of Canada
Name of the primary contact for this submission:	[REDACTED]
Position or title with patient group	[REDACTED]
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Website	www.cardiachealth.ca
Permission is granted to post this submission	Yes

Submitting Organization

The Cardiac Health Foundation of Canada is celebrating its 52nd anniversary. Our initial focus involved helping to fund cardiac rehabilitation programs in Toronto and ultimately across the nation. Since its inception in 1965, the Cardiac Health Foundation of Canada has raised more than \$13 million nationally for facilities, scholarships and research, patient and public awareness, professional education and medical equipment. The Cardiac Health Foundation of Canada has a Board of Directors and a Medical Advisory Committee of physicians from across the country. The Cardiac Health Foundation of Canada expanded its mission to include prevention, education and recovery from cardiovascular disease and atherosclerosis. The mission of the Cardiac Health Foundation of Canada is listed as follows: "Prevention, Education & Cardiovascular Rehabilitation; To promote and develop cardiac rehabilitation services including undertaking public education, primary and secondary prevention initiatives in reducing cardiovascular disease in Canada and in promoting active recovery from such disease" Our organizational Objectives include: To raise funds for cardiovascular rehabilitation programs and expansion of these services across Canada ;To undertake public education activities and resources aimed at Prevention & Management of cardiovascular disease in Canada; To fund and promote applied research on cardiovascular rehabilitation and management of cardiovascular disease in Canada; To engage in advocacy services in promoting access to and awareness of medications, treatment services and programs for those affected by cardiovascular disease in Canada. Cardiac Health Foundation of Canada members include national and local corporate sponsors and individual donors who support the organization directly or through its major event, the WALK OF LIFE. The National WALK OF LIFE Campaign involves over 7,000 participants across the country, supporting and giving grants to 30 centers and collectively raising over \$ 1 million annually for cardiac rehab, education and prevention of cardiovascular disease. The GTA WALK OF LIFE alone raises over \$520,000 and has over 2,000 active participants.

Conflict of Interest Declarations

We have the following declaration(s) of conflict of interest in respect of corporate members and joint working, sponsorship, or funding arrangements:

Cardiac Health Foundation of Canada receives corporate sponsorships from a number of companies including from the pharmaceutical sector and health care organizations. Aspirin (Bayer) is a national sponsor, and Self Care Catalysts and Amgen are local sponsors of the Walk of Life. Boehringer Ingelheim and Lily Canada Diabetes Alliance is also a sponsor of our Healthy Hearts Chef Challenge in honour of Heart Month. Amgen has provided annual funding to support the work that Cardiac Health Foundation of Canada does to further educate stakeholders about the patient experience and needs in cardiovascular disease management.

We have the following declaration(s) of conflict of interest in respect of those playing a significant role in compiling this submission:

None to declare

Condition and Current Therapy Information

Information Gathering

Information was gathered through a national online survey emailed to patients and/or their caregivers, and posted on the Cardiac Health Foundation of Canada website from February 24 to March 8, 2017. The survey link was also provided to 26 cardiac rehabilitation programs to provide to their patients. The survey was targeted to patients living with atherosclerosis, and their caregivers. We also approached the CRNO who although willing to reach out to their patients indicated there simply was not enough time to complete the surveys. There were a total of 55 respondents to the online survey, with two responses from patients who have experience with Repatha.

Additionally, one patient who has experience with Repatha participated in a one-to-one telephone interview on March 8, 2017.

Impact of Condition on Patients

Patients and caregivers noted a number of physical issues about living with atherosclerosis. Of the 40 (of 55) patients who described the impact of their condition:

- 78 per cent experience fatigue and tiredness
- 40 per cent said shortness of breath is a common aspect of living with their illness
- 38 per cent said they experience dizziness or light-headedness
- Other common symptoms included chest pain or pressure (angina); pins and needles in arms and legs; numbness or weakness in arms or legs; and pain in leg or arm, or anywhere that has a blocked artery.

Fatigue is a major concern for most patients to control, as is controlling the progression of their disease. One patient noted that *“my fatigue is disproportionate to the amount of limited activity I can do.”*

Twenty-three patients (23) had experienced a heart attack and 18 indicated they had been treated for angina (chest pain). The anxiety about having a heart attack or stroke, or a recurrence for those who had one, was cited by 34 respondents as affecting their quality of life. Thirty (30) patients said they are fearful and worried about their deteriorating health. Depression was also noted by close to a third of patients. Close to half of patients expressed concern about the impact of their illness on their family, spouse or partner.

Patients' Experiences With Current Therapy

Patients were asked about their experience with several current treatments. They were asked to select all treatments they had received since their diagnosis. Sixty (60) per cent had been prescribed Crestor (rosuvastatin) and 40 per cent Lipitor (atorvastatin).

Five patients received Ezeterol (ezetimibe). Fifty-four (54) per cent of patients had bypass surgery. Of the patients who had experience with Crestor (n=30 who provided answers), 18 patients found it very effective, nine somewhat effective, one not very effective, and two not effective at all. Of the patients who had experience with Lipitor (n= 20 who provided answers), 10 found it very effective, seven somewhat effective, one not very effective, and two not effective at all. Of the patients who had bypass surgery (n=24), close to fifty-four (54) per cent found the surgery to be very effective in controlling their symptoms.

The most common side effect noted by 16 (of 25) patients was sore muscles, cramping or weakness. Twenty-three (23) of 25 patients noted they experienced digestive symptoms such as gas, constipation and upset stomach with current treatments. The most difficult to tolerate symptoms from current medications include muscle pain and discomfort, and muscle weakness. Patient comments included, *"I had to stop the medication as the pain had spread from my chest to my shoulders and legs. This got so bad it was interfering with walking, and at the time was the only exercise I could do."* Another patient said, *"I still get severe foot cramping at night."*

Seven patients noted that they had unmet needs with current treatments because they could not take statins, and three said they have too many side effects on current treatments. Other comments included not being able to achieve their optimum cholesterol targets on statins.

Impact on Caregivers

Twenty-one (21) patients and caregivers provided comments about the challenges faced in caring for someone with atherosclerosis. These included:

- Their spouse having to take on more physically demanding daily tasks that the patient could no longer do as a result of fatigue.
- Managing the fatigue and limiting getting things done or not being able to do the things that they previously enjoyed.
- Many patients and caregivers commented that they both had to adjust to a new lifestyle of diet and exercise.

One patient said, *"I am the patient. My husband goes with me to every doctor appointment and he would listen to the cardiologist. His worry never stops."* Another said that taking daily medications is a constant worry as are the side effects on high doses without controlling the progression of the disease.

Information about the Drug Being Reviewed

Information Gathering

The information for Section 3 was obtained from the online survey posted by the Cardiac Health Foundation of Canada., as noted above in the Information Gathering on page 4. This section also includes feedback from a one-to-one telephone interview with one patient whose name was provided to the Cardiac Health Foundation of Canada by their physician.

What Are the Expectations for the New Drug or What Experiences Have Patients Had With the New Drug?

- Most patients (53) who completed the survey did not have experience with Repatha. Their overarching expectation of this drug would be to lower their cholesterol with minimal side effects, predominantly not to experience the loss of muscle function or muscle weakness experienced with statins. The loss of muscle function is a side effect that most patients are not willing to tolerate. One patient commented about what they have heard about Repatha, *"I know that other [patients] need this drug and clinical trials have shown incredible results."* Another patient worried about not having private insurance to cover the cost of the new medication, and what other medications would need to be taken with Repatha.

- There were two patients from the survey and one telephone interview with a patient and their caregiver who had experience with Repatha. Two of the three found Repatha very effective in lowering their cholesterol and that they had more energy with limited to no side effects. The other patient found Repatha not very effective, mentioning that they had lowering of their cholesterol but the side effect of sore arms. One patient, on Repatha for close to one year, said he had a runny nose but was not sure if it was from Repatha or having a slight cold. He said, *“I will take the runny nose to have my cholesterol at target.”*
- None of the patients commented about any issues with an injection versus another pill. In fact, one patient said, *“It’s nice not to have another pill to count and put in my pill box.”* One patient commented that being on a fixed income made it difficult to pay for Repatha, however they were managing to find the funds to pay for the drug, and would continue to do so because of the benefits it was providing.