



OPIS

Organisation for the
Prevention of
Intense Suffering

PRESS RELEASE

Health Canada provides legal access to psilocybin for first cluster headache patient

OPIS partnership leads to milestone in treatment of this excruciating condition

Geneva, Switzerland, 20 June 2024 – The Organisation for the Prevention of Intense Suffering (OPIS), a non-profit think-and-do tank promoting compassionate governance, is pleased to announce that Health Canada has granted approval for a cluster headache patient to receive psilocybin treatment under Canada’s Special Access Program (SAP), and also to possess psilocybin for self-treatment under a Section 56 exemption. This is the first time that Canada has allowed a cluster headache patient to legally use a psychedelic to treat their condition.

This milestone is the culmination of a partnership that OPIS initiated three years ago with the non-profit TheraPsil, which had previously obtained legal exemptions for patients in Canada with end-of-life distress to use psilocybin, in order to also seek such access for cluster headache patients. The positive decision, dated 7 June, follows a recent ruling by the Federal Court overturning an initial rejection of the application, submitted by neurologist Dr. Jephth Davenport on behalf of patient Jody Lance – a rejection which the ruling judge termed “unreasonable” – and demanding a re-evaluation of the application.

Cluster headaches cause excruciating pain

[Cluster headaches](#), also termed “suicide headaches”, are considered one of the most excruciating conditions known to medicine, with the pain often rated 10 on a scale of 0-10 – significantly higher than childbirth, kidney stones or migraines. Most patients have had suicidal ideations, and some commit suicide to escape the pain. Attacks affect one side of the head, and the sensation is often compared to being stabbed in the eye with a red-hot poker or ice pick. Attacks can last an hour or longer and recur many times a day. Cluster headaches affect about 1 in 1000 people, a prevalence similar to multiple sclerosis. Most patients have episodic clusters lasting 1-3 months and occurring seasonally, while 15% have chronic clusters that can occur daily for years without a break.

Efficacy of psilocybin and other psychedelic indoleamines

Standard medical options to treat cluster headaches are helpful but insufficient, as they cannot reliably prevent attacks, not all patients respond, and side effects limit their use. But there is overwhelming evidence, from a large number of patient reports, systematic scientific [studies](#) based on patient surveys, and now also the recently published [results](#) of a small clinical

trial extension, that psilocybin – found in hallucinogenic “magic” mushrooms – and several chemically related substances known as indoleamines, such as LSD and DMT, are effective, often dramatically, in aborting and preventing attacks and even entire cycles. There is also some evidence for the efficacy of psilocybin in treating [migraines](#).

Although cluster headache patients, often traumatised by their condition, may also benefit psychologically from these substances, the mechanism of action on cluster headaches appears to be independent of their psychedelic effect, as sub-hallucinogenic doses can also be effective, as is a non-hallucinogenic analogue of LSD. Unfortunately, the legal status of psychedelics in most countries makes it difficult for patients to access them.

Canada and Switzerland at the forefront

Canada now joins Switzerland as one of the few countries where cluster headache patients have been explicitly authorised to use psychedelics outside of clinical trials. Under present Canadian regulations, a patient’s physician will still need to go through an application process, and the permission granted is for limited access and personal possession of Health Canada-approved psilocybin administered over a limited period.

In Switzerland, about 60 physicians are currently authorised to administer psychedelics for various conditions, though they also need to apply to the Federal Office of Public Health on a case-by-case basis. The high price of pharmaceutical grade psilocybin, which is not covered by Swiss health insurance, and the need for it to be administered each time by a physician, make this treatment less accessible to all who need it.

The excruciating character of cluster headache attacks means that current laws and regulatory frameworks, including in these two countries, have substantial room for improvement to allow rapid access to all patients in need.

Jonathan Leighton, Executive Director of OPIS, said, “This decision represents a step forward for cluster headache patients everywhere, with the Canadian government acknowledging the therapeutic potential of psilocybin. I am pleased that our partnership with TheraPsil, initiated in 2021, has achieved the first goal we established. We are hopeful that the barriers to access will continue to fall, in Canada and elsewhere, so that all patients with this horrific condition can rapidly and legally access treatment with psychedelics, and also self-administer them if they choose.”

Spencer Hawkswell, president and CEO of TheraPsil, commenting on the Canadian context, said, “This represents a shift in Canadian psilocybin access. It is also a clear signal that the courts expect Health Canada to consider charter rights and to be more ‘intelligible’ in their decision-making. To me, those strong words from our justice system imply that we need to grant people access to medical psilocybin if it’s effective for them.”

OPIS’s advocacy on behalf of cluster headache patients

OPIS is a prominent international advocate for cluster headache patients and their right to legally access psychedelics to effectively treat their agonising condition, without unnecessary administrative hurdles. This work is part of our larger efforts to improve access to effective [pain](#) medication and, more generally, to encourage governments to make the prevention of

intense suffering of all sentient beings an overriding priority. OPIS has been collaborating with various other organisations in advocating for more compassionate drug policies, including Clusterbusters, the Finnish Horton Association, the International Drug Policy Consortium (IDPC), the Conservative Drug Policy Reform Group (CDPRG, now Centre for Evidence Based Drug Policy) and TheraPsil. On the topic of cluster headaches, OPIS has produced:

- a [cluster headaches web page](#) with many resources
- a [policy paper](#) on legalising access to psilocybin for cluster headaches, with patient testimonials
- an [animated video](#) to support our advocacy
- a new [case study](#) in the medical journal *Headache* on the successful use of psychedelics to treat SUNCT (an excruciating condition in the same family as cluster headaches)

About OPIS

The Organisation for the Prevention of Intense Suffering (OPIS) is a think-and-do tank promoting a shift in global priorities towards the prevention and alleviation of the intense suffering of all sentient beings. We develop and communicate guiding principles for compassionate governance and systemic change, and promote effective, evidence-based solutions to specific causes of suffering. OPIS has been focusing on improving access to effective pain medication, including therapeutic [morphine](#) for terminal cancer patients in lower-income countries and psychedelics for the treatment of [cluster headaches](#), and on ending the horrors of factory farming and other torture of non-human animals. OPIS was founded in 2016 as a Swiss non-profit association and is headquartered in Geneva.

www.preventsuffering.org

For more information

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