Spravato® Coverage Guidelines

Prior authorization is required for all Spravato® prescriptions.

Coverage guidelines for Spravato® are made in accordance with the Department of Social Services (DSS) definition of Medical Necessity, as established by state law. The following factors are guidelines *only.* Coverage determinations are based on an assessment of the individual and his or her unique clinical needs. If the guidelines conflict with the definition of Medical Necessity, the definition of Medical Necessity shall prevail.

Spravato® nasal spray is a novel medication for the treatment of treatment-resistant major depressive disorders in adults, as well as symptoms of major depressive disorder in adult patients experiencing acute suicidal thoughts or actions.

Prior authorization is necessary in order to demonstrate that the patient for whom Spravato® is being recommended and prescribed meets the clinical criteria for the use of Spravato®, and to ensure that the prescribing physician, who will also be administering Spravato®, is registered in the Spravato REMS program.

Spravato®(esketamine) nasal spray CIII is only available through the Spravato® Risk Evaluation and Mitigation Strategy (REMS) program because of the risks of serious adverse outcomes resulting from sedation and dissociation caused by Spravato® administration, and potential for abuse and misuse of Spravato®. The Spravato® REMS is managed by the manufacturer of Spravato®, as required by the U.S. Food and Drug Administration (FDA). Further information about Spravato® REMS can be found at https://www.spravatorems.com/.

Spravato® is indicated in the treatment of treatment-resistant depression in adults, and for depressive symptoms in adults with major depressive disorder (MDD) with suicidal thoughts or actions.

According to federal regulations, only physicians registered in the Risk Evaluation and Mitigation Strategy (REMS) program can prescribe and administer Spravato®. For further information, refer to https://www.spravatorems.com/.

Spravato® can be dispensed by pharmacies enrolled in the Spravato® REMS, or by medical offices or clinics that are enrolled in the REMS. In order to register in the Spravato® REMS, visit the webpage of the Spravato® REMS (https://www.spravatorems.com/) for instructions about the program. Patients also need to be enrolled in the Spravato® REMS before a prescription of Spravato® is written for, and filled on their name.

Patients may not self-administer Spravato®. The medication must be administered under the supervision and monitoring of a REMS-registered licensed physician. Details of the required procedures for administration of Spravato® and monitoring are described in the full prescribing information of Spravato®.

REMS-registered physicians can access Spravato® to treat their patients in two different ways:

a) transmit an electronic prescription to a REMS-registered pharmacy, or
b) purchase Spravato® from the manufacturer and dispense medication at the time of administration.

In order to obtain authorization for Spravato® in the CMAP, the REMS-registered physician who is prescribing the medication, and who will be administering Spravato® and monitoring the patient, needs to complete, sign, and submit a prior-authorization form.

Two separate forms are used to request prior authorization, depending if you are prescribing and administering Spravato®, or if you are prescribing, **dispensing**, and administering Spravato®. If you are writing a prescription of Spravato® and transmitting that prescription to a REMS-registered pharmacy, PA requests for coverage of Spravato® must be submitted by the prescriber using the Spravato® PA form located on the www.ctdssmap.com Web site. From the Home page, go to Pharmacy Information → Pharmacy Program Publications → Spravato® PA Form.If you are writing a prescription for Spravato® and will be **dispensing** Spravato® that you have purchased, the Spravato® PA Request Form for outpatient hospitals is available on CT BHP Web site at: www.ctbhp.com web page under For Providers →

Provider Resources → Forms.

The initial authorization will be issued for 6 months. Re-authorization will be based on documentation of clinical response as demonstrated by a greater than 50% reduction in severity of symptoms from baseline documented on a validated rating scale of depressive symptoms, and exacerbation of depressive symptoms following the discontinuation of Spravato® for at least two weeks following initial course of treatment.

The following factors will be considered in the Department's prior authorization decision

Indication for adult patients with treatment-resistant major depression:

1. Member is 18 years of age or older
   AND
2. Has documented depression defined as a DSM-V diagnosis of Major Depressive Disorder (MDD)
   AND
3. The diagnosis was made by, or in consultation with, a qualified medical professional
   AND
4. Documentation of an inadequate response (less than 50% improvement on severity of symptoms according to a validated rating scale) to at least two different antidepressants from different classes at adequate doses, duration (minimum 4 weeks for each medication), and adherence in the current depressive episode
   AND
5. One of the following:
   a. Documentation of an inadequate response or adverse reaction to one of the following antidepressant augmentation therapies:
      i. second-generation antipsychotic; or
      ii. lithium; or
      iii. second antidepressant from a different class; or
      iv. thyroid hormone;
      OR
   b. contraindication to all augmentation strategies.
   AND
6. Documentation using a validated rating scale to measure severity of depressive symptoms indicating moderate to severe major depressive disorder (MDD).
   AND
7. Prescriber and/or the prescriber's healthcare setting is certified in the Spravato REMS program
   a. AND
8. Spravato will be used in combination with an oral antidepressant (to which the patient had not shown a previous nonresponse)
   AND
9. The requested dose is within the recommended dose approved by the FDA
   AND
10. Patient does not have any of the following contraindications:
    a. Severe hepatic disease (Child-Puch class C)
    b. Hypersensitive to ketamine, esketamine, or any component of the formulation
    c. Aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels)
    d. Arteriovenous malformation
    e. History of intracerebral hemorrhage
    f. Women must be either of not child-bearing potential (postmenopausal or permanently sterilized, or incapable of pregnancy), or of child bearing potential but using a highly effective contraceptive (IUD, intravaginal hormone ring, implantable hormonal contraception, etc.) and with a negative pregnancy test at the time of request.

g. Patient has no history of primary psychotic disorder, mood disorder with psychotic features, substance-induced psychosis, or any other history of psychotic symptoms.
h. Patient does not meet criteria for moderate or severe substance use disorder, except nicotine use disorder, or those substance use disorders are in remission at the time of request.

Indication for patients with major depressive disorder presenting with suicidal thoughts or behaviors:

1. Patient is between ages 18 and 64
   AND
2. Meets the DSM-V diagnostic criteria for major depressive disorder, severe, without psychotic features.
   AND
3. Severity of depressive symptoms is rated as severe using a validated rating scales for depressive symptoms.
   AND
4. Patient has current suicidal ideation with intent to act on those ideations.
   AND
5. In the opinion of the physician evaluation patient, acute psychiatric hospitalization is clinically warranted due to imminent risk of suicide.
   AND
6. As part of the standard of care treatment, patient agrees to be hospitalized voluntarily for at least five days of inpatient psychiatric treatment, and take prescribed antidepressants other than Spravato®.
   AND
7. Patient must be medically stable on the basis of physical examination, medical history, vital signs, 12-lead ECG at the time of request, and laboratory test deemed relevant by evaluation physician (blood chemistry, CBC, etc.). Women must be either of not child-bearing potential (postmenopausal or permanently sterilized, or incapable of pregnancy), or of child bearing potential but using a highly effective contraceptive (IUD, intravaginal hormone ring, implantable hormonal contraception, etc.) and with a negative pregnancy test at the time of request.
   AND
8. Patient is not intoxicated by alcohol or other drugs of abuse, and urine toxicology does not indicate the presence of any drug of abuse at the time of request for authorization.
   AND
9. Patient does not meet criteria for moderate or severe substance use disorder, except nicotine use disorder.
   AND

Patient has no history of primary psychotic disorder, mood disorder with psychotic features, substance-induced psychosis, or any other history of psychotic symptoms