

WORK SAFE. FOR LIFE.
WORKERS' COMPENSATION BOARD OF NOVA SCOTIA

2011 Update

***Clinical Efficacy of Medical Marijuana:
Summary of Evidence-Based Research***

FOR PUBLIC DISTRIBUTION

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Overview

In September 2008, the WCB issued a position statement and background paper on the approval of Medical Marijuana, based largely on a comprehensive review of the scientific literature regarding herbal marijuana commissioned by the Workers' Compensation Board of Alberta in 2002. In this 2008 position statement, the WCB concluded that:

- Approval of medical marijuana is not recommended under any circumstances due to:
 - The lack of objective data supporting its effectiveness;
 - The lack of objective data supporting its safety;
 - It is not a generally accepted practice in medicine in Canada.

The objectives of this 2011 update to the position statement on medical marijuana are:

- to determine if there is any new evidence to change the WCB position on medical marijuana; and
- to examine evidence regarding the efficacy of newer synthetic versions of marijuana (including Marinol[®], Cesamet[®] and Sativex[®]).

Background

Legislation / Policy

The following legislative provisions are relevant to determining entitlement to medical aid, including medical marijuana:

Medical aid is defined by section 2(r) of the Workers' Compensation Act (the Act) which states:

(r) "medical aid" includes

(i) any health care service, product or device that may be authorized by the Board and is provided to a worker as a result of a compensable injury, including those forms and reports required by the Board respecting the aid or services, and

(ii) reasonable expenses, authorized by the Board, incurred by a worker in order to obtain medical aid

This means that medical aid includes not only health care services, products and devices but also any expenses incurred to obtain the health care (i.e. medical aid travel).

Section 102 of the Act provides discretionary authority for the WCB to determine entitlement to medical aid. Specifically, Section 102 states:

(1) The Board may provide for any worker entitled to compensation pursuant to this Part, or any worker who would have been entitled to compensation had the worker suffered a loss of earnings equivalent to the amount determined pursuant to subsection 37(4), any medical aid the Board considers necessary or expedient as a result of the injury.

(2) The medical aid provided pursuant to subsection (1) shall be

(a) furnished or arranged for by the Board as it may direct or approve;

(b) subject to the supervision and control of the Board; and

(c) paid for out of the Accident Fund.

(3) The Board may include the costs of providing medical aid in any amount charged to the employer or to the employer's class or subclass.

In making the determination of whether the medical aid is considered necessary or expedient, the WCB considers *Policy 2.3.1R – Provision of Health Care Services* which states:

1. The WCB will assist in providing health care (services and treatments) by WCB-approved service providers to injured workers. Assistance is provided where the health care is:

(a) appropriate for the type of compensable injury, and

(b) consistent with standards of health care practices in Canada.

2. The WCB uses the following information to determine the most appropriate, effective and efficient health care for its clients:

a) recommendations from WCB-approved health care providers;

b) up-to-date scientific evidence about effective health care;

c) evidence-based guidelines developed by professional health organizations across Canada and the United States; and

d) standards developed by the WCB to ensure quality health care.

3. The WCB may obtain additional information and opinions, as needed, to determine the appropriateness of any type of health care.

4. The WCB will not pay for health care that is not considered appropriate as set out in this policy.

In providing the medical aid, the WCB has the authority to determine the necessity, character and sufficiency of the medical aid, as per Section 104 of the *Act*. This means the WCB determines the need for the medical aid, the type of medical aid and the extent to which the medical aid is required.

Medical Marijuana Background

Herbal (smoked) Marijuana*

Marijuana (marihuana, cannabis) is the common name for *Cannabis*, a hemp plant that grows throughout temperate and tropical climates. Although the leaves and flowering tops of *Cannabis* plants yield more than 60 different phyto-cannabinoids, the primary active component is the complex chemical delta-9-tetrahydrocannabinol (Δ^9 -THC)¹. The concentration of THC and other cannabinoids in marijuana varies significantly depending on growing conditions, plant genetics and processing after harvest.

Herbal marijuana (cannabis) has not been approved by Health Canada for sale as a therapeutic product in Canada. Marijuana is categorized as a controlled substance, and it is not legal to grow or possess marijuana except with legal permission by Health Canada. On July 30, 2001, Health Canada issued the *Marihuana Medical Access Regulations*². These Regulations allow access to marijuana to people who are expected to experience some medical benefit that outweighs the risk of its use.

Synthetic Cannabinoids³

In addition to herbal marijuana, pharmaceutical companies have manufactured 3 synthetic versions of THC available by prescription, collectively referred to as synthetic cannabinoids:

- Dronabinol is an oral form of synthetic THC available in capsules and is marketed in Canada as Marinol® since 1994.
- Nabilone is also an oral form of synthetic THC and is marketed in Canada as Cesamet® since 1981.
- Sativex® is a buccal spray containing synthetic THC that has been available in Canada since 2005.

* The term “herbal marijuana” is interchangeable with the terms “medical marijuana” and “smoked marijuana”.

Review of Evidence-Based Research

Herbal (smoked) Marijuana

In 2010, Health Canada states that while there are many anecdotal reports of the therapeutic value of smoked marijuana, scientific studies supporting the safety and efficacy of marijuana for therapeutic claims are generally inconclusive. Health Canada has issued the following statement regarding herbal marijuana:

“Marihuana (marijuana, cannabis) is not an approved therapeutic substance in Canada and no marihuana product has been issued a notice of compliance by Health Canada authorizing sale in Canada.”⁴

Since 2004, the Nova Scotia Pharmacare* program has relied on the *Atlantic Expert Advisory Committee*⁵ and the *Canadian Expert Drug Advisory Committee (CEDAC)* recommendations to determine if drugs should be listed on the provincial drug formulary.⁶ CEDAC is an advisory body to the *Canadian Agency for Drugs and Technologies in Health*, composed of individuals with expertise in drug therapy and drug evaluation, and public members. CEDAC's approach is evidence-based, and the advice reflects medical and scientific knowledge, current clinical practice, and patient and public impact. CEDAC makes recommendations to the participating federal, provincial, and territorial publicly funded drug plans regarding the listing on their formularies.⁷

For drugs developed prior to 2004, the NS Pharmacare program determined if a drug should be listed on the formulary based on recommendations from Health Canada. As herbal marijuana was in existence prior to 2004, the NS Pharmacare program has followed the above Health Canada recommendation and does not include herbal marijuana on the provincial drug formulary.

Synthetic Cannabinoids

Dronabinol (Marinol®):

An oral form of synthetic THC that is available in the Canadian market. This drug has approved indication by Health Canada for the management of severe nausea and vomiting associated with cancer chemotherapy and approved indication for second line treatment of AIDS-related anorexia associated with weight loss.⁸

As Marinol® was in existence prior to 2004, the NS Pharmacare program has followed the above Health Canada indications, with Marinol® not included on the provincial drug formulary but granted the following exception status:

* Nova Scotia provides assistance to eligible residents through various programs to help pay for prescribed medications and supplies listed in the Nova Scotia Formulary.

- *for treatment of severe nausea and vomiting associated with cancer chemotherapy in patients who have failed a traditional stepwise approach to antiemetic therapy*
- *for second line treatment of AIDS-related anorexia associated with weight loss*⁹

Nabilone (Cesamet®):

Also an oral form of synthetic THC, available in the Canadian market. This drug has approved indication by Health Canada for the management of severe nausea and vomiting associated with cancer chemotherapy.¹⁰

As Cesamet® was in existence prior to 2004, the NS Pharmacare program has followed the above Health Canada indication, with Cesamet® not included on the provincial drug formulary but granted the following exception status:

- *for management of severe nausea and vomiting associated with cancer chemotherapy*¹¹

Sativex®:

A buccal spray containing synthetic THC, available in Canada since 2005. This drug has approved indication by Health Canada (under a conditional notice of compliance) as an adjunctive treatment for the symptomatic relief of neuropathic pain in adults with multiple sclerosis (MS) and as an adjunctive analgesic in adult patients with advanced cancer who experience moderate to severe pain during the highest tolerated dose of strong opioid therapy for persistent background pain. Health Canada's conditional Notice of Compliance states:

*"Marketing authorisations with conditions reflect the promising nature of the clinical evidence and the need for confirmatory studies to verify the clinical benefit. Patients should be advised of the conditional nature of the authorizations with conditions."*¹²

As Sativex® was developed post 2004, the NS Pharmacare program has relied on CEDAC's recommendations to determine if Sativex® should be included on the provincial drug formulary. CEDAC released its final recommendation on Sativex® in relation to MS in September 2007. In this release, CEDAC recommended that Sativex® not be listed on the drug formulary for the symptomatic relief of neuropathic pain in MS patients as the efficacy of this drug in MS patients has been evaluated in only one small, short-term randomized controlled trial which reported clinically modest improvement in pain relief compared to placebo.¹³

CEDAC released its final recommendation on Sativex® in relation to advanced cancer in February 2008. In this release, CEDAC recommended that Sativex® not be listed on the drug formulary for treatment in advanced cancer patients as the efficacy of this drug in advanced cancer patients has been evaluated in one 2-week randomized controlled trial which reported clinically modest improvement in pain relief compared to placebo.¹⁴

Based on both of the above CEDAC recommendations, the NS Pharmacare program has not included Sativex® on the provincial drug formulary and has not granted the drug any exception status.

A search of the Cochrane database was also conducted. No Cochrane Reviews* were found on the medicinal use of cannabis or synthetic cannabinoids for pain.

Jurisdictional Comparison

In August 2011, Canadian workers' compensation jurisdictions were polled to determine if practices regarding approval of medical marijuana had changed since the previous polling done in 2008. Results indicate that practices regarding approval of medical marijuana have not changed since 2008 and all jurisdictions continue to not authorize medical marijuana. A small subset provide exceptions if treatment is in relation to MS or occupational cancers, on a case-by-case basis. The following table summarizes jurisdictional responses:

JURISDICTION	PROCEDURE FOR MEDICAL MARIJUANA APPROVAL
British Columbia	There has been no change in WorkSafeBC's policy re approval of medical marijuana for treatment of chronic pain, since 2008: we do not approve these requests. We do, on occasion, approve for synthetic cannabinoids: when being prescribed for M.S. or occupational cancers etc, they are reviewed on a case by case basis.
Manitoba	The WCB of Manitoba has not yet approved medical marijuana for chronic pain. They have approved synthetic versions of marijuana in a few instances after weighing the risk-benefit ratio but these cases are the exception. They do not have a specific policy on this matter but instead review each case on its own merits.
Newfoundland and Labrador	Medical marijuana is not contained within any of the Commission's drug formularies. Should there be a request, it must go through a medical consultant. In general, the only indication for medical approval is for the treatment of the side effects of chemotherapy in the case of occupational cancer.
Ontario	WSIB does not approve medical marijuana for the treatment of non-malignant pain. Synthetic cannabis preparations (Cesamet, Marinol, Sativex) may be considered as an exception in some specific cancer cases consistent with the scientific literature.
Prince Edward Island	The WCB of PEI does not pay for medical marijuana. This is outlined in Policy POL04-70. There have not been any cases whereby medical marijuana was approved for the treatment of chronic pain.
Yukon	The YWCHSB does not approve, and has not approved, medical marijuana.
NWT and Nunavut	The WSCC only compensates for medications identified by the Canadian Pharmacists Association (CPA) in the Compendium of Pharmaceuticals and Specialties (CPS). The SCC accepts medication with a valid Drug Identification

* Cochrane Reviews are systematic reviews of primary research in human health care and health policy, and are internationally recognised as the highest standard in evidence-based health care

JURISDICTION	PROCEDURE FOR MEDICAL MARIJUANA APPROVAL
	Number (DIN) as found in the CPS. Prescription and non-prescription drugs must be identified by the CPA for treating the work-related injury or disease and, as per the CPS, follow a proper and advisable course of treatment.

Recommendation

Taking into consideration the evidence-based research for herbal marijuana and synthetic cannabinoids, as well as procedures followed by other workers' compensation jurisdictions, the following are the recommendations with respect to herbal marijuana and synthetic cannabinoids at the WCB of Nova Scotia:

Herbal Marijuana: Scientific studies supporting the safety and efficacy of marijuana for therapeutic claims continue to be generally inconclusive. As a result, Health Canada in 2010 has declared marijuana is not an approved therapeutic substance in Canada and has not issued a notice of compliance authorizing its sale in Canada. Following Health Canada's position, the NS Pharmacare program does not include herbal marijuana on the provincial drug formulary. In addition, all other workers' compensation jurisdictions continue to support the position that medical marijuana is not an approved treatment. Therefore, the WCB of Nova Scotia should maintain its current position statement that approval of medical marijuana is not recommended under any circumstances.

Synthetic Cannabinoids

Dronabinol (Marinol®) and Nabilone (Cesamet®): Both of these drugs have approved indication by Health Canada for the management of severe nausea and vomiting associated with cancer chemotherapy. In addition, Dronabinol (Marinol) has approved indication by Health Canada for second line treatment of AIDS-related anorexia associated with weight loss. Following Health Canada's approved indications, the NS Pharmacare program has granted exception status for both drugs for nausea and vomiting associated with cancer chemotherapy and for Dronabinol for AIDS-related anorexia, but has not included these drugs on the provincial formulary (exception status only). Jurisdictional review indicates that BC and NFLD also provide exceptions for these drugs if treatment is in relation to occupational cancers, on a case-by-case basis. Therefore, the WCB of Nova Scotia should adopt the position that approval of these synthetic cannabinoids is not recommended, however exceptions may be considered in claims accepted for occupational cancers.

Sativex®: This drug has a conditional Notice of Compliance by Health Canada for symptomatic relief of neuropathic pain in MS patients and for moderate to severe pain in advanced cancer patients. The *Canadian Expert Drug Advisory Committee* (CEDAC) has recommended Sativex® not be listed on provincial formularies in relation to MS or advanced cancer due to the lack of scientific evidence on the efficacy of the drug. Following CEDAC's recommendations, the NS Pharmacare program does not include Sativex® on the provincial drug formulary (no exception status). Jurisdictional review indicates that only BC provides exceptions for this drug if

treatment is in relation to MS. NB explicitly states they do not provide exceptions for Sativex® in relation to MS as MS is a non-compensable condition. The WCB of NS has adopted the following position regarding MS:

Approval of claims associated with the development of MS due to the work environment or the exacerbation of symptoms of MS due to the work environment is not recommended due to:

- *The lack of objective data supporting a definitive causal link between environment and the development and/or exacerbation of MS;*
- *The inconclusive results from the evidence-based research on this topic.*

Considering all of the above evidence, it is recommended the WCB of Nova Scotia should adopt the position that approval of the synthetic cannabinoid Sativex® is not recommended under any circumstances.

Concluding Remarks

The table below provides a summary of the WCB updated Position Statement on Medical Marijuana:

ISSUE	POSITION STATEMENT
Approval of medical marijuana (herbal)	Approval is not recommended under any circumstances due to: <ul style="list-style-type: none"> • the lack of objective data supporting its effectiveness; • the lack of objective data supporting its safety; • it is not a generally accepted practice in medicine in Canada.
Approval of medical marijuana (synthetic cannabinoids)	Approval is not recommended due to the lack of objective data supporting the safety and efficacy of synthetic cannabinoids. Exceptions may be considered for approval of Dronabinol (Marinol®) and Nabilone (Cesamet®) in claims accepted for occupational cancers for management of severe nausea and vomiting associated with cancer chemotherapy as there is objective data supporting efficacy for this indication. Approval is not recommended for Sativex®, under any circumstances due to the lack of objective data supporting its efficacy.

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- ⁵ Atlantic Common Drug Review website. Last viewed 6 September 2012. Available at: <http://www.gov.ns.ca/health/Pharmacare/committees/acdr.asp>
- ⁶ NS Pharmacare website. Last viewed 6 September 2012. Available at: <http://www.gov.ns.ca/health/pharmacare/benefitsfaq.asp> under “Who makes the decisions regarding the benefit status of medications listed in the Nova Scotia Formulary?”
- ⁷ Canadian Agency for Drugs and Technologies in Health website . Last viewed 6 September 2012. Available at: <http://www.cadth.ca/en/cadth>
- ⁸ MARINOL Product Monograph. Last viewed 7 September 2012. Available at: http://www.abbott.ca/static/cms_workspace/en_CA/content/document/MARINOL-PM-01JAN11.pdf
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- ¹⁰ Cesamet Product Monograph. Last viewed 7 September 2012. Available at: http://www.calefbiomedicalconsulting.com/misc_files/product_cesamet_monograph.doc
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- ¹³ Canadian Agency for Drugs and Technologies in Health website – CEDAC Final Recommendation on Sativex for MS patients. Last viewed 21 September 2011. Available at: http://cadth.ca/media/cdr/complete/cdr_complete_Sativex_September-26-2007.pdf
- ¹⁴ Canadian Agency for Drugs and Technologies in Health website - CEDAC Final Recommendation on Sativex for advanced cancer. Last viewed 21 September 2011. Available at: http://www.cadth.ca/media/cdr/complete/cdr_complete_Sativex-Resubmission_February-20-2008.pdf