I. Policy:
Spravato (esketamine)

II. Purpose/Objective:
To provide a policy of coverage regarding Spravato (esketamine)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.
DESCRIPTION:
Spravato (esketamine) is a nonselective, noncompetitive N-methyl-D-aspartate (NMDA) receptor antagonist. The mechanism by which it exerts its antidepressant effect is unknown. The major circulating metabolite noresketamine demonstrated activity at the same receptor with less affinity.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

Spravato (esketamine) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation of age ≥ 18 AND
- Medical record documentation of diagnosis of major depression disorder (MDD) AND
- Medical record documentation of Spravato being used for treatment-resistant depression as defined by failure of at least two antidepressants from two different classes at an optimized dose for at least 6 weeks AND
- Medical record documentation that Spravato will be used in combination with a newly initiated antidepressant AND
- Medical record documentation of the patient’s baseline depression status using an appropriate rating scale (e.g. PHQ-9, Clinically Useful Depression Outcome Scale, Quick Inventory of Depressive Symptomatology-Self Report 16 Item, MADRS, HAM-D) AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to olanzapine/fluoxetine capsules

Authorization Duration:
Initial approval will be for 1 month or less if the reviewing provider feels it is medically appropriate. For continued coverage, the following criteria is required.

- Medical record documentation of clinical improvement in depression symptoms as measured by an appropriate rating scale (compared to previous measurement).

Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. For continued coverage, the following criteria is required.

- Medical record documentation of clinical improvement or lack of progression in depression symptoms as measured by an appropriate rating scale (compared to previous measurement).

Quantity Limits:
For the initial 1 month authorization: 23 devices per 28 days
For subsequent authorizations: 12 devices per 28 days

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 5/21/19

Revised: 

Reviewed: 2/1/20