

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	pasireotide
Brand Name	Signifor®
Dosage Form(s)	0.3 mg, 0.6 mg and 0.9 mg ampoules
Manufacturer	Novartis Pharmaceuticals Canada Inc.
Submission	New Submission
Review	
Use Reviewed	For the treatment of adult patients with Cushing's disease for whom medical therapy is appropriate
Common Drug	Yes, CDR recommended: Do not list .
Review (CDR)	Visit the CDR website for more details: www.cadth.ca/node/88649 .
Drug Benefit	Pasireotide was not reviewed by the DBC as the CDR recommended not to list pasireotide for
Council (DBC)	this indication.
Drug Coverage	Non-Benefit
Decision	
Date	September 1, 2015
Reason(s)	 Pasireotide was not reviewed by the DBC because it received a "Do not list" recommendation from the CDR. The Ministry of Health reviewed clinical evidence and pharmacoeconomic reports prepared by the CDR, the Final Canadian Drug Expert Committee (CDEC) Recommendation and Reasons, Clinical Practice Reviews from two specialists and public input from one patient, one caregiver and one patient group collected through the Ministry's patient input mechanism, Your Voice. CDEC concluded that the clinical benefit of pasireotide for the treatment of Cushing disease is uncertain, due to limitations in the design of the single uncontrolled trial and the absence of a clear rationale for the response rate threshold. Pasireotide did not achieve the primary end point with the 0.6 mg twice daily recommended dose of pasireotide. Primary end point was defined as a reduction in urinary-free cortisol (UFC) level within the upper limit of the normal range without dose increase in the first six months.
	 There was a high proportion of participants who discontinued treatment within 12 months (60%).
Other	None
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:

- advice from a national group called the Common Drug Review
- whether the drug is safe and effective
- whether it is a good value for the people of B.C.
- the ethics of covering or not covering the drug
- input from physicians, patients, caregivers, patient groups and drug submission sponsors

The Ministry makes a decision based on many factors, including:

- advice from the DBC
- drugs used to treat similar medical conditions that B.C. PharmaCare already covers
- the overall cost of covering the drug

Visit the B.C. <u>Drug Review Process</u> and <u>PharmaCare</u> program 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.