Alabama Board of Medical Examiners

Guidelines for the Off-Label Use of Ketamine for Treatment-Resistant Depression in Outpatient Settings

WHO CAN PRESCRIBE?

Ketamine must be prescribed by a physician who holds an active license to practice medicine in Alabama. The physician must be trained in the use of ketamine and the diagnosis and treatment of treatment-resistant depression ("TRD"). If the administering physician is not a psychiatrist, a diagnosis of TRD must be confirmed by the patient's treating psychiatrist or primary care physician prior to initiating treatment.

PATIENT SELECTION

Patients must have a current diagnosis of major depressive disorder as defined by DSM-5-TR or have major depressive disorder with suicidal ideation for which a rapid treatment onset is important.

Ketamine should not be used as a first-line treatment for depression. Ketamine should only be considered after a failed response to an adequate trial of at least two antidepressants from at least two different antidepressant classes of adequate dose and duration.

Whether ketamine is an appropriate treatment for a particular patient shall be determined by clinical interview or use of a standardized depression scale.

EXCLUSION CRITERIA

Ketamine should not be administered to patients with a current diagnosis or history of schizophrenia, schizoaffective disorder, patients with current uncontrolled hypertension, patients who are pregnant, or patients who have had previous serious adverse effects to ketamine. Ketamine should not be used in individuals with previous or current ketamine use disorder. Physicians must use extreme caution when using ketamine in individuals with a history of or active substance use disorder. Physicians should not administer ketamine to patients who are acutely intoxicated.

This information sheet is a summary of Board guidelines. Please refer to the complete guidelines at www.albme.gov, or scan the QR code.

Physicians must obtain written informed consent, a complete history and physical, including a history of previous antidepressant use, conduct a physical examination, obtain a urine toxicology screen, and obtain informed consent prior to the administration of ketamine. Physicians should prescribe the minimum dose necessary to achieve the desired clinical effect.

Requirements for Location of Administration, Monitoring and Recovery

- Ketamine should be administered in a space large enough to accommodate the patient and required personnel.
- Ketamine should be administered in a facility which has the means to monitor a patient's heart rate, blood pressure, respiratory rate and oxygen saturation level. Oxygen and medications must be available in the event of sustained alterations in cardiovascular function or potentially dangerous behavioral symptoms by the patient during treatment.
- Any facility in which ketamine is administered should be equipped with the personnel and equipment necessary for resuscitation (i.e., crash/code cart, AED).
- The prescribing physician must be ACLS certified and trained to establish an airway if necessary.
- When a physician prescribes ketamine for TRD, other licensed professionals may assist in the administration of ketamine and psychotherapy as long as the prescribing physician remains onsite and the licensed professional is under the physician's supervision. Licensed professionals who assist in the administration of ketamine must also be ACLS certified.
- The prescribing physician or ACLS certified licensed professional must be present during the administration of ketamine. The patient should remain at the outpatient setting for monitoring. The physician must monitor the patient's blood oxygen saturation level, blood pressure and heart rate every five to fifteen minutes, and monitor the patient's level of consciousness / mental status by watching for signs of dissociation or distress. The monitoring of the patient can be delegated to other licensed professionals as long as the physician remains onsite. The patient may be discharged after a minimum two hour monitoring period, and once vital signs are stable and within acceptable limits, mentation has returned to baseline or an appropriate level of alertness, and the patient exhibits no more than minimal nausea, vomiting, or dizziness.
- The physician should have patients complete a questionnaire such as the Patient Health Questionnarie-9 in order to evaluate whether ketamine is providing the desired response. The physician should discontinue use of the anesthetic agent if the patient shows no improvement after a reasonable trial of four to six infusions.
- Treatment by psychotherapy should be considered in tandem with ketamine administration.

DOSING AND TITRATION

The physician must determine the appropriate dose for each patient. The most common dose is 0.5 mg/kg of body weight administered by IV infusion over 40 minutes. Higher doses may be more likely to result in adverse cardiovascular effects. Ketamine infusions should not be given more than twice a week.

SAFETY PRECAUTIONS

- A physician should never allow the patient to administer ketamine for psychiatric reasons at home and should never allow a family member to monitor the patient.
- The infusion should be discontinued if there is a significant increase in blood pressure or heart rate, the patient develops respiratory symptoms such as shortness of breath or wheezing, or if there is evidence of cardiac involvement.
- After an infusion of ketamine, the patient should not drive or operate machinery for the remainder of the day. The patient must be driven home by a caregiver.

These guidelines apply only to the off-label use of racemic ketamine for treatment-resistant depression and not the administration of intranasal esketamine (SPRAVATO®) when used in accordance with FDA guidelines.

These guidelines do not apply to anesthesiologists administering ketamine for the induction and maintenance of anesthesia in a hospital setting or to physicians administering ketamine for palliative care.

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