

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

mmp-016

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.

1. Petitioner Information

Name: _____
Street Address: _____
City, State, Zip Code: _____
Telephone Number: _____
Email Address: _____

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

TRANSFORMED MIGRAINE also known as CHRONIC MIGRAINE

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.

RECEIVED

AUG 25 2016

OFFICE OF THE
CHIEF OF STAFF

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

Transformed migraine (TM) is a migraine condition that initially began as episodic migraine attacks, which then increase in frequency over a period of month to years. Transformed migraines occur daily or almost daily and appear to be a mixture of tension-type headaches and migraine attacks.

While the pathophysiology of migraines is still not fully understood, research suggests they're the result of fundamental neurological abnormalities caused by genetic mutations in the brain. This fluctuation in neuronal activity likely activates the trigeminovascular system, which includes both the nerve and vascular system in the meninges, and the associated inflammatory response causes pain. Genetics are also likely involved in the cause of migraines.

While most sufferers experience attacks once or twice a month, more than **4 million people** have chronic daily migraine, with at least 15 migraine days per month. More than 90% of sufferers are unable to work or function normally during their migraine

I have seen experts in the field from the head of Neurology at New York Hospital, Jefferson Hospital Headache Center, the New York Headache Center, Michigan Headache and Neurological Institute, and the Headache Center at the Mayo Clinic. All of the experts agree that Transformed Migraine is the correct diagnosis. What this means for me and 4 million others, is that we are in a chronic, almost non-stop state of migraine. My brain no longer knows how to not be in a migrainous state. I have had this condition for 15 years.

There is a relationship between migraine and seizures

There is definitely a link between migraine and seizures. Doctors have long recognized that migraine and epilepsy occur together more often than they would expect by chance alone. So people with migraines are more likely to also have a seizure disorder and people with epilepsy are more likely to also get migraines. For example, research shows that people with epilepsy are over twice as likely to also get migraines compared with people without a seizure disorder. In some cases, migraines can actually trigger seizures.

"There are many reasons two diseases occur together, but it has not really been clear until now that these two diseases are genetically linked," says researcher Melodie R. Winawer, MD. She is an assistant professor of neurology at Columbia University in New York City.

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.

Treatments do not cause the migraine patients suffering. It is a genetic mutation that causes it. However, as soon as one develops Transformed Migraine, they are firmly on the path to suffering, not only from the disease, but from the HUNDREDS of severe side effects from the HUNDREDS of medicines our doctors try on us, to try to find ONE that will manage the pain.

The best migraine treatment professionals use a combination of medication, preventatives and on-set

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medications, and homeopathic remedies of all sorts. Personally, I have been treated with all of these therapies, but there are sadly no medications on the market which treat "chronic" / "transformed" migraine.

Most of us who suffer daily, 24/7, with this migraine condition, have never had any long term success with medicines prescribed on label ,or off label, for this condition. I have literally been prescribed at least 100 medicines to try to control my chronic transformed migraines, all of which have severe side effects. Some of these medicines work for a little while, but ultimately, my migraines find a way to come back.

Here is a list of the medications used that do cause suffering due to side effects:

Triptans, such as "Imitrex, Maxalt, and "Relpax" works by narrowing blood vessels in the brain. They work for several hours, if at all, and one becomes accustom to their effects within days or weeks. Triptans are designed for episodal migraine, not transformed or chronic migraine.

- Side effects are sleepiness, weight gain, mouth infections, chest pain, heaviness, tightness or pressure in chest, burning sensation, tingling of skin, dizziness, nausea.

Calcium channel antagonists, which are more often used to treat conditions like high blood pressure and irregular heartbeat, are also used for migraines. These drugs include nifedipine (Procardia or Adalat), nifedipine (Cardene) and verapamil (Calan).

- Common side effects of calcium channel blockers include: headache, constipation, rash, nausea, flushing, edema (fluid accumulation in tissues), drowsiness, low blood pressure, and dizziness

"**Antidepressants, anti-seizure medications and beta-blockers** are also used for prevention of migraines. They have not ever alleviated pain for more than a few weeks for me.

- **Antidepressant side effects** : Drowsiness, nausea, dry mouth, insomnia, diarrhea, nervousness, agitation, restlessness. Dizziness, sexual problems, headache, blurred vision.
- **Anti-seizure meds:** dizziness, sleepiness, dry mouth, peripheral edema, blurred vision, weight gain, difficulty concentrating.
- **Beta-blockers side effects** : dizziness, tiredness, blurred vision, cold hands and feet, slow heartbeat.

Opiates, which are used as on-set medicine, are known to be worse for migraine than for other types of chronic pain, in that it creates a rebound headache cycle, which is then harder to stop, but also because where some pain management patients get months to years of relief from each opiate, or each dosage of opiate, migraine patients such as myself only have relief for 11 days or so before they come back and have to be put on stronger medications.

I have tried every opiate, and have had horrible side effects from them. Eventually, my pain management doctors give up on me and say "there is nothing more we can do for you", leaving me to withdrawal from these medications with no help, which is very difficult and draining to my body. Unfortunately, without legal marijuana, pain management is often where I and my fellow chronic migrainuers end up because we have no other choice. The pain is relentless.

- **Opiate use side effects** : Physical and psychological cravings, Nausea, Stomach pain, cold sweat, Chills, vomiting, Diarrhea, and Agitation.

Here is a list of medicines I have been prescribed from 2002- Present. I also have a detailed log of this time, and can certainly submit it, if requested. All of these medications cause suffering from adverse side effects:

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acetaminophen with codine, ambien, amitiza, amitriptyline, aricept, atacand, axert, baclofen, benedril, betanecol, biacin, blocadren, botox, buspar, buspirone, celebrex, centrum, ciprofloxacin, citracel, clonazepam, CoQ, Cymbalta, decadrin, demerol, depakote, dexamethasone, DHE, compozine IV, phenergan IV, Diltiazem, Donatol, doxepin hydrochloride, doxycyclin, Elivil, endocet, fiorocet, frova, geodon, Imitrex, Imitrex nasal spray, Injectable Imitrex, Indomethacin, IV Magnesium, Keppra, Levbid, Lunesta, Lyrica, Maxalt, Melatonin, Metaclopramide, Metformin, Methadone, Methergene, Midrin, Migranol, Namenda, Naproxin, Noretrotyline, Ondandetron, Opana, Paxil, ER, Oxycodone-0Acetaminophen, Oxycontin, Alprazolam, Hydroxyzine, Methocarbamol, Olanzapine, Oxycodone, Oxycontin, Sumatriptan injectable, Dicyclomine, Clonidine HCL, Movantik, Sertraline HCL, Ranitidine, Carbamazepine, Fluconazole, Hydroxyzine, Metaxalone, Methocarbamol, Seroquel, Seroquel XR, Topamax, Ranitidine, Ketorolac, Tranylcypromine, cetirzine, latuda, Methylprednisolone, olanzapine, oxcarbazepine, Quetiapine fumarate. Pedatdolex, Percocet, Phenargren, Polyethylene Glycol, Prednisone, Prochlorperazine, Promethazone, Propranolol, Reglan, Relistor injections, Replax, Seroquel, Temazepam, Timolol, Topamax, Tramadol, Verapamil, Vicodin, vicoprofin, Vitimin B, C, D, xanax, zanaflex, Zomig, Zonegran, IV Ketamine, Nadolol, Carbamazepine, Prochlorperazine, Mexiletine, Dihydroergotamine, Simvastatin, Metoclopramide, Nexium, Prozac, Tramadol, Opana, IV toradol.

- 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.**

15 years ago, I got my first migraine. I am 46 years old. Prior to that, I had a very productive life, and a great job as a manager of a large Information Technology department at a fortune 500 company. At 32 years old, I had a problem with uterine fibroid tumors and became very anemic for a few months. During that time, the migraines began and within a few weeks, they were non-stop, every day, every night, 24/7. I had never heard of this, and thought, "I must have brain tumor". Much to my surprise, "Chronic" migraine, or "Transformed Migraine" is a wide-spread and widely understood, incurable genetic disease. I had to quit my job because of my condition, and haven't been able to work since.

The pain starts like a skewer through the eye, and is accompanied by a more diffuse and vise-like pain behind both eyes, and spreads all the way back to my occipital ridge at the base of my neck. In addition to the two types of pain, I also get terrible chronic ringing or "tinnitus" which is almost as bad as the pain. Additionally, as my disease has progressed, I have developed chronic nausea, bloating and a general intolerance for food, which has left me very weak and thin. I do my best to eat right, take supplements, and stay in shape, although exercising causes more discomfort. Also, I experience excessive light and noise sensitivity, (Photophobia and Phonophobia), which makes me unable to leave my house or even my bedroom 90 percent of the time.

When they became daily, it became impossible to work, socialize, clean the house, interact with family members or friends, or do anything that involves getting out of bed or talking to people. I cannot work at all because I cannot plan ahead of time. I cannot visit family or have them visit me because I cannot plan ahead of time. I am totally isolated.

When my migraines transformed from episodic to daily, I immediately sought help from the head of Neurology at New York Hospital and was with him for about 7 years. During this time, the tinnitus, chronic nausea and stomach aches started and have progressively become more severe.

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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 following treatments and medical therapies do not cause suffering, but they also do not alleviate suffering:

Tylenol is just one commonly used off-label [medication for migraines](#). It's not effective for chronic migraine, and is one of the highest contributing factor to "rebound headache" .

"NSAIDs [nonsteroidal anti-inflammatory drugs], such as ibuprofen or naproxen, [over-the-counter medications](#) Motrin Migraine and Excedrin Migraine are approved but again, are not effective for Transformed/ Chronic Migraine. They are also addictive and cause rebound migraine.

Vitamin B2 (riboflavin), magnesium, coenzyme Q10, butterbur and melatonin, are commonly prescribed. I take most of these daily, but they have not helped me.

Botox, Nerve Blocks and Nerve Stimulation treatments- These therapies are very popular because their side effect profile is very minimal. However, they are only "partially" helpful to approximately 50% of migraine patients. I have tried all three, two separate times, and have had no reduction in pain or frequency of migraine attacks. By the way, they are very expensive and not covered by insurance.

Biofeedback, Meditation, Acupuncture, and CBT. The sad fact is that nothing works for me. I have been told to do all of these homeopathic methods, and continue to do meditation, biofeedback, yoga and acupuncture to this day. Acupuncturists have told me that it works for about 50% of migraine patients in reducing pain and frequency. This does not work for me. I did it for a year 13 years ago, and have begrudgingly begun doing it again, although I find it to be uncomfortable and a waste of time and money.

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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.

Marijuana is something that I may be able to use INSTEAD of taking an opiate. The "marinol" pill, which is straight THC, gave me so much relief, that I was able to stave off dangerous opiates while I used THC. It is an essential tool. I've been prescribed "marinol" once, but the cost is too high for me to take it regularly. It's about \$100.00 per pill and I need two of them to stop the migraines and nausea. I don't have that kind of money.

I have had 2 separate, very well respected Neurologists say to me "marijuana can be very helpful". However, they are both in New York state, where Medical Marijuana is legal for Neurological Pain. It is not legal in New Jersey yet.

The following exert is from <http://www.medicalmarijuanainc.com/migraine-medical-marijuana-research/> Please also see references below.

Findings: Effects of Cannabis on Migraines

Cannabis has been used to treat migraines for centuries. Between the years of 1874 and 1942, it was among the most prominent remedy used by physicians^[6,10].

Research suggests that cannabis' effectiveness for migraine relief can be attributed to the cannabinoids contained in cannabis, including cannabidiol (CBD) and tetrahydrocannabinol (THC). CBD and THC activate the CB1 and CB2 receptors of the body's endocannabinoid system, which in turn inhibits responses of the trigeminovascular system and restricts the inflammation that causes migraine pain^[1,2,4].

A January 2016 study found medical marijuana to be effective at decreasing the frequency of migraine headaches. In a first-of-its-kind study, because of previous federal regulations, the researchers found that 103 of 121 of participants diagnosed with migraines saw a decrease in migraine frequency. The average migraine frequency reduced from 10.4 a month to 4.6 per month^[9].

Further, studies suggest that cannabis is effective at providing analgesia effects caused by chronic neuropathic pain conditions that are otherwise resistant to other pain relief treatments^[3]. The findings of one study even suggest that a dysfunction of the endocannabinoid system may contribute to the development of migraines. Researchers then came to a conclusion that the activation of the CB1 and CB2 receptors would correct this dysfunction and be useful in treating migraine pain^[5].

Because of the effectiveness of cannabinoids on migraines, there continues to be prominent marijuana use by migraine patients outside of physician recommendations and in locations where medical cannabis use continues to be illegal^[6].

In 2015, the Brazilian government, otherwise known for having strict legislation against cannabis, [announced it would allow for legal importation of Real Scientific Hemp Oil™](#), a CBD hemp oil product from [HempMeds Brasil™](#), for the treatment of [epilepsy](#), [Parkinson's disease](#), and chronic pain, which includes migraine headaches. Through Brazil's medical marijuana program, 100 percent of costs associated with RSHO™ hemp oil products are covered by the Brazilian government.

References

1. Akerman, S., Holland, P.R., Lasalandra, M.P. and Goadsby, P.J. (2013, September). Endocannabinoids in the

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headache/basics/definition/con-20026358.

8. NINDS Migraine Information Page. (n.d.) *National Institute of Neurological Disorders and Stroke*. Retrieved from <http://www.ninds.nih.gov/disorders/migraine/migraine.htm>.
9. Rhyne, D.N., Anderson, S.L., Gedde, M., and Borgelt, L.M. (2016, January 9). Effects of Medical Marijuana on Migraine Headache Frequency in an Adult Population. *Pharmacotherapy*, doi: 10.1002/phar.1673. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/26749285>.
10. Russo, E.B. (2008, February). Cannabinoids in the management of difficult to treat pain. *Therapeutics and Clinical Risk Management*, 4(1), 245-259.
11. Russo, E.B. (1998). Cannabis for migraine treatment: the once and future prescription? An historical and scientific review. *Pain*, 76, 3-8.
12. Russo, E.B. (2001). Hemp for Headache: An In-Depth Historical and Scientific Review of Cannabis in Migraine Treatment. *Journal of Cannabis Therapeutics*, 1(2), Retrieved from http://www.drugpolicy.org/docUploads/hemp_for_headache.pdf.

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.

I have asked my physicians for letters of support, but since it's not legal yet in New Jersey, and none of my doctors are willing to write letters of support. My two Neurologists in New York State would probably write support letters, but they are not licensed to practice in New Jersey. I have not attempted to contact a licenced medical marijuana doctor in New Jersey, because my disease is not yet covered.

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.

Signature of Petitioner		Date
		8/23/16