

B.C. Ministry of Health Services Drug Coverage Decisions

About PharmaCare

B.C. PharmaCare helps British Columbians with the cost of eligible prescription drugs and specific medical supplies.

PharmaCare Coverage

The Ministry of Health Services (Ministry) makes PharmaCare coverage decisions by considering existing PharmaCare policies, programs and resources and the evidence-based recommendations of an independent advisory body called the Drug Benefit Council (DBC). The DBC's advice to the Ministry is based upon a review of many considerations, including available clinical and pharmacoeconomic evidence, clinical practice and ethical considerations, and the recommendations of the national Common Drug Review, when applicable.

Inside

Page 1 includes the Ministry decision and reasons in wording that is easier for readers without a medical background to understand. **Page 2** summarizes the DBC recommendation, the Ministry's decision and the reasons for the Ministry's decision.

Delta-9-tetrahydrocannabinol plus cannabidiol (Sativex®) for add-on nerve pain relief in multiple sclerosis

Understanding the DBC Recommendation and PharmaCare Coverage Decision

Background

- **Multiple sclerosis (MS)** is a condition where the protective covering (myelin) of the nerve cells in the brain and spinal cord break down. The nerve cells no longer function properly. This results in muscle weakness, poor muscle control, and problems with vision.
 - Some patients experience intense sharp or burning pain. This is called nerve pain.
 - MS is different for each person. Some patients have mild symptoms and others have serious symptoms affecting their daily lives.
 - Most patients with MS experience mild to serious symptoms which may progress at a slow rate. There may be times with no symptoms or only mild symptoms.
- The drug product that contains extracts of marijuana with the chemical names of **delta-9-tetrahydrocannabinol plus cannabidiol** has the brand name **Sativex®**.
 - These drugs have a direct action on the nerves to relieve pain.
 - Delta-9-tetrahydrocannabinol plus cannabidiol is used to treat nerve pain in patients with multiple sclerosis. It is also used to treat pain in advanced cancer not controlled by high doses of strong painkillers known as opioid analgesics.
 - This drug product is sprayed under the tongue or on the inside of the cheek (**buccal administration**).

Why was this drug reviewed?

- Drug company request.

What did the review find?

- One study shows that delta-9-tetrahydro-cannabinol plus cannabidiol was only modestly effective in treating nerve pain in patients with MS. It was not effective in improving day-to-day function.
 - Side effects in this study included dizziness.
- This drug product is more costly than other medications used to treat nerve pain in MS.

What decision was made?

- Delta-9-tetrahydrocannabinol plus cannabidiol will not be covered.

Key Term(s)

- No key term.

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

Please visit us online to find out more about the Pharmaceutical Services Division and the PharmaCare program at www.health.gov.bc.ca/pharme. To find out more about how drugs are considered for PharmaCare coverage, visit www.health.gov.bc.ca/pharme/formulary.



Delta-9-tetrahydrocannabinol plus cannabidiol (Sativex®) as adjunctive neuropathic pain relief in multiple sclerosis

Drug Class

- Cannabinoid analgesic

Available Dosage Forms

- 27 mg/mL / 25 mg/mL buccal spray

Sponsor/Requestor

- Bayer Inc.

Submission (Request) to PharmaCare

- Drug review of delta-9-tetrahydrocannabinol plus cannabidiol (Sativex®) for the following Health Canada-approved indication:
 - Adjunctive treatment for the symptomatic relief of neuropathic pain in multiple sclerosis (MS) in adults.

Drug Benefit Council (DBC)

Recommendations

- Delta-9-tetrahydrocannabinol plus cannabidiol not be listed.

Reasons for the Ministry of Health Services Decision

- A literature search identified one small randomized controlled trial (RCT) comparing delta-9-tetrahydrocannabinol plus cannabidiol to placebo in adult patients with neuropathic pain associated with MS.
 - This RCT enrolled 66 patients, and was four weeks in duration. This trial was designed to detect a between-group difference of 1.75 on an 11-point numerical rating scale (NRS-11) for pain. Delta-9-tetrahydrocannabinol plus cannabidiol significantly reduced NRS-11 pain scores from baseline by 2.7 points (a 42% relative reduction) compared to a reduction of 1.4 points (a 23% relative reduction) with placebo.

- The DBC determined that this statistically significant difference only represented a modest clinical benefit, with wide variability in effect. Delta-9-tetrahydrocannabinol plus cannabidiol was associated with statistically significant improvements in neuropathic pain scale scores (NRS-11) and sleep disturbances, but there were no statistically significant differences in patient global impression of change, MS function status, Guy's Neurological Disability Score, or neuropsychological tests.
- In the RCT, there were no statistically significant differences in adverse drug events (ADEs) or serious ADEs, but there was a higher rate of dizziness in the treatment group, with a number needed to harm (NNH) of 3.
- In the RCT, the mean daily dose was 9.6 sprays which would cost \$25.62 per day. This is more costly than other agents used to manage neuropathic pain in MS.

Decision and Status

- **Not a benefit.**
- December 23, 2008

Key Term(s)

- No key term.