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**Office of Pharmacy Services
Prior Authorization Criteria
SPRAVATO™ (esketamine – nasal spray)
Effective 5/24/2024**

Prior Authorization Request Form

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 or depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior.

Prior authorization requests for Spravato may be approved if the following criteria are met:

- 1) Diagnosis of treatment resistant depression (TRD) or depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior by an M.D./D.O. identified psychiatrist; **AND**
- 2) Prescribed by a M.D./D.O. psychiatrist; **AND**
- 3) The prescriber/treatment facility, pharmacy and patient are enrolled in the SPRAVATO REMS program; **AND**
- 4) Patient is within the age range as recommended by the FDA label; **AND**
- 5) Progress notes are required as documentation of the patient's diagnosis of treatment-resistant Major Depressive Disorder and must include screening to rule out Bipolar Disorder as well as all previous therapies failed; **AND**
- 6) The patient's baseline depression symptoms must be measured and documented using an objective clinical rating scale such as (but not limited to) the PHQ-9, Clinically Useful Depression Outcome Scale, Quick Inventory of Depressive Symptomatology-Self Report 16 Item, MADRS, or HAM-D; **AND**
- 7) Patient has failed to achieve a satisfactory response after attempting a minimum of THREE separate therapeutic trials* for 12 weeks each. These trials* must include antidepressants from at least two (2) different therapeutic drug classes as well as at least one trial* using augmentation therapy; **AND**
- 8) All medications for the above trials* must be taken compliantly for at least **12 weeks** within the past three years based on pharmacy claims data (if claims data is not available, a medication fill history report must be obtained from the dispensing pharmacy and is required to be submitted); **AND**
- 9) Spravato must be used in combination with an oral antidepressant; **AND**
- 10) Patient is not concurrently being prescribed or utilizing ketamine.

Updated PS 5/24/2024 @ DUR Board Meeting
Original DUR Board Approval: 11/18/2020



***All trials must be within an FDA approved therapeutic dose range. Agents must be prescribed at/titrated up to the maximum dose.**

Initial approvals will be for 30 days. Further approvals may be granted for 6 months after all of the continuation of therapy criteria has been met.

CONTINUATION OF THERAPY CRITERIA (only applicable for treatment resistant depression)

- 1) Patient's claims history must indicate compliant (compliance being defined as having no longer than a 10-day gap between when a prescription may be refilled and actually is refilled) concurrent use of an oral antidepressant; **AND**
- 2) Patient must show demonstrable improvement over baseline as measured by the same scale used for the initial approval.

REFERENCES:

- 1) Spravato package insert revised 10/23 (accessed 5/2024)
- 2) UpToDate Articles accessed 05/2024: Unipolar depression in adults: Choosing treatment for resistant depression
- 3) Lexi-Comp Clinical Application (accessed 5/2024)

