Spravato withMe

Spravato® (esketamine) CIII
28 mg nasal spray

SPRAVATO withMe Savings Program

for eligible commercially insured patients

Eligible patients pay as little as $10 per treatment

Maximum program benefit per calendar year and program limits shall apply. Treatment may include up to three devices administered on the same day. There is a program benefit limit of list price of the medicine 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. Terms expire at the end of each calendar year. Offer subject to change or end without notice. Restrictions, including monthly maximums, may apply.

Program does not cover the cost of treatment observation.

See program requirements on pages 3 and 4.

Depending on the patient's health insurance plan, savings may apply toward co-pay, co-insurance, or deductible. Patients may participate without sharing their income information.

1. Get started

Express Enrollment Available

Portal.JNJwithMe.com

Check eligibility to enroll eligible patients in the SPRAVATO withMe Savings Program and get a Savings Program card

Indications:

SPRAVATO® (esketamine) CIII Nasal Spray is indicated for the treatment of:

- Treatment-resistant depression (TRD) in adults as monotherapy or in conjunction with an oral antidepressant.
- Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior in conjunction with an oral antidepressant.

Limitations of Use:

- The effectiveness of SPRAVATO® in preventing suicide or in reducing suicidal ideation or behavior has not been demonstrated. Use of SPRAVATO® does not preclude the need for hospitalization if clinically warranted, even if patients experience improvement after an initial dose of SPRAVATO®.
- SPRAVATO® is not approved as an anesthetic agent. The safety and effectiveness of SPRAVATO® as an anesthetic agent have not been established.

IMPORTANT SAFETY INFORMATION

WARNING: SEDATION; DISSOCIATION; RESPIRATORY DEPRESSION; ABUSE AND MISUSE; and SUICIDAL THOUGHTS AND BEHAVIORS

See full prescribing information for complete boxed warning

- **Risk for sedation, dissociation, and respiratory depression after administration. Monitor patients for at least two hours after administration (5.1, 5.2, 5.3).**
- **Potential for abuse and misuse. Consider the risks and benefits of using SPRAVATO® prior to use in patients at higher risk of abuse. Monitor for signs and symptoms of abuse and misuse (5.4).**
- **SPRAVATO® is only available through a restricted program called the SPRAVATO® REMS (5.5).**
- **Increased risk of suicidal thoughts and behaviors in pediatric and young adult patients taking antidepressants. Closely monitor all antidepressant-treated patients for clinical worsening and emergence of suicidal thoughts and behaviors. SPRAVATO® is not approved for use in pediatric patients (5.6).**

Please see additional Important Safety Information on pages 5-7 and full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO®.

2. How to use the Savings Program

How the Savings Program can be used depends on the insurance used to pay for patient's treatment

If using patient's medical/primary insurance for their medicine:

The patient is responsible for submitting a rebate request to SPRAVATO withMe Savings Program or, at the patient's direction, the provider may submit the rebate request on behalf of the patient. Confirm with your patient who will submit rebate requests to the Savings Program.

If the provider is submitting a rebate request:

- If you have been authorized by your patient to receive payment directly for the appropriate value of the medical claim submission, you may submit rebate requests to the SPRAVATO withMe Savings Program on their behalf

If the patient is submitting a rebate request:

- Patient will need to complete, sign, and submit a **Rebate Request Form**. Patients may refer to the Rebate Request Form for instructions on submitting rebate requests

How the provider can submit a claim using patient's medical/primary insurance for their medicine:

1. **Submit claim to patient's insurance:** Submit a primary claim to the patient's insurance using the medical claims form (CMS-1500 (HICF) or CMS-1450 (UB-04)). Patient and the provider will receive an Explanation of Benefits (EOB) statement from patient's insurance company.
2. **Submit rebate claim to Savings Program:** If the patient has a remaining co-pay greater than $10, you may submit a rebate claim to the SPRAVATO withMe Savings Program using a medical claim form (CMS-1500 or CMS-1450) or electronic versions 837P or 837I (electronic submission is preferred).

   NOTE: Before you submit a rebate claim electronically, contact your clearinghouse to request Payer ID# 56155 and 56165 be added to their system, if needed.

   - To complete the medical claim form, you will need to use the Medical Claims information from the front of the patient's Savings Program card
   - Include the primary payer EOB or Payment Remittance, showing the patient's co-pay for one of these approved billing codes:
     - G2082 or G2083
     - S0013
     - J3490 (Use with NDC #50458-0028-02 or NDC #50458-0028-03)
3. **Receive payment:** You will receive funds for approved claims through your preferred payment method: Electronic Funds Transfer (EFT) or check.

If using patient's pharmacy/prescription insurance for their medicine from a pharmacy:

- Patients may provide the Pharmacy Claims information from the front of the Savings Program card to the pharmacy to receive instant savings on the cost of their medicine
- The pharmacy will collect patient's co-pay or co-insurance amount

To facilitate a timely approval and reimbursement of the claim you are submitting, please use the **SPRAVATO withMe Claims Reimbursement Checklist** to confirm required documentation and information is included.

The patient support and resources provided by SPRAVATO withMe are not intended to provide medical advice, replace a treatment plan from the patient's doctor or nurse, provide case management services, or serve as a reason to prescribe SPRAVATO®.

Savings Program Requirements

Patients may be eligible for the SPRAVATO withMe Savings Program if they are:

- Age 18 or older, use commercial or private health insurance for their prescribed SPRAVATO® (esketamine) Nasal Spray CIII, and must pay an out-of-pocket cost for their medicine.
- Enrolled in the SPRAVATO® Risk Evaluation and Mitigation Strategy (REMS). Learn more at **SpravatoREMS.com**.

Patients may participate without sharing their income information.

Some health plans have programs or benefit designs known as "accumulators" or "maximizers." These programs divert patient assistance funds away from patients.

- Accumulators don't allow patient assistance to count toward the patient's deductible and out-of-pocket maximum until the maximum value of the patient assistance is reached.
- Maximizers also don't allow patient assistance to count toward the patient's deductible and out-of-pocket maximum. Maximizers apply the full value of the patient assistance over the year. This could be either the same amount each month or a larger amount early in the year that tapers off, without allowing any of those funds to count toward the patient's annual deductible or out-of-pocket maximum.
- The SPRAVATO withMe Savings Program is designed solely for the benefit of the patient. Thus, Johnson & Johnson reserves the right to reduce the SPRAVATO withMe Savings Program maximum benefit for patients in an accumulator or maximizer program or benefit design, except where prohibited by law.

In addition, some health plans have "non-essential health benefit maximizers" that conflict with the program requirements of the SPRAVATO withMe Savings Program.

- These programs or benefit designs, like the services offered by SaveOnSP, classify certain specialty medicines such as SPRAVATO® as "non-essential." This takes away protections for patients provided by the Affordable Care Act (ACA) related to maximum out-of-pocket limits.
- The SPRAVATO withMe Savings Program is designed solely for the benefit of the patient. If the patient's insurance company or health plan partners with SaveOnSP, then except where prohibited by law, they will not be eligible for, and they agree not to use, the SPRAVATO withMe Savings Program.
- The patient needs to let SPRAVATO withMe know if their insurance company or health plan has one of these programs or benefit designs, including SaveOnSP, by calling **1-844-4S-WITHME** (1-844-479-4846) to discuss their options. Since they may not know they are subject to one of these programs or benefit designs when they enroll in SPRAVATO withMe, J&J will monitor their utilization.
- J&J reserves the right to discontinue cost support if the patient no longer meets eligibility requirements.
- If their health plan removes SPRAVATO® from its partnership with SaveOnSP or other non-essential health benefit maximizer, they may be eligible to be reinstated in the SPRAVATO withMe Savings Program.

By utilizing this Savings Program, the patient accepts and agrees to abide by these program requirements. Any individual or entity who enrolls or assists in the enrollment of a patient in the Savings Program represents that the patient meets the eligibility criteria and other requirements described.

Savings Program Requirements (CONTINUED)

Other requirements

- **This program is only available to people age 18 or older using commercial or private health insurance who must pay an out-of-pocket cost for their SPRAVATO®. This includes plans from the Health Insurance Marketplace.** This program is not for people who use any state or federal government-funded healthcare program. Examples of these programs are Medicare, Medicaid, TRICARE, Department of Defense, and Veterans Administration.
- By enrolling in this program, patients agree that this program is intended solely for the benefit the patient. Patients may not seek payment for the value received from this program from any health plan, patient assistance foundation, flexible spending account, or healthcare savings account.
- Patients must meet the program requirements every time they use the Savings Program.
- Program terms will expire at the end of each calendar year. The program may change or end without notice, including in specific states.
- Program participants are subject to an annual maximum benefit. Program benefits are set at the discretion of J&J and may change without notice.
- Patients who are subject to programs, health plans, or benefits that claim to **reduce** the patients' out-of-pocket co-pay, co-insurance, or deductible obligations for certain prescription drugs based upon the availability of, or patient's enrollment in, manufacturer-sponsored co-pay assistance for such drugs will be subject to a reduced annual maximum program benefit per calendar year (not applicable to patients in Maine).
- Patients who are subject to programs, health plans, or benefits that claim to **eliminate** their out-of-pocket costs are not eligible for the SPRAVATO withMe Savings Program, because this program is only for people who must pay an out-of-pocket cost for SPRAVATO®.
- Notwithstanding any other term of this program, patients who are members of health plans that partner with SaveOnSP, or who are subject to services administered by SaveOnSP, are not eligible for the SPRAVATO withMe Savings Program. If your health plan removes SPRAVATO® from its partnership with SaveOnSP, you may be eligible for the SPRAVATO withMe Savings Program.
- To use this program, patients must follow any health plan requirements, including telling their health plan how much co-payment support they get from this program. By getting a Savings Program benefit, patients confirm that they have read, understood, and agree to the program requirements on this page, and are giving permission for information about their Savings Program transactions to be shared with their healthcare provider(s). These transactions include rebates and any funds placed on the card or balance remaining on the card.
- Before patients enroll in the program, they will be asked to provide personal information that may include their name, address, phone number, email address, and/or other information, including information related to their prescription medicine insurance and treatment. The use of their information will be governed by our **Privacy Policy**.
- If patients use medical/primary insurance to pay for their medicine, they need to submit a rebate request with an Explanation of Benefits (EOB) to get payment from the Savings Program. With the patient's permission, the provider may submit the rebate request and EOB for the patient. By submitting an EOB on behalf of a patient, the healthcare provider certifies that they have been authorized by the patient to receive payment directly for the appropriate value of the medical claim submission. Rebate requests must be submitted within 365 days of the date of service.
- This program offer may not be used with any other coupon, discount, prescription savings card, free trial, or other offer. Offer good only in the United States and its territories. Void where prohibited, taxed, or limited by law.

Patients may end their participation in SPRAVATO withMe at any time by calling a Care Navigator at **1-844-4S-WITHME** (1-844-479-4846).

IMPORTANT SAFETY INFORMATION (CONTINUED)

CONTRAINDICATIONS

SPRAVATO® is contraindicated in patients with:

- Aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial and peripheral arterial vessels) or arteriovenous malformation.
- History of intracerebral hemorrhage.
- Hypersensitivity to esketamine, ketamine, or any of the excipients.

WARNINGS AND PRECAUTIONS

Sedation: SPRAVATO® may cause sedation or loss of consciousness. In some cases, patients may display diminished or less apparent breathing. In clinical trials, 48% to 61% of SPRAVATO®-treated patients developed sedation and 0.3% to 0.4% of SPRAVATO®-treated patients experienced loss of consciousness.

Because of the possibility of delayed or prolonged sedation, patients must be monitored by a healthcare provider 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.

Closely monitor for sedation with concomitant use of SPRAVATO® with CNS depressants (e.g., benzodiazepines, opioids, alcohol).

Dissociation: The most common psychological effects of SPRAVATO® were dissociative or perceptual changes (including distortion of time, space and illusions), derealization and depersonalization (61% to 84% of SPRAVATO®-treated patients developed dissociative or perceptual changes). Given its potential to induce dissociative effects, carefully assess patients with psychosis before administering SPRAVATO®; treatment should be initiated only if the benefit outweighs the risk.

Because of the risks of dissociation, patients must be monitored by a healthcare provider 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.

Respiratory Depression: In postmarketing experience, respiratory depression was observed with the use of SPRAVATO®. In addition, there were rare reports of respiratory arrest.

Because of the risks of respiratory depression, patients must be monitored for changes in respiratory status by a healthcare provider for at least 2 hours (including pulse oximetry) at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave the healthcare setting.

Abuse and Misuse: SPRAVATO® contains esketamine, a Schedule III controlled substance (CIII), and may be subject to abuse and diversion. Assess each patient's risk for abuse or misuse prior to prescribing and monitor all patients for the development of these behaviors or conditions, including drug-seeking behavior, while on therapy. Individuals with a history of drug abuse or dependence are at greater risk; therefore, use careful consideration prior to treatment of individuals with a history of substance use disorder and monitor for signs of abuse or dependence.

SPRAVATO® Risk Evaluation and Mitigation Strategy (REMS): SPRAVATO® is available only through a restricted program called the SPRAVATO® REMS because of the risks of serious adverse outcomes from sedation, dissociation, respiratory depression, and abuse and misuse.

Important requirements of the SPRAVATO® REMS include the following:

- Healthcare settings must be certified in the program and ensure that SPRAVATO® is:
  - Only dispensed and administered in healthcare settings.
  - Patients treated in outpatient settings (e.g., medical offices and clinics) must be enrolled in the program.
  - Administered by patients under the direct observation of a healthcare provider and that patients are monitored by a healthcare provider for at least 2 hours after administration of SPRAVATO®.
- Pharmacies must be certified in the REMS and must only dispense SPRAVATO® to healthcare settings that are certified in the program.

Further information, including a list of certified pharmacies, is available at **www.SPRAVATOrems.com/** or 1-855-382-6022.

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

Suicidal Thoughts and Behaviors in Adolescents and Young Adults: In pooled analyses of placebo-controlled trials of antidepressant drugs (SSRIs and other antidepressant classes) that included adult and pediatric patients, the incidence of suicidal thoughts and behaviors in patients age 24 years and younger was greater than in placebo-treated patients. SPRAVATO® is not approved in pediatric (<18 years of age) patients.

There was considerable variation in risk of suicidal thoughts and behaviors among drugs, but there was an increased risk identified in young patients for most drugs studied.

Monitor all antidepressant-treated patients for clinical worsening and emergence of suicidal thoughts and behaviors, especially during the initial few months of drug therapy and at times of dosage changes. Counsel family members or caregivers of patients to monitor for changes in behavior and to alert the healthcare provider. Consider changing the therapeutic regimen, including possibly discontinuing SPRAVATO® and/or the concomitant oral antidepressant, in patients whose depression is persistently worse, or who are experiencing emergent suicidal thoughts or behaviors.

Increase in Blood Pressure: SPRAVATO® causes increases in systolic and/or diastolic blood pressure (BP) at all recommended doses. Increases in BP peak approximately 40 minutes after SPRAVATO® administration and last approximately 4 hours.

Approximately 3% to 19% of SPRAVATO®-treated patients experienced an increase of more than 40 mmHg in systolic BP and/or 25 mmHg in diastolic BP in the first 1.5 hours after administration at least once during the first 4 weeks of treatment. A substantial increase in blood pressure could occur after any dose administered even if smaller blood pressure effects were observed with previous administrations. SPRAVATO® is contraindicated in patients for whom an increase in BP or intracranial pressure poses a serious risk (e.g., aneurysmal vascular disease, arteriovenous malformation, history of intracerebral hemorrhage). Before prescribing SPRAVATO®, patients with other cardiovascular and cerebrovascular conditions should be carefully assessed to determine whether the potential benefits of SPRAVATO® outweigh its risk.

Assess BP prior to administration of SPRAVATO®. In patients whose BP is elevated prior to SPRAVATO® administration (as a general guide: >140/90 mmHg), a decision to delay SPRAVATO® therapy should take into account the balance of benefit and risk in individual patients.

BP should be monitored for at least 2 hours after SPRAVATO® administration. Measure blood pressure around 40 minutes post-dose and subsequently as clinically warranted until values decline. If BP remains high, promptly seek assistance from practitioners experienced in BP management. Refer patients experiencing symptoms of a hypertensive crisis (e.g., chest pain, shortness of breath) or hypertensive encephalopathy (e.g., sudden severe headache, visual disturbances, seizures, diminished consciousness, or focal neurological deficits) immediately for emergency care.

Closely monitor blood pressure with concomitant use of SPRAVATO® with psychostimulants (e.g., amphetamines, methylphenidate, modafinil, armodafinil) or monoamine oxidase inhibitors (MAOIs).

In patients with a history of hypertensive encephalopathy, more intensive monitoring, including more frequent blood pressure and symptom assessment, is warranted because these patients are at increased risk for developing encephalopathy with even small increases in blood pressure.

Cognitive Impairment

Short-Term Cognitive Impairment: In a study in healthy volunteers, a single dose of SPRAVATO® caused cognitive performance decline 40 minutes post-dose. Compared to placebo-treated subjects, SPRAVATO®-treated subjects required a greater effort to complete the cognitive tests at 40 minutes post-dose. Cognitive performance and mental effort were comparable between SPRAVATO® and placebo at 2 hours post-dose. Sleepiness was comparable after 4 hours post-dose.

Long-Term Cognitive Impairment: Long-term cognitive and memory impairment have been reported with repeated ketamine misuse or abuse. In 1-year and 3-year, long-term, open-label clinical trials in adults, the effect of SPRAVATO® on cognitive functioning remained stable over time as evaluated by the Cogstate computerized battery and Hopkins Verbal Learning Test-Revised.

Please see additional Important Safety Information on next page and full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO®.

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

Impaired Ability to Drive and Operate Machinery: Before SPRAVATO® administration, instruct patients 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 following a restful sleep. Patients will need to arrange transportation home following treatment with SPRAVATO®.

Ulcerative or Interstitial Cystitis: Cases of ulcerative or interstitial cystitis have been reported in individuals with long-term off-label use or misuse/abuse of ketamine. In clinical studies with SPRAVATO® nasal spray, there was a higher rate of lower urinary tract symptoms (pollakiuria, dysuria, micturition urgency, nocturia, and cystitis) in SPRAVATO®-treated patients than in placebo-treated patients. No cases of esketamine-related interstitial cystitis were observed in any of the studies, which involved treatment for up to a year.

Monitor for urinary tract and bladder symptoms during the course of treatment with SPRAVATO® and refer to an appropriate healthcare provider as clinically warranted.

PREGNANCY, EMBRYO-FETAL TOXICITY, AND LACTATION

SPRAVATO® is not recommended during pregnancy. SPRAVATO® may cause fetal harm when administered to pregnant women. Advise pregnant women of the potential risk to an infant exposed to SPRAVATO® *in utero*. Advise women of reproductive potential to consider pregnancy planning and prevention.

There are risks to the mother associated with untreated depression in pregnancy. If a woman becomes pregnant while being treated with SPRAVATO®, treatment with SPRAVATO® should be discontinued and the patient should be counseled about the potential risk to the fetus.

Pregnancy Exposure Registry: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to antidepressants, including SPRAVATO®, during pregnancy. Healthcare providers are encouraged to register patients by contacting the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or online at https://womensmentalhealth.org/research/pregnancyregistry/antidepressants/.

SPRAVATO® is present in human milk. Because of the potential for neurotoxicity, advise patients that breastfeeding is not recommended during treatment with SPRAVATO®.

SELECT USE IN SPECIFIC POPULATIONS

Geriatric Use: No overall differences in the safety profile were observed between patients 65 years of age and older and patients younger than 65 years of age. At the end of a 4-week, randomized, double-blind study, there was no statistically significant difference between groups on the primary efficacy endpoint.

Hepatic Impairment: SPRAVATO®-treated patients with moderate hepatic impairment may need to be monitored for adverse reactions for a longer period of time.

SPRAVATO® has not been studied in patients with severe hepatic impairment (Child-Pugh class C). Use in this population is not recommended.

ADVERSE REACTIONS

TRD: The most commonly observed adverse reactions in patients treated with SPRAVATO® plus oral antidepressant (incidence ≥5% and at least twice that of placebo nasal spray plus oral antidepressant) were dissociation, dizziness, nausea, sedation, vertigo, hypoesthesia, anxiety, lethargy, blood pressure increased, vomiting, and feeling drunk.

Treatment of depressive symptoms in adults with MDD with acute suicidal ideation or behavior: The most commonly observed adverse reactions in patients treated with SPRAVATO® plus oral antidepressant (incidence ≥5% and at least twice that of placebo nasal spray plus oral antidepressant) were dissociation, dizziness, sedation, blood pressure increased, hypoesthesia, vomiting, euphoric mood, and vertigo.

The most common adverse reactions with SPRAVATO® TRD monotherapy (≥5% and at least twice that of placebo nasal spray) were dissociation, nausea, dizziness, headache, anxiety, vomiting, feeling drunk, blood pressure increased, and sedation.

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Please read full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO®.