Spravato™ (esketamine) CIII nasal spray

Medical vs Pharmacy Benefits Guide

Indication

SPRAVATO™ (esketamine) CIII Nasal Spray is indicated, in conjunction with an oral antidepressant (AD), for the treatment of treatment-resistant depression (TRD) in adults.

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

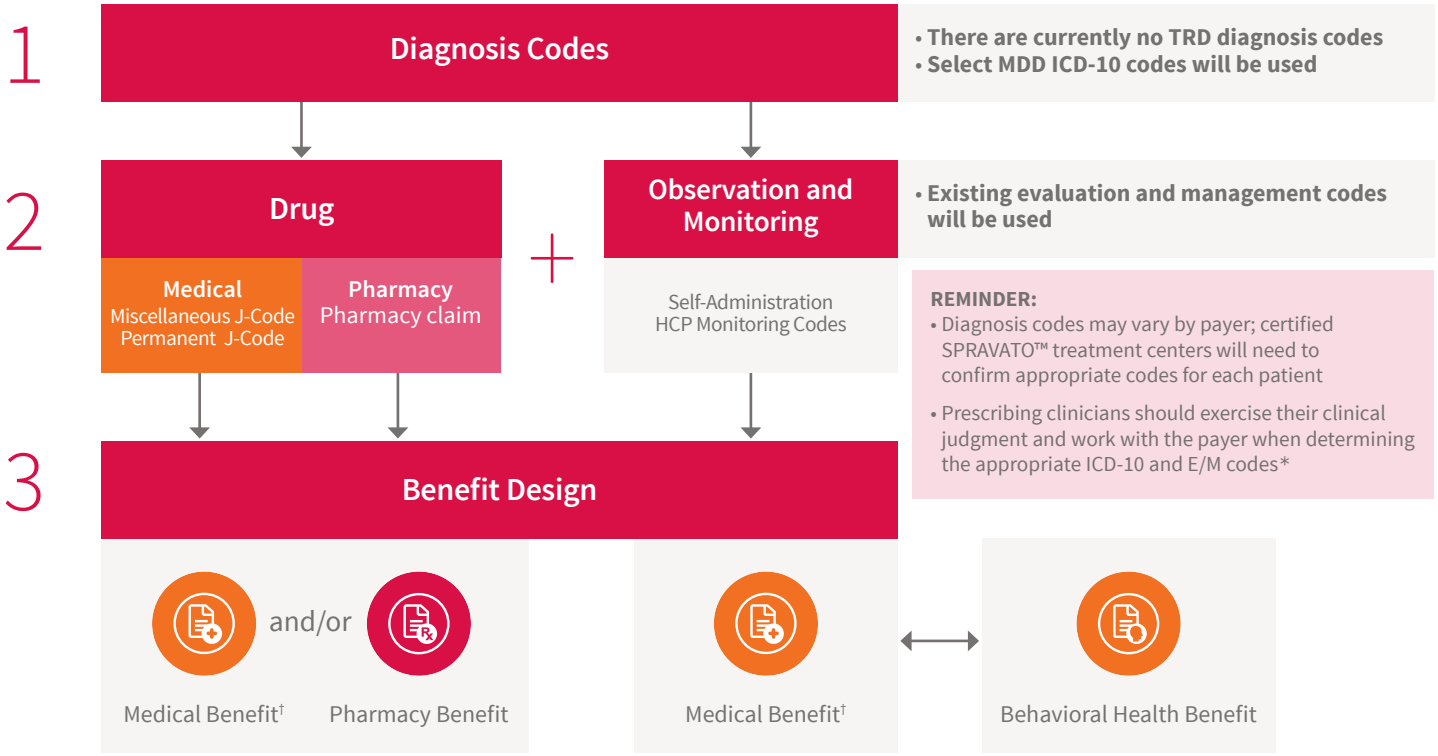
WARNING: SEDATION, DISSOCIATION; ABUSE AND MISUSE; and SUICIDAL THOUGHTS AND BEHAVIORS

See full prescribing information for complete boxed warning

- **Risk for sedation and dissociation after administration. Monitor patients for at least two hours after administration (5.1, 5.2).**
- **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 (5.3).**
- **SPRAVATO™ is only available through a restricted program called the SPRAVATO™ REMS (5.4).**
- **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 (5.5).**

Please see Important Safety Information, including Boxed WARNINGS, on pages 7-10.
Please see full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO™.

Coverage, Coding, and Reimbursement for SPRAVATO™ and Associated Observation and Monitoring



Reimbursement Considerations for SPRAVATO™

- SPRAVATO™ will be reimbursed as a drug. There will also be separate reimbursement for the required observation and monitoring
- Depending on the certified treatment center location and patient benefit design, SPRAVATO™ will be covered via either a medical or pharmacy benefit‡
- **There is currently no unique, designated code to describe the observation and monitoring of SPRAVATO™ administration. Healthcare providers (HCPs) must consult with each patient's payer since coverage will vary. Please note that healthcare providers are responsible for selecting appropriate codes for any particular claim based on the patient's condition, the items and services that are furnished, and any specific payer requirements. It is advisable to contact your local payer with regard to local payment policies**

*Documentation must support the level of E/M code selected.
†Some plans may require the use of an independent mental health benefit for treatment reimbursement under medical benefit and for reimbursement of patient monitoring associated with treatment with SPRAVATO™.
‡The required observation and monitoring will be paid via the medical benefit.

Third-party reimbursement is affected by many factors. This document and the information and assistance provided by Janssen Pharmaceuticals, Inc., (Janssen) are presented for informational purposes only. They do not constitute reimbursement or legal advice. Janssen does not promise or guarantee coverage, levels of reimbursement, or payment.

Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. Accordingly, the information may not be current or comprehensive. Janssen and its third-party service providers strongly recommend you consult your payer for its most current coverage, reimbursement, and coding policies. Janssen and its third-party service providers make no representations or warranties, expressed or implied, as to the accuracy of the information provided. In no event shall the third-party service providers or Janssen, or their employees or agents, be liable for any damages resulting from or relating to any information provided by, or accessed to or through, Janssen. All HCPs and other users of this information agree that they accept responsibility for the use of this program.

Please see Important Safety Information, including Boxed WARNINGS, on pages 7-10.
Please see full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO™.

Spravato™ (esketamine) C III
nasal spray

SPRAVATO™ (esketamine) CIII Nasal Spray

SPRAVATO™ nasal spray

The drug may be covered under the medical or pharmacy benefit.

SPRAVATO™ observation and monitoring

HCP observation and monitoring are covered under the medical benefit only.

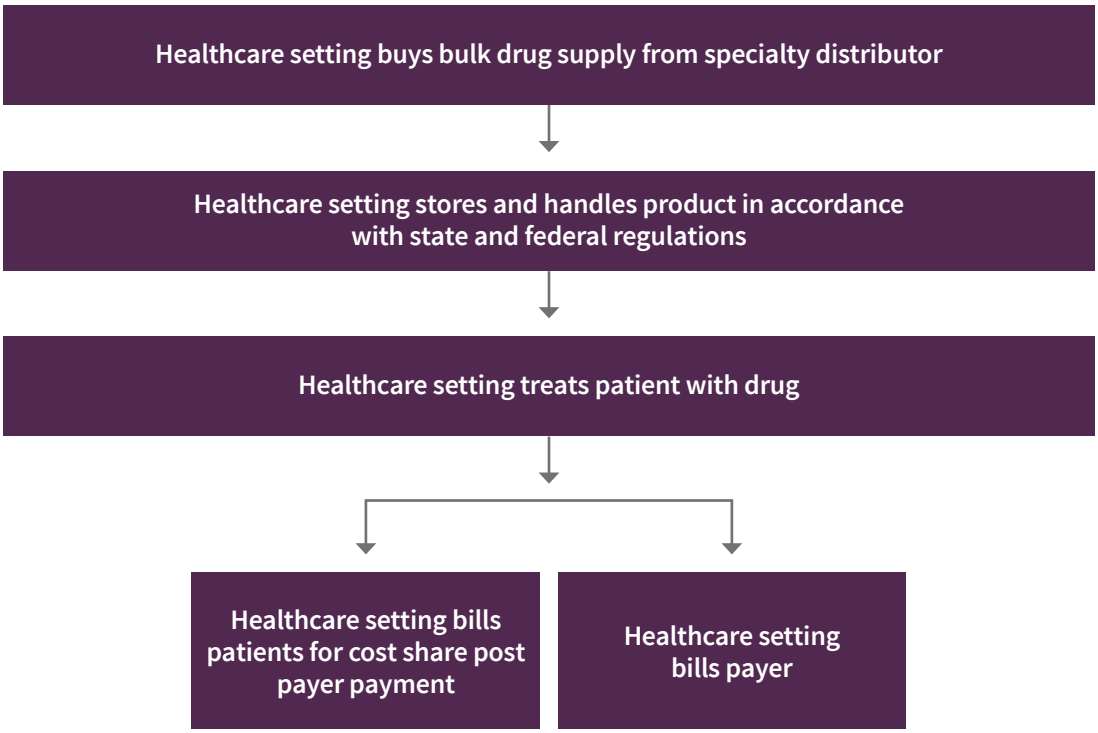
SPRAVATO™ nasal spray is administered by patients under the supervision of a healthcare professional, with observation and monitoring following each administration.[1] Therefore, reimbursement and billing & coding for SPRAVATO™ require coverage for both SPRAVATO™ nasal spray and the associated observation and monitoring.

SPRAVATO™ treatment may be covered through the pharmacy benefit, medical benefit, or both. Both patient benefit design and location of certified SPRAVATO™ treatment centers will influence reimbursement for SPRAVATO™. Coverage will be determined by the patient's insurance plan and the plan's specific benefit design.

Health plan coverage varies and can change over time—please see each patient's plan for specific coverage before beginning treatment.

Buy-and-Bill Pathway

In the buy-and-bill process, a healthcare provider purchases a drug from a pharmaceutical wholesaler or specialty distributor. After administering the drug, the provider submits a claim for reimbursement for the drug and any other medical services.[2-4]



Please see Important Safety Information, including Boxed WARNINGS, on pages 7-10.
Please see full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO™.

Spravato™ (esketamine) CIII nasal spray

Considerations for Accessing and Billing SPRAVATO™ Nasal Spray Under a Medical or Pharmacy Benefit

SPRAVATO™ Nasal Spray

SPRAVATO™ nasal spray may be covered under the pharmacy or medical benefit. It is important to check the patient's insurance plan for coverage under both pharmacy benefit and medical benefit.

Out-of-pocket costs can vary, depending on a patient's health plan coverage.

If the patient's plan covers SPRAVATO™ nasal spray under the **pharmacy benefit…**

- Verify if any prior authorization requirements are in place for the patient and coordinate with the pharmacy provider to share clinical information that may be necessary to support that process
- Confirm that the pharmacy will ship the nasal spray directly to the certified treatment center in the patient's name
- Establish tracking mechanism for individual patient inventory management

If the patient's plan covers SPRAVATO™ nasal spray under the **medical benefit…**

- Acquire SPRAVATO™ from a Janssen-approved specialty distributor*
- Verify if any prior authorization requirements are in place for the patient and submit information directly to payer, in accordance with the plan's policies
- Confirm the plan's requirements for the HCPCS code that is acceptable to report the drug
- Submit a claim, under the patient's medical benefit, for the drug

SPRAVATO™ Nasal Spray: Observation and Monitoring

Observation and Monitoring for administration of SPRAVATO™ nasal spray will be covered only under the medical benefit.

Consider using appropriate Evaluation and Management codes based on documented services.†

- Confirm the plan's requirements for the CPT code(s)‡ that are acceptable to report for the observation and monitoring
- Submit a claim, under the patient's medical benefit, for the required HCP observation and monitoring

CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System.

*SPRAVATO™ is available only through a limited distribution program that is part of the SPRAVATO™ REMS. All healthcare settings and pharmacies are required to enroll in the SPRAVATO™ REMS via a designated authorized representative before they can purchase product from a distributor, dispense, or supervise administration of SPRAVATO™. All patients must also be enrolled in the SPRAVATO™ REMS before they can receive SPRAVATO™.

†There is currently no unique, designated code to describe the observation and monitoring of SPRAVATO™ administration. Healthcare providers (HCPs) must consult with each patient's payer since coverage will vary.

Please see Important Safety Information, including Boxed WARNINGS, on pages 7-10.
Please see full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO™.

Spravato™ (esketamine) C III nasal spray

A Summary of Medical and Pharmacy Health Plan Benefit Structures

The following table presents a general overview of medical and pharmacy benefit structures for Medicare and commercial payers. Payers may cover SPRAVATO™ nasal spray as a medical or pharmacy benefit, or both. Checking with the payer directly is the best way to determine the benefit type and design.

	Medical Benefits		Pharmacy Benefits	
	Medicare[5,6]	**Commercial**	**Medicare[7]***	**Commercial[8‡]**
Co-pay or coinsurance %	Physician services require 20% coinsurance after the patient has satisfied the annual deductible	Varies by plan	Coinsurance 25% up to catastrophic coverage limit[†]	**Average co-pay** • $11 for 1st tier • $33 for 2nd tier • $59 for 3rd tier • $105 for 4th tier **Average coinsurance** • 19% for 1st tier • 26% for 2nd tier • 36% for 3rd tier • 31% for 4th tier *Co-pay and coinsurance may vary by payer*
Deductible	$185/year	Varies by plan	$415/year	Varies by plan

*Based on standard Part D benefit design.
[†]For total drug costs above the catastrophic threshold, Medicare pays 80%, plans pay 15%, and enrollees pay either 5% of total drug costs or $3.40/$8.50 for each generic and brand-name drug, respectively.
[‡]Average co-pay among covered workers in plans with 3 or more tiers of cost sharing for prescription drugs.

Please see Important Safety Information, including Boxed WARNINGS, on pages 7-10.
Please see full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO™.

Spravato™ (esketamine) C III nasal spray

Cost Support Options for Patients Taking SPRAVATO™

Janssen CarePath can help you find out what affordability assistance may be available for your patients taking SPRAVATO™. For patients using commercial insurance, we offer the Janssen CarePath Savings Program for SPRAVATO™. For patients with government coverage or no insurance coverage, Janssen CarePath can provide information about other resources that may be able to help your patients with their out-of-pocket medication costs.

Support for patients using commercial or private insurance to pay for medication:

Janssen CarePath Savings Program for SPRAVATO™

Eligible commercially-insured patients **pay $10 per treatment** for SPRAVATO™ medication costs with a $7,150 maximum program benefit per calendar year. *Treatment* may include up to three devices administered on the same day. Quantity limits apply. Depending on how their insurance covers SPRAVATO™, the quantity limit is 3 devices per day or up to 23 devices per 28-day period. Not valid for patients using Medicare, Medicaid, or other government-funded programs to pay for their medications. Terms expire at the end of each calendar year and may change. There is no income requirement. Program does not cover the cost to give patients their treatment. See full eligibility requirements at **Spravato.JanssenCarePathSavings.com**.

Patients can register and activate a card online

At Register.JanssenCarePathSavings.com patients can:

- Determine eligibility and register for the Janssen CarePath Savings Program
- Print a card online if they need one

Janssen CarePath

We can help make it simple for you to help your patients

Janssen CarePath is your one source for access, affordability, and treatment support for your patients
Janssen CarePath helps verify insurance coverage for your patients, provides reimbursement information, helps find financial assistance options for eligible patients, and provides ongoing support to help patients start and stay on SPRAVATO™ treatment that you prescribed.

Call a Janssen CarePath Care Coordinator at 844-777-2828 Monday–Friday, 8:00 AM to 8:00 PM ET
Visit www.JanssenCarePath.com

Please see Important Safety Information, including Boxed WARNINGS, on pages 7-10.
Please see full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO™.

Spravato™ (esketamine) CIII nasal spray

Important Safety Information for SPRAVATO™ (esketamine) CIII Nasal Spray

Indication

SPRAVATO™ (esketamine) CIII Nasal Spray is indicated, in conjunction with an oral antidepressant (AD), for the treatment of treatment-resistant depression (TRD) in adults.

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; ABUSE AND MISUSE; and SUICIDAL THOUGHTS AND BEHAVIORS

See full prescribing information for complete boxed warning

- **Risk for sedation and dissociation after administration. Monitor patients for at least two hours after administration (5.1, 5.2).**
- **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 (5.3).**
- **SPRAVATO™ is only available through a restricted program called the SPRAVATO™ REMS (5.4).**
- **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 (5.5).**

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: In clinical trials, 49% to 61% of SPRAVATO™-treated patients developed sedation and 0.3% 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 *[see Drug Interaction (7.1)]*.

SPRAVATO™ is available only through a restricted program under a REMS.

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 75% 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.

SPRAVATO™ is available only through a restricted program under a REMS.

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™ is available only through a restricted program under a REMS.

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, 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 in healthcare settings and administered to patients who are 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™.

(continued on next page)

Please see full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO™.

Spravato™ (esketamine) CIII nasal spray

Important Safety Information for SPRAVATO™ (esketamine) CIII Nasal Spray (continued)

- 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.

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 dosages. Increases in BP peak approximately 40 minutes after SPRAVATO™ administration and last approximately 4 hours.

Approximately 8% to 17% 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, 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 be taken into account to balance the 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 or monoamine oxidase inhibitors (MAOIs) *[see Drug Interactions (7.2, 7.3)]*.

In patients with 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. 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. No adverse effects of SPRAVATO™ nasal spray on cognitive functioning were observed in a one-year open-label safety study; however, the long-term cognitive effects of SPRAVATO™ have not been evaluated beyond one year.

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.

(continued on next page)

Please see full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO™.

Spravato™ (esketamine) CIII nasal spray

Important Safety Information for SPRAVATO™ (esketamine) CIII Nasal Spray (continued)

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.

Embryo-fetal Toxicity: 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.

DRUG INTERACTIONS

CNS depressants (e.g., benzodiazepines, opioids, alcohol): Concomitant use may increase sedation. Closely monitor for sedation with concomitant use of CNS depressants.

Psychostimulants (e.g., amphetamines, methylphenidate, modafinil, armodafinil): Concomitant use may increase blood pressure. Closely monitor blood pressure with concomitant use of psychostimulants.

Monoamine oxidase inhibitors (MAOIs): Concomitant use may increase blood pressure. Closely monitor blood pressure with concomitant use of MAOIs.

USE IN SPECIFIC POPULATIONS

Pregnancy: 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*. 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/clinical-and-research-programs/pregnancyregistry/antidepressants/*.

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

Females and Males of Reproductive Potential: SPRAVATO™ may cause embryo-fetal harm when administered to a pregnant woman. Consider pregnancy planning and prevention for females of reproductive potential during treatment with SPRAVATO™.

Pediatric Use: The safety and effectiveness of SPRAVATO™ in pediatric patients have not been established.

Geriatric Use: Of the total number of patients in Phase 3 clinical studies exposed to SPRAVATO™, 12% were 65 years of age and older, and 2% were 75 years of age and older. 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.

The mean esketamine C_{max} and AUC values were higher in elderly patients compared with younger adult patients.

The treatment of TRD in geriatric patients was evaluated in a 4-week, randomized, double-blind study comparing flexibly-dosed intranasal SPRAVATO™ plus a newly initiated oral antidepressant compared to intranasal placebo plus a newly initiated oral antidepressant in patients ≥65 years of age. At the end of four weeks, there was no statistically significant difference between groups on the primary efficacy endpoint of change from baseline to Week 4 on the Montgomery-Åsberg Depression Rating Scale (MADRS).

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.

DRUG ABUSE AND DEPENDENCE

Controlled Substance: SPRAVATO™ contains esketamine hydrochloride, the (S)-enantiomer of ketamine and a Schedule III controlled substance under the Controlled Substances Act.

Abuse: Individuals with a history of drug abuse or dependence may be at greater risk for abuse and misuse of SPRAVATO™. Abuse is the intentional, non-therapeutic use of a drug, even once, for its psychological or physiological effects. Misuse is the intentional use, for therapeutic purposes, of a drug by an individual in a way other than prescribed by a healthcare provider or for whom it was not prescribed. Careful consideration is advised prior to use of individuals with a history of substance use disorder, including alcohol.

(continued on next page)

Please see full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO™.

Spravato™ (esketamine) CIII nasal spray

Important Safety Information for SPRAVATO™ (esketamine) CIII Nasal Spray (continued)

SPRAVATO™ may produce a variety of symptoms including anxiety, dysphoria, disorientation, insomnia, flashback, hallucinations, and feelings of floating, detachment and to be "spaced out." Monitoring for signs of abuse and misuse is recommended.

ADVERSE REACTIONS

The most common adverse reactions with SPRAVATO™ plus oral AD (incidence ≥5% and at least twice that of placebo nasal spray plus oral AD) were dissociation, dizziness, nausea, sedation, vertigo, hypoesthesia, anxiety, lethargy, blood pressure increased, vomiting, and feeling drunk.

Please see pocketed full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO™.

cp-79821v1

Spravato™ (esketamine) CIII nasal spray

References

1. SPRAVATO™ [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc. May 2019.
2. Drug Channels. How specialty pharmacy is penetrating buy-and-bill oncology channels. https://www.drugchannels.net/2016/07/how-specialty-pharmacy-is-penetrating.html. Accessed June 20, 2019.
3. Magellan Rx Management. 2016 Medical Pharmacy Trend Report™. 2016. https://www1.magellanrx.com/magellan-rx/publications/medical-pharmacy-trend-report.aspx. Accessed June 20, 2019.
4. Health Affairs. Prescription drug briefing. Health Policy Brief. August 10, 2017. https://www.healthaffairs.org/do/10.1377/hpb20171008.000171/full. Accessed June 20, 2019.
5. Centers for Medicare & Medicaid Services. Medicare Part B Monthly Actuarial Rates, Premium Rates, and Annual Deductible Beginning January 1, 2019. *Federal Register*. 2018;82(201):52462-52471. https://www.govinfo.gov/content/pkg/FR-2018-10-17/pdf/2018-22530.pdf. Accessed June 20, 2019.
6. Medicare Part B. Henry J. Kaiser Family Foundation website. https://www.kff.org/chart2_2/. Accessed June 20, 2019.
7. An overview of the Medicare Part D prescription drug benefit. Henry J. Kaiser Family Foundation website. https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/. Accessed June 20, 2019.
8. 2018 employer health benefits survey. Henry J. Kaiser Family Foundation website. http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2018. Accessed June 20, 2019.

Please see Important Safety Information, including Boxed WARNINGS, on pages 7-10.
Please see full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO™.

janssen Neuroscience
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Spravato™ (esketamine) CIII
nasal spray