ALASKA MEDICAID
Prior Authorization Criteria

SPRAVATO®
(esketamine)

FDA INDICATIONS AND USAGE[1]

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 and depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior.

APPROVAL CRITERIA[1,2,3,4,5,6,7]

1. Patient is 18 years of age or older **AND**;
2. Prescribed by or in consultation with a psychiatrist **AND**;
3. Patient has the diagnosis of treatment-resistant depression or major depressive disorder (MDD) with acute suicidal ideation or behavior with documentation of at least one of the following baseline scores:
    a. Baseline score on the 17-item Hamilton Rating Scale for Depression (HAMD17)
    b. Baseline score on the 16-item Quick Inventory of Depressive Symptomatology (QIDS-C16)
    c. Baseline score on the 10-item Montgomery-Asberg Depression Rating Scale (MADRS)
    d. Baseline score on the Beck Depression Scale (BDI) **AND**;
4. Medication will be administered under the direct supervision of a health care provider **AND**;
5. Patient's blood pressure will be assessed prior to and after each administration **AND**;
6. Patient has had a trial, failure, or contraindication to two of the following antidepressant classes taken for a period of at least 8 weeks:
    a. Selective serotonin reuptake inhibitors
    b. Serotonin norepinephrine reuptake inhibitors
    c. Serotonin modulators
    d. Aminoketone
    e. Noradrenaline and specific serotoninergic antidepressants
    f. Tricyclic antidepressants
    g. Monoamine oxidase inhibitors **AND**;
7. Patient has tried and failed at least one antidepressant augmented therapy for a period of at least 8 weeks (i.e., antidepressant plus a second-generation antipsychotic or lithium, two concurrent antidepressants with different mechanisms of action, etc.) **AND**;
8. Spravato® will be used in combination with an oral antidepressant **AND**;
9. Prescriber is enrolled in the Spravato® REMS program.

DENIAL CRITERIA [1]

1. Failure to meet approval criteria **OR**;
2. Patient has aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial and peripheral arterial vessels) or arteriovenous malformation **OR**;
3. Patient has an intracerebral hemorrhage **OR**;
4. Patient has a history of psychosis or the prescriber has not attested that the benefits of Spravato® outweigh the risks.

CAUTIONS[1]

- Patients with cardiovascular and cerebrovascular conditions and risk factors may be at an increased risk of associated adverse effects.
- Spravato® may impair attention, judgment, thinking, reaction speed and motor skills.
- Patients should not drive or operate machinery until the next day after a restful sleep.
- Spravato® may cause fetal harm. Consider pregnancy planning and prevention in females of reproductive potential.

DURATION OF APPROVAL

- Initial Approval: 3 months
- Reauthorization 12 months with chart notes indicating the patient has had improvements from the baseline depression score.

QUANTITY LIMIT[1]

- 8 - 56mg dose kits per month
- 8 - 84mg dose kits per month
- Max dose is 84mg twice weekly

- HCPCS – S0013 (max 84 HCPCS per treatment)

REFERENCES / FOOTNOTES:

1. Spravato® [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; July 2020.
2. Huda Akil, Joshua Gordon, Rene Hen, et al. Treatment Resistant Depression: A Multi-Scale, Systems Biology Approach. Neurosci Biobehav Rev. 2018 Jan; 84: 272–288.
3. American Psychiatric Association (APA). Practice guideline for the treatment of patients with major depressive disorder. 3rd ed. Arlington (VA): American Psychiatric Association (APA); 2010 Oct.
4. Rush AJ, Bernstein IH, Trivedi MH, et al. An evaluation of the Quick Inventory of

Depressive Symptomatology and the Hamilton Rating Scale for Depression: a Sequenced Treatment Alternatives to Relieve Depression (STAR*D) trial report. Biol Psychiatry 2006; 59:493–501.
5. Canuso CM, Singh JB, Fedgchin M, et al. Efficacy and Safety of Intranasal Esketamine for the Rapid Reduction of Symptoms of Depression and Suicidality in Patients at Imminent Risk for Suicide: Results of a Double-Blind, Randomized, Placebo-Controlled Study. Am J Psychiatry. 2018 Jul 1;175(7):620-630.
6. Popova V, Daly EJ, Trivedi M, et al. Efficacy and Safety of Flexibly Dosed Esketamine Nasal Spray Combined With a Newly Initiated Oral Antidepressant in Treatment-Resistant Depression: A Randomized Double-Blind Active-Controlled Study. Am J Psychiatry. 2019 Jun 1;176(6):428- 438.
7. Fu DJ, Ionescu DF, Li X, et al. Esketamine Nasal Spray for Rapid Reduction of Major Depressive Disorder Symptoms in Patients Who Have Active Suicidal Ideation With Intent: Double-Blind, Randomized Study (ASPIRE I). J Clin Psychiatry. 2020 May 12;81(3):19m13191.