New Hampshire Medicaid Fee-for-Service Program

Spravato® (esketamine) Criteria

Approval Date: August 13, 2021

Indications

Esketamine (Spravato®) nasal spray received United States Food and Drug Administration approval on March 5, 2019 for treatment-resistant depression (TRD) in adults. On July 31, 2020, it received a new indication for depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior. In addition, a new limitation of use was added, which states that its effectiveness in preventing suicide or in reducing suicidal ideation or behavior has not been demonstrated and its use does not preclude the need for hospitalization, when clinically warranted, regardless of if the patient improves following initial treatment.

Medications

Brand Names	Generic Names	Dosage
Spravato®	esketamine	Nasal spray: 28 mg/0.2 mL

Criteria for Approval

1. Patient is ≥ 18 years old; **AND**
2. Patient has a Diagnostic and Statistical Manual of Mental Disorders (DSM-5) diagnosis of major depressive disorder (MDD); **AND**
3. Patient must have a baseline depression assessment using any validated depression rating scale (e.g., Montgomery-Asberg Depression Rating Scale [MADRS], Hamilton Depression Rating Scale [HAM-D], Patient Health Questionnaire Depression Scale [PHQ-9], Beck Depression Inventory [BDI]); **AND**
4. Esketamine is prescribed by or in consultation with a psychiatrist or psychiatric mental health nurse practitioner (PMHNP); **AND**
5. Patient must NOT have any of the following conditions:
    a. Aneurysmal vascular disease; **OR**
    b. Arteriovenous malformation; **OR**
    c. History of intracerebral hemorrhage; **OR**
    d. Uncontrolled hypertension (> 140/90 mmHg in patients < 65 years old or > 150/90 mmHg in patients ≥ 65 years); **AND**

6. Patient must NOT be pregnant; **AND**
7. Patient must NOT have known hypersensitivity to any component of the product; **AND**
8. Patient is NOT receiving concomitant ketamine therapy; **AND**
9. Patient must be taking esketamine in conjunction with an antidepressant medication (esketamine is not to be used as monotherapy); **AND**
10. Attestation that prescriber's healthcare setting is certified in the Spravato Risk Evaluation and Mitigation Strategies (REMS) program; **AND**
11. Attestation that the prescriber will check blood pressure prior to each administration AND is capable of monitoring patient as directed following administration, ensuring patient has been stable for ≥ 2 hours, with baseline or decreasing blood pressure, prior to cessation of monitoring; **AND**
12. Prescriber attestation that he/she has reviewed the dosing schedule with the patient; **AND**
13. Prescriber attestation that patient understands and is committed to receiving scheduled doses AND has the capability of being available twice a week with adequate transportation to and from treatment facility**; AND**
14. If used for **treatment-resistant depression (TRD)**, patient meets the following criteria:
    a. Patient has a history of adherence with oral therapy (compliant with ≥ 80% of their doses as demonstrated by refill history or prescriber attestation during current depressive episode); **AND**
    b. Patient has tried psychotherapy alone or in combination with oral antidepressants, if psychotherapy resource is available; **AND**
    c. Patient must NOT have failed prior ketamine treatment for MDD; **AND**
    d. Patient is NOT receiving concomitant electroconvulsive therapy (ECT), vagus nerve stimulation (VNS), transcranial magnetic stimulation (TMS), or deep brain stimulation (DBS); **AND**
    e. Patient has failed a trial of ≥ 2 antidepressants of *different* classes for a duration of ≥ 6 weeks each at generally accepted doses unless contraindicated or clinically significant adverse effects are experienced (failed trial defined as < 50% reduction in symptom severity using any validated depression rating scale); **AND**
    f. Patient has failed a trial of antidepressant augmentation therapy for a duration of ≥ 6 weeks with ≥ 1 of the following, unless contraindicated or clinically significant adverse effects are experienced (failed trial as defined above):
        i. An atypical antipsychotic; **OR**
        ii. Lithium; **OR**
        iii. An antidepressant from a different class

Criteria for Renewal

1. Patient must continue to meet the above criteria; **AND**
2. Patient must demonstrate disease improvement and/or stabilization as a result of the medication, as documented by a 50% reduction in symptom severity using a validated depression rating scale; **AND**
3. Patient has not experienced unacceptable toxicity (e.g., dissociation, cognitive impairment); **AND**
4. Prescriber attestation that patient has committed to receiving all scheduled doses thus far in treatment and will continue to do so.

Criteria for Denial

1. Above criteria are not met; **OR**
2. Patient has any of the following conditions:
   a. aneurysmal vascular disease; **OR**
   b. Arteriovenous malformation; **OR**
   c. History of intracerebral hemorrhage; **OR**
   d. Uncontrolled hypertension (> 140/90 mmHg in patients < 65 years old or > 150/90 mmHg in patients ≥ 65 years); **OR**
   e. Patient is pregnant.

Length of Authorization

- **For Treatment-Resistant Depression (TRD) and Major Depressive Disorder (MDD) with Acute Suicidal Ideation/Behavior**
  - **Initial**: 4 weeks
  - **Renewal**: 4 weeks for first renewal; 3 months for subsequent renewals

Quantity Limit

- **Treatment-Resistant Depression (TRD)**
  - Weeks 1 to 4 ("Induction Phase"): 2 kits/week (56 mg or 84 mg kit)
  - Week 5 and thereafter ("Maintenance Phase"): 1 kit/week (56 mg or 84 mg kit)
- **Major Depressive Disorder (MDD) with Acute Suicidal Ideation/Behavior**
  - 2 kits/week (56 mg or 84 mg kit)

References

Available upon request.

Revision History

Reviewed by	Reason for Review	Date Approved
DUR Board	New	06/08/2021
Commissioner Designee	Approval	08/13/2021