CareSource

PHARMACY POLICY STATEMENT **Ohio Medicaid**	
DRUG NAME	Spravato (esketamine)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy or Medical
SITE OF SERVICE ALLOWED	Office
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) 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 diagnosis of treatment resistant depression; 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); AND
5. Member has had a 60-day trial and failure of **at least two** of the following:
   a) Selective Serotonin Reuptake Inhibitor (e.g., citalopram, fluoxetine, etc.);
   b) Selective Norepinephrine Reuptake Inhibitor (e.g., duloxetine, venlafaxine, etc.);
   c) Tricyclic Antidepressant (e.g., amitriptyline);

   d) Monoamine Oxidase Inhibitor (e.g., selegiline);
   e) Bupropion;
   f) Mirtazapine;
   g) Trazodone; AND
6. Documentation of the member's baseline depression status using an appropriate rating scale (e.g., PHQ-9, Clinically Useful Depression Outcome Scale, Quick Inventory of Depressive Symptomatology-Self Report 16 Item, MADRS, HAM-D).
7. **Dosage allowed:**
   a) Induction (week 1 to 4): starting dose of 56 mg with subsequent doses 56 mg or 84 mg twice per week.
   b) Maintenance (week 5 and after): 56 mg or 84 mg once weekly or every 2 weeks. Maximum of 4 kits per month regardless of strength.

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

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Documented maintenance of clinical improvement in depressive symptoms as measured by improvement from baseline score on an appropriate rating scale.

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 the 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.

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. Mithawala PK, Davis DM. Managing treatment-resistant depression. *US Pharm*. 2020;45(5):15-19.
6. Weber AN, Michail M, Thompson A, Fiedorowicz JG. Psychiatric Emergencies: Assessing and Managing Suicidal Ideation. *Med Clin North Am*. 2017;101(3):553-571.
7. 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).
8. Hirschfeld RM, Russell JM. Assessment and treatment of suicidal patients. N Engl J Med. 1997;337(13):910-915.
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 II). Identifier: NCT03097133. Available at: https://clinicaltrials.gov/ct2/show/NCT03097133.
10. 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.

Effective date: 04/01/2021
Revised date: 11/06/2020