

CADTH Reimbursement Review Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0737-000
Brand name (generic)	finerenone
Indication(s)	Adult patients with chronic kidney disease and type 2 diabetes
Organizations	The Kidney Foundation of Canada, Diabetes Canada
Contact information ^a	Name: Carrie Thibodeau
Stakeholder agreement with the draft recommendation	
1. Does the stakeholder agree with the committee's recommendation.	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
<p>The Kidney Foundation of Canada and Diabetes Canada agree with the overall recommendation that finerenone be reimbursed in adult patients with chronic kidney disease (CKD) and type 2 diabetes (T2D).</p> <p>However, we disagree with recommendation 3.3, which specifies that treatment with finerenone not be reimbursed in patients receiving a SGLT2i, regardless of indication, on these grounds:</p> <ul style="list-style-type: none"> • This recommendation would effectively require a choice between two therapies demonstrated to slow the progression of CKD and reduce the risk of heart disease, which would have a profound effect on the health and quality of life of CKD and T2D patients and their families. • There have been significant developments in the treatment of CKD and T2D since the research on finerenone was initiated. At the time of the trials, SGLT2 inhibitors were not the standard of care. This is also true for many similar drug trials for CKD and T2D patients. • The 2020 Diabetes Canada clinical practice guidelines recommend the use of SGLT2 inhibitors in people living with T2D and CKD as Grade A, Level 1 evidence. An increasing number of patients are therefore likely to be prescribed a SGLT2 inhibitor, and the proposed condition would exclude many of the very patients who would benefit the most from finerenone. • The 2022 KDIGO (Kidney Disease Improving Global Outcomes) Clinical Practice Guideline for Diabetes Management in CKD listed SGLT2 inhibitors for T2D and CKD patients as a way to reduce the risk of kidney failure and cardiovascular disease while lowering blood sugar. The guideline also suggested non-steroidal MRAs to reduce the risk of CKD progression and cardiovascular events for patients with T2D and residual albuminuria that hasn't responded to other treatments. These two recommendations were not linked or conditional in the guideline. • This recommendation discriminates against those living with CKD and T2D. A similar exclusion has not been made in other chronic disease drug recommendations. For example, for the treatment of heart failure, Entresto does not include a restriction for SGLT2i despite having fewer people in those trials who were on both SGLT2i and Entresto. 	

Expert committee consideration of the stakeholder input		
2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<p>A fulsome consideration of the following would benefit patients:</p> <ul style="list-style-type: none"> • Finerenone and SGLT2 inhibitors have each been shown to slow the progression of CKD, which vastly improves the quality of life of patients who might eventually progress to kidney failure and require dialysis or a transplant, or suffer a cardiovascular event. • Patients with CKD and type 2 diabetes and their caregivers often face significant out-of-pocket costs, which may be compounded by reduced income due to absence from or inability to work. This is especially true of those with end-stage kidney disease, some of whom reported going without food or basic necessities due to the financial burden of dialysis treatment. A significant delay in the progression of CKD reduces these out-of-pocket costs in a population already grappling with financial burdens, including transportation and medication costs.¹ • Should CKD progress to kidney failure, hemodialysis is the most common treatment. In Canada, 23,708 people were on dialysis in 2020, and that number has nearly doubled in the last 20 years². The cost of hemodialysis to the health care system per person per year, which ranges from \$56,000 to \$107,000, far outweighs the cost of treating the early stages of CKD. • In a Diabetes Canada survey from 2015, 25 percent of all people with diabetes indicated treatment adherence was affected by cost. An updated report by Diabetes Canada on out-of-pocket costs for medications and devices found that people with type 2 diabetes can pay up to 17% of their gross annual income on prescribed medications and devices, and, in some cases, can exceed \$10,000 per year.^{3,4} • 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. 		
Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
While the recommendations were stated per CADTH's process, we feel that the recommendations require further consideration.		
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
No implementation guidelines were stipulated in Table 1.		
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
The rationale given does not reflect full consideration of the importance of early access to these two medication options for CKD and type 2 diabetes, which can delay kidney failure for many years, avoiding the need for dialysis, increasing patients' lifespans and significantly improving their quality of life.		

^a CADTH may contact this person if comments require clarification.

References

- ¹ https://kidney.ca/KFOC/media/images/PDFs/3-2-1-NAT-Burden_of_Out-of-Pocket_Costs.pdf
- ² Canadian Institute for Health Information. [Trends in end-stage kidney disease in Canada, 2020 — Infographic](#) [infographic]. Accessed November 30, 2022.
- ³ 2015 Report on Diabetes – Driving Change. Ottawa: Diabetes Canada; 2015.
- ⁴ Diabetes and Diabetes-Related Out-of-Pocket Costs: 2022 Updates, Ottawa: Diabetes Canada; 2022.

Appendix 1. Conflict of Interest Declarations for Patient Groups

A. Patient Group Information				
Name	<i>Lydia Lauder</i>			
Position	<i>National Director of Programs and Public Policy</i>			
Date	<i>01/12/2022</i>			
<input checked="" type="checkbox"/>	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.			
B. Assistance with Providing Feedback				
1. Did you receive help from outside your patient group to complete your feedback?			No	<input type="checkbox"/>
			Yes	<input checked="" type="checkbox"/>
There was collaboration with Diabetes Canada on this response.				
2. Did you receive help from outside your patient group to collect or analyze any information used in your feedback?			No	<input checked="" type="checkbox"/>
			Yes	<input type="checkbox"/>
The Kidney Foundation of Canada consulted several clinical subject matter experts in preparing our feedback.				
C. Previously Disclosed Conflict of Interest				
1. Were conflict of interest declarations provided in patient group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section D below.			No	<input checked="" type="checkbox"/>
			Yes	<input type="checkbox"/>
D. New or Updated Conflict of Interest Declaration				
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
<i>Alexion</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>AstraZeneca</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<i>Horizon</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<i>Janssen</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Appendix 1. Conflict of Interest Declarations for Patient Groups

A. Patient Group Information				
Name	<i>Amanda Sterczyk</i>			
Position	<i>Senior Manager, Policy</i>			
Date	<i>01/12/2022</i>			
<input checked="" type="checkbox"/>	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.			
B. Assistance with Providing Feedback				
4. Did you receive help from outside your patient group to complete your feedback?	No	<input type="checkbox"/>		
	Yes	<input checked="" type="checkbox"/>		
There was collaboration with The Kidney Foundation of Canada on the feedback.				
5. Did you receive help from outside your patient group to collect or analyze any information used in your feedback?	No	<input type="checkbox"/>		
	Yes	<input type="checkbox"/>		
C. Previously Disclosed Conflict of Interest				
2. Were conflict of interest declarations provided in patient group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section D below.	No	<input type="checkbox"/>		
	Yes	<input checked="" type="checkbox"/>		
D. New or Updated Conflict of Interest Declaration				
6. 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
<i>AstraZeneca</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<i>Bayer</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<i>Janssen</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<i>Eli Lilly</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<i>Novo Nordisk</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<i>Paladin</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<i>Sanofi</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<i>Takeda</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>