

Beacon NMNC 7.200.02 Spravato™ (Esketamine) Nasal Spray for MDD with Suicidality

MEDICAL NECESSITY CRITERIA

Admission Criteria

Member must meet ALL of the following criteria for admission:

1. Member is 18 years of age or older
2. Has documented depression defined as a DSM-5 diagnosis of Major Depressive Disorder (MDD) without psychotic features
3. The (unipolar) MDD diagnosis has been made by or in consultation with a qualified medical professional
4. Member does not have a DSM-5 diagnosis of active substance use disorder, opioid use disorder, or alcohol use disorder in the last 6 months
5. Has confirmed suicidal ideation with intent in the last 48 hours based on the evidence-based suicide risk assessment tool (e.g., member responded with a “Yes” response to the Mini-International Neuropsychiatric Interview (MINI) questions B3 (“Think about suicide [killing yourself]?”) and B10 (“Intend to act on thoughts of killing yourself in the past 24 hours?”))
6. Documentation of a standard rating scale that reliably measures depressive symptoms, indicating moderate to severe MDD
7. Prescriber and/or the prescriber’s healthcare setting is certified in the Spravato REMS program
8. Spravato will be used in combination with an oral antidepressant (to which the patient had not shown a previous nonresponse)
9. The requested dose is within the recommended dose approved by the FDA for (unipolar) MDD with suicidality
10. The first dose will be given in an inpatient hospital setting
11. Does not have any of the following contraindications:
 - a. Severe hepatic disease (Child-Pugh class C)
 - b. Hypersensitive to ketamine, esketamine, or any component of the formulation

- c. Aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels)
- d. Arteriovenous malformation
- e. History of intracerebral hemorrhage

Boxed Warning: While safety of esketamine was demonstrated, it has a boxed warning for sedation, dissociation, abuse & misuse, and suicidal thoughts. Esketamine should be used with caution in patients at high risk for sedation, dissociative or perceptual changes, abuse and misuse, suicidal thoughts and behavior.

Warning and Precautions: Patients with cardiovascular and cerebrovascular conditions should be carefully assessed for benefits and risks since an increase in blood pressure or intracranial pressure poses a serious risk

Limitations of Use:

The effectiveness of Spravato in preventing suicide or in reducing suicidal ideation or behavior has not been demonstrated.

The authorization will be issued for 4 weeks

CONTINUED STAY CRITERIA

N/A

DISCHARGE CRITERIA

N/A

REFERENCES

1. Fu DJ, Ionescu DF, Li X, et al. Esketamine nasal spray for rapid reduction of major depressive disorder symptoms in patients who have active suicidal ideation with intent: double-blind-, randomized study (ASPIRE I). *J Clin Psychiatry* 2020;81(3):19m13191.
2. Ionescu DF, Fu DJ, Qiu X, et al. Esketamine nasal spray for rapid reduction of depressive symptoms in patients with major depressive disorder who have active suicide ideation with intent: results from a phase 3, double-blind, randomized study (ASPIRE II). *Int J Neuropsychopharmacol* 2020 Aug 29;pyaa068. doi:10.1093/ijnp/pyaa068.