Geisinger Health Plan

POLICIES AND PROCEDURE MANUAL

Policy: MBP 195.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Spravato (esketamine)

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
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. 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:

For Treatment Resistant Depression

- 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 **AND**
- Medical record documentation that all potential drug interactions have been addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary about the risks associated with the use of both medications when they interact).

For acute suicidal ideation and behavior

- Medical record documentation of age ≥ 18 years **AND**
- Medical record documentation that Spravato will be used in combination with an oral antidepressant **AND**
- Medical record documentation of diagnosis of major depression disorder (MDD) **AND**
- Medical record documentation of a recent hospital admission (within 4 weeks) due to depressive symptoms with acute suicidal ideation and behavior **AND**
- Medical record documentation that Spravato was started inpatient **AND**
- Medical record documentation that Spravato will not exceed the FDA-approved duration of 4 weeks **AND**
- Medical record documentation that all potential drug interactions have been addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary about the risks associated with the use of both medications when they interact).

*Note to reviewer: The standard of care for patients with acute suicidal ideation and behavior is to hospitalize for safety. Spravato should be started inpatient for acute suicidal ideation requests.

Authorization Duration for treatment resistant depression:
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 treatment resistant depression:
For the initial 1 month authorization: 23 devices per 28 days
For subsequent authorizations: 12 devices per 28 days

Authorization Duration for depressive episodes with acute suidical ideation: Approval will be for one (1) 4 week approval for the FDA approved maximum of 24 devices. Requests for authorizations exceeding these limits will require the following medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improvement by dosing beyond the FDA-approved treatment duration.

Quantity Limits for depressive episodes with acute suicidal ideation:
56 mg dose pack: 16 devices per 28 days
84 mg dose pack: 24 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: 9/15/20 (acute suicidal ideation)

Reviewed: 2/1/20, 9/15/21