

Patient Input Template for CADTH Reimbursement Reviews

Name of Drug: finerenone

Indication: Adult patients with chronic kidney disease and type 2 diabetes

Name of Patient Groups: The Kidney Foundation of Canada, Diabetes Canada

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1. About Your Patient Groups

Kidney Foundation of Canada:

Over nearly six decades, the Kidney Foundation of Canada has been guided by the fundamental principles of innovation, leadership, and collaboration, and has been committed to excellent kidney health, optimal quality of life for those affected by kidney disease, and a cure.

The Kidney Foundation of Canada is the leading charity committed to eliminating the burden of kidney disease through:

- Funding and stimulating innovative research for better prevention, treatments and a cure;
- Providing education and support to prevent kidney disease in those at risk and empower those with kidney disease to optimize their health status;
- Advocating for improved access to high quality health care;
- Increasing public awareness and commitment to advancing kidney health and organ donation.

For more information, please visit kidney.ca.

Diabetes Canada:

Diabetes Canada is a national health charity representing millions of Canadians affected by diabetes. Diabetes Canada leads the fight against diabetes by helping people live healthy lives, preventing the onset and consequences of diabetes, and discovering a cure. It has a heritage of excellence and leadership, and its co-founder, Dr. Charles Best, along with Dr. Frederick Banting, is credited with the co-discovery of insulin. Diabetes Canada is supported in its efforts by a community-based network of volunteers, employees, health care professionals, researchers, and partners. By providing education and services, advocating on behalf of people living with diabetes, supporting research and translating it into practical applications, Diabetes Canada is delivering on its mission. Diabetes Canada will continue to change the world for those affected by diabetes through healthier communities, exceptional care, and high-impact research.

A world free of the effects of diabetes is our vision. That's why we're working together to

improve the quality of life of people living with diabetes. We're sharing knowledge and creating connections for individuals and the health professionals who care for them; advocating through public policy; and funding research to improve treatments and find a cure to end diabetes.

For more information, please visit: diabetes.ca.

2. Information Gathering

Patient input was collected in May 2022 by the Kidney Foundation of Canada in both official languages via a self-administered questionnaire to people across Canada. The survey was directed at people living with chronic kidney disease and type 2 diabetes and their caregivers and inquired about respondents' lived experience with chronic kidney disease and medications and expectations for new drug therapies in Canada. The survey posed a number of questions specifically about the drug under review, finerenone. Awareness about the surveys was generated through the Kidney Foundation's social media channels (Twitter and Facebook), as well as the website and e-newsletter. A link to the survey was also shared via Diabetes Canada's social media channels (Twitter and Facebook), as well as via an online portal for health-care providers in Diabetes Canada's Professional Section.

A total of 24 people responded to the survey with 9 completed and 15 partially completed surveys. Of the 8 people who responded to the questions about their current age or the current age of the person they care for, 2 were between the ages of 40 and 54, 2 were 55 to 69 years old, and 4 were over 70 years old.

8 respondents identified as being a person living with chronic kidney disease and 1 identified as being a caregiver for a person with chronic kidney disease. 8 respondents answered the questions about how long they had lived with kidney disease. 2 respondents reported living with chronic kidney disease for 1 to 2 years, 2 for 3 to 5 years, 1 for 6 to 10 years, 2 for 11 to 20 years and 1 respondent reported more than 20 years living with the disease.

10 respondents answered the question about whether they live with diabetes. Of those, 6 identified as people living with type 2 diabetes, and 4 reported that they do not have diabetes. 6 respondents answered the questions about how long they had lived with type 2 diabetes. 1 respondent reported living with type 2 diabetes for 1 to 2 years, 1 for 11 to 20 years and 4 respondents reported more than 20 years living with the disease.

3. Disease Experience

Kidney disease describes a variety of disease and disorders that affect the kidneys. Most diseases of the kidney attack the nephrons and damage their ability to eliminate wastes and excess fluids. Diseases of the kidney are a common finding in people with diabetes, with up to one-half demonstrating signs of renal damage in their lifetime. Diabetes is the leading cause of kidney failure, and people living with kidney disease often experience additional medical conditions such as high blood pressure and heart disease.

Chronic kidney disease (CKD) is the presence of kidney damage, or a decreased level of kidney function, for a period of three months or more. Kidney disease can range from mild to severe and in some cases, lead to kidney failure (sometimes referred to as end-stage kidney disease, or ESKD). There are usually no specific symptoms of kidney disease until the damage is severe. When the kidneys fail, wastes accumulate in the body and dialysis treatments or a kidney transplant are needed to survive.

Dialysis is the most common treatment for kidney failure, with kidney transplant being another option. There are two types of dialysis: peritoneal dialysis and hemodialysis. Canadians with kidney failure and their families face significant out-of-pocket costs. This burden is further compounded by the loss of income that is often associated with starting dialysis. It is important to note that poverty is a determinant of health. This means that patients and their families that live in poverty may not be able to achieve optimal management of their medical issues.

In the early stages of chronic kidney disease, self-management strategies such as lifestyle changes; engaging in regular physical activity, maintaining a healthy body weight, stopping smoking and reducing sodium, managing other medical conditions and medications may slow or stop damage to the kidneys.

Normally, healthy kidneys balance the body's minerals, however if the kidneys are not working well, potassium, sodium, calcium, and phosphate levels can be too high or too low. Depending on the stage of chronic kidney disease, a restricted diet and/or medications may be necessary. For example, some people in the early stages of CKD do not need to limit their potassium intake, while others may need to restrict it via dietary restrictions. People on dialysis usually need to limit potassium intake to avoid hyperkalemia between treatments. This diet is highly restrictive and negatively impacts quality of life for patients with CKD.

Most survey respondents reported that chronic kidney disease has had a negative effect on their daily life, especially with regard to fatigue. One respondent said "I'm constantly fatigued, find it extremely hard to balance work and family life", while another said "I've had to leave my job at 55, fatigued, hard on myself for not having energy to do stuff, think I'm just being lazy." Two respondents reported trouble sleeping, with one saying that they "have to take meds to sleep, don't get to sleep

through the night.” Swelling, itching and dry skin were also mentioned, as were the limitations of the dietary restrictions associated with the disease. Two respondents talked about the difficulty of eating at restaurants or friends’ houses, with one stating: “Very rarely eat out as difficult to choose foods that follow the diet.”

Most survey respondents who participated in the survey spoke negatively of their experience living with both CKD and diabetes. Respondents talked about the challenges of fatigue and anemia. They said “sometimes if my blood sugars are high this brings fatigue along with fatigue from CKD”. Many also said that their diet is a constant challenge, and two mentioned the high cost of healthy foods specifically. “It is a constant challenge trying to keep my glucose levels at a reasonable level due to a lack of funds needed to buy fresh meats, veggies and fruit.” One person said that a “low carb, low Na [sodium] and low fat [diet] can be difficult when you’re cooking for others as well as yourself”. Another said “It appears as if one chronic disease diet does not correlate (sic) with the other very well. Especially in the foods I enjoy”.

Many people dealing with CKD have a number of other conditions. 7 respondents reported having or having had high blood pressure, 3 reported high cholesterol, and 1 said their potassium levels have been high. 5 reported that their chronic kidney disease is worsening, one person reported heart disease, and 1 reported having had a heart attack. One respondent said “I have been very tired and unable to focus on certain tasks as a result of my multiple conditions”.

4. Experiences With Currently Available Treatments

Of the 10 respondents to a question about whether they’ve ever taken medication to reduce the risk of worsening kidney disease, 6 said that they had, and 4 said that they had not. 3 take or have taken angiotensin-converting enzyme (ACE) inhibitors, 2 reported taking angiotensin-receptor blockers (ARBs), and other medications mentioned including diuretics, tacrolimus, erythropoietin, and dapagliflozin.

6 people responded to a question about how satisfied they are with their current medication/blend of medications, and of those 3 reported being satisfied, 1 very satisfied, and 2 neither satisfied nor unsatisfied. One respondent said that “Tacrolimus causes nausea, heartburn and flushing for me,” and others said “My kidneys have got better” and “It keeps my numbers within range.” One person reported that their medication “helps maintain the itch and burning feeling in the feet and legs with the excess fluid.”

5. Improved Outcomes

When asked about their expectations for CKD therapies, respondents rated these questions as most important: “Does it make me tired? Does it interfere with my other medications? How much does it

cost?” Respondents mentioned that side effects were important and said that it was important that kidney disease medication “preserves my one remaining kidney,” and that it delays dialysis.

Respondents’ hopes for new therapies for CKD or for CKD and diabetes together are “limiting or arresting the progression of both diseases”, “make kidneys better,” “a longer life span,” and “maintain and improve quality of life overall.”

6. Experience With Drug Under Review

This drug is not available in Canada and therefore patients and caregivers have no experience with the medication.

7. Companion Diagnostic Test

Not applicable to this submission.

8. Anything Else?

Living with chronic kidney disease can involve not only health and quality of life challenges, but significant financial challenges as well. People may experience a decrease in income if they limit their working hours due to their symptoms, and out-of-pocket costs increase as they change their diet and follow up more often with their health care team. Those living with kidney disease also tend to be part of a low income and high cost population, and government coverage and financial support varies across jurisdictions, which can lead to inequities. For more on the financial burden of kidney disease, visit <https://kidney.ca/Get-Involved/Be-Their-Voice/Financial-Burden-of-Kidney-Disease>.

Should chronic kidney disease progress to kidney failure, hemodialysis is the most common treatment. The cost of hemodialysis to the health care system per person per year ranges from \$56,000 to \$107,000, so the savings to the system associated with slowing the progression of kidney disease are significant. Hospitalization and treatment of cardiac events in patients with chronic kidney disease also represent a significant cost to the health care system.

Canadians living with both chronic kidney disease and type 2 diabetes often experience additional health and financial challenges. Medication, equipment, devices, and supplies required to treat diabetes can cost people thousands of dollars annually. A 2011 Statistics Canada survey showed that 32 percent of people with diabetes take three to four medications, 40 percent take five to nine medications and 12 percent take 10 medications or more, as part of their treatment. In a Diabetes Canada survey from 2015, 25 percent of all people with diabetes indicated treatment adherence was affected by cost. Every day, diabetes costs the Canadian health-care system almost \$50 million to treat.

The combined financial burden of these illnesses means that many would benefit from effective, affordable treatments that they can access equitably and in a timely manner. As finerenone may slow the progression of kidney disease and reduce the risk of cardiac events, it should be available as an option for people living with CKD and type 2 diabetes.