

Prior Authorization Toolkit

Essential tools and resources to help you navigate the PA process

Don't let Prior Authorization denials hold back timely treatment for your patients...

82% of medication denials are preventable¹

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.

This resource is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Laws, regulations, and policies concerning reimbursement are complex and updated frequently. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. In addition, this information does not represent any statement, promise, or guarantee by Johnson & Johnson about coverage, levels of reimbursement, payment, or charge. Please consult with your payer organization(s) for local or actual coverage and reimbursement policies and determination processes. Please consult with your counsel or reimbursement specialist for any reimbursement or billing questions specific to your institution.

Please see Important Safety Information, including Boxed WARNINGS, on pages 7-10.

Please see <u>Prescribing Information</u>, including Boxed WARNINGS, and <u>Medication Guide</u> for SPRAVATO®

Overcome PA challenges and minimize delays in patient care



A prior authorization (PA) is a common process used by insurers that requires providers to substantiate why certain drugs or services are medically necessary before coverage is authorized. PA forms and coverage rules may vary between insurers, so it's important to confirm specific requirements for SPRAVATO® with each plan.

The PA Toolkit is designed to support you in navigating the PA submission process for SPRAVATO®, by helping you to identify and gather all the required information and complete the PA form accurately. Here, you will also find essential tools and resources to help better manage the PA process and avoid denials for SPRAVATO® including:

SPRAVATO® Payer Coverage Look-up Tool

Search for and download state- and payer-specific PA forms and coverage documents.

Visit the SPRAVATO® Payer Coverage Look-up Tool

covermymeds[®]

CoverMyMeds is a no-cost solution that automates the process providers and pharmacists use for prior authorization requests to help patients access their medication faster.*

Questions? Live support available: 1-866-452-5017 or chat at www.covermymeds.health

Spravato with Me

Once your patient is enrolled, as part of the benefits investigation, SPRAVATO withMe will evaluate

■ Medical and pharmacy benefit coverage ■ PA requirements, followed by an appeals process if needed For more information or to enroll your patient Call 1-844-4S-WITHME (1-844-479-4846) or visit SPRAVATO withMe

The patient support and resources provided by SPRAVATO withMe are not intended to give medical advice, replace a treatment plan from the patient's healthcare provider, offer services that would normally be performed by the provider's office, or serve as a reason to prescribe SPRAVATO®.

Tips to avoid common reasons for denials



PA checklist



Important supporting documentation and reauthorizations



Contact your SPRAVATO® representative for additional PA support followed by appeals support, if needed

*Compared to phone and fax.

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Tips to help avoid potential reasons for denials

Top reasons for denials	Considerations to prevent denials
Missing information and errors	 Ensure the PA form is completed with all required information outlined in the payer policy. Confirm all relevant diagnostic and patient information with proof of nonresponse to at least 2 oral antidepressants is included Be sure to include all information from the referring physician, if applicable Include baseline clinical scores and prior therapies, with dosages, duration, and responses
Diagnosis-related denial	 Be certain to include the proper ICD-10 CM code for major depressive disorder and date of diagnosis. (Note: There is no ICD-10-CM code for treatment- resistant depression [TRD] or for depressive symptoms in adults with major depressive disorder [MDD] with acute suicidal ideation or behavior [MDSI]) SPRAVATO® ICD-10 CM codes
Wrong benefit submitted (Medical vs Pharmacy)	 Complete a benefits investigation and confirm if the patient's coverage is under the pharmacy or medical benefit, as some plans may cover SPRAVATO® under one or both. Learn more about how SPRAVATO withMe can help If the patient is covered under the medical benefit and you are acquiring SPRAVATO® through a specialty pharmacy (SP), ensure the SP is Risk Evaluation and Mitigation Strategy (REMS)-certified and able to process medical benefit claims For dedicated SP support, learn more about our Enhanced Service Pharmacy Network
Step therapy required	 Include documentation of all prior therapies, detailing duration, response, and reasons for discontinuation in the PA request If step therapy wasn't completed, provide clinical justification for bypassing it
Prescribed by a psychiatrist or advanced practice practitioner (APP)	 Verify if the policy requires a psychiatrist to prescribe SPRAVATO® or allows for prescriptions by a physician "in consultation with a psychiatrist" Ensure the PA request clearly states the prescribing physician's qualifications and includes documentation of the consultation if needed
Specialty pharmacy (SP) is out of network	 Confirm that the SP is within the patient's insurance network and contracted with the payer For medical benefit coverage, ensure the SP can process medical authorizations

Spravato® (esketamine) (© (28 mg nasal spray

SPRAVATO® PA checklist

Some payers may have developed PA processes with varying requirements. Please check the payer's website for more information or visit our Payer Coverage Look-up Tool

Patient Information
☐ Personal information
□ Date of birth, gender, phone, email, home address
☐ Insurance information
□ Policyholder name
□ Plan ID number
Group number
 Confirm which benefit—pharmacy and/or medical—your patient is covered under and check the patient out-of-pocket costs to choose the best path forward
☐ Attach copies of both sides of the patient's prescription [drug] and health [medical] cards to the PA
 Be sure that a benefits investigation has been completed and coverage verified
 □ Diagnosis □ Major depressive disorder □ ICD-10-CM code and date of diagnosis (Note: There is no ICD-10-CM code for TRD or for MDSI)
SPRAVATO® ICD-10 CM codes 😜
☐ Patient medical history
□ Patient medical records (eg, chart notes, laboratory values)
☐ Provide name and baseline score on at least one plan-specific clinical assessment (eg, BDI, HDRS/ HAM-D, MADRS, PHQ-9, QIDS-C16)
☐ Psychosis (No history of psychosis or prescriber believes the use of SPRAVATO® outweigh its risks)
 Obtain all medical records from the referring physician Some plans may require ruling out bipolar disorder
Does the patient have a history of substance or alcohol use? Confirm if the plan requires a

BDI=Beck Depression Inventory; HDRS/HAM-D=Hamilton Depression Rating Scale; ICD-10=International Classification of Diseases, 10th Revision; MADRS=Montgomery-Åsberg Depression Rating Scale; PHQ-9=Patient Health Questionnaire-9; QIDS-C16=Quick Inventory of Depressive Symptomatology.

negative drug test and alcohol screen. It may not be explicitly stated on the form. Some plans may require the patient's history of controlled substance prescriptions to be checked using the

Please see Important Safety Information, including Boxed WARNINGS, on pages 7-10.

state prescription monitoring program

Please see Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO®

Spravato® (esketamine) (12) (23 mg nosal spray

SPRAVATO® PA checklist (cont'd)



Diagnosis and Clinical Information (cont'd)

- Medication/treatment history
 - ☐ Antidepressant/augmentation medications
 - Document all current and past medication trials, including dose, duration, fill dates, and reasons for discontinuation (eg, inadequate response)
 - Patient not responding to ≥2 different antidepressants is a common plan requirement. Confirm the
 exact number of required antidepressants tried, as this may vary by plan



Has the patient experienced an inadequate response with an adequate trial of evidence-based psychotherapy (eg, cognitive behavioral therapy)?



Drug Information

- Prescribed by
 - ☐ Psychiatrist or in consultation with a psychiatrist (if applicable)
- Prescription information
 - Dosage
 - 56 mg Dose Kit: Unit-dose carton containing two 28-mg nasal spray devices (56 mg total dose) (NDC 50458-028-02)
 - 84 mg Dose Kit: Unit-dose carton containing three 28-mg nasal spray devices (84 mg total dose) (NDC 50458-028-03)
 - ☐ Number of treatment sessions (or units) requested and day supply
 - ☐ Usage in adults
 - SPRAVATO® in combination with an oral antidepressant for TRD
 - SPRAVATO® alone for TRD
 - SPRAVATO® in combination with an oral antidepressant for MDSI



Treatment Facility/Provider Information

- Demographics
 - ☐ Name, address, phone, email, fax
 - ☐ Tax ID Number (TIN) or National provider identifier (NPI)
- Licenses/certificates
 - ☐ Healthcare setting must be certified in SPRAVATO® REMS in order to treat patients with SPRAVATO®
 - ☐ Patient must enrolled in SPRAVATO® REMS in order to receive SPRAVATO®
 - ☐ Send the prescription only to a pharmacy that is REMS-certified to dispense SPRAVATO®

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Important supporting documentation and reauthorizations





Letter of Medical Necessity (LMN)

A Letter of Medical Necessity is used to support why you believe treatment of your patient with SPRAVATO® is medically necessary. Check with the payer to confirm whether there are specific coverage requirements or information needed as part of the request. **Download a template** for drafting an LMN that contains examples of information that payers may require from the healthcare provider to request coverage of SPRAVATO®.



Appealing a denial

A Letter of Appeal is used if the member or provider disagrees with the denied coverage from the payer. An appeal may be submitted when the payer has adjudicated the claim for SPRAVATO® and there is an explanation of benefits for the claim documenting the reason for the denial. <u>Download</u> a template for drafting a Letter of Appeal that includes examples of required information for appealing a denial.



Requesting a formulary exception

Use a formulary exception request letter for payers that don't require a specific request form. An exception may be needed for SPRAVATO® if it's not on formulary, requires step therapy, or has a National Drug Code (NDC) block. <u>Download a template</u> for drafting a letter that includes examples of required information for requesting an exception for SPRAVATO®.



Reauthorizations

Reauthorizations are often required by payers to confirm that the patient has responded to SPRAVATO® and that continued use remains medically necessary. Initial authorizations may range from 1 to 3 months. Reauthorization periods can range from 3 to 12 months, so it's crucial to verify the specific requirements with each insurance plan.

Additional downloadable support for your PA needs



<u>SPRAVATO® coding and reimbursement resources</u>



Access a wide range of interactive tools and resources for your practice and patients including SPRAVATO®Interactive Code Finder, Coverage Look-up Tool, and Access Coding and Reimbursement Guide

Indications and Important Safety Information



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- 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).

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).

Important Safety Information (cont'd)



WARNINGS AND PRECAUTIONS (cont'd)

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.

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 placebotreated 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.

Important Safety Information (cont'd)



WARNINGS AND PRECAUTIONS (cont'd)

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

<u>Short-Term Cognitive Impairment</u>: 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.

<u>Long-Term Cognitive Impairment</u>: 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.

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®.

Important Safety Information (cont'd)



WARNINGS AND PRECAUTIONS (cont'd)

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.

<u>Pregnancy Exposure Registry:</u> 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.

Please see full <u>Prescribing Information</u>, including Boxed WARNINGS, and <u>Medication Guide</u> for SPRAVATO®. cp-170362v7

References: 1. Optum. The Optum 2022 Revenue Cycle Denials Index. Accessed November 13, 2024. https://www.changehealthcare.com/insights/denials-index 2. American Medical Association. ICD-10-CM 2023 Tabular List of Diseases and Injuries. Chicago, IL: Optum 360 LLC; 2022.

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Tips to help avoid potential reasons for denials

ICD-10-CM Diagnosis Codes for Consideration^{2*†}

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Code	Description	
Code Considerations for Patients New to SPRAVATO®		
F32.0	Major depressive disorder, single episode, mild	
F32.1	Major depressive disorder, single episode, moderate	
F32.2	Major depressive disorder, single episode, severe without psychotic features	
F32.9	Major depressive disorder, single episode, unspecified	
F33.0	Major depressive disorder, recurrent, mild	
F33.1	Major depressive disorder, recurrent, moderate	
F33.2	Major depressive disorder, recurrent, severe without psychotic features	
R45.851	Suicidal Ideations	
Code Considerations for Patients Already Receiving SPRAVATO®		
F32.4	Major depressive disorder, single episode, in partial remission	
F32.5	Major depressive disorder, single episode, in full remission	
F33.41	Major depressive disorder, recurrent, in partial remission	
F33.42	Major depressive disorder, recurrent, in full remission	

^{*}These codes are not intended to be promotional or to encourage or suggest a use of drug that is inconsistent with FDA-approved use. The codes provided are not exhaustive and additional codes may apply.

[†]F33.9 Major depressive disorder, recurrent, unspecified; F33.40 Major depressive disorder, recurrent, in remission, unspecified.

^{*}Source: covermymeds® SPRAVATO® Denial Analysis. September 2024



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