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REGISTRAR: Karen Shaw, M.D.

2022.11.17

Dear Colleague

Re: Updated Guidance for Ketamine/Esketamine as treatment for mental health and chronic pain diagnoses in community settings.

The College of Physicians and Surgeons of Saskatchewan (CPSS) is updating the guidance to physicians regarding the use of Ketamine for mental health conditions and chronic pain in community settings.

Guidance from the College provides information to express or clarify the College's view on a particular matter. It is intended as guidance for physicians 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 bylaw, policy, or professional guideline is developed. It is available on the College's webpage under <u>Guidance to the Profession</u>.

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1. Overview:

For the purpose of this document, a community-based setting refers to a Physician's office or designated clinic that is not affiliated with a hospital, health authority, nor a <u>Non-Hospital</u> <u>Treatment facility</u>. In appropriate circumstances this may also apply to a patient's home when the patient is managed by a palliative care team.

For the purpose of this document, when the referring to Ketamine, it will include all salts and/or enantiomers, in all dosage forms, as a single active ingredient or as a combination product.

Important amendments to previous guidance document of January 19 2021, and updated December 2021:

- The Intravenous administration of Ketamine continues to only be permitted in a Non-Hospital Treatment Facility (NHTF), and the College is not considering exemptions at this time.
- Physicians who consider the administration of Ketamine by any other route (Intramuscular/subcutaneous/oral/sublingual/intranasal/transdermal) in a communitybased setting should contact the College to be considered for a possible exemption under the College's Regulatory Bylaw 26.1, <u>Operation of Non-Hospital Treatment Facilities in</u> <u>the Province of Saskatchewan</u>
- Patients registered under the Palliative Care Program, where Ketamine is used as part of a multimodal treatment approach and prescribed by a physician with skill, knowledge, and experience in palliative care, will be exempt from this requirement.
- Ketamine, when prescribed for self-administration by any route (Intramuscular/subcutaneous/oral/sublingual/intranasal), fall under the College's Policy <u>Complementary and Alternative Therapies</u>

The use of Ketamine for mental health and chronic pain is not yet fully supported by professional consensus or established clinical evidence; however, the College does not explicitly prohibit the off-label uses of medications, including Ketamine, as this may fall under research in approved clinical trials, evolving clinical practice, and complementary and alternative medicine.

Physicians are reminded not to prescribe or practise any therapy that departs from prevailing medical practice unless they are able to demonstrate that the potential benefits of the therapy outweigh the risks. It is unethical to engage in or to aid and abet in treatment which has no acceptable scientific basis, may be dangerous, may deceive the patient by giving false hope, or which may cause the patient to delay in seeking conventional care until his or her condition becomes irreversible.

Physicians are encouraged to review <u>The Canadian Network for Mood and Anxiety Treatments</u> (CANMAT) Task Force Recommendations for the Use of Racemic Ketamine in Adults with <u>Major Depressive Disorder</u>.

2. Intravenous administration of Ketamine:

The College is <u>NOT</u> considering exemptions for the administration of intravenous Ketamine in community settings at this time. Intravenous Ketamine, as off-label use for depression and/or chronic pain management outside of a SHA accredited hospital or emergency room, continues to **only be permitted in accredited non-hospital facilities setting** under the CPSS Regulatory Bylaw 26.1 *Operation of Non-Hospital Treatment Facilities in the Province of Saskatchewan*

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(e) a non-hospital treatment facility is one in which any of the following are performed:

(i) the use of drugs which are intended, or which may induce general anaesthesia or sedation requiring the monitoring of vital signs, including all uses of intravenously administered sedatives or narcotics, except in emergency circumstances.

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3. <u>Palliative Care:</u>

Patients registered under the Palliative Care Program, where Ketamine is used as part of a multimodal and multidisciplinary treatment approach and prescribed by a physician with skill, knowledge, and experience in palliative care, all formulations and routes of administration will be exempt from this requirement.

4. <u>For all other routes of parenteral administration of Ketamine, when considering</u> <u>administration in a community-based setting:</u>

The College's <u>Regulatory Bylaw 26.1</u> was amended to allow a physician to make an application to the College for an exemption to use agents that can produce sedation without the facility being approved as a non-hospital treatment facility:

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(viii) Notwithstanding anything contained in this bylaw 26.1, a physician who seeks to provide medical care which involves the use of drugs which are intended or may induce sedation requiring the monitoring of vital signs may apply to the College for an exemption from the requirement that the facility be approved as a nonhospital treatment facility to utilize such drugs.

(ix) The College may grant an exemption under paragraph (viii) subject to any terms and conditions and may require the physician to provide an undertaking to the College related to the request for the exemption.

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Physicians can contact the Office of the Registrar, to apply for an exemption.

Practitioners in community-based settings must only administer Ketamine in subdissociative/sub-anesthetic doses, that:

- a. is congruent with clinical guidelines and consensus statements for the specific treatment indication, and
- b. could not be reasonably foreseen to cause a decreased level of consciousness/alertness.

For Intranasal administration, physicians are reminded that pursuant to the Canadian product monograph, <u>SPRAVATO®</u> is only available through a controlled distribution program called the <u>Janssen JourneyTM Program</u>. The goal of the Janssen JourneyTM Program is to mitigate the risks of adverse outcomes related to sedation, dissociation, blood pressure changes, and the risk of misuse and abuse.

It is an expectation of the College that physicians not only observe and monitor the patient, but also have the necessary equipment and competence to manage any adverse reactions that may occur.

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. A more comprehensive document setting out the expectations for physicians and clinics will be provided to physicians who make an exemption application to the College.

Furthermore, the use of Ketamine carries a risk of misuse or diversion, and the College also expects attention to these risks.

5. <u>For all other routes of administration of Ketamine, when prescribed for self-administration:</u>

The College's position is that physicians should <u>NOT</u> prescribe Ketamine by any route (Intramuscular/subcutaneous/oral/sublingual/intranasal/transdermal) for unsupervised self administration by the patient.

The College is aware that topical compounds containing Ketamine is being prescribed for self administration, and caution is advised, as there is no definitive evidence regarding the safety profile of such compounds, and abuse, misuse and overdose have been reported.

The exception to this is palliative care, in very select circumstances to patients registered under the Palliative Care Program, where Ketamine is used as part of a multimodal and multidisciplinary treatment approach and prescribed by a physician with skill, knowledge, and experience in palliative care.

If prescribing for self administration is considered, The College advises that the physician contact the College to discuss this on a case-by-case basis.

The College's <u>Complementary and Alternative Therapies policy</u> will apply to physicians who consider prescribing Ketamine for self-administration by the patient.

6. <u>College Monitoring:</u>

Ketamine falls under the list of monitored drugs of the College's Regulatory bylaw <u>18.1 The</u> <u>Prescription Review Program</u> and physicians are reminded about the risk for abuse, misuse and diversion.

7. <u>Scope of Practice:</u>

Prescribing:

Ketamine/esketamine prescribing in community settings should be limited to psychiatrists or duly qualified physicians in related fields of practice, with appropriate training and experience (for mental health indications) and physicians with training and experience in pain medicine or duly qualified physicians in related fields (for pain indications)

Administration/monitoring:

Ketamine administration and monitoring should be limited to physicians who:

- are trained in the use of Ketamine for sedation and anesthesia (anesthesiologists, ED physicians, critical care, GP anesthesia, pain fellowships etc. This will include psychiatrists/or other duly qualified physicians who have the appropriate training, experience, and currency when intranasal ketamine is used for mental health conditions),
- can perform the appropriate monitoring, and
- possess the appropriate training, skills, and currency in the use of this medication and in the appropriate emergency response to any adverse events.

For physicians who consider the prescribing and/or administration of Ketamine outside of what would be considered the usual scope of practice for the physician's discipline, training, and experience, must apply for a <u>scope-of practice change</u> to comply with the College's <u>Regulatory</u> <u>Bylaw 4.1</u>, Returning to Practice in Saskatchewan after an absence or disability, inactive practise, or change in scope of practice.

8. General:

Physicians are encouraged to contact the <u>CMPA</u> for advice before proceeding with therapies that are not considered conventional treatment options.

The College of Physicians and Surgeons of Saskatchewan recognizes the College of Physicians and Surgeons of BC (CPSBC) and College of Physicians and Surgeons of Alberta (CPSA), regarding guidelines and standards for the prescribing and administration of Ketamine.

The CPSS acknowledges the use of the communique of the College of Physicians and Surgeons of British Columbia <u>Interim Guidance Ketamine Administration via Intranuscular, Oral,</u> <u>Sublingual, and Intranasal Routes as Treatment for Mental Health Conditions and Chronic Pain</u> <u>in the Community Setting</u> The CPSA has a clinical toolkit, <u>Ketamine and Esketamine: Key considerations</u>, which may be helpful in decision making.

Should further evidence become available regarding the use of Ketamine, the CPSS may consider revising this guidance.

References:

- CADTH Rapid Response Report: Summary with Critical Appraisal, <u>Ketamine for Chronic Non-Cancer Pain: A Review of Clinical Effectiveness, Cost-</u> <u>Effectiveness, and Guidelines</u>
- <u>The Canadian Network for Mood and Anxiety Treatments (CANMAT) Task Force</u> <u>Recommendations for the Use of Racemic Ketamine in Adults with Major Depressive</u> <u>Disorder</u>
- The CPSA clinical toolkit, <u>Ketamine and Esketamine: Key considerations</u>,
- College of Physicians and Surgeons of British Columbia <u>Interim Guidance Ketamine</u> <u>Administration via Intramuscular, Oral, Sublingual, and Intranasal Routes as Treatment</u> <u>for Mental Health Conditions and Chronic Pain in the Community Setting</u>
- American Society of Regional Anesthesia and Pain Medicine: <u>Consensus Guidelines on</u> <u>the Use of Intravenous Ketamine Infusions for Chronic Pain</u>
- JAMA: <u>A Consensus Statement on the Use of Ketamine in the Treatment of Mood</u> <u>Disorders</u>

Sincerely,

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