

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	cyclosporine
Brand Name	Verkazia™
Dosage Form(s)	Topical ophthalmic suspension 0.1%
Manufacturer	Santen Inc.
Submission Type	New Submission
Use Reviewed	Verkazia is used for the treatment of severe vernal keratoconjunctivitis in children four years of age and older.
Common Drug Review (CDR)	Yes, CDR recommended: to Reimburse with clinical criteria and/or conditions.
	Visit the CDR website for more details: www.cadth.ca/node/88649 .
Drug Benefit Council (DBC)	The DBC met on November 18, 2019. The DBC considered the following: the final reviews completed by the Common Drug Review (CDR) on November 18, 2019, which included clinical and pharmacoeconomic evidence review material and the recommendations from the Canadian Drug Expert Committee (CDEC). The DBC received no Patient Input Questionnaire responses from patients, caregivers, or Patient Groups. The DBC also considered patient input received by the CDR, a Clinical Practice Review from a specialist, an Other Drug Agencies Review Recommendations document prepared by the Canadian Agency for Drugs and Technologies in Health (CADTH), and a Budget Impact Assessment.
Drug Coverage Decision	Non-Benefit
Date	March 23, 2021

Reason(s)	Drug coverage decision is consistent with the DBC recommendation.
	One double-masked, triple-arm, parallel-group, phase III randomized controlled trial (RCT)
	comparing two cyclosporine 0.1% arms (four times daily, or twice daily) to vehicle (placebo)
	found cyclosporine 0.1% was statistically significantly better than vehicle using both
	treatment regimens in a composite efficacy outcome representing response to treatment
	and improvement in ocular surface (corneal fluorescent staining score at assessment visit
	adjusted through penalties based on the use of rescue medication and the development of
	corneal ulcerations). There was no evidence found for the validity, reliability, responsiveness,
	or minimum important difference of the composite primary end point.
	At the submitted price Verkazia was not considered cost-effective for this indication. The
	Ministry participated in the pan-Canadian Pharmaceutical Alliance negotiations with the
	manufacturer which were not able to address the concerns identified by the CDEC with
	respect to the cost-effectiveness and value for money.
Other	Verkazia is the first drug to receive the indication for vernal keratoconjunctivitis.
Information	

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 Common Drug Review (CDR)
- 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 <u>The Drug Review Process in B.C. - Overview</u> and <u>Ministry of Health - PharmaCare</u> 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.