Spravato™
(esketamine) CIII
nasal spray

Access & Reimbursement Guide

Information to Support the Access & Reimbursement Process for SPRAVATO™.

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 22-25.
Please see full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO™.

Introduction

Janssen Pharmaceuticals, Inc., is pleased to provide you and your office staff with information to assist you in requesting reimbursement for SPRAVATO™ (esketamine) CIII Nasal Spray on behalf of your patients. We have developed this *Access and Reimbursement Guide* to provide coding information, a list of authorized SPRAVATO™ distributors, and important product information that we hope will be helpful to you and your practice.

- This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice
- There is no ICD-10-CM code for treatment-resistant depression. Payer requirements for diagnosis codes will vary. It is essential to verify correct diagnosis coding with each payer
- 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
- 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
  — Similarly, all Current Procedural Terminology (CPT®)* and Healthcare Common Procedure Coding System (HCPCS) codes are supplied for informational purposes only, and this information does not represent any statement, promise, or guarantee by Janssen Pharmaceuticals, Inc., about coverage, levels of reimbursement, payment, or charge
  — Please consult with your payer organizations for local or actual coverage and reimbursement policies and with your internal reimbursement specialist for any reimbursement or billing questions

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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).

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Medication Guide for SPRAVATO™.**

SPRAVATO™ Indication and Usage[1]

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

Limitations of Use:

SPRAVATO™ is not approved as an anesthetic agent. The safety and effectiveness of SPRAVATO™ as an anesthetic agent have not been established.

REMS (Risk Evaluation and Mitigation Strategy) Information for SPRAVATO™

The goal of the REMS is to mitigate the risks of serious adverse outcomes resulting from sedation and dissociation caused by SPRAVATO™ administration, and abuse and misuse of SPRAVATO™ , by:

- Ensuring that SPRAVATO™ is only dispensed and administered to patients in a medically supervised healthcare setting that monitors these patients
- Ensuring pharmacies and healthcare settings that dispense SPRAVATO™ are certified
- Ensuring that each patient is informed about the serious adverse outcomes resulting from sedation and dissociation and the need for monitoring
- Enrollment of all patients in the REMS (registry) to further characterize the risks and support safe use

SPRAVATO™ is intended for patient administration under the direct observation of a healthcare provider, and patients are required to be monitored by a healthcare provider for at least 2 hours after SPRAVATO™ administration. SPRAVATO™ must never be dispensed directly to a patient for home use.

SPRAVATO™ Dosage and Administration

Dosage – Adult[1]

SPRAVATO™ requires a 2-phase dosing regimen: induction and maintenance. A treatment session consists of nasal administration of SPRAVATO™ and post-administration observation under the supervision of a healthcare professional. The dosage recommendations for SPRAVATO™ are shown in Table 1. Dose adjustments should be made based on efficacy and tolerability to the previous dose.

Table 1: Recommended Dosage for SPRAVATO™[1]

		Adults
Induction Phase	**Weeks 1-4:** Administer twice per week	Day 1 starting dose: 56 mg Subsequent doses: 56 mg or 84 mg
Maintenance Phase	**Weeks 5 to 8:** Administer once weekly	56 mg or 84 mg
	Weeks 9 and after: Administer every 2 weeks or once weekly*	56 mg or 84 mg

*Dosing frequency should be individualized to the least frequent dosing to maintain remission/response.

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Administration Instructions[1]

SPRAVATO™ is for nasal use only. The nasal spray device delivers a total of 28 mg of esketamine. To prevent loss of medication, do not prime the device before use. Use 2 devices (for a 56-mg dose) or 3 devices (for an 84-mg dose), with a 5-minute rest between use of each device.

SPRAVATO™ must be self-administered under the direct supervision of a healthcare provider. A treatment session consists of nasal administration of SPRAVATO™ and post-administration observation under supervision.

Blood Pressure Assessment

- Assess blood pressure prior to dosing with SPRAVATO™
- If baseline blood pressure is elevated, consider the risks of short-term increases in blood pressure and benefit of SPRAVATO™ treatment
- Do not administer SPRAVATO™ if an increase in blood pressure or intracranial pressure poses a serious risk
- After dosing with SPRAVATO™, reassess blood pressure at approximately 40 minutes and subsequently as clinically warranted
- If blood pressure is decreasing and the patient appears clinically stable for at least 2 hours, the patient may be discharged at the end of the post-dose monitoring period; if not, continue to monitor

Food and Liquid Intake Recommendations Prior to Administration

- Because some patients may experience nausea and vomiting after administration of SPRAVATO™, advise patients to avoid food for at least 2 hours before administration and to avoid drinking liquids at least 30 minutes prior to administration

Nasal Corticosteroid or Nasal Decongestant

- Patients who require a nasal corticosteroid or nasal decongestant on a dosing day should administer these medications at least 1 hour before SPRAVATO™

Post-Administration Observation[1]

During and after SPRAVATO™ administration at each treatment session, observe the patient for at least 2 hours until the patient is safe to leave. Before SPRAVATO™ administration, instruct patients not to engage in potentially hazardous activities, such as driving a motor vehicle or operating machinery, until the next day after a restful sleep.

Missed Treatment Session(s)[1]

If a patient misses treatment sessions and there is worsening of depression symptoms, per clinical judgement, consider returning to the patient's previous dosing schedule (i.e., every 2 weeks to once weekly, weekly to twice weekly; see Table 1).

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SPRAVATO™ Coverage Considerations

Factors That Influence Coverage

Third-party payers (e.g., commercial insurers, Medicare, Medicaid) may cover drugs that require healthcare provider (HCP) management for their approved U.S. Food and Drug Administration indications, and the associated administration services. However, benefits may vary depending upon the payer and the specific plan ("insurance product") in which a patient is enrolled.

Medical Necessity

When third-party payers review drug claims, they will first determine if the type of service provided is covered under their policies. Next, payers will look for evidence supporting the medical necessity of the therapy. This evidence may include:

- Information about the patient's medical condition and history
- A physician's statement or letter of medical necessity
- Supporting literature (e.g., peer-reviewed studies and compendia monographs)
- Prescribing information
- Availability of other treatment alternatives

Medical necessity refers to a decision by a health plan that a treatment, test, or procedure is necessary for health or to treat a diagnosed medical problem. Health insurance companies provide coverage only for health-related services that they define or determine to be medically necessary. Commercial insurers, Medicaid program coverage policies, Medicare National Coverage Determinations (NCDs) and Medicare Administrative Contractors' (MACs') Local Coverage Determinations (LCDs) define medical necessity requirements. These documents contain guidance on covered diagnoses, required documentation, and limitations of coverage for specific medical services or items. Reimbursement policies and guidelines may vary by payer.

Administrative Considerations

Other considerations may be involved in a payer's decision to cover a product or service:

- **Site of care:** Does the payer contract specifically indicate the sites of care that may bill for the drug and its administration? Payers may have site-specific coverage rules. For example, does the plan require that the drug be administered only in a physician practice setting and restrict coverage if provided in a hospital outpatient setting?

- **Participating providers:** Is the billing provider a "participating" member of, or "in-network" provider for, that specific plan? Payers contract with providers to deliver services to the plan's members. Providers are thus "participating" within that plan's network, requiring them to abide by the contract charge structure when providing care for that plan's members. Services provided by "non-participating providers may not be covered in the absence of an approved "exception request" or other pre-approval from a health plan

- **Prior authorization:** If required by the plan, has the appropriate referral or prior authorization been obtained? Many plans require that nonemergency services be pre-approved or that a primary care physician make the referral for specialty care. Failing to obtain appropriate referrals or pre-authorization can result in nonpayment by the plan.

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SPRAVATO™ Coverage Considerations (continued)

Coverage for SPRAVATO™

Coverage for SPRAVATO™ will vary by payer, individual contracts, and treatment setting. When provided under the supervision of an HCP in an authorized site of care, the drug will often be covered under the payer's medical benefit. Alternatively the drug may be covered under the pharmacy benefit and delivery to the site of care will be through a specialty pharmacy distributor.

Table 2: SPRAVATO™ Coverage Summary

Site of Care	Medicare Part A	Medicare Part B	Medicare Part D	Commercial Insurance
Inpatient Hospital (Acute Care)	• IPPS • Covered within the MS-DRG	N/A	N/A	• Payer reimbursement policies • Typically covered within the DRG
Inpatient Psychiatric Facility (IPF)	• IPF-PPS • Covered within the MS-DRG	N/A	N/A	• Payer reimbursement policies • Typically covered within the DRG
Hospital Outpatient Department (HOPD)	N/A	• OPPS • May be covered separately • Local Coverage Determinations (LCDs) may apply	• PDP • May be covered under pharmacy benefit • Specialty pharmacy distribution[†] • Payer management tools* may apply	• Payer reimbursement policies • May be covered as a medical or pharmacy benefit • May require specialty pharmacy distribution[†] • Payer management tools* may apply
Physician Practice	N/A	• PFS • Covered separately, incident to physician services • Local Coverage Determinations (LCDs) may apply	• PDP • May be covered under pharmacy benefit • Specialty pharmacy distribution[†] • Payer management tools* may apply	• Payer reimbursement policies • May be covered as a medical or pharmacy benefit • May require specialty pharmacy distribution[†] • Payer management tools* may apply

*Prior authorization, step therapy, quantity limits, etc.
[†]At this time specialty pharmacy distribution is not available.

Key

IPPS	Inpatient Prospective Payment System
MS-DRG	Medicare Severity Diagnosis-Related Group
IPF-PPS	Inpatient Psychiatric Facility Prospective Payment System
OPPS	Outpatient Prospective Payment System
PDP	Prescription Drug Plan
PFS	Physician Fee Schedule

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Coding for SPRAVATO™ (esketamine)

ICD-10-CM Diagnosis Codes

There is no ICD-10-CM code for treatment-resistant depression. Payer requirements for ICD-10 codes will vary. It is essential to verify correct diagnosis coding with each payer. All parties covered by the Health Insurance Portability and Accountability Act (HIPAA), not just providers who bill Medicare and Medicaid, are required to use the International Classification of Diseases, 10th revision, Clinical Modification (ICD-10-CM) codes to document patient diagnoses. ICD-10-CM far exceeds previous coding systems in the number of concepts and codes provided, allowing for greater specificity when describing patient conditions.

ICD-10-CM diagnosis codes use 3 to 7 alpha and numeric characters to achieve this level of detail. Codes with three characters are included in ICD-10-CM as the heading of a category of codes that may be further subdivided by use of additional characters to provide greater detail. A three-character code is to be used only if it is not further subdivided. A code is invalid if it has not been coded to the full number of characters required for that code, including the 7th character, if applicable.[2]

There is no ICD-10-CM code for treatment-resistant depression. The codes below are provided for your consideration, since our clinical trials included patients with Major Depressive Disorder (MDD) who failed at least 2 treatments of adequate dose and duration. Payer requirements for ICD-10 codes will vary. It is essential to verify correct diagnosis coding with each payer.

Table 3: ICD-10-CM Diagnosis Codes for Consideration*

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
F33.9	Major depressive disorder, recurrent, unspecified
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
F33.40	Major depressive disorder, recurrent, in remission, unspecified
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.

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Coding for SPRAVATO™ (esketamine) (continued)

National Drug Code (NDC)

The National Drug Code (NDC) is a unique number that identifies a drug's labeler, product, and trade package size. The NDC is most often used on pharmacy claims, including drugs provided for home infusion. However, the NDC is also required on Medicare claims for dual-eligible beneficiaries (Medicaid cross-over claims), Medicaid fee-for-service claims and by some private payers.[4] Although the FDA uses a 10-digit format when registering NDCs, payer requirements regarding the use of the 10- or 11-digit NDC may vary. Electronic data exchange generally requires use of the 11-digit NDC. To convert the 10-digit format to the 11-digit format, insert a leading zero into the middle sequence, as illustrated below:

Table 4: SPRAVATO™ NDC[1]

10-Digit NDC	11-Digit NDC	Description
50458-028-02	50458-0028-02	56 mg Dose Kit: Unit-dose carton containing two 28 mg nasal spray devices (56 mg total dose)
50458-028-03	50458-0028-03	84 mg Dose Kit: Unit-dose carton containing three 28 mg nasal spray devices (84 mg total dose)

Payer requirements for NDC use and format can vary widely. Please contact your payers for specific coding policies and more information on correct billing and claims submission.

NDC Units

The NDC unit of measure is determined by how the drug is supplied. GR (Gram) applies to drugs measured by weight[5] and is typically used for ointments, creams or inhalers.[4] The number of NDC units dispensed is based on the packaging and numeric quantity administered to the patient. Here are examples for 56-mg and 84-mg doses of SPRAVATO™:

Table 5: SPRAVATO™ NDC Units

Dose to Be Billed	11-Digit NDC	Packaging	NDC Unit of Measure	NDC Units
56-mg	50458-0028-02	56 mg Dose Kit	GR	0.056
84-mg	50458-0028-03	84 mg Dose Kit	GR	0.084

Accurate NDC coding typically requires the following components:

- Reporting the NDC with 11 digits in a 5-4-2 configuration (this may require converting a 10-digit NDC to an 11-digit NDC)
- Reporting the correct NDC unit of measure
- Reporting the number of NDC units dispensed
- Reporting the qualifier, N4, in front of the NDC

For a 56-mg dose, use the 56 mg Dose Kit (NDC 50458-028-02) containing two 28 mg nasal spray devices. This is how the NDC coding format will appear:

N450458002802 GR0.056

For an 84-mg dose, use the 84 mg Dose Kit (NDC 50458-028-03) containing three 28 mg nasal spray devices. This is how the NDC coding format will appear:

N450458002803 GR0.084

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Coding for SPRAVATO™ (esketamine) (continued)

Healthcare Common Procedure Code System (HCPCS) Level II Codes

Drugs are typically reported using permanent, product-specific HCPCS codes (e.g., J codes) assigned by the Centers for Medicare & Medicaid Services (CMS). Miscellaneous or "unclassified" codes allow physician offices and hospital outpatient departments to begin billing immediately for a service or item as soon as FDA allows it to be marketed and until assignment of a permanent code. Accurate reporting of miscellaneous drug codes can vary by site of care, payer, and timing after FDA approval. Table 6 summarizes those variables:

Table 6: Transition to Permanent Drug Code by Payer and Site of Care[6]

Site of Care	Payer	Claims following FDA approval up to the assignment of a permanent HCPCS code		Permanent National Code
Physician Office	Medicare	J3490 – unclassified drug[7]		The permanent HCPCS code is expected to be issued for first use on January 1, 2020
	Non-Medicare			
Site of Care	**Payer**	**Claims immediately following FDA approval**	**Claims beginning 3 to 6 months after FDA approval**	
Hospital Outpatient Department	Medicare	C9399 – unclassified drugs or biologics[8]	Temporary, drug-specific C code	
	Non-Medicare	J3490 – unclassified drug[7]		

When using unclassified drug codes, you will usually be required to submit additional information:

- Drug name
- Strength
- Dose administered
- Route of administration
- NDC

Some payers may require that you include the drug purchase invoice, prescribing information, documentation of medical necessity or other support for the claim. Because requirements may vary by payer, it is advisable to check local requirements before submitting claims using unclassified codes. Unclassified codes are not drug-specific and, thus, are always reported as 1 unit. When billing on the CMS-1500, enter the unclassified drug code in Item 24D and report additional information in item 19.[9] When billing on the CMS-1450, enter the unclassified code in Locator Box 44 and report additional information in "remarks," Locator Box 80.[10] (Please see sample claims beginning on p18.)

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Coding for Observation and Monitoring of SPRAVATO™ Administration Under HCP Supervision Consistent with REMS Requirements

Evaluation and Management (E/M)

The type and level of E/M service for office/outpatient settings is selected first based on the key components of history, examination, and complexity of medical decision-making. Time, although included in the code descriptors, is an average of the intra-service time typically required for each level and is considered an adjunct – not the sole determinant – of the appropriate E/M level.[11]

For office and outpatient visits E/M time is defined as *only* that time the physician spends face-to-face with the patient and/or family performing tasks such as obtaining a history, examining the patient, or counseling. Measurement of time does not include pre/post encounter time spent in activities such as reviewing records or tests.[11]

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Coding for Observation and Monitoring of SPRAVATO™ Administration Under HCP Supervision Consistent with REMS Requirements (continued)

There is currently no unique, designated code to describe the observation and monitoring of SPRAVATO™ administration as required by REMS. 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.

The following table summarizes the E/M codes to consider for SPRAVATO™ administration:

Table 7: SPRAVATO™ Administration – E/M Code[11] Considerations*

E/M Code	Key Components	Typical Face-to-Face Time	Usual Severity of Presenting Problem(s)
New Patients (codes require all 3 key components)			
99201	• Problem-focused history • Problem-focused examination • Straightforward medical decision making	10 minutes	Self-limited or minor
99202	• Expanded problem-focused history • Expanded problem-focused examination • Straightforward medical decision making	20 minutes	Low to moderate
99203	• Detailed history • Detailed examination • Low complexity medical decision making	30 minutes	Moderate
99204	• Comprehensive history • Comprehensive examination • Moderate complexity medical decision making	45 minutes	Moderate to high
99205	• Comprehensive history • Comprehensive examination • High complexity medical decision making	60 minutes	Moderate to high
Established Patients (codes require at least 2 of the 3 key components)			
99212	• Problem-focused history • Problem-focused examination • Straightforward medical decision making	10 minutes	Self-limited or minor
99213	• Expanded problem-focused history • Expanded problem-focused examination • Low complexity medical decision making	15 minutes	Low to moderate
99214	• Detailed history • Detailed examination • Moderate complexity medical decision making	25 minutes	Moderate to high
99215	• Comprehensive history • Comprehensive examination • High complexity medical decision making	40 minutes	Moderate to high
Medicare E/M Code for the Hospital Outpatient Site of Care			
G0463 – Hospital outpatient clinic visit for assessment and management of a patient[7] *This code is used exclusively for coding E/M services provided to Medicare beneficiaries in the hospital outpatient setting. It applies to all levels of E/M for both new and established patients.*			

*Payer requirements for SPRAVATO™ administration coding may vary. Please contact your payers for specific coding policies.

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Coding for Observation and Monitoring of SPRAVATO™ Administration Under HCP Supervision Consistent with REMS Requirements (continued)

Note that under Medicare, all levels of E/M services provided in the hospital outpatient department, for both new and established patients, are to be reported with a single HCPCS code (G0463). Other payer policies may vary. Table 7a summarizes E/M coding options by payer:

Table 7a: SPRAVATO™ Administration – E/M Code Considerations by Payer

Site of Care	Medicare	Commercial	Medicaid
Physician Practice	CPT® 99201-99205 CPT® 99212-99215	CPT® 99201-99205 CPT® 99212-99215	CPT® 99201-99205 CPT® 99212-99215
Hospital Outpatient Department (HOPD)	G0463	CPT® 99201-99205 CPT® 99212-99215	CPT® 99201-99205 CPT® 99212-99215

For additional information regarding Evaluation and Management codes, please see Appendix A of this guide.

Prolonged Clinical Staff Services*

Prolonged clinical staff service codes may be used when an E/M service involves prolonged clinical staff face-to-face time beyond the typical face-to-face time of the E/M service, as stated in the code description.[11] The physician must be present to provide direct supervision of the clinical staff and the prolonged service(s) is reported in addition to the designated E/M service. The Prolonged Clinical Staff Services codes are:

- **99415** – Prolonged clinical staff service (beyond the typical staff service time) during an evaluation and management service in the office or outpatient setting, direct patient contact with physician supervision; first hour[11]
- **99416** – Each additional 30 minutes[11]

These codes are used to report the total duration of face-to-face time spent by clinical staff on a given date providing prolonged service, even if the time spent by the clinical staff on that date is not continuous. Prolonged service of less than 45 minutes' total duration on a given date is not separately reported because the clinical staff time involved is included in the E/M codes. The typical face-to-face time of the primary service is used in defining when the prolonged service time begins. For example, prolonged clinical staff services for 99214 begin after 25 minutes, and 99415 is not reported until at least 70 minutes' total face-to-face clinical staff time has been performed.[11] Time spent with the patient must be clearly documented in the medical record.

*Payer requirements for SPRAVATO™ administration coding may vary. Please contact your payers for specific coding policies.

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Other Coding Considerations

Place of Service (POS) Codes

The POS code set provides setting information necessary to appropriately pay professional service claims. The place of service is the location of the provider's face-to-face encounter with the beneficiary. POS codes are required on all claims for professional services (billed on CMS-1500). The physician practice setting is indicated with POS code 11. To differentiate between on-campus and off-campus provider-based departments (PBDs), CMS created a new POS code (POS 19) and revised the POS code description for outpatient hospitals (POS 22). Professional services delivered in outpatient hospital settings must specifically include the off-campus or on-campus POS on the claim form.

Table 8: Place of Service Codes[9]

POS Code	POS Name	POS Descriptor
11	Office	Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, state or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.
19	Off Campus – Outpatient Hospital	A portion of an off-campus hospital provider-based department that provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.
22	On Campus – Outpatient Hospital	A portion of a hospital's main campus that provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.
53	Community Mental Health Center	A facility that provides the following services: outpatient services, including specialized outpatient services for children, the elderly, individuals who are chronically ill, and residents of the CMHC's mental health services area who have been discharged from inpatient treatment at a mental health facility; 24-hour a day emergency care services; day treatment, other partial hospitalization services, or psychosocial rehabilitation services; screening for patients being considered for admission to state mental health facilities to determine the appropriateness of such admission; and consultation and education services.

Revenue Codes

Many payers require use of American Hospital Association (AHA) revenue codes to bill for services provided in hospital outpatient departments. Revenue codes consist of a leading zero followed by three other digits and are used on claim forms to assign costs to broad categories of hospital revenue centers. Codes used for Medicare claims are available from Medicare contractors. The following revenue codes may be applicable to CMS-1450 claims for drugs and their administration:

- **0510** – Clinic, General
- **0636** – Pharmacy, drugs requiring detailed coding[12]

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Other Coding Considerations (continued)

HCPCS and CPT® Modifiers

Modifiers are used to indicate that a service or procedure has been altered by some specific circumstance but not changed in its definition or code. They add more information and help to eliminate the appearance of duplicate billing and unbundling. Appropriately used, modifiers increase coding and reimbursement accuracy. The following table summarizes modifiers that may be applicable to SPRAVATO™ coding and billing in physician offices and hospital outpatient departments.

Table 9: Summary of Code Modifiers

Modifier	Description	Indication and Placement	CMS-1500 (Item 24D)	CMS-1450 (Box 44)
PO*	Services, procedures, and/or surgeries furnished at *excepted* off-campus provider-based outpatient departments.[13]	• To be reported with every HCPCS code for all hospital items and services furnished in an *excepted* off-campus, PBD of a hospital[13]	N/A	❗ Required by Medicare
PN*	Nonexcepted service provided at an off-campus, outpatient, PBD of a hospital[13]	• To be reported on each claim line with each nonexcepted item and service furnished in a nonexcepted, off-campus, PBD of a hospital[13]	N/A	❗ Required by Medicare
JG	Drug or biological acquired with 340B Drug Pricing Program Discount[7]	• Must be reported by providers that are **NOT** excepted[†] from the 340B payment policy[14] • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs[14]	N/A	❗ Required by Medicare
TB	Drug or biological acquired with 340B Drug Pricing Program Discount, reported for informational purposes[7]	• Must be reported by providers that **ARE** excepted[†] from the 340B payment policy[14] • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs[14]	N/A	❗ Required by Medicare

*The PO and PN modifiers are NOT to be reported for dedicated emergency departments, remote locations or satellite facilities of a hospital, or a PBD that is "on campus".[13]

[†]For 2019 the following provider types are excepted from the 340B payment policy: rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals.[14] The 340B payment policy does not apply to Critical Access Hospitals (CAHs) or Maryland waiver hospitals and they are not required to report these modifiers.[14]

Please see Important Safety Information, including Boxed WARNINGS, on pages 22-25. Please see full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO™.

Spravato™
(esketamine) Ⅲ
nasal spray

Other Coding Considerations (continued)

Modifiers PO and PN: Excepted and Nonexcepted Items and Services

Medicare rules now require that services furnished in off-campus PBDs of a hospital that began billing under the OPPS on or after November 2, 2015, are no longer paid under the OPPS. These services are referred to as "nonexcepted" and paid under the Medicare Physician Fee Schedule (MPFS). CMS established a new modifier:

> **"PN" (nonexpected service provided at an off-campus, outpatient, PBD of a hospital)**

to identify and pay nonexcepted items and services billed on an institutional claim. Nonexcepted off-campus PBDs of a hospital are required to report this modifier on each claim line with a HCPCS for nonexcepted items and services. The use of modifier "PN" will trigger a payment rate under the MPFS. CMS expects the PN modifier to be reported with each nonexcepted line item and service including those for which payment will not be adjusted, such as separately payable drugs, clinical laboratory tests, and therapy services.[13]

Excepted off-campus PBDs of a hospital must continue to report existing modifier:

> **"PO" (services, procedures, and/or surgeries provided at excepted off-campus provider-based outpatient departments) for all excepted items and services with an HCPCS.**

This modifier should not be reported for remote locations of a hospital, satellite facilities of a hospital, or services furnished in an emergency department.[13] Neither the PN nor the PO modifier is to be reported by the following hospital departments:

- A dedicated emergency department
- A PBD that is "on the campus," or within 250 yards, of the hospital or a remote location of the hospital[15]

Drugs Supplied at No Cost to Provider

Payers, including Medicare Part D, may cover a drug under the patient's pharmacy benefit. Under this model, SPRAVATO™ may be delivered to the administering site via a specialty pharmacy channel ("white bagging"). When the drug is supplied by a specialty pharmacy it cannot be billed by the administering provider. However, the HCP observation and monitoring of the drug's administration is a service that represents an expense to the provider. Therefore, this service is payable if the drug would have been covered if the provider purchased it.[16] When reporting drug administration services for pharmacy-supplied drugs, it may be necessary to include drug information on the claim and enter "0.01" charges.[16] Payer policies may vary.

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Filing Healthcare Claims

Physician Office Claims (CMS-1500)

The Form CMS-1500 is the basic form prescribed by CMS for the Medicare and Medicaid programs for claims from suppliers and noninstitutional providers that qualify for a waiver from the Administrative Simplification Compliance Act (ASCA) requirement for electronic submission of claims. It has also been adopted by the TRICARE Program. For detailed guidance on completing the CMS-1500 items, please see the Medicare Claims Processing Manual, Pub. 100-04, Chapter 26, available at

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26.pdf

The 837P (Professional) is the standard format used by healthcare professionals and suppliers to transmit healthcare claims electronically. The American National Standards Institute (ANSI) Accredited Standards Committee (ASC) X12N 837P (Professional) Version 5010A1 is the current electronic claim version. Data elements in the CMS uniform electronic billing specifications are consistent with the hard copy data set to the extent that one processing system can handle both. Medicare Administrative Contractors may include a crosswalk between the ASC X12N 837P and the CMS-1500 on their websites.

Hospital Outpatient Claims (CMS-1450)

The Form CMS-1450, also known as the UB-04, is a uniform institutional provider bill suitable for use in billing multiple third-party payers. It is the basic form prescribed by CMS for the Medicare and Medicaid programs for claims from hospitals, including HOPDs. Because it serves many payers a particular payer may not need some data elements. For detailed guidance on completing the CMS-1450 items, please see the Medicare Claims Processing Manual, Pub. 100-04, Chapter 25, available at:

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c25.pdf

The 837I (Institutional) is the standard format used by institutional providers to transmit healthcare claims electronically. The American National Standards Institute (ANSI) Accredited Standards Committee (ASC) X12N 837I (Institutional) Version 5010A2 is the current electronic claim version. Data elements in the uniform electronic billing specifications are consistent with the hard copy data set to the extent that one processing system can handle both. Medicare Administrative Contractors may include a crosswalk between the ASC X12N 837I and the CMS-1450 on their websites.

For more information on electronic claims, please see the CMS website at
https://www.cms.gov/medicare/billing/electronicbillingeditrans/healthcareclaims.html

Spravato™
(esketamine) ⒞
nasal spray

Sample CMS-1500 Claim Form

SPRAVATO™ (esketamine): 2019 Physician Office Sample Claim

1 | Item 19   When submitting a claim for a Not Otherwise Classified (NOC) drug, enter the drug's name, dose, route of administration and NDC (11-digit format). Payer requirements for information and codes may vary.*

2 | Item 21   Indicate diagnosis using appropriate ICD-10-CM codes. Use diagnosis codes to the highest level of specificity for the date of service and enter the diagnoses in priority order.

3 | Item 24A   If line item NDC information is required, it will be entered in the shaded portion of Item 24A.[9]

For example:

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS | MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #	
1 N450458002802 GR0.056 04 01 19	04 01 19			J3490	A		1		NPI	123 456 7890	OR SUPPLIER INFORMATION
2									NPI		
3									NPI		
4									NPI		

Payer requirements for NDC entries may vary.*

4 | Item 24D   Indicate appropriate CPT,® HCPCS codes, and modifiers, if required.

SPRAVATO™

J3490 – unclassified drug

Observation and Monitoring for SPRAVATO™ Administration

99201-99205 – Office or other outpatient visit for the evaluation and management of a new patient

99212-99215 – Office or other outpatient visit for the evaluation and management of an **established** patient

Payer requirements for observation and monitoring coding may vary.*

5 | Item 24E   Refer to the diagnosis for this service (see box 21). Enter only one diagnosis pointer per line.

6 | Item 24G   **Drug**
J3590 – Enter 1 unit and enter additional information in Item 19
Observation and Monitoring for SPRAVATO™ Administration
Report appropriate E&M code; enter 1 unit

*Contact your local payer or Janssen CarePath at 844-777-2828, Monday to Friday, 8:00 AM to 8:00 PM
E-mail: Submit questions via our askjanssenmedinfo.com site

**Please see Important Safety Information, including Boxed WARNINGS, on pages 22-25.
Please see full Prescribing Information, including Boxed WARNINGS, and
Medication Guide for SPRAVATO™.**

Spravato™
(esketamine) ℂⅢ
nasal spray

Sample CMS-1500 Claim Form

Sample CMS-1500 Claim Form: 56-mg Dose of SPRAVATO™

HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

| | | PICA | | | | | | | | | | | | | PICA | | |

CARRIER

1. MEDICARE [ ] (Medicare#)　MEDICAID [ ] (Medicaid#)　TRICARE [ ] (ID#/DoD#)　CHAMPVA [ ] (Member ID#)　GROUP HEALTH PLAN [ ] (ID#)　FECA BLK LUNG [ ] (ID#)　OTHER [ ] (ID#)

Medicare: **X**

1a. INSURED'S I.D. NUMBER (For Program in Item 1)
000-00-1234

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)
Doe, John B.

3. PATIENT'S BIRTH DATE　MM **07** DD **01** YY **45**　SEX M **X** F [ ]

4. INSURED'S NAME (Last Name, First Name, Middle Initial)
Doe, John B.

5. PATIENT'S ADDRESS (No., Street)
3914 Spruce Street

6. PATIENT RELATIONSHIP TO INSURED
Self **X**　Spouse [ ]　Child [ ]　Other [ ]

7. INSURED'S ADDRESS (No., Street)
3914 Spruce Street

CITY **Anytown** STATE

8. RESERVED FOR NUCC USE

CITY **Anytown** STATE **AS**

ZIP CODE **01010** TELEPHONE (Include Area Code) **(203) 555-1234**

ZIP CODE **01010** TELEPHONE (Include Area Code) **(203) 555-1234**

PATIENT AND INSURED INFORMATION

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES [ ] NO [ ]

a. INSURED'S DATE OF BIRTH MM DD YY　SEX M [ ] F [ ]

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES [ ] NO [ ] PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES [ ] NO [ ]

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES [ ] NO [ ] *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED _____ DATE _____

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED _____

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE
Dr. Johns
17a.
17b. NPI **123 456 7890**

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY

1 19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)
SPRAVATO™ (esketamine) 56 mg. intranasally. NDC 50458-0028-02

20. OUTSIDE LAB? YES [ ] NO [ ] $ CHARGES

2 21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. | |
A. **F32.2**　B. _____　C. _____　D. _____
E. _____　F. _____　G. _____　H. _____
K. _____

22. RESUBMISSION CODE _____ ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE						B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances)		E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
From MM	DD	YY	To MM	DD	YY			CPT/HCPCS	MODIFIER	POINTER					
3 1　04	01	19	04	01	19	11		J3490	**4**	A	**5**	1	**6**	PI	123 456 7890
2　04	01	19	04	01	19	11		99203		A		1		NPI	123 456 7890
3														NPI	
4														NPI	
5														NPI	
6														NPI	

25. FEDERAL TAX I.D. NUMBER SSN [ ] EIN [ ]

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES [ ] NO [ ]

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)
SIGNED _____ DATE _____

32. SERVICE FACILITY LOCATION INFORMATION
a.　b.

33. BILLING PROVIDER INFO & PH # **(203) 987-6543**
Dr. Jones
4231 Center Road
Anytown, AS 01010
a. **123 456 7890**　b.

PHYSICIAN OR SUPPLIER INFORMATION

NUCC Instruction Manual available at: www.nucc.org　　*PLEASE PRINT OR TYPE*　　OMB APPROVAL PENDING

Please see Important Safety Information, including Boxed WARNINGS, on pages 22-25. Please see full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO™.

Spravato™ (esketamine) Ⓒ III nasal spray

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Sample CMS-1450 Claim Form

SPRAVATO™ (esketamine): 2019 HOPD Sample Claim

1 | Locator Box 42 List revenue codes in ascending order.

2 | Locator Box 43 Enter narrative description for corresponding revenue code (eg, clinic visit). If line item NDC information is required, enter it in the unshaded portion of Locator Box 43.[10]
Payer requirements for NDC entries may vary.*

3 | Locator Box 44 Indicate appropriate CPT®, HCPCS codes, and modifiers as required by payer.

SPRAVATO™
C9399 – Unclassified drugs or biologicals (required for Medicare claims)
J3490 – Unclassified drug (may be required by other payers)

Observation and Monitoring for SPRAVATO™ Administration
Medicare
G0463 – Hospital outpatient clinic visit for assessment and management of a patient

Non-Medicare Payers
99201-99205 – Office or other outpatient visit for the evaluation and management of a new patient
99212-99215 – Office or other outpatient visit for the evaluation and management of an established patient

Payer requirements for observation and monitoring coding may vary.*

Modifiers:

- PO or PN modifiers must be reported by all off-campus hospital outpatient departments. The PO modifier is to be reported with every HCPCS code for all items and services furnished in an *excepted*, off-campus, PBD of a hospital. The PN modifier is to be reported on each claim line for all items and services furnished in a *nonexcepted*, off-campus, PBD of a hospital.[13]

- Modifiers must be reported for all 340B-acquired drugs. Providers that are not excepted from the 340B payment policy will report modifier "JG." Providers that are excepted from the 340B payment policy will report modifier "TB."[14]

4 | Locator Box 46 Enter the number of HCPCS units.
Drug
C9399 or J3490 – enter 1 unit and enter additional information in Locator Box 80 ("Remarks")

Observation and Monitoring for SPRAVATO™ Administration
Report appropriate E&M code; enter 1 unit

5 | Locator Box 67 Indicate diagnosis using appropriate ICD-10-CM codes. Code to the highest level of specificity for the date of service and enter diagnoses in priority order.

6 | Locator Box 80 When submitting a claim for an unclassified drug, enter the drug's name, dose, route of administration, and NDC (11-digit format). Payer requirements for information and codes may vary.*

*Contact your local payer or Janssen CarePath at 844-777-2828, Monday to Friday, 8:00 AM to 8:00 PM
  E-mail: Submit questions via our askjanssenmedinfo.com site

**Please see Important Safety Information, including Boxed WARNINGS, on pages 22-25.
Please see full Prescribing Information, including Boxed WARNINGS, and
Medication Guide for SPRAVATO™.**

Spravato™
(esketamine) CⅢ
nasal spray

Sample CMS-1450 Claim Form

Sample CMS-1450 Claim Form: 84-mg Dose of SPRAVATO™

1 ¹ Anytown Hospital 160 Main Street Anytown, Anystate 01010	² Pay-to-name Pay-to-address Pay-to-city/state	3a PAT. CNTL # XX-XXXX		4 TYPE OF BILL
		b. MED. REC. # DOE 1234-97		
		5 FED. TAX NO. 010001010	6 STATEMENT COVERS PERIOD FROM THROUGH	7

8 PATIENT NAME	a John B. Doe	9 PATIENT ADDRESS	a 3914 Spruce Street				
b		b Any Town			c AS	d 01010	e US

10 BIRTHDATE 07-01-45 **11 SEX** M **12 DATE** ADMISSION **13 HR 14 TYPE 15 SRC 16 DHR 17 STAT 18 19 20 21** CONDITION CODES **22 23 24 25 26 27 28 29 ACDT STATE 30**

31 OCCURRENCE CODE DATE 32 OCCURRENCE CODE DATE 33 OCCURRENCE CODE DATE 34 OCCURRENCE CODE DATE 35 OCCURRENCE SPAN CODE FROM THROUGH 36 OCCURRENCE SPAN CODE FROM THROUGH 37

38   **39 VALUE CODES CODE AMOUNT 40 VALUE CODES CODE AMOUNT 41 VALUE CODES CODE AMOUNT**

[1] [2] [3] [4]

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
0510	Clinic visit	G0463	04-01-19	1			
0636	SPRAVATO (esketamine)	C9399	04-01-19	1			

PAGE ____ OF ____   **CREATION DATE**   **TOTALS ▶**

50 PAYER NAME	51 HEALTH PLAN ID	52 REL INFO	53 ASG. BEN.	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56 NPI
A						57 OTHER PRV ID
B						
C						

58 INSURED'S NAME	59 P.REL	60 INSURED'S UNIQUE ID	61 GROUP NAME	62 INSURANCE GROUP NO.
A				
B				
C				

63 TREATMENT AUTHORIZATION CODES	64 DOCUMENT CONTROL NUMBER	65 EMPLOYER NAME
A		
B		
C		

[5]

66 DX F33.2 **A B C D E F G H 68**

69 ADMIT DX 70 PATIENT REASON DX 71 PPS CODE 72 ECI 73

74 PRINCIPAL PROCEDURE CODE DATE a. OTHER PROCEDURE CODE DATE b. OTHER PROCEDURE CODE DATE 75 **76 ATTENDING NPI QUAL / LAST FIRST**

c. OTHER PROCEDURE CODE DATE d. OTHER PROCEDURE CODE DATE e. OTHER PROCEDURE CODE DATE **77 OPERATING NPI QUAL / LAST FIRST**

[6]

80 REMARKS	81 CC a b c d	78 OTHER NPI QUAL LAST FIRST
SPRAVATO™ (esketamine) 84 mg. intranasally. NDC 50458-0028-03		79 OTHER NPI QUAL LAST FIRST

UB-04 CMS-1450   APPROVED OMB NO. 0938-0997   NUBC™ National Uniform Billing Committee LIC9213257   THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

Please see Important Safety Information, including Boxed WARNINGS, on pages 22-25. Please see full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO™.

Spravato™ (esketamine) Ⓒ 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 <u>Prescribing Information</u>, including Boxed WARNINGS, and <u>Medication Guide</u> for 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 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™.

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

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

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Spravato™
(esketamine) CIII
nasal spray

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.

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.

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Janssen CarePath

Janssen CarePath can help make it simple for you to help your patients

janssen CarePath

Your one source for Access, Affordability and Treatment Support for your patients

Access support to help navigate payer processes

Janssen CarePath helps verify insurance coverage for your patients taking SPRAVATO™ and provides reimbursement information.

Affordability support to help your patients start and stay on the treatment you prescribe

Janssen CarePath can help you find out what affordability assistance may be available for your patients taking SPRAVATO™.

Janssen CarePath Savings Program

Eligible commercially insured patients pay $10 per treatment for SPRAVATO™ medication costs.*

Treatment support to help your patients get informed and stay on prescribed Janssen treatment

Janssen CarePath provides additional support to your patients, including patient education, web-based resources, and assistance finding a location that offers SPRAVATO™ treatment.

*$7,150 maximum program benefit per calendar year. *Treatment* may include up to three devices administered on the same day. Not valid for patients using Medicare, Medicaid, or other government-funded programs to pay for SPRAVATO™ medication. Terms expire at the end of each calendar year and may change. There is no income requirment. Program does not cover the cost to give patients their treatment. See full eligibility requirements at Spravato.JanssenCarePathSavings.com.

Need help? | Call **844-777-2828**
Monday to Friday, 8:00 AM to 8:00 PM

Visit www.JanssenCarePath.com/hcp/Spravato

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(esketamine) Ⓒ
nasal spray

APPENDIX A: Evaluation and Management

There is currently no unique, designated code to describe the intranasal administration of SPRAVATO™ as required by REMS. 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.

The levels of Evaluation and Management (E/M) services include examinations, evaluations, treatments, and similar medical services. E/M codes must be selected based on the content of the service. The duration of the visit is an ancillary factor and does not control the level of the service to be billed unless more than 50 percent of the face-to-face time is spent providing counseling or coordination of care.[17]

Key Components

The key components for selecting the appropriate level of E/M services are: history, examination, and medical decision making. Documentation must support the services provided for the selected E/M level.

History[11]

The extent of the history is dependent upon clinical judgment and on the nature of the presenting problem(s). The levels of E/M services recognize four types of history:

- **Problem focused:** Chief complaint; brief history of present illness or problem.
- **Expanded problem focused:** Chief complaint; brief history of present illness; problem-pertinent system review.
- **Detailed:** Chief complaint; extended history of present illness; problem-pertinent systems review extended to include a review of a limited number of additional systems; pertinent past, family and/or social history directly related to the patient's problems.
- **Comprehensive:** Chief complaint; extended history of present illness; review of systems that is directly related to the problem(s) identified in the history of the present illness plus a review of all additional body systems; complete past, family, and social history.

Examination[11]

The extent of the examination performed is dependent on clinical judgment and the nature of the presenting problem(s). The levels of E/M recognize four types of examination:

- **Problem focused:** A limited examination of the affected body area or organ system.
- **Expanded problem focused:** A limited examination of the affected body area or organ system and other symptomatic or related organ system(s).
- **Detailed:** An extended examination of the affected body area(s) and other symptomatic or related organ system(s).
- **Comprehensive:** A general multisystem examination or a complete examination of a single organ system. For the purposes of CPT definitions, the following organ systems are recognized: eyes; ears, nose, mouth and throat; cardiovascular; respiratory; gastrointestinal; genitourinary; musculoskeletal; skin; neurologic; psychiatric, and hematologic/lymphatic/immunologic.

For the purposes of CPT definitions, the following organ systems are recognized: eyes; ears, nose, mouth and throat; cardiovascular; respiratory; gastrointestinal; genitourinary; musculoskeletal; skin; neurologic; psychiatric, and hematologic/lymphatic/immunologic.

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Medical Decision Making[11]

Medical decision making refers to the complexity of establishing a diagnosis and/or selecting a management option as measured by:

- The number of possible diagnoses and/or the number of management options that must be considered
- The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be obtained, reviewed, and analyzed
- The risk of significant complications, morbidity, and/or mortality, as well as comorbidities, associated with the patient's presenting problem(s), the diagnostic procedure(s), and/or the possible management options.

Four types of medical decision making are recognized: straightforward, low complexity, moderate complexity, and high complexity. To qualify for a given type of decision making, two of the three elements in the following table must be met:

Table 10: Complexity of Medical Decision Making[11]

Number of Diagnoses or Management Options	Amount and/or Complexity of Data to Be Reviewed	Risk of Complications and/or Morbidity or Mortality	Type of Decision Making
Minimal	Minimal or none	Minimal	**Straightforward**
Limited	Limited	Low	**Low Complexity**
Multiple	Moderate	Moderate	**Moderate Complexity**
Extensive	Extensive	High	**HIgh Complexity**

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Appendix B: Working With Payers

Sample format letters of medical necessity and letters to request a formulary exception are shown below. You can also download editable letter templates at www.JanssenCarePath.com/hcp/Spravato.

Sample Format Letter of Medical Necessity

[Insert Physician Letterhead]

[Insert Name of Medical Director]	RE:	Member Name: [Insert Member Name]
[Insert Payer Name]		Member Number: [Insert Member Number]
[Insert Address]		Group Number: [Insert Group Number]
[Insert City, State Zip]		

REQUEST: Authorization for treatment with SPRAVATO™ (esketamine) Nasal Spray CIII

DIAGNOSIS: [Insert Diagnosis] [Insert ICD]

DOSE AND FREQUENCY: [Insert Dose & Frequency]

REQUEST TYPE: ☐ Standard ☐ EXPEDITED

Dear [Insert name of Medical Director or name of individual responsible for prior authorization]:

I am writing to support my request for an **authorization** for the above-mentioned patient to receive treatment with SPRAVATO™ for [Insert Indication], dosed concomitant with [insert oral antidepressant]. My request is supported by the following:

Summary of Patient's Diagnosis

[Insert patient's diagnosis, date of diagnosis, lab results and date, current condition]

Summary of Patient's History

[Insert:
- Previous therapies/procedures, including dose and duration, response to those interventions
- Description of patient's recent symptoms/condition
- Site of medical service—include appropriate site type: inpatient, hospital outpatient, outpatient clinic, private practice, or other
- Rationale for not using drugs that are on the plan's formulary
- Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment with SPRAVATO™.

Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]

Rationale for Treatment

[Insert summary statement for rationale for treatment such as: Considering the patient's history, condition, and the full Prescribing Information supporting uses of SPRAVATO™, I believe treatment with SPRAVATO™ at this time is medically necessary, and should be a covered and reimbursed service.]

[You may consider including documents that provide additional clinical information to support the recommendation for SPRAVATO™ for this patient, such as the full Prescribing Information, peer-reviewed journal articles, or clinical guidelines.]

[Given the urgent nature of this request,] please provide a timely authorization. Contact my office at [Insert Phone Number] if I can provide you with any additional information.

Sincerely,

[Insert Physician Name and Participating Provider Number]

Enclosures [Include full Prescribing Information and the additional support noted above]

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nasal spray

Appendix B: Working With Payers (continued)

Sample format letters of medical necessity and to request a formulary exception are shown below. You can also download editable letter templates at www.JanssenCarePath.com/hcp/Spravato.

Sample Format Letter to Request a Formulary Exception

[Insert Physician Letterhead]

[Insert Name of Medical Director]   RE: Member Name: [Insert Member Name]
[Insert Payer Name]   Member Number: [Insert Member Number]
[Insert Address]   Group Number: [Insert Group Number]
[Insert City, State Zip]

REQUEST: Authorization for treatment with SPRAVATO™ (esketamine) Nasal Spray CIII
DIAGNOSIS: [Insert Diagnosis] [Insert ICD]
DOSE AND FREQUENCY: [Insert Dose & Frequency]
REQUEST TYPE: ☐ Standard ☐ EXPEDITED

Dear [Insert Name of Medical Director]:

I am writing to request a **formulary exception** for the above-mentioned patient to receive treatment with SPRAVATO™ for [insert indication], dosed concomitant with [insert oral antidepressant]. My request is supported by the following:

Summary of Patient's Diagnosis
[Insert patient's diagnosis, date of diagnosis, lab results and date, current condition]

Summary of Patient's History
[Insert:
- Previous therapies/procedures, including dose and duration, response to those interventions
- Description of patient's recent symptoms/condition
- Site of medical service—include appropriate site type: Inpatient, hospital outpatient, outpatient clinic, private practice, or other
- Rationale for not using drugs that are on the plan's formulary
- Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment with SPRAVATO™.
Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]

Rationale for Treatment
[Insert summary statement for rationale for treatment such as: Considering the patient's history, condition, and the full Prescribing Information supporting uses of SPRAVATO™, I believe treatment with SPRAVATO™ at this time is medically necessary, and should be a covered and reimbursed service.]

[You may consider including documents that provide additional clinical information to support the recommendation for SPRAVATO™ for this patient, such as the full Prescribing Information, peer-reviewed journal articles, or clinical guidelines.]

[Given the urgent nature of this request,] please provide a timely authorization. Contact my office at [Insert Phone Number] if I can provide you with any additional information.

Sincerely,
[Insert Physician Name and Participating Provider Number]

Enclosures [Include full Prescribing Information and the additional support noted above]

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APPENDIX C: Ordering Information

The following are authorized SPRAVATO™ Full-Line Wholesalers:

Full-Line Wholesalers	Phone Number	Fax	Website
Amerisource Bergen	1-844-222-2273	1-888-292-9774	www.AmerisourceBergen.com
Cardinal Health	1-800-926-3161	—	www.cardinalhealth.com
McKesson Pharmaceutical Distribution	1-855-625-7385	—	www.mckesson.com

The following specialty distributors are authorized to sell SPRAVATO™:

Specialty Distributor	Phone Number	Fax	Website
Besse Medical	1-800-543-2111	1-800-543-8695	www.Besse.com
Cardinal Health Specialty Distribution	1-877-453-3972	1-877-274-9897	https://www.cardinalhealth.com/en/services/acute/logistics-solutions-acute/distribution/specialty-distribution
CuraScript Specialty Distribution	1-877-599-7748	1-800-862-6208	www.curascriptsd.com
McKesson Specialty Health	1-855-477-9800	—	www.mckessonspecialtyhealth.com

This list is provided for informational purposes only. Janssen Pharmaceuticals, Inc., does not endorse the use of any particular distributor. This information was current at time of publication.

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To contact Janssen Medical Information Center
Call: **1-800-JANSSEN (1-800-526-7736)**
Monday to Friday, 9:00 AM to 8:00 PM ET
E-mail: Submit questions via our **askjanssenmedinfo.com** site

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