

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	teduglutide
Brand Name	Revestive®
Dosage Form(s)	5 mg/vial powder solution for subcutaneous injection
Manufacturer	Shire Pharma Canada ULC
Submission Type	New Submission
Use Reviewed	Short Bowel Syndrome (SBS)
Common Drug Review (CDR)	Yes, CDR recommended: to Reimburse with clinical criteria and/or conditions. Visit the CDR website for more details: https://www.cadth.ca/about-cadth/what-we-do/products-services/cdr/reports
Drug Benefit Council (DBC)	DBC met on September 12, 2016. DBC considered various inputs including: final reviews completed by the CDR, which included clinical and pharmacoeconomic evidence review material and the recommendations from the Canadian Drug Expert Committee (CDEC). The DBC also considered Patient Input Questionnaire responses from one Patient Group through the Ministry's patient input mechanism, Your Voice, Clinical Practice Reviews from one specialist, and a Budget Impact Assessment.
Drug Coverage Decision	Non-Benefit
Date	August 15, 2017
Reason(s)	<p>Drug coverage decision is consistent with the DBC recommendation.</p> <ul style="list-style-type: none"> Based on two randomized controlled trials (RCTs) reviewed by the CDR comparing teduglutide with placebo, only one RCT showed that teduglutide 0.05mg/kg/day dose was associated with statistically significant higher reduction in parenteral nutrition (PN) volume and a reduction in the number of PN days/week. Results from one trial failed to show statistical difference between the higher 0.10 mg/kg/day dose and placebo, and neither trial showed an improvement in quality of life measures. The CDR and DBC concluded there continues to be substantial uncertainty on the impact of teduglutide on clinical outcomes due to small sample sizes in the RCTs, the exploratory nature of one RCT and the inconsistent results between the two RCTs. Based on economic considerations and the submitted product price, teduglutide is not cost effective. Some jurisdictions through the pan-Canadian Pharmaceutical Alliance (pCPA) entered into negotiations with the manufacturer, but BC not to participate in the negotiations because the DBC recommended teduglutide not be listed due to uncertain clinical benefit.
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 [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 the [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.