



MONTANA HEALTHCARE PROGRAMS

January 21, 2020

Physician Administered Drug Prior Authorization Criteria for Spravato™

Version 1, 1-21-20

Spravato™ esketamine

Spravato™ is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist.

Indications:

Spravato™ is indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults.

Criteria for Approval:

1. Member is 18 years of age or older; AND
2. Member has a Diagnostic and Statistical Manual of Mental Disorders (DSM-5) diagnosis of major depressive disorder (MDD); AND
3. Member must have a baseline depression assessment using a validated depression rating scale; AND
4. Member has failed ≥ 3 antidepressants with different mechanisms of action in the current depressive episode. A failure is defined as having an inadequate response after at least 6 weeks duration at a generally accepted dose; AND
5. Member has failed a trial of augmented antidepressant therapy (with an atypical antipsychotic, lithium, or other appropriate therapy) in the current depressive episode; AND
6. Member has failed psychotherapy; AND
7. Medication is prescribed by a psychiatrist; AND
8. Treatment session must include post-treatment observation until clinically stable. Minimum of 2 hours; AND
9. Member's risk for abuse or misuse is assessed prior to initiating treatment and periodically while on therapy; AND
10. Member and facility are enrolled in the Spravato™ REMS program; AND
11. Provider and member attest that member is able to make it to all scheduled appointments; AND

12. Member continues to take an antidepressant in conjunction with Spravato™ and is adherent; AND
13. Member is not pregnant or breastfeeding.

Initial approval is 4 weeks.

Criteria for Denial:

1. Member has a contraindication including aneurysmal vascular disease, arteriovenous malformation, history of intracerebral hemorrhage, or hypersensitivity to any component of the medication.
2. Member does not have a current DSM-5 diagnosis or any of the following:
 - a. Bipolar or related disorder, intellectual disability, or cluster b personality disorder
 - b. Borderline personality disorder
 - c. Psychotic disorder, major depressive disorder (MDD) with psychosis, or obsessive-compulsive disorder
 - d. Active moderate to severe substance or alcohol use disorder

Quantity Limit:

Weeks 1 to 4: 2 kits/week

Week 5 and after: 1 kit/week

Criteria for Renewal Authorization Approval:

1. Member continues to meet the initial criteria.
2. Member must not have missed any doses.
3. Member must show disease improvement by a 50% reduction in symptom severity compared to the baseline depression assessment utilizing the same rating scale.

Renewal authorization is for 6 months.

References:

1. Spravato™ [package insert] Titusville, NJ; Janssen Pharmaceuticals, Inc.; 05/2019, Accessed January 20, 2020.
2. [Thase, Michael. Unipolar depression in adults: Choosing treatment for resistant depression. Solomon, David, ed. UpToDate. Waltham, MA: UpToDate Inc. <http://www.uptodate.com> \(Accessed January 20, 2020\)](#)
3. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; January 20, 2020
4. Janssen Research & Development, LLC. A Double-blind Study to Assess the Efficacy and Safety of Intranasal Esketamine for the Rapid Reduction of the Symptoms of Major Depressive [Disorder, Including Suicidal Ideation, in Participants Who Are Assessed to be at Imminent Risk for Suicide.](#) <https://clinicaltrials.gov/ct2/show/NCT02133001> (Accessed January 20, 2020)