CPSBC College of Physicians and Surgeons of British Columbia

Interim Guidance

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
Last revised:	August 10, 2021
Version:	1.0
Related topic(s):	Charging for Uninsured Services; Complementary and Alternative Therapies; Conflict of Interest; Sale and Dispensing of Drugs

Interim guidance from the College provides information to express or clarify the College's view on a particular matter. It is intended as guidance for registrants in areas where research and current practice are evolving or changing rapidly, the implementation of processes and procedures may be premature, or it is timely to communicate the College's stance on an issue before a practice standard or professional guideline is developed.

Registrants may seek advice on these issues by contacting the College and asking to speak with a member of the registrar staff, or by seeking medical legal advice from the CMPA or other entity.

PREAMBLE

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

COLLEGE'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, registrants 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. Registrants 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.

Registrants 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 registrant 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 online at www.JanssenJourneyHCP.ca.

It is an expectation of the College that registrants 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 the College.

As with any therapeutic intervention, informed consent is paramount. 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.

Registrants 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.

Registrants must be aware of and comply with the College's relevant practice standards including *Charging for Uninsured Services*, *Complementary and Alternative Therapies*, *Conflict of Interest*, and *Sale and Dispensing of Drugs*.

Registrants are encouraged to contact the CMPA for advice before proceeding with therapies that are not considered conventional treatment options.

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.

The College acknowledges the assistance of the College of Physicians and Surgeons of Saskatchewan and the College of Physicians and Surgeons of Alberta whose guidance to their registrants has been used in forming this interim guidance.

Note: This interim guidance will remain effective until a practice standard has been drafted and circulated for feedback through the College's usual consultation process. Once developed, the practice standard will be presented to the Board for endorsement and published on the College website.