Montana Healthcare Programs
Physician Administered Drug Coverage Criteria

SPRAVATO® (esketamine)

I. Medication Description

Spravato ® is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist indicated, in conjunction with an oral antidepressant, for the treatment of:

- Treatment-resistant depression (TRD) in adults.
- Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior.

II. Position Statement

Coverage is determined through a prior authorization process **that must include** supporting clinical documentation for each request.

III. Initial Coverage Criteria

Member must meet all the following criteria:

- Member is 18 years of age or older.
- Spravato® is prescribed by a psychiatric specialist.
- Member has a Diagnostic and Statistical Manual of Mental Disorders (DSM-5) diagnosis of major depressive disorder (MDD).
- Member must have had a baseline depression assessment using a validated depression rating scale (e.g., MADRS, PHQ-9, HAM-D, etc.) within the last 2 weeks.
- Member is currently taking an oral antidepressant and will continue to take the oral antidepressant in conjunction with Spravato®.
- Member must have **one** of the following diagnoses:
    1. Treatment-resistant depression (TRD), along with **all** of the following:
        a. Inadequate treatment response after at least 6 weeks duration at a generally accepted dose, intolerance, or contraindication to at least three antidepressants with different mechanisms of action in the current depressive episode.
        b. Inadequate treatment response, intolerance, or contraindication to augmented antidepressant therapy (with concomitant atypical antipsychotic, lithium, or other appropriate therapy) in the current depressive episode.
        c. Actively involved in psychotherapy or inadequate response to psychotherapy.

    OR

    2. Major Depressive Disorder (MDD) with acute suicidal ideation or behavior.
        a. Must provide documentation of psychiatric assessment of suicidal ideation or behavior.
- Member does not have aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial and peripheral arterial vessels), arteriovenous malformation, or history of intracerebral hemorrhage.

- Provider attests to the following:
    - Member's risk for abuse or misuse is assessed prior to initiating treatment and will be assessed periodically while on therapy.
    - Member and facility are enrolled in the Spravato® REMS program.
    - Treatment sessions will include post-treatment observation until clinically stable for a minimum of 2 hours.

IV. Renewal Coverage Criteria

Member must meet all the following criteria:

- Treatment-resistant depression:
    - Member has been compliant with an oral antidepressant and continues to meet the initial criteria.
    - Member has been compliant with Spravato® therapy.
    - Member is receiving a benefit from Spravato® therapy, as demonstrated by a reduction in symptom severity compared to the baseline depression assessment utilizing the same rating scale.
- MDD in adults with acute suicidal ideation or behavior:
    - Not renewable, as has not been clinically studied beyond first 4 weeks.

V. Quantity Limitations

Treatment-resistant depression:

Weeks 1 to 4: 2 kits/week
Weeks 5 and after: 1 kit/week

MDD in adults with acute suicidal ideation or behavior:

Weeks 1 to 4: 2 kits/week

VI. Coverage Duration

Treatment-resistant depression:
Initial approval duration: 4 weeks
Renewal approval duration: 6 months

MDD in adults with acute suicidal ideation or behavior:
Initial approval duration: 4 weeks
Renewal approval duration: N/A