SPRAVATO® REMS

Patient Enrollment Form - Outpatient Use Only

INSTRUCTIONS:

This form is intended only for use by outpatient medical offices or clinics, excluding emergency departments

1. Complete this form online at www.SPRAVATOrems.com, or complete the paper form and fax to the SPRAVATO® REMS at 1-877-778-0091

This section is to be completed by the Prescriber

**** Indicates required field***

Healthcare Setting Information

Healthcare Setting Name*: Greater Houston Psychiatric Associates, PLLC		
Healthcare Setting DEA License Number* (associated with the Healthcare Setting address):		
Address 1*: 4888 Loop Central Dr., Ste #510	Address 2:	
City*: Houston	State*: TX	ZIP*: 77081-2226
Phone*: 713-346-1555	Fax*: 713-346-1579	

Prescriber Information

First Name*:	Last Name*:	
Credentials*: ☐ Physician ☐ Physician Assistant ☐ Nurse ☐ Pharmacist ☐ Other _____ **Specialty*:** ☒ Psychiatry ☐ Internal Medicine ☐ Family Practice ☐ Other_____		Prescriber DEA License Number*:
Phone*: 713-346-1555	Fax: 713-346-1579	Email*: Esketamine@ghpa.net
Prescriber Signature*:		**Date*:**

Referring Healthcare Provider – if different from Prescriber

First Name:	Last Name:

Relevant Clinical Information

Has the patient previously been treated with ketamine or esketamine for major depressive disorder, treatment-resistant depression, pain syndromes, or any other condition?*	☐ Yes ☒ No

If YES, list all pre-existing conditions treated with ketamine or esketamine:

_____

_____

List all pre-existing medical and psychiatric conditions*:

_____

_____

List concomitant medications (e.g., adjunctive depression medications, sedative hypnotics, psychostimulants, monoamine oxidase inhibitors [MAOIs])*:

_____

_____

Healthcare providers should report suspected adverse events or product quality complaints associated with SPRAVATO® to Janssen at 1-800-JANSSEN or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.

SPRAVATO® REMS

Patient Enrollment Form - Outpatient Use Only

This section is to be completed by the Patient

Your healthcare provider will help you complete this form and provide you with a copy.

**** Indicates required field***

Patient Information

First Name*:	MI:	Last Name*:	Birthdate*: (MM/DD/YYYY):	Sex*: ☐ Male ☐ Female ☐ Other
Email*: (Email is required for online enrollment only)		Phone Number*:		
Address 1*:		Address 2:		
City*:		State*:		ZIP*:

Patient Agreement

By signing this form, I understand and acknowledge that:

Before my treatment begins, I will:

- Enroll in the SPRAVATO® REMS by completing this *Patient Enrollment Form* with my healthcare provider. Enrollment information will be submitted to the SPRAVATO® REMS.
- Receive counseling on safety risks and the need for monitoring to observe for resolution of sedation and dissociation, and for any changes in vital signs.

During treatment, and after administration I will:

- Use the SPRAVATO® nasal spray myself under the direct observation of a healthcare provider.
- Be observed at the healthcare setting where I get SPRAVATO® for at least 2 hours after each treatment until the healthcare provider determines I am ready to leave the healthcare setting.

I understand:

- Sedation and dissociation can result from treatment with SPRAVATO® and I must stay after each treatment.
  Until these effects resolve, I may feel:
  - sleepy and/or
  - disconnected from myself, my thoughts, feelings and things around me.
- I should make arrangements to safely get home.
- I should not drive or use heavy machinery for the rest of the day on which I receive SPRAVATO®.
- I should contact my doctor or inform him/her at my next visit if I believe I have a side effect or reaction from SPRAVATO®.
- In order to receive SPRAVATO® as an outpatient, I am required to be enrolled in the REMS, and my information will be stored in a database of all outpatients who receive SPRAVATO® in the United States.
- Janssen Pharmaceuticals, Inc. and its agents, including trusted vendors, may contact me or my prescriber via phone, mail, fax, or email to support administration of the REMS.
- Janssen Pharmaceuticals, Inc. and its agents, including trusted vendors, may use, disclose, and share my personal health information for the purpose of the operations of the REMS, including enrolling me into the REMS and administering the REMS, coordinating the dispensing of SPRAVATO®, and releasing and disclosing my personal health information to the Food and Drug Administration (FDA), as necessary, and as otherwise required by law.

Patient Name (please print):	
Patient Signature*:	**Date*:**

GHPA

Leaders in Psychiatric Medicine

Greater Houston Psychiatric Associates, PLLC

SPRAVATO™ TREATMENT FOR DEPRESSION
INFORMED CONSENT AND DISCLOSURE

- I understand the risks associated with SPRAVATO™ nasal treatment include but are not limited to: Dissociation, Dizziness, Nausea, Sedation, Vertigo, Headache, Dysgeusia (altered taste), Hypoesthesia (numbness), Anxiety, Lethargy, Increased Blood Pressure, Vomiting, Insomnia, and Diarrhea.

- I understand that the potential side effects from SPRAVATO™ nasal treatment may include: Nasal Discomfort, Throat Irritation, Feeling Drunk, Dry Mouth, Hyperhidrosis (excessive sweating), Euphoric Mood, Dysarthria (slurred speech), Tremor, Oropharyngeal Pain, Mental Impairment, Constipation, Pollakiuria (frequent urination), Feeling Abnormal, and Tachycardia (fast heart rate).

- I agree to remain abstinent from any illegal drugs, alcohol, and controlled medications that I am not prescribed. If I cannot remain abstinent from these substances, I agree to inform the office prior to my treatment session, as this could jeopardize my safety and affect my ability to continue treatment.

- I understand that I may not drive nor operate machinery for at least 12 hours after my nasal treatment is completed. And that I will only be discharged to the care of a responsible adult.

- I understand that satisfactory results are expected but not guaranteed. My depression may not improve with SPRAVATO™ treatment even if I follow the complete treatment protocol.

- I understand that to achieve the desired results that a series of nasal treatments are needed, and it is my full intent to complete the course of treatment.

- I understand that SPRAVATO™ nasal treatment is not a substitute for continued behavioral medicine treatment. My psychiatrist will determine if any oral medications or other treatments may be stopped if my depression improves.

- I have been educated and informed about the use of SPRAVATO™ for Major Depression and I had the opportunity to ask all the relevant questions I felt necessary. I am confirming that I have received and reviewed the pre-treatment instructions, post treatment instructions and that I can fully comply.

- I voluntarily request Greater Houston Psychiatric Associates, PLLC to administer SPRAVATO™ for the treatment of my condition.

- I understand that I can revoke this consent at any time including during treatment.

- I understand that SPRAVATO™ nasal spray is indicated, and FDA approved, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression in adults.

- I fully consent and agree the Greater Houston Psychiatric Associates, PLLC may bill my insurance carrier for services rendered. I am aware that I bear full fiscal responsibility for monies not received by Greater Houston Psychiatric Associates, PLLC from my insurance carrier.

Patient Name : Date :

Patient Signature :

4888 Loop Central Drive ○ Suite 510 ○ Houston, Texas 77081
www.ghpa.net ○ (713) 346-1555 ○ Fax (713) 346-1579

GHPA

Leaders in Psychiatric Medicine

Greater Houston Psychiatric Associates, PLLC

CREDIT CARD PAYMENT AGREEMENT

CREDIT CARD USAGE CONSENT

You will be required to maintain an active credit card on file. Greater Houston Psychiatric Associates, PLLC (GHPA) will use this card for processing co-payments, co-insurance, and deductibles in accordance with the details outlined in your insurance carrier's explanation of benefits. Should your credit card information change, expire, or face any issue causing denial, you commit to promptly furnish GHPA with valid credit card information before your next scheduled session following notification.

INSURANCE

As a courtesy, GHPA will submit claims to your insurance provider on your behalf. We will also share with you the eligibility and benefits information that your carrier provides to us. However, please note that this does not guarantee payment from your insurance carrier. The determination of your benefits is made after your carrier processes the claim, and you will receive this information from your carrier through the Explanation of Benefits. Any services not covered by your carrier are your financial responsibility. While we will collaborate with you to resolve any disputes, in the event of non-payment by your carrier, you are obligated to settle the payment directly with GHPA and manage any disputes with your insurance provider. It is your responsibility to remain informed about your insurance benefits and the requirements for pre-authorization.

PREAUTHORIZATIONS

Many insurance carriers mandate prior authorization for treatment based on their determination of medical necessity. GHPA will make diligent efforts to secure authorization before treatment. If your carrier demands authorization for treatment, it is your responsibility to coordinate with GHPA and your carrier to acquire the necessary approvals. In the event of a request for peer review or a denial/appeal for continued sessions, there might be treatment that is not covered by your carrier. You are responsible for any non-covered treatment.

ACKNOWLEDGEMENT

I have reviewed the above and understand the Payment Agreement and my financial obligations. I agree to abide by the terms of this agreement.

Patient's Name:_____ Date of Birth: _____

Name on card: _____

Credit Card #:_____ Expiration Date:_____

Signature:_____ Date:_____

4888 Loop Central Drive • Suite 510 • Houston, Texas 77081

www.ghpa.net • (713) 346-1555 • Fax (713) 346-1579

NEW
UPDATE 01/24

Spravato withMe Program Enrollment Form

Spravato® (esketamine) CIII
28 mg nasal spray

Fax completed form to 844-577-7282 | For assistance, call 844-4S-WITHME (844-479-4846)

TO BE COMPLETED BY PROVIDER

Providers can also complete this form online at SpravatoProviderPortal.com

SPRAVATO withMe is unable to process any information without the signed Patient Authorization, included on the Patient section of this form. The information you provide will be used by Johnson & Johnson Health Care Systems Inc., our affiliates, and our service providers for your patient's enrollment and participation in SPRAVATO withMe. Our **Privacy Policy** governs the use of the information you provide. By submitting this form, you indicate that you read, understand, and agree to these terms.

1. Patient Information

Required information in order to process this form.

Patient First Name _____ Patient Last Name _____

Date of Birth (mm/dd/yyyy) _____ Sex: ☐ M ☐ F Patient Phone _____

Patient Address _____

Patient City _____ Patient State _____ Patient ZIP _____

2. Patient Insurance Information

Please either attach a copy of the front and back of insurance card(s) OR complete insurance information below.

Required information in order to process this form. If attaching copy of insurance card(s), information below is not needed.

Primary Medical Insurance (PMI) _____ **PMI Phone** _____

PMI Cardholder First Name _____ PMI Cardholder Last Name _____

PMI Employer _____ PMI Policy # _____ PMI Group # _____

Secondary Medical Insurance (SMI) _____ **SMI Phone** _____

SMI Cardholder First Name _____ SMI Cardholder Last Name _____

SMI Employer _____ SMI Policy # _____ SMI Group # _____

Behavioral Health Insurance (BHI) _____ **BHI Phone** _____

BHI Cardholder First Name _____ BHI Cardholder Last Name _____

BHI Employer _____ BHI Policy # _____ BHI Group # _____

Prescription Drug Insurance (Rx) _____ **Rx Phone** _____

Rx Cardholder First Name _____ Rx Cardholder Last Name _____ Rx Employer _____

Rx BIN # _____ Rx Policy # _____ Rx Group # _____ Rx PCN # _____

Information about your patient's insurance coverage, cost support options, and treatment support is given by service providers for SPRAVATO withMe. The information you get does not require you or your patient to use any Janssen product. Because the information we give you comes from outside sources, SPRAVATO withMe cannot promise the information will be complete. Each healthcare provider and patient is responsible for verifying or confirming any information provided. SPRAVATO withMe cost support is not for patients in the Johnson & Johnson Patient Assistance Foundation.

SPRAVATO withMe is limited to education for patients about SPRAVATO®, its administration, and/or their disease, and is not intended to provide medical advice, replace a treatment plan from the patient's doctor or nurse, or provide case management services.

Please see the full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO®. Provide the Medication Guide to your patients and encourage discussion.

NEW

Spravato withMe Program Enrollment Form

Spravato® (esketamine) CIII
28 mg nasal spray

Fax completed form to 844-577-7282 | For assistance, call 844-4S-WITHME (844-479-4846)

Patient First Name _____ Patient Last Name _____ DOB _____

3. Prescriber Information

Required information in order to process this form.

Which treatment setting would you like to investigate benefits for?

■ Prescriber Office ☐ Outpatient Facility

Prescriber First Name _____ Prescriber Last Name _____

Site Name Greater Houston Psychiatric Associates, PLLC

Site Contact First Name Brandi Site Contact Last Name Pipes

Site Address 4888 Loop Central Dr., Ste #510

Site City Houston Site State TX Site ZIP 77081-2226

Site Phone 713-346-1555 Site Fax 713-346-1579 Prescriber NPI # _____

After Hours Phone 713-346-1555 Prescriber Email Esketamine@ghpa.net Prescriber Tax ID # 76-0675947

4. Clinical Information (This form does NOT serve as a valid prescription. The information requested here is needed to investigate benefits. Benefits will be investigated for both 84 mg and 56 mg dose strengths.)

Common ICD-10 Codes*: ☐ F32.1 ☐ F32.2 ☐ F33.2 ☐ Other ICD-10 Code _____

**These codes do not represent all available codes.*

Treatment History

Concomitant Oral Antidepressant _____

Other therapies prescribed within the current depressive episode (specific to treatment-resistant depression)

_____

Indication

■ **Treatment-resistant depression in adults**

The patient with MDD and in the current depressive episode has not responded adequately to at least 2 different oral antidepressants of adequate dose and duration.

☐ **Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior**

5. Prior Authorization Form Assistance and Status Monitoring

Janssen automatically provides Prior Authorization form assistance, including status updates where required by a patient's health plan, when you enroll your patient into SPRAVATO withMe.

☐ By checking this box, I am requesting to opt out of receiving Prior Authorization form assistance for my patient.

Please see the full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO®. Provide the Medication Guide to your patients and encourage discussion.

NEW UPDATE 01.24

Spravato with Me

Program Enrollment Form

Spravato® (esketamine) CIII
28 mg nasal spray

Fax completed form to 844-577-7282 | For assistance, call 844-4S-WITHME (844-479-4846)

TO BE COMPLETED BY THE PATIENT

Patients can also complete the Program Enrollment Form, including the Janssen Patient Support Program Patient Authorization Form, online. Visit SpravatowithMePatientAuth.com or scan the QR code. Data rates may apply.

SPRAVATO withMe is unable to process any information without the signed Patient Authorization, included in pages 5 and 6 of this form. The information you provide will be used by Johnson & Johnson Health Care Systems Inc., our affiliates, and our service providers for your enrollment and participation in SPRAVATO withMe. Our **Privacy Policy** governs the use of the information you provide. By submitting this form, you indicate that you read, understand, and agree to these terms.

1. Patient Information

Required information in order to process this form.

Patient First Name _____ Patient Last Name _____ Sex ☐ M ☐ F

Date of Birth (mm/dd/yyyy) _____ Preferred Language if not English: _____

Patient Address _____

Patient City _____ Patient State _____ Patient ZIP _____

Preferred Patient Phone _____ (■ Cell ☐ Home)

Best Time to Contact: ☐ AM ☐ PM Patient Email _____

Caregiver/Contact _____ Relationship to Patient _____
(A caregiver/contact is someone who can be contacted in place of the patient.)

Caregiver Phone _____ (☐ Cell ☐ Home) Best Time to Contact: ☐ AM ☐ PM Caregiver Email _____

■ I consent to receive voicemails from the SPRAVATO withMe program that include my medication name and/or disease state.

☐ If I cannot be reached, I authorize SPRAVATO withMe to contact my caregiver.

☐ I prefer and authorize SPRAVATO withMe to contact my caregiver in place of me.

2. Care Navigator Support (optional)

A Care Navigator will be assigned to support you as part of your enrollment with SPRAVATO withMe, unless you opt out by checking the box below.

Care Navigators provide one-to-one educational support throughout your treatment journey, including sharing information about what to expect during treatment, and helping you understand your insurance coverage. Once your enrollment is complete, a Care Navigator will call you from 844-479-4846 ("Janssen" will appear on your caller ID).

Note: Care Navigators do not provide medical advice. Please ask your doctor any questions you might have about your disease and treatment.

☐ **By checking this box, I am requesting to opt out of Care Navigator Support.**

3. Text Message and Marketing Communications Opt-ins (optional)

Text Message Opt-in

You can opt to receive communications from the Care Navigator program via text message. Opting into text messaging allows your Care Navigator to contact you to check your availability to schedule a call or share program updates. We may also send you other messages about the SPRAVATO withMe program.

■ Yes, I would like to receive text messages from the SPRAVATO withMe program. By selecting this option, I agree to receive text messages at the following cell number.* I understand I am not required to provide my permission to receive text messages to participate in the SPRAVATO withMe program or to receive any other communications I have selected. Cell Phone (required) _____

*Message and data rates may apply. Message frequency varies. Reply STOP to opt out.

Permission for communications outside of Janssen patient support programs

☐ I would like to receive communications relating to my Janssen medication.

☐ I would like to receive communications relating to other Janssen products and services.

For privacy rights and choices specific to California residents, please see Janssen's California privacy notice available at https://www.janssen.com/us/privacy-policy#california

Please read the full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO® and discuss any questions you may have with your healthcare provider. 01/24 cp-68044v13

NEW Spravato withMe

Program Enrollment Form

Spravato® (esketamine) C-III
28 mg nasal spray

Fax completed form to 844-577-7282 | For assistance, call 844-4S-WITHME (844-479-4846)

Patient First Name _____ Patient Last Name _____ DOB _____

4. SPRAVATO withMe Savings Program and Observation Rebate Program Enrollment (optional)

If you use commercial or private health insurance to pay for your medication:

SPRAVATO withMe Savings Program

Eligible patients pay $10 per treatment for SPRAVATO® medication costs, with an $8,150 maximum program benefit per calendar year. Treatment may include up to three devices administered on the same day. Program limits apply. There is a program benefit limit of list price of the medication and a quantity limit of three devices per day or 23 devices in a 24-day period. There is a quantity limit of 24 devices in a 24-day period for one use per lifetime. Not valid for patients using Medicare, Medicaid, or other government-funded programs to pay for their medication. Terms expire at the end of each calendar year and may change. See full program requirements at **Spravato.com/SavingsRequirements**.

SPRAVATO withMe Observation Rebate Program

Eligible patients pay $0 after rebate to patient for observation of each treatment, with a $500 maximum program benefit per calendar year. Not valid for patients using Medicare, Medicaid, or other government-funded programs to pay for their treatments. Terms expire at the end of each calendar year and may change. Not valid for residents of MA, MI, MN, or RI. There is no income requirement. See full program requirements at **Spravato.com/Observation**.

By attesting to the statements below, I authorize SPRAVATO withMe to check my eligibility for the SPRAVATO withMe Savings Program and the SPRAVATO withMe Observation Rebate Program and enroll me in the Programs, if eligible.

- ☐ I attest that I have commercial or private health insurance that I will use for my SPRAVATO® medication or treatment costs.*
- ☐ I attest that I will NOT use any government-funded healthcare program to cover any of my SPRAVATO® medication or treatment costs.†
- ☐ I attest that I will NOT submit any amounts paid or reimbursed by these programs as a claim for payment to any health plan, patient assistance foundation, Flexible Savings or Health Savings account.

*Examples are commercial insurance from a current/former employer, government employee health insurance, or insurance the patient buys privately or through the Health Insurance Marketplace.

†Examples are Medicare Parts A, B, C (also known as Medicare Advantage Plan), D, and Medicare Supplement, Medicaid, TRICARE, Department of Defense, or Veterans Administration.

You can also enroll online at **MyJanssenCarePath.com/express**.

Information about your insurance coverage, cost support options, and treatment support is given to you by service providers for SPRAVATO withMe. The information you get does not require you to use any Janssen product. The information about whether your treatment is covered by your health plan comes from outside sources, and SPRAVATO withMe cannot guarantee that the information will be complete. It is not a promise of coverage or payment. You are responsible for verifying or confirming any information provided. You should contact your health plan directly for the most current information. You are responsible for meeting your health plan requirements. SPRAVATO withMe cost support is not for patients in the program offered by Johnson & Johnson Patient Assistance Foundation.

SPRAVATO withMe is limited to education about SPRAVATO®, its administration, and/or the condition it treats. It is not intended to provide medical advice, replace a treatment plan you receive from your doctor or nurse, or serve as a reason for you to start or stay on treatment.

Please read the full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO® and discuss any questions you may have with your healthcare provider.

NEW

Janssen Patient Support Program
Patient Authorization Form

Patient First Name _____ **Patient Last Name** _____ **DOB** _____

Patients should read the Patient Authorization, sign, and return all pages of the Form to the Janssen Patient Support Program.

- Completed Form may be faxed to 844-577-7282 or mailed to SPRAVATO withMe, 2250 Perimeter Park Drive, Suite 300, Morrisville, NC 27560
- Patients may also read, eSign, and submit a digital version of this form at **SpravatowithMePatientAuth.com**

I give permission for each of my "Healthcare Providers" (eg, my physicians, pharmacists, specialty pharmacies, other healthcare providers, and their staff) and "Insurers" (eg, my health insurance plans) to share my Protected Health Information as described on this Form.

My "Protected Health Information" includes any and all information related to my medical condition, treatment, prescriptions, and health insurance coverage.

The following person(s) or class of person(s) are given permission to receive and use my Protected Health Information (collectively "Janssen"):

- Johnson & Johnson Health Care Systems Inc., its affiliated companies, agents, and representatives
- Providers of other sources of funding, including foundations and co-pay assistance providers
- Service providers for the patient support programs, including subcontractors or healthcare providers helping Janssen run the programs
- Service providers maintaining, transmitting, de-identifying, aggregating, or analyzing data from Janssen patient support programs

Also, I give permission to Janssen to receive, use, and share my Protected Health Information in order to:

- see if I qualify for, sign me up for, contact me about, and provide services relating to Janssen patient support programs, including in-home services
- manage the Janssen patient support programs
- give me educational and adherence materials, information, and resources related to my Janssen medication in connection with Janssen patient support programs
- communicate with my Healthcare Providers regarding access to, reimbursement for and fulfillment of my Janssen medication, and to tell my Healthcare Provider that I am participating in Janssen patient support programs
- verify, assist with, and coordinate my coverage for my Janssen medication with my Insurers and Healthcare Providers
- coordinate prescription or treatment location and associated scheduling
- conduct analysis to help Janssen evaluate, create, and improve its products, services, and customer support for patients prescribed Janssen medications
- share and give access to information created by the Janssen patient support programs that may be useful for my care

NEW

Janssen Patient Support Program
Patient Authorization Form

I understand that my Protected Health Information may be shared by Janssen for the uses written in this Form to:

- My Insurers
- My Healthcare Providers
- Any of the persons given permission to receive and use my Protected Health Information as mentioned above
- Any individual I give permission as an additional contact

Janssen and the other data recipients listed on this Form may share information about me as permitted on this Form or if any information that specifically identifies me is removed. I understand that Janssen will use reasonable efforts to keep my information private but once my Protected Health Information is disclosed as allowed on this Form, it may no longer be protected by federal privacy laws.

I understand that I am not required to sign this Form. My choice about whether to sign will not change how my Healthcare Providers or Insurers treat me. If I do not sign this Form, or cancel or remove my permission later, I understand I will not be able to participate or receive assistance from Janssen's patient support programs.

I understand that pharmacies that dispense and ship my medication and service providers for the patient support programs may be paid by Janssen for their services and data. This may include payment for sharing Protected Health Information and other data in connection with these programs, as allowed on this Form.

This Form will remain in effect 10 years from the date of signature, except where state law requires a shorter time, or until I am no longer participating in any Janssen patient support programs. Information collected before that date may continue to be used for the purposes set forth in this Form.

I understand that I may cancel the permissions given by this Form at any time by letting Janssen know in writing at: SPRAVATO withMe, 2250 Perimeter Park Drive, Suite 300, Morrisville, NC 27560.

I can also cancel my permission by letting my Healthcare Providers and Insurers know in writing that I do not want them to share any information with Janssen.

I further understand that if I cancel my permission it will not affect how Janssen uses and shares my Protected Health Information received by Janssen prior to my cancellation.

I understand I may request a copy of this Form.

Required information in order to process this form.

Patient name (print): _____

Patient sign here: _____ **Date:** _____

If the patient cannot sign, patient's legally authorized representative must sign below:

By: _____ **Print Name:** _____ **Date:** _____

(Signature of person legally authorized to sign for patient)

Describe relationship to patient and authority to make medical decisions for patient:

_____

Janssen
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Name: DOB: Date:

Montgomery-Åsberg Depression Rating Scale (MADRS)

The rating should be based on a clinical interview moving from broadly phrased questions about symptoms to more detailed ones which allow a precise rating of severity. The rater must decide whether the rating lies on the defined scale steps (0, 2, 4, 6) or between them (1, 3, 5) and then report the appropriate number. The items should be rated with regards to how the patient has done over the past week.

1. Apparent sadness

Representing despondency, gloom and despair (more than just ordinary transient low spirits), reflected in speech, facial expression, and posture. Rate by depth and inability to brighten up.

0 = No sadness.
2 = Looks dispirited but does brighten up without difficulty.
4 = Appears sad and unhappy most of the time.
6 = Looks miserable all the time. Extremely despondent

2. Reported sadness

Representing reports of depressed mood, regardless of whether it is reflected in appearance or not. Includes low spirits, despondency or the feeling of being beyond help and without hope.

0 = Occasional sadness in keeping with the circumstances.
2 = Sad or low but brightens up without difficulty.
4 = Pervasive feelings of sadness or gloominess. The mood is still influenced by external circumstances.
6 = Continuous or unvarying sadness, misery or despondency.

3. Inner tension

Representing feelings of ill-defined discomfort, edginess, inner turmoil, mental tension mounting to either panic, dread or anguish. Rate according to intensity, frequency, duration and the extent of reassurance called for.

0 = Placid. Only fleeting inner tension.
2 = Occasional feelings of edginess and ill-defined discomfort.
4 = Continuous feelings of inner tension or intermittent panic which the patient can only master with some difficulty.
6 = Unrelenting dread or anguish. Overwhelming panic.

4. Reduced sleep

Representing the experience of reduced duration or depth of sleep compared to the subject's own normal pattern when well.

0 = Sleeps as normal.
2 = Slight difficulty dropping off to sleep or slightly reduced, light or fitful sleep.
4 = Moderate stiffness and resistance
6 = Sleep reduced or broken by at least 2 hours.

5. Reduced appetite

Representing the feeling of a loss of appetite compared with when-well. Rate by loss of desire for food or the need to force oneself to eat.

0 = Normal or increased appetite.
2 = Slightly reduced appetite.
4 = No appetite. Food is tasteless.
6 = Needs persuasion to eat at all.

Name: DOB: Date:

6. Concentration difficulties

Representing difficulties in collecting one's thoughts mounting to an incapacitating lack of concentration. Rate according to intensity, frequency, and degree of incapacity produced.

0 = No difficulties in concentrating.
2 = Occasional difficulties in collecting one's thoughts.
4 = Difficulties in concentrating and sustaining thought which reduced ability to read or hold a conversation.
6 = Unable to read or converse without great difficulty.

7. Lassitude

Representing difficulty in getting started or slowness in initiating and performing everyday activities.

0 = Hardly any difficulty in getting started. No sluggishness.
2 = Difficulties in starting activities.
4 = Difficulties in starting simple routine activities which are carried out with effort.
6 = Complete lassitude. Unable to do anything without help.

8. Inability to feel

Representing the subjective experience of reduced interest in the surroundings, or activities that normally give pleasure. The ability to react with adequate emotion to circumstances or people is reduced.

0 = Normal interest in the surroundings and in other people.
2 = Reduced ability to enjoy usual interests.
4 = Loss of interest in the surroundings. Loss of feelings for friends and acquaintances.
6 = The experience of being emotionally paralysed, inability to feel anger, grief or pleasure and a complete or even painful failure to feel for close relatives and friends.

9. Pessimistic thoughts

Representing thoughts of guilt, inferiority, self-reproach, sinfulness, remorse and ruin.

0 = No pessimistic thoughts.
2 = Fluctuating ideas of failure, self-reproach or self- depreciation.
4 = Persistent self-accusations, or definite but still rational ideas of guilt or sin. Increasingly pessimistic about the future.
6 = Delusions of ruin, remorse or irredeemable sin. Self- accusations which are absurd and unshakable.

10. Suicidal thoughts

Representing the feeling that life is not worth living, that a natural death would be welcome, suicidal thoughts, and preparations for suicide. Suicide attempts should not in themselves influence the rating.

0 = Enjoys life or takes it as it comes.
2 = Weary of life. Only fleeting suicidal thoughts.
4 = Probably better off dead. Suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intenstion.
6 = Explicit plans for suicide when there is an opportunity. Active preparations for suicide.

Patient Health Questionnaire and General Anxiety Disorder
(PHQ-9 and GAD-7)

Date_____ Patient Name:_____ Date of Birth: _____

Over the last 2 weeks, how often have you been bothered by any of the following problems?
Please circle your answers.

PHQ-9	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
1. Little interest or pleasure in doing things.	☐ 0	☐ 1	☐ 2	☐ 3
2. Feeling down, depressed, or hopeless.	☐ 0	☐ 1	☐ 2	☐ 3
3. Trouble falling or staying asleep, or sleeping too much.	☐ 0	☐ 1	☐ 2	☐ 3
4. Feeling tired or having little energy.	☐ 0	☐ 1	☐ 2	☐ 3
5. Poor appetite or overeating.	☐ 0	☐ 1	☐ 2	☐ 3
6. Feeling bad about yourself – or that you are a failure or have let yourself or your family down.	☐ 0	☐ 1	☐ 2	☐ 3
7. Trouble concentrating on things, such as reading the newspaper or watching television.	☐ 0	☐ 1	☐ 2	☐ 3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual.	☐ 0	☐ 1	☐ 2	☐ 3
9. Thoughts that you would be better off dead, or of hurting yourself in some way.	☐ 0	☐ 1	☐ 2	☐ 3
Add the score for each column		0	0	0

Total Score (add your column scores): 0_____

If you checked off any problems, how difficult have these made it for you to do your work, take care of things at home, or get along with other people? (Circle one)

◯ **Not difficult at all** ◯ **Somewhat difficult** ◯ **Very Difficult** ◯ **Extremely Difficult**

Over the last 2 weeks, how often have you been bothered by any of the following problems?
Please circle your answers.

GAD-7	**Not at all sure**	**Several days**	**Over half the days**	**Nearly every day**
1. Feeling nervous, anxious, or on edge.	☐ 0	☐ 1	☐ 2	☐ 3
2. Not being able to stop or control worrying.	☐ 0	☐ 1	☐ 2	☐ 3
3. Worrying too much about different things.	☐ 0	☐ 1	☐ 2	☐ 3
4. Trouble relaxing.	☐ 0	☐ 1	☐ 2	☐ 3
5. Being so restless that it's hard to sit still.	☐ 0	☐ 1	☐ 2	☐ 3
6. Becoming easily annoyed or irritable.	☐ 0	☐ 1	☐ 2	☐ 3
7. Feeling afraid as if something awful might happen.	☐ 0	☐ 1	☐ 2	☐ 3
Add the score for each column				

Total Score (add your column scores): 0_____

If you checked off any problems, how difficult have these made it for you to do your work, take care of things at home, or get along with other people? (Circle one)

◯ **Not difficult at all** ◯ **Somewhat difficult** ◯ **Very Difficult** ◯ **Extremely Difficult**

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SPRAVATO™ FAQ'S

WHAT IS KETAMINE?

Ketamine a 50:50 mixture of two differently oriented versions of the same molecule, known as enantiomers (or optical isomers). The two enantiomers of ketamine are known as S-ketamine (Esketamine) and R-ketamine (arketamine). Ketamine has been approved by the FDA (Food and Drug Administration) for use in anesthesia and as a pain reliver during medical procedures. Studies have shown that ketamine may be helpful in the treatment of depression.

WHAT IS ESKETAMINE?

Studies have shown that Esketamine is more potent than ketamine and can be used at a lower dose with fewer side effects. While other antidepressants modulate a group of chemicals in the brain called monoamines, esketamine targets glutamate.

HOW DOES ESKETAMINE WORK?

Esketamine is working on the glutamatergic system which is thought to create synapses in the brain. When we have depression, sometimes we do not have as many connections or synapses within the brain cells, so those synapses go away. Esketamine is thought to create these synapses, or connections, between our brain cells again.

IS SPRAVATO™ SAFE?

SPRAVATO™ is a very safe depression medication in the hands of trained healthcare professionals. SPRAVATO™ is used along with an antidepressant taken by mouth to treat Adults with treatment-resistant depression (TRD) and depressive symptoms in adults with major depressive disorder (MDD) with suicidal thoughts or actions. The appropriate dosage is determined by your physician and is below those necessary to induce general anesthesia.

IS SPRAVATO™ A RECREATIONAL DRUG?

SPRAVATO™ is esketamine, however Ketamine has been abused as a recreational drug. Street drug use is in doses vastly higher than the sub-anesthetic doses used for the treatment of depression and other mental health conditions. As mentioned above, SPRAVATO™ is used legally and safely and is a very safe medication in experienced hands. The key is administering the right dose to the right patient in the right setting.

IS INTRANASAL SPRAVATO™ THE ONLY WAY TO DELIVER SPRAVATO™ FOR TREATMENT RESISTANT DEPRESSION?

SPRAVATO™ is only administered intranasally. The effectiveness and predictability of response and most scientific studies of SPRAVATO™ for depression and mental health conditions have been performed using intranasal SPRAVATO™. In short, intranasal SPRAVATO™ is the gold standard route for SPRAVATO™ administration.

CAN I CONTINUE TO TAKE MY REGULAR MEDICATIONS?

Yes, you should not stop your antidepressant medications to receive SPRAVATO™. It is essential that we review your current medication list prior to beginning SPRAVATO™ treatments.

CAN SPRAVATO™ HELP ME?
Research over the last 5-10 years has shown that Intranasal administration of SPRAVATO™ in sub-anesthetic doses benefits 70% of people suffering from severe depression. While the benefits can truly be remarkable, they often occur in ways that differ from some patients' expectations. That is, the changes produced by SPRAVATO™ can be subtle, and while they occur quickly, they do not always manifest themselves immediately. This phenomenon stands in contrast to some patients' expectations of a benevolent "thunderbolt" response from SPRAVATO™ treatment. With this in mind, we will work closely with you to identify and evaluate the benefits of SPRAVATO™ as a depression medication.

HOW MANY INTRANASAL ADMINISTRATIONS WILL I NEED?
The standard SPRAVATO™ protocol for depression that has resulted from scientific trials and clinical experience around the U.S. is about 2 times per week for the first 4 weeks, and then weekly for 2-4 weeks and then maintenance (usually once every 2 weeks). It has been shown that serial Intranasal administrations are more effective than single Intranasal administrations, and many patients who respond to SPRAVATO™ treatment require maintenance Intranasal administrations on an ongoing basis following the initial series. The frequency of these maintenance Intranasal administrations varies from person to person. It is important to note that SPRAVATO™ Intranasal administrations should not be viewed as a cure for depression, but a depression treatment that is a piece of a multi-modal approach that may include ongoing mental health therapy or other depression medication.

IS SPRAVATO™ ADDICTING?
SPRAVATO™ is not physically addicting but it could be psychologically addicting in those using it recreationally at much higher doses and in far greater frequencies than we will use. There is potential for abuse and misuse. All patients will be monitored for signs and symptoms of abuse and misuse.

IS THERE A DIFFERENCE BETWEEN SPRAVATO™ NASAL SPRAY AND KETAMINE INFUSIONS?
SPRAVATO™ ™(esketamine) is the s-enantiomer of racemic ketamine. There are no head-to-head studies comparing esketamine and ketamine infusion. SPRAVATO™ (esketamine) is delivered in a nasal spray form and ketamine is delivered intravenously.

HOW MUCH DOSE SPRAVATO™ COST?
The cost of SPRAVATO™ is dependent on your insurance plan. Janssen CarePath may be able to offer access and affordability options, depending on your plan. You may enroll in Jansen CarePath at https://www.janssencarepath.com/

CAN SPRAVATO™ BE TAKEN WITH OTHER MEDICATIONS FOR DEPRESSION?
SPRAVATO™ ™ should be administered in conjunction with an oral antidepressant (AD). The new open-label oral AD initiated during Study 1 (short-term) was an SSRI in 32% of patients and an SNRI in 68% of patients.

WHAT IF I MISS A DOSE OF SPRAVATO™?
If a patient misses a treatment session, and depression symptoms worsen, your provider may consider returning a patient to their previous dosing schedule per clinical judgment.

CAN I PICK UP SPRAVATO™ AND SELF-ADMINISTER AT HOME?
No, under the REMS (Risk Evaluation & Mitigation Strategy) Program, SPRAVATO™ must be administered in a certified healthcare setting. Due to the possibility of delayed or prolonged sedation or dissociation in some cases, patients should be monitored by a healthcare professional for at least 2 hours following each treatment session, or until the clinician determines the patient is safe to leave.

HOW SOON CAN PATIENTS DRIVE AFTER TAKING SPRAVATO™?
Patients are cautioned that SPRAVATO™ may impair their ability to drive or operate machinery. Patients are instructed not to engage in potentially hazardous activities requiring complete mental alertness and motor coordination, such as driving a motor vehicle or operating machinery, until the next day after a restful sleep

WHAT SHOULD I EXPECT DURING MY FIRST INITIAL SPRAVATO™ VISIT?
The initial assessment involves a review of your medical history and then a second visit for your initial treatment. The initial assessment, or consultation, will be used to evaluate the appropriateness of SPRAVATO™ (esketamine) in treating your depression. Your SPRAVATO™ prescribing psychiatrist, will use the assessment to determine a diagnosis and the risks and benefits of SPRAVATO™ compared to other available treatments for your diagnosis. The doctor will want details about previous treatment for your depression including counseling history, names of medications and maximum dosage, duration of treatment, and reasons treatment was discontinued. You should be prepared to complete formal medical history evaluations and sign consent forms during the initial assessment.

If SPRAVATO™ is right for you, your psychiatrist will create a treatment plan for you. Your next appointment will be your first treatment. Prior to administering SPRAVATO™, your blood pressure will be recorded to ensure SPRAVATO™ can be safely administered. Then we will begin the intranasal administration while you are seated with your head at a 45-degree incline. Afterwards, we will monitor you for approximately 120 minutes (2 hours) before you are released to a friend or relative who can drive you safely home. During the treatment, patients may occasionally experience nausea, mild non-threatening hallucinations, or dizziness. You will be awake during the treatment and able to interact with those around you. It is best to relax quietly or listen to relaxing music during the session. Please feel free to bring a blanket or anything else that makes you feel comfortable. Although the effects of SPRAVATO™ wear off quickly, we ask that you refrain from driving until the day after the treatment. Please do not eat solid foods, milk, pulp-filled juices, or soup for 4-hours prior to your appointment. You may have clear liquids such as water, Gatorade, apple juice, black coffee, or tea up to two hours prior to your appointment