MMP-010

New Jersey Department of Health
Medicinal Marijuana Program
PO 360
Trenton, NJ 08625-0360

MEDICINAL MARIJUANA PETITION
(N.J.A.C. 8:64-5.1 et seq.)

INSTRUCTIONS

This petition form is to be used only for requesting approval of an additional medical condition or treatment thereof as a "debilitating medical condition" pursuant to the New Jersey Compassionate Use Medical Marijuana Act, N.J.S.A. 24:6I-3. Only one condition or treatment may be identified per petition form. For additional conditions or treatments, a separate petition form must be submitted.

NOTE: This Petition form tracks the requirements of N.J.A.C. 8:64-5.3. Note that if a petition does not contain all information required by N.J.A.C. 8:64-5.3, the Department will deny the petition and return it to petitioner without further review. For that reason the Department strongly encourages use of the Petition form.

*This completed petition **must** be postmarked **August 1 through August 31, 2016** and sent by **certified mail** to:*

New Jersey Department of Health
Office of Commissioner - Medicinal Marijuana Program
Attention: Michele Stark
369 South Warren Street
Trenton, NJ 08608

Please complete each section of this petition. If there are any supportive documents attached to this petition, you should reference those documents in the text of the petition. If you need additional space for any item, please use a separate piece of paper, number the item accordingly, and attach it to the petition.

RECEIVED
AUG 23 2016
OFFICE OF THE CHIEF OF STAFF

MEDICINAL MARIJUANA PETITION
(Continued)

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1. **Petitioner Information**

   Name: [redacted]

   Street Address: [redacted]

   City, State, Zip Code: [redacted]

   Telephone Number: [redacted]

   Email Address: [redacted]

2. **Identify the medical condition or treatment thereof proposed. Please be specific. Do not submit broad categories (such as "mental illness").**

   Neuropathic Pain

3. **Do you wish to address the Medical Marijuana Review Panel regarding your petition?**

   ☒ Yes, in Person

   ☐ Yes, by Telephone

   ☐ No

4. **Do you request that your personally identifiable information or health information remain confidential?**

   ☐ Yes

   ☒ No

   If you answer "Yes" to Question 4, your name, address, phone number, and email, as well as any medical or health information specific to you, will be redacted from the petition before forwarding to the panel for review.

5. **Describe the extent to which the condition is generally accepted by the medical community and other experts as a valid, existing medical condition.**

Neuropathic pain is a subcategory of pain that results from damage to or dysfunction of the peripheral or central nervous system, rather than stimulation of pain receptors. Diagnosis is suggested by pain out of proportion to tissue injury, dysesthesia (eg, burning, tingling), and signs of nerve injury detected during neurologic examination. (1.https://www.merckmanuals.com/professional/neurologic-disorders/pain/neuropathic-pain)

Neuropathic pain is a very well-established medical condition. It's main diagnostic code is ICD-9-CM 729.2 (Neuralgia, neuritis, and radiculitis, unspecified).

Disorders of the central and peripheral nervous system that may result in neuropathic pain include ICD-9-CM codes 338.0 (central pain syndrome, which includes brain and spinal cord damage) 350.1 (Trigeminal neuralgia) 353.6 (phantom limb and associated pain), 354-355 (entrapment neurologies that may include pain), 357 (inflammatory and toxic neurology) 358 (Myoneural disorders), 250.6 (Diabetes with neurological manifestations), 357.2 (Polyneuropathy in diabetes) 357.4 (Polyneuropathy in other diseases classified elsewhere).

This is not a complete list of neuropathic diseases/conditions that may result in neuropathic pain. Some of these diseases, such as Multiple Sclerosis and AIDS, overlap existing CUMMA qualifying conditions.

6. If one or more treatments of the condition, rather than the condition itself, are alleged to be the cause of the patient's suffering, describe the extent to which the treatments causing suffering are generally accepted by the medical community and other experts as valid treatments for the condition.

Opioids are a secondary or tertiary treatment for neuropathic pain. However, because neuropathic pain is often a long-term condition, the side-effects of opioids (somnolence, constipation, etc.) and risks (addiction, increased mortality) often outweigh the limited effectiveness of these drugs for this condition.

"Whereas there is evidence for significant short-term pain relief, there is no substantial evidence for maintenance of pain relief or improved function over long periods of time without incurring serious risk of overdose, dependence, or addiction," wrote Gary M. Franklin, MD, in a position paper published in *Neurology,* the official medical journal of the American Academy of Neurology (AAN).
(2. http://nationalpainreport.com/neurologists-opioid-risks-outweigh-benefits-8824947.html)

However, opioid use is often a last resort for treatment of neuropathic pain when other treatments fail. Patients are willing to risk the effects of treatment for an improved quality of life.

7. Describe the extent to which the condition itself and/or the treatments thereof cause severe suffering, such as severe and/or chronic pain, severe nausea and/or vomiting or otherwise severely impair the patient's ability to carry on activities of daily living.

Health-related quality of life (HR-QOL) is substantially impaired among patients with NP. Patients describe pain-related interference in multiple HR-QOL and functional domains, as well as reduced ability to work and reduced mobility due to their pain. (2.http://www.ncbi.nlm.nih.gov/pubmed/19254044)

Pain is the primary reason for patients seeking healthcare, and it has been estimated to result in more than $100 billion per year in direct medical costs. Neuropathic pain (NP) alone has been associated with an approximately 3-fold increase in use of healthcare resources. The indirect costs associated with chronic pain result from increased absenteeism and decreased productivity at work, and they also have been estimated to total $100 billion each year in the United States. NP contributes substantially to these costs. Results from one study indicated that employment was affected in 43% of patients with NP. Quality of life is also significantly reduced in such patients. Patients with chronic pain also have difficulty in initiating and maintaining sleep, and sleep deprivation has the potential to exacerbate pain. Sleep deprivation is also associated with both anxiety and depression, and both of these conditions can exacerbate sleep disturbances.
(3. Am J Manag Care. 2006;12:S263-S268)

The primary neuropathic pain treatment drugs, for instance anti-seizure and tricyclic antidepressants, of course, have their own well-known list of side effects. Whether these side-effects outweigh their benefits would depend on the individual patient's response to these medications.

8. Describe the availability of conventional medical therapies other than those that cause suffering to alleviate suffering caused by the condition and/or the treatment thereof.

The current primary long-term treatment drugs for neuropathic pain are the anti-seizure and antidepressant class of drugs. They are readily available and often inexpensive options. However. neuropathic pain is often very difficult to treat with conventional medications.

A meta-analysis of neuropathic pain reduction was performed which found that of the antidepressant and anti-seizure drugs examined, the standards of neuropathic treatment, achieved at best a 1.31 reduction of pain, compared to placebo, on the 11 point Likert scale.
(4. http://www.ncbi.nlm.nih.gov/books/NBK61827/ see Table 6)

Obviously, better treatment is needed.

9. Describe the extent to which evidence that is generally accepted among the medical community and other experts supports a finding that the use of marijuana alleviates suffering caused by the condition and/or the treatment thereof. *[**Note:** You may attach articles published in peer-reviewed scientific journals reporting the results of research on the effects of marijuana on the medical condition or treatment of the condition and supporting why the medical condition should be added to the list of debilitating medical conditions.]*

Several placebo controlled studies by UC and Canada were analyzed to compare smoked cannabis to traditional treatments, which found it worked as well as gabapentin, with similar numbers to treat.
(5. http://journalofethics.ama-assn.org/2013/05/oped1-1305.html)

Inhaled cannabis can blunt the pain of diabetic neuropathy without seriously impairing cognitive function, a new study shows. "This small, short-term, placebo-controlled trial of inhaled cannabis demonstrated a dose-dependent reduction in diabetic peripheral neuropathy pain in patients with treatment-refractory pain. This adds preliminary evidence to support further research on the efficacy of the cannabinoids in neuropathic pain."
(6. http://www.jpain.org/article/S1526-5900(15)00601-X/abstract)
(7. http://www.medscape.com/viewarticle/848539#vp_1)

"Peripheral neuropathic pain (PNP) associated with allodynia poses a significant clinical challenge. The efficacy of Δ(9) -tetrahydrocannabinol/cannabidiol (THC/CBD) oromucosal spray, a novel cannabinoid formulation, was investigated in this 15-week randomized, double-blind, placebo-controlled parallel group study.
In total, 303 patients with PNP associated with allodynia were screened; 128 were randomized to THC/CBD spray and 118 to placebo, in addition to their current analgesic therapy. The co-primary efficacy endpoints were the 30% responder rate in PNP 0-10 numerical rating scale (NRS) score and the mean change from baseline to the end of treatment in this score. Various key secondary measures of pain and functioning were also investigated.
At the 30% responder level, there were statistically significant treatment differences in favor of THC/CBD spray in the full analysis (intention-to-treat) dataset:
(8. http://www.ncbi.nlm.nih.gov/pubmed/25270679)

"A double-blind, placebo-controlled, crossover study evaluating the analgesic efficacy of vaporized cannabis in subjects, the majority of whom were experiencing neuropathic pain despite traditional treatment. ...
The analgesia obtained from a low dose of delta-9-tetrahydrocannabinol (1.29%) in patients, most of whom were experiencing neuropathic pain despite conventional treatments, is a clinically significant outcome. In general, the effect sizes on cognitive testing were consistent with this minimal dose. "
(9. http://www.ncbi.nlm.nih.gov/pubmed/23237736)

Cannabis is also synergistic with opioid therapy, allowing smaller quantities of the opioids and likely reducing the side effects and risks of therapy. (10. http://www.medscape.com/viewarticle/755388#vp_1). Access to medical cannabis is associated with significant reductions in opioid mortality. (11. http://archinte.jamanetwork.com/article.aspx?articleid=1898878)

10. Attach letters of support from physicians or other licensed health care professionals knowledgeable about the condition. List below the number of letters attached and identify the authors.

Attached is a letter from Dr. Marshall Lauer supporting the use of cannabis for neuropathic pain.

I certify, under penalty of perjury, that I am 18 years of age or older; that the information provided in this petition is true and accurate to the best of my knowledge; and that the attached documents are authentic.

Sig	Date Aug. 17, 2016

MARSHALL LAUER, MD
BOARD CERTIFIED IN INTERNAL MEDICINE AND
BOARD CERTIFIED IN ADDICITION MEDICINE

May 26, 2016

To whom it may concern:

I have several patients with intractable skeletal spasticity for whom I am writing medical marijuana recommendations. They report that the cannabis also helps with their associated neuropathic pain symptoms.

Several patients could not tolerate the side effects from the prescribed drugs for neuropathic pain including tricyclics and antiepileptic drugs, but reported good efficacy with the cannabis treatment and tolerable side effects.

Based on my experience, I feel the New Jersey Medical Marijuana Panel should consider adding neuropathic pain as an approved condition to the New Jersey program.

If there are any questions in regard to the above described the information please contact me at my office.

Sincerely,

Marshall Lauer, MD

414 HADDON AVENUE, COLLINGSWOOD, NEW JERSEY • 08108
PHONE: 856 854 7800 • FAX: 856 854 1687