



## *INFORMED CONSENT FOR THERAPY*

It is important to understand the benefits and risks of ketamine therapy for depression. This form will help to explain both. We also encourage you to ask questions of any of the physician members of Ketamine Infusion Specialists.

Ketamine is a widely used, FDA-approved, anesthetic that has been available for this purpose since 1970. In recent years, it has also been found to alleviate or cure the symptoms of severe, treatment-resistant depression at doses lower than that given for anesthesia. Although intravenous ketamine is not FDA-approved for the treatment of depression, like many drugs, it may be used in what is called an “off-label” manner. This means that licensed physicians, because of their extensive training and understanding of medications, may use a drug to treat a condition that is not listed on the drug’s label.

The response to ketamine therapy and the duration of that response is unique for each patient. In general, 75% of patients achieve improvements in their symptoms. The duration of this improvement also varies with each patient. Reports exist that show improvements in symptoms of depression for weeks, months or permanently. Those who show the most sustained improvement are actively involved in comprehensive care of their depression that involves their psychiatrist or primary care practitioner.

Our depression protocol, based on the best available evidence for relief from depression, is to provide six infusion sessions over three weeks. However, it is possible you may require or desire additional infusions in the future. There are many clinical studies to support these findings and we will provide you with copies of these resources at your request. If you do not achieve improvements in your depression after three ketamine infusions, we will advise discontinuation of this therapy.

In the following paragraphs, you will find a detailed description of ketamine infusion therapy at our clinic so that you know what to expect over the next 3 weeks.

The diagnosis of treatment-resistant, major depressive disorder will be made by a psychiatrist or other qualified practitioner (Nurse Practitioner, Physician Assistant) prior to the patient receiving ketamine therapy. Referrals to a qualified practitioner may be made via a patient's primary care provider or by an emergency department provider. The patients will continue to have comprehensive treatment via their psychiatrist and/or primary provider in addition to ketamine infusion.

After receiving the diagnosis of treatment-resistant, major depressive disorder from a qualified practitioner, the patient will be scheduled for ketamine infusion therapy with Ketamine Infusion Specialists under the direct supervision of a physician anesthesiologist.

*-Therapy is twice weekly for 3 weeks.*

-Patients will receive a History and Physical examination within 30 days of their infusion therapy with the goal of that one examination to encompass the entirety of their treatment.

-Patients will be examined and assessed for appropriate physical and cognitive condition immediately prior to therapy per the standard American Society of Anesthesiologists guidelines.

*-Prior to each infusion:*

-Patients will complete a survey assessing side effects of the treatment to determine tolerance.

-Patients will complete a depression self-assessment questionnaire based upon PSQ-9 criteria for their clinical response to ketamine therapy. This will be used to determine efficacy.

-If patients are not responding to infusion therapy after the third infusion, they will be advised to withdraw from ketamine treatment.

*-Infusion Therapy*

-An IV will be placed to deliver the ketamine infusion.

- Dose: 0.5mg/kg (ideal body weight) of intravenous ketamine administered over 40 minutes.

-Patients will be monitored with pulse oximetry, EKG and non-invasive blood pressure.

-Medications to treat dysphoria (unpleasant visions or feelings), nausea and possible but transient elevations in blood pressure and heart rate will be immediately available.

-Patients will be monitored for recovery for approximately 20-30 minutes following the infusion

-Patients will be discharged with an appropriate caregiver who will provide transportation for them.

The benefits of ketamine therapy are the improvement in the symptoms of severe depression and possibly curing the depression.

The risks include the following common side effects: nausea/vomiting, dysphoria (unpleasant visions or feelings), short-term elevations in blood pressure and heart rate, increased saliva production, dizziness, blurred vision and changes in motor skills. These common side effects of ketamine are short-lived after the infusion is stopped and we will have medicines available to treat many of these symptoms if necessary. You will undergo a recovery period after the infusion before you leave the clinic.

It is possible that ketamine will interact with other medications you may be taking. You must disclose all medications you are taking as well as any substances including alcohol, illegal drugs and legal drugs such as marijuana.

Rare risks of low-dose ketamine therapy include allergic reaction, changes in heart rhythm, cystitis of the bladder (ulcers, inflammation), pain at the site of your IV and damage to a blood vessel during IV placement.

Ketamine infusion may not improve or eliminate your symptoms of depression. You may require additional infusions. To increase your possibility of success, you should continue to take your antidepressant medications under the direction of your primary provider, continue to follow-up with your primary provider in the treatment of your depression and continue to pursue and manage the cause of your depression.

By signing this consent, you agree you understand what is discussed in these pages..

Patient Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Physician Signature: \_\_\_\_\_ Date: \_\_\_\_\_