COLLEGE OF PHYSICIANS AND SURGEONS OF BRITISH COLUMBIA

PROFESSIONAL GUIDELINE

Ketamine Administration via Intramuscular, Oral, Sublingual, and Intranasal Routes as Treatment for Mental Health Conditions and Chronic Pain in the Community Setting

Effective:	August 10, 2021
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Related topic(s):	Charging for Uninsured Services; Complementary and Alternative Therapies; Conflict of Interest; Consent to Treatment; Sale and Dispensing of Drugs

A **professional guideline** reflects a recommended course of action established based on the values, principles and duties of the medical profession. Licensees may exercise reasonable discretion in their decision-making based on the guidance provided.

Preamble

The College of Physicians and Surgeons of BC (CPSBC) has received inquiries from licensees regarding the prescribing and administration of ketamine for the treatment of mental health conditions and chronic pain in adults.

Licensees are encouraged to contact the CMPA for advice before proceeding with therapies that are not considered conventional treatment options and/or additions to their scope of practice.

CPSBC's position

Intravenous administration of ketamine is only acceptable in hospital settings or in accredited non-hospital medical and surgical facilities. For further information on intravenous ketamine in accredited facilities, licensees should contact the Non-Hospital Medical Surgical Facility Accreditation Program at nhmsfap@cpsbc.ca.

For all other routes of administration (IM, oral, sublingual, intranasal, transdermal), caution is advised due to the potential safety risks associated with ketamine, particularly for off-label use. Licensees are reminded not to prescribe or use a treatment that departs from prevailing medical practice, unless they are able to demonstrate that the potential benefits of the treatment outweigh the risks.

Licensees should note that certain products like intranasal esketamine (Spravato) have manufacturer-specific guidelines for use.

Pursuant to the Canadian product monograph, SPRAVATO® is only available through a controlled distribution program called the Janssen Journey™ Program. The goal of the Janssen Journey™ Program is to mitigate the risks of adverse outcomes related to sedation, dissociation, blood pressure changes, and the risk of misuse and abuse.

- SPRAVATO® can only be prescribed by a licensee who is experienced and proficient in the management of major depressive disorder and enrolled in the Janssen Journey™ Program.
- Only pharmacists enrolled in the Janssen Journey™ Program can dispense SPRAVATO®.
- Physicians who prescribe SPRAVATO® and pharmacists who dispense SPRAVATO® must complete training on the risks of the product and agree to adhere to the requirements of the Janssen Journey™ Program.
- Prior to being prescribed SPRAVATO®, patients must be enrolled in the Janssen Journey™ Program.
- Prescribers must ensure that the patients are informed of and understand the conditions of use and risks of treatment with SPRAVATO®.
- SPRAVATO® can only be dispensed to sites of care where patients self-administer the product under the direct supervision of a health-care professional and are monitored by a health-care professional post administration.
- Questions may be directed to Health Canada at hcinfo.infosc@canada.ca, or the Janssen Journey™ Program at 1-833-257-7191 or by email at contact@janssenjourneyprogram.ca.

It is an expectation of CPSBC that licensees not only observe and monitor the patient, but have the necessary equipment and competence to manage any adverse reactions. Beyond simply monitoring patients' vital signs during peak drug effects, patients receiving ketamine have a high risk of dissociation and sedation post administration that requires monitoring. Furthermore, the use of ketamine carries a risk of misuse or diversion, and attention to these risks is an additional expectation of CPSBC.

As with any therapeutic intervention, informed consent is paramount. Licensees must ensure that informed consent is obtained from the patient in accordance with the *Consent to Treatment* practice standard. It is expected that patients be fully informed of the risks, benefits (and unknown nature of the risks and benefits) of any off-label treatments. Particular attention should be paid to informed consent in the off-label use of ketamine, and the details of such discussions should be available in the patient's medical record.

Licensees are expected to only prescribe and administer a drug if

- they have the knowledge, skill, and judgement to do so safely and effectively,
- they have appropriate training and competence, and
- they have immediate access to equipment used to manage adverse events.

Licensees must be aware of and comply with CPSBC's relevant practice standards including *Charging for Uninsured Services*, *Complementary and Alternative Therapies*, *Conflict of Interest*, and *Sale and Dispensing of Drugs*. Licensees must only recommend treatment when it is justified by the patient's condition and is in the patient's best interest. As ketamine assisted therapy is currently an uninsured service, the CPSBC expects licensees to communicate and set fees clearly and fairly.

Licensees must also ensure they are acting in accordance with CPSBC's *Advertising and Communication with the Public* practice standard. Information provided on clinic websites must be represented accurately and come from reputable, peer-reviewed publications or respected external organizations. It is the expectation of CPSBC that all licensees follow federal regulations regarding medical devices and drug therapies.

In other jurisdictions, ketamine is scheduled as a controlled drug requiring a duplicate prescription form (Saskatchewan, Alberta). This prospect is being studied in BC as well.