

Title: Off-label use of ketamine

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Purpose: Provide guidance on medical board expectations concerning the off-label use of ketamine, especially for mental illness

Approved by: Medical Board vote

A Joint Advisory from New Mexico Boards of Nursing and Medicine Review by Board of Pharmacy

Over the past decade, the use of Ketamine has expanded beyond anesthesia and pain management in surgical, hospital and emergency departments. There is some evidence that this medication, as well as an enantiomer, esketamine, may be effective in the treatment of certain psychiatric disorders. See selected research at the conclusion of this advisory, particularly the well-done documents adopted by Texas and Pennsylvania.

The use of these medications in the treatment of severe resistant unipolar depression and possibly other mental illnesses is evolving, but usually entails using significantly lower doses (aka "VLD" Ketamine, "Very Low Dose") administered by intravenous, intramuscular, subcutaneous, oral, and intranasal routes. Guidelines for the use of these medications have been published but still indicate some variability and the need to establish effective treatment, dosing and delivery methods and plans.

While Ketamine is an approved medication for anesthesia, its subanesthetic use for mental health treatment is **off label**, so it is subject to additional caution and review, including clinical and ethical guidelines.

Ketamine is also a controlled substance and therefore subject to additional state and federal laws and requirements. There is risk for abuse, misuse, diversion, and drug seeking, therefore extra care in its procurement, storage, security, records, and use is necessary. It is required to be reported in the Prescription Monitoring Program.

It is becoming apparent from the national press and health care publications that Ketamine is being provided by health care providers across the country for reasons outside of the legitimate treatment of medical illnesses as well as for illnesses outside their area of expertise.

This is a concern of the Board, as we are compelled by the Medical Practice Act to "Protect the public". This includes protecting the public from improper, unprofessional, incompetent, and unlawful practice. Ketamine for mental health diagnosis requires the provider, to have education and certification in the diagnosis and management of this population.

Therefore, in the interest of promoting the safe, effective, and ethical practice of medicine, the NMMB offers the following guidance in the use of Ketamine.

1. If Ketamine is being offered as a treatment, it must be for the treatment of a legitimate, medically recognized illness. This includes a valid provider-patient relationship, including a full history and physical, a complete medical record, a full treatment plan, ongoing monitoring, and documentation of patient response by the provider.
2. Ketamine must be offered as a treatment only if there is a valid scientific basis, such as recognized evidence-based standards for its use for a particular diagnosis and it is administered as outlined per protocols developed by the relevant professional society.
3. Before being considered as a candidate for Ketamine treatment, the patient must be evaluated and diagnosed by a provider with documented and validated educational expertise in the diagnosis and treatment of the patient's condition, and the provider is certified as such.
4. Ketamine, if utilized, must be part of a complete ongoing treatment plan for the patient's condition, which includes a safety plan and appropriate concomitant therapy, such as anti-psychotic and anti-depressant medications.
5. Ketamine must be administered only by a provider that has been trained in its clinical indications, effect monitoring, and outcomes evaluation; including appropriate safety measures (for example, safety response equipment and trained staff, including Advanced Cardiac Life Support, as recommended by relevant treatment protocols).
6. Safety measures for the use of this medication must be in place for managing both immediate, short-term, and long-term side effects, to include on-going follow-up once ketamine treatment ends.

Using ketamine outside these guidelines may subject licensees to investigation for violations of the Medical Practice Act and its regulations.

References:

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Sanacora, G., et al. (2017). A Consensus Statement on the Use of Ketamine in the Treatment of Mood Disorders. *JAMA Psychiatry*. 2017;74(4):399-405. doi: [10.1001/jamapsychiatry.2017.0080](https://doi.org/10.1001/jamapsychiatry.2017.0080) Published online March 1, 2017.

Shiroma et al. (2020) A randomized, double-blind, active placebo-controlled study of efficacy, safety, and durability of repeated vs single subanesthetic ketamine for treatment-resistant depression, *Translational Psychiatry*, 10:206. <https://doi.org/10.1038/s41398-020-00897-0>

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