CareSource

# PHARMACY POLICY STATEMENT
## Ohio Medicaid

| | |
|---|---|
| DRUG NAME | Spravato (esketamine) |
| BILLING CODE | Must use valid NDC or HCPCS code |
| BENEFIT TYPE | Pharmacy or Medical |
| SITE OF SERVICE ALLOWED | Office |
| COVERAGE REQUIREMENTS | Prior Authorization Required (Non-Preferred Product)<br>QUANTITY LIMIT – 8 kits per month |
| LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY | Click Here |

Spravato (esketamine) is a **non-preferred** product and will only be considered for coverage under the **medical or pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with the following disease state and meet the individual criteria as stated.

## MAJOR DEPRESSIVE DISORDER WITH SUICIDAL IDEATION

For **initial** authorization:

1. Member is 18 years of age or older; AND
2. Member has a diagnosis of major depressive disorder (MDD) with documentation of acute suicidal ideation or behavior requiring immediate intervention; AND
3. Medication is being prescribed by a psychiatrist in a Spravato REMS certified center; AND
4. Medication must be used in conjunction with an oral antidepressant (e.g., citalopram, duloxetine, venlafaxine, bupropion, trazodone).
5. **Dosage allowed:** 84 mg (1 kit) twice per week for 4 weeks (8 kits total).

**Note:** If member also has concomitant treatment resistant depression (TRD), must meet criteria for TRD in order to qualify for longer approval duration.

***If member meets all the requirements listed above, the medication will be approved for 1 month.***

For **reauthorization**:

Continuation of Spravato beyond 4 weeks has not been established for the same episode. If this is a new suicidal ideation episode, must follow initial criteria.

## TREATMENT RESISTANT DEPRESSION

For **initial** authorization:

1. Member is 18 years of age or older; AND
2. Member has a diagnosis of treatment resistant major depressive disorder; AND
3. Medication is being prescribed by a psychiatrist in a Spravato REMS certified center; AND
4. Medication will be used in conjunction with an oral antidepressant; AND
5. Member has tried and failed at least TWO of the following oral antidepressants from different drug classes at optimized doses for at least 8 weeks, at least one of which must be an SSRI or SNRI:
   a) Selective Serotonin Reuptake Inhibitor (e.g. citalopram, fluoxetine);
   b) Selective Norepinephrine Reuptake Inhibitor (e.g. duloxetine, venlafaxine);
   c) Tricyclic Antidepressant (e.g. nortriptyline);

d) Monoamine Oxidase Inhibitor (e.g. tranylcypromine);
e) Bupropion;
f) Mirtazapine; AND

6. Documentation of the member's baseline depression status using an appropriate rating scale [e.g., Patient Health Questionnaire (PHQ-9), Beck Depression Inventory (BDI), Quick Inventory of Depressive Symptomatology (QIDS), Montgomery-Åsberg Depression Rating Scale (MADRS), Hamilton Rating Scale for Depression (HAM-D)].
7. **Dosage allowed:**

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

***If member meets all the requirements listed above, the medication will be approved for 2 months.***

For **reauthorization**:

1. Member must be compliant with concomitant use of an oral antidepressant; AND
2. Documented improvement of depressive symptoms as measured by an appropriate rating scale (e.g. PHQ-9, BDI, etc.).

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.***

## CareSource considers Spravato (esketamine) not medically necessary for the treatment of diseases that are not listed in this document.

| DATE | ACTION/DESCRIPTION |
|---|---|
| **05/23/2019** | New policy for Spravato created. |
| **11/06/2020** | New diagnosis of MDD with suicidal ideation added. For TRD: added that medication must be prescribed by psychiatrist in a REMS certified center in accordance with package insert. |
| **01/11/2021** | TRD: Changed "depression" to "major depressive disorder." Clarified the dosing. Added dose requirement to step drugs and that one must be an SSRI or SNRI (first line). Removed trazodone. Revised list of severity scales. Reworded renewal criteria. |

References:


1. Spravato [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; July, 2020.
2. Daly EJ, Singh JB, Fedgchin M, et al. Efficacy and Safety of Intranasal Esketamine Adjunctive to Oral Antidepressant Therapy in Treatment-Resistant Depression: A Randomized Clinical Trial. *JAMA Psychiatry*. 2018;75(2):139-148.
3. Daly EJ, Trivedi MH, Janik A, et al. Efficacy of Esketamine Nasal Spray Plus Oral Antidepressant Treatment for Relapse Prevention in Patients With Treatment-Resistant Depression: A Randomized Clinical Trial. *JAMA Psychiatry*. 2019;76(9):893-903.

4. Gelenberg A., Freeman M., Markowitz J., et. al. Practice guideline for the treatment of patients with major depressive disorder. *Am J Psychiatry*. May 2010. Available at: https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf.
5. Weber AN, Michail M, Thompson A, Fiedorowicz JG. Psychiatric Emergencies: Assessing and Managing Suicidal Ideation. *Med Clin North Am*. 2017;101(3):553-571.
6. American Psychiatric Association. Practice Guideline for the Assessment and Treatment of Patients With Suicidal Behaviors. 2003. https://psychiatryonline-org.cedarville.ohionet.org/guidelines (Accessed on November 06, 2020).
7. Hirschfeld RM, Russell JM. Assessment and treatment of suicidal patients. N Engl J Med. 1997;337(13):910-915.
8. ClinicalTrials.gov. A Study to Evaluate the Efficacy and Safety of Intranasal Esketamine in Addition to Comprehensive Standard of Care for the Rapid Reduction of the Symptoms of Major Depressive Disorder, Including Suicidal Ideation, in Adult Participants Assessed to be at Imminent Risk for Suicide (Aspire II). Identifier: NCT03097133. Available at: https://clinicaltrials.gov/ct2/show/NCT03097133.
9. ClinicalTrials.gov. A Study to Evaluate the Efficacy and Safety of Intranasal Esketamine in Addition to Comprehensive Standard of Care for the Rapid Reduction of the Symptoms of Major Depressive Disorder, Including Suicidal Ideation, in Adult Participants Assessed to be at Imminent Risk for Suicide (Aspire I). Identifier: NCT03039192. Available at: https://clinicaltrials.gov/ct2/show/NCT03039192.
10. Mithawala PK, Davis DM. Managing treatment-resistant depression. *US Pharm*. 2020;45(5):15-19.
11. Gaynes BN, Asher G, Gartlehner G, et al. *Definition of Treatment-Resistant Depression in the Medicare Population*. Rockville (MD): Agency for Healthcare Research and Quality (US); February 9, 2018.
12. Fekadu A, Donocik JG, Cleare AJ. Standardisation framework for the Maudsley staging method for treatment resistance in depression. *BMC Psychiatry*. 2018;18(1):100. Published 2018 Apr 11. doi:10.1186/s12888-018-1679-x
13. Rush AJ, Trivedi MH, Wisniewski SR, et al. Acute and longer-term outcomes in depressed outpatients requiring one or several treatment steps: a STAR*D report. *Am J Psychiatry*. 2006;163(11):1905-1917. doi:10.1176/ajp.2006.163.11.1905

Effective date: 07/01/2021
Revised date: 01/11/2021