

Ketamine Therapy (IV/IM) Informed Consent Form (2026.2)

Off-label Use of Ketamine

Our clinic provides ketamine infusion (IV) or intramuscular injection (IM) as self-funded (non-insured) treatment, using an approved domestic anesthetic product (Ketalar® injection) for off-label indications such as depression, anxiety, PTSD, and chronic pain.

Source of medication: The drug is purchased through licensed domestic pharmaceutical wholesalers.

Domestic approval status: Ketamine is approved in Japan as an anesthetic agent, but not approved for psychiatric or chronic pain indications.

Foreign safety information: Overseas, studies report short-term reduction of suicidal ideation, but risks such as sedation, dissociation, and elevated blood pressure are known. Post-treatment monitoring is emphasized.

Long-term outcomes remain uncertain.

Relief system: The PMDA adverse drug reaction relief system generally does not apply to off-label use (judged case-by-case and generally excluded for off-label indications). Please see official PMDA information for details.

Efficacy varies individually. This treatment is not a substitute for standard care. Indication is determined individually by the physician.

Treatment Overview

Ketamine is a dissociative anesthetic. At low doses, it may relieve pain or improve mood symptoms, as reported in some studies.

Our clinic administers ketamine via IV infusion or IM injection in an outpatient setting, based on the physician's evaluation.

Procedure and Monitoring

- During administration: Continuous monitoring of SpO₂ and pulse rate.
- Observation: Bed rest and monitoring for 30–90 minutes after dosing.
- Pre-discharge check: SpO₂, pulse, and blood pressure are measured. The physician makes the final decision for discharge after nurse assessment.
- Returning home: An accompanying person is required in principle. If you must return home alone, please use a taxi. Driving or hazardous tasks are prohibited on the day of treatment. In emergencies, contact our clinic during business hours, or seek advice/assessment at an emergency department outside business hours.

Eating/Drinking and Medications (before treatment)

Eating: Please finish solid food and dairy products at least 4 hours before treatment.

Drinking: Clear fluids such as water or tea may be consumed in small amounts until immediately before treatment, unless otherwise instructed (patients with high risk of reflux or nausea may need stricter limits).

Certain medications such as benzodiazepines, barbiturates, or opioid analgesics may affect the efficacy or safety of ketamine. Do not change your medications without consulting your doctor.

Contraindications and Cautions

Cautions: Coronary artery disease, untreated hyperthyroidism, obstructive sleep apnea, severe anxiety/dissociative tendency, breastfeeding, etc.

Contraindications: Hypersensitivity to ketamine or history of severe adverse reaction; severe hypertension (SBP ≥160 or DBP ≥100); elevated intracranial pressure; severe heart failure; history of seizures; pregnancy (unless benefits outweigh risks); psychotic disorders such as schizophrenia; active substance misuse; recreational drug use; active suicidal planning (requires emergency psychiatric evaluation).

Expected Effects and Limitations

Rapid symptom improvement has been reported, but some patients may have little effect or short duration of benefit.

Multiple sessions may be recommended depending on response.

Alternative treatments include electroconvulsive therapy (ECT), repetitive transcranial magnetic stimulation (rTMS), medications, and psychotherapy.

Risks and Side Effects

Common: dizziness, lightheadedness, nausea, vomiting, transient increases in blood pressure/heart rate, sensory changes (visual, auditory, bodily), anxiety, drowsiness.

Sometimes: headache, agitation or confusion, persistent hypertension, injection-site pain.

Rare: allergic reactions, respiratory depression, delirium, lower urinary tract symptoms (e.g., urinary frequency, discomfort), liver function abnormalities.

If you feel unwell, please contact our clinic during business hours. Outside business hours, consult or visit a nearby emergency department.

Important adverse events: laryngospasm/respiratory depression, arrhythmias, elevated intraocular pressure, allergy (including anaphylaxis). These are acute adverse events mainly occurring in-clinic. If you experience shortness of breath, severe chest pain, or impaired consciousness after discharge, contact our clinic during business hours, or seek urgent care at an emergency department outside hours.

Consciousness/Perceptual changes (therapeutic experience)

During treatment, psychedelic-type experiences, vivid dreams, dissociation, or altered sense of time may occur. These are expected therapeutic effects and usually subside after infusion. If they persist after discharge and interfere with daily life, please contact our clinic during business hours, or seek advice at an emergency department outside hours.

Additional note: Some perspectives consider dissociative/perceptual changes not merely as side effects, but as experiences that may contribute to psychological processing and cognitive reorganization. Our clinic prioritizes safety at all times; if the experience becomes distressing, we will adjust the dose/infusion rate or discontinue treatment as needed. Reflection on the experience (“integration”) may be offered after stabilization, based on the patient’s preference.

Drug interactions

Barbiturates, benzodiazepines, and opioid analgesics (central depressants) may potentiate effects and delay recovery. Please disclose all medicines, supplements, and recreational substances.

Abuse/Dependence and Legal Position

In Japan, ketamine is designated as a narcotic and is strictly controlled. It is used only for medical purposes under strict storage and handling. Parallel treatment with other clinics is not permitted.

Fees and Discontinuation

This treatment is self-funded (not covered by insurance). Please see our clinic’s website for details.

The physician may discontinue or postpone treatment for safety reasons. Patients may also withdraw consent and stop treatment at any time.

Consent Checklist (please check)

- I understand this treatment is off-label and not covered by health insurance.
- I understand that efficacy varies individually and is not guaranteed.
- I understand that driving or hazardous tasks are prohibited on the day, and that returning home requires an accompanying person (or a taxi if alone).
- I will follow the eating/drinking and medication instructions.
- I have been informed about alternative treatments (ECT, rTMS, etc.) and understand my freedom of choice.

Signature

Signature (Patient): _____

Date: ____ / ____ / 2026