Protocol for Spravato (esketamine) Nasal Spray

Approved July 2020
Updated January 2022

Addendum:
Added new FDA-approved indication for "depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior" – July 2020

Background:
Spravato is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults and for depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior.

Criteria for approval:

Patient meets ALL the following:

1. Patient is 18 years of age or older
   A. Patient has been diagnosed with treatment-resistant depression; OR
   B. Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior.

2. (a) For TRD, there is documentation showing that the patient had therapeutic failure or had an intolerance for at least 3 weeks each to at least two (2) antidepressants, unless the patient has contraindications to all antidepressants.
   (b) For MDD with suicidal ideation or behavior, 2-drugs trial not applicable

3. Patient must use Spravato nasal spray in conjunction with an oral antidepressant therapy

4. Spravato will be administered under the supervision of a healthcare provider and the patient will be monitored for at least 2 hours after administration

5. Patient has been assessed and determined not to be at risk for abuse and misuse of Spravato

6. Patient has no contraindications to therapy: a. Patient has no aneurysmal vascular disease (including in the brain, chest, abdominal aorta, arms and legs) or arteriovenous malformation, or history of bleeding in the brain

7. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital

Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer reviewed evidence

Initial Approval Duration: 3 months

Continuation of therapy:

1. Documentation showing the patient responded to therapy demonstrated by an improvement from baseline in the Montgomery-Asberg Depression Rating Scale (MADRS)
2. Patient must use Spravato nasal spray in conjunction with an oral antidepressant therapy
3. Spravato will be administered under the supervision of a healthcare provider and the patient will be monitored for at least 2 hours after administration
4. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Lexi-Drugs, national guidelines, or other peer-reviewed evidence

Warning:
Because of the risks of serious adverse outcomes resulting from sedation, dissociation, and abuse and misuse, SPRAVATO is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the SPRAVATO REMS

Renewal Approval Duration: 6 months

References:

1. Spravato [package insert]. Janssen Pharmaceuticals, Inc., Titusville, NJ 08560. July 2020
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2018. Updated periodically
3. Canuso C, Singh J, et al: Efficacy and Safety of Intranasal Esketamine for the Rapid Reduction of Symptoms of Depression and Suicidality in Patients at Imminent Risk for Suicide: Results of a Double-Blind, Randomized, Placebo Controlled Study. Am J Psychiatry. 2018. Accessed online on May 24, 2019 at: https://adaa.org/sites/default/files/Canuso-AJP-2018.pdf