JOYOUS

Joyous At-Home Treatment Program - Medical Approval Form

Patient Information:

Patient Name: _____ Date of Birth: _____

Psychiatric Assessment:

- Patient Diagnosis:
  - Depression _____
  - Anxiety _____
  - PTSD _____
  - Adjustment Disorder _____
  - ADHD _____
  - Other(Specify): _____
- Stability Assessment:
  - Stable Condition _____
  - Unstable Condition (Please provide details below)

_____

Medical Assessment:

- Patient Diagnosis:
  - (Specify): _____
  - (Specify): _____
- Stability Assessment:
  - Stable Condition _____
  - Unstable Condition (Please provide details below)

_____

  - Last Blood Pressure Reading: / Date taken: _____

- How long have you been treating this patient?
  - Less than 6 months _____
  - 6 months to 1 year _____
  - 1 to 2 years _____
  - More than 2 years _____

Practice Name: _____
Provider Full Name: _____
Provider NPI Number: _____
Contact Number: _____
Email Address: _____

The protocol includes the use of ketamine with dosages ranging between 10 mg- 120 mg in the form of a troche with bioavailability of approximately 25-30%. The ketamine treatment will be monitored through following with periodic consultations with Joyous medical providers and enrollment in digital daily dose and personalized feedback automation. The length of the treatment varies but is expected to last a minimum of 3 months. Medication dosing starts daily and can work up to twice daily and then titrated out to less frequent use (ie QOD, q 3 day, weekly, biweekly to prn) as fits each individual patient's needs. We will not ask patients to refrain from their prescribed medications. Please review the benefits and side effects, we are asking for medical clearance because our mutual patient may have a medical condition that may be impacted by the ketamine therapy. Before participating in the ketamine treatment program, the patient will be carefully screened to determine if you are eligible, including a live video-telemedicine visit, medical history, psychiatric history, and psychological testing. They will not be asked to come off any medication but will be made aware of medication that can mitigate treatment response.

Repeated, high dose, chronic abuse of ketamine, has been shown to cause urinary tract symptoms and even permanent bladder dysfunction, though in medical use this is rare. Ketamine and addiction: attached is a recently published article in Nature.com:Dual action of ketamine confines addiction liability.“In summary, the dual action of ketamine leads to a unique constellation of dopamine-driven positive reinforcement, but low addiction liability.”

The patient is currently seeking alternative treatment of symptoms. We will discuss the use of low dose ketamine therapy as one part of their treatment plan for their symptoms. Ketamine is sometimes prescribed off-label to treat Depression, Anxiety, Chronic pain, PTSD, OCD, and Alcohol and Substance dependencies. It has safely been used as an FDA-approved anesthetic since 1970. Ketamine at low doses in the form of a troche is off-label prescribing ie when a clinician prescribes a medication in a different way than was explicitly approved by the FDA.

Esketamine, a component of the ketamine molecule, was recently deemed a breakthrough therapy for treatment-resistant depression, and Spravato (esketamine) nasal spray received FDA approval for this indication in early 2019. We will discuss the risks and benefits and alternatives of treatment.

The low dose of ketamine in a psycholytic dosing and not at a dose where there is a profound dissociate effect. The patient will have to sign a ketamine treatment agreement and informed consent and adhere to compliance metrics. The risks include worsening of suicidal ideation. 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). While ketamine has been known to have potential adverse effects, the occurrence of lasting side effects is rare when patients diligently follow our medical protocols.

The treatment guidelines we have in place are specifically crafted to reduce the risk of adverse outcomes related to ketamine use and to optimize the potential benefits it offers. Ketamine's half-life is 2.5 hours. In clinical trials giving procedural doses of ketamine at 1.5 mg/kg IV (99% bioavailability) patients were found to have a transient increase of blood pressure on average 8 mmhg without signs of ischemia. In uncommon situations, individuals who are frequent and heavy users have mentioned experiencing heightened frequency of urination, urinary incontinence, pain during urination, passage of blood in the urine, or reduced bladder size. It's important to note that, by strictly adhering to our treatment guidelines, we have not observed any patients facing long-term adverse outcomes.

In terms of psychological risk, ketamine has been shown to worsen certain psychotic symptoms in people who suffer from schizophrenia or other serious mental disorders, but alternatively has also been occasionally used to successfully treat psychotic depression. It may also worsen underlying psychological problems in people with severe personality disorders and suicidal ideation. For patients with a history of mania or bipolar we would not give ketamine to someone actively manic. We require patients to agree to stop ketamine if rapid thoughts and insomnia increase.

Potential benefits of ketamine treatment:

Rapid relief of symptoms
Mental reset
Builds new neural connections
Improves neuroplasticity
Reduction in cravings
Improved sleep quality

Potential side effects of ketamine treatment:

Nausea
Dizziness
Increased heart rate and blood pressure
Risk of falls if walking unassisted
Vivid Dreams
Bladder Irritation
Worsening of suicidal ideation

Additional Comments (if any):

(Please provide any additional information relevant to the patient's psychiatric condition and your assessment of their suitability for the at-home ketamine treatment program.)

Medical Provider's Approval:

I, the undersigned provider, hereby confirm that I have evaluated the above-named patient and provide approval for their participation in the Joyous At-Home Ketamine Treatment Program.

Signature: _____

Date: _____

Medical Provider Note:
(Please provide any additional comments or clarifications regarding the patient's psychiatric or medical condition and the decision to participate in the ketamine treatment program.)