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Policy Number: C16762-A

Spravato (esketamine)

PRODUCTS AFFECTED

Spravato (esketamine)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Major depressive disorder, Treatment resistant depression

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. MAJOR DEPRESSIVE DISORDER, TREATMENT-RESISTANT (TR-MDD), INITIAL:
(IF PATIENT IS CONTINUING SPRAVATO [ESKETAMINE] THERAPY WITHIN 24-48 HOURS POST INPATIENT DISCHARGE, AUTHORIZATION WILL BE PROVIDED FOR 4 WEEKS.)
1. Documented diagnosis of major depressive disorder (MDD) or recurrent MDD, without psychotic

features
AND

2. Documentation that the member's baseline depression symptoms are measured and documented with an appropriate rating scale (such as PHQ-9, Clinically Useful Depression Outcome Scale, Quick Inventory of Depressive Symptomatology-Self Report 16 Item, MADRS, HAM-D) or Hamilton Depression Rating Scale (HDRS) as a tool for monitoring response to therapy [DOCUMENTATION REQUIRED]
AND
3. Documentation that member has had a trial (minimum of 6 consistent weeks of therapy) and failure of monotherapy treatments (or labeled contraindications to all agents in a class) of TWO formulary drugs from ANY of these drug class: Selective serotonin reuptake inhibitor, Serotonin-norepinephrine reuptake inhibitor, Atypical antidepressant, Serotonin modulator, Tricyclic antidepressant, OR Monoamine oxidase inhibitor
AND
4. Documentation that member will be on a concomitant oral SSRI or SNRI for full duration of Spravato therapy OR if previous trial, failure or contraindication to SSRI/SNRI, concomitant use of ONE oral antidepressant
AND
5. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Spravato (esketamine) include: Aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial and peripheral arterial vessels) or arteriovenous malformation, intracerebral hemorrhage, hypersensitivity to esketamine, ketamine, or any of the excipients]
AND
6. Prescriber attests to provide appropriate pre- and post-dose monitoring (at least 2 hours) for blood pressure, sedation, and dissociative symptoms in presence of healthcare provider
AND
7. Prescriber attestation there will be appropriate monitoring for persistent worsening of depression or the emergence of suicidal thoughts and behaviors

B. MAJOR DEPRESSIVE DISORDER, WITH ACUTE SUICIDAL IDEATION OR BEHAVIOR: (IF PATIENT IS CONTINUING SPRAVATO [ESKETAMINE] THERAPY WITHIN 24-48 HOURS POST INPATIENT DISCHARGE, AUTHORIZATION WILL BE PROVIDED FOR 4 WEEKS.)
   1. Documented diagnosis of major depressive disorder (MDD) or recurrent MDD, with acute suicidal ideation or behavior
   AND
   2. Prescriber attestation that the member's baseline depression symptoms will be measured and documented with an appropriate rating scale (such as PHQ-9, Clinically Useful Depression Outcome Scale, Quick Inventory of Depressive Symptomatology-Self Report 16 Item, MADRS, HAM-D) or Hamilton Depression Rating Scale (HDRS) as a tool for monitoring response to therapy
   AND
   3. Documentation that member is/had recently (within the last 5 days) discharged from acute or subacute inpatient care for suicidality
   AND
   4. Documentation that requested therapy is prescribed in combination with initiation or optimization of oral antidepressant therapy
   AND
   5. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Spravato (esketamine) include: Aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial and peripheral arterial vessels) or arteriovenous malformation, intracerebral hemorrhage, hypersensitivity to esketamine, ketamine, or any of the excipients]

AND

6. Prescriber attests to provide appropriate pre- and post- dose monitoring (at least 2 hours) for blood pressure, sedation, and dissociative symptoms in presence of healthcare provider
   AND
7. Prescriber attestation there will be appropriate monitoring for persistent worsening of depression or the emergence of suicidal thoughts and behaviors

CONTINUATION OF THERAPY:

A. MAJOR DEPRESSIVE DISORDER TREATMENT-RESISTANT (TR-MDD):

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history
   AND
2. Documentation of a positive clinical response to therapy evidenced by improvement in depression symptoms measured by the same rating scale used at baseline. [DOCUMENTATION REQUIRED]
   AND
3. Prescriber attests to continued appropriate monitoring for worsening of depression or emergence of suicidal thoughts and behavior and signs of potential drug abuse.
   AND
4. Prescriber attests to continued pre- and post-dose monitoring for blood pressure, dissociation, and sedation in presence of healthcare provider.
   AND
5. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity or development of labeled contraindications (Aneurysmal vascular disease [including thoracic and abdominal aorta, intracranial and peripheral arterial vessels] or arteriovenous malformation, intracerebral hemorrhage)
   AND
6. Prescriber attests or clinical reviewer has found that requested therapy continues to be used in combination with oral antidepressant therapy

B. MAJOR DEPRESSIVE DISORDER WITH ACUTE SUICIDAL IDEATION OR BEHAVIOR: N/A

DURATION OF APPROVAL:

Treatment-Resistant Depression: Initial authorization: 4 weeks, Continuation of therapy: 6 months

Depressive Symptoms in Patients with Major Depressive Disorder with Acute Suicidal Ideation or Behavior: Initial authorization: 4 weeks, Continuation of therapy: N/A- the use of SPRAVATO, in conjunction with an oral antidepressant, beyond 4 weeks has not been systematically evaluated in the treatment of depressive symptoms in patients with MDD with acute suicidal ideation or behavior.

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a psychiatrist or behavioral health specialist. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

Treatment-Resistant Depression: 28 mg per device. Induction Phase: Week 1-4 Dosing: Day 1 56mg THEN 56 OR 84 mg twice per week THEN, Maintenance Phase: Weeks 5-8 Dosing: 56 OR 84 mg once weekly THEN Week 9 and after: 56 OR 84 mg every 2 weeks or ONCE weekly

Depressive Symptoms in Patients with Major Depressive Disorder with Acute Suicidal Ideation or Behavior: 84 mg twice per week for 4 weeks. Dosage may be reduced to 56 mg twice per week based on tolerability.

PLACE OF ADMINISTRATION:
The recommendation is that intranasal medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-inpatient hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intranasal

DRUG CLASS:
NMDA receptor antagonist

FDA-APPROVED USES:
Spravato is indicated, in conjunction with an oral antidepressant, for the treatment of treatment- resistant depression (TRD) in adults and 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.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information
State Marketplace
Illinois (Source: Illinois General Assembly)
"(215 ILCS 200/60) Sec. 60. Length of prior authorization approval. *A prior authorization approval shall be valid for the lesser of 6 months after the date the health care professional or health care provider receives the prior authorization approval or the length of treatment as determined* by the patient's health care professional or the renewal of the plan, and the *approval period shall be effective regardless of any changes, including any changes in dosage for a prescription drug* prescribed by the health care professional. All dosage increases must be based on established evidentiary standards and nothing in this Section shall prohibit a health insurance issuer from having safety edits in place. This Section shall not apply to the prescription of benzodiazepines or Schedule II narcotic drugs, such as opioids. Except to the extent required by medical exceptions processes for prescription drugs set forth in Section 45.1 of the Managed Care Reform and Patient Rights Act, nothing in this Section shall require a policy to cover any care, treatment, or services for any health condition that the terms of coverage otherwise completely exclude from the policy's covered benefits without regard for whether the care, treatment, or services are medically necessary. (Source: P.A. 102-409, eff. 1-1-22.)"
"(215 ILCS 200/65) Sec. 65. Length of prior authorization approval for *treatment for chronic or long-term conditions*. If a health insurance issuer requires a prior authorization for a recurring health care service or maintenance medication for the treatment of a chronic or long-term condition, *the approval shall remain valid for the lesser of 12 months from the date the health care professional or health care provider receives the prior authorization approval or the length of the treatment as determined by the patient's health care professional*. This Section shall not apply to the prescription of benzodiazepines or Schedule II narcotic drugs, such as opioids. Except to the extent required by medical exceptions processes for prescription drugs set forth in Section 45.1

of the Managed Care Reform and Patient Rights Act, nothing in this Section shall require a policy to cover any care, treatment, or services for any health condition that the terms of coverage otherwise completely exclude from the policy's covered benefits without regard for whether the care, treatment, or services are medically necessary. (Source: P.A. 102-409, eff. 1-1-22.)"

Kentucky (Source: Kentucky Revised Statutes)
KY304.17A-167 Time span of authorizations
(Subsection 2) "Unless otherwise provided in subsection (3) of this section or prohibited by state or federal law, if a provider receives a prior authorization for a drug prescribed to a covered person with a condition that requires ongoing medication therapy, and the provider continues to prescribe the drug, and the drug is used for a condition that is within the scope of use approved by the United States Food and Drug Administration or has been proven to be a safe and effective form of treatment for the patient's specific underlying condition based on clinical practice guidelines that are developed from peer-reviewed publications, the prior authorization received shall: (a) Be valid for the lesser of: 1. One (1) year from the date the provider receives the prior authorization; or 2. Until the last day of coverage under the covered person's health benefit plan during a single plan year; and (b) Cover any change in dosage prescribed by the provider during the period of authorization." (Subsection 3) "Except as provided in paragraph (b) of this subsection, the provisions of subsection (2) of this section shall not apply to: 1. Medications that are prescribed for a non-maintenance condition; 2. Medications that have a typical treatment period of less than twelve (12) months; 3. Medications where there is medical or scientific evidence that does not support a twelve (12) month approval; or 4. Medications that are opioid analgesics or benzodiazepines. (b) Paragraph (a) of this subsection shall not apply to any medication that is prescribed to a patient in a community-based palliative care program."
Re-authorization (approved authorization previously issued by Molina Healthcare) for maintenance medications within this policy shall be approved for a 12 month duration when request meets policy requirements, unless exceptions noted above have been met.

Mississippi (Source: Mississippi Legislature)
"SECTION 13. Length of approvals. (1) A prior authorization approval shall be valid for the lesser of six (6) months after the date the health care professional or health care provider receives the prior authorization approval or the length of treatment as determined by the patient's health care professional or the renewal of the policy or plan, and the approval period shall be effective regardless of any changes, including any changes in dosage for a prescription drug prescribed by the health care professional. Notwithstanding the foregoing, a health insurer and an enrollee or his/her health care professional may extend a prior authorization approval for a longer period, by agreement. All dosage increases must be based on established evidentiary standards, and nothing in this section shall prohibit a health insurance issuer from having safety edits in place. This section shall not apply to the prescription of benzodiazepines or Schedule II narcotic drugs, such as opioids.
(2) Nothing in this section shall require a policy or plan to cover any care, treatment, or services for any health condition that the terms of coverage otherwise completely exclude from the policy's or plan's covered benefits without regard for whether the care, treatment or services are medically necessary.
SECTION 14. Approvals for chronic conditions. (1) If a health insurance issuer requires a prior authorization for a recurring health care service or maintenance medication for the treatment of a chronic or long-term condition, including, but not limited to, chemotherapy for the treatment of cancer, the approval shall remain valid for the lesser of twelve (12) months from the date the health care professional or health care provider receives the prior authorization approval or the length of the treatment as determined by the patient's health care professional. Notwithstanding the foregoing, a health insurer and an enrollee or his or her health care professional may extend a prior authorization approval for a longer period, by agreement. This section shall not apply to the prescription of benzodiazepines or Schedule II narcotic drugs, such as opioids.
(2) Nothing in this section shall require a policy or plan to cover any care, treatment or services for any health condition that the terms of coverage otherwise completely exclude from the policy's or plan's covered benefits without regard for whether the care, treatment, or services are medically necessary."

Nevada (Source: Nevada Legislature)

"Chapter 689A of Nevada Revised Statutes (NRS) is hereby amended by adding thereto a new section to read as follows:

1. A policy of health insurance which provides coverage for prescription drugs must not require an insured to submit to a step therapy protocol before covering a drug approved by the Food and Drug Administration that is prescribed to treat a psychiatric condition of the insured, if:
    a. The drug has been approved by the Food and Drug Administration with indications for the psychiatric condition of the insured or the use of the drug to treat that psychiatric condition is otherwise supported by medical or scientific evidence;
    b. The drug is prescribed by:
        i. A psychiatrist
        ii. A physician assistant under the supervision of a psychiatrist;
        iii. An advanced practice registered nurse who has the psychiatric training and experience prescribed by the State Board of Nursing pursuant to NRS 632.120; or
        iv. A primary care provider that is providing care to an insured in consultation with a practitioner listed in subparagraph (1), (2) or (3), if the closest practitioner listed in subparagraph (1), (2) or (3) who participates in the network plan of the insurer is located 60 miles or more from the residence of the insured; and
    c. The practitioner listed in paragraph (b) who prescribed the drug knows, based on the medical history of the insured, or reasonably expects each alternative drug that is required to be used earlier in the step therapy protocol to be ineffective at treating the psychiatric condition…
3. As used in this section:
    c. *'Step therapy protocol' means a procedure that requires an insured to use a prescription drug or sequence of prescription drugs other than a drug that a practitioner recommends for treatment of a psychiatric condition of the insured before his or her policy of health insurance provides coverage for the recommended drug*."

Molina Reviewer Note: Medical necessity review for a psychiatric condition cannot require trial of other medications first. This is applicable to formulary medications that require prior authorization and non-formulary medications and is not limited to only medications designated 'ST'. If the requested drug is a brand name and the generic is on formulary, request can be reviewed for specific medical reason generic cannot be used.

Ohio (Source: Ohio Revised Code)
Chapter 3923 Sickness And Accident Insurance Section 3923.041 Policies with prior authorization requirement provisions "(B)(6)(a) For policies issued on or after January 1, 2017, *for a prior approval related to a chronic condition*, the insurer or plan shall honor a prior authorization *approval for an approved drug for the lesser of the following from the date of the approval: (i) Twelve months*; (ii) The last day of the covered person's eligibility under the policy or plan. (b) The duration of all other prior authorization approvals shall be dictated by the policy or plan."

State Medicaid

Kentucky (Source: Kentucky Revised Statutes)
KY304.17A-167 Time span of authorizations
(Subsection 2) "Unless otherwise provided in subsection (3) of this section or prohibited by state or federal law, if a provider receives a prior authorization for a drug prescribed to a covered person with a condition that requires ongoing medication therapy, and the provider continues to prescribe the drug, and the drug is used for a condition that is within the scope of use approved by the United States Food and Drug Administration or has been proven to be a safe and effective form of treatment for the patient's specific underlying condition based on clinical practice guidelines that are developed from peer-reviewed publications, the prior authorization received shall: (a) Be valid for the lesser of: 1. One (1) year from the date the provider receives the prior authorization; or 2. Until the last day of coverage under the covered person's health benefit plan during a single plan year; and (b) Cover any change in dosage prescribed by the provider during the period of authorization." (Subsection 3) "Except as provided in paragraph (b) of this subsection, the provisions of subsection (2) of this section shall not apply to: 1. Medications that are prescribed for a non-maintenance condition; 2. Medications that have a typical treatment period of less than twelve (12) months; 3. Medications where there is medical or scientific evidence that does not support a twelve (12) month approval; or 4. Medications that are opioid analgesics or benzodiazepines. (b) Paragraph (a) of this subsection shall not apply to any medication that is prescribed to a patient in a community-based palliative care program."

Re-authorization (approved authorization previously issued by Molina Healthcare) for maintenance medications within this policy shall be approved for a 12 month duration when request meets policy requirements, unless exceptions noted above have been met.

Mississippi (Source: Mississippi Legislature)
"SECTION 13. Length of approvals. (1) A prior authorization approval shall be valid for the lesser of six (6) months after the date the health care professional or health care provider receives the prior authorization approval or the length of treatment as determined by the patient's health care professional or the renewal of the policy or plan, and the approval period shall be effective regardless of any changes, including any changes in dosage for a prescription drug prescribed by the health care professional. Notwithstanding the foregoing, a health insurer and an enrollee or his/her health care professional may extend a prior authorization approval for a longer period, by agreement. All dosage increases must be based on established evidentiary standards, and nothing in this section shall prohibit a health insurance issuer from having safety edits in place. This section shall not apply to the prescription of benzodiazepines or Schedule II narcotic drugs, such as opioids.
(2) Nothing in this section shall require a policy or plan to cover any care, treatment, or services for any health condition that the terms of coverage otherwise completely exclude from the policy's or plan's covered benefits without regard for whether the care, treatment or services are medically necessary.
SECTION 14. Approvals for chronic conditions. (1) If a health insurance issuer requires a prior authorization for a recurring health care service or maintenance medication for the treatment of a chronic or long-term condition, including, but not limited to, chemotherapy for the treatment of cancer, the approval shall remain valid for the lesser of twelve (12) months from the date the health care professional or health care provider receives the prior authorization approval or the length of the treatment as determined by the patient's health care professional. Notwithstanding the foregoing, a health insurer and an enrollee or his or her health care professional may extend a prior authorization approval for a longer period, by agreement. This section shall not apply to the prescription of benzodiazepines or Schedule II narcotic drugs, such as opioids.
(2) Nothing in this section shall require a policy or plan to cover any care, treatment or services for any health condition that the terms of coverage otherwise completely exclude from the policy's or plan's covered benefits without regard for whether the care, treatment, or services are medically necessary."

Appendix 1:
PHQ-9, MADRS, and HAM-D Rating Scales

The MADRS is a 10-item diagnostic questionnaire used to measure the severity of depressive episodes in patients with mood disorders.

MADRS Score Depression	**Rating**
0 – 6	Normal/symptom absent
7 – 19	Mild depression
20 – 34	Moderate depression
>34	Severe depression

The PHQ-9 is a 9-item multiple choice questionnaire used for diagnosis, screening, monitoring and measuring the severity of depression.

PHQ-9 Score Depression	**Severity**
5 – 9	Minimal symptoms
10 – 14	Minor depression, Major depression, mild
15 – 19	Major depression, moderately severe
>20	Major depression, severe

The HAM-D17 scale is a 17-item depression assessment scale to assess severity of, and change in, depressive symptoms.

HAM-D Score	**Depression Rating**
0 – 7	Normal, absence or remission of depression

8 – 16	Mild depression
17 – 23	Moderate depression
>24	Severe depression

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Major depressive disorder (MDD) is a behavioral disorder defined as when an individual experiences one or more major depressive episodes without a history of manic, mixed, or hypomanic episodes. Treatment resistant depression is defined as major depressive episodes that do not respond to two adequate trials of antidepressant therapy. MDD patients are 2x at risk of developing cardiovascular disease.1st line treatment consists of psychotherapy with or without SSRI/SNRIs (take 4-8 weeks for full effect), Mirtazapine, or Bupropion (APA 2010 guidelines). 2nd line recommendations include switching to a different medication or adding on another antidepressant with a different mechanism, or an atypical antipsychotic. Add-on therapy can include TCAs, lithium, triiodothyronine. Last line treatment-resistant therapy can consist of MAOIs or ECT.

Spravato is indicated for treatment-resistant depression. It's unique mechanism of action offers an alternative to treatment-failed patients who have tried oral monotherapy. It is a schedule III- controlled substance due to potential for abuse and misuse. Two studies (short-term and long-term) were evaluated by the FDA for approval of Spravato. The short-term study was a 4-week trial with primary efficacy endpoint of improvement in MADRS (Montgomery Adams Depression Rating Scale) score, and Spravato demonstrated superiority over placebo in reduction of MADRS score. The long- term study lasted more than 80 weeks and placebo-controlled. Spravato demonstrated superiority over placebo in primary efficacy endpoint of maintaining remission in therapy. Participants relapsed in the placebo group at quicker and higher rates. In both trials, Spravato and placebo nasal spray were administered with an oral antidepressant of choice between the following: duloxetine, escitalopram, sertraline, or venlafaxine with goal of maximally titrated doses.

Spravato Risk Evaluation and Mitigation Strategy (REMS)

Spravato is available only through a restricted program under a REMS called the Spravato REMS because of the risks of serious adverse outcomes from sedation, dissociation, and abuse and misuse. Important requirements of the Spravato REMS include the following:

- Healthcare settings must be certified in the program and ensure that Spravato is:
  - Only dispensed 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.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Spravato (esketamine) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Spravato (esketamine) include: Aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial and peripheral arterial vessels) or arteriovenous malformation, intracerebral hemorrhage, hypersensitivity to esketamine, ketamine, or any of the excipients.

OTHER SPECIAL CONSIDERATIONS:

Spravato is a schedule III-controlled substance.

Spravato has a black box warning for sedation; dissociation; respiratory depression; abuse and misuse; and suicidal thoughts and behaviors.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
S0013	Esketamine, nasal spray, 1 mg

AVAILABLE DOSAGE FORMS:
Spravato (56 MG Dose) SOPK 28MG/DEVICE
Spravato (84 MG Dose) SOPK 28MG/DEVICE

REFERENCES

1. Spravato (esketamine) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; October 2023.
2. Yonkers KA, Wisner KL, Stewart DE, et al. The management of depression during pregnancy: a report from the American Psychiatric Association and the American College of Obstetricians and Gynecologists. Obstet Gynecol. 2009;114(3):703-713.
3. Gelenberg AJ, Freeman MP, Markowitz JC. Practice Guideline for the Treatment of Patients with Major Depressive Disorder, Third Edition. American Psychiatric Association. 2010: pg(s) 31-40. American Psychiatric Association. Practice guideline for the treatment of patients with major depressive disorder, third edition. November 2010. Available at: http://psychiatryonline.org/guidelines.aspx
4. Ochs-Ross R, Daly EJ, Zhang Y et al. Efficacy and safety of esketamine nasal spray plus an oral antidepressant in elderly patients with treatment-resistant depression TRANSFORM-3. Am J Geriatric Psychiatry. 2020 Feb;28(2):121-141

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy FDA-Approved Uses Other Special Considerations Available Dosage Forms References	Q1 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Prescriber Requirements Place of Administration Background Contraindications/Exclusions/Discontinuation Other Special Considerations HCPCS Code and Description	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file