

Patient Input Template for CADTH CDR and pCODR Programs

Name of the Drug and Indication	Sodium zirconium cyclosilicate, Hyperkalemia, Adults
Name of the Patient Group	The Kidney Foundation of Canada Diabetes Canada
Author of the Submission	Lydia Lauder
Name of the Primary Contact for This Submission	Lydia Lauder
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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 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

Diabetes Canada is a national health charity representing close to 11 million Canadians living with diabetes or prediabetes. The priorities of our mission are diabetes prevention, care and cure. Our focus on research and policy initiatives helps us to deliver impact at a population level, and our partnerships broaden our reach in communities across the country. We drive excellence in disease management by putting practical, evidence-based tools into the hands of health-care providers. We advocate for environments that make the healthy choice the easy choice. We continue our search for a cure, as well as for better prevention and treatment strategies, by funding the work of innovative scientists. In 1921, Canada changed diabetes for the world with the discovery of insulin. By 2021, we will change the world for those affected by diabetes through healthier communities, exceptional care, and high-impact research.

For more information, please visit: www.diabetes.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 May 2019 via a collaboration between The Kidney Foundation of Canada and Diabetes Canada. A self-administered questionnaire to people across Canada was open for two weeks. 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, Lokelma (sodium zirconium cyclosilicate). Awareness about the surveys was generated through both the Kidney Foundation of Canada's and Diabetes Canada's social media channels (Twitter and Facebook). It was also promoted on the Kidney Foundation of Canada's website.

A total of 7 people responded to the survey. 7 respondents identified as being a person living with chronic kidney disease. Of the 6 people that responded to the questions about age and time since diagnosis, 2 were aged 40-54 and 4 were 55-69. There were 2 respondents who reported having lived with chronic kidney disease for 3-5 years and 4 respondents who reported more than 20 years with the disease. 4 out of the 7 respondents identified themselves as living with diabetes.

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.

Diabetes is the leading cause of kidney failure in Canada. Diabetes is a chronic, progressive disease of different types, but none with any known cure. Type 1 diabetes occurs when the pancreas does not produce any insulin at all or makes such an insufficient amount that daily exogenous insulin (delivered via injection or infusion) is required for survival. Type 2 diabetes occurs when the pancreas does not produce enough insulin or the body does not effectively use the insulin that is produced. Common symptoms of diabetes include extreme fatigue, unusual thirst, frequent urination and weight change (gain or loss).

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 “I’m tired”, “lack of energy has to be number one” and “I am constantly exhausted daily, cannot walk anywhere without a walker now scared to go out by myself as I may fall”.

Some respondents spoke about the impact that CKD has on their day-to-day lives; “Can’t work. Too tired, nauseous and itchy” and “I push myself to get household chores done and then am too tired to get daily exercise.” Others too commented on their inability to exercise; “I am too tired to get into a daily exercise routine as I had before.” A respondent commented on the impact dialysis had on their life “I also find dialysis time consuming – not allowing me the freedom to pursue other interests in my life.”

Many people dealing with CKD have a number of other conditions. Of the respondents to this question, 57% reported living with diabetes, 86% reported high blood pressure, 57% high cholesterol and 86% high potassium levels. 72% also reported having dietary restrictions.

When asked if there are particular challenges living with both CKD and diabetes, a respondent said “having to adjust both meds (sic) for diabetes and kidney disease...constant pain in feet.”

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).

72% of respondents said they had a dietary restriction, however the nature of the dietary restriction was not identified. Sodium polystyrene sulfonate had been taken by 2 respondents, with one indicating they no longer take this medication for high potassium levels, but currently use dialysis and diet restrictions to manage their potassium levels.

One person indicated that they were 'satisfied' with the medication they are currently taking for high potassium, whilst another indicated they are not taking medications for high potassium. The person currently taking something for high potassium stated "I do not like the texture and taste. Would be nice if it could be made into a pill form".

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 (n=6) stated that cost and affect on mood was neither important or unimportant.

Additionally, patients when asked what else was important to them when choosing a kidney disease medication said "side effects" and "what are my chances of it working?".

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 and CKD and diabetes therapies, respondents wanted therapies to "help us feel better", "To cut down on invasive therapies such as surgery" and "of (sic) it does become available I would love to try it".

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?

This drug is not available in Canada and therefore patients and caregivers have no experience with this medication to be able to give comments.

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. Sodium zirconium cyclosilicate 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.

Appendix A: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH CDR and pCODR programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This Patient Group Conflict of Interest Declaration is required for participation. Declarations made do not negate or preclude the use of the patient group input. CADTH may contact your group with further questions, as needed.

1. Did you receive help from outside your patient group to complete this submission? If yes, please detail the help and who provided it.

Yes, Collaboration with Diabetes Canada on the survey questions and awareness of the survey on social media.

2. Did you receive help from outside your patient group to collect or analyze data used in this submission? If yes, please detail the help and who provided it.

There was no external assistance with data collection or analysis used for this submission.

3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Alexion Pharma Canada Corp		X		
Amgen Canada Inc.			X	
Astellas Pharma Canada Inc.			X	
AstraZeneca Canada Inc.			X	
Boehringer Ingelheim (Canada)	X			
Fresenius Medical Care Canada Inc		X		
Horizon Pharma Inc.				X
Jamp Pharma Corporation	X			
Janssen Pharmaceutical Companies				X
Otsuka Canada Pharmaceutical Inc.				X
Pharmascience	X			
Sanofi		X		

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: Lydia Lauder
 Position: National Director, Programs and Public Policy
 Patient Group: The Kidney Foundation of Canada
 Date: May 27, 2019

Appendix B: Patient Group Conflict of Interest Declaration – Diabetes Canada

To maintain the objectivity and credibility of the CADTH CDR and pCODR programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This Patient Group Conflict of Interest Declaration is required for participation. Declarations made do not negate or preclude the use of the patient group input. CADTH may contact your group with further questions, as needed.

1. Did you receive help from outside your patient group to complete this submission? If yes, please detail the help and who provided it.

Diabetes Canada provided input to the Kidney Foundation of Canada in the preparation of this joint patient input submission.

2. Did you receive help from outside your patient group to collect or analyze data used in this submission? If yes, please detail the help and who provided it.

There was no external assistance with data collection or analysis used for this submission.

3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000

Please find attached a list of organizations who have recently supported Diabetes Canada financially, along with the amounts provided.

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: Ann Besner, MScA, RD, CDE
 Position: Manager, Research and Policy Analysis
 Patient Group: Diabetes Canada
 Date: May 27, 2019

Financial Contributions to Diabetes Canada (updated 2017)

Constituent/Name	Funder range (\$)
<i>AstraZeneca Canada Inc</i>	350,000+
<i>LifeScan Canada Ltd.</i>	350,000+
<i>Novo Nordisk Canada Inc</i>	350,000+
<i>Sanofi Canada</i>	350,000+
<i>Sun Life Financial</i>	350,000+
<i>Eli Lilly Canada Inc</i>	250,000-349,999
<i>Ascensia Diabetes Care</i>	175,000-249,999
<i>Janssen Inc</i>	175,000-249,999
<i>Medtronic Of Canada Ltd</i>	175,000-249,999
<i>Dairy Farmers Of Canada</i>	100,000-174,999
<i>Merck Canada Inc</i>	100,000-174,999
WEIGHT WATCHERS	100,000-174,999
<i>Abbott Diabetes Care</i>	50,000-99,999
<i>Canola Council Of Canada</i>	50,000-99,999
<i>Insulet Canada Corporation</i>	50,000-99,999
<i>Knight Therapeutics Inc.</i>	50,000-99,999
<i>Manulife Financial</i>	50,000-99,999
<i>Nestle Health Science</i>	50,000-99,999
<i>RBC Foundation</i>	50,000-99,999
<i>The Bank of Nova Scotia</i>	50,000-99,999
<i>Abbott Nutrition</i>	25,000-49,999
<i>BD Medical Diabetes Care</i>	25,000-49,999
<i>Beer Canada</i>	25,000-49,999
<i>Dexcom Canada</i>	25,000-49,999
<i>Dynacare</i>	25,000-49,999
<i>Heartland Food Products Group</i>	25,000-49,999
<i>McNeil Consumer Healthcare</i>	25,000-49,999
<i>Rexall Foundation</i>	25,000-49,999
<i>Roche Diabetes Care</i>	25,000-49,999
<i>SaskCanola</i>	25,000-49,999
<i>Auto Control Medical Inc</i>	5,000-24,999
<i>Bayer Pharmaceuticals</i>	5,000-24,999
<i>Boehringer Ingelheim (Canada) Ltd</i>	5,000-24,999
<i>Canadian Association of Optometrists</i>	5,000-24,999
<i>Canadian Produce Marketing Association</i>	5,000-24,999
CHICKEN FARMERS OF CANADA	5,000-24,999
<i>Edelman Canada</i>	5,000-24,999
<i>EOCI Pharmacomm Ltd.</i>	5,000-24,999
<i>Euro Harvest Bakery Wholesalers</i>	5,000-24,999
<i>Farleyco Marketing Inc</i>	5,000-24,999
<i>ForaCare Technology Canada Inc.</i>	5,000-24,999

<i>Holista Foods</i>	5,000-24,999
<i>InBody Canada</i>	5,000-24,999
<i>Innovative Medicines Canada</i>	5,000-24,999
<i>Ipsen</i>	5,000-24,999
<i>Jays Care Foundation</i>	5,000-24,999
<i>mdBriefCase Group Inc.</i>	5,000-24,999
<i>Montmed</i>	5,000-24,999
<i>Myelin & Associates</i>	5,000-24,999
<i>Novartis Pharmaceuticals Canada Inc</i>	5,000-24,999
<i>Ontario Pork Council</i>	5,000-24,999
<i>Original Energy Sales</i>	5,000-24,999
<i>Paladin Labs Inc</i>	5,000-24,999
<i>Pharmasave Drugs (National) Ltd</i>	5,000-24,999
<i>Prime Strategies Inc.</i>	5,000-24,999
<i>PULSE CANADA</i>	5,000-24,999
<i>Royal College Of Physicians And Surgeons Of Canada</i>	5,000-24,999
<i>Tykess Pharmaceuticals</i>	5,000-24,999
<i>Urban Poling Inc</i>	5,000-24,999
<i>Valeant Canada LP</i>	5,000-24,999
<i>VitalAire Canada Inc</i>	5,000-24,999

