Ketamine-Assisted Psychotherapy (KAP) Information

This document contains important information about my professional services regarding Ketamine-assisted Psychotherapy (KAP), my partnership with medical professionals and prescribers, as well as about Ketamine itself. The information is curated from various sources such as Fluence, Psychedelic Support, the FDA and the Healing Realms Center to aid in your research process; all information reflect the current state of research and information on Ketamine.

Please read the information carefully, and feel free to ask any questions about the information in this document or the information you are reading about elsewhere, before you decide to participate in KAP. It is very important to feel safe, informed, and respected, and to address any concerns you might have about the process before getting started.

What is Ketamine?

Ketamine is a synthetic pharmaceutical compound, classified as a dissociative anesthetic. Discovered in 1962 and patented in 1963, Ketamine was approved by the FDA in 1970 as an anesthetic and analgesic and has been listed on the World Health Organization's List of Essential Medicines since 1985.

Ketamine is also prescribed off-label to treat a wide range of mental health issues. (Off-label prescribing is when a clinician prescribes a medication in a different way than was explicitly approved by the FDA.) Ketamine is commonly used in surgical settings, including pediatric surgery, due to its excellent safety profile, particularly around breathing/airway management. It has also been utilized successfully in managing acute and chronic pain conditions due to its analgesic properties. Known for its therapeutic potential, ketamine is increasingly being used at subanesthetic doses as an off-label treatment for various chronic treatment-resistant mental health conditions, such as depression, alcoholism, substance dependencies, PTSD, OCD (obsessive compulsive disorder), and other psychiatric diagnoses. At lower doses, ketamine can disrupt negative feelings and preoccupations and help the brain create new, healthier patterns.

How Ketamine Works.

Ketamine is classified as a dissociative anesthetic, "dissociation" meaning a sense of disconnection between mind and body, disconnection between thought or emotion,

and/or from one's ordinary reality and usual sense of self. It can rapidly —often within an hour or two— lift the symptoms of anxiety, depression, PTSD, OCD, and other conditions. In addition, the subjective effects on consciousness and the psyche often lead to profound emotional and psychological insights.

Long-lasting stress takes a toll on the neurons of the cortex. Constant high levels of the stress hormone cortisol can make neurons atrophy—they shrivel and shrink. Brain imaging shows that in depressed people, the prefrontal cortex is reduced in size. Shriveled connections in the cortex mean the neural pathways that control memory, decision-making, emotions, and attention don't work as well.

Research into the full pharmacological action of ketamine is revealing just how complex the response to this drug is, but the glutamate receptors seem to play the most important role. Neurons have several different binding sites for glutamate, but when it comes to ketamine, two are of particular interest: the NMDA (N-methyl-D-aspartate) receptor and the AMPA (α-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid) receptor. At the very low dose shown to have an antidepressant effect, ketamine preferentially blocks glutamate at the NMDA receptors but doesn't block glutamate binding to adjacent AMPA receptors. **The net effect is to increase AMPA activation**. By increasing the level of glutamate transmission while also shifting the balance of glutamate activation from NMDA to AMPA receptors, ketamine rapidly upregulates neuronal production and release of BDNF (brain-derived neurotrophic factor), a protein that helps promote the growth, maintenance, and survival of neurons—in other words, it enhances neuroplasticity.

At the same time, ketamine stimulates a central cell pathway called mTOR (mammalian target of rapamycin), responsible for improving synaptic connectivity in the prefrontal cortex and hippocampus, key areas of the brain associated with emotional regulation. Owing to these neuroplastic effects, regrowth of dendritic spines can happen within a few hours of a therapeutic ketamine dose. When the atrophied neurons can repair the damage and regrow their connections with other neurons, symptoms of depression and anxiety improve.

Methods of Ketamine Administration.

Ketamine can be administered in a variety of ways. Here's a quick overview of the different methods one can expect when working with ketamine; routes vary in the onset, bioavailability and duration of active effects for each person. Though research has shown antidepressant responses to low doses that are minimally psychoactive, this

effect tends to be cumulative, requiring repeated administrations over short periods of time. While experiences vary greatly from person to person, it is generally thought that lower doses provide empathogenic (heart-opening) responses, while higher doses are more likely to create out-of-body, ego-dissolving peak responses.

I provide lower-dose sublingual lozenge Ketamine treatment in my office and psychotherapeutic integration therapy for all other routes of administration (a deeper discussion of the nature and role of Ketamine psychotherapy will follow).

- Sublingual Tablets/Lozenges/Troches. Compounded tablets from a pharmacy that are absorbed into the brain/bloodstream sublingually by being held in the mouth and gently take effect over 10-15 minutes. It's a lower-dose strategy which may allow for psychotherapy during the treatment.
- Other routes of Ketamine administration: IV Infusions or IM Injections: Intravenous (IV) infusions or Intramuscular (IM) ketamine injections have similar effects. The difference is that IV is typically infused into a vein with a bag that drips the substance in while IM is injected directly into the shoulder or hip, with a rapid onset. IM can provide the same dose as in sublingual administration, or at higher doses that create a more dissociative experience.

 Additionally, there is the Ketamine nasal spray option, a synthesized mist stored in a spray bottle that is applied according to the delivery timeline outlined by the clinician. This is the latest delivery method to gain FDA approval with the introduction of Spravato. I can provide integration or long-term/short-term psychotherapy alongside these options for greater psychological insight and life integration.

The choice of dose and route of administration depends on multiple factors, including client preference, therapeutic goals, prior exposure to ketamine and other psychedelics, body height and weight, and sensitivity. You may discuss these different routes in-depth with your medical professional.

The Ketamine experience.

The Ketamine experience is characterized by the relaxation of ordinary concerns and usual mindset, all while maintaining conscious awareness. This tends to lead to a disruption of negative feelings and preoccupations. Some Ketamine providers feel that this interruption, and the exploration of other possible states of consciousness, can lead to significant shifts in overall well-being.

The subjective effects of ketamine are highly dependent on the dose administered, the environment where ketamine is taken, as well as the type of support or adjunctive therapies. All these factors strongly impact the drug effects and the subjective interpretations.

At lower doses, you will most likely experience mild anesthetic, anxiolytic, antidepressant, and psychoactive effects. You might experience drowsiness, increased sensitivity to light and sound, as well as an altered sense of time. Some people experience empathogenic (heart-opening) effects in this dose range. This state may also enhance participation in psychotherapy, as defenses are relaxed, yet communication with others is still possible.

Higher doses are more likely to produce psychedelic, dissociative states that are largely internal journeys away from the external world. Body sensations are greatly diminished. One may experience ego dissolution, transcendence of space and time, mystical experiences, experiences of death and rebirth, or a feeling of awe and wonder. Such journeys may provide a more robust treatment effect, often assisting in the resolution of existential concerns, accelerating psychological growth, and promoting a positive change in outlook.

Sensory effects at either dosage level may include distorted visualizations of colors, feeling suspended in space or floating, experiencing out-of-bod sensations, vivid imagery, changes in perception or cognition (or emotion), visual hallucinations or distortions, altered auditory perception and proprioception. Synesthesia (a mingling of the senses) may occur. Familiar music may not be recognizable.

The effects typically start 5 to 10 minutes after lozenge ketamine dosing. The peak effects last 20 to 30 minutes, and then slowly diminish for the next hour. Some alterations in sensory perception, speech, and motor ability may continue for some time after the session, but typically, two to three hours after ketamine administration, clients can return home with another driver. Driving an automobile or engaging in hazardous activities should not be undertaken on the day of administration, and not until all effects have stopped.

What is Ketamine-Assisted Therapy (KAP)?

While still under-researched, the administration of Ketamine may be most effective when paired with psychotherapy, either immediately after the effects of ketamine dissipate, and/or in the (3) days to follow. Ketamine-assisted psychotherapy is

presumed to amplify the neurobiological properties of ketamine by addressing underlying psychological issues and bolstering transformational healing. As a psychotherapist, I serve as a guide, and I will assist in processing the experience and its impact on your life.

Ketamine's altered state can create conditions of relational and psychological openness; research for work with other psychedelics has shown that trust in your providers enables the deepest possible work to occur for more impactful outcomes. Preparation sessions are therefore meant to establish a sense of trust and connection to increase the therapeutic effects of the Ketamine.

Research with other psychedelics has also shown that setting an intention for the experience can be beneficial. In the words of Gabor Mate, an expert on trauma, addiction, growth and psychedelics, an intention captures your active part on the journey, your willingness to be present for what emerges from within, your openness to learning from your psyche, your guides, your group (if you are doing Ketamine in a group setting). An example for an open, active intention may be e.g., "teach me about peace or happiness", rather than expecting to control final destinations such as "make me happy". It is strongly suggested to let go of any attempts to control the experience, as such attempts can produce anxiety instead.

"Be present for what emerges. The deepest teachings come from beyond your mind. Between sessions, keep your intentions alive and pay attention to what comes up and to how it relates to your intention. That's it." - Gabor Mate

Your experience will be unique to you, and it may change from session to session. You can't create mystical experiences at will, nor can you control any part of the experience. The experience will be uniquely yours, that day, it will evolve from your being in relation to the medicine, the environment and your mindset. It's best to just be open and present for what emerges, to be ok with confusion, to ask for help. That's why you have a guide (and/or the group) - for support and integration. Many enjoy the journey, while others do not. Everyone comes through it, and often with greater insight into themselves and their lives. Shifts may happen during treatment, and/or in the days and weeks that follow.

As a byproduct of your Ketamine experience, you may feel improvement in your emotional state and reduction in symptoms due to the neurobiological mechanisms explained previously. But ultimately, I am assisting you in changing patterns of mind, mood and behavior that is causing you difficulty and distress, combining medicine and psychotherapy for the best possible and most powerful outcome for your investment.

My treatment process.

My treatment team consistent of myself, a licensed clinical social worker (who specializes in psychedelic integration and KAP), a medical professional prescriber (who has also completed a certificate in psychedelic-assisted psychotherapy) and a psychiatrist (with Ketamine training). In some cases, your own psychotherapist may serve on the treatment team.

There will be a minimum of three preparation/planning sessions before dosing day:

- 1. I will start getting to know you and your history first, in my first (of 2) meetings with you. We will have time for questions, and we will discuss the Informed Consent for Ketamine Assisted Psychotherapy that will need to be signed before the next step. While virtual psychotherapy sessions are growing in popularity, I would strongly suggest meeting in person at my office. Research on psychedelics shows us that the client/therapist relationship, the connection, trust and safety, is a key contributor to your experience and your outcomes. For you to maximize the positive effects of your treatment, I would therefore strongly advise to start building a relationship in person and getting to know the environment where you will have your Ketamine journey.
- 2. If you consent to KAP, I will refer you to one of my medical team members (Physician Assistant or Psychiatrists, depending on your unique situation) for evaluation, clearance, ketamine dosage/frequency planning and the actual Ketamine prescription.
- 3. Once the medical prescriber has determined fit for KAP based on your health profile (medical history, current and recent medications, vital signs including blood pressure, pulse, respiratory rate, and oxygen saturation), you will meet with me again, at least one more time, before your first Ketamine administration. (The frequency depends on your level of readiness for dosing day.) In this second preparatory session with me, I will help you reflect on your intentions, and I will help you frame them for your journey, so that you may use them at the day of your journey, or to hold them close for reflection until then. I may teach you grounding breathing exercises to help manage anxiety going into the session or during the session. We will also discuss the use of music or drumming during the Ketamine experience. People often find music helpful, as it grounds them. Research has shown that music can potentially enhance the experience, while drumming increases theta waves and trance-like states to ease into the session.

I provide playlists designed to optimize your benefits from the journey, and I can also assist you in creating a playlist based on your preferences. (It is suggested to stay away from novel music, music in a language you understand, as language or familiar songs may trigger existing patterns of thought and be too directive or suggestive.)

In summary, as a team (including the client), we will plan to assess and discuss if KAP is the right intervention for you at this time. We will collaboratively decide on the most optimal path of your treatment, including the number and frequency of ketamine and integration sessions. You can withdraw consent at any point throughout this process.

Dosing day.

On the day of your Ketamine administration, **it is very important** to follow the directions given on your <u>KAP Preparation and Aftercare Guide</u> about food and medication intake.

We will take some time when you arrive to discuss your current state and remind us of your intentions. We may do a "pearl dive", using guided imagery to open yourself to the process of going deeper into your psyche, diving for insights (pearls).

You will wrap a blood pressure cuff on your arm and place a pulse oximeter on your finger, which will be demonstrated by your doctor (and both tools will be provided to you in my office, there is no need to purchase your own cuff or pulse oximeter). You will read your own vital signs as taught by your doctor and report the data back to me to assure you are safe to proceed.

As already mentioned, you will feel the effects of the Ketamine quickly after placing the lozenge under the tongue, in your mouth. It will then dissolve in your mouth, for the designated time advised by your prescriber. The Ketamine will be absorbed through the lining of your mouth. It is safe to swallow Ketamine, but it may not be absorbed as well if you do so (and it might make you more nauseous). By the time you spit out your saliva/Ketamine, you will most likely start feeling the effects. The acute, stronger effects then last for about 45-60 minutes, after which you may still feel the Ketamine a little bit, but you will likely feel more relaxed and open, and you may want to talk about what happened, about how you are feeling or anything else that is on your mind. The effects of the Ketamine will start to wear off over this period of integration; about 2 hours after Ketamine administration, we will assess to make sure you are oriented again and able to get home safely. People can vary greatly in terms of how quickly the effects clear, so your departure time may vary. We will also discuss a plan for the rest of your

day/evening, to make sure you will have quiet time to focus on yourself, your experience and on what happened.

Throughout the Ketamine session, I will be present for support. I will typically offer you an eye mask to wear while laying down during the active phase, to help with turning your attention inward. If you need to go to the bathroom or need help with calming or guidance throughout the session, I will always be there to help. You will have the option for headphones, to not get distracted by any noises. My attention will be on you at all times and the use of physical touch for calming (e.g. holding your hand) will be discussed with you and practiced prior to the experience.

Please arrange for some trusted person to pick you up and take you home. I cannot release you to a taxi or Uber/Lyft driver, and I ask that you do not drive at all for the rest of the day. I will do a follow-up call the next day, for the first treatment, to make sure you are oriented, and we will discuss the schedule for follow-up psychotherapy and integration sessions within 3 days (maximum one week) of the dosing session.

How long will the effects last?

Ketamine treatment can result in a number of benefits, and there are now many studies demonstrating its efficacy, however, Ketamine is not an FDA approved treatment model for psychiatric conditions, and there are no guarantees of your outcome.

But we have good reason to believe that Ketamine will be beneficial to you in conjunction with therapy, and we will judge its impact and helpfulness based on your experience. Ketamine makes the brain more susceptible to learning and in the period after your Ketamine administration, there will be a phase where new insight and behaviors may stick better. In the end, effects are connected to your participation in your own process - but overall, there is again good reason to believe that it will be more likely for you to identify and establish new habits. As such, I'd like to think of Ketamine work as ongoing work. The length of treatment will be discussed and determined in partnership with you and the prescriber.

Medical and Psychiatric Eligibility for KAP.

In order to schedule the dosing session, I will wait for clearance from the medical provider who will interview you carefully to determine if you are a good candidate for Ketamine treatment at this time. This will include discussing your medical and

psychiatric history, review of medical and psychiatric records, if necessary, assessment of vital signals as discussed above.

Some medical and psychiatric conditions need to be treated before you can safely take Ketamine. These conditions include hallucinations, untreated mania, unstable angina (chest pain/heart disease), uncontrolled hyperthyroidism, increased intracranial pressure, evidence of liver disease, untreated or uncontrolled hypertension, history of cystitis or other bladder issues or a previously demonstrated allergy to ketamine.

Pregnant women and nursing mothers are not eligible for Ketamine treatment because of undetermined potential effects on the fetus or nursing child.

Those with a primary psychotic or dissociative disorder or who are currently in a manic or mixed episode are not eligible for Ketamine treatment. Your prescriber will also discuss the impact of medications on your Ketamine treatment, including opiates and anxiety medications. Anxiety medications can blunt the antidepressant effects of Ketamine and opiates cannot be taken concurrently with Ketamine treatment. Other interactions will be discussed with your prescriber.

Potential risks of Ketamine.

Ketamine has an extensive record of safety and has been used at much higher doses for surgical anesthesia, without respiratory depression. As with other medication, there are some potential risks and side effects to be informed of and consider.

The most common physical side effect is a short-term spike in blood pressure, pulse, or heart rate, which may be a risk to those with heart disease.

Important FDA Safety Information.

Ketamine is not FDA-approved for the treatment of depression or anxiety.

Side effects of ketamine treatment may include altered sense of time, anxiety, blurred vision, diminished ability to see/hear/feel, dry mouth, elevated blood pressure or heart rate, elevated intraocular or intracranial pressure, excitability, loss of appetite, mental confusion, nausea/vomiting, nystagmus (rapid eye movements), restlessness, slurred speech, synesthesia (a mingling of the senses).

Do not proceed with ketamine treatment if any of the following apply to you:

- Allergic to ketamine
- Symptoms of psychosis or mania
- Uncontrolled high blood pressure
- CHF or other serious heart problem
- Severe breathing problem
- History of elevated intraocular or intracranial pressure
- History of hyperthyroidism
- Other serious medical illness
- Pregnant, nursing, or trying to become pregnant

Ketamine has been reported to produce issues including, but not limited to, those listed below. However, lasting adverse side-effects are rare when medical protocols are carefully followed.

Ketamine does not meet criteria for chemical dependence, since it does not cause tolerance and withdrawal symptoms. While ketamine has not been shown to be physically addictive, it has been shown to cause moderate psychological dependency in some recreational users. Ketamine belongs to the same group of chemicals as phencyclidine (Sernyl, PCP, "Angel dust"). Collectively, this group is in the chemical class of arylcyclohexylamines, and are further classified as hallucinogens ("psychedelics"). Ketamine is a controlled substance and is subject to Schedule III 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, which are low risk in terms of abuse liability. However, cravings have been reported by some individuals and there are documented cases of overuse of illicitly obtained and diverted ketamine. 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 the direct supervision of a licensed physician.

In rare cases, frequent, heavy users have reported increased frequency of urination, urinary incontinence, pain urinating, passing blood in the urine, or reduced bladder size Ketamine may worsen problems in people with schizophrenia, severe personality disorders, or other serious mental disorders.

Users with a personal or family history of psychosis should be cautious using any psychoactive substance, including ketamine, and discuss potential risks with your prescriber before proceeding with treatment.

The dissociative effects of ketamine may increase patient vulnerability and the risk of accidents.

Management of adverse effects.

My preparation, the setting, the client instructions from your prescriber and the <u>KAP</u> <u>Preparation and Aftercare Guide</u> are all intended to minimize Ketamine's adverse effects as much as possible.

It is very important to abstain from eating or drinking in the 4 hours prior to your treatment to avoid nausea or vomiting. Additionally, due to possible blurred or altered vision, as well as impaired balance and coordination, you will be advised to lie still and keep your eyes closed or use the eye mask provided until the main effects have worn off.

You will self-administer measuring your vital signs and we will do breathing exercise if vital signs are elevated.

I reserve the right to call 9-1-1 if I determine by clinical judgment that your safety requires a higher level of care than can be provided in my setting.

Voluntary nature of participation.

Your decision to undertake KAP is completely voluntary. Once you indicate that you have understood the benefits and risks of this treatment, I will ask you to sign the informed consent form in my office, at your first visit. The <u>Informed Consent for</u> Ketamine Assisted Psychotherapy can be found on my webpage.

Your consent can be withdrawn at any point by you, and you may discontinue your participation, at any time up until the lozenge has been taken.

By signing the <u>Informed Consent for Ketamine Assisted Psychotherapy</u>, you indicate that you understand the information provided, that any questions or concerns you have regarding my services have been answered and resolved, and that you give your consent to the outlined therapeutic procedures to be performed during your participation in KAP.

Thank you for taking the time to read this important information!