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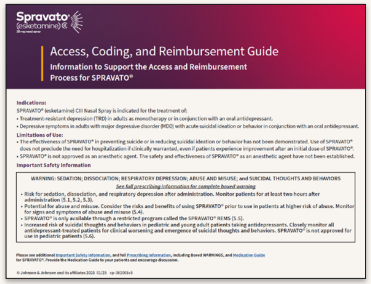
Billing and Coding for SPRAVATO®:

Evaluation and Management (E/M) and Prolonged Service Codes

For Physician Offices and Outpatient Facilities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Access, Coding, and Reimbursement Guide

Information to Support the Access and Reimbursement Process for SPRAVATO®

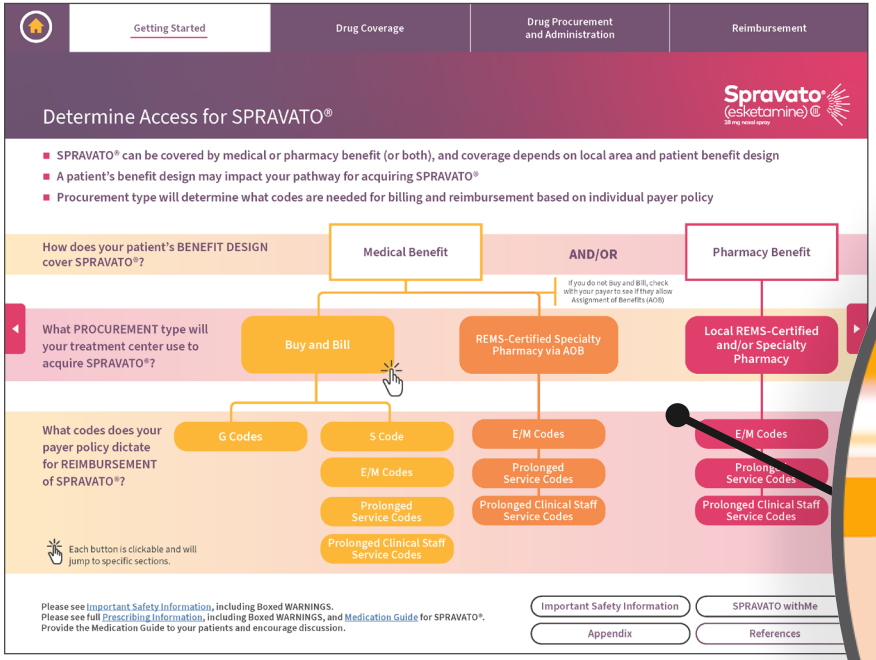
SPRAVATO® treatment requires coverage for the drug as well as administration and monitoring. This resource provides a billing and coding overview for the administration and monitoring portion of SPRAVATO® treatment and is intended to be used as a supplementary resource after you have reviewed and familiarized yourself with the Access, Coding, and Reimbursement Guide.

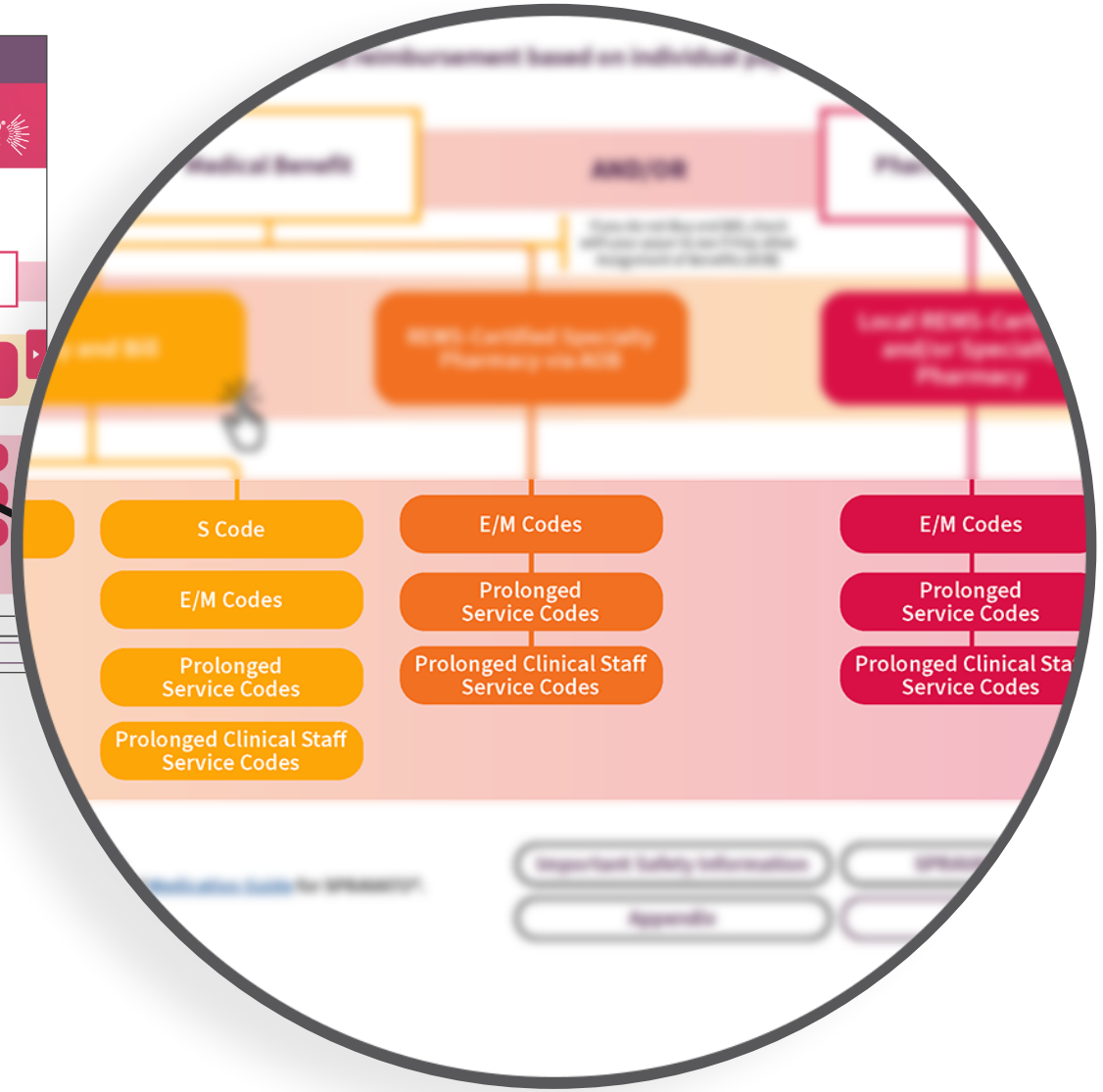
Learn More

Please click here to view the Access, Coding, and Reimbursement Guide.

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

Getting Started: Determine Access for SPRAVATO®





- Prior to reviewing this resource, be sure to read the Access, Coding, & Reimbursement Guide to familiarize yourself with key topics related to SPRAVATO® reimbursement
- This resource focuses on E/M codes and Prolonged Service codes with examples of their utilization when billing and coding for SPRAVATO®

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 Johnson & Johnson 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.

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

Important Safety Information

E/M and Prolonged Service Code Considerations: How Will They Affect Your SPRAVATO® Treatment Center?

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- Code based on total time personally spent by the physician or other qualified healthcare professional (HCP) or based on the complexity of medical decision making (MDM)*
- Account for non–face-to-face time specific to the patient encounter on the day of service
- Note that when advanced practice nurses and physician assistants are working with physicians, they are considered as working in the exact same specialty and subspecialty as the physician

Note: Be sure to check the latest reimbursement rates.

For additional SPRAVATO® coding and reimbursement resources, click here.

Each button is clickable and will open a pop-up.

*It is commonplace for SPRAVATO® to select the appropriate E/M codes on the basis of time alone and not on the complexity of monitoring.

The fact that a drug, device, procedure, or service is assigned a 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.

E/M and Prolonged Service Code Considerations: How Will They Affect Your SPRAVATO® Treatment Center?

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Code based on total time personally spent by the physician or other qualified healthcare professional (HCP) or based on the complexity of medical decision making (MDM)*

Accoun e patient encounter on the day of service

Note th hysician assistants are working with physicians, they ar e specialty and subspecialty as the physician

Note: Be su

- When using time for E/M code selection, note that time refers to the total time, both face-to-face and non–face-to-face, spent only on the day of the encounter

For additional SPRAVATO® coding and reimbursement resources, click here.

Each button is clickable and will open a pop-up.

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Account for non–face-to-face time specific to the p

Note that when advanced practice nurses and phy cians, they are considered as working in the exact same s ian

Note: Be sure to check the latest reimbursement rates.

- Non–face-to-face time may include activities such as reviewing and communicating test results, ordering medications, tests, or procedures, and documenting clinical information in the electronic or other health record

For additional SPRAVATO® coding and reimbursement resources, click here.

Each button is clickable and will open a pop-up.

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E/M and Prolonged Service Code Considerations: How Will They Affect Your SPRAVATO® Treatment Center?

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Code based on total time personally spent by the physician or other qualified healthcare professional (HCP) or based on the complexity of medical decision making (MDM)*

Accoun… …e patient encounter on the day of service

Note th… …hysician assistants are working with physicians, they ar… …ne specialty and subspecialty as the physician

Note: Be su…

- A "physician or other qualified healthcare professional" is defined as an individual who is qualified by education, training, licensure/ regulation (when applicable), and facility privileging (when applicable) who performs a professional service within his/her scope of practice and independently reports that professional service

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*It is commonplace for SPRAVATO® to select the appropriate E/M codes on the basis of time alone and not on the complexity of monitoring.

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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[2]

Historically, the code levels for E/M services were based on the complexity of MDM. Within the code definitions, time was included as an adjunct, intended to assist in the selection of the most appropriate E/M level.

Beginning in 2021, time alone may be used to select the appropriate code level for office or other outpatient E/M service codes (99202-99205 and 99212-99215).

E/M services can be billed based on total time spent during a SPRAVATO® treatment session

When using time to report E/M services, use the time showed in E/M code descriptors to determine the appropriate code.

Considerations for determining total HCP time

- ✔ HCPs can include non–face-to-face time when billing for E/M services
- ✔ Both face-to-face and non–face-to-face time count as total time, even if the activities are not continuous
- ✔ Only time from the same day of service can be included
- ✔ Activities counted toward a time-based code must be clearly documented in the medical record

Examples of Activities Performed by a Physician or Other Qualified HCP

The fact that a drug, device, procedure, or service is assigned a 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.

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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[2]

Examples of activities performed by a physician or other qualified HCP may include:

- Reviewing a patient's medical record, any recent health results, referrals, etc (HCP non–face-to-face)
- Evaluating a patient's clinical status to determine readiness/appropriateness for treatment (HCP face-to-face)
- Confirming orders and reviewing the plan with staff (HCP non–face-to-face)
- Assessing patient's response to treatment (HCP face-to-face)
- Completing medical record documentation (HCP non–face-to-face)

- ✔ Only time from the same day of service can be included
- ✔ Activities counted toward a time-based code must be clearly documented in the medical record

Examples of Activities Performed by a Physician or Other Qualified HCP

The fact that a drug, device, procedure, or service is assigned a 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.

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Time-based E/M Service Codes for New and Established Patients

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SPRAVATO® administration—E/M code considerations by patient[1*†]

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

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*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.[3]

‡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.

The fact that a drug, device, procedure, or service is assigned a 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.

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Prolonged Service Codes

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Prolonged service with or without direct patient contact (physician time)

- 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
- When billing prolonged services, Non-Medicare and Medicare payers can require providers to bill using either 99417 or G2212, while Medicare payers may use G2212*

SERVICE CODES

Each button is clickable and will open a pop-up.

99417[1†‡] **G2212**[4,5§]

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

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.

Time-Based Example 1 **Time-Based Example 2**

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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 HCP 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.
‡List separately in addition to code of the outpatient E/M service.
§List separately in addition to CPT codes 99205, 99215 for office or other outpatient evaluation and management services.

The fact that a drug, device, procedure, or service is assigned a 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.

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Prolonged service with or without direct patient contact (physician time)

- If a physician's time spent with a patient for a SPRAVATO® encounter exceeds the time stated in the standard E/M codes,

Prolonged Service Code 99417[1†]

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 × 1 and 99417 × 1
90-104 minutes	99205 × 1 and 99417 × 2
105 minutes or more	99205 × 1 and 99417 × 3 or more for each additional 15 minutes
ESTABLISHED PATIENTS (use with 99215)	
Less than 55 minutes	Not reported separately
55-69 minutes	99215 × 1 and 99417 × 1
70-84 minutes	99215 × 1 and 99417 × 2
85 minutes or more	99215 × 1 and 99417 × 3 or more for each additional 15 minutes

- 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.

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§List separately in addition to CPT codes 99205, 99215 for office or other outpatient evaluation and management services.

The fact that a drug, device, procedure, or service is assigned a 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.

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Prolonged service with or without direct patient contact (physician time)

- If a physician's time spent with a patient for a SPRAVATO® encounter exceeds the time stated in the standard E/M codes,

Prolonged Service Code G2212[4,5]

Use of Prolonged Service Code (G2212)

Total Duration	Code(s)
NEW PATIENTS (use with 99205)	
60-74 minutes	99205
89-103 minutes	99205 × 1 and G2212 × 1
104-118 minutes	99205 × 1 and G2212 × 2
119 minutes or more	99205 × 1 and G2212 × 3 or more for each additional 15 min
ESTABLISHED PATIENTS (use with 99215)	
40-54 minutes	99215
69-83 minutes	99215 × 1 and G2212 × 1
84-98 minutes	99215 × 1 and G2212 × 2
99 minutes or more	99215 × 1 and G2212 × 3 or more for each additional 15 min

- 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.

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[§]List separately in addition to CPT codes 99205, 99215 for office or other outpatient evaluation and management services.

The fact that a drug, device, procedure, or service is assigned a 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.

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Prolonged service with or without direct patient contact (physician time)

- If a physician's time spent with a patient for a SPRAVATO® encounter exceeds the time stated in the standard E/M codes,

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

The following 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 a 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.

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Example 1

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It is important to note that payer requirements for SPRAVATO® administration coding may vary. Please contact your payers for specific coding policies.

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

Here is an example of an established patient's SPRAVATO® treatment session based on a physician or other qualified HCP's time of 2 hours and 9 minutes (129 minutes)

Established Patients‡§	
Total Duration of E/M Services (mins)	Code(s)
10 minutes must be met or exceeded	99212
20 minutes must be met or exceeded	99213
30 minutes must be met or exceeded	99214
40 minutes must be met or exceeded	99215
55-69	99215 and 99417
70-84	99215 and 99417 (× 2)
85-99	99215 and 99417 (× 3)
100-114	99215 and 99417 (× 4)
115-134	99215 and 99417 (× 5)

In this example:

- E/M code 99215 may be billed after 40 minutes has been met or exceeded, and each unit of 99417 may be billed after each additional 15-minute increment
- To account for the remaining 75 minutes of the total time spent (129 minutes), 5 units of prolonged service code 99417 are added
- Each unit of 99417 covers 15 minutes; therefore, 5 units of 99417 are used

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*Payer requirements for SPRAVATO® administration coding may vary. Please contact your payers for specific coding policies.
†This is not an actual patient being treated with SPRAVATO®. This scenario is an example only; actual times may vary based on each particular patient.
‡If the total duration of E/M services for a patient exceeds the above ranges, continue to use 1 unit of 99417 for each 15-minute increment.
§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.

Back to Disclaimers

Example Calculations

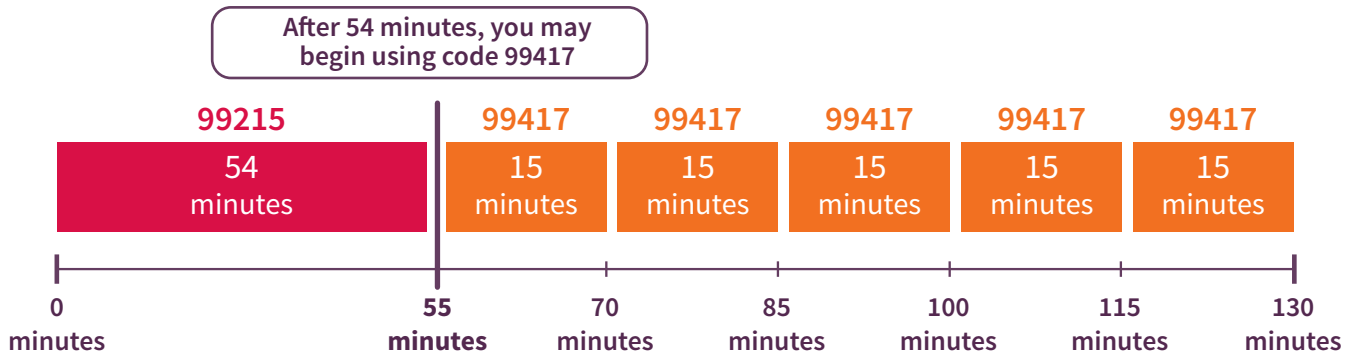
Time-Based E/M and Prolonged Service Code Example 1*† (cont'd)

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

1. Calculate total time spent by a physician or other qualified HCP.
2. Identify the relevant E/M codes.
3. After 54 minutes of total HCP time, you may use prolonged service code 99417.‡§‖
4. Calculate the number of units of code 99417 that must be reported.

Click the Question Mark for additional information.

Total time spent by a physician or other qualified HCP is 129 minutes



REMEMBER: 15 minutes of time must be reached to report a unit of 99417. Do not report 99417 for any time increment of less than 15 minutes.
NOTE: Per label, patients should be monitored for at least 2 hours after administration.

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†This is not an actual patient being treated with SPRAVATO®. This scenario is an example only; actual times may vary based on each particular patient.
‡For commercial and other non-Medicare patients, prolonged service code 99417 is used when the primary service has been selected using time alone as the basis and after the HCP time required to report the highest-level service has been exceeded by 15 minutes.
§Because the total HCP time has exceeded the time allowed in the highest-level E/M code (99215).
‖This time is estimated based on clinical experience; all other times are sourced to CMS input files for E/M codes.

Back to Example 1
Sample CMS-1500 Form

Time-Based E/M and Prolonged Service Code Example 1*† (cont'd)

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

1. Calculate total time spent by a physician or other qualified HCP.
2. Identify the relevant E/M codes.
3. After 54 minutes of total HCP time, you may use prolonged service code 99417.‡§‖
4. Calculate the number of units of code 99417 tha

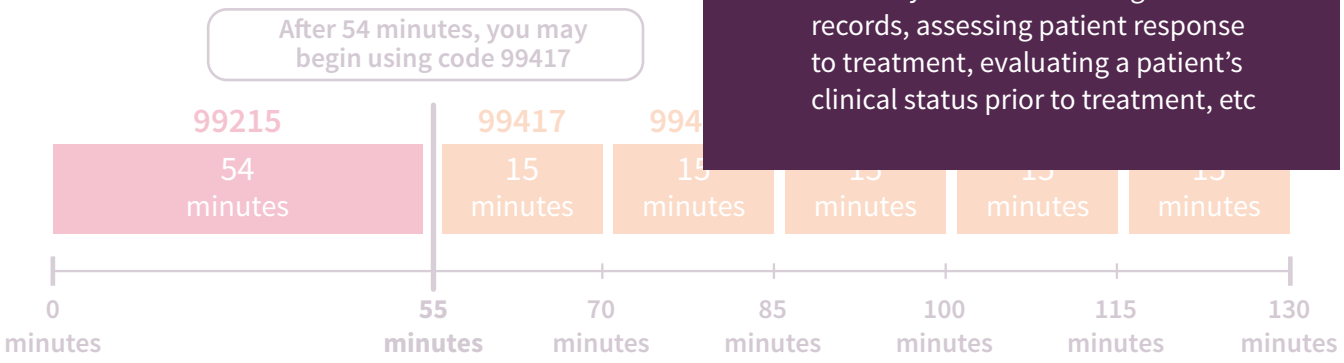
Click the Question Mark for additional information.

- In this example, the time spent by a physician or other qualified HCP is 129 minutes
- Examples of activities performed by a physician or other qualified HCP may include reviewing medical records, assessing patient response to treatment, evaluating a patient's clinical status prior to treatment, etc

Back to Example 1

Sample CMS-1500 Form

Total time spent by a physician or ot



REMEMBER: 15 minutes of time must be reached to report a unit of 99417. Do not report 99417 for any time increment of less than 15 minutes.
NOTE: Per label, patients should be monitored for at least 2 hours after administration.

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†This is not an actual patient being treated with SPRAVATO®. This scenario is an example only; actual times may vary based on each particular patient.
‡For commercial and other non-Medicare patients, prolonged service code 99417 is used when the primary service has been selected using time alone as the basis and after the HCP time required to report the highest-level service has been exceeded by 15 minutes.
§Because the total HCP time has exceeded the time allowed in the highest-level E/M code (99215).
‖This time is estimated based on clinical experience; all other times are sourced to CMS input files for E/M codes.

Time-Based E/M and Prolonged Service Code Example 1*† (cont'd)

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

1. Calculate total time spent by a physician or other qualified HCP.
2. Identify the relevant E/M codes.
3. After 54 minutes of total HCP time, you may use prolonged service code 99417.‡§‖
4. Calculate the number of units of code 99417 tha

Click the Question Mark for additional information.

- When selecting the appropriate E/M code based on time for this patient, the highest-level E/M code, 99215, would be used because the total HCP time has surpassed 54 minutes

Total time spent by a physician or ot

After 54 minutes, you may begin using code 99417

REMEMBER: 15 minutes of time must be reached to report a unit of 99417. Do not report 99417 for any time increment of less than 15 minutes.
NOTE: Per label, patients should be monitored for at least 2 hours after administration.

Back to Example 1

Sample CMS-1500 Form

CPT® - Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association.

*Payer requirements for SPRAVATO® administration coding may vary. Please contact your payers for specific coding policies.
†This is not an actual patient being treated with SPRAVATO®. This scenario is an example only; actual times may vary based on each particular patient.
‡For commercial and other non-Medicare patients, prolonged service code 99417 is used when the primary service has been selected using time alone as the basis and after the HCP time required to report the highest-level service has been exceeded by 15 minutes.
§Because the total HCP time has exceeded the time allowed in the highest-level E/M code (99215).
‖This time is estimated based on clinical experience; all other times are sourced to CMS input files for E/M codes.

Time-Based E/M and Prolonged Service Code Example 1*† (cont'd)

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

1. Calculate total time spent by a physician or other qualified HCP.
2. Identify the relevant E/M codes.
3. After 54 minutes of total HCP time, you may use prolonged service code 99417.‡§‖
4. Calculate the number of units of code 99417 tha

Click the Question Mark for additional information.

129 minutes-54 minutes=75 minutes

Total time spent by a physician or other qualified HCP is 129 minutes

REMEMBER: 15 minutes of time must be reached to report a unit of 99417. Do not report 99417 for any time increment of less than 15 minutes.
NOTE: Per label, patients should be monitored for at least 2 hours after administration.

Back to Example 1

Sample CMS-1500 Form

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§Because the total HCP time has exceeded the time allowed in the highest-level E/M code (99215).
‖This time is estimated based on clinical experience; all other times are sourced to CMS input files for E/M codes.

Time-Based E/M and Prolonged Service Code Example 1*† (cont'd)

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

1. Calculate total time spent by a physician or other qualified HCP.
2. Identify the relevant E/M codes.
3. After 54 minutes of total HCP time, you may use prolonged service code 99417 ‡§‖
4. Calculate the number of units of code 99417 tha

Click the Question Mark for additional information.

- Since code 99417 must be reported in 15-minute increments, 5 units of code 99417 would be used
  - 75 minutes/15 minutes=5 units

Total time spent by a physician or ot

REMEMBER: 15 minutes of time must be reached to report a unit of 99417. Do not report 99417 for any time increment of less than 15 minutes.
NOTE: Per label, patients should be monitored for at least 2 hours after administration.

Back to Example 1

Sample CMS-1500 Form

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*Payer requirements for SPRAVATO® administration coding may vary. Please contact your payers for specific coding policies.
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§Because the total HCP time has exceeded the time allowed in the highest-level E/M code (99215).
‖This time is estimated based on clinical experience; all other times are sourced to CMS input files for E/M codes.

Time-Based E/M and Prolonged Service Code Example 1*† (cont'd)

When filling out the Sample CMS-1500 claim form for SPRAVATO® observation and monitoring, use 1 unit of 99215 and 5 units of 99417

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

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

a **Item 24A:** The total physician or other qualified HCP 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

Note: In this example, only time personally spent by the HCP on the day of service can be included when determining total time and therefore the appropriate E/M code(s). Time spent on activities normally performed by clinical staff are not included for coding purposes. For more information on appropriate codes for prolonged clinical staff services with physician supervision, click here.

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

†This is not an actual patient being treated with SPRAVATO®. This scenario is an example only; actual times may vary based on each particular patient.

Back to Example Calculations

Spravato® (esketamine) C-III
28 mg nasal spray

Prolonged service with or without direct patient contact (physician time)

- If a physician's time spent with a patient for a SPRAVATO® encounter exceeds the time stated in the standard E/M codes,

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

The following 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 a 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

99417.

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It is important to note that payer requirements for SPRAVATO® administration coding may vary. Please contact your payers for specific coding policies.

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

Here is an example of an established patient's SPRAVATO® treatment session based on a physician or other qualified HCP's time of 1 hour and 9 minutes (69 minutes)

Established Patients‡§	
Total Duration of E/M Services (mins)	**Code(s)**
10 minutes must be exceeded	99212
20 minutes must be exceeded	99213
30 minutes must be exceeded	99214
40 minutes must be exceeded	99215
55-69	99215 and 99417
70-84	99215 and 99417 (× 2)
85-99	99215 and 99417 (× 3)
100-114	99215 and 99417 (× 4)
115-134	99215 and 99417 (× 5)

In this example:

- E/M code 99215 may be billed after 40 minutes has been met or exceeded, and each unit of 99417 may be billed after each additional 15-minute increment
- To account for the remaining 15 minutes of the total time spent (69 minutes), 1 unit of prolonged service code 99417 is added
- Each unit of 99417 covers 15 minutes; therefore, 1 unit of 99417 is used

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*Payer requirements for SPRAVATO® administration coding may vary. Please contact your payers for specific coding policies.
†This is not an actual patient being treated with SPRAVATO®. This scenario is an example only; actual times may vary based on each particular patient.
‡If the total duration of E/M services for a patient exceeds the above ranges, continue to use 1 unit of 99417 for each 15-minute increment.
§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.

Back to Disclaimers

Example Calculations

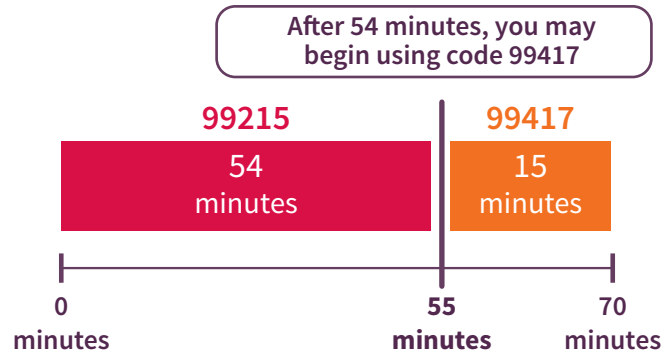
Time-Based E/M and Prolonged Service Code Example 2*† (cont'd)

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

1. Calculate total time spent by a physician or other qualified HCP.
2. Identify the relevant E/M codes.
3. After 54 minutes of total HCP time, you may use prolonged service code 99417.‡§‖
4. Calculate the number of units of code 99417 that must be reported.

Click the Question Mark for additional information.

Total time spent by a physician or other qualified HCP is 69 minutes



REMEMBER: 15 minutes of time must be reached to report a unit of 99417. Do not report 99417 for any time increment of less than 15 minutes.
NOTE: Per label, patients should be monitored for at least 2 hours after administration.

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‡For commercial and other non-Medicare patients, prolonged service code 99417 is used when the primary service has been selected using time alone as the basis and after the HCP time required to report the highest-level service has been exceeded by 15 minutes.
§Because the total HCP time has exceeded the time allowed in the highest-level E/M code (99215).
‖This time is estimated based on clinical experience; all other times are sourced to CMS input files for E/M codes.

Back to Example 2
Sample CMS-1500 Form

Time-Based E/M and Prolonged Service Code Example 2*† (cont'd)

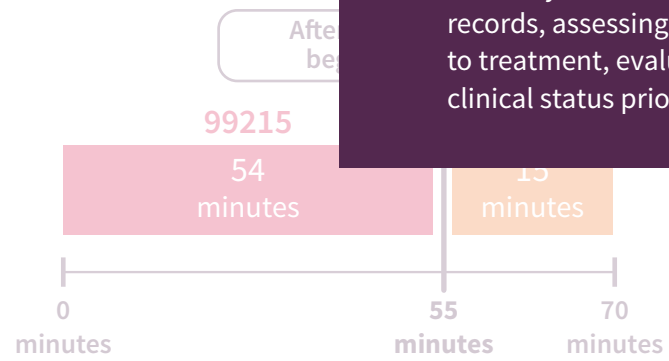
Here is an example of a patient's SPRAVATO® treatment session based on a physician's or other qualified HCP's time

1. Calculate total time spent by a physician or other qualified HCP.
2. Identify the relevant E/M codes.
3. After 54 minutes of total HCP time, you may use prolonged service code 99417.‡§‖
4. Calculate the number of units of code 99417 tha

Click the Question Mark for additional information.

- In this example, the time spent by a physician or other qualified HCP is 69 minutes
- Examples of activities performed by a physician or other qualified HCP may include reviewing medical records, assessing patient response to treatment, evaluating a patient's clinical status prior to treatment, etc

Total time spent by a physician or



REMEMBER: 15 minutes of time must be reached to report a unit of 99417. Do not report 99417 for any time increment of less than 15 minutes.
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Back to Example 2

Sample CMS-1500 Form

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Time-Based E/M and Prolonged Service Code Example 2*† (cont'd)

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

1. Calculate total time spent by a physician or other qualified HCP.
2. Identify the relevant E/M codes.
3. After 54 minutes of total HCP time, you may use prolonged service code 99417.‡§‖
4. Calculate the number of units of code 99417 tha

Click the Question Mark for additional information.

- When selecting the appropriate E/M code based on time for this patient, the highest-level E/M code, 99215, would be used because the total HCP time has surpassed 54 minutes

Total time spent by a physician or

REMEMBER: 15 minutes of time must be reached to report a unit of 99417. Do not report 99417 for any time increment of less than 15 minutes.
NOTE: Per label, patients should be monitored for at least 2 hours after administration.

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Back to Example 2
Sample CMS-1500 Form

Time-Based E/M and Prolonged Service Code Example 2*† (cont'd)

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

1. Calculate total time spent by a physician or other qualified HCP.
2. Identify the relevant E/M codes.
3. After 54 minutes of total HCP time, you may use prolonged service code 99417.‡§‖
4. Calculate the number of units of code 99417 tha

Click the Question Mark for additional information.

- 69 minutes-54 minutes=15 minutes

Total time spent by a physician or other qualified HCP is 69 minutes

REMEMBER: 15 minutes of time must be reached to report a unit of 99417. Do not report 99417 for any time increment of less than 15 minutes.
NOTE: Per label, patients should be monitored for at least 2 hours after administration.

Back to Example 2

Sample CMS-1500 Form

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Time-Based E/M and Prolonged Service Code Example 2*† (cont'd)

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2. Identify the relevant E/M codes.
3. After 54 minutes of total HCP time, you may use prolonged service code 99417.‡§‖
4. Calculate the number of units of code 99417 tha

Click the Question Mark for additional information.

- Since code 99417 must be reported in 15-minute increments, 1 unit of code 99417 would be used
  - 15 minutes/15 minutes=1 unit

Total time spent by a physician or

REMEMBER: 15 minutes of time must be reached to report a unit of 99417. Do not report 99417 for any time increment of less than 15 minutes.
NOTE: Per label, patients should be monitored for at least 2 hours after administration.

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Back to Example 2
Sample CMS-1500 Form

Time-Based E/M and Prolonged Service Code Example 2*† (cont'd)

When filling out the Sample CMS-1500 claim form for SPRAVATO® observation and monitoring, use 1 unit of 99215 and 1 unit of 99417

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

	24. A. DATE(S) OF SERVICE From MM	DD	YY	To MM	DD	YY	B. PLACE OF SERVICE	C.	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGE	G. DAYS OR UNITS
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 HCP 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

Back to Example Calculations

Note: In this example, only time personally spent by the HCP on the day of service can be included when determining total time and therefore the appropriate E/M code(s). Time spent on activities normally performed by clinical staff are not included for coding purposes. For more information on appropriate codes for prolonged clinical staff services with physician supervision, click here.

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Additional Coding Considerations That May Be Applicable for Your Patient's SPRAVATO® Treatment Session

Spravato® (esketamine) C-III
28 mg nasal spray

When SPRAVATO® is obtained via specialty pharmacy and the HCP provides the associated services, report HCPCS code G2212* instead of CPT® 99417 for prolonged HCP services for Medicare patients and some commercial patients who accept this code[4]

- Apply G2212 only after the maximum time required to report 99205 or 99215 has been exceeded by 15 minutes
- 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
- If SPRAVATO® is purchased and billed by the provider, Medicare requires the G codes for combined drug and service (G2082 or G2083)

Example coding for G2212:

- If the total time spent on day of service is 89-103 minutes for a new patient, report 99205 × 1 and G2212 × 1
- If the total time spent on day of service is 69-83 minutes for an established patient, report 99215 × 1 and G2212 × 1

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 the product is acquired from a specialty pharmacy.

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*For Medicare, G2212 typically applies to Medicare Advantage and not Medicare Part B.

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It is important to note that payer requirements for SPRAVATO® administration coding may vary. Please contact your payers for specific coding policies.

Additional Coding Considerations That May Be Applicable for Your Patient's SPRAVATO® Treatment Session (cont'd)

Spravato® (esketamine) C III
28 mg nasal spray

Prolonged clinical staff services with physician supervision

- Codes 99415 and 99416 are prolonged clinical staff service codes that 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

Codes 99415 and 99416 may be used:

- For the first hour, use 99415; for each additional 30 minutes, use 99416*
- Prolonged service of longer than 30 minutes' total duration on a given date

Codes 99415 and 99416 may not be reported:

- In conjunction with HCP prolonged service code (99417 or G2212†)
- For more than 2 simultaneous patients or with SPRAVATO® G codes (G2082 and G2083)

Total Duration of Prolonged Services (mins)	Code(s)
Less than 30	Not reported separately
30-74	99415 × 1
75-104	99415 and 99416
105 or more*	99415 and 99416 (× 2)

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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*List separately in addition to code for outpatient E/M service.
†For Medicare, G2212 typically applies to Medicare Advantage and not Medicare Part B.

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It is important to note that payer requirements for SPRAVATO® administration coding may vary. Please contact your payers for specific coding policies.

SPRAVATO® Risk Evaluation and Mitigation Strategy (REMS)

Spravato® (esketamine) CIII
28 mg nasal spray

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 from sedation, dissociation, respiratory depression, and abuse and misuse. 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).

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

Important Safety Information

Indications and Important Safety Information

Spravato® (esketamine) CIII
28 mg nasal spray

Indications:

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

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

Limitations of Use:

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

Important Safety Information

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

See full prescribing information for complete boxed warning

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

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.

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

Important Safety Information (cont'd)

Spravato® (esketamine) C III
28 mg nasal spray

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

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

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

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

Important requirements of the SPRAVATO® REMS include the following:

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

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

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

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

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

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

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

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Important Safety Information (cont'd)

Spravato® (esketamine) C-III
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Increase in Blood Pressure (cont'd): Assess BP prior to administration of SPRAVATO®. In patients whose BP is elevated prior to SPRAVATO® administration (as a general guide: >140/90 mmHg), a decision to delay SPRAVATO® therapy should take into account the balance of benefit and risk in individual patients.

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

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

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

Cognitive Impairment

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

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

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

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

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

PREGNANCY, EMBRYO-FETAL TOXICITY, AND LACTATION

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

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

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

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Important Safety Information (cont'd)

Spravato® (esketamine) C III
28 mg nasal spray

PREGNANCY, EMBRYO-FETAL TOXICITY, AND LACTATION (cont'd)

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

SELECT USE IN SPECIFIC POPULATIONS

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

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

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

ADVERSE REACTIONS

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

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

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

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

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Spravato® (esketamine) C III
28 mg nasal spray

References: 1. American Academy of Professional Coders (AAPC). CPT® Codes Lookup. Accessed February 27, 2025. https://www.aapc.com/codes **2.** American Medical Association. Evaluation and management (E/M) coding. Accessed February 27, 2025. https://www.ama-assn.org/topics/evaluation-and-management-em-coding **3.** Centers for Medicare and Medicaid Services. CMS Manual System. Transmittal 2845. December 27, 2013. Accessed February 27, 2025. https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r2845cp.pdf **4.** Centers for Medicare and Medicaid Services. Fact Sheet - Physician Fee Schedule (PFS) Payment for Office/Outpatient Evaluation and Management (E/M) Visits. January 11, 2021. Accessed February 27, 2025. https://www.cms.gov/files/document/physician-fee-schedule-pfs-payment-officeoutpatient-evaluation-and-management-em-visits-fact-sheet.pdf **5.** Centers of Medicare and Medicaid Services. CMS Manual System. Transmittal 10505. December 4, 2020. Accessed February 27, 2025. https://www.cms.gov/files/document/r10505cp.pdf

For additional SPRAVATO® coding and reimbursement resources, click here.

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