

Patient Input for CADTH Reimbursement Review

Name of Drug: dapagliflozin

Indication: Adult patients with chronic kidney disease (CKD)

Name of Patient Groups: The Kidney Foundation of Canada

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1. About Your Patient Group

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.

2. Information Gathering

Patient input was collected in July and August 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 their caregivers and inquired about respondents' lived experience with chronic kidney disease and medications and expectations for new drug therapies in Canada. The survey also posed questions specifically about the drug under review, dapagliflozin. Awareness about the surveys was generated through the Kidney Foundation's social media channels (Twitter and Facebook), as well as the Kidney Foundation website.

A total of 36 people responded to the survey with 18 completed and 18 partially completed surveys. Of the 12 people who responded to the questions about their current age or the current age of the person they care for, 1 was between the age of 15 and 24, 2 were aged 25 to 39, 2 were between the ages of 40 and 54, 3 were 55 to 69 years old, and 3 were over 70 years old. One person preferred not to answer.

19 respondents identified as being a person living with chronic kidney disease and 2 identified as being a caregiver for a person with chronic kidney disease.

3. Disease Experience

Kidney disease describes a variety of diseases and disorders that affect the kidneys. Most diseases of the kidney attack the nephrons and damage their ability to eliminate wastes and excess fluids. High blood pressure is one of its leading causes, and kidney disease can often lead to additional medical conditions, including 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, can 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 engaging in regular physical activity, maintaining a healthy body weight, stopping smoking and reducing sodium, and managing other medical conditions and medications may slow or stop damage to the kidneys.

Most survey respondents reported that chronic kidney disease has had a significant effect on their quality of life. One person said *“CKD impacts every aspect of my life, physically, emotionally, financially. My quality of life is poor because of medication side effects.”*

38% of respondents indicated that they have had to give up or reduce their physical activity, including one person who said that they *“can barely exercise due to lower energy levels.”*

29% of the people surveyed reported that they’ve had to stop working or reduce their hours, including a caregiver who said they *“had to take a leave of absence from work to help my loved one with day to day chores.”*

Many of the survey participants also indicated that time family and friends was affected. One person said they are *“[...] unable to do fun things with family and friends due to frequent hospitalizations and depression.”* There were many reports of fatigue: *“[...] my kids are very young and I want to play with*

them but whenever I try to play with them I got tired in 15 minutes”, and “[...] my family has to adjust plans to make sure I have places to rest or can sit out with something to do.”

There was also frequent mention of insomnia, with one person saying that they are “*unable to sleep without multiple medications*” and another stating “*sleep is very difficult to get most nights.*” Other symptoms reported included itchiness, swelling, dizziness and nausea/vomiting.

In addition, many people dealing with CKD have a number of other conditions. Over 71% of respondents reported having or having had high blood pressure and 48% reported high cholesterol.

4. Experiences With Currently Available Treatments

Of the 20 respondents to a question about whether they’ve ever taken medication to reduce the risk of worsening kidney disease, 45% said that they had, and 35% said that they had not. 20% did not know. 33% of respondents to a question about specific medications said that they take or have taken angiotensin-converting enzyme (ACE) inhibitors, 44% reported taking angiotensin-receptor blockers (ARBs), and 22% said that they are taking flozins/SGLT2 inhibitors. Other medications included atorvastatin, bisoprolol, and mycophenolate, and there was also mention of the use of calcium, iron, and vitamin D.

9 people responded to a question about how satisfied they are with their current medication/blend of medications, and of those 1 reported being satisfied, 2 very satisfied, and 4 neither satisfied nor unsatisfied. 2 were unsatisfied. When asked about the challenges or difficulties they’ve experienced with their existing treatments, one respondent said “*ease of access,*” and another said that “*some medications are not covered under any drug private or OHIP.*” Others respondents reported that remembering to take medications and the number of medications are issues.

5. Improved Outcomes

When asked about their expectations for CKD therapies, respondents rated these questions as most important: Does it interfere with my other medications? “Does it affect my mood? How much does it cost?” “How long will I be on it?” Survey participants mentioned that side effects were important, as are cost and availability.

Overwhelmingly, respondents’ hopes for new therapies for CKD were increased energy and increased well-being and quality of life. Other important expectations included less medication overall, less time away from work, and fewer hospital visits.

6. Experience With Drug Under Review

21 people responded to a question about their experience with dapagliflozin. 17 indicated that they have never taken it, with 2 indicating that they have. Both paid out of pocket for the prescription. The remaining 2 respondents said they did not know whether they've taken dapagliflozin.

Both respondents who have had experience with dapagliflozin reported that their dizziness was about the same. Other effects listed as “much better” by both patients included potassium levels and sodium levels, while tiredness/weakness, high blood pressure, nausea/vomiting, trouble breathing, and swelling/edema were also considered better by one person. Tiredness/weakness, high blood pressure, and low blood pressure were deemed worse by one participant each.

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 must limit their working hours due to their condition, and at the same time out-of-pocket costs increase as they change their diet, begin taking medications, 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.

The financial burden of kidney disease and the treatment of associated heart disease means that many would benefit from effective, affordable treatments that they can access equitably and in a timely manner. As dapagliflozin 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.