

## CADTH Drug Reimbursement Review Patient Input Template

**Name of the Drug and Indication:** Veltassa - Hyperkalemia

**Name of the Patient Group:** The Kidney Foundation of Canada

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### 1. About Your Patient Group

If you have not yet registered with CADTH, describe the purpose of your organization. Include a link to your website.

The Kidney Foundation of Canada is committed to achieving excellent kidney health, optimal quality of life, and a cure for kidney disease.

The Kidney Foundation of Canada is the national volunteer organization committed to eliminating the burden of kidney disease through:

- Funding and stimulating innovative research for better 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 healthcare;
- Increasing public awareness and commitment to advancing kidney health and organ donation.

For more information, please visit: [www.kidney.ca](http://www.kidney.ca)

### 2. Information Gathering

CADTH is interested in hearing from a wide range of patients and caregivers in this patient input submission. Describe how you gathered the perspectives: for example, by interviews, focus groups, or survey; personal experience; or a combination of these. Where possible, include **when** the data were gathered; if data were gathered **in Canada** or elsewhere; demographics of the respondents; and **how many** patients, caregivers, and individuals with experience with the drug in review contributed insights. We will use this background to better understand the context of the perspectives shared.

Patient input was collected in October and November 2020 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 posed a number of questions specifically about the drug under review, Veltassa. Awareness about the surveys was generated through the Kidney Foundation's social media channels (Twitter and Facebook). It was also promoted on the Kidney Foundation's website and e-newsletter.

A total of 33 people responded to the survey with 15 completed and 18 partially completed surveys. 9 respondents identified as being a person living with chronic kidney disease and 5 identified as being a caregiver for a person with chronic kidney disease. Of the 13 people that responded to the questions about their current age or the current age for the person they care for, 1 was under 14 years old, 1 was 25 to 39 years old, 9 were 55-69, one was over 70 years old. 13 respondents answered the questions about how long they had lived with kidney disease. 1 respondent reported living with chronic kidney disease for under one year, 1 for 1 to 2 years, 2 for 3 to 5 years, 2 for 6 to 10 years, 2 for 11 to 20 years and 5 respondents who reported more than 20 years with the disease.

### 3. Disease Experience

CADTH involves clinical experts in every review to explain disease progression and treatment goals. Here we are interested in understanding the illness from a patient's perspective. Describe how the disease impacts patients' and caregivers' day-to-day life and quality of life. Are there any aspects of the illness that are more important to control than others?

Kidney disease describes a variety of disease and disorders that affect the kidneys. Most disease of the kidney attack the nephrons and damage their ability to eliminate wastes and excess fluids. Often, kidney disease is associated with other medical conditions such as diabetes, 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 right amount of potassium in the body, however if the kidneys are not working well, the potassium levels can be too high (hyperkalemia, for which the drug under review is indicated) or too low (hypokalemia). 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 who participated in the survey spoke negatively of their experience with CKD. Respondents talked about their constant tiredness. They said “2.5 years on dialysis - now 24 years post-transplant. Still working after 44 years - but fatigue and sleep problems have been huge issues last 10 years. But still well.”, “I get tired easy”, “Recurrent state of exhaustion - great fatigue - little energy - difficulty sleeping” and “It has affected my energy levels and my ability to be motivated”.

Caregivers spoke of how it affects them; “When I'm done caring for my spouse I'm too tired to do things for me like seeing friends or going to lunch- between taking him to dialysis and the house chores it's tiring” and “I have a hard time with keeping him on track with meds, with diet and with everyday life! He is tired all the time, he does not sleep well, he has a lot of pain and some swelling of his joints. He is depressed. It's sad, it breaks my heart”.

Some respondents spoke about the impact that CKD has on their day-to-day lives; “CKD has affected me the (sic) and my spouse significantly from PKD and family members, Transplant to rejection to 24 years on Hemodialysis but never giving up! If you can imagine being diagnosed at 20 waiting for your kidneys to fail, not having children, Bi lateral (sic) nephrectomy, spinal fusion, osteoarthritis, not being able to continue my working career and much more.” and “I'm missing lots of school because I need to go to [hospital name removed] lots. This makes me very sad. I hate taking so much (sic) medications everyday. I am afraid my scars and stretch marks will never go away.”

Many people dealing with CKD have a number of other conditions. Of the respondents to this question, 86% reported high blood pressure, 72% high potassium levels, 86% reported low hemoglobin and 93% reported low iron levels. 86% also reported having dietary restrictions currently or in the past.

#### **4. Experiences With Currently Available Treatments**

CADTH examines the clinical benefit and cost-effectiveness of new drugs compared with currently available treatments. We can use this information to evaluate how well the drug under review might address gaps if current therapies fall short for patients and caregivers.

Describe how well patients and caregivers are managing their illnesses with currently available treatments (please specify treatments). Consider benefits seen, and side effects experienced and their management. Also consider any difficulties accessing treatment (cost, travel to clinic, time off work) and receiving treatment (swallowing pills, infusion lines).

64% of respondents said they currently had a dietary restriction and 22% had a dietary restriction in the past but not anymore for high potassium. 93% of respondents indicated they follow a special diet to manage high potassium. 50% of respondents had taken medication for high potassium. Sodium polystyrene sulfonate had been taken by 4 respondents, 2 respondents had taken calcium polystyrene sulfonate and 3 had taken patiromer (Veltassa) .

One person indicated that they were ‘satisfied’ with the medication they are currently taking for high potassium, 2 were ‘neither satisfied nor unsatisfied’, 3 were ‘unsatisfied’ whilst another indicated they are not taking medications for high potassium. Those who responded about what they liked or didn't like about the medications they took for high potassium was the taste, frequency and causing constipation. Some comments included “ I hate the taste of Veltassa. I have to combine it with ice cream to get it down

easier”, “taste and frequency”, “don’t like anything about calcium resonium, tastes terrible and causes terrible constipation” and “causes constipation”.

When asked about what factors were “very important” or “important” in choosing chronic kidney disease medications in general, the following factors were identified as “very important” or “important” by the majority of respondents: tiredness, interference with sleep, foot edema, effect on mood, interference with other medications, changes in appetite, cost and length of time on the medication. One respondent stated change in appetite was neither important or unimportant, two respondents also stated that cost was neither important or unimportant. One respondent also reported that length of time being on the medication was unimportant.

Additionally, patients when asked what else was important to them when choosing a kidney disease medication a number of responses included side effects, impact on health, effectiveness and interactions with other medications. A respondent stated “One that does not add to the burden of other symptoms or does not increase risk long term complications. Reduce symptoms, prolong life and QUALITY OF LIFE.”

## 5. Improved Outcomes

CADTH is interested in patients’ views on what outcomes we should consider when evaluating new therapies. What improvements would patients and caregivers like to see in a new treatment that is not achieved in currently available treatments? How might daily life and quality of life for patients, caregivers, and families be different if the new treatment provided those desired improvements? What trade-offs do patients, families, and caregivers consider when choosing therapy?

When asked about their expectations for new CKD therapies, respondents wanted therapies to “Inexpensive, minimal side effects - and effective.”, “make condition (sic) more liveable”, “I want to have the best medications available”, “make living with CKD easier”, “being affordable”, “Not impact other bodily systems in a negative way”, “simplicity of taking the medication (frequency and ease).”, and “live long healthy lives. Give a good quality of life.”

## 6. Experience With Drug Under Review

CADTH will carefully review the relevant scientific literature and clinical studies. We would like to hear from patients about their individual experiences with the new drug. This can help reviewers better understand how the drug under review meets the needs and preferences of patients, caregivers, and families.

How did patients have access to the drug under review (for example, clinical trials, private insurance)? Compared to any previous therapies patients have used, what were the benefits experienced? What were the disadvantages? How did the benefits and disadvantages impact the lives of patients, caregivers, and families? Consider side effects and if they were tolerated or how they were managed. Was the drug easier to use than previous therapies? If so, how? Are there subgroups of patients within this disease state for whom this drug is particularly helpful? In what ways? If applicable, please provide the sequencing of therapies that patients would have used prior to and after in relation to the new drug under review. Please also include a summary statement of the key values that are important to patients and caregivers with respect to the drug under review.

3 respondents reported that they were taking Veltassa right now. None of the respondents had switched from another medication and 100% had their prescription covered by private insurance. 2 said that their potassium levels were better compared to before taking Veltassa. 1 respondent stated that their

tiredness or weakness was better, while 2 reported that their tiredness or weakness was worse. In regards to nausea or vomiting, 1 respondent it was better, 1 reported it being the same and 1 reported it being worse.

1 respondent stated that their trouble breathing was better and 2 said it was about the same. Swelling and edema was reported as being much better by 1 respondent, better by 1 and worse by 1. Finally, 1 respondent reported that palpitations or irregular heart beat was much better, 1 reported it being about the same and 1 didn't know.

## 7. Companion Diagnostic Test

If the drug in review has a companion diagnostic, please comment. Companion diagnostics are laboratory tests that provide information essential for the safe and effective use of particular therapeutic drugs. They work by detecting specific biomarkers that predict more favourable responses to certain drugs. In practice, companion diagnostics can identify patients who are likely to benefit or experience harms from particular therapies, or monitor clinical responses to optimally guide treatment adjustments.

What are patient and caregiver experiences with the biomarker testing (companion diagnostic) associated with regarding the drug under review?

Consider:

- Access to testing: for example, proximity to testing facility, availability of appointment.
- Testing: for example, how was the test done? Did testing delay the treatment from beginning? Were there any adverse effects associated with testing?
- Cost of testing: Who paid for testing? If the cost was out of pocket, what was the impact of having to pay? Were there travel costs involved?
- How patients and caregivers feel about testing: for example, understanding why the test happened, coping with anxiety while waiting for the test result, uncertainty about making a decision given the test result.

This question is not applicable to this submission.

## 8. Anything Else?

Is there anything else specifically related to this drug review that CADTH reviewers or the expert committee should know?

Canadians living with kidney failure face significant financial challenges as a result of dialysis treatment. Starting dialysis often results in a decrease of income at the same time that out-of-pocket costs increase, such as those for transportation to treatment and medication. Government coverage and financial support for people on dialysis varies, resulting in inequalities across jurisdictions. Those living with kidney failure tend to be part of a low-income and high-cost population. In order to address the financial burden for people with kidney disease and to minimize disparities in accessing medications for people with kidney disease, mechanisms need to be developed to offset costs equitably across jurisdictions.

Those living with chronic kidney disease experience additional health and financial challenges when they are dealing with comorbid conditions, like diabetes. Many would benefit from effective, affordable treatments that they can access equitably and in a timely manner. Veltassa may help people to achieve better health outcomes and improve their quality of life. For this reason, it should be available as an option for people living with CKD.