Beacon NMNC 7.201.03 Spravato for Treatment-Resistant Depression

Initial Authorization Criteria
Member must meet ALL of the following criteria for the *initial* authorization:

1. Member is 18 years of age or older

AND

2. Has documented depression defined as a DSM-V diagnosis of Major Depressive Disorder (MDD)

AND

3. The diagnosis has been made by or in consultation with a qualified medical professional

AND

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

AND

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.

AND

6. Documentation of a standard rating scale that reliably measures depressive symptoms, indicating moderate to severe MDD *(recommended)*

AND

7. Prescriber and/or the prescriber's healthcare setting is certified in the Spravato REMS program

AND

8. Spravato will be used in combination with an oral antidepressant (to which the patient had not shown a previous nonresponse)

AND

9. The requested dose is within the recommended dose approved by the FDA

AND

10. Does not have any of the following contraindications:
    a. Severe hepatic disease (Child-Puch 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

The initial authorization will be issued for 3 months.

Re-authorization Criteria

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

The re-authorization will be issued for 3 months.

Note. Authorization by Beacon is to be performed for services billed to Beacon where the provision of the medication is completed by the practitioner (purchase of medication and administration/observation, procedure codes G2082 and G2083).

Note. Authorization for services billed to Beacon where the medication is not purchased/provided by the practitioner is to be submitted for claims payment with E/M code 99215 and additional 15 minute 99417 (or G2212 for Medicare) codes to cover the visit and extended observation time. These codes are not specific to esketamine and do not require preauthorization in the claims system. In these scenarios, Beacon will accept the medical necessity determination/prior authorization process for the medication from the MCO or PBM and allow the visit(s) to pay without separate authorization.

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

1. Fedgchin M, Trivedi M, Daly E, et al. Efficacy and safety of fixed-dose esketamine nasal spray combined with a new oral antidepressant in treatment-resistant depression: results of a randomized, double-blind, active-controlled study (TRANSFORM-1). *International Journal of Neuropsychopharmacology*. 2019;22(1):616-630.
2. Popova V, Daly E, Trivedi M, et al. Efficacy and safety of flexibly dosed esketamine nasal spray combined with a newly initiated oral antidepressant in treatment-resistant depression: a randomized, double-blind active-controlled study. *Am J Psychiatry*. 2019 June 1;176(6): 428-438.
3. Daly E, Trivedi M, J Adam, et al. Efficacy of esketamine nasal spray plus oral antidepressant treatment for relapse prevention in patients with treatment-resistant depression. *JAMA Psychiatry*. 2019 Sep; 76(9):893-903.
4. Daly E, Singh J, Fedchin 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.

* Coverage is subject to benefit allowance.