Drug Coverage Decision for B.C. PharmaCare

About PharmaCare B.C. PharmaCare is a government-funded drug plan. It helps British Columbians with the cost of eligible prescription drugs and specific medical supplies.

Details of Drug Reviewed

Drug	**finerenone**
Brand Name	Kerendia®
Dosage Form(s)	10 mg and 20 mg tablets
Manufacturer	Bayer Inc.
Submission Type	**New Submission**
Use Reviewed	As an adjunct to standard of care therapy to delay progression of kidney disease and to reduce the risk of major adverse cardiovascular events (cardiovascular [CV] death, non-fatal myocardial infarction, non-fatal stroke) and hospitalization for heart failure in adults with chronic kidney disease (CKD) and type 2 diabetes (T2D).
Canada's Drug and Health Technology Agency (CADTH) Reimbursement Reviews (CRR)	Yes, CRR recommended: **to Reimburse with clinical criteria and/or conditions**. Visit the CRR website for more details: Finerenone (Kerendia) (cadth.ca)
Drug Benefit Council (DBC)	The DBC met on July 10, 2023. The DBC considered various inputs including: the final reviews completed by the CADTH CRR on March 8, 2023, which included clinical and pharmacoeconomic evidence review material and the Canadian Drug Expert Committee (CDEC) recommendations. The DBC received no Patient Input Questionnaire responses from patients, caregivers, or patient groups and instead considered patient input provided to CADTH, as well as a Clinical Practice Review from a specialist and a Budget Impact Assessment.
Drug Coverage Decision	**Limited Coverage Benefit** **Access the finerenone criteria from www.gov.bc.ca/pharmacarespecialauthority**

Date	February 27, 2024
Reason(s)	• **Drug coverage decision is consistent with the CDEC and DBC recommendations** that Kerendia® be reimbursed as an adjunct to standard of care therapy in adult patients with CKD and T2D to reduce the risk of end-stage kidney disease (ESKD) and a sustained decrease in estimated glomerular filtration rate (eGFR), and CV death, non-fatal myocardial infarction and hospitalization for heart failure, if certain conditions and price reduction are met**.** • Standard of care therapies in patients with CKD and T2D who have persistent albuminuria, is defined as maximally tolerated doses of an angiotensin-converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB), in combination with a sodium-glucose cotransporter-2 inhibitor (SGLT2i), unless SGLT2i are contraindicated or not tolerated. • Evidence from two randomized, placebo-controlled, double-blind, active-controlled, phase III trials (*FIDELIO* and *FIGARO*) demonstrated that patients with CKD and T2D treated with finerenone experienced reduction in the risk of developing ESKD and CV events compared with placebo. • At the submitted price, finerenone was not considered cost-effective. The Ministry participated in the pan-Canadian Pharmaceutical Alliance negotiations with the manufacturer which were able to address the concerns identified by the CDEC with respect to the cost-effectiveness and value for money.
Other Information	None

The Drug Review Process in B.C.

A manufacturer submits a request to the Ministry of Health (Ministry).

An independent group called the Drug Benefit Council (DBC) gives advice to the Ministry. The DBC looks at:

- whether the drug is safe and effective
- advice from a national group called the Canadian Agency for Drugs and Technologies in Health (CADTH) Reimbursement Reviews(CRR)
- what the drug costs and whether it is a good value for the people of B.C.
- ethical considerations involved with covering or not covering the drug
- input from physicians, patients, caregivers, patient groups and drug submission sponsors

The Ministry makes PharmaCare coverage decisions by taking into account:

- the existing PharmaCare policies, programs and resources
- the evidence-informed advice of the DBC
- the drugs already covered by PharmaCare that are used to treat similar medical conditions
- the overall cost of covering the drug

Visit The Drug Review Process in B.C. - Overview and Ministry of Health - PharmaCare for more information.

This document is intended for information only.
It does not take the place of advice from a physician or other qualified health care provider.

Appendix
Drug Benefit Council (DBC)
Recommendation and Reasons for Recommendation

FINAL

Finerenone (Kerendia®)
Bayer Inc.

Description:

Drug review of **finerenone (Kerendia®)** for the following Health Canada approved indications:

> (MACE) (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke) and hospitalization for heart failure in adults with chronic kidney disease (CKD) and type 2 diabetes (T2D).

In their review, the DBC considered the As an adjunct to standard of care (SoC) therapy to delay progression of kidney disease and to reduce the risk of major adverse cardiovascular events following: the final reviews completed by the Canadian Agency for Drugs and Technologies in Health (CADTH) on March 8, 2023, which included clinical and pharmacoeconomic evidence review material and the CADTH recommendations. The DBC received no Patient Input Questionnaire responses from patients, caregivers, or patient groups and instead considered patient input provided to CADTH, as well as a Clinical Practice Review from a specialist and a Budget Impact Assessment.

Dosage Forms:

Kerendia® is available as finerenone 10 mg or 20 mg oral tablets.

Recommendations:

1. The Drug Benefit Council (DBC) recommends not to list finerenone (Kerendia®) at the submitted price.

Of Note:

- If a significant price reduction is achieved, the reimbursement criteria and conditions recommended by CADTH are an appropriate basis for coverage, with one change: the CADTH Reimbursement Condition 4 ("finerenone should be prescribed in consultation with a nephrologist with experience in the diagnosis and management of patients with CKD and T2D") should be removed.

Reasons for the Recommendation:

1. **Summary**

- Evidence from two randomized, double-blind, active-controlled, phase III trials demonstrated that patients with CKD and T2D treated with finerenone experienced reduction in the risk of developing end-stage kidney disease (ESKD) and cardiovascular (CV) events compared with placebo.
- Patients and clinical experts identified a need for treatment options that reduce the risk of progression to kidney failure and CV events and improve health-related quality of life (HRQoL). Finerenone appears to reduce the risk of progression to kidney failure and CV events but no definitive conclusions could be made regarding the effects of finerenone on the improvement of HRQoL.
- At the manufacturer's submitted price, finerenone is not considered cost-effective. CADTH recommended a price reduction (not specified) would be required.

2. **Clinical Efficacy**

- The DBC considered the CADTH systematic review, which included two phase III, randomized, double-blind, placebo-controlled, parallel-group, multicentre, event-driven studies of finerenone compared with placebo in patients with CKD and T2D, FIDELIO (N = 5,734) and FIGARO (N = 7,437).
- The primary objective in FIDELIO was time to the first occurrence of the 40% renal composite end point comprising onset of kidney failure, a sustained decrease of estimated glomerular filtration rate (eGFR) of 40% or more from baseline over at least 4 weeks, or renal death, in both the finerenone and placebo groups,
- The primary objective in FIGARO was time to the first occurrence of the composite end point comprising cardiovascular death, nonfatal MI, nonfatal stroke, or hospitalization for heart failure in both the finerenone and placebo groups.
- Secondary objectives in each study included the primary objective of the other study, as well as time to first occurrence of a more severe renal composite end point, time to all-cause mortality, time to all-cause hospitalization, and change in urinary albumin-to-creatinine ratio (UACR) from baseline to month 4.
- In FIDELIO, after 36 months of treatment, finerenone was associated with a 17.5% risk reduction in the time to the first occurrence of the 40% renal composite end point, with a hazard ratio (HR) of 0.825 in favour of finerenone. In FIGARO, after 48 months of treatment, the HR for this end point was 0.87, which was not statistically significant.
- In FIDELIO, finerenone was associated with a 14% risk reduction in the time to first occurrence of the cardiac composite end point, with an HR of 0.86 in favour of finerenone, whereas in the FIGARO trial, finerenone was associated with a 13% risk reduction, with an HR of 0.87 in favour of finerenone.
- In FIDELIO, the primary and key secondary end points met the preplanned criteria for significance and all-cause mortality, the next secondary end point was tested hierarchically and it did not reach statistical significance, so the remaining secondary end points were tested in an exploratory manner. In FIGARO, the primary end point met the preplanned criteria for significance and the key secondary end point did not; therefore, the remaining secondary end points were tested in an exploratory manner.
- For detailed information on the systematic review of finerenone please see the CDEC Final Recommendation at: https://www.cadth.ca/finerenone.

3. Safety

- The rates of adverse events (AEs), serious adverse events (SAEs), and withdrawals due to adverse events (WDAEs) were similar in the treatment and placebo groups in both FIGARO and FIDELIO.
- The most common AE in the finerenone group was hyperkalemia (14% vs. 6.9% in the placebo group), and the most common AEs in the placebo group were hypertension (9% vs. 6.4% in the finerenone group) and peripheral edema (5.9% vs. 9% in the finerenone group).
- A total of 2,060 (31.6%) patients in the finerenone group and 2,186 (33.7%) in the placebo group experienced at least 1 SAE. The most commonly reported SAE was pneumonia (2.2% in the finerenone group vs. 3.3% in the placebo group).
- There was a total of 110 (1.7%) deaths and 151 (2.3%) deaths due to treatment-emergent AEs in the finerenone and placebo groups, respectively.
- For detailed information on the safety and tolerability of finerenone, please see the CDEC Final Recommendations at the links above.

4. Economic Considerations

- CADTH's reanalyses of the manufacturer's submission reported that, based on the sponsor's submitted price for finerenone and publicly listed prices for all other drug costs, the incremental cost-effectiveness ratio (ICER) ranged from $70,052 to $2,994,490 per quality-adjusted life-year (QALY) gained. Price reductions would be required for finerenone to achieve an ICER of $50,000 per QALY.

5. Of Note

- Patients and clinical experts identified a need for treatment options that reduce the risk of progression to kidney failure and cardiovascular events and improve health-related quality of life (HRQoL).
- CADTH concluded that, based on the evidence, finerenone appears to address some of the needs identified by patients by reducing the risk of progression to kidney failure and cardiovascular events; however, no definitive conclusions could be made regarding the effects of finerenone on the improvement of HRQoL.