Carencia
Mental Healthcare

Ketamine Treatment

Educational Information

Ketamine/esketamineis a schedule III controlled substance. Ketamine was originally researched in the 1960's as a dissociative anesthetic and approved in 1970 by the FDA for this reason. Ketamine is prescribed off-label for treatment resistant depression. Spravato(esketamine) is an FDA-approved prescription medicine for treatment resistant depression in adults, used in addition with an oral antidepressant. Ketamine is a noncompetitive,N-methyl-D-aspartate receptor antagonist (NMDA).

Ketamine/esketamine is known to have short-term effectiveness for the treatment of nonpsychotic, treatment resistant depression with results lasting for a few days to months. There is no way to predict how any single person will respond to ketamine therapy. These effects may not be long lasting and will require further treatments. The safety of long term use ketamine is not known.

There is a serious risk of adverse side effects involving increased sedation and dissociation.

There is a serious risk of abuse or misuse of ketamine/ esketamine. There is limited information currently about abuse of ketamine and its prevalence in the U.S. There are concerns about the adverse effects from indefinite ketamine exposure including cognitive impairment, bladder toxicity, increased propensity for delusions and abuse.

There is a serious risk of increased suicidal thoughts or actions. Tell your healthcare provider right away if you have any of the following symptoms: attempted to commit suicide, are having new/worsening thoughts about suicide or dying, worsening depression, or other unusual changes inbehavior or mood.

Practice Policies

- Ketamine/esketamine is only administered under the direct observation of a health care provider.
- Ketamine/esketamine is never dispensed directly to a patient for home-use, however patients self-administer in the office under healthcare provider supervision.
- Patients are required to be monitored by a health care provider for up to two hours after administration. If
- receiving Spravato, patient must be enrolled in the Spravato REMS program prior to receiving medication.

We require certain treatment adherence policies.

Patient Responsibilities

- I agree to report all of my medical conditions, history and symptoms honestly to treatment staff. I also agree to inform treatment staff of all other healthcare providers whom I am seeing; of all prescription and non-Prescription drugs I am taking; of any alcohol or street drugs I have recently been using; and whether I have become pregnant or have developed hepatitis.

- I understand that ketamine is not an FDA-approved treatment for depression. I understand that Spravato (esketamine) is an FDA-approved treatment, used along with an oral antidepressant, for nonpsychotic, treatment resistant depression in adults.

- I understand that I am consenting for this treatment. I also understand that I can refuse this treatment at any time.

- I understand that my healthcare provider can stop the treatment without my consent.

- I understand that ketamine may not help my depression.

- I have the right to ask my healthcare provider questions about this treatment. I confirm that I have asked these questions and my healthcare provider has answered those questions to my satisfaction.

- I understand that the possible alternative methods of treatment, the risks involved, and the possibility of complications have been fully explained to me.

- I understand that I must attend all of my appointments. If patient follow-up visits are not adhered to treatment termination could result.

I agree that I do not have blood vessel disease (including in the brain, chest, abdominal aorta, arms and legs).

- I agree that I do not have an abnormal connection between my veins and arteries (arteriovenous malformation).

- I confirm that I have not had a history of bleeding in the brain.

- I do not have any documented allergy to ketamine/esketamine, or any of the other ingredients of Spravato.

- I have been provided a copy of the patient medication guide on Spravato and the package insert. I confirm I have reviewed both documents before consenting to treatment.

- I confirm that I will not use any central nervous system depressants, including but not limited to benzodiazepines, opioids, or alcohol, one week before and throughout treatment with ketamine/esketamine.

- I confirm that I will not use any psychostimulants, including but not limited to amphetamine, methylphenidate, modafinil, armodafinil, and phentermine, one week before and throughout the treatment with ketamine/esketamine.

- I confirm that I have not taken any MAOI's within 14-days of beginning treatment of ketamine/esketamine.

- I understand that I will have to provide and agree to cooperate with a urine-drug screen (additionally for female patients a pregnancy test) at the time of each appointment. I understand that if an unexpected result occurs, treatment with ketamine/esketamine may be withheld and/or discontinued.

- I will not drive, operate machinery, or do anything where I need to be completely alert after taking ketamine/ esketamine. I will not take part in any of these activities until the next day following a restful sleep. This also means I will arrange transportation to and from the prescriber's office during this time.

I acknowledge that buprenorphine and naloxone could have teratogenic effects or effects to a fetus. It is the

- suggestion of Carencia to use protective sex or a form of birth control while taking these products.

I also agree to tell my prescriber immediately if I become aware that I am pregnant.

- I agree that I will be open and honest with my prescriber and inform treatment staff about cravings, potential for illicit drug or ETOH use to the extent that I am aware of such, and specifically about any illicit drug or ETOH use which has occurred --before a drug test result shows it.

- I agree to keep appointments and let appropriate staff know if I will be unable to show up as scheduled.

- I understand that if a medical urgency or emergency occurs and my healthcare provider recommends emergency service care, I will follow this advice and if emergency transportation services are required, this will be at my own expense.

- I understand that if I decline the administration of Ketamine, or are no longer receiving Ketamine from Carencia, (including not making appointments), any shipments to the Carencia office or remaining doses on hand

will be deemed as samples for potential patients 45 days after the medication was received by the office.

Risks/Side Effects

Common Side Effects, greater than 1% and less than 10%:

- Hallucinations Nausea and vomiting
- Increased saliva production
- Dizziness
- Blurred vision
- Increased heart rate and blood pressure during treatment Change in motor skills

Uncommon side effects, greater than 0.1% and less than 1%:

- Rash
- Double vision
- Increased pressure in the eye
- Jerky arm movements resembling a seizure

Rare side effects, greater than 0.01% and less than 0.1%:

- Allergic reaction
- Irregular or slow heart rate Arrhythmia
- Low blood pressure
- Cystitis of the bladder: inflammation, ulcers, and fibrosis

Other Risks:

- Ketamine can cause various symptoms including but not limited to flashbacks, hallucinations, feelings of unhappiness, restlessness, anxiety, insomnia and disorientation
- There is a potential risk of dosing error or unknown drug interaction that may require medical intervention
- Risk of discomfort in answering questionnaires about your mental health and drug and alcohol use.
- Risk of other medications interacting with ketamine. It is very important that you disclose all medications, both prescription and over- the-counter, that you are taking.

What To Expect On The Day Of Visit

- You will arrive 30 minutes prior to your appointment.
- If you take a nasal corticosteroid or nasal decongestant medicine take these medicines at least 1 hour before taking ketamine/esketamine.
- Topreventanynausea/vomiting,youshouldnoteatforatleast2hoursbeforetakingketamine/esketamine

and not drink any liquids at least 30 minutes before taking ketamine/esketamine.

- You will need to plan to have a support person to drive you home after taking ketamine/esketamine.
- You will administer ketamine/esketamine yourself, under the supervision of a healthcare provider in a healthcare setting. Your healthcare provider will show you how to use the Spravato/ketamine nasal spray device, tell you how much Spravato you will take, and when you will take it.
- You will be assessed and monitored by a healthcare provider throughout the visit.
- You will not be able to take home ketamine/esketamine. It will remain at the provider's office.

Additional Education References:

- https://www.spravato.com/files/SPRAVATO-Patient-Brochure.pdf Spravato Education Brochure
- -https://labeling.pfizer.com/ShowLabeling.aspx?id=4485 ketamine package Insert

Patient Name (Printed):_____

Patient Signature: _____ Date:_____