Carencia

1006 N. Bowen Road, Suite 126, Arlington, Texas 76012
P 682-478-5333 | F 682-499-7705 | hello@carencia.com

Ketamine Treatment Agreement

Treatment resistant depression is a form of major depressive disorder (MDD) that is often defined by two or more treatment failures. These treatment failures can include both pharmacological and psychotherapeutic treatment options. In patients aged between 15-39 years of age, depression is the third-leading cause of disability and the second cause of disability on a global scale in middle-aged adults (Fabbri et al., 2019).

Treatment resistant depression is a form of depression that poses an increased risk for experiencing severe adverse effects, even death. Carencia utilizes ketamine/esketamine as a prescription medication, along with an antidepressant taken by mouth, for treatment resistant depression in adults. Spravato (esketamine) was made for treatment resistant depression; it is not intended to help prevent or relieve pain. Carencia has completed the Risk Evaluation and Mitigation Strategy (REMS) process for esketamine and is a certified administration site.

Educational Information

Ketamine/esketamine is 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). This is important for two reasons. One is the current prevailing hypothesis for mood disorder such as depression, is that there is a disruption in monoamines, which are chemicals such as serotonin, norepinephrine, and dopamine. The problem is that up to 50% of patient with depression due not respond to medications that target these chemicals and ones that due have a delay by several weeks. The second, is that ketamine works in a different way and on another chemical called glutamate which is the most abundant excitatory neurotransmitter in the body. There is research now supporting glutamate, or the NMDA receptor in the role of depression. Glutamate regulates brain neurological and synaptic plasticity which simply means it helps with growth and the building of new connections in the brain. Lastly, too much glutamate can be toxic.

Ketamine/esketamine is known to have short-term effectiveness for the treatment of nonpsychotic, treatment resistant depression with results lasting for days to weeks to months. There is no way to predict how any single person will respond to ketamine intranasal therapy. These effects may not be long lasting and will most likely 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 in behavior 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 at least 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. For ketamine/esketamine, we require 1-2 visits per week.

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 physicians and dentists 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 agree that this medication has to be dispensed within 14 days of my healthcare provider receiving the medication. I also understand that I am responsible for the financial cost of this medication. If the medication is not administered within 14 days by my healthcare provider, it will be disposed of, per Federal guidelines, at the patient's expense.

_____ 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 agree to use protected sex or a form of birth control while taking ketamine/esketamine due to the unknown and possible safety of this drug during pregnancy. I also agree to tell my prescriber immediately of being aware 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 I my own expense.

_____ I understand that the fee for a missed/late cancel appointment is different than standard fee amounts due to the length of the visit time. The fee is $250.00 and I agree to pay this amount at the time of the missed visit.

Carencia

1006 N. Bowen Road, Suite 126, Arlington, Texas 76012
P 682-478-5333 | F 682-499-7705 | hello@carencia.com

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.
- Ketamine may not help your depression.

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.
- To prevent any nausea/vomiting, you should not eat for at least 2 hours before taking ketamine/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 take 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 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 every 5-15 minutes to assess vital signs, signs of dissociation, other side effects, and current rating of depression symptoms.
- You will not be able to take home ketamine/esketamine. It will remains at the providers office at Maestro Healthcare, LLC
- You will be required to sign off on the administration for our inventory records of use

Patient Name (Printed): _____

Patient Signature: _____ Date: _____