Minnesota Department of Health
OFFICE OF MEDICAL CANNABIS

Intractable Pain Certification in the MN Medical Cannabis Program:
A Primer for Health Care Practitioners

Contents

Frequently Asked Questions

1. What is the program's definition of "intractable pain"?

At time of certification (and recertification) the certifying health care practitioner must check a box indicating the following:

> *"I certify that this patient has intractable pain. That is, this patient has pain whose cause cannot be removed and, according to generally accepted medical practice, the full range of pain management modalities appropriate for this patient has been used without adequate result or with intolerable side effects."*

2. Does the Office of Medical Cannabis require certain treatments for "intractable pain"?

The Office of Medical Cannabis does not require particular therapeutic modalities for specific patients. Instead, it relies on the professional judgement of the health care practitioner to assess pain management therapies already used and then to develop, in consultation with the patient, a comprehensive paint management plan going forward.

3. Do opioid medications need to be tried before meeting the definition of "intractable pain"?

The Office of Medical Cannabis relies on the professional judgment of the certifying health care practitioner as to whether the full range of treatment approaches appropriate for an individual patient have been sufficiently used to meet the program's definition of intractable pain. It is not required that opioid medications be tried before meeting the definition of intractable pain, because opioid medications are not appropriate for some patients with chronic pain.

4. Are there limitations on the types of pain that are included?

Certification is not limited to certain types or causes of pain. However, the certifying health care practitioner must acknowledge that the patient meets the program's definition of intractable pain (see above).

5. Is consultation with a pain management specialist required? Is a second opinion required?

Consultation with a pain management specialist is not required. A second opinion is not required.

6. Are there certain things I need to include in medical record documentation?

Your documentation should include:

- History, physical findings, and results of imaging and laboratory studies relevant to the pain condition,
- Results of pain management strategies already used by the patient and their effectiveness and tolerability – in sufficient detail to justify the program's definition of intractable pain,
- The patient's comprehensive pain management plan going forward,
- And the patient's treatment course after he or she started using medical cannabis.

The MN Department of Health has the authority to request medical records for several purposes, including validating compliance with program requirements.

Certification/ Recertification

When certifying or re-certifying patients for intractable pain, you will answer three additional pain related questions.

These questions ask you to do the following:

1. Acknowledge that the patient meets the program's definition of intractable pain,
2. Indicate the medical condition that is the primary cause of the pain,
3. Indicate what pain rating scale you will use to follow the patient's pain over time and the date and score of the most recent assessment

To see the information collected at certification for all patients and for detailed information on how to complete a certification,

Reference Guide Patient Registry: HCP Account Management
http://www.health.state.mn.us/topics/cannabis/materials/refguidehcp.pdf

1. Acknowledge that the patient meets the program's definition of intractable pain.

There is a check box indicating agreement with the following:

> *"I certify that this patient has intractable pain. That is, this patient has pain, the cause of which cannot be removed and the full range of pain management modalities appropriate for this patient, according to generally accepted medical practice, has been used without adequate result or with intolerable side effects."*

The program relies on the professional opinion of participating health care practitioners as to whether the range of treatment approaches used for an individual patient meet this definition. Use of opioid medications is not required to meet the definition, as opioid analgesics are not appropriate for all patients with chronic pain.

2. Indicate the medical condition that is the primary cause of the pain

A drop-down menu of 31 conditions is provided, along with an "Other" option. Choose the one that fits best. If "Other" is selected a free-text field is provided to specify a medical condition different from the available options.

3. Indicate what pain rating scale will be used to follow the patient's pain over time and date and score of most recent assessment

Several common pain rating scales are provided, plus an "Other" option if the one you plan to use isn't on the list. We recommend use of the PEG scale because it is short, combining one question on pain intensity and two on limitation of function but clinicians are free to use the scale of their choice. This question on pain scale score and date is asked at certification/recertification and on a survey conducted by the Office of Medical Cannabis six months after certification/recertification.

PEG 3 Item Pain Scale http:/www.health.state.mn.us/topics/cannabis/intractable/PEG_pain_scale.pdf

Surveys

Short surveys are a primary source of information the Office of Medical Cannabis receives from health care providers about patients they certify. These surveys occur every six months. MDH sends an email notifying certifying health care practitioners that a survey is due and ready to be filled out. A practitioner can also access surveys through his or her provider account home page. The home page lists all the patients the provider has certified. An "Open Survey" button appears for each patient when a survey is due. Failure to complete the surveys may result in the Office of Medical Cannabis requesting the patient's medical records.

The surveys for patients certified with intractable pain contain two additional questions compared to the surveys for other qualifying conditions.

Survey sent six months after certification/recertification of a patient for intractable pain:

Health Care Practitioner 6mo Survey
http:/www.health.state.mn.us/topics/cannabis/intractable/IP180_Days_HCP_Survey.pdf

Survey sent immediately after recertification:

Health Care Practitioner Survey
http://www.health.state.mn.us/topics/cannabis/intractable/IP_Re-Approval_HPC_Survey.pdf

1. Impact of medical cannabis on other pain medications

This question will be asked on the survey every 6 months, starting with the survey 6 months after certification:

> *"Over the past 6 months has this patient's use of medical cannabis assisted in reducing dosage or eliminating other medications used for pain? Responses: Yes (specify the change(s) in medication(s); No; Not Applicable (patient not taking any medications for pain 6 months ago). We are interested in changes in use of opioids, of course, but also other medications used for pain management, including benzodiazepines.*

2. Date and score of most recent pain assessment and pain assessment scale used

This is asked at certification and recertification and on the surveys six months after certification/recertification (see description above under "Certification/Recertification").

Patient Assessment and Management

The Office of Medical Cannabis does not require particular therapeutic modalities for specific patients. Instead, it relies on the professional judgement of the health care practitioner to assess and document results of a comprehensive pain management strategy used by the patient – in sufficient detail to justify the program's definition of intractable pain. The Office of Medical Cannabis expects the certifying clinician to have an ongoing role in managing the patient's pain and to document the patient's treatment course after he or she started using medical cannabis. The MN Department of Health has the authority to request medical records for several purposes, including validating compliance with program requirements.

A few aspects of patient assessment and management worth emphasizing include the following:

- Use of medical cannabis before the full range of treatment modalities appropriate for the patient have been used – without adequate effect or with intolerable side effects – is not consistent with the rules of the program,
- Use of opioid medications is not required to meet the program's definition of intractable pain, since opioid medications are often not appropriate for patients with chronic pain.

Key aspects of high quality, comprehensive chronic pain assessment and management are outlined below, derived from the Institute for Clinical Systems Improvement (ICSI) 2013 Guideline for Assessment and Management of Chronic Pain. The guideline is a rich resource of information, including references to an extensive bibliography, for these topics

ICSI, Pain, Chronic; Assessment and Management of
http://www.icsi.org/guidelines__more/catalog_guidelines_and_more/catalog_guidelines/catalog_pain_guidelines/pain_chronic/

Assessment

- Use validated tools to assess pain and function
- Determine pain generator, including nerve and tissue damage
- Opioid status and history
- Psychological impact of pain and potential presence of concomitant psychiatric disease
- Screen for substance use disorders
- Discussion with patient about their expectations

Comprehensive, Multidisciplinary Treatment Plan

- Engage with the patient to develop realistic goals and expectations
- Develop and document a comprehensive, multidisciplinary treatment plan including the following, unless deemed inappropriate for a particular patient:
  - Physical modalities and rehabilitation
  - Complementary treatment modalities
  - Behavioral health/Psychological management
  - Pharmacotherapy
  - Interventional procedures

Follow-Up

- Set into motion the initial components of the treatment plan
- Communicate with and/or examine the patient at sufficient intervals to determine response
- Document results and input from referral sources
- Proceed with other aspects of the treatment plan, revising plan as needed

Resources for Chronic Pain Assessment and Management

The Institute for Clinical Systems Improvement (ICSI) developed a guideline for assessment and management of chronic pain, released late in 2013. ICSI is now in the process of producing an updated comprehensive pain management guideline. The currently available guideline is an excellent resource for information on chronic pain assessment and management and it includes references to an extensive bibliography. This guideline and a library of ICSI's publicly available guidelines can be accessed through the ICSI website https://www.icsi.org/

ICSI, Pain, Chronic; Assessment and Management of
http://www.icsi.org/guidelines__more/catalog_guidelines_and_more/catalog_guidelines/catalog_pain_guidelines/pain_chronic/

Resources for Medical Cannabis as a Component of Pain Management

MEDICAL CANNABIS FOR NON-CANCER PAIN: A SYSTEMATIC REVIEW; OCTOBER, 2015.
The Minnesota Department of Health contracted with the Minnesota Evidence-based Practice Center to do a systematic literature review and grading of evidence on cannabis use for treating chronic non-cancer pain. This is the report resulting from that effort, released in early October, 2015. It can be accessed on the MDH Office of Medical Cannabis web site at:
http://www.health.state.mn.us/topics/cannabis/intractable/medicalcannabisreport.pdf

A REVIEW OF MEDICAL CANNABIS STUDIES RELATING TO CHEMICAL COMPOSITIONS AND DOSAGES FOR QUALIFYING MEDICAL CONDITIONS; MAY, 2016.
This report summarizes clinical trials and prospective observational studies in humans, published in peer-reviewed journals that focus on the Minnesota medical cannabis program's qualifying conditions and on medical cannabis formulations consistent with the program's specifications. It was originally produced in December, 2014 and it is periodically updated to include more recent articles and newly-added qualifying conditions. The update produced in May, 2016 contains summaries of clinical trials of medical cannabis for treating chronic non-cancer pain. This report can be accessed on the MDH Office of Medical Cannabis web site at:
http://www.health.state.mn.us/topics/cannabis/practitioners/dosagecompositionreportdec2015.pdf

GUIDELINES DEVELOPED BY PROFESSIONAL ASSOCIATIONS AND HEALTH AGENCIES
Attal N, Cruccu G, Baron R, Haanpaa M, Hansson P, Jensen TS, Numikko T. European Federation of Neurological Societies Guidelines on the pharmacological treatment of neuropathic pain. 2010 revision. *Eur J Neurol*. 2010;17:1113-e88. doi: 10.1111/j.1468-1331.2010.02999.x. Epub 2010 Apr 9. Review.
Update of 2006 guidelines based on review of strength of RCTs. Recommendations divided into common types of neuropathic pain, including diabetic, post-herpetic, classical trigeminal neuralgia, central pain (MS, post-stroke, spinal cord injury), HIV, post-traumatic/post-surgical, chronic radiculopathy, cancer, phantom pain, and mixed-etiology neuropathic pain. Cannabinoids mentioned for only two types of neuropathic pain. Cannabinoids recommended

in MS only if all other treatments fail. Cannabinoids mentioned as having evidence of inefficacy/poor efficacy or discrepant results for use in post-traumatic or post-surgical NP, and not recommended for use.

Moulin D, Boulanger A, Clark, et al. Pharmacological management of chronic neuropathic pain: Revised consensus statement from the Canadian Pain Society. Pain Res Manag. 2014;19:328-335.

The Canadian Pain Society developed its first guideline on pharmaceutical management of neuropathic pain (NeP) in 2007. This guideline update is based on systematic review and grading of trial literature and the work of a consensus committee. "The current guidelines are based on quality of evidence of analgesic efficacy, side-effect profiles and ease of use. Medications were considered to be first line if there was a high-quality evidence of efficacy (at least one class I study or two consistent class II studies- level of recommendation Grade B or better; positive results in at least two NeP models; and if they were considered to be straightforward and of sufficient tolerability to prescribe and monitor. Medications were considered to be second or their line if there was high-quality evidence of efficacy, but the medication required more specialized follow-up and monitoring. Fourth-line treatments had at least one positive RCT, but require further study. A limitation of this algorithmic classification is the grading of tolerability and ease of use was based solely on consensus opinion of the authors." "The cannabinoids have now advanced to third-line agents in the management of chronic NeP based on increasing evidence of efficacy in multiple pain models including HIV neuropathy, post-traumatic postsurgical NeP, painful diabetic neuropathy and spinal cord injury pain (Lynch 2011; Toth 2012). However, the cannabinoids also require close monitoring, are contraindicated in patients with a history of psychosis and most of these agents, including the oral mucosal spray, are expensive."

Neuropathic Pain: The pharmacological management of neuropathic pain in adult in non-specialist settings. Centre for Clinical Practice at NICE (UK). 2013. National Institute for Health and Clinical Excellence Guidance.

"There is some evidence that cannabis sativa decreases pain compared with placebo, but in the analyses it appeared consistently worse than other treatments at reducing pain." Following is a summary of the recommendations regarding "All neuropathic pain". "Offer a choice of amitriptyline, duloxetine, gabapentin or pregabapentin as initial treatment for neuropathic pain (except trigeminal neuralgia); if the initial treatment is not effective or is not tolerated, offer one of the remaining 3 drugs, and consider switching again if the second and third drugs tried are also not effective or not tolerated; consider tramadol only if acute rescue therapy is needed; consider capsaicin cream for people with localized neuropathic pain who wish to avoid, or who cannot tolerate, oral treatments; do not start the following to treat neuropathic pain in non-specialist settings, unless advised by a specialist to do so ("cannabis sativa extract" is on this list of 10 medications, which also includes morphine). In their review of literature, regarding cannabinoids, they list Nurmikko (2007); Rog (2005); Selvarrajah (2010), and Wade (2004). Regarding peripheral neuropathic pain, "There is some evidence that cannabis sativa and capsaicin patch reduce pain compared with placebo but both drugs appeared consistently worse at reducing pain than other drugs." Regarding Central NP: "Low and very-low quality evidence from 2 small studies suggests that cannabis sativa and duloxetine may be better than placebo at follow-up periods of less than 12 weeks. However, confidence in the results is low

…" "Low quality evidence from 2 studies shows that cannabis sativa may be better than placebo at improving sleep at 4 weeks and pregabalin may be better than placebo at improving sleep at 12 weeks, but it is not clear if this is clinically significant."

Review articles and opinion pieces

Aggarwal SK. Cannabinergic pain medicine: A concise clinical primer and survey of randomized-controlled trial results. *Clin J Pain* 2013;29:162-171.
This article attempts to cover a lot of content in just 6 pages. It includes 121 references, so it gives plenty of leads for those who want to pursue topics in more depth.

Bostwick JM. The use of cannabis for management of chronic pain. *Gen Hosp Psychiatry.* 2014;36:2-3.
Short, lively opinion piece that covers many of the observations regarding medical cannabis and pain that appear in "PRO" opinion pieces on the subject. Bostwick is a Mayo psychiatrist.

D'Souza DC and Ranganathan M. Medical marijuana: Is the cart before the horse? *JAMA.* 2015;313:2431-2432.
This editorial covers many of the observations regarding medical cannabis and pain that appear in "CON" opinion pieces on the subject. Both authors are Yale psychiatrists.

Elikottil J, Gupta P, Gupta K. The analgesic potential of cannabinoids. *J Opioid Manag* 2009;5:341-357.
This paper presents a good brief history of medical use of cannabis, and detailed discussions of the different types of cannabinoids and pain-related cannabinoid receptors and signaling pathways. Animal studies of cannabinoids for anesthesia in neuropathic, inflammatory, and cancer pain are described. Approximately 20 clinical trials of cannabinoids in multiple sclerosis, neuropathic, and non-neuropathic pain populations are summarized and discussed.

Hill KP. Medical marijuana for treatment of chronic pain and other medical and psychiatric problems: A clinical review. *JAMA* 2015;313:2474-2483.
A literature review and case presentation based on a Grand Rounds conference at Beth Israel Deaconess Medical Center, Boston, in May, 2014. The patient discussed is a 60 year old with back pain since a fall 19 years ago and extensive surgical and medical treatment for pain since then. From the FINDINGS section of the abstract, "Use of marijuana for chronic pain, neuropathic pain, and spasticity due to multiple sclerosis is supported by high-quality evidence. Six trials that included 325 patients examined chronic pain, 6 trials that included 396 patients investigated neuropathic pain, and 12 trials that included 1600 patients focused on multiple sclerosis. Several of these trials had positive results, suggesting that marijuana or cannabinoids may be efficacious for these indications." Of particular note is the clinical approach to evaluation of a patient for medical cannabis certification, beginning on page 2478 and summarized in a box on page 2480.

Russo EB, Guy GW, Robson PJ. Cannabis, pain, and sleep: Lessons from therapeutic clinical trials of *Sativex*®, a cannabis-based medicine. *Chemistry and Biodiversity* 2007;4:1729-1743.
This article reviews evidence of effect of THC and CBD on sleep from clinical trials of cannabinoids as therapy for patients with multiple sclerosis, neuropathic pain, and rheumatoid arthritis where sleep was a secondary outcome measure. Their conclusion is that a combination of THC and CBD appears to cause improvements in sleep – sometimes large improvements – in some, but not all patients. Among those who do respond, the benefit is maintained consistently over time without evidence of tolerance. Most of the cited studies involve Sativex, the cannabis extract spray with an approximate 1:1 ratio of THC:CBD produced by GW Pharma. As the article makes clear at the outset, the authors are employees of GW Pharma.

Whiting PF, Wolff RF, Deshpande S, Di Nislo M, Duffy S, et al. Cannabinoids for medical use: A systematic review and meta-analysis. *JAMA* 2015;313:2456-2473.
In the June 23/30, 2015 issue of *JAMA* there appeared this major research article, a clinical education and review piece (the Hill article above), and an editorial (D'Souza and Ranganathan, above).

Here is *JAMA*'s summary of the Whiting article, "In a systematic review, Whiting and colleagues identified 79 randomized trials, involving 6462 participants, that compared cannabinoid use with active comparators or placebo for the treatment of several medical conditions. The authors found moderate-quality evidence supporting cannabinoid treatment of chronic pain and spasticity due to multiple sclerosis or paraplegia. Low-quality evidence suggests cannabinoids may lessen nausea and vomiting due to chemotherapy, foster weight gain in patients with HIV infection, and improve symptoms of sleep disorders or Tourette syndrome. In an Editorial, D'Souza and Ranganathan discuss the need for high-quality evidence to guide decisions about medical marijuana use."

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