Cat. No. V32-444/2022E-PDF
ISBN 978-0-660-45391-0

April 2022

AUDIT OF HEALTH CARE BENEFITS

Cannabis for Medical Purposes

Audit and Evaluation Division

VETERANS.GC.CA

Canada

Acknowledgements

The audit team gratefully acknowledges staff members from Veterans Affairs Canada, Medavie Blue Cross, and McMaster University's Michael G. DeGroote Centre for Medicinal Cannabis Research. Their contributions were essential to the success of this audit.

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EXECUTIVE SUMMARY

Why we did this audit

Since 2008, Veterans Affairs Canada (VAC) has reimbursed Veterans for the cost of Cannabis for Medical Purposes (CMP) when obtained following federal regulations. More and more Veterans are now seeking reimbursement for CMP either because conventional treatments fail to relieve their pain or cause negative side effects.

While it is legal to access CMP, Health Canada has yet to approve cannabis as a therapeutic product in Canada. There is a need for more research on CMP's effectiveness and safety. Ultimately, health care practitioners must weigh all of the risks with the potential benefits before authorizing the use of CMP as a treatment for a specific condition.

While VAC waits for research to better guide how cannabis might be used as a therapeutic treatment, this audit assessed what the department is doing right now to address the potential health concerns and financial impacts of this treatment benefit.

Key facts, figures and findings

- Through its policy, the Department reimburses Veterans up to three grams of CMP per day at a fixed rate of up to $8.50 per gram. However, it can reimburse up to 10 grams/day if a Veteran meets exceptional criteria. As of 31 December 2020:
    - 19% are being reimbursed less than 3 grams/day
    - 61% are being reimbursed the maximum 3 grams/day
    - 20% are being reimbursed more than 3 grams/day per exceptional criteria
    - Those that meet exceptional criteria are reimbursed on average 7.1 grams/day, which is extremely high compared to the Health Canada-reported average of 2 grams/day for Canadians accessing CMP.
    - The vast majority have mental health conditions, in particular Post Traumatic Stress Disorder (PTSD), which are considered a contraindication by health organizations such as the College of Family Physicians of Canada and Health Canada.

- An extremely small number of health professionals (11) are responsible for authorizing a disproportionately large percentage (more than 6,000 or roughly 40%) of the Veterans being reimbursed for CMP.

- Between 2015-16 and 2019-20, Veterans authorized for CMP increased by 660%. Currently, more than 13,000 clients are being reimbursed for CMP.

- In 2020, CMP spending was at $85.2 million. By 2026, VAC anticipates spending of more than $300 million, with an additional $12 million in transactional costs.

- VAC continues to assess current research and support areas of needed research into CMP as a treatment for Veterans. However, VAC can do more to identify trends in the CMP program that may be problematic and adjust policy to safeguard the health and well-being of Veterans.

- As demand for the CMP program continues to grow exponentially, VAC will need to properly manage resources and examine policy and program effectiveness.

Highlights of our recommendations

As Health Canada has not approved CMP as a therapeutic treatment, VAC must take considerate and cautious measures to improve oversight when supporting Veterans in this treatment through the reimbursement of costs.

VAC has an opportunity to consult stakeholders and engage with health experts in developing a stronger policy and monitoring framework that will support the health needs of Veterans and their families.

What Veterans Affairs Canada will do

VAC will continue to update the *Reimbursement Policy for Cannabis for Medical Purposes* based on the evolving environment and consultation with health experts and stakeholders. This update will include guidance on which conditions are eligible to have CMP reimbursed, daily gram limits, and the nature of products.

Under the revised policy, program updates will include a new CMP authorization form for health care providers to complete, indicating specific details on conditions being treated, CBD/THC composition, and plan for follow-up care. Veterans accessing reimbursement for larger amounts of CMP will also need to complete a new follow-up assessment tool with their health care provider.

VAC will strategically analyze information gathered through its CMP program to inform future policy adjustments and help identify Veterans who may be at high risk for negative health effects.

1.0 BACKGROUND

Cannabis for medical purposes

In Canada, and other countries around the world, CMP is an evolving area of study and course of treatment. Scientific evidence substantiating the efficacy and safety of this treatment remains limited. Anecdotally, people report that using cannabis is a natural product that helps manage symptoms for various conditions. Currently, cannabis is being authorized as a treatment for a variety of medical conditions.

Increasing numbers of Veterans are now using CMP, either because conventional treatments fail to relieve their pain or because they suffer from severe negative side effects caused by those treatments.[1]

Legal access to CMP falls under the *Cannabis Act*, which was established in October 2018, replacing the *Access to Cannabis for Medical Purposes Regulations*.

> Although it is legal to access CMP, Health Canada has not approved cannabis as a therapeutic product in Canada, and warns:
>
> *"the use of this product involves risks to health, some of which may not be known or fully understood. Studies supporting the safety and efficacy of cannabis for therapeutic purposes are limited and do not meet the standard required by the Food and Drug Regulations for marketed drugs in Canada."*
>
> Health Canada Santé Canada

There are a couple of pharmaceutical medications which have been developed (Sativex® and Cesamet®) that contain cannabinoids and have been approved for specific indications by Health Canada.

Herbal medical cannabis, such as dried cannabis and oils, have not gone through Health Canada's drug review and approval process, and do not have a Drug Identification Number (DIN) or Natural Product Number (NPN). [2]

[1] Subcommittee on Veterans Affairs, Standing Senate Committee on National Security, Canadian Use of Cannabis for medical Purposes (June 2019, Ottawa) p.8
[2] Canadian Pharmacist Association, Medical Cannabis Q&A, (2017) p.1

The Canadian Medical Association and the College of Family Physicians of Canada echo this point and caution their members in authorizing CMP as a treatment.

Both the Canadian Medical Association and the College of Family Physicians of Canada note that there is insufficient evidence and clinical information on the safety and efficacy for most therapeutic claims of CMP.[3] [4]

That said, CMP research has shown some success with low- tetrahydrocannabinol (THC) and high cannabidiol (CBD) products. This has laid the groundwork for national health insurance providers to cover CMP for specific conditions, including:

- Pain and other symptoms in a palliative setting;
- Loss of appetite or nausea due to treatments for cancer or HIV/AIDS;
- Spasticity or neuropathic pain associated with Multiple Sclerosis;
- Spasticity due to spinal cord injury;
- Refractory pediatric onset epilepsy; and
- Chronic Neuropathic Pain

Insurance providers who cover CMP do so under very controlled circumstances with limitations on quantity, cost, methods of administration, and requirements for continued monitoring and reporting.

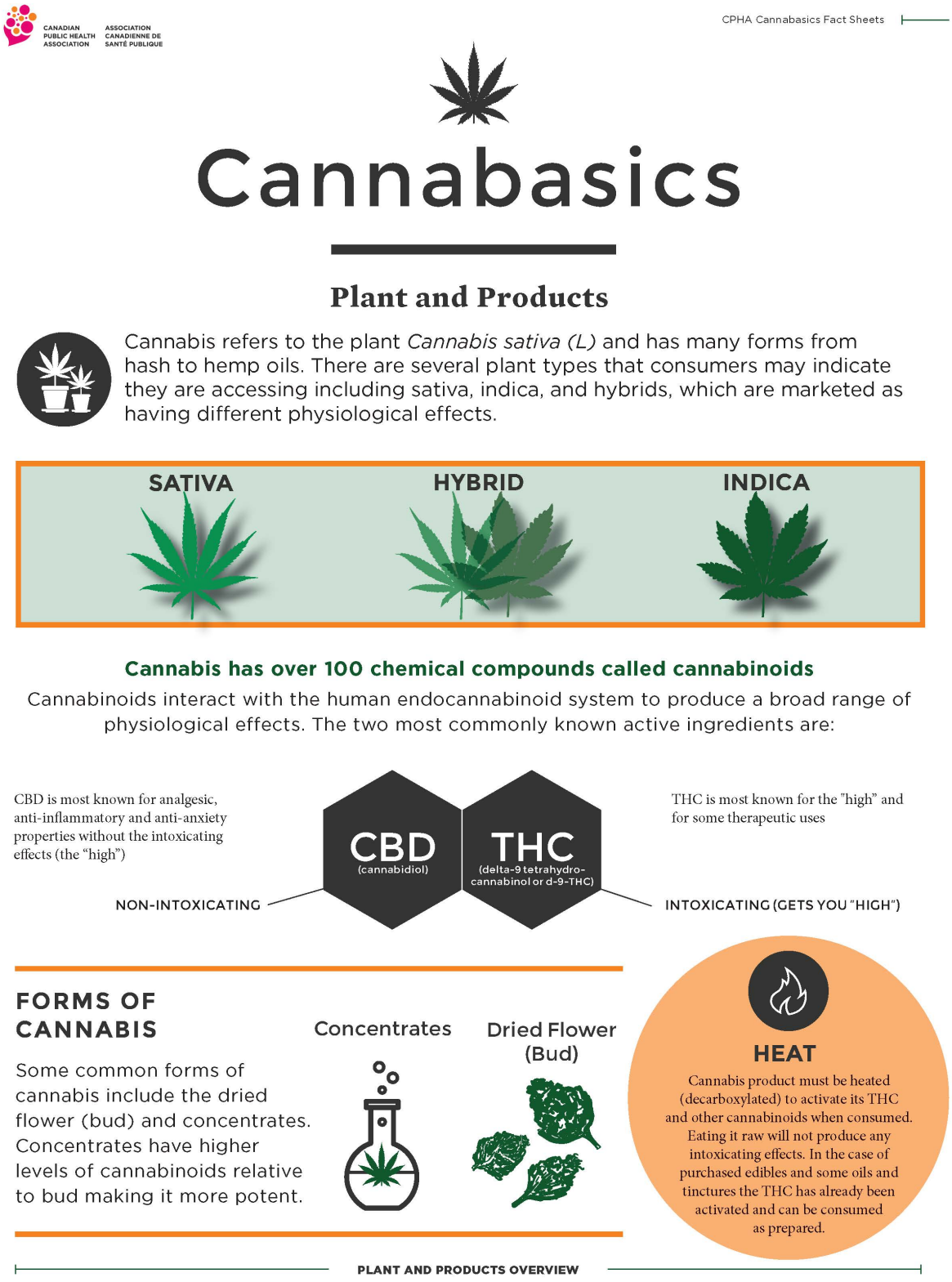
The College of Family Physicians of Canada also states that physicians should follow the regulations and guidelines of their provincial College when authorizing CMP as a treatment. The guidelines set out by the provincial and territorial Colleges are relatively similar in nature and include:

- physicians must weigh the available evidence in support of cannabis against other available treatment options
- advise patients about the material risks and benefits of cannabis
- physicians must exhaust other possible treatments before authorizing cannabis and must document the treatments that were attempted but failed.
- assess a patient's risk of addiction using a validated addiction risk tool

The following fact sheet, shown in **Figure 1**, provides a basic overview of common cannabis plants and products, methods of consumption as well as information to better understand consumption and harm reduction.

[3] Canadian Medical Association, Authorizing Cannabis for Medical Purposes (2020)
[4] College of Family Physicians of Canada, Guidance in Authorizing Cannabis Products Within Primary Care (2021)

Figure 1: *Cannabasics*, Canadian Public Health Association[5]



[5] Canadian Public Health Association, Cannabasics (2018), p1

Benefits and risks

There is limited medical evidence for the use of CMP. However, the field of study is continuing to grow as cannabis is more used as a treatment and has also been legalized in some areas of the world.

In addition to the need for more research on CMP's effectiveness and safety, there is currently no scientifically defined dose of cannabis for any specific medical condition. Dosing remains highly individualized and relies greatly on finding the right dose where potential therapeutic effects are maximized while adverse effects are minimized.[6]

Different strains of cannabis have varying degrees of potential effects depending on the relative THC and CBD content. Both THC and CBD are associated with pain relieving and anti-inflammatory effects. However, THC may produce psychoactive effects while CBD has been linked to anti-nausea, anti-anxiety and muscle relaxing effects.

THC causes the intoxicating effects (or "high") and the impairing effects, but it can also cause anxiety and other adverse effects. CBD is not intoxicating and may reduce some of the effects of THC; however, it does have an effect on the brain. Higher levels of THC can cause greater levels of impairment and increase your risk of experiencing serious adverse effects.

The College of Family Physicians of Canada guidelines on CMP recommend that an authorization for a CMP product that contains THC should also have CBD in it to balance out the psychoactive effects. They go further to note that for smoked cannabis, "original doses should be at most nine percent THC (with appropriate CBD) at doses of 0.4grams to 0.7 grams per day. If the THC percentage increases, the gram dosing should be decreased appropriately."[7]

Concerns have also been raised by the Canadian Centre on Substance Use and Addiction. Despite its legalization and promising research for its medical application, regular use of cannabis can lead to adverse health outcomes. Regular cannabis use can affect mental health; cognitive functioning, including attention and memory; as well as respiratory and cardiovascular health. Also noting that regular cannabis use can increase the risk of developing psychosis and schizophrenia.[8]

The Centre also acknowledged that it is presently not clear on the extent to which regular cannabis use leads to depression or anxiety, after accounting for common factors (e.g., socioeconomic status, alcohol use etc.). However, problematic cannabis use and cannabis use disorder is more common among individuals with mood and anxiety disorders compared to those who are not experiencing these conditions. Regular cannabis use is generally associated with more harms than benefits among individuals with mental health

[6] Health Canada, Access to Cannabis for Medical Purposes Regulations – Daily Amount Fact Sheet (2016), p.1
[7] College of Family Physicians of Canada, Guidance in Authorizing Cannabis Products Within Primary Care (2021) p. 10
[8] Canadian Centre on Substance Use and Addiction, Clearing the Smoke on Cannabis; Highlights (2020), p.3

conditions. [9]

Ultimately, it is critical that health care practitioners authorizing the use of CMP as a treatment weigh all of the risks with the potential benefits. Extensive education and rigorous follow-up care are essential to quickly identify if the treatment stops working as intended. Follow-up care is also needed to identify and address negative side effects that can hurt a patient's long-term rehabilitation.

The equivalency factor

Oil, edibles, extracts and topicals: How does it all weigh up?

The equivalency factor is based on the quantity of dried cannabis that is required to produce 1 mL of cannabis oil.

The formula for converting dried cannabis into oils, edibles, extracts or topicals are often considered proprietary in nature by a Federal Licensed Seller based on the specific product.

When processing a CMP order, the Federal Licensed Seller will use their formula to deduct the equivalent of dried grams of cannabis based on the client's authorization.

However, there is a gram equivalency that the government of Canada uses to identify possession limits based on weights.

For example:

1 gram of dried cannabis = 0.25 grams of concentrates (solids or liquid)

[9] Canadian Centre on Substance Use and Addiction, Clearing the Smoke on Cannabis; Highlights (2020), p.3

Accessing cannabis for medical purposes in Canada

Canadians wishing to purchase CMP must adhere to the *Cannabis Act and Regulations*. Under these regulations, the general process to purchase CMP is as follows:

A patient meets with their healthcare practitioner to discuss whether CMP is a good treatment choice.

The healthcare practitioner (a licensed physician or nurse practitioner) provides them with a formal "medical document" which is the "authorization" for the patient to access CMP from one of Canada's federal licensed sellers.

Once the patient has the medical document (i.e., the authorization), they register with a federally licensed seller(s). The medical document is sent to the federal licensed seller and kept on file.

Once registered with a federal licensed seller, the patient can order product and have it delivered.

Interestingly, other than authorizing the number of grams/day, the medical document template provided by Health Canada provides no details on important information such as condition being treated, the method of administration (smoking, topical oil, etc.) or the type of cannabis product. Essentially, a patient is free to purchase any product from the federal licensed seller as long as they stay within the daily dosage limit.

The Michael G. DeGroote Centre for Medicinal Cannabis Research sums this up on its website as follows: "Fundamentally, 'prescriptions' for medicinal cannabis are authorizations for access, not a precise identification of a controlled medication that is prepared and dispensed by a trained pharmacist. They are more like permission slips with non-binding recommendations than actual prescriptions for medications."[10]

[10] Corinne Hodgson and Dr. Ramesh Zacharias, When is a prescription not a prescription? (2017)

In contrast, the use of prescription for a regulated drug would be filled through a pharmacy. A pharmacist provides a layer of oversight to ensure patients understand proper dosing information and to identify any negative drug interactions. For CMP, there is no pharmacy oversight required. Although some clients choose to go through a pharmacy service that offers cannabis, most do not.

The Canadian Pharmacist Association echoes these concerns in their independent assessment report: *Improving Medical Marijuana Management in Canada.*

Canadian Pharmacists Association / Association des pharmaciens du Canada

While Health Canada has published guidelines that include available clinical evidence, potential risks, and daily use limits, there is still insufficient formalized guidance for health care practitioners regarding strains, dosages and forms.

In their report, the Canadian Pharmacist Association also noted that when protecting patient safety, "the aim should be to move the bar as high as we'd expect for any product that is used for medical purposes." As well as the "Adoption of prescription drug-like attributes for CMP leads to appropriate controls being in place to better protect public health safety.[11]

Health Canada reported that in March 2021, more than 292,000 Canadians were registered to access CMP. The average daily amount authorized by health care practitioners for these individuals who access from federally licensed sellers has remained relatively constant at 2 grams/day since the coming into force of the *Cannabis Act* in October 2018.[12]

Cannabis for medical purposes at VAC

VAC's mandate is to support the well-being of Veterans and their families. One of the ways this is achieved is through listening to the suggestions of Veterans, their representatives and stakeholders to guide work and research, and strive to design and deliver programs that meet the modern and changing needs of Veterans and their families.

In 2008, VAC started reimbursing for the cost of CMP on an exceptional basis to Veterans who obtained the product following federal regulations. VAC then continued to cover costs of CMP for Veterans who were approved by Health Canada through the *Medical Marihuana Access Regulations* based on certain categories of symptoms and conditions. In 2012, VAC implemented guidelines to help provide direction for requests of CMP as a treatment as federal regulations continued to change. In 2016, the Office of the Auditor General of Canada released a report on VAC drug benefits. The report included a recommendation for

[11] Canadian Pharmacists Association, *Improving Medical marijuana Management in Canada* (2016)
[12] Health Canada, Data on cannabis for medical purposes (2021),

VAC to explore ways to manage the rising costs of CMP.

In March 2016, the Minister of Veterans Affairs announced a comprehensive review of CMP. The Audit and Evaluation Division's review resulted in a report recommending, among other things, the development and implementation of a policy for CMP. VAC has acknowledged that CMP is an evolving area of treatment and that it would monitor information and continue to adjust the policy to ensure the well-being of Veterans and their families.

VAC's policy on CMP coverage falls under the Treatment Benefits Program of Choice "POC 10" that covers prescription drugs. The CMP program is managed by a small staff of 3.5 full time employees, with support from VAC's Health Professionals group.

The VAC's Reimbursement Policy on Cannabis for Medical Purposes (the Policy) became effective on 22 November 2016. The policy has been updated to remain current with the changes to federal regulations.

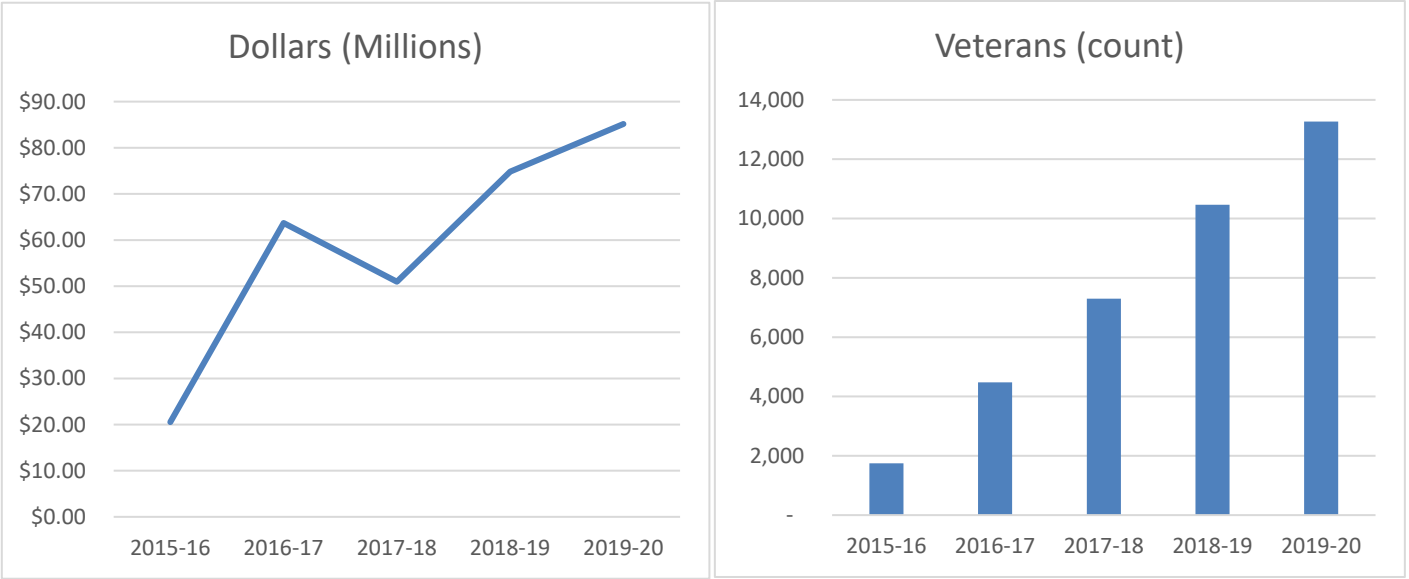
The Policy:

- establishes a reimbursement limit of 3 grams/day of cannabis sold by licensed sellers or its equivalent in fresh cannabis, cannabis oil, cannabis edibles, cannabis extracts or cannabis topicals.
- outlines an exceptional approval process for Veterans seeking reimbursement for more than 3 grams/day limit through consultation with relevant medical specialists.
- states reimbursement will be made based on a maximum rate per gram of cannabis.

Veterans order their CMP directly from the federal licensed seller which then bills VAC for the cost. The Veteran is not out of pocket. VAC uses a third-party service provider to manage the authorization process and to pay these invoices.

The number of VAC clients with active authorizations for CMP has been increasing year over year resulting in a 660% increase between 2015-16 and 2019-20. Costs for CMP reimbursements have increased significantly as well. See **Figure 2** for details.

Figure 2 : Historical Cannabis Reimbursement Dollars and Veteran Count



Source: AED analysis based on data extracted from FHCPS system

There was a slight decrease in 2017-18 costs showing the impact of the implementation of the Policy. However, in subsequent years, this was more than offset by an increase in demand for CMP. The stakeholders interviewed have attributed the increase in demand to the legalization of cannabis in Canada in 2018 citing increased acceptance from both prospective patients and authorizing health care professionals.

VAC has two streams for Veterans to be reimbursed for CMP: up to 3 grams/day and the exceptional process for more than 3 grams/day.

- **Up to 3 grams/day** will be approved as long as the medical authorization lists the Veterans' disability benefits entitled conditions (or "entitled condition"). VAC does not restrict CMP to certain conditions. VAC does not know for which condition (if there are multiple conditions) the CMP is being used to treat.

- **Exceptional Process (in excess of 3 grams/day)** requires additional information. The request must have a supporting letter by a medical specialist with expertise in the condition for which CMP is authorized (psychiatrist, pain specialist, etc.). The specialist is not the authorizer, they are supporting the request for the excess of 3 grams/day. The Department has added an administrative cap on the program of 10 grams/day.

As shown in **Figure 3**, on 31 December 2020, 60% of Veterans are receiving reimbursement for the maximum 3 grams/day, and 20% were exceptionally approved for more than 3 grams/day.

Figure 3: Active CMP Authorizations as of December 31, 2020

User Group	Veteran Count	% of Total Authorizations
Under 3 grams/day	2,674	19.4%
3 grams/day	8,395	60.9%
Over 3 grams/day	2,747	19.9%

Source: AED analysis based on data extracted from FHCPS system

VAC Supported Research

In 2018, the Subcommittee on Veterans Affairs of the Standing Senate Committee on National Security and Defence launched a study on Canadian Veterans' use of CMP. Their report addressed VAC's reimbursement policy for CMP and reiterated the consensus view that more research on the use of CMP is greatly needed.[13]

VAC is working closely with partners, such as McMaster University's Michael G. DeGroote Centre for Medicinal Cannabis Research, that continues to review and pursue study into CMP.

In 2021, McMaster University released the results of a systematic review and meta-analysis of randomized clinical trials regarding medical cannabis or cannabinoids for chronic non-cancer and cancer related pain. This research was funded by VAC. The expert panel provided a summary of recommendations and was confident that non-inhaled medical cannabis or cannabinoids:

- Result in a small increase in the proportion of people living with chronic pain experiencing an important improvement in pain and sleep quality (high and moderate certainty evidence, respectively);
- Result in a very small increase in the proportion of people living with chronic pain experiencing an important improvement in physical function (high certainty evidence); and
- Do not improve emotional functioning, role functioning, or social functioning (high certainty evidence).[14]

VAC continues to assess and support the research needs in the area of CMP treatment for Veterans. The rapid recommendations that resulted from the research done by McMaster University is the starting point for the VAC-funded development of clinical guidelines for cannabis use in treating chronic pain, which will wrap up in 2024.

[13] Subcommittee on Veterans Affairs, Standing Senate Committee on National Security, Canadian Use of Cannabis for medical Purposes (June 2019, Ottawa) p.8

[14] Wang L, Hong PJ, May C, Rehman Y, Oparin Y, Hong CJ, Hong BY, AminiLari M, Gallo L, Kaushal A, Craigie S, Couban RJ, Kum E, Shanthanna H, Price I, Upadhye S, Ware MA, Campbell F, Buchbinder R, Agoritsas T, Busse JW. Medical cannabis or cannabinoids for chronic non-cancer and cancer related pain: a systematic review and meta-analysis of randomised clinical trials. BMJ. 2021 Sep 8;374:n1034. doi: 10.1136/bmj.n1034. PMID: 34497047

2.0 ABOUT THE AUDIT

2.1 Audit objectives and scope

Audit objectives:

While VAC waits for research to catch up, this audit assessed what the Department is doing right now to address serious risks with this treatment benefit.

- Given the experimental nature of CMP as a treatment, has VAC implemented controls to mitigate the risk to Veterans' health and well-being?

- Given the exponential growth of demand for the CMP treatment benefit, has VAC established controls to manage the financial impact on public funds?

Scope:

The scope of the audit is VAC's management of the treatment benefit CMP from 1 April 2019, to 31 December 2020. The audit excludes:

- Health Canada's licensing and inspection of Federal Licensed Sellers and
- Medavie Blue Cross's process for setting up / registering providers and Authorizers

The audit team conducted their work and analysis within the appropriate authorities of the department and following the *Privacy Act*. The audit findings and conclusions contained in this report are based on sufficient and appropriate audit evidence gathered in accordance with procedures that meet the Institute of Internal Auditors' International Standards for the Professional Practice of Internal Auditing as supported by the results of the quality assurance and improvement program.

The opinions expressed in this report are based on conditions as they existed at the time of the audit and apply only to the entity examined.

Additional information including the audit criteria and methodology are provided in Appendices A and B.

3.0 AUDIT RESULTS

3.1 Non-exceptional stream (3 grams and under per day)

Veterans can easily access reimbursement for CMP through VAC's Health Care benefits, especially if their authorization is under 3 grams a day of dried cannabis or the equivalent in fresh cannabis, edible cannabis, cannabis extracts (including cannabis oil) or cannabis topicals.

VAC currently covers CMP for any pensionable condition, even though Cannabis is not an approved therapeutic treatment in Canada. In doing so, VAC must ensure the benefits outweigh the risk to Veteran's health and well-being, including their risks for substance misuse, substance use disorders, and related health consequences.

While there are countless anecdotal reports concerning the therapeutic uses of cannabis, clinical studies supporting the safety and efficacy of cannabis for therapeutic purposes in a variety of disorders are limited. As noted, there is no scientifically defined dose of cannabis for any specific medical condition. Dosing remains highly individualized. The current available information suggests most individuals use less than 3 grams daily of dried cannabis.

Given these uncertainties, VAC established a maximum reimbursement of 3 grams/day of dried CMP (or equivalent in other product types) when it developed its Reimbursement Policy on Cannabis for Medical Purposes (the Policy) in 2016 as a means to mitigate the potential health risks to Veterans.

For the 3 gram/day threshold to be effective, the audit team expected that the majority of Veterans would be reimbursed for fewer than 3 grams/day. We found that the 3 grams/day maximum was not effective in limiting the health risk to Veterans as shown by the low decline rates and by the high percentage of authorizations at the 3 grams/day and over at 31 December 2020.

VAC policy does not address conditions covered or comorbid health conditions

VAC has only one requirement for accessing CMP reimbursement for this group: that the medical document lists an entitled condition. Decline rates for requests up to 3 grams/day are very low. The audit determined that decline rates for this group was at most 1.9% during our scope. The low decline rates are a direct result of the fact that VAC has not restricted / mapped specific entitled conditions to access CMP reimbursement like it has for other treatment benefits.

The audit noted that insurance providers have begun to offer coverage for CMP, but for

only very few conditions (none of which are mental health related) and with other limitations, such as dollar caps and the need for extensive documentation.

The Canadian Medical Association and the College of Family Physicians of Canada caution its members in authorizing CMP. In the College of Family Physicians of Canada's guidance in authorizing CMP, they note that there is little research evidence to support the authorization of cannabis as a treatment for pain conditions commonly seen in primary care. They do suggest authorizations for CMP can be considered for patients with chronic neuropathic pain or palliative cancer pain that has failed to respond to standard treatments.[15]

Percentage of authorizations at 3 grams/day and over

VAC's CMP policy is driving behavior resulting in the majority of Veterans who apply for the benefit are receiving coverage for the daily maximum of 3 grams/day.

VACs external website questions and answers about the Policy notes that "the policy was based on the published guideline from the College of Family Physicians of Canada, that advises that, '...the upper level to the safe use of dried cannabis will be on the order of 3.0 g per day, and that even this level of use should be considered only in very circumscribed conditions.'"

As shown in the following table (**Figure 4**), at 31 December 2020, 81% of the active authorizations were for 3 grams/day or more.

Figure 4: Active CMP Authorizations by User Group
31 December 2020

User Group	Veteran Count	% of Total Authorizations	Average Grams Authorized
Under 3 grams /day	2,674	19.4%	1.7
3 grams/day	8,395	60.9%	3
Over 3 grams/day	2,747	19.9%	7.1

Our data analysis shows a very high correlation between an increase in the number of grams/day authorized with each subsequent authorization. If these trends continue, we will see more Veterans accessing CMP through the exceptional process, which is already high at almost 19% of authorizations. Internal medical experts have indicated that the exceptional rate should be closer to 1-2%.

Data analysis also showed that the average grams/day authorized for Veterans in the exceptional group (i.e., over 3 grams/day) is 7.1 grams which is very high in comparison to the Health Canada reported average of 2.0 grams/day for Canadians accessing CMP.

[15] College of Family Physicians of Canada, Guidance in Authorizing Cannabis Products Within Primary Care (2021) p.6

Health Canada estimates that 1 in 11 (9%) of those who use cannabis will develop an addiction to it. However, if a person smokes cannabis daily, the risk of addiction is 25% to 50%.[16]

VAC's policy does not address THC / CBD content

As noted, THC has some therapeutic effects, but it also has harmful effects. CBD is another therapeutic cannabinoid. Unlike THC, CBD does not produce a "high" or intoxication.

Experts agree that as THC increases, the health risk increases. Clinical practice guidelines are limited and evolving. VAC's policy is silent on THC content and business rules don't require that physicians note THC on authorizations. However, the College of Family Physicians of Canada notes that "although it is not required by regulations, physicians should specify the percentage of THC on all medical documents authorizing cannabis, just as they would specify dosing when prescribing any other analgesic."

The College of Family Physicians of Canada also recommends using the following harm reduction strategy for establishing dosage: "We recommend that initial total daily dose for oil consumption does not exceed 2 grams/day. Inhaled (and smoked) cannabis could be started at 0.5 grams/day. We recommend using the smallest effective dose and keeping the total maximum daily dose at 5 grams/day or lower." They also note that, "while 2.5 grams to 3.0 grams a day is considered an appropriate upper limit of individual dosing, larger amounts might be required when using oils. To approximate, 1.0 grams (or 1 mL or 1 cc) of cannabis oil could require approximately 3.0 grams to 3.5 grams of dried cannabis."[17]

Without collecting and analyzing critical information about Veterans' use of CMP, the Department cannot identify trends that may be problematic and adjust policy to safeguard the health and well-being of Veterans.

Recommendation #1:

Part 1: It is recommended that the Assistant Deputy Minister of Strategic Policy and Commemoration in consultation with the Assistant Deputy Minister of Service Delivery reviews and updates the policy for CMP with a lens for the health and well-being of Veterans. This review and update would include:

a) Seeking external expert guidance on the Policy for CMP

b) Updates to the policy must address guidance around:

[16] Health Canada, Addiction to cannabis (2021)
[17] College of Family Physicians of Canada, Guidance in Authorizing, Cannabis Products within Primary Care, (2021), p.40, p36, p.40

I. Conditions covered;
II. Comorbid health conditions and contraindications that would affect the use of CMP as a treatment option;
III. Limits on daily grams/day, as well as guidance and limits to the THC/CBD content in CMP products covered; and
IV. Method of administration and what types of products are covered under the policy.

c) Continue to review and update the policy regularly based on the evolving research and regulations concerning CMP.

Part 2: It is also recommended that the Assistant Deputy Minister of Service Delivery update and adjust related program processes and business rules to align with policy changes.

Management agrees with this recommendation.

Since 2016, the policy has been updated four times to reflect the evolving environment associated with cannabis. Similar to 2016, external experts and internal stakeholders will be engaged to provide guidance that will inform an updated policy.

The updated policy will include more detailed guidance around the nature of conditions for which CMP will be reimbursed, daily gram limits, and the nature of products included.

Service Delivery Program Management division is committed to working with Contract Administration, the Policy and Research Division, the Health Professionals Division and the third-party service provider to support, implement and operationalize changes to the Reimbursement Policy for Cannabis for Medical Purposes.

This includes developing functional guidance, developing and delivering required training and effectively communicating changes to program processes and requirements to Veterans, the medical community, federal licensed sellers and external stakeholders.

Recommendation #2:

It is recommended that the Assistant Deputy Minister of Service Delivery develop a detailed authorization form for CMP that would allow the authorizing Health Care Practitioner to demonstrate their due diligence in recommending CMP as a treatment option for the Veteran. The health care practitioner will need to provide more specifics on the course of CMP treatment for their client's condition(s).

This would include, but not be limited to:

- the primary and secondary conditions being treated,

- type of CMP to be used,
- method of administration and frequency, and
- the specific THC/CBD composition.

The form should note any comorbid conditions as well as previous treatments that were unsuccessful. It should also note if the authorizer is the client's family doctor or include assurance that the information will be provided to the family doctor by the authorizing health care practitioner. The authorization form should include the plan for ongoing follow-up with the Veteran over the course of the CMP treatment.

Only the products purchased from a Federal Licensed Seller that match the detailed authorization form would be eligible for reimbursement by VAC.

Management agrees with this recommendation.

Program Management has been developing a detailed VAC authorization form to be completed by health care practitioners authorizing cannabis for medical purpose.

Service Delivery and Program Management is committed to finalizing development of this form in consultation with Health Professionals, Access to Information and Privacy, and VAC Legal Services, and effectively communicating new requirements regarding the use of this form to Veterans, the medical community, federal licensed sellers and external stakeholders.

3.2 Exceptional authorizations above the CMP limit (over 3 grams per day)

The exceptional process business rules are being followed. However, the demand for exceptional approval of more than 3 grams a day continues to grow.

Veterans who routinely take high dosages of CMP (especially with high THC) over a prolonged time can:

- result in psychological dependence (addiction),
- increase the risk of triggering or aggravating psychiatric and/or mood disorders (schizophrenia, psychosis, anxiety, depression, bipolar disorder)

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[18] Health Canada, Consumer Information - Cannabis (Marihuana, marijuana) (2016)

The “exceptional process” refers to the policy enacted steps needed for Veterans requesting access to reimbursement for more than the 3 grams/day maximum. The exceptional process involves additional requirements to address the heightened risk of accessing additional daily amounts of CMP. In addition to needing the medical document to list the entitled condition, the exceptional process requires a letter from a medical specialist supporting the necessity of the additional amount.

VAC’s policy requirements are broken down into detailed “business rules” which inform the third-party service provider on the detailed steps necessary to approve authorization requests and to pay invoices to federal licensed sellers. We expected that the additional controls VAC implemented for this group of Veterans would be effective in addressing the heightened risk and in supporting the health of Veterans.

The audit found that the business rules for the exceptional process were being followed by the third party service provider; however, they were not effective in addressing the heightened risk of this group. Essentially, rules have been streamlined for expediting access and are not balanced with the well-being of Veterans.

Patient Follow-up Care by Health Care Practitioners

While guidelines from the provincial Colleges of Physicians and Surgeons vary, there is a general consensus that a health care practitioner must be considerate of all previous health issues, treatments and potential risks when authorizing CMP. They also note the importance of a follow-up plan and evaluating the patient regularly.

In their guidance on authorizing CMP, the College of Family Physicians of Canada recommends regularly monitoring patients and using harm reduction strategies such as:

- When initiating CMP, establish specific and realistic treatment objectives,
- Schedule follow-up visits every four to eight weeks after initiating the treatment and as needed, or every three months when the dose is stable, and
- With regular CMP users, plan for periodic re-assessments of CMP therapy effectiveness and possibility of tapers.[19]

The recommendations that came from the research conducted by McMaster University also provide insight into the importance of follow-up appointments between a patient using CMP and their health practitioner. It notes that, once a trial of medical cannabis has been initiated, unexperienced cannabis users should be reviewed at least every month until a stable dose is achieved; experienced users can be reviewed after three months.

[19] College of Family Physicians of Canada, Guidance in Authorizing, Cannabis Products within Primary Care, (2021), p.36

The recommendations also explained that if benefits are limited or problematic side effects are reported, health care practitioners may choose to end treatment, adjust dosage (grams and THC/CBD content), or change the route of administration. Cannabis should be discontinued if, despite these strategies, patients continue to experience problematic side effects, a maximum dose is achieved without important benefits, or patients are diverting cannabis or develop a cannabis use disorder. If management with medical cannabis is successful, patients should be followed up (for example, every three to six months) after a stable dose has been achieved.[20]

Denial rates for exceptional authorization requests

Given the potential risks to Veteran's health and the additional measure put in place by VAC for those seeking reimbursement of more than 3 grams/ day, we expected denial rates to be relatively high. The third-party provider reported that the denial rate for this group was approximately 22%. However, this rate was calculated based on individual instances of denials and was not adjusted for those requests that were denied and later approved. Audit and Evaluation Division adjusted the reported denial rate for those that were subsequently approved and noted that the actual denial rate was at most 7.8% during the scope period. Again, this low denial rate illustrates how the controls put in place to mitigate the increased health risk for the exceptional access group are not as effective as intended.

Authorizers with high Veteran patient counts

Experts agree that given the lack of evidence for efficacy and safety coupled with the lack of guidance on dosing, it is important that patients accessing CMP are under careful watch of a medical professional.

VAC's role is to help Veterans access the supports and services they need. VAC does not interfere with the physician-patient relationship of a Veteran. VAC, however, is able to analyze the population and identify concerning areas. For example, there are small number of CMP physician authorizers with a very large Veteran patient loads bringing into question the robustness of the medical oversight. During the audit scope, out of the total 13,796 Veterans being reimbursed for CMP:

- One health practitioner authorized access to CMP for 1,294 Veterans;
- Three more authorized between 700-830 Veterans; and
- Six more authorized over 300 Veterans.

[20] Busse J W, Vankrunkelsven P, Zeng L, Heen A F, Merglen A, Campbell F et al. Medical cannabis or cannabinoids for chronic pain: a clinical practice guideline BMJ 2021; 374 :n2040 doi:10.1136/bmj.n2040

Medical Specialist letters

Medical specialists have become more familiar with VAC's eligibility requirements. They are conscious of the requirements when designing their letters to ensure acceptance. We also noted that specialist letters show very little sign of a strong physician / patient relationship:

- Follow-up recommendations were vague, using wording such as "follow up in six months or as clinically required;"

- Just over half of the specialist letters we reviewed did not mention anything about follow-up;

- Specialists are required to list the contraindications that were considered in their patient evaluation. We noted that the contraindications information provided varied in depth and detail as some noted simply "no contraindications." Additionally, we noted instances where the support letter would make reference in the background section to known contraindications (mental health conditions primarily) but would not list them as outright contraindications with supporting rationale that the benefits would outweigh the risks of the CMP treatment.

Recommendation #3:

For Veterans receiving exceptional amounts of CMP, it is recommended that the Assistant Deputy Minister of Service Delivery incorporate a level of assurance that the health care practitioner authorizing the treatment has provided follow-up assessments with the Veteran, monitoring their symptoms, progress and well-being throughout their CMP treatment.

This level of assurance should happen at least once between the annual renewal of a CMP authorization, and it should provide assurance that the goals of the treatment are being met, and that a mental health assessment was completed which included monitoring for signs of substance use dependency.

Management agrees with this recommendation.

Service Delivery and Program Management commits to implementing a follow-up assessment tool to be completed by the authorizing health care practitioner at intervals established in consultation with the Health Professionals Division.

This includes developing functional guidance, providing required training and effectively communicating changes to program processes and requirements to Veterans, the medical community, federal licensed sellers and external stakeholders, and collecting and reporting pertinent data.

3.3 Collection of data and trends to inform policy

VAC can do more to analyze data and identify trends to inform policy.

As the CMP program continues to mature, and the demand for the program continues to grow exponentially, the department will need to properly manage resources and examine policy and program effectiveness.

There is opportunity to improve data collection efforts such that key information is captured, analyzed, and used for policy decisions.

We expected that VAC would capture and monitor important data and trends to inform its policy regarding CMP. Important data would be on the types of conditions being treated, the type of cannabis being used, the CBD/THC content of products used, and the method of administration.

The audit found that since the Policy for CMP at VAC is relatively new, the program area's focus has been on setting up the reimbursement process and fine tuning the business rules with the third-party provider. Similar to other entitlement-based treatment benefits, the management focus has been on eligibility and access. The program area has collected and monitored some data, however, trend analysis on health and well-being of the Veteran has not been the priority. There is regular reporting from the third-party service provider, but it is more transactional and volume-based reporting.

VAC does require some information to be input into the claims system from both the authorization (authorizer name, grams authorized, federal license seller) and the invoice (grams reimbursed, benefit code of product); however, there is opportunity to improve data collection efforts such that key information is captured, logged in the system, and used for policy decisions. We noted that during our field work, VAC was working on a pilot project with one of the federal licensed sellers to implement an electronic billing process in an effort to reduce transactional costs. It was pointed out that VAC intended to use this opportunity to gather additional information by having a dedicated field for the level of THC content of the product being purchased by the Veteran, and to ensure both the authorizer and specialist information are both collected.

Recommendation #4:

It is recommended that the Assistant Deputy Minister of Service Delivery in consultation with the Assistant Deputy Minister Strategic Policy and Commemoration and the Assistant Deputy Minister of Chief Financial Officer and Corporate Services, develop a strategy for the collection and analyses of important data (including but not limited to: conditions treated, cannabis type, CBD/THC, methods of administration, etc.) to inform policy and a

monitoring framework.

Management agrees with this recommendation.

Service Delivery and Program Management is committed to collaborating with the Policy and Research Division, the Health Professionals Division, the Access to Information and Privacy Division, and the Statistics Division, to develop a strategy for the proper collection and analysis of additional data to inform both policy and a monitoring framework within the Department's authority.

3.4 Monitoring usage trends

VAC does not monitor trends in usage of CMP.

Without collecting and analyzing critical information about Veterans' use of CMP, the department cannot identify trends that may be problematic and adjust policy to safeguard the health and well-being of Veterans.

VAC's mandate, the treatment benefits performance indicators, and the Reimbursement Policy on Cannabis for Medical Purposes (the Policy) all have objectives centered around Veteran health. Given this objective and the lack of research and evidence supporting the efficacy and safety of CMP, we expected VAC to monitor CMP usage trends and take action where warranted. We expected VAC to monitor things such as:

- significant increases in dosages;
- links to conditions that medical organizations characterize as "contraindications;" and
- high CMP use coupled with problematic drug groups.

We found that VAC did not monitor these trends in usage. Most people we spoke to at the Department stated that VAC should be doing more in this regard; however, no action has yet been taken. We also spoke to one independent insurance company who advised that they do monitor drug usage for specific types of drugs and take action when amounts exceed recommended rates. They regularly contact pharmacies and physicians when problems are identified.

One recommendation from The College of Family Physicians of Canada (CFPC) in their guidance for authorizing CMP is that "until further research clarifies effectiveness/harms in treating anxiety, PTSD, or insomnia, cannabis is not an appropriate therapy for these conditions."

However, they did note that when a physician decides to authorize cannabis treatment for patients with co-existing anxiety and neuropathic pain, it is recommended that they:

- keep the dose low to avoid triggering anxiety;
- considers indicating low THC content or CBD-only strains on the medical document; and
- discontinue cannabis if the patient's anxiety or mood worsens.

Further, the CFPC notes that physicians should consider tapering patients on high doses of opioids or benzodiazepines.[21]

Health Canada has also cautioned physicians to use extra care when considering authorizing CMP to patients with:

- respiratory diseases such as asthma or COPD;
- a history of substance abuse; and
- mood disorders or who are taking sedatives or other psychoactive drugs

Given that VAC had not done any analyses on these higher risk situations, the audit team conducted its own analyses on contraindications of disability benefit entitled conditions and drug usage. The audit team analyzed information on all the Veterans being reimbursed for CMP during our scope period and found that:

- the vast majority have mental health conditions, in particular Post Traumatic Stress Disorder (PTSD), which are considered a contraindication by health organizations such as the College of Family Physicians of Canada and Health Canada; and
- 45 Veterans whose entitled condition is for a substance abuse disorder.
- 46 Veterans had been reimbursed for a high amount of CMP (7-10 grams/day) and had also been reimbursed for all four categories of high-risk drugs: anti-depressants, anti-psychotics, Benzodiazepines, and opioid/narcotics.

[21] Guidance in Authorizing Cannabis Products Within Primary Care, College of Family Physicians of Canada (2021) P. 16

- In addition to those 46 Veterans, 149 Veterans had been reimbursed for a high amount of CMP (7-10 g/day) and had also been reimbursed for three of the four categories of high-risk drugs.

VAC does have a policy entitled Prescription Drugs (POC 10) where it describes its adverse drug utilization evaluation (ADUE) process, stating “The Department can impose quantity limits on a case-by-case basis where a client's use of POC 10 benefits is deemed possibly to be excessive, including situations of adverse drug utilization.”

Further information on VAC’s website indicates that the ADUE may result in several actions including education of the client on the ramifications of inter-drug relationships, consultation with the physician, consultation with the pharmacist, and referral of suspected breach of ethics or malpractice by a physician.

The audit team was advised that CMP was excluded from ADUE process because it is technically not an approved regulated drug. We were further advised that VAC was undergoing changes to its ADUE process to look at global trends rather than at the individual Veteran level.

3.5 Monitoring Authorizers

VAC does not monitor trends in CMP authorizers.

With limited guidance available on authorizing CMP, there is a risk that some health care practitioners may be over-prescribing the treatment.

CMP is authorized by the number of grams per day, not prescribed like drugs which have standardized dosages. Medical professionals essentially are the gatekeepers for patients seeking to access CMP in Canada. Federal laws allow authorizers to be physicians or nurse practitioners. VAC has outlined an additional requirement for those Veterans seeking reimbursement under the exceptional process (i.e., greater than 3 grams/day). In these cases, a physician with a specialty in the particular medical diagnoses (for example chronic pain, mental health, etc.) must recommend/endorse the request.

Given the potential risk to Veteran health and well-being, we expected VAC would monitor trends in CMP authorizers and take action where warranted. We found that VAC did not monitor trends in CMP authorizers. The audit did note that other organizations operating in an insurance payer model did not take the same hands-off approach. Rather, these organizations conducted data analyses on physician transactions to identify outliers and took actions where warranted.

Since VAC did not monitor these trends, the audit team conducted its own analyses. In its attempts, the team noted serious data integrity issues with the authorizer data that made it impossible to know the full picture. Specifically:

- For roughly one third of the Veterans authorized during our scope, the authorizer field was blank. The third-party service provider indicated that these would be instances of nurse practitioner authorizations; however, information from our file review showed this was not always the case.

- The authorizer field, when populated, had data integrity issues where there were multiple instances where the same physician was listed multiple times, with multiple id numbers, and with variations on spelling.

- The authorizer field, when populated, was used inconsistently. In some cases, it was the authorizing physician and in other cases, it was the specialist physician.

Even though we were unable to determine the complete profile of the physician authorizer's activities, there were some concerning trends. Removing the blank providers from the calculation, the audit noted:

- Eleven authorizers accounted for almost 40% of the Veterans authorized for CMP.

- Five authorizers accounted for just over 1/4, and these authorizers all authorized high average daily dosages as well.

- Only a small proportion (6.5%) of authorizers were authorizing for more than 3 grams/day.

Recommendation #5:

It is recommended that the Assistant Deputy Minister of Service Delivery develop a risk-based monitoring framework for CMP use with a lens for the health and well-being of Veterans. The framework would support the data strategy (noted in recommendation #4) and include:

a) monitoring such things as increased usage, links to conditions being treated, mental health conditions, other drugs being used, contraindications, cannabis type and method of administration, as well as CBD and THC strengths.

b) criteria that would identify Veterans that are at high risk and ensure they have the appropriate supports available (i.e., Case management, additional treatment benefits, substance abuse supports, Operational Stress Injury clinics).

c) criteria for monitoring authorizations and escalating trends of over-prescribing CMP to the appropriate provincial medical regulatory bodies (i.e., college of physicians) for their own investigation.

Management agrees with this recommendation.

Service Delivery and Program Management will develop a risk-based monitoring framework for CMP use with a lens for the health and well-being of Veterans.

Consultations will be held with the Health Professionals Division, the Access to Information and Privacy Division, Information Technology, Legal Services and the Policy and Research Division to develop a monitoring framework within our authority to identify Veterans at risk and develop a strategy to address those at risk.

3.6 Daily authorized limits

Veterans are not being reimbursed for more cannabis than for which they were authorized.

An authorizing health care practitioner will indicate on the medical document the amount of grams/day being authorized. We expected that VAC would have controls in place to limit reimbursements to the amount of cannabis that had been authorized. Our file testing found that the process is manual in nature and complicated with various dates; however even with these elevated risk factors, Veterans were not being reimbursed for more cannabis than for which they were authorized.

3.7 Monitoring spending

Program Spending:

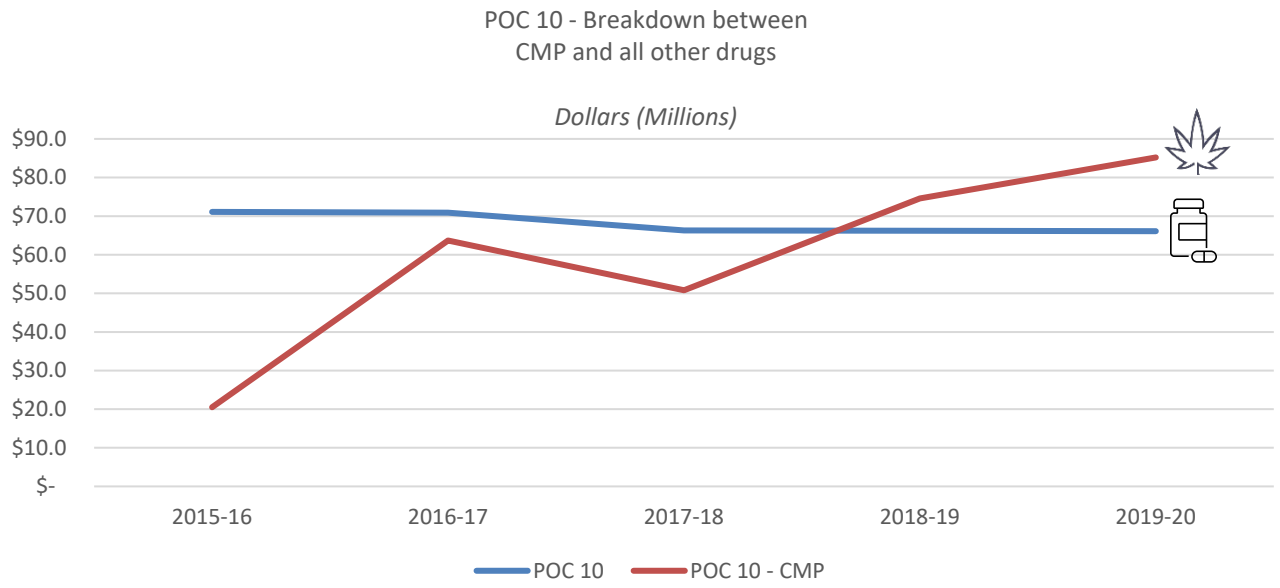
Spending on CMP is increasing at a significant rate. While the department did see a temporary decrease in spending after the implementation of the Reimbursement Policy for Cannabis for Medical Purposes in November 2016, demand for CMP continues to grow.

The Prescription Drug Program (also known as POC 10) is one of 14 treatment benefit programs, or Programs of Choice (POC), offered by VAC to eligible clients. POC 10 provides drug products and other pharmaceutical benefits to eligible clients who have:

- a demonstrated medical need and;
- health professional authorized to prescribe pharmaceuticals

As shown in **Figure 5**, VAC now spends more on CMP than it does for all prescription drugs combined.

Figure 5 : CMP vs Other Prescriptions



Given the significant growth, the audit team expected VAC would monitor CMP spending. We found that VAC had monitored and forecasted spending on CMP primarily through its annual budgeting exercise which is conducted by VAC finance.

The process is systematic and robust and finance staff consult with program area as needed. However, VAC flat-lined its CMP projections in its most recently available Facts and Figures publication. This meant that VAC showed actual 2019-20 CMP spending at $85.2 million and forecasted CMP spending at $143.6 million for each of the 5 next fiscal years. VAC does not flat-line other forecasts. Departmental staff advised that they did not forecast out like other programs because it was relatively new and hard to predict.

Upon discussion with the audit team, VAC staff agreed that sufficient time had passed to formulate projections for CMP spending. At the time of writing, new projections were as shown in **Figure 6**.

Figure 6: CMP Forecasted Expenditures
(millions of dollars)

2020-21	2021-2022	2022-2023	2023-2024	2024-2025	2025-2026
$119.0	$156.0	$195.2	$233.9	$276.0	$321.5

Transactional spending:

In addition to program costs (i.e. the cost of the cannabis itself), there are also transactional costs paid to the 3rd party service provider to process authorization requests and invoice payments. These fees are outlined in the contract terms and conditions. The contract is managed by VAC's Contracting Administration Unit. We found that VAC's Contracting Administration Unit, in consultation with the program area, had monitored and forecasted spending related to the transactional costs associated with CMP processing (FHCPS contract). Transactional costs are high and VAC's Contracting Administration Unit has forecasted these costs to rise to $1 million per month by 2026.

3.8 Maximizing Value of Public Funds

VAC has recognized the growth in demand for CMP but could implement more measures to maximize value of public funds.

Program spending:

Given the historical growth in cannabis spending coupled with the projected continued growth in spending, we expected VAC would have recognized the growth and devised mitigation strategies to address value for cost (e.g., industry partnerships, generic options etc.). We found that VAC had recognized the growth in CMP program spending but had not taken action to identify solutions that would maximize the value of funding for the program.

Reimbursement for CMP falls under treatment benefits which is one of the twenty-five separate quasi-statutory programs managed by VAC. This quasi-statutory funding is demand driven and non-discretionary. In essence, if a Veteran is eligible to use CMP VAC must reimburse the Veteran for the amount and price that fall within the policy.

VAC Finance is monitoring the expenditures monthly as is required under the Treasury Board Financial Management Policy to ensure the sound and prudent use of public funds and accountability to Canadians.

Transactional spending:

VAC's Contracting Administration Unit had recognized the growth in CMP transactional spending and had identified various options to attempt to reduce these costs. VAC's Contracting Administration Unit has a planned pilot project with one of the Federal Licensed Sellers to operationalize one of these cost mitigating options.

Recommendation #6:

It is recommended that the Assistant Deputy Minister of Service Delivery in consultation with the Assistant Deputy Minister of Chief Financial Officer and Corporate Services implement cost-effective solutions related to administrative or product costs.

Management agrees with this recommendation.

Service Delivery and Program Management is committed to consult with Finance Division to seek out ways to identify cost-effective ways to manage the growth of the program.

3.9 Reimbursement rate per gram

VACs Reimbursement Policy for Cannabis for Medical Purposes (the Policy) states that it will reimburse Veterans based on a maximum rate per gram. The policy does not outline the maximum rate, but at the time the policy was established in 2016, the rate was set at $8.50/gram of dried cannabis (or its equivalent in other forms) based on market research at the time.

We expected that VAC would have actively monitored the reasonableness and relevancy of the $8.50/gram reimbursement rate. We found that VAC has been unable to conduct the necessary market research to ascertain whether the $8.50 rate remained appropriate. Federal License Sellers no longer report their prices publicly on their websites, and as such, VAC has not been able to access the market comparables.

Since completing the audit fieldwork, VAC was able to assess and validate the daily reimbursement rate through the third-party service provider that manages the CMP claims.

3.10 Audit Opinion

VAC has taken steps to operationalize its policy to provide Veterans with access to reimbursement for their CMP treatment. However, there remain serious gaps in internal controls in the areas of Veteran health and program management.

As Health Canada has not approved CMP as a therapeutic treatment, VAC must take considerate and cautious measures in improving oversight when supporting Veterans in this treatment through the reimbursement of costs. VAC has an opportunity to consult stakeholders and engage with health experts in further developing a stronger policy and monitoring framework within our authority that will support the health needs of Veterans and their families.

Appendix A - Audit Criteria

Objective	Criteria
1. Given the experimental nature of CMP as a treatment, has VAC implemented controls to mitigate the risk to Veterans' health and well-being?	A. The 3g/day threshold is effective in limiting access to (i.e., reducing risk).
	B. The exceptional process internal controls are effective in addressing heightened risk for this group of Veterans.
	C. Veterans are not reimbursed for more cannabis than for which they have been authorized.
	D. VAC monitors trends in usage (increased usage, linked conditions, mental health conditions, other drugs, contraindications) and takes action where warranted.
	E. VAC monitors trends in authorizations and takes action where warranted.
	F. VAC captures and monitors important data and trend (conditions treated, cannabis type, CBD/THC, methods of administration, etc.) to inform policy.
2. Given the exponential growth of demand for the CMP treatment benefit, has VAC established controls to mitigate the financial risk to VAC?	A. VAC monitors Cannabis spending for trends and forecasting.
	B. VAC has recognized the growth in Cannabis spending and has devised mitigation strategies to address.
	C. VAC actively monitors the reasonableness and relevance of its $8.50/gram reimbursement rate.

* The audit team confirmed that all of the above criteria were met unless otherwise stated in this audit report.

Appendix B - Methodology

Methodology	Purpose
Interviews	Interviews were conducted with VAC staff in program management, policy, health professionals and research. Interviews were also held with research experts in the area of CMP and with the third-party health care practitioner managing the CMP claims for VAC. Interviews were conducted to gather information about the program and its activities, to ensure proper understanding of application of controls, and to validate audit observations.
Documentation Review	Documentation reviews were conducted supporting the audit's objectives. The audit team examined policy documents, business process documents, applications and claims. An environmental analysis was conducted including national and international research and media articles. Industry practices were also examined taking into account guidelines and policies within the health industry and the insurance industry regarding CMP.
File Review	Two separate file reviews were conducted to assess controls over applicant assessments, payments, and monitoring activities. The file reviews included both approved and denied applications.
Data Analyses	Data available was reviewed and analyzed for trends in growth, authorizations, authorizers, contraindications of disability benefit entitled conditions and drug usage.