

Beacon NMNC 7.100.01 Spravato™ (esketamine) Nasal Spray (Medicare Only)

INITIAL AUTHORIZATION CRITERIA

All of the following criteria must be met for an initial authorization of 3 months:

1. Member is 18 years of age or older
2. Has documented depression defined as a DSM-V diagnosis of Major Depressive Disorder (MDD)
3. The diagnosis has been made by or in consultation with a qualified medical professional
4. Documentation of an inadequate response (e.g., <25% improvement on a standard rating scale) to at least two different antidepressants from different classes at an adequate dose, duration (minimum 6 weeks for each medication) and adherence (e.g., taken >80% of the prescribed dose for each medication) in the current depressive episode
5. One of the following:
 - a. Documentation of an inadequate response or adverse reaction to one of the following antidepressant augmentation therapies:
 - i. second-generation antipsychotic; or
 - ii. lithium; or
 - iii. second antidepressant from a different class; or
 - iv. thyroid hormone; or
 - b. contraindication to all augmentation strategies.
6. Documentation of a standard rating scale that reliably measures depressive symptoms, indicating moderate to severe MDD (*recommended*)
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
10. 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

RE-AUTHORIZATION CRITERIA

All of the following criteria must be met for a re-authorization of 3 months:

1. Documentation of clinical response as demonstrated by an improvement from baseline on a validated standard rating scale
2. Prescriber and/or the prescriber's healthcare setting is certified in the Spravato REMS program

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.

REFERENCES

Beacon's Medical Necessity Criteria incorporate generally accepted standards of behavioral health practice. In the course of reviewing the criteria annually there is an extensive literature search conducted and each of the following sources are consulted to determine if there is any relevant research or update:

1. Professional societies: American Psychiatric Association (APA); American Academy of Psychiatrists in Alcoholism and Addictions (AAPAA); American Academy of Child and Adolescent Psychiatry (AACAP)
2. National care guideline and criteria entities: American Society of Addiction Medicine (ASAM); MCG Behavioral Health Care Guidelines (formerly known as Milliman Care Guidelines); Change Healthcare's InterQual ® Behavioral Health Criteria
3. National health institutes: National Institutes of Health (NIH); National Institute on Alcohol Abuse and Alcoholism (NIAAA); National Institutes of Drug Abuse (NIDA); Substance Abuse and Mental Health Services Administration (SAMHSA)
4. Professional publications and psychiatric texts
5. Federal/state regulatory and industry accreditation requirements, including CMS's National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs)
6. National industry peer organizations, including managed care organizations (MCOs) and behavioral health organizations (BHOs)