C·B·H

a division of DBHIDS

Spravato® (Esketamine): Protocol and Procedures for Behavioral Health Provider Implementation of the Two-Hour Monitoring Period

Updated February 2025

Community Behavioral Health

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1. BACKGROUND AND PURPOSE

Spravato® (Esketamine) is a newly designated treatment option for individuals diagnosed with treatment-resistant depression (TRD) or individuals with major depressive disorder (MDD) with acute suicidal ideation or behavior. In addition, medications for severe depression and neuromodulation therapies, including Electroconvulsive therapy (ECT) and transcranial magnetic stimulation (TMS), comprise the continuum of treatment options for the affected population.

1.1. Medication Overview and Indications

- NMDA antagonist, targeting different receptors than traditional antidepressants, designed to be self-administered as a nasal spray, under the supervision of a medical professional, in a health care setting
- Schedule III medication with risk for abuse and misuse
- Indicated for the treatment of:
  - TRD in adults
  - Depressive symptoms in adults with MDD with acute suicidal ideation or behavior

1.2. PA Formulary Status and Prior Authorization Core Elements

- Non-preferred agent on the **Pennsylvania Preferred Drug List (PDL)**
- See the full prior authorization information in **PA DHS Medical Assistance Bulletin 01-25-05** (Check the **DHS Bulletin search** online for any updates.).

1.3. PHMCO Payment and Logistical Support

- If a member has met the prior authorization criteria referenced above, the medication will be approved by the Physical Health Managed Care Organization (PH-MCO).
- The clinic will need to coordinate the delivery of medication with the pharmacy.

- Medication may never be dispensed directly to members.
- The PH-MCO will cover 100% of the medication's cost (members may have a $0-3 copay).

2. PROVIDER READINESS

2.1. FDA-Required Risk Evaluation and Mitigation Strategy (REMS) Program

- A Spravato REMS is required due to risks of serious adverse outcomes resulting from sedation and dissociation as well as potential for abuse and misuse.
- More information about Spravato REMS and how to enroll in the program is available online at **spravatorems.com**.
- Also available for providers' support and reference is the primary contact in Philadelphia County from Janssen, the manufacturer of Spravato:
  - Chris Gibson, Key Account Specialist (point person for setting up a Spravato treatment center or treatment center operations), at **JGibso16@ITS.JNJ.com**.

2.2. Space Considerations for Patients

- Consider which room or designated area in your treatment center can be used as a dedicated space for patients taking Spravato, including a treatment chair where a patient can comfortably sit during the two-hour monitoring period.
- Spravato is a Schedule III controlled substance, and your treatment center must store the product appropriately.
- See **Managing REMS-Certified SPRAVATO® Treatment Center Operations** for examples of how treatment spaces can be set up.
  - Single chair in a private dedicated space
  - Multiple chairs in shared space

2.3. Member Recruitment Plan

CBH providers are encouraged to utilize the diagnostic criteria, detailed in Section 1 above, to identify members who could benefit from Spravato. Proactive recruitment has the potential to minimize CBH members' needless suffering from ongoing trials with additional antidepressant medications. Providers can also collaborate with other providers (including inpatient) that do not offer Spravato for referrals to their agency. CBH requests that appropriate processes be in place to maximize care coordination for members who are referred from other agencies and still receiving other services concurrently.

2.4. Staffing for Oversight

The REMS program does not dictate the provider type that should provide the member monitoring over the two-hour time frame. As such, CBH encourages the use of the available team member from the medical staff who is trained to provide all of the assessments required. In the demonstration pilot phase, over the course of each two-hour block, providers utilized a mix of medical assistants and nurses, with psychiatrists often being leveraged as needed. Also, monitoring can be done by student/trainee health care professionals with existing licenses (e.g., a physician during residency training, a nurse practitioner student who is already a registered nurse). The reimbursement rate for the two-hour post-administration period is a flat rate independent of the staff member type providing oversight. CBH's expectation is that each provider will implement a monitoring plan that fits their staffing availability without compromising the quality of care warranted to administer Spravato to CBH members.

3. CBH BILLING

- The provider must be contracted with CBH for specified billing codes prior to delivering the service.
- The level of care (LOC) code for Spravato is 300-225. The Appendix A must include the provider's offering of this service, which is initiated by contacting one's agency's assigned CBH provider representative.
- The provider can also submit the 99211 E&M code for the assessment that occurs prior to member self-administration of Spravato. The goals of that time typically include administering the PHQ-9, inquiring how the member did since the last visit, and reviewing pre-treatment requirements (e.g., no food two hours prior to

treatment, no liquids 30 minutes prior to treatment). This code is to be submitted for each treatment episode where applicable.

3.1. For Outpatient Clinics

The provider should submit the H0034 code which is specifically for the two-hour post-Spravato administration code. This code is to be submitted for each treatment episode.

3.2. For Physician Groups

The provider should submit the H2010 code which is a 15-minute code that's to be used only by private physician practices. For the post-Spravato administration, eight units must be billed to total the two-hour time frame. This code is to be submitted for each treatment episode.

4. CLINICAL GUIDANCE

- Providers should administer structured tools to assess clinical symptoms and psychosocial functioning before and during treatment with Spravato. Specifically, a mental status examination should be completed and documented at each visit, along with structured tools including the PHQ 9, Columbia Suicide Severity Rating Scale, and social determinants of health (SDOH) screening tools.
- Special consideration should be given to the management of individuals with substance use disorders (SUD) during treatment with Spravato. Specifically, providers should regularly assess for active substance use and provide education regarding the benefits of SUD treatment.
- Providers should provide education to individuals enrolled in Spravato treatment and regularly monitor for potential side effects including dissociation, elevated blood pressure, and respiratory side effects.
- Documentation should adhere to standards governed and monitored by DBHIDS (NIAC) and CBH (Compliance and Quality).

5. ACCESS TO MEMBERS

For providers who are not certified but who want to refer patients they believe may benefit from Spravato treatment, please contact your Provider Representative for the

up-to-date list of CBH providers who are Spravato-certified and actively treating CBH members. It is CBH's intention that any of its members who have the appropriate diagnoses and whom the prescriber believes will benefit from Spravato should be able to have access to it.

As with access to other services, SDOH have an impact on members' experience and outcomes. For Spravato, due to frequency of treatment—especially in the first several weeks—the type of employment, access to paid time off, and transportation are the most frequently observed drivers of adherence to treatment. As such, CBH requires that providers include these factors, and others as applicable to members, in the consideration process for members' fit for Spravato. Members' buy-in must include full awareness of the time, energy, and logistical commitment needed for successful treatment with Spravato.

The **Medical Assistance Transportation Program** (MATP) is a shared ride transportation service available to people receiving Medical Assistance (MA) and is paid for by the **Pennsylvania Department of Human Services** (PA DHS). In Philadelphia County, the MATP Program is run by **Modivcare**. In Philadelphia, you do not need to fill out an application for MATP services.

You can use MATP rides to go to medical appointments or to any service covered by MA. These medical services include but are not limited to: doctors, dentists, SUD treatment and treatment clinics, hospitals for tests (e.g., lab work, x-rays, etc.), psychologists, psychiatrists, medical equipment suppliers, pharmacies for prescriptions, therapies (i.e., physical, occupational), and mental health treatment.

CBH regularly updates a **detailed webpage on its website** about transportation support for its members; providers' partnership in ensuring transportation support is critical to maximizing benefit from consistent Spravato treatment.

*Send inquiries about this protocol and procedures document to **CBH.Pharmacyinitiatives@phila.gov**.*