

INFORMED CONSENT FOR MEDICATION

Completion of this form is voluntary. If informed consent is not given, the medication cannot be administered without a court order unless in an emergency.

This consent is maintained in the client’s record and is accessible to authorized users.

Name – Patient / Client (Last, First MI)		ID Number	Living Unit	Date of Birth
Name – Individual Preparing This Form		Name – Staff Contact		Name / Telephone Number – Institution

MEDICATION CATEGORY	MEDICATION	RECOMMENDED DAILY TOTAL DOSAGE RANGE	ANTICIPATED DOSAGE RANGE
Antidepressant	Spravato® (esketamine)	56-84 mg intranasally twice weekly for 4 weeks.	

The anticipated dosage range is to be individualized, may be above or below the recommended range but no medication will be administered without your informed and written consent.

Recommended daily total dosage range of manufacturer, as stated in *Physician’s Desk Reference* (PDR) or another standard reference.

This medication will be administered ☐ Orally ☐ Injection ☐ Other – Specify:

1. Reason for Use of Psychotropic Medication and Benefits Expected (note if this is ‘Off-Label’ Use)

Include DSM-5 diagnosis or the diagnostic impression (“working hypothesis”).

2. Alternative mode(s) of treatment other than OR in addition to medications include

Note: Some of these would be applicable only in an inpatient environment.

- ☐ Environment and/or staff changes
- ☐ Rehabilitation treatments/therapy (OT, PT, AT)
- ☐ Positive redirection and staff interaction
- ☐ Treatment programs and approaches (habilitation)
- ☐ Individual and/or group therapy
- ☐ Use of behavior intervention techniques

Other Alternatives:

3. Probable consequences of NOT receiving the proposed medication are

Impairment of ☐ Work Activities ☐ Family Relationships ☐ Social Functioning

Possible increase in symptoms leading to potential

- ☐ Use of seclusion or restraint
- ☐ Limits on recreation and leisure activities
- ☐ Limits on access to possessions
- ☐ Intervention of law enforcement authorities
- ☐ Limits on personal freedoms
- ☐ Risk of harm to self or others
- ☐ Limit participation in treatment and activities

Other Consequences:

Note: These consequences may vary depending upon whether or not the individual is in an inpatient setting. It is also possible that in unusual situations, little or no adverse consequences may occur if the medications are not administered.

Client Initial _____ Date _____

4. Possible side effects, warnings, and cautions associated with this medication are listed below. This is not an all-inclusive list but is representative of items of potential clinical significance to you. For more information on this medication, you may consult further with your physician or refer to a standard text, such as the PDR. As part of monitoring some of these potential side effects, your physician may order laboratory or other tests. The treatment team will closely monitor individuals who are unable to readily communicate side effects in order to enhance care and treatment.

Continued – Possible side effects, warnings, and cautions associated with this medication.

Most Common Side Effects: Nausea, altered sense of taste, vomiting, dizziness, hypoesthesia, lethargy, vertigo, anxiety, increased blood pressure, sedation, dissociative disorder, constipation

Less Common Side Effects: Feeling intoxicated, tachycardia, hyperhidrosis, diarrhea, throat irritation, euphoria, self-inflicted injury, increased frequency of urination

Rare Side Effects: Impaired cognition, loss of consciousness, suicidal thoughts, respiratory depression, substance dependence

Caution:

Precautions

- **Abuse**
Increased risk of abuse and misuse in patients with a history of drug abuse or dependence.
- **Cardiovascular**
Increase in blood pressure has been reported at all recommended doses; monitoring recommended especially in patients with history of hypertensive encephalopathy due to increased risk for developing encephalopathy.
- **Neurologic**
Short-term cognitive impairment has been reported; instruct patients to avoid potentially hazardous activities requiring complete mental alertness and motor coordination (e.g., driving a motor vehicle or operating machinery) until the next day following a restful sleep.
- **Renal**
Lower urinary tract symptoms (e.g., pollakiuria, dysuria, micturition urgency, nocturia, and cystitis) have been reported.
- **Reproductive**
May cause fetal harm; consider pregnancy planning and prevention.

Warning: Black box warning- Nasal (Spray)

Sedation; Dissociation; Abuse and Misuse; and Suicidal Thoughts and Behaviors: Patients are at risk for sedation after administration of esketamine. Patients are at risk for dissociative or perceptual changes after administration of esketamine. Respiratory depression has been observed in postmarketing experience. Because of the risks of sedation, dissociation, and respiratory depression patients must be monitored for at least 2 hours at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave the healthcare setting. Esketamine has the potential to be abused and misused. Consider the risk and benefits of prescribing esketamine prior to use in patients at higher risk of abuse. Monitor patients for signs and symptoms of abuse and misuse. Because of the risks of serious adverse outcomes resulting from sedation, dissociation, respiratory depression, and abuse and misuse, esketamine is only available through a restricted program under Risk Evaluation and Mitigation Strategy (REMS) called the SPRAVATO(TM) REMS. Antidepressants increased the risk of suicidal thoughts and behavior in pediatric and young adult patients in short-term studies. Closely monitor all antidepressants-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors. Esketamine is not approved for use in pediatric patients.

Syndrome Note

See standard reference text for an all-inclusive list of side effects.

By my signature below, I GIVE consent for the named medication on Page 1 and anticipated dosage range. My signature also indicates that I understand the following:

1. I can refuse to give consent or can withdraw my consent at any time with written notification to the institution director or designee. This will not affect my right to change my decision at a later date. If I withdraw consent after a medication is started, I realize that the medication may not be discontinued immediately. Rather, it will be tapered as rapidly as medically safe and then discontinued so as to prevent an adverse medical consequence, such as seizures, due to rapid medication withdrawal.
2. Questions regarding this medication can be discussed with the Interdisciplinary Team, including the physician. The staff contact person can assist in making any necessary arrangements.
3. Questions regarding any behavior support plan or behavior intervention plan, which correspond with the use of the medication, can be directed to the client's social worker, case manager, or psychologist.
4. I have the right to request a review at any time of my record, pursuant to § 51.30(4)(d) or § 51.30(5)(b).
5. I have a legal right to file a complaint if I feel that client rights have been inappropriately restricted. The client's social worker, case manager, or agency/facility client rights specialist may be contacted for assistance.
6. My consent permits the dose to be changed within the **anticipated dosage range** without signing another consent.
7. I understand the reasons for the use of the medication, its potential risks and benefits, other alternative treatment(s), and the probable consequences that may occur if the proposed medication is not given. I have been given adequate time to study the information and find the information to be specific, accurate, and complete.
8. This medication consent is for a period effective immediately and not to exceed fifteen (15) months from the date of my signature. The need for and continued use of this medication will be reviewed at least quarterly by the Interdisciplinary Team. The goal, on behalf of the client, will be to arrive at and maintain the client at the minimum effective dose.

SIGNATURES**DATE SIGNED**

Client – If Presumed Competent to Consent/Parent of Minor/Guardian (POA-HC)	Relationship to Client <input type="checkbox"/> Self <input type="checkbox"/> Parent <input type="checkbox"/> Guardian (POA-HC)	
Staff Present at Oral Discussion	Title	
Client / Parent of Minor / Guardian (POA-HC) Comments		

As parent/guardian (POA-HC) was not available for signature, he/she was verbally informed of the information in this consent.

Verbal Consent

Obtained by – PRINT – Staff Name	Date Obtained	Written Consent Received <input type="checkbox"/> Yes <input type="checkbox"/> No
Obtained from – PRINT – Parent / Guardian (POA-HC) Name	Date Expires	Date Received