

EMERGING MENTAL HEALTH TREATMENTS FOR VETERANS

- The health, safety and well-being of Veterans and their families is paramount for our Department. We rely on the most up-to-date scientific evidence, evidence-based clinical practice guidelines, and guidance from recognized medical professionals' regulatory bodies and researchers.
- We know that people diagnosed with military or combat-related PTSD may respond to varying degrees to psychotherapy or antidepressants.
- The Government of Canada is committed to definitive research in the use of psychedelics.
- Health Canada will assess new drugs' safety, efficacy and quality before regulating them under the *Food and Drugs Act*.

If pressed:

- Veterans Affairs Canada provides coverage to Veterans who qualify to pay for health care benefits and services supported by scientific evidence.
- VAC reimburses treatment costs for Veterans but is not a direct health care provider, nor does it conduct

pharmacological research or approve pharmacological products.

- The Department bases its drug formulary and benefit grid on evidence-based clinical research and approved scientific guidelines.

WHEN PRESSED:

Q1 – What is the quality of the current scientific research on psychedelic-assisted psychotherapy? How long will it take to get solid findings?

- The research on psychedelic-assisted psychotherapy continues to evolve.
- Further research is needed to assess efficacy, safety and effectiveness.
- Much of the neuromechanisms with regard to the therapeutic effects of psychedelics remain unknown.
- Studies to date have had relatively short follow-ups and there has been considerable heterogeneity (variation) between studies.
- Relevant treatment guidelines have not yet been developed.
- More research is required on long-term benefits and side effects.
- Currently, there is insufficient data available on safety for persons with psychotic disorders, disorders with risk of psychosis, dissociative disorders, suicidal risk, or family history of these conditions or risk factors.

Q2 – What is VAC doing to build the necessary evidence on psychedelic-assisted psychotherapy? Is VAC funding research in psychedelic-assisted psychotherapy and if not, why not?

The Department works with Health Canada and the Canadian Institutes for Health Research (CIHR). These organizations have the Government of Canada mandate to lead the research, and provide advice and expertise on emerging treatments, such as psychedelic-assisted psychotherapy.

Is VAC funding research in psychedelic-assisted psychotherapy and if not, why not?

- VAC does not fund research in psychedelic-assisted psychotherapy. Health Canada is the federal regulator responsible for the review of Phase I, II, III clinical trial applications filed by clinical trial sponsors.
- CIHR is currently funding limited clinical trials (not Veteran-specific) for psilocybin for patients with advanced cancer, alcohol use disorder, and treatment-resistant depression.
- Health Canada has approved 69 companies to produce the psilocybin; and has authorized 36 clinical trials.
- VAC remains in contact with Health Canada and CIHR to obtain updates on research on psychedelic-assisted psychotherapy.

Q3 – Can you comment on the position of the Director of the Emory Healthcare (U.S.) Veterans Program, psychiatrist Dr. Barbara Rothbaum, on the subject of psychedelics? She appears to be favorable to the possibility of using psychedelic-assisted psychotherapy to treat PTSD.

Our understanding is that Dr. Rothbaum is also of the opinion that traditional evidence-based interventions should be delivered before attempting a newer therapy. She recommends a stepped approach, starting with traditional treatments, virtual reality treatments, and then possibly psychedelic-assisted psychotherapy. At this time, VAC disagrees on the last point given the current lack of scientific evidence available on psychedelic-assisted psychotherapy and related interventions' efficacy and safety in the Veteran population.

Q4 – Clinics already exist where psychedelic-assisted psychotherapy is administered by fully licensed, regulated, and qualified health professionals. If these health professionals can freely administer these treatments, does it not mean that it is an acceptable treatment? As such, how can VAC refuse to fund in a context of ill Veterans with PTSD?

Psychedelics are illicit drugs in Canada with the exception of Ketamine. As such, we believe the clinics referred to are Ketamine Clinics. VAC will consider funding Ketamine as a pharmacological treatment (as a medically prescribed drug) when prescribed by the treating psychiatrist and administered in the following ways:

- Ketamine infusion, Oral Ketamine or Spravato (esketamine) nasal spray for treatment-resistant depression or as a co-existing condition with PTSD
- Ketamine infusion, Ketamine compounded cream/topical or oral Ketamine for treatment of chronic pain

VAC does not currently support the funding of psychedelic-assisted psychotherapy, including Ketamine-assisted psychotherapy, given that providing psychotherapy to someone in a drug-induced psychedelic state remains an emerging therapy without sufficient scientific evidence as to its effectiveness and safety.

Health Canada's Special Access Program (SAP) is not an approval or endorsement for treatment and is not linked to the specific clinical trials. Access via SAP is not given to the individual patient or provider, but to the manufacturer to release the medication to the provider once an application to SAP has been carefully reviewed. The role of SAP is strictly regulatory in nature.

Q5 – What are the alternative mental health treatments available to Canadian Veterans with PTSD given that psychedelic-assisted psychotherapy is not yet approved for funding?

Veterans have a variety of evidence-based PTSD psychological and psychiatric treatments available to them. Psychological treatments that are recognized as first-line evidence-based treatments include cognitive processing therapy, exposure therapy, and eye movement desensitization and reprocessing (EMDR) therapy.

Q6 – The Senate Subcommittee (VEAC) “...believes that VAC’S wait-and-see approach does not fit with the leadership role it should be taking on in addressing the suffering experienced by veterans. It is clear that, while it is important to minimize risks, psychedelic-assisted psychotherapy could be a solution for some veterans. There is no reason not to immediately explore how to take advantage of this rare opportunity for a new treatment.”

Why has VAC not actioned on this, why wait?

Veterans Affairs Canada has considered the Subcommittee’s recommendation and is receptive to the exploration of any and all treatment options to improve the mental health and wellbeing of Veterans. That said, VAC is not a direct health care provider nor does it conduct pharmacological research or approve pharmacological products (medicines). The Department relies on the expertise of Departments such as Health Canada and CIHR, to have confidence that emerging treatments, including pharmacotherapies and psychotherapies, are safe, effective and are supported by high quality research and approved scientific guidelines.

VAC has an obligation to be stewards of Veterans’ health and wellbeing, by ensuring Veterans have safe treatments available to them. – and that they are not placed in a position of additional vulnerability, or intentional or unintentional harm.

BACKGROUND — MENTAL HEALTH TREATMENTS FOR VETERANS

Mental Health care is an ever-evolving field greatly influenced by research and innovations. While there are always new and emerging treatments, in an effort to ensure Veterans are receiving safe and effective care, Veterans Affairs Canada provides coverage for health care benefits and/or services that are evidence-based; that is where the value and safety of the benefit and/or service is supported by scientific research findings.

Psychedelic-assisted psychotherapy is an emerging mental health treatment which includes the ingestion of substances such as lysergic acid diethylamide (LSD), Psilocybin, 3-4 methylenedioxymethamphetamine (MDMA, i.e., ecstasy, molly), Ketamine or Ibogaine, to induce a psychedelic state prior to or at the beginning of a psychotherapy session. The hypothesis or belief is that the psychedelic drug can bring meaningful insight for the patient in regard to their condition, as well as diminishing their fear and arousal responses, thereby augmenting the psychotherapeutic process. In Canada, there are no guidelines or standardized protocols for the inclusion of a psychedelic drug into the psychotherapeutic treatment. Health regulators are emphasizing that the provision of therapy to a person under the influence of a psychedelic or dissociative drug should be done only if a licensed and authorized professional is able to demonstrate that the use of drug assisted therapy is supported by evidence, and is appropriate based upon client needs. As this therapy is emerging and there is not sufficient scientific evidence and literature available to date to support the effectiveness and safety of this approach, it has not been recognized as a Veterans Affairs Canada-approved treatment.

The use of Ketamine as a pharmacologic treatment is however approved as a non-formulary product administered orally, by infusion, nasal spray or compounded cream, to treat treatment-resistant major depression disease or chronic pain. Criteria has been established for these uses only.

The use of Ketamine to induce a psychedelic state as required for psychedelic-assisted psychotherapy, is not currently approved by Veterans Affairs Canada.

CIHR is currently funding limited clinical trials (not Veteran-specific) for psilocybin for patients with advanced cancer, alcohol use disorder, and treatment-resistant depression. If there is intention for a comprehensive federal research program for psychedelic-assisted psychotherapy, there would need to be new funding.

Drug research and development is a lengthy process. MDMA is further along the regulatory approval pathway than other substances and still requires, at minimum, 2-3 more years of review before approval could be sought as a pharmaceutical. It is only after Health Canada approval that VAC would normally undertake a review of evidence to consider reimbursement.

An acceleration of research activities outside of the normal drug development cycle signals to industry and the general public that the government wants to see these products approved. This will generate expectations of future reimbursement for Veterans as well as market expectations about future government direction.

Safety of a drug/treatment is not the same as safety of its use. Many of those engaged in supporting the use of psychedelic-assisted psychotherapy stand to benefit financially, not only from possible future approval but also from the government simply announcing plans to engage in research. This is of particular concern in terms of marketing activities aimed at vulnerable groups, including Veterans.

Australia's approval of MDMA and psilocybin for PTSD and depression has faced criticism as being premature and based on insufficient evidence. This is despite the requirement for ethics committee approval for every patient case.

On February 6 2024, California introduced a bipartisan bill to allow people 21 years and older to consume psychedelic mushrooms under professional supervision as part of an agenda to tackle the state's mental health and substance use crises. Colorado and Oregon have already decriminalized psychedelic mushrooms and establish regulated systems for therapeutic use of the substances. In California, San Francisco, Oakland and Santa Cruz have effectively decriminalized possession of psychedelic mushrooms, meaning a person cannot be arrested or prosecuted for possessing limited amounts of plant-based hallucinogens.

Veterans Affairs Canada monitors emerging treatments for Veterans, and once there is sufficient scientific evidence available to support a safe and effective treatment, it may adjust its benefit grids and drug formulary accordingly.

VEAC Report (Senate Subcommittee on Veterans Affairs)

Report: *The Time is Now: Granting equitable access to psychedelic-assisted therapies*
[COM TEMP Accessible-Committee-Report 2022-09-27 E.docx \(sencanada.ca\)](#)

Release date: November 8, 2023

Background:

The Subcommittee conducts work/studies on issues relating to Veterans Affairs, including services and benefits provided, commemorative activities, and the continuing implementation of the Veteran's Well-being Act.

Their November report focussed on operational stress injuries, such as PTSD. It urged the federal government to urgently act on every possibility to alleviate the suffering of these injuries. More specifically, the report spoke to emerging psychedelic-assisted psychotherapies.

The report cited VAC's Chief Psychiatrist and the Mental Health Treatment Review Committee stating that *"the studies did not clearly demonstrate that the benefits outweighed the risks for these substances and had insufficient data on risks to certain at-risk populations (people with psychotic or dissociative disorders, severe PTSD or suicidal ideation). VAC's position is to wait for the preliminary findings of existing studies to be confirmed by future studies that may address veterans specifically."*

The Subcommittee concluded that *"Psychedelic-assisted psychotherapy is a developing field of study that may hold therapeutic promise in a variety of mental disorders and other conditions in Veterans."*

The report had one recommendation; namely:

"That Veterans Affairs Canada and the Department of National Defence, in collaboration with Health Canada and the Canadian Institutes of Health Research, as well as the applicable provincial and territorial authorities, immediately launch and fund a large-scale research program on psychedelic-assisted psychotherapy for treating those mental disorders and other conditions that have been identified as potentially being therapeutic targets for these types of interventions."

On May 21, 2024, the Senate of Canada adopted a motion requesting a Government Response to this recommendation. The Government is required to table this response within 150 days, or by October 17, 2024.

Veterans Affairs, in consultation with Health Canada and the Department of National Defence, prepared and tabled the government response within the required timeline. VAC has noted that psychedelic-assisted psychotherapy (PAP) is an emerging mental health treatment, however the neuromechanisms regarding the therapeutic effects of psychedelic-assisted psychotherapy remain unknown though under active investigation. To date, with regards to psychedelic drugs, Health Canada has only received one submission for market authorization, which was approved, for the intranasal spray Spravato (esketamine) in combination with an SSRI (selective serotonin reuptake inhibitor) or SNRI (serotonin-norepinephrine reuptake inhibitor). This drug product is authorized for the treatment of major depressive disorder in adults who have not responded adequately to at least two separate courses of treatment with different antidepressants, and as a short-term treatment for the rapid reduction of symptoms in adult patients with a moderate to severe episode of major depressive disorder which requires urgent psychiatric care.

As such, the government is taking note of the recommendation, will continue to actively monitor the research being conducted on psychedelic-assisted psychotherapy (PAP) and will engage the Departments of National Defence and Veterans Affairs to provide Veteran related subject matter expertise. The mental health of Veterans is of utmost importance and the government is working to support them.