Serenity Health, LLC

Spravato® (esketamine) CIII
28 mg nasal spray

Serenity Health, LLC Now REMS Certified and Ready to Provide a Treatment Option in Two Subpopulations of Adults with Major Depressive Disorder (MDD)

We are now Risk Evaluation and Mitigation Strategy (REMS)–certified to provide SPRAVATO® (esketamine) CIII, a nasal spray approved for use, in conjunction with an oral antidepressant, to treat treatment-resistant depression (TRD) in adults and depressive symptoms in adults with MDD with acute suicidal ideation or behavior. The effectiveness of SPRAVATO® in preventing suicide or in reducing suicidal ideation or behavior has not been demonstrated. Use of SPRAVATO® does not preclude the need for hospitalization if clinically warranted, even if patients experience improvement after an initial dose of SPRAVATO®. SPRAVATO® is not approved as an anesthetic agent. The safety and effectiveness of SPRAVATO® as an anesthetic agent have not been established.

Because of the risks for sedation, dissociation, abuse and misuse, and suicidal thoughts and behaviors, SPRAVATO® carries a Boxed WARNING and is available only through a restricted program called the SPRAVATO® Risk Evaluation and Mitigation Strategy (REMS) Program. SPRAVATO® can be administered only at healthcare settings certified in the SPRAVATO® REMS Program and to patients enrolled in the program. SPRAVATO® is never dispensed directly to a patient for home use.

The medical staff at our certified treatment center are trained to prescribe, dispense, and administer SPRAVATO®, and we have established processes and procedures in accordance with the REMS. A healthcare provider will provide direct medical supervision as the patient self-administers SPRAVATO® and will monitor every patient after every dose for at least two hours for resolution of sedation and dissociation and changes in vital signs.

SPRAVATO® must never be dispensed directly to a patient for home use. Additionally, all patients require transportation from Serenity Health following the observation period, as they should not drive or operate machinery until the day after a treatment session, following a restful sleep.

At Serenity Health, we understand that finding an appropriate treatment option for these patients can be complex. We are committed to partnering with your practice to provide a well-coordinated treatment experience with SPRAVATO® for appropriate adult patients. Our healthcare providers are proactive about coordinating care and will ensure an open line of communication with referring providers about the patient's progress. In addition, our care team will help provide patients with a clear understanding of what to expect with SPRAVATO® treatment sessions. Our treatment center will carry out benefits investigation to ensure that you and your patients are aware of coverage and costs prior to SPRAVATO® treatment.

To learn more about our treatment center and how we can work together to provide appropriate adult patients with SPRAVATO®, please email info@serenitymo.com.

For more information about SPRAVATO®, please refer to the manufacturer's Prescribing Information and Medication Guide or visit www.spravatohcp.com.