EpiphanyPsychServices

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**Introduction**

Ketamine is now an “off-label” treatment for various chronic ‘treatment-resistant” mental conditions.

Ketamine is a DEA Schedule 3 medication that has long been used safely as an anesthetic and analgesic agent and now, often effectively for treatment of depression, alcoholism, substance dependencies, PTSD and other psychiatric diagnoses as well as for existential, psychological and spiritual crises and growth.

**How Does It Work?** The current, most probable, understanding of ketamine’s mode of action is as an NMDA antagonist working through the glutamate neurotransmitter system. This is a very different pathway than that of other psychiatric drugs such as the SSRIs, SNRIS, lamotrigine, anti-psychotic, benzodiazepines, etc.

Ketamine is classified as a dissociative anesthetic, dissociation meaning a sense of disconnection from one’s ordinary reality and usual self. At the dosage level administered to you, you will most likely experience mild anesthetic, anxiolytic, antidepressant and, potentially, psychedelic effects. While more recent work has demonstrated the possibility of an antidepressant/anti-anxiety response to low dosages of ketamine administered intravenously and intramuscular injection, this effect tends to be more sustained with repeated use- in other words, a cumulative effect—it is our view that psychedelic ‘dissociative’ experiences may well be instrumental in providing a more robust effect. Psychotherapy is necessary and therapeutic results include a positive change in outlook and character that we term a ‘transformative’ response.

Essential to both methods are time-outs from usual experiences, this period being of varying duration, usually 30 minutes to 2 hours, that tends to be dose and method of administration related. Relaxation from ordinary concerns and usual mind, while maintaining conscious awareness of the flow of mind under the influence of ketamine is characteristic. This tends to lead to a disruption of negative feelings and obsessional preoccupations. It is our view that this relief and the exploration and experience of others possible states of consciousness are singularly impactful. As therapists, we act as guides to the experience and process the experience and its impacts with our patients before and after the sessions.

**Medical Monitoring**

It is essential that you be followed very closely during and after your treatment. This may include Blood Pressure and pulse measurements, psychological measures before each session (We are very serious about understanding what we and ketamine are accomplishing). We follow up and support your treatment by telephone, email and in-person contact. We guide you and look forward to your reports.

You will be entering psychotherapy programs that will prepare you for your ketamine session(s) and assist you in integrating you experience(s) afterwards. This program emphasizes the possibilities for change and the seriousness of your condition and our efforts to assist you.

**Why Ketamine Assisted Psychotherapy?**

The purpose of the IM injection sessions is to generate a robust immediate anti-depressant/anxiety benefit that often occurs over time with repetition of administration of the IM sessions.

The literature indicates a response rate to treatment resistant depression (TRD) (information coming primary from using the low dose IV drip method) of 40-50%--the percentage of patients having remissions, this with multiple sessions. Relapses do occur and may require periodic additional sessions. Over time, a certain small number of patients may become unresponsive to further ketamine sessions.

**In our ever-growing experience, IM sessions within framework of psychotherapy will exceed this rate of response.**

The purpose of the **intramuscular ketamine experience** is to create a non-ordinary (“altered”) state of consciousness in order of facilitate profound transpersonal (“transcendental”, “mystical”, “spiritual”, “religious”) peak experiences. These may prove to be auspicious in resolving your existential problems, acceleration your psycho-spiritual growth and leading to a deep personal transformation and optimization of your lifestyle. Such change is best facilitated within a structured supportive psychotherapeutic milieu in connection with therapists who have a view of your issues, hopes, desires, and struggles. As a byproduct of your experience, you may well feel improvement in your emotional state and reduction in symptoms that bother you such as depression, anxiety, post-traumatic manifestations, and the troubled worries about impending death. You may well notice that you are a bit different after a ketamine experience and that difference may well be liberating and allow for new mindfulness and new behavior.

We may well ask that new patients undergoing IM treatment make a commitment for six IM sessions as a minimum exposure to this method of employing ketamine. This allows for familiarization with this potent experience and the amplification of its benefits.

**How Long Will It Take Before I Might See Beneficial Effects?**

You may experience important positive changes in personality, mood and cognition during treatment, in the aftermath, and in the days and weeks that follow. Some experiences may be temporarily disturbing to you. The ketamine experience itself is designed to enable your own healing wisdom to be accessed and beneficial to you. The psychotherapy support you will receive will aid you in making your experience(s) valuable and understandable to you. We will endeavor to assist you in changing patterns of mind and behavior that are of concern and cause you difficulty.

Your experience will be unique to you. If you and we decide to have additional sessions using ketamine, each of your sessions will be different. The number of sessions varies based on personal needs and treatment responses. We cannot pre-program your experiences. We do our best to give a prognostic view as we learn with you how KAP affects you. All KAP journeys are adventures that cannot be programmed. They evolve from your own being in relation to this substance. Journeys vary in intensity from the IM experiences. While it is best to form an intention for your journey, you may or may not be able to hold onto that. Indeed, no holding on is best and the journey will flow whether or not you hold on and resist or follow the path that

unfolds and relax into it. Holding on is the main source of anxiety in this and other related journeys. A ketamine session can be light, dark, or both. There will be concepts, visions, encounters, and you may well deal with your own death, mortality, and immortality. Some journeys are enjoyable and filled with

awe and some are difficult, but everyone grows from their experiences.

**Eligibility for Ketamine Treatment**

Before participating in ketamine treatment, you will be carefully interviewed to determine if you are eligible for ketamine therapy, including a medical history, physical exam if deemed necessary, review of your medical/psychiatric records, a psychiatric history and administration of brief psychological tests to assess your state of mind.

Pregnant women and nursing mothers are not eligible because of potential effects on the fetus, or nursing child. The effects of ketamine on pregnancy and the fetus are undetermined, and therefore, it is advisable to protect against pregnancy while exposing yourself to ketamine or in the immediate aftermath of its use.

Untreated hypertension is a contra-indication to ketamine use as the substance causes a rise in BP. Similarly, a history of heart disease may make you ineligible to participate.

Information on ketamine’s interaction with other medicines is only partially available and it will be assessed as to your eligibility for KAP.

Ketamine should not be taken if you had untreated hyperthyroidism. There have also been reports of some decrease in immune function in patients receiving surgical doses of ketamine.

Ketamine has an extensive record of safety and had been used at much higher doses for surgical anesthesia, with our respiratory depression.

**Overview of Ketamine Therapy –KAP**

During the ketamine administration session, you will be asked to make two (2) agreements with the therapist(s) to ensure your safety and well-being:

1. You agree to follow any direct instructions given to you by the therapist(s) until it is determined that the

session is over, and

2. You agree to remain as the location of the session until the therapist(s) decides you are ready to leave.

The length of ketamine sessions varies from person-to-person and from experience-to-experience. You will be mostly internally focused for the first 45 minutes to one-hour-and-a-half following IM administration of ketamine. You will continue to remain under ketamine’s influence at a lesser level for at least one hour. Under my care, ketamine will be given as an intramuscular injection into the shoulder or buttocks at doses of 50mg to 100mg (130mg maximally). The choice of dose will depend on prior exposure to ketamine and other psychedelics, body weight, and sensitivity. Naïve subjects will receive a lower dose initial session. It is always better to start with a lower dose to reduce anxiety and become familiar with what a substance might produce in you.

There is always an opportunity to make a choice for larger dose at a future date. It is more difficult to correct a bad experience because of too high an initial dose and the anxiety it may engender. Individuals experienced with psychedelics may receive a higher initial dose. Ketamine IM creates an unusual experience of formlessness and a dissolving of boundaries and has novel effects on the mind.

Preparation for a ketamine session requires assessment by your therapist of our readiness and a sense of connection between you and your therapist. We are engaging in a therapeutic endeavor to benefit you and those who are affected by you. Together, we are creating an altered state of mind (set) in safe and therapeutically conducive setting. After ketamine IM, you will have follow-up sessions that focus on integration of your experience and may lead to further sessions, if you so wish, and if that is in accord with your therapist’s view of your treatment.

You may ask the therapist(s) any questions you may have concerning the procedure or effects of ketamine at any time. Your consent to receive ketamine may be withdrawn by you, and you may discontinue your participation, at any time up until the injection has been given.

**Potential Risks of Ketamine KAP Therapy**

You will be asked to lie still during the ketamine administration because your sense of balance and coordination will be adversely affected until the drug’s effect has worn off—generally two and up to four hours after injection. It is possible you may fall asleep. Other possibilities for adverse effects include blurred and uncomfortable vision (you are advised to keep your eyes closed until the main effects have worn off), slurred speech, mental confusion, excitability, diminished ability to see things that are actually present, diminished ability to hear or to feel objects accurately including one’s own body, anxiety, nausea and vomiting. Visual, tactile and auditory processing are affected by the drug. Music that may be familiar is not ordinary. Synesthesia-a mingling of the senses may occur. Ordinary sense of time will morph into time dilation.

**Because of the risk of nausea and vomiting, please refrain form eating and drinking for at least 3-4 hours preceding the session. Take your morning meds with a few sips of water but stop 3-4 hours before your session.**

**If you are unduly nauseated, you may be offered an anti-nausea medication-ondansetron-in pill or oral dissolving tablet forms.**

**Ketamine generally causes a significant increase in blood pressure but usually not pulse rate. If blood pressure monitoring reveals that your blood pressure is too high, you may be offered clonidine to remedy this.**

**Agitation may occur during the course of a ketamine session. If your agitation is severe, you may be offered alprazolam orally.**

**You will not be allowed to drive for 24 hours. Someone special will need to transport you. You will be assessed for safety prior to leaving the office premises. Relax, rest and be still. You deserve it.**

The administration of Ketamine may also cause the following adverse reactions: tachycardia (elevation of pulse), diplopia (double vision), nystagmus (rapid eye movements), elevation of intraocular pressure (feeling of pressure in the eyes) and anorexia (loss of appetite). The above reactions occurred after rapid intravenous

administration of ketamine or intramuscular administration of high doses of ketamine (in a range of greater than 5mg/kg used for a surgical anesthesia). The dose to be used in this sub-anesthetic ketamine therapy is much lower (2mg/kg or less).

In terms of psychological risks, ketamine has been shown to worsen certain psychotic symptoms in people who suffer from Schizophrenia or other serious Mental Disorders. It may also worsen underlying psychological problems in people with Personality Disorders. During the experience itself, some people have reported frightening and unusual experiences. These frightening experiences, however, may be of paramount value to your transition to recovery from the suffering that brought you to your KAP work. They will stop! You will receive Psychotherapeutic hep and ongoing guidance from your therapist.

**Potential for Ketamine Abuse and Physical Dependence**

Ketamine belongs to the same group of chemicals as Phencyclidine (Sernyl, PCP, “Angel dust”). This group of chemical compounds is known chemically as Arylcyclohexylamines and is classified as Hallucinogens (“Psychedelics”). Ketamine is controlled substance and is subject to Schedule 3 rules under the Controlled Substance Act of 1970. Medical evidence regarding the issue of drug abuse and dependence suggests that ketamine’s abuse potential is equivalent to that of phencyclidine and other hallucinogenic substances.

Phencyclidine and other hallucinogenic compounds do not meet criteria for chemical dependence, since they do not cause tolerance and withdraw symptoms. However, “cravings” have been reported by individuals with the history of heavy use of “psychedelic” drugs. In addition, ketamine can have effects on mood (feelings), cognition (thinking), and perception (imagery) that may make some people want to use it repeatedly. Therefore, ketamine should never be used except under direct supervision of a licensed physician.

Repeated, high dose, chronic use of ketamine has caused urinary tract symptoms and even permanent bladder dysfunction in individuals abusing the drug. This does not occur within the framework of our study.

**Alternative Procedures and Possibilities**

No other procedure is available in medicine that produces ketamine’s effects. Major Depression (MDD), PTSD and Bipolar Disorders are usually treated with antidepressant medications, tranquilizers, mood stabilizers and psychotherapy. Electroconvulsive therapy (ECT), and the recently introduced Transcranial Magnetic Stimulation (TMS) are also in the use for the treatment-resistant-depression. Ketamine has also been used in treatment of addictions and alcoholism as part of comprehensive and usually residential treatment programs, primarily abroad.

**Confidentiality**

Your privacy and all therapy record will be kept confidential. They will be maintained with the same precautions as ordinary medical records. To allow others access to your records, you will have to provide a signed release form. The results of this ketamine therapy may be published in clinical literature. Published reports will not include your name or any other information that would identify you.

**Voluntary Nature of Participation**

Please be aware that the Food and Drug Administration (FDA) has not yet established the appropriateness of Ketamine Assisted Psychotherapy and its use is considered off-label, the only official ‘indication’ for use of ketamine being anesthesia. Your awareness of this situation is key to understanding any liability associated with your use of ketamine. Your informed consent indicates you are aware of this situation.

Ketamine is a new psychiatric treatment-the primary studies have been with depression, bipolar disorders and alcoholism. It is not yet a mainstream treatment, though there are now many studies that demonstrate that it may be an effective treatment. There is an expanding array of ketamine clinics across the country, primarily administering ketamine intravenously, and usually without a therapy component-in other words, as a drug. Preliminary results reveal that *PSYCHOTHERAPY* is essential as opposed to medications alone. This applies to standard mental health care. Psychiatric medications always work better with Psychotherapy.

That therapeutic effect generally occurs with more than one treatment and is most robust when part of an overall treatment program. It may not permanently relieve depression. If your depressive symptoms respond to Ketamine Assisted Psychotherapy, you may still elect to be treated with medications and ongoing psychotherapy to try to reduce the possibility of relapse. Over time, you may also need additional ketamine treatments or other therapies to maintain your remission.

Your decision to undertake Ketamine Assisted Psychotherapy is completely voluntary. Before you make your decision about participating in KAP, you may ask and will be encouraged to ask any questions you may have about the process.

**Withdrawal from Ketamine Assisted Psychotherapy is always your option!!!**

Even after agreeing to undertake Ketamine Assisted Psychotherapy, you may decide to withdraw from treatment at any time.

**I understand that I am to have no food or drink 3-4 hours prior to my Ketamine session.**

**I understand that I need to have someone drive me home from the sessions, and not engage in any driving or hazardous activity for at least 4 hours or more—depending on the continued presence of effects after my session has concluded.**

**No alcohol is allowed 5 days prior to the procedure plus we believe it is harmful to well being**

**Eligibility for KAP**

This consent form contains information about the use of sub-anesthetic dosages of ketamine for psychiatric purposes including depression. Ketamine was approved by the FDA for use as an anesthetic agent several decades ago. The administration of ketamine is lower, sub-anesthetic doses to treat pain, depression, or other psychiatric diagnoses is a newer, off0lable use of ketamine. Psychiatric use of ketamine has become relatively widespread in recent years, has been studied and promoted by researchers at the National Institute of Mental Health, and has had front-page publicity as the new antidepressant with its own novel pharmacological mechanism of action. Ketamine has been administered by intravenous, intramuscular (IM), sublingual, oral, and intranasal routes. Often, it has been used after other treatment approaches have been unsuccessful.

Once you indicate that you have understood the benefits and risks of this treatment, you will be asked to sign this form in order to participate in this treatment. You will be given a signed copy of this form to keep for your own records. This process is known as giving informed consent.

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**By signing this document, you indicate that you understand the information provided and that you give your consent to the medical procedure to be performed during your participation in ketamine treatment.**

**Please read this consent carefully, and feel free to ask questions about any of the information in it.**

**Informed Consent**

By signing this form, I agree that:

I have fully read this Informed Consent form describing Ketamine Assisted Psychotherapy and agree to

its terms holding harmless the practitioner(s) involved in my care—waving, releasing and discharging all claims, rights, and or causes of action, which may arise out of or in connection with my participation in

Ketamine Assisted Psychotherapy. No oral or written statements, representations, or inducements have been made to cause me to enter into this agreement.

1. I have had the opportunity to raise questions and have received satisfactory answers.
2. I fully understand that the ketamine session(s) can result in a profound change in mental state and may

result in unusual psychological and physiological effects.

3. I gave my consent to the use of diazepam if deemed necessary for agitation, to ondansetron for nausea,

and for clonidine for high blood pressure.

4. I have been given a signed copy of this Informed Consent form, which is mine to keep.

5. I understand the risks and benefits, and I freely give my consent to participate in KAP as outlined in this form, and under the conditions indicated in it.

6. I understand that I may withdraw from KAP at any time, up until the actual injection has been given.

I voluntarily sign my name evidencing acceptance of the provisions of this agreement.

Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Physician/Therapist Statement**

I have carefully explained the nature of Ketamine Assisted Psychotherapy to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. I hereby certify that to the best of my knowledge, the individual signed this consent form understands the nature, conditions, risks and potential benefits involved in participating in KAP.

A medical problem or language or educational barrier has not precluded a clear understanding of the subject’s involvement in KAP.

Eugene Huang, M.D.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Michelle Huang, Psy.D.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_