Division: Pharmacy Policy	Subject: State of Florida's Agency for Health Care Administration's Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	October 3, 2019, August 5, 2020

SPRAVATO™ (esketamine)

LENGTH OF AUTHORIZATION: 3 months

INITIAL THERAPY REVIEW CRITERIA:

- Patient is ≥ 18 years old.
- Diagnosis of Major Depressive Disorder (MDD) with acute suicidal ideation/behavior or Treatment-Resistant Depression (TRD).
- Documented trial and failure of preferred oral antidepressants in different therapeutic classes (e.g. SSRIs, SNRIs, TCAs) taken at an adequate dose for a minimum of four (4) weeks.
- Patient must have been compliant with the preferred oral antidepressant regimens.
- Patient is using Spravato in conjunction with an oral antidepressant.

CONTINUATION OF THERAPY REVIEW CRITERIA:

- Patient met initial review requirements.
- Patient is using Spravato in conjunction with an oral antidepressant.
- Documentation submitted indicating the patient clinically benefited from the therapy.

DOSING AND ADMINISTRATION:

- TRD
  - *Induction Phase:* Weeks 1-4: Administer twice per week, day 1 starting dose 56mg, subsequent doses 56mg or 84mg intranasally.
  - *Maintenance Phase:* Weeks 5-8: Administer once weekly 56mg or 84mg intranasally.
    Weeks 9 and thereafter: Administer every 2 weeks or once weekly 56mg or 84mg intranasally.
  - Evidence of therapeutic benefit should be evaluated at the end of the induction phase to determine need for continued treatment.
- MDD with acute suicidal ideation/behavior
  - Administer 84mg intranasally twice per week for 4 weeks. Dosage may be reduced to 56mg based on tolerability.
  - Evidence of therapeutic benefit should be evaluated after 4 weeks of treatment to determine need for continued treatment.
- The nasal spray delivers 28 mg per device. Use 2 devices for a 56 mg dose or 3 devices for an 84 mg dose, with a 5-minute rest between use of each device.
- SPRAVATO must be administered under the direct supervision of a healthcare professional only in a setting with adequate patient monitoring facilities. Monitor patients for at least two hours after administration.
- Spravato is only available through a restricted program called the Spravato (esketamine) REMS due to serious risk of sedation, dissociation, and abuse/misuse.