Spravato®
(esketamine) CIII
28 mg nasal spray

Access, Coding, and Reimbursement Guide

Information to Support the Access and Reimbursement Process for SPRAVATO®

Indications:

SPRAVATO® (esketamine) CIII Nasal Spray is indicated, in conjunction with an oral antidepressant, for the treatment of:

• Treatment-resistant depression (TRD) in adults.

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

Limitations of Use:

• The effectiveness of SPRAVATO® in preventing suicide or in reducing suicidal ideation or behavior has not been demonstrated. Use of SPRAVATO® does not preclude the need for hospitalization if clinically warranted, even if patients experience improvement after an initial dose of SPRAVATO®.

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

Important Safety Information

> **WARNING: SEDATION; DISSOCIATION; RESPIRATORY DEPRESSION; ABUSE AND MISUSE; and SUICIDAL THOUGHTS AND BEHAVIORS**
>
> *See full prescribing information for complete boxed warning*
>
> • **Risk for sedation, dissociation, and respiratory depression after administration. Monitor patients for at least two hours after administration (5.1, 5.2, 5.3).**
> • **Potential for abuse and misuse. Consider the risks and benefits of using SPRAVATO® prior to use in patients at higher risk of abuse. Monitor for signs and symptoms of abuse and misuse (5.4).**
> • **SPRAVATO® is only available through a restricted program called the SPRAVATO® REMS (5.5).**
> • **Increased risk of suicidal thoughts and behaviors in pediatric and young adult patients taking antidepressants. Closely monitor all antidepressant-treated patients for clinical worsening and emergence of suicidal thoughts and behaviors. SPRAVATO® is not approved for use in pediatric patients (5.6).**

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

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## Introduction

This Access, Coding, and Reimbursement Guide contains important information about SPRAVATO®, including its uses and Important Safety Information, the Risk Evaluation & Mitigation Strategy (REMS), information about how to identify authorized distributors, and guidance on access and reimbursement.

This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice, nor does it promise or guarantee coverage, levels of reimbursement, payment, or charge. Similarly, all CPT® and HCPCS codes are supplied for informational purposes only and represent no statement, promise, or guarantee by Janssen Pharmaceuticals, Inc., that these codes will be appropriate or that reimbursement will be made. It is not intended to increase or maximize reimbursement by any payer. Laws, regulations, and policies concerning reimbursement are complex and are 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. We strongly recommend you consult the payer organization for its reimbursement policies.

Each button is clickable and will jump to specific sections.
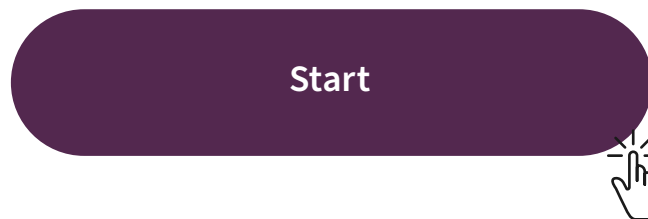
Start

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

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Getting Started

| SPRAVATO® REMS | SPRAVATO® Coverage and Acquisition Considerations | Determine Access for SPRAVATO® |

| | Find Your Patient's ICD-10 Code | |

Each button is clickable and will jump to specific sections.

Before Treatment, Understand the 3 AREAS OF ACCESS

| Drug Coverage | Drug Procurement and Administration | Reimbursement |

ICD-10=International Classification of Diseases, Tenth Revision.

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SPRAVATO® Risk Evaluation and Mitigation Strategy (REMS)

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REMS Manages Known or Potential Risks Associated With a Drug and Is Required by the U.S. FDA to Ensure that the Benefits of the Drug Outweigh its Risks

SPRAVATO® nasal spray CIII is available only through a restricted distribution program called the SPRAVATO® REMS because of the risks of serious adverse outcomes resulting from sedation, dissociation, and respiratory depression caused by SPRAVATO® administration, and abuse and misuse of SPRAVATO®. SPRAVATO® is intended for use only in a certified healthcare setting.

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. SPRAVATO® must never be dispensed directly to a patient for home use.

What are the REMS requirements?*

1 **Healthcare setting certification**
All healthcare settings must be certified in the REMS in order to receive, dispense, and/or treat patients with SPRAVATO®. See below healthcare settings considerations.

2 **Pharmacy certification**
Pharmacies must be certified in the REMS in order to receive and dispense SPRAVATO®.

3 **Patient enrollment**
Patients in an **outpatient** setting must be enrolled in the REMS with their prescriber in order to receive SPRAVATO® treatment.

Healthcare Settings Type

All REMS-certified Inpatient and Outpatient Healthcare Settings must have a healthcare provider counsel patients on the safety risk of SPRAVATO® and monitor patients post-dose.

Inpatient healthcare settings
- Covers inpatient units, inpatient pharmacy, and emergency departments
- Before prescribing SPRAVATO® treatment, complete and submit the *inpatient healthcare setting enrollment form*
- Before starting SPRAVATO® treatment, inpatient settings are NOT required to enroll the patient in the SPRAVATO® REMS
- During SPRAVATO® treatment, inpatient settings do NOT require the *patient monitoring form*. Report all suspected adverse events to the SPRAVATO® REMS

Outpatient healthcare settings
- Covers outpatient medical offices and clinics
- Before prescribing SPRAVATO® treatment, complete and submit the *outpatient healthcare setting enrollment form*
- Before starting SPRAVATO® treatment, enroll the patient by completing and submitting the *patient enrollment form* to the SPRAVATO® REMS
- During SPRAVATO® treatment, submit the *patient monitoring form* and report all suspected adverse events to the SPRAVATO® REMS

*To get started, find more information on how to certify as a healthcare setting and/or pharmacy, and view all REMS requirements and attestations by type of REMS stakeholder, visit **www.SPRAVATOrems.com** or call 1-855-382-6022 (8:00 AM to 8:00 PM ET).

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SPRAVATO® Coverage and Acquisition Considerations

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To understand reimbursement for SPRAVATO®, it is important to fully review individual payer policies and understand payer-specific requirements.

Reference the list below to help you better understand and navigate the SPRAVATO® reimbursement process.

Click each number for additional considerations.

1 Find and review the patient-specific benefits and payer policy for SPRAVATO®.

2 Determine what type of coverage the plan will use to cover SPRAVATO® and its associated service.

3 Review the plan's pre-approval requirements.

4 Identify the appropriate procurement method.

5 Review plan-specific codes to report appropriate drug and service codes based on the services provided.

Reach out to your Patient Access Specialist if additional information is needed

Prior to treatment, you may want to consider ensuring that drug and service codes are included in your payer contract.

Each button is clickable and will jump to specific sections.

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SPRAVATO® Coverage and Acquisition Considerations

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Reference the list below to help you better understand and navigate the SPRAVATO® reimbursement process.

Click each num

1 ✕

    a.   What type of insurance does the patient have?

    b.   Is the billing provider a "participating" member of or "in-network" provider for that specific plan?

    c.   Does the patient have a Medicare or non-Medicare plan?

1   Find an _____ d payer policy for SPRAVATO®.

2   Determ _____ use to cover SPRAVATO® and its _____

3   Review _____

4   Identify the appropriate procurement method.

5   Review plan-specific codes to report appropriate drug and service codes based on the services provided.

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SPRAVATO® Coverage and Acquisition Considerations

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Reference the list below to help you better understand and navigate the SPRAVATO® reimbursement process.

Click each number for additional considerations.

1 Find and review the patient-specific benefits and payer policy

2 Determine what type of coverage the plan will use to cover SP and its associated service.

3 Review the plan's pre-approval requirements.

4 Identify the appropriate procurement method.

5 Review plan-specific codes to report appropriate drug and ser based on the services provided.

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a. Is SPRAVATO® covered under medical, pharmacy, or both?

b. Do the payer requirements specifically indicate the sites of care that may bill for the drug and its administration?

c. Does the plan have a behavioral health organization (BHO) carve out?

d. Is your office in-network for the payer and BHO (if a BHO manages the patient's behavioral health services)?

e. Did you consider if all codes are contracted with all parties involved, including the BHO?

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Prior to treatment, you may want to consider ensuring that drug and service codes are included in your payer contract.

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SPRAVATO® Coverage and Acquisition Considerations

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To understand reimbursement for SPRAVATO®, it is important to fully review individual payer policies and understand payer-specific requirements.

Reference the list below to help you better understand and navigate the SPRAVATO® reimbursement process.

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a. Have you confirmed the appropriate clinical documentation that is required to support the patient's diagnosis?

b. If required by the plan, has the appropriate referral or prior authorization been obtained?

c. Do you understand the plan's prior authorization criteria?

d. Does the payer require a letter of medical necessity?

e. Does the payer require any additional information?

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ropriate drug and service codes

Reach out to your Patient Access Specialist if additional information is needed

Prior to treatment, you may want to consider ensuring that drug and service codes are included in your payer contract.

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SPRAVATO® Coverage and Acquisition Considerations

To understand reimbursement for SPRAVATO®, it is important to fully review individual payer policies and understand payer-specific requirements.

Reference the list below to help you better understand and navigate the SPRAVATO® reimbursement process.

Click each number for additional considerations.

1 Find and review the patient-specific benefits and p...

2 Determine what type of coverage the plan will use ... and its associated service.

3 Review the plan's pre-approval requirements.

4 Identify the appropriate procurement method.

5 Review plan-specific codes to report appropriate ... based on the services provided.

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4 ✕

a. Does payer policy determine the procurement method?

b. What type of procurement method does the payer policy allow?

   i. Buy and Bill

   ii. REMS-Certified Specialty Pharmacy

   iii. REMS-Certified Specialty Pharmacy via Medical Assignment of Benefits (AOB)

...ach out to your ...ient Access ...ecialist if additional ...ormation is needed

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Prior to treatment, you may want to consider ensuring that drug and service codes are included in your payer contract.

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SPRAVATO® Coverage and Acquisition Considerations

To understand reimbursement for SPRAVATO®, it is important to fully review individual payer policies and understand payer-specific requirements.

Reference the list below to help you better understand and navigate the SPRAVATO® reimbursement process.

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5 ✕

a. Does the payer require specific drug and service codes to be utilized?

b. Have the appropriate ICD-10, CPT®, and HCPCS codes been billed?

c. Did you fill out the CMS-1500 and/or CMS-1450 forms correctly?

d. If using Evaluation and Management (E/M) codes, are they aligned with the work performed and by whom?

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...ropriate drug and service codes

Reach out to your Patient Access Specialist if additional information is needed

Prior to treatment, you may want to consider ensuring that drug and service codes are included in your payer contract.

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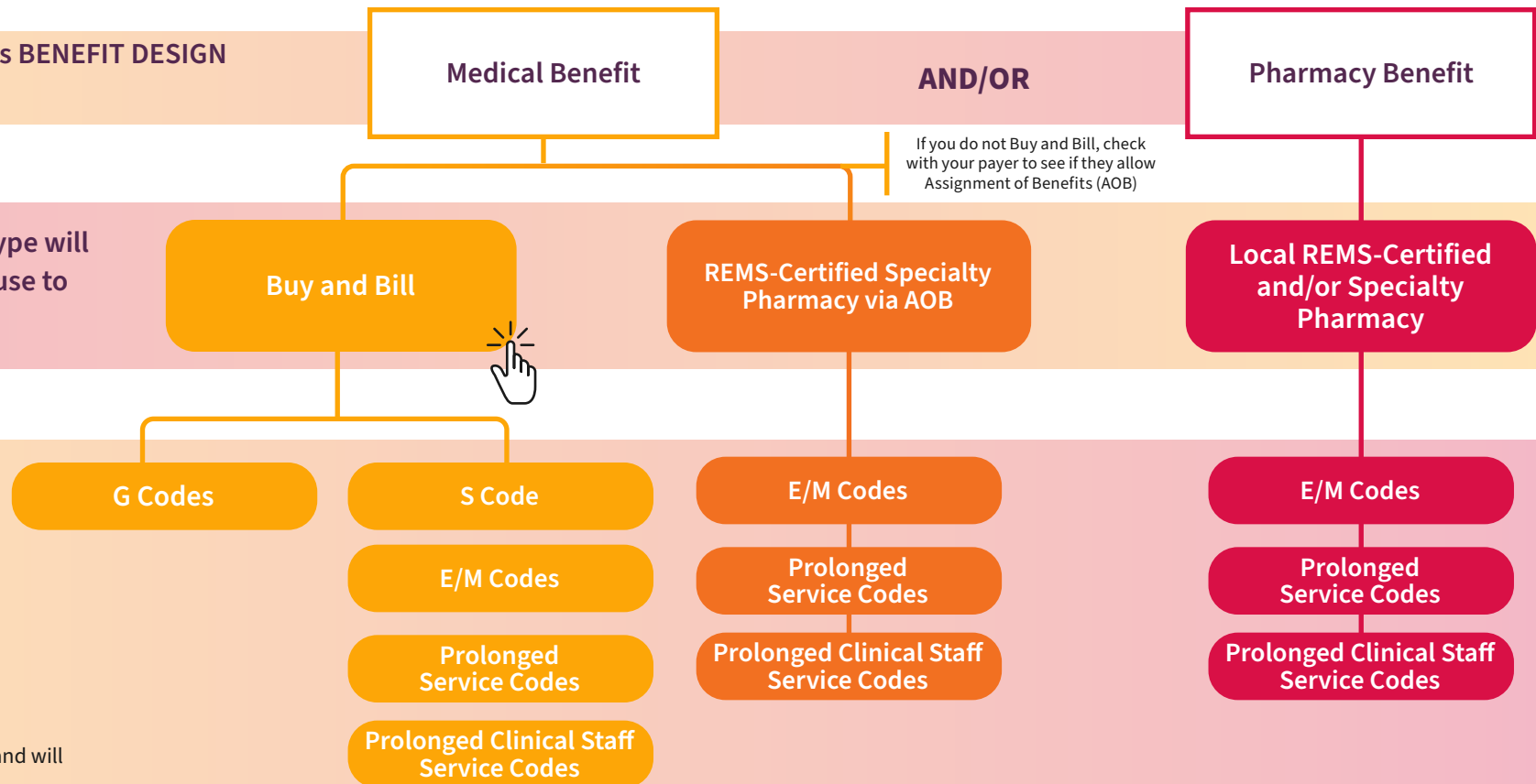# Determine Access for SPRAVATO®

- SPRAVATO® can be covered by medical or pharmacy benefit (or both), and coverage depends on local area and patient benefit design
- A patient's benefit design may impact your pathway for acquiring SPRAVATO®
- Procurement type will determine what codes are needed for billing and reimbursement based on individual payer policy

How does your patient's BENEFIT DESIGN cover SPRAVATO®?

Medical Benefit **AND/OR** Pharmacy Benefit

If you do not Buy and Bill, check with your payer to see if they allow Assignment of Benefits (AOB)

What PROCUREMENT type will your treatment center use to acquire SPRAVATO®?

Buy and Bill

REMS-Certified Specialty Pharmacy via AOB

Local REMS-Certified and/or Specialty Pharmacy

What codes does your payer policy dictate for REIMBURSEMENT of SPRAVATO®?

Buy and Bill		REMS-Certified Specialty Pharmacy via AOB	Local REMS-Certified and/or Specialty Pharmacy
G Codes	S Code	E/M Codes	E/M Codes
	E/M Codes	Prolonged Service Codes	Prolonged Service Codes
	Prolonged Service Codes	Prolonged Clinical Staff Service Codes	Prolonged Clinical Staff Service Codes
	Prolonged Clinical Staff Service Codes		

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Benefit Design

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Determine if the patient's insurance covers SPRAVATO® under the medical benefit and/or pharmacy benefit

Medical benefit provides coverage for provider-administered medications or those in an outpatient setting[1]

Pharmacy benefit provides coverage for prescription drugs and self-administered medications[1]

- Ensure your office collects the appropriate information from the patient's medical benefit card and separate pharmacy benefit card, if applicable
- Review any prior authorization requirements
- If coverage for SPRAVATO® is denied, ensure the other benefit was tried and consider submitting a Letter of Medical Necessity, if necessary

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Buy-and-Bill Procurement Method

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- **The buy-and-bill pathway is a method of procurement where a practice directly acquires product and bills for product and administration, and is typically covered under the medical benefit**
- **The buy-and-bill procurement method is a medical claim where the provider acquires the product and submits a claim after the provider purchases and administers the drug**
  - **Claims are made only "after" the drug has been administered**
- **Payer policy will dictate coding and may be:**
  - **Drug and Service billed separately (nonbundled)**
  - **Drug and Service billed together (bundled)**

🖐 Each button is clickable and will jump to specific sections.

DRUG AND SERVICE (NONBUNDLED)

| **S Code** | Drug Code | | **Prolonged Service Codes*** | If a physician's time spent with a patient for a SPRAVATO® encounter exceeds the time stated in the standard E/M codes, the code for prolonged service with or without direct patient contact may apply |

| **E/M Codes** | Service Code | | **Prolonged Clinical Staff Service Codes*** | 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, prolonged clinical staff service codes may be used |

DRUG AND SERVICE (BUNDLED)*

| **G Codes** 🖐 | Drug + Service Code |

*Prolonged service codes and other codes are subject to payer discretion.

Please check the plan policy to see if additional codes are required, including Place of Service Codes, Revenue Codes, and Code Modifiers.

The fact that a drug, device, procedure, or service is assigned an Healthcare Common Procedure Coding System (HCPCS) code and a payment rate does not imply coverage by the Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal Intermediaries (FIs)/Medicare Administrative Contractors (MACs) and/or state Medicaid administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage. It is important to note that payer requirements for SPRAVATO® administration coding may vary. Please contact your payers for specific coding policies.

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REMS-Certified Specialty Pharmacy Procurement Method

- **The specialty pharmacy procurement method is typically used when payers cover a drug under the patient's pharmacy benefit**

- **Under this model, SPRAVATO® may be delivered to the administering site via a REMS-certified pharmacy and cannot be billed by the administering provider**

- **Healthcare professional (HCP) observation and monitoring of the drug's administration is a billable service**

- **When reporting drug administration services associated with pharmacy-supplied drugs, consider reporting the services with the relevant evaluation and management codes**

🖱 Each button is clickable and will jump to specific sections.

SERVICE CODES

E/M Codes — Service Code

Prolonged Service Codes*
If a physician's time spent with a patient for a SPRAVATO® encounter exceeds the time stated in the standard E/M codes, the code for prolonged service with or without direct patient contact may apply

Prolonged Clinical Staff Service Codes*
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, prolonged clinical staff service codes may be used

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REMS-Certified Specialty Pharmacy via Assignment of Benefits (AOB) Procurement Method

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- The specialty pharmacy via AOB procurement method allows practices to acquire drugs through a pharmacy when the patient is only covered under the medical benefit

- This is typically accomplished using an agreement to allow a patient's insurance to pay the provider directly

- The pharmacy will dispense the drug while the practice bills for service

👆 Each button is clickable and will jump to specific sections.

SERVICE CODES

E/M Codes 👆 Service Code

Prolonged Service Codes*

If a physician's time spent with a patient for a SPRAVATO® encounter exceeds the time stated in the standard E/M codes, the code for prolonged service with or without direct patient contact may apply

Prolonged Clinical Staff Service Codes*

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, prolonged clinical staff service codes may be used

*Prolonged service codes and other codes are subject to payer discretion.

Please check the plan policy to see if additional codes are required, including Place of Service Codes, Revenue Codes, and Code Modifiers.

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S Codes

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- **Commercial payers utilize S codes to report drugs, services, and supplies**
- **CMS has established an HCPCS code to identify SPRAVATO® and is available to separately report SPRAVATO® to non-Medicare payers[2]*:**
  - **S0013 – Esketamine, nasal spray, 1 mg**
- **Each 28 mg spray device of SPRAVATO® represents 28 units of S0013**
- **These codes may not be used to bill services paid under any Medicare payment system**

| 56-mg dose 2 devices | S0013* | 56 units |
| 84-mg dose 3 devices | S0013* | 84 units |

SPRAVATO® HCPCS Billing Units for Non-Medicare Payers in a Physician Office or HOPD Using S0013 – Esketamine, nasal spray, 1 mg[†]

Number of 28-mg Spray Devices of SPRAVATO®	Total Milligrams (mg)	# of Billing Units Based on S0013 (1-mg SPRAVATO® per unit)
2	56	56
3	84	84

In lieu of S0013, payers may continue to require J3490 (Unclassified drugs). Use of this miscellaneous code will require submission of supporting information. Because requirements may vary by payer, it is advisable to check local requirements before submitting claims. **Unclassified codes are not drug-specific, thus always reported as 1 unit.**

HCPCS = Healthcare Common Procedure Coding System; HOPD = hospital outpatient department.

*This is a product-specific billing code, intended to facilitate commercial payer claims processing for SPRAVATO®.
[†]When coding for S0013, report the total number of 1-mg increments administered.

The fact that a drug, device, procedure, or service is assigned an Healthcare Common Procedure Coding System (HCPCS) code and a payment rate does not imply coverage by the Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal Intermediaries (FIs)/Medicare Administrative Contractors (MACs) and/or state Medicaid administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage. It is important to note that payer requirements for SPRAVATO® administration coding may vary. Please contact your payers for specific coding policies.

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G Codes

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- G codes are a type of HCPCS code established by CMS under Medicare Part B[3]
- SPRAVATO®-specific G codes incorporate both the provision of the drug and associated professional services
- These codes are required for billing Medicare on both physician office (CMS-1500) and hospital outpatient (CMS-1450) claims
- Selection of the appropriate code is dose dependent
  - G2082 is used to report SPRAVATO® doses of 56 mg or less
  - G2083 is used to report doses greater than 56 mg (ie, 84 mg, 3 devices)

56-mg dose 2 devices	G2082	1 unit
84-mg dose 3 devices	G2083	1 unit

G Codes Used to Report SPRAVATO® on Medicare and Non-Medicare Claims[3]

HCPCS Code	HCPCS Code Descriptor
G2082	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care provider and provision of **up to 56 mg of esketamine** nasal self-administration, includes 2 hours post-administration observation
G2083	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care provider and provision of **greater than 56 mg of esketamine** nasal self-administration, includes 2 hours post-administration observation.

Non-Medicare payers may choose to accept the G codes but are not required to do so.
The 2-hour post-administration period is consistent with REMS requirements and remains the same for both doses.
Medicare Advantage plans may choose to cover the product through a different benefit design. Confirm the plan's preferred benefit and the appropriate product and E/M codes that would be used.

Bundled G codes may only be billed when the product is acquired by an office through a specialty distributor. They may not be used if product is acquired from a specialty pharmacy

The fact that a drug, device, procedure, or service is assigned an Healthcare Common Procedure Coding System (HCPCS) code and a payment rate does not imply coverage by the Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal Intermediaries (FIs)/Medicare Administrative Contractors (MACs) and/or state Medicaid administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage. It is important to note that payer requirements for SPRAVATO® administration coding may vary. Please contact your payers for specific coding policies.

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Evaluation & Management (E/M) Codes

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- Evaluation and Management (E/M) codes are types of CPT® codes used for billing purposes and to describe visits and services that involve evaluating and managing patient health, including time spent with the patient[4]

- Time alone may be used to select the appropriate E/M codes*

- For coding purposes, time for these services is the total time on the date of the encounter†

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

- E/M codes only apply to Medicare when SPRAVATO® is obtained via specialty pharmacy and the HCP provides the associated services

- If the drug is purchased and billed by the provider, Medicare requires use of G codes (bundled drug and service)

For more information on E/M codes, please refer to the
Evaluation and Management (E/M) and Prolonged Service Codes Brochure

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*When time is used for reporting E/M service codes, the time defined in the code descriptors is used for selecting the appropriate level of service. The E/M services to which these guidelines apply require a face-to-face encounter with the physician or other qualified healthcare professionals and the patient and/or family/caregiver.

†It includes both the face-to-face time with the patient and/or family/caregiver and non-face-to-face time personally spent by the physician and/or other qualified healthcare professional(s) on the day of the encounter (includes time in activities that require the physician or other qualified healthcare professional and does not include time in activities normally performed by clinical staff).

‡Other than within the SPRAVATO®-specific G codes.

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

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Evaluation & Management (E/M) Codes (cont'd)

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Physician or other qualified health care professional time may include the following activities:

✔ Preparing to see the patient (eg, review of tests)

✔ Obtaining and/or reviewing separately obtained history

✔ Performing a medically appropriate examination and/or evaluation

✔ Counseling and educating the patient/family/caregiver

✔ Ordering medications, tests, or procedures

✔ Referring to and communicating with other healthcare professionals (when not separately reported)

✔ Documenting clinical information in the electronic or other health record

✔ Independently interpreting results (not separately reported) and communicating results to the patient/family/caregiver

✔ Care coordination (not separately reported)

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Important Safety Information

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Appendix

References

Evaluation & Management (E/M) Codes (cont'd)

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SPRAVATO® Administration-E/M Code Considerations by Patient[5]*†

E/M Code	Descriptor	Total Time Spent on Day of Encounter
New Patients		
99202	Medically appropriate history and/or examination Straightforward medical decision making	15 minutes must be met or exceeded
99203	Medically appropriate history and/or examination Low level of medical decision making	30 minutes must be met or exceeded
99204	Medically appropriate history and/or examination Moderate level of medical decision making	45 minutes must be met or exceeded
99205	Medically appropriate history and/or examination High level of medical decision making	60 minutes must be met or exceeded
Established Patients‡		
99212	Medically appropriate history and/or examination Straightforward medical decision making	10 minutes must be met or exceeded
99213	Medically appropriate history and/or examination Low level of medical decision making	20 minutes must be met or exceeded
99214	Medically appropriate history and/or examination Moderate level of medical decision making	30 minutes must be met or exceeded
99215	Medically appropriate history and/or examination High level of medical decision making	40 minutes must be met or exceeded

> E/M codes are selected based on the required level of medical decision making or total time spent by the qualified HCP on the day of the encounter and if the patient is new or established

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For 2024, the CPT Editorial Panel has made further refinements to the evaluation and management (E/M) visit codes. They have eliminated any references to specific time ranges and, instead, introduced a minimum time requirement when using time to select a level of E/M service.

Please note that you will see time ranges in the prolonged service code tables. These ranges are included because minimum time requirements are required in order to bill prolonged service codes.

*Payer requirements for SPRAVATO® administration coding may vary. Treatment centers should contact payers for specific policy information.

†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): Hospital outpatient clinic visit for assessment and management of a patient.[6]

‡CPT® code 99211 (sometimes called a "nurse visit") is not applicable to SPRAVATO® administration. This code does not require the presence of a physician or other qualified HCP, as presenting problems are usually minimal and services are typically performed in 5 minutes.

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

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Prolonged Service
With or Without Direct Patient Contact (physician time)

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- **If a physician's time spent with a patient for a SPRAVATO® encounter exceeds the time stated in the standard E/M codes, the code for prolonged service with or without direct patient contact may apply**
- **For prolonged service, Non-Medicare and Medicare payers can use either 99417 or G2212, while Medicare payers may use G2212***
- **Code 99417 is used only when the office or other outpatient service has been selected using time alone as the basis and only after the minimum time required to report the highest-level service (ie, 99205 or 99215) has been exceeded by 15 minutes[†]**
- **Medicare Advantage plans may cover the product through the pharmacy benefit, so when billing for observation time, use the appropriate codes for the services rendered. If needing to bill for prolonged time above 99205 or 99215, use G2212 instead of CPT 99417. Confirm all codes with each payer ahead of billing**

Prolonged Service Codes[5,7]

Codes	Code Descriptors
99417	Prolonged outpatient evaluation and management service(s) time with or without direct patient contact beyond the required time of the primary service when the primary service level has been selected using total time, each 15 minutes of total time. (List separately in addition to code of the outpatient E/M service)
G2212	Prolonged office or other outpatient evaluation and management service(s) beyond the maximum required time of the primary procedure which has been selected using total time on the date of the primary service; each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (List separately in addition to CPT codes 99205, 99215 for office or other outpatient evaluation and management services).

Neither 99417 or G2212 may be reported with SPRAVATO® G codes (G2082 and G2083)

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

[†]99417 is used to report prolonged total time (ie, combined time with or without direct patient contact) provided by the physician or other qualified healthcare professional on the date of office or other outpatient services (ie, 99205, 99215). Time spent with the patient must be clearly documented in the medical record.

Please see additional Important Safety Information, and full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO®. Provide the Medication Guide to your patients and encourage discussion.
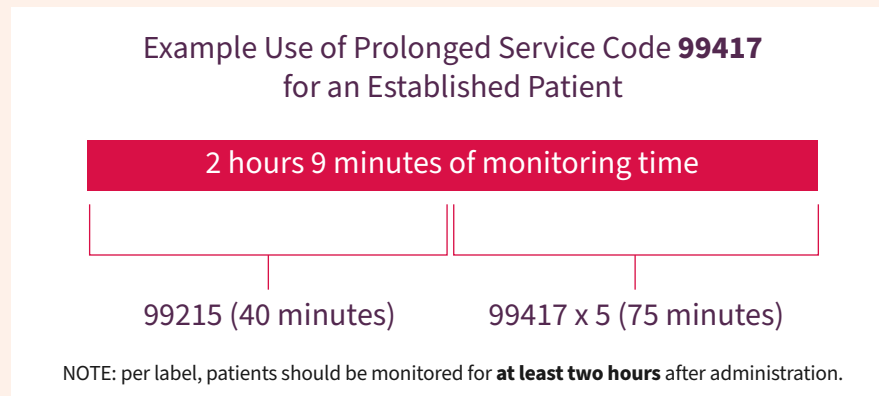
Important Safety Information   SPRAVATO withMe
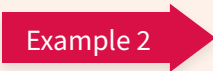
Appendix   References

Prolonged Service
With or Without Direct Patient Contact (physician time) (cont'd)

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- **Do not report 99417 or G2212 on the same date of service as the Prolonged Clinical Staff Service codes (99415, 99416)**
- **Do not report 99417 or G2212 for any time unit less than 15 minutes**

Use of Prolonged Service Code (99417)

Total Duration	Code(s)
NEW PATIENTS (use with 99205)	
Less than 75 minutes	Not reported separately
75-89 minutes	99205 x1 and 99417 x1
90-104 minutes	99205 x1 and 99417 x2
105 minutes or more	99205 x1 and 99417 x3 or more for each additional 15 minutes
ESTABLISHED PATIENTS (use with 99215)	
Less than 55 minutes	Not reported separately
55-69 minutes	99215 x1 and 99417 x1
70-84 minutes	99215 x1 and 99417 x2
85 minutes or more	99215 x1 and 99417 x3 or more for each additional 15 minutes

Use of Prolonged Service Code (G2212)

Total Duration	Code(s)
NEW PATIENTS (use with 99205)	
60-74 minutes	99205
89-103 minutes	99205 x1 and G2212 x1
104-118 minutes	99205 x1 and G2212 x2
119 minutes or more	99205 x1 and G2212 x3 or more for each additional 15 min
ESTABLISHED PATIENTS (use with 99215)	
40-54 minutes	99215
69-83 minutes	99215 x1 and G2212 x1
84-98 minutes	99215 x1 and G2212 x2
99 minutes or more	99215 x1 and G2212 x3 or more for each additional 15 min

Did you check with the patient's health plan to see which prolonged codes are included in their contract?

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[**Time-Based E/M and Prolonged Service Code Examples**]

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

[Important Safety Information] [SPRAVATO withMe]
[Appendix] [References]

Time-Based E/M and Prolonged Service Code Example 1*

Here is an example of a patient's SPRAVATO® treatment session based on physician or other qualified health care professional time

Example Use of Prolonged Service Code **99417**
for an Established Patient

2 hours 9 minutes of monitoring time

99215 (40 minutes)   99417 x 5 (75 minutes)

NOTE: per label, patients should be monitored for **at least two hours** after administration.

Sample CMS-1500 claim form for SPRAVATO® observation and monitoring

a 24. A.	DATE(S) OF SERVICE		B. PLACE OF SERVICE	C. EMG	**b** D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS
	From MM DD YY	To MM DD YY						
1	01 01 23	01 01 23			99215			1
2	01 01 23	01 01 23			99417			5 **c**
3								
4								

a **Item 24A:** The total physician or other qualified health care professional time must occur within the same date; the date of the SPRAVATO® treatment session should be reported for each code

b **Item 24D:** Report 99215 after 40 minutes has been met or exceeded, and report each unit of 99417 after each additional 15-minute increment

c **Item 24G:** Since the total HCP time exceeds 15 minutes beyond the minimum time within the range for 99215, report 5 units of 99417 in addition to the 1 unit of 99215

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

The above example is for illustrative purposes only. **It is not intended to represent a recommended coding approach. It represents one of many coding scenarios for the professional services related to SPRAVATO® treatment.** Actual times for patient and practice will vary. Total time for each patient receiving SPRAVATO® treatment may differ based on dosing schedule and observation activities performed for each individual patient. Please refer to the full Prescribing Information for more administration and observation details.

The fact that a drug, device, procedure, or service is assigned an Healthcare Common Procedure Coding System (HCPCS) code and a payment rate does not imply coverage by the Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal Intermediaries (FIs)/Medicare Administrative Contractors (MACs) and/or state Medicaid administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage. It is important to note that payer requirements for SPRAVATO® administration coding may vary. Please contact your payers for specific coding policies.

Example 2

Appendix   References

Time-Based E/M and Prolonged Service Code Example 2*

Here is an example of a patient's SPRAVATO® treatment session based on physician or other qualified health care professional time

Example Use of Prolonged Service Code **99417** for an Established Patient

1 hour and 9 minutes of monitoring time

99215 (40 minutes)   99417 x 1 (15 minutes)

NOTE: per label, patients should be monitored for **at least two hours** after administration.

Sample CMS-1500 claim form for SPRAVATO® observation and monitoring

a — **Back to Example 1**
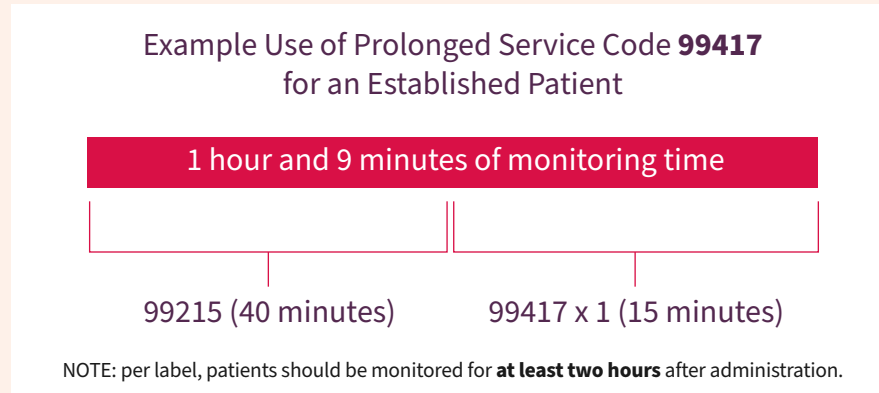
24. A. DATE(S) OF SERVICE						B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS
From MM	DD	YY	To MM	DD	YY						
1 01	01	23	01	01	23			99215			1
2 01	01	23	01	01	23			99417			1
3											
4											

a **Item 24A:** The total physician or other qualified health care professional time must occur within the same date; the date of the SPRAVATO® treatment session should be reported for each code

b **Item 24D:** Report 99215 after 40 minutes has been met or exceeded, and report each unit of 99417 after each additional 15-minute increment

c **Item 24G:** Since the total HCP time exceeds 15 minutes beyond the minimum time within the range for 99215, report 1 unit of 99417 in addition to the 1 unit of 99215

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

The above example is for illustrative purposes only. **It is not intended to represent a recommended coding approach. It represents one of many coding scenarios for the professional services related to SPRAVATO® treatment.** Actual times for patient and practice will vary. Total time for each patient receiving SPRAVATO® treatment may differ based on dosing schedule and observation activities performed for each individual patient. Please refer to the full Prescribing Information for more administration and observation details.

The fact that a drug, device, procedure, or service is assigned an Healthcare Common Procedure Coding System (HCPCS) code and a payment rate does not imply coverage by the Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal Intermediaries (FIs)/Medicare Administrative Contractors (MACs) and/or state Medicaid administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage. It is important to note that payer requirements for SPRAVATO® administration coding may vary. Please contact your payers for specific coding policies.

Appendix   References

Prolonged Clinical Staff Services With Physician Supervision*

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- **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***

- **The physician must be present to provide direct supervision of the clinical staff, and both the designated E/M service and the prolonged service(s) are reported**

- **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[†]**

- **The highest total time in the time ranges of the code descriptions is used in defining when prolonged service time begins[‡]**

SPRAVATO® Prolonged Clinical Staff Service With Physician Supervision Codes[5]

Prolonged Service Codes	Code Descriptors
99415	Prolonged clinical staff service (the service beyond the highest time in the range of total time of the service) during an evaluation and management service in the office or outpatient setting, direct patient contact with physician supervision; first hour (List separately in addition to code for outpatient E/M service)
99416	Each additional 30 minutes (List separately in addition to code for prolonged service)

Additional Considerations

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

[†]Prolonged service of fewer than 30 minutes' total duration on a given date is not separately reported because the clinical staff time involved is included in the E/M codes.

[‡]For example, prolonged clinical staff service for 99214 begins after 39 minutes, and 99415 is not reported until at least 69 minutes of total face-to-face clinical staff time has been performed.

The fact that a drug, device, procedure, or service is assigned an Healthcare Common Procedure Coding System (HCPCS) code and a payment rate does not imply coverage by the Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal Intermediaries (FIs)/Medicare Administrative Contractors (MACs) and/or state Medicaid administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage. It is important to note that payer requirements for SPRAVATO® administration coding may vary. Please contact your payers for specific coding policies.

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

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Appendix   **References**

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Prolonged Clinical Staff Services With Physician Supervision*

Additional Considerations*

- When face-to-face time is noncontinuous, use only the face-to-face time provided to the patient by the clinical staff
- Code 99416 is used to report each additional 30 minutes of prolonged clinical staff service beyond the first hour
- Time spent with the patient must be clearly documented in the medical record
- Prolonged Clinical Staff Service codes may not be reported with the SPRAVATO® G codes (G2082 and G2083)
- 99415 and 99416 may not be reported for more than 2 simultaneous patients
- Do not report 99415 or 99416 in conjunction with 99417 or G2212[7]

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

The fact that a drug, device, procedure, or service is assigned an Healthcare Common Procedure Coding System (HCPCS) code and a payment rate does not imply coverage by the Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal Intermediaries (FIs)/Medicare Administrative Contractors (MACs) and/or state Medicaid administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage. It is important to note that payer requirements for SPRAVATO® administration coding may vary. Please contact your payers for specific coding policies.

*Payer re...
†Prolong...
‡For exa...
clinical staff time has been performed.

The fact that a drug, device, procedure, or service is assigned an Healthcare Common Procedure Coding System (HCPCS) code and a payment rate does not imply coverage by the Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal Intermediaries (FIs)/Medicare Administrative Contractors (MACs) and/or state Medicaid administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage. It is important to note that payer requirements for SPRAVATO® administration coding may vary. Please contact your payers for specific coding policies.

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Filing Healthcare Claims

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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 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 information from the National Uniform Claim Committee, available at: https://www.cms.gov/Medicare/Billing/ElectronicBillingEDITrans/1500

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 and 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

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

Example 1: Sample CMS-1500 Claim Form
Coding for Medicare and Other Payers That Accept G Codes

Example 2: Sample CMS-1500 Claim Form
Coding for Non-Medicare Payers That Accept the S Code

Example 3: Sample CMS-1450 Claim Form
Coding for Medicare and Other Payers That Accept G Codes

Determine Access for SPRAVATO®

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Sample CMS-1500 Claim Form: Coding for Medicare and Other Payers That Accept G Codes

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

1 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.

2 Item 24B: List the appropriate place of service code (POS).
11-Office

3 Item 24D: Indicate appropriate HCPCS code and modifiers, as required by payer.

For Medicare claims, and non-Medicare payers that require the G codes, enter the applicable code based on the dose of SPRAVATO®:

For 56 mg or less
G2082 – Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified healthcare provider and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation.

For more than 56 mg (ie, 84 mg)
G2083 – Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified healthcare provider and provision of greater than 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation.
Payer requirements for coding may vary.*

4 Item 24E: Refer to the diagnosis for this service (see box 21). Enter only 1 diagnosis pointer per line.

5 Item 24G: Enter 1 unit for the G code as it describes both drug and related services.

*For any questions, please contact your local Patient Access Specialist.

The above example reflects the most common scenario based on real-world claims data from Q1 2021 through Q2 2022. However, it is important to note that there may be instances where the level of coding is different than the example provided. Thus, this example should serve as a general guide. Healthcare professionals should use their judgment and follow all applicable guidelines, regulations, and policies when submitting claims for reimbursement.

The fact that a drug, device, procedure, or service is assigned an Healthcare Common Procedure Coding System (HCPCS) code and a payment rate does not imply coverage by the Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal Intermediaries (FIs)/Medicare Administrative Contractors (MACs) and/or state Medicaid administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage. It is important to note that payer requirements for SPRAVATO® administration coding may vary. Please contact your payers for specific coding policies.

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

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

1 **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.

2 **Item 24B:** List the appropriate place of service code (POS). 11-Office

3 **Item 24D:** Indicate appropriate HCPCS code and modifiers, as required by payer.

For Medicare claims, and non-Medicare payers that require the G codes, enter the applicable code based on the dose of SPRAVATO®:

For 56 mg or less
G2082 – Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified healthcare provider and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation.

For more than 56 mg (ie, 84 mg)
G2083 – Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified healthcare provider and provision of greater than 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation.

Payer requirements for coding may vary.*

4 **Item 24E:** Refer to the diagnosis for this service (see box 21). Enter only 1 diagnosis pointer per line.

5 **Item 24G:** Enter 1 unit for the G code as it describes both drug and related services.

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Sample CMS-1500 Claim Form: Coding for Non-Medicare Payers That Accept the S Code

Spravato® (esketamine) 28 mg nasal spray

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

1 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.

2 Item 24A: If line-item NDC information is required, it will be entered in the shaded portion of Item 24A.[8] For example:

3 Item 24B: List the appropriate place of service code (POS). 11-Office

4 Item 24D: Indicate appropriate CPT®, HCPCS codes, and modifiers, if required.
SPRAVATO®
S0013 – Esketamine, nasal spray, 1 mg
Observation and Monitoring for SPRAVATO® Administration
99202-99205 – 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
99415, 99416, 99417, G2212 – Prolonged services
Payer requirements for observation and monitoring coding may vary.*

5 Item 24E: Refer to the diagnosis for this service (see Item 21). Enter only 1 diagnosis pointer per line.

6 Item 24G: Drug
S0013 – Enter number of HCPCS units based on dose administered (1 mg = 1 unit)
56 mg = 56 units   84 mg = 84 units
Observation and Monitoring for SPRAVATO® Administration
Report appropriate E&M code; enter 1 unit
Report appropriate prolonged service code(s); enter units as applicable

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*For any questions, please contact your local Patient Access Specialist.

The above example reflects the most common scenario based on real-world claims data from Q1 2021 through Q2 2022. However, it is important to note that there may be instances where the level of coding is different than the example provided. Thus, this example should serve as a general guide. Healthcare professionals should use their judgment and follow all applicable guidelines, regulations, and policies when submitting claims for reimbursement.

The fact that a drug, device, procedure, or service is assigned an Healthcare Common Procedure Coding System (HCPCS) code and a payment rate does not imply coverage by the Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal Intermediaries (FIs)/Medicare Administrative Contractors (MACs) and/or state Medicaid administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage. It is important to note that payer requirements for SPRAVATO® administration coding may vary. Please contact your payers for specific coding policies.

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

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

1 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.

2 Item 24A: If line-item NDC information is required, it will be entered in the shaded portion of Item 24A.[13]
For example:

3 Item 24B: List the appropriate place of service code (POS) 11-Office

4 Item 24D: Indicate appropriate CPT®, HCPCS codes, and modifiers, if required.
SPRAVATO®
S0013 – Esketamine, nasal spray, 1 mg
Observation and Monitoring for SPRAVATO® Administration
99202-99205 – 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
99415, 99416, 99417, G2212 – Prolonged services
Payer requirements for observation and monitoring coding may vary.*

5 Item 24E: Refer to the diagnosis for this service (see Item 21). Enter only 1 diagnosis pointer per line.

6 Item 24G: Drug
S0013 – Enter number of HCPCS units based on dose administered (1 mg = 1 unit)
56 mg = 56 units   84 mg = 84 units
Observation and Monitoring for SPRAVATO® Administration
Report appropriate E&M code; enter 1 unit
Report appropriate prolonged service code(s); enter units as applicable

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SPRAVATO® administration coding may vary. Please contact your payers for specific coding policies.

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

Important Safety Information | SPRAVATO withMe | Appendix | References

Once a decision has been made to prescribe SPRAVATO®

SPRAVATO withMe can help navigate access and affordability processes efficiently so you can focus on your patients

Spravato®
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28 mg nasal spray

Learn how to minimize delays in the access process with the help of SPRAVATO withMe Case Managers.

They will provide you with educational support to help your patients navigate the process and get them started on treatment quickly.

Benefits investigations for medical and pharmacy coverage

Prior authorization and appeals support

Coding and reimbursement support

Real-time notifications via a custom portal view with updates on your individual patients and accounts

A progress tracker that provides visibility to your patients' access status

Patient affordability support

Confirmation on which pharmacies accept your patients' insurance

SPRAVATO withMe Care Navigators — dedicated support for your patients at every step of their treatment journey. Your adult patients prescribed SPRAVATO®, regardless of their insurance, will have access to SPRAVATO withMe Care Navigators, healthcare professionals* with mental health experience who can offer supplemental one-to-one support.

*Care Navigators do not provide medical advice.

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

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

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

Important Safety Information

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Appendix

References

Resources

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Acquiring SPRAVATO®

- [Pathway to Acquire SPRAVATO® Through an Authorized Specialty Distributor](#)
- [Pathway to Acquire SPRAVATO® Through a National Specialty Pharmacy](#)
- [Complete List of Authorized SPRAVATO® Full-Line Wholesalers and Specialty Distributors](#)

Coding and Reimbursement

- [Drug & Procedure Coding Overview for SPRAVATO®](#)
- [Evaluation and Management (E/M) and Prolonged Service Codes Brochure](#)
- [Healthcare Provider Exceptions & Appeals Guide](#)

Patient Support

- [SPRAVATO withMe](#)

Affordability

- [Savings Program](#)

Additional Resources

- [The Johnson & Johnson Patient Assistance Foundation, Inc.](#)

Important Safety Information

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Appendix A: ICD-10-CM Diagnosis Codes

- ICD-10 is a medical coding system used to classify and group diagnoses, symptoms, and procedures and uses 3 to 7 alpha and numeric characters to achieve the greatest level of specificity

- There is no ICD-10-CM code for treatment-resistant depression (TRD) or major depressive disorder (MDD) with acute suicidal ideation or behavior

ICD-10-CM Diagnosis Codes for Consideration[9]*†

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

Please check with the patient's insurer to understand diagnosis reporting requirements when billing for SPRAVATO®

*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.

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Appendix B: National Drug Code (NDC)

- **The NDC is a unique number that identifies a drug's labeler, product, and trade package size**
- **The NDC unit of measure is determined by how the drug is supplied**
- **The number of NDC units dispensed is based on the packaging and numeric quantity administered to the patient**

SPRAVATO® NDC and Units[10]*

10-Digit NDC	11-Digit NDC	Description	Dose to Be Billed	Packaging	NDC Unit of Measure	NDC Units
50458-028-02	50458-0028-02	Dose Kit: Unit-dose carton containing two 28-mg nasal spray devices (56-mg total dose)	56 mg	56-mg Dose Kit	UN	2
50458-028-03	50458-0028-03	84-mg Dose Kit: Unit-dose carton containing three 28-mg nasal spray devices (84-mg total dose)	84 mg	84-mg Dose Kit	UN	3

Examples
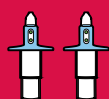
56-mg dose 2 devices

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 UN2
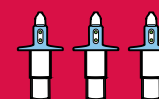
84-mg dose 3 devices

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 UN3

*Payer policies for NDC entries may vary.

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Appendix C: Place of Service Codes

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Place of Service (POS) Codes

- The POS code provides setting information necessary to appropriately pay professional service claims and is required on all claims for professional services (billed on CMS-1500)
- The POS is the location of the provider's face-to-face encounter with the beneficiary

Place of Service Codes[11]

Code	Name	Descriptor
11	Office	Location, other than a hospital, skilled nursing facility, military treatment facility, community health center, state or local public health clinic, or intermediate care facility, where the healthcare provider 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.

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Appendix D: Revenue Codes and Code Modifiers

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Revenue Codes

- Many payers require use of American Hospital Association revenue codes to bill for services provided in hospital outpatient departments and assign costs to broad categories of hospital revenue centers
- Codes used for Medicare claims are available from Medicare contractors

Revenue Codes That May Be Applicable to CMS-1450 Claims for Drugs and Their Administration[12]

Code	Description
0510	Clinic, General
0513	Psychiatric, clinic
0636	Pharmacy, drugs requiring detailed coding

Code 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

Summary of Code Modifiers[13]

Modifier	Description	Indication and Placement	CMS-1500 (Item 24-D)	CMS-1450 (Box 44)
CG	Policy criteria applied	To be reported with HCPCS codes as required by payer policy	Carrier discretion	Carrier discretion
PO*	Services, procedures, and/or surgeries furnished at excepted off-campus provider-based outpatient departments	To be reported with every HCPCS code for all hospital items and services furnished in an excepted off-campus, PBD of a hospital	N/A	❗ Required by Medicare
PN*	Nonexcepted service provided at an off-campus, outpatient, PBD of a hospital	To be reported on each claim line with each nonexcepted item and service furnished in a nonexcepted, off-campus, PBD of a hospital campus, outpatient, PBD of a hospital	N/A	❗ Required by Medicare

PBD=provider-based department.

*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."

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Appendix E: Summary of Potential Coding Scenarios for SPRAVATO® Treatment in a Physician's Office

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Payer	Benefit Type	Site of Care	Procurement	Activity	Potential Coding Options	Potential Applicable Add-on Codes
Non-Medicare	Medical	Physician Office	Buy and Bill	Drug and Service	**Drug:** S0013 or J3490 **Service:** (E/M Codes) 99202-99205; 99212-99215	**Prolonged Clinical Staff Service:** 99415, 99416 **Prolonged Service:** 99417, G2212
Non-Medicare	Medical	Physician Office	Buy and Bill	Drug and Service	**Drug and Service:** G2082 or G2083	**Payer discretion**
Non-Medicare	Pharmacy	Physician Office	REMS-Certified Pharmacy	Service	**Service:** (E/M Codes) 99202-99205; 99212-99215	**Prolonged Clinical Staff Service:** 99415, 99416 **Prolonged Service:** 99417, G2212
Non-Medicare	Medical	Physician Office	REMS-Certified Pharmacy via Assignment of Benefits (AOB)	Service	**Service:** (E/M Codes) 99202-99205; 99212-99215	**Prolonged Clinical Staff Service:** 99415, 99416 **Prolonged Service:** 99417, G2212
Medicare	Medical	Physician Office	Buy and Bill	Drug and Service	**Drug and Service:** G2082 or G2083	N/A
Medicare	Pharmacy	Physician Office	REMS-Certified Pharmacy	Service	**Service:** (E/M Codes) 99202-99205; 99212-99215	**Prolonged Clinical Staff Service:** 99415, 99416 **Prolonged Service:** G2212
Medicare	Medical	Physician Office	REMS-Certified Pharmacy via Assignment of Benefits (AOB)	Service	**Service:** (E/M Codes) 99202-99205; 99212-99215	**Prolonged Clinical Staff Service:** 99415, 99416 **Prolonged Service:** G2212

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Appendix F: Summary of Potential Coding Scenarios for SPRAVATO® Treatment in the Hospital Outpatient Office Department (HOPD)

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Payer	Benefit Type	Site of Care	Procurement	Activity	Potential Coding Options	Potential Applicable Add-on Codes
Non-Medicare	Medical	Hospital Outpatient Department	Buy and Bill	Drug and Service	**Drug and Service:** G2082 or G2083	**Payer discretion**
Non-Medicare	Medical	Hospital Outpatient Department	Buy and Bill	Drug and Service	**Drug:** S0013 or J3490 **Service:** (E/M Codes) 99202-99205; 99212-99215	**Prolonged Clinical Staff Service:** 99415, 99416 **Prolonged Service:** 99417, G2212
Non-Medicare	Pharmacy	Hospital Outpatient Department	REMS-Certified Pharmacy	Service	**Service:** (E/M Codes) 99202-99205; 99212-99215	**Prolonged Clinical Staff Service:** 99415, 99416 **Prolonged Service:** 99417, G2212
Non-Medicare	Medical	Hospital Outpatient Department	REMS-Certified Pharmacy via Assignment of Benefits (AOB)	Service	**Service:** (E/M Codes) 99202-99205; 99212-99215	**Prolonged Clinical Staff Service:** 99415, 99416 **Prolonged Service:** 99417, G2212
Medicare	Medical	Hospital Outpatient Department	Buy and Bill	Drug and Service	**Drug and Service:** G2082 or G2083	**N/A**
Medicare	Pharmacy	Hospital Outpatient Department	REMS-Certified Pharmacy	Service	**Service:** G0463	**N/A**
Medicare	Medical	Hospital Outpatient Department	REMS-Certified Pharmacy via Assignment of Benefits (AOB)	Service	**Service:** G0463	**N/A**

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Appendix G: Sample CMS-1450 Claim Form: Coding for Medicare and Other Payers That Accept G Codes

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

1 **Box 42:** List revenue code.

2 **Box 43:** Enter narrative description for corresponding revenue code (eg, clinic visit).

3 **Box 44:** For Medicare claims, and non-Medicare payers that require the G codes, enter the applicable code based on the dose of SPRAVATO®:

For 56 mg or less
G2082 – Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified healthcare provider and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation.

For more than 56 mg (ie, 84 mg)
G2083 – Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified healthcare provider and provision of greater than 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation.

Payer requirements for coding may vary.*

Modifiers: PO or PN modifiers must be reported by all off-campus HOPDs. 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.

4 **Box 46:** Enter 1 unit for the G code as it describes both drug and related services.

5 **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.

*For any questions, please contact your local Patient Access Specialist.

The above example reflects the most common scenario based on real-world claims data from Q1 2021 through Q2 2022. However, it is important to note that there may be instances where the level of coding is different than the example provided. Thus, this example should serve as a general guide. Healthcare professionals should use their judgment and follow all applicable guidelines, regulations, and policies when submitting claims for reimbursement.

The fact that a drug, device, procedure, or service is assigned an Healthcare Common Procedure Coding System (HCPCS) code and a payment rate does not imply coverage by the Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal Intermediaries (FIs)/Medicare Administrative Contractors (MACs) and/or state Medicaid administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage. It is important to note that payer requirements for SPRAVATO® administration coding may vary. Please contact your payers for specific coding policies.

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

1 **Box 42:** List revenue code.

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS
0513	Psychiatric clinic	G2083	01-01-23	1

2 **Box 43:** Enter narrative description for corresponding revenue code (eg, clinic visit).

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS
0513	Psychiatric clinic	G2083	01-01-23	1

3 **Box 44:** For Medicare claims, and non-Medicare payers that require the G codes, enter the applicable code based on the dose of SPRAVATO®:

For 56 mg or less
G2082 – Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified healthcare provider and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation.

For more than 56 mg (ie, 84 mg)
G2083 – Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified healthcare provider and provision of greater than 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation.

Payer requirements for coding may vary.*

Modifiers: PO or PN modifiers must be reported by all off-campus HOPDs. 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.

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS
0513	Psychiatric clinic	G2083	01-01-23	1

4 **Box 46:** Enter 1 unit for the G code as it describes both drug and related services.

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS
0513	Psychiatric clinic	G2083	01-01-23	1

5 **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.

63 TREATMENT AUTHORIZATION CODES	64 DOCUMENT CONTROL NUMBER
0513	

encourage discussion.

Appendix H: Letter of Medical Necessity

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28 mg nasal spray

- A sample **Letter of Medical Necessity template** is shown here.
- Please find additional information in the **Exceptions & Appeals guide**.

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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SAMPLE

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Appendix I: Formulary Exception Request

- A sample **Formulary Exception Request template** is shown here.

- Please find additional information in the **Exceptions & Appeals guide**.

Sample Format: Formulary Exception Request

[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 J: Ordering Information

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If you are procuring SPRAVATO® using buy and bill, please contact an authorized specialty distributor

Specialty Distributor	Phone Number	Fax	Website
Besse Medical	1-800-543-2111	1-800-543-8695	www.besse.com
Cardinal Health Specialty Distribution	1-877-488-3572	1-614-553-6301	N/A
CuraScript Specialty Distribution	1-877-599-7748	1-800-862-6208	www.curascriptsd.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.

If you are procuring SPRAVATO® through a specialty pharmacy, please contact an authorized full-line wholesaler

Full-line Wholesalers	Phone Number	Fax	Website
Cencora	1-844-222-2273	1-888-292-9774	https://www.cencora.com
Cardinal Health	1-800-926-3161	—	www.cardinalhealth.com
McKesson Pharmaceutical Distribution	1-855-625-7385	—	www.mckesson.com
Mutual Drug	1-800-804-0153	1-919-598-4991	www.mutualdrug.com
Smith Drug	1-864-582-1216	1-864-607-4750	www.smithdrug.com
Value Drug	1-800-252-3786	—	www.valuedrugco.com

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Appendix K: Select Glossary

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Term	Definition
Assignment of Benefits	Specialty pharmacy via assignment of benefits (AOB) acquisition method allows practices to acquire drugs through a pharmacy when the patient is only covered under the medical benefit.
Buy and Bill	Buy and bill is a procurement pathway where a practice directly acquires product and bills for product and administration and is typically covered under the medical benefit.
CMS-1500 Claim 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 requirement for electronic submission of claims.
CMS-1450 Claim Form	CMS-1450, also known as the UB-04, is a uniform institutional provider bill suitable for use in billing multiple third-party payers and is the basic form prescribed by CMS for the Medicare and Medicaid programs for claims from hospitals, including HOPDs.
Evaluation & Management (E/M) Codes	Evaluation and Management (E/M) codes are types of CPT codes used for billing purposes and describe visits and services that involve evaluating and managing patient health, including time spent with the patient.
G Codes	G codes are types of HCPCS codes established by CMS under Medicare Part B. For SPRAVATO®, G codes cover both the drug and treatment visit.
ICD-10 Codes	The ICD tenth revision (ICD-10) is a code system that contains codes for diseases, signs and symptoms, abnormal findings, circumstances, and external causes of diseases or injury.
J Codes	J codes are types of HCPCS codes used for billing specific non-oral medications, such as chemotherapy, inhalation products, and immunosuppressant drugs, as well as a handful of other non-self-administered oral medications and services.
Medical Benefit	Medical benefit coverage is used for provider-administered medications or those in an outpatient setting.
Medical Necessity	Medical necessity refers to a decision by a health plan that a treatment, test, or procedure is necessary for a patient's health or to treating a diagnosed medical problem.
NDC Codes	NDC codes are unique numbers that identify a drug's labeler, product, and trade package size.
Pharmacy Benefit	Pharmacy benefit provides coverage for prescription drugs and self-administered medications.
Prior Authorization	Prior authorization is a utilization management tool used by insurances to determine whether to cover a specific drug or service.
S Codes	S codes are types of HCPCS codes used by non-Medicare payers for supplies and services. They may be temporary codes until finalized codes are established.
Specialty Pharmacy	Specialty pharmacy is an accredited pharmacy that provides medications for complex medical conditions, such as cancer, rheumatoid arthritis, and multiple sclerosis.

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Appendix | References

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Important Safety Information (cont'd)

Spravato®
(esketamine) CIII
28 mg nasal spray

CONTRAINDICATIONS
SPRAVATO® is contraindicated in patients with:

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

WARNINGS AND PRECAUTIONS

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

Because of the possibility of delayed or prolonged sedation, patients must be monitored by a healthcare provider for at least 2 hours at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave the healthcare setting.

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

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

Because of the risks of dissociation, patients must be monitored by a healthcare provider for at least 2 hours at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave the healthcare setting.

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

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

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

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

Important requirements of the SPRAVATO® REMS include the following:

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

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Important Safety Information (cont'd)

Spravato®
(esketamine) Ⅲ
28 mg nasal spray

- 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 doses. Increases in BP peak approximately 40 minutes after SPRAVATO® administration and last approximately 4 hours.

Approximately 8% 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 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.

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Important Safety Information (cont'd)

Spravato® (esketamine) CⅢ
28 mg nasal spray

Cognitive Impairment

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

Long-Term Cognitive Impairment: Long-term cognitive and memory impairment have been reported with repeated ketamine misuse or abuse. No adverse effects of SPRAVATO® nasal spray on cognitive functioning were observed in a one-year open-label safety study; however, the long-term cognitive effects of SPRAVATO® have not been evaluated beyond one year.

Impaired Ability to Drive and Operate Machinery: Before SPRAVATO® administration, instruct patients not to engage in potentially hazardous activities requiring complete mental alertness and motor coordination, such as driving a motor vehicle or operating machinery, until the next day following a restful sleep. Patients will need to arrange transportation home following treatment with SPRAVATO®.

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

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

PREGNANCY, EMBRYO-FETAL TOXICITY, AND LACTATION

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

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

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

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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

The most common adverse reactions with SPRAVATO® plus oral antidepressant (incidence ≥5% and at least twice that of placebo nasal spray plus oral antidepressant) were:

TRD: 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: dissociation, dizziness, sedation, blood pressure increased, hypoesthesia, vomiting, euphoric mood, and vertigo.

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

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Spravato®
(esketamine) Ⅲ
28 mg nasal spray

For more information, please contact a SPRAVATO withMe
Case Manager at **1-844-4S-WITHME (1-844-479-4846)**.

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