Drug Coverage Decision for BC PharmaCare

About PharmaCare BC PharmaCare is a publicly funded drug plan that helps B.C. residents pay for most prescription drugs and pharmacy services, and some medical devices and supplies.

Details of Drug Reviewed

Drug	**vericiguat**
Brand name	Verquvo®
Dosage form(s)	2.5 mg, 5 mg, and 10 mg oral tablets
Manufacturer	Bayer Inc.
Submission type	**New Submission**
Indication reviewed	For the treatment of symptomatic chronic heart failure (HF) in adult patients with reduced ejection fraction who are stabilized after a recent HF decompensation event requiring hospitalization and/or intravenous diuretic therapy. Verquvo should be taken in combination with other standard of care therapies for HF.
Canada's Drug Agency (CDA-AMC) Clinical Reimbursement Reviews (CRR))	CDA-AMC recommended: **to Reimburse with clinical criteria and/or conditions**. Visit the CRR website for more details.
Drug Benefit Council (DBC)	The DBC met on September 11, 2023. The DBC considered various input, including clinical and pharmacoeconomic evidence review material and the recommendations of the Canadian Drug Expert Committee (CDEC). The DBC also considered patient input provided to CDEC and a budget impact assessment. The DBC received Your Voice patient input questionnaire responses from one patient group, and one response to clinical questions from a specialist.

Drug Coverage Decision	**Limited Coverage benefit.** https://www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/pharmacare/programs/special-authority
Date	October 15, 2024
Reason(s)	Drug coverage decision is consistent with the CDEC and DBC recommendations that Verquvo be reimbursed for the treatment of symptomatic chronic HF in adult patients with reduced ejection fraction who are stabilized after a recent HF decompensation event requiring hospitalization and/or IV diuretic therapy if costs are addressed. • Evidence from a randomized clinical trial demonstrated that patients with symptomatic chronic HF who were treated with Verquvo were less likely to die from cardiovascular events or be hospitalized due to HF compared to standard of care alone. • Based on CRR's assessment of the health economic evidence, Verquvo does not represent good value to the health care system at the public list price. • The Ministry participated in the pan-Canadian Pharmaceutical Alliance (pCPA) negotiations with the manufacturer which were able to address the concerns identified by the CDEC and DBC with respect to the cost-effectiveness and value for money.

The drug review process in B.C.

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

An independent group called the Drug Benefit Council (DBC) gives advice to the Ministry by considering:

- whether the drug is safe and effective
- advice from a national group called Canada's Drug and Health Technology Agency (CADTH)
- what the drug costs and whether funding it provides good value to the province
- ethical considerations of covering and not covering the drug
- input from physicians, patients, caregivers, patient groups and drug submission sponsors

The Ministry makes a BC PharmaCare coverage decision by taking into account:

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

Visit BC PharmaCare and Drug reviews 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.

Drug Benefit Council (DBC) Recommendation and Reasons for Recommendation

FINAL

Vericiguat (Verquvo®)

Bayer Inc.

Description:

Drug review of **vericiguat (Verquvo®)** for the following Health Canada approved indications:

> For the treatment of symptomatic chronic heart failure (HF) in adult patients with ejection fraction (EF) less than 45% who are stabilized after a recent worsening HF event.

In their review, the DBC considered the following: the final reviews completed by the Common Drug Review (CDR) of the Canadian Agency for Drugs and Technologies in Health (CADTH) on June 30, 2023, which included clinical and pharmacoeconomic evidence review material and the CADTH recommendations. The DBC also considered Patient Input Questionnaire responses from one patient group, as well as patient input provided to the CDR, a Clinical Practice Reviews from a specialist, and a Budget Impact Assessment.

Dosage Forms:

Verquvo® is available as vericiguat 2.5 mg, 5 mg, and 10 mg oral tablets.

Recommendations:

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

Of Note:

- If a price reduction is achieved, the reimbursement criteria and conditions recommended by CADTH are an appropriate basis for coverage.
- The DBC noted that the current standard of quadruple HF therapy includes treatment with a sodium-glucose cotransporter 2 (SGLT-2) inhibitor. The trial did not include patients receiving background treatment with an SGLT-2 inhibitor because the VICTORIA trial was designed and completed before the current therapeutic paradigm, that now includes SGLT-2 inhibitors, was widely adopted.

Reasons for the Recommendation:

1. Summary

- Results from one phase III, multicentre, double-blind, randomized placebo-controlled trial demonstrated that treatment with vericiguat when added to dual or triple background HF therapy resulted in added clinical benefit for patients with symptomatic chronic HF with a reduced ejection fraction (HFrEF) who are stabilized after a recent HF decompensation event.
- Compared with placebo, treatment with vericiguat was associated with a statistically significant and clinically meaningful reduction in the hazard of a first event of cardiovascular (CV) death or hospitalization for heart failure (HHF).
- A price reduction would be required for vericiguat to be considered cost-effective.

2. Clinical Efficacy

- The DBC considered the CADTH systematic review, which included one phase III, randomized, multicentre, double-blind, event-driven, placebo-controlled trial (VICTORIA, n= 5,050) designed to assess the efficacy and safety of vericiguat versus placebo as an adjunct to standard of care therapy in adults with symptomatic chronic HF and an ejection fraction of less than 45% who are stabilized after a recent worsening HF event.
- Background therapy included beta blockers, angiotensin-converting enzyme inhibitors (ACEis), angiotensin receptor blockers (ARBs), or an angiotensin receptor–neprilysin inhibitor (ARNI), and mineralocorticoid receptor antagonists (MRAs).
- The primary efficacy end point was the time to first event of the adjudicated CV death or HHF, and the key secondary end points were time to CV death, time to first event of HHF, time to total events (first and recurrent) of HHF, time to first event of all-cause mortality or HHF, and time to all-cause mortality.
- Compared with placebo, treatment with vericiguat was associated with a statistically significant and clinically meaningful reduction in the hazard of a first event of CV death or HHF.
- The hazard of total HHF events (first and recurrent) was lower in the vericiguat group relative to placebo in the VICTORIA trial. Compared to placebo, the hazard of the first event of all-cause mortality or HHF was lower in the vericiguat group.
- Health-related quality of life (HRQoL) was assessed using the Kansas City Cardiomyopathy Questionnaire (KCCQ, a self-administered, 23-item, disease-specific questionnaire used to measure HRQoL in patients with HF over a 2-week recall period) and EQ-5D instruments (a generic self-reported HRQoL outcome measure that can be applied to a variety of health conditions and treatments).

- No clinically meaningful differences in HRQoL were found between treatment groups in change from baseline KCCQ scores and 5-Level EQ-5D (EQ-5D-5L) index scores at week 32.
- For detailed information on the systematic review of vericiguat please see the CDEC Final Recommendation at: https://www.cadth.ca/vericiguat.

3. Safety

- Vericiguat is a soluble guanylate cyclase (sGC) stimulator. Another drug in its class, riociguat (Adempas®), is indicated for chronic thromboembolic pulmonary hypertension (CTEPH) and pulmonary arterial hypertension (PAH).
- No new safety signals for vericiguat were identified in patients with HFrEF.
- For detailed information on the safety and tolerability of vericiguat, please see the CDEC Final Recommendations at the links above.

4. Economic Considerations

- At the manufacturer's submitted price, the incremental cost-effectiveness ratio (ICER) for vericiguat in combination with background therapy was $62,778 per quality-adjusted life-year (QALY) compared with background therapy alone.
- Vericiguat is not cost-effective at a willingness-to-pay threshold of $50,000 per QALY for adults with chronic HF and reduced ejection fraction who are stabilized after a recent HF decompensation event. A price reduction would be required for vericiguat to be considered cost-effective at this threshold.
- The BIA indicated that listing vericiguat would incur a significant budget impact.

5. Of Note

- According to the patient group input, HF is a leading cause of death and hospitalization in Canada, with an estimated 750,000 people living with heart failure, and an additional 100,000 people diagnosed with this incurable condition each year.
- HF is uncurable and progressive, and symptoms may include shortness of breath, extreme fatigue, low blood pressure, dizziness, edema, bloating, palpitations, and arrhythmia.
- None of the patients responding to the patient group survey had experience with vericiguat. Patient group input indicated that vericiguat may alleviate a gap in current therapy for HFrEF patients with worsening symptoms and hospitalization for HF in the past 6 months.