Spravato (esketamine) CIII Nasal Spray

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What is Spravato?

Spravato is the first and only FDA approved nasal spray, used in conjunction with an oral antidepressant, to treat adults with treatment resistant depression (TRD) and to treat depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior.

How does Spravato Work?

Spravato is an NMDA (N-methyl-D-aspartate) receptor antagonist that is believed to work differently by acting on a pathway in the brain that affects glutamate. The exact way Spravato works is not fully understood.

Who is a Good Candidate for Spravato?

Adult patients with treatment-resistant depression are those with challenging-to-treat major depressive disorder (MDD) who have not adequately responded to at least 2 different oral antidepressants of adequate dose and duration in their current depressive state.

Who Should Not Take Spravato?

Spravato is contraindicated in patients who:

- Have blood vessel (aneurysmal vascular) disease (including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels)
- Have an abnormal connection between your veins and arteries (arteriovenous malformation)
- Have a history of bleeding in the brain (intracerebral hemorrhage)
- Hypersensitivity to esketamine, ketamine, or any of the other ingredients in Spravato

How Effective is Spravato?

Those who added esketamine, the active ingredient in Spravato, to their oral antidepressant experienced a greater reduction of depressive symptoms at four weeks compared to those who received placebo plus an oral antidepressant (based on an overall score on a standardized rating scale).

The Spravato short-term study lasted four weeks

In a short-term study, more patients using Spravato plus oral antidepressant demonstrated rapid and superior reduction in depressive symptoms at four weeks compared to those who received placebo plus an oral antidepressant.

Most of the reduction in depressive symptoms was seen at 24 hours.

Between 24 hours and four weeks, both groups continued to improve; the difference in improvement between the groups remained but did not appear to increase through four weeks.

Spravato was also studied in a long-term maintenance-of-effect trial

The long-term study was designed for patients in remission to see if the effect of treatment was maintained. The trial compared patients who stayed on Spravato and oral antidepressant vs placebo and oral antidepressant long-term.

Patients who stayed on Spravato were less likely to experience a return in depressive symptoms (known as relapse).

Safety and Side Effects

The most common side effects that can occur during and after taking Spravato include:

- Dissociation
- Dizziness
- Nausea
- Sedation
- Spinning sensation
- Numbness
- Feeling anxious
- Lack of energy
- Increased blood pressure
- Vomiting
- Feeling drunk
- Feeling very happy or excited

If Spravato side effects occur, they usually happen right after taking Spravato and go away the same day.

Less than 7% of patients stopped Spravato treatment due to side effects in short- and long-term clinical studies.

Tolerability

Spravato plus oral antidepressant offers a similar safety profile to previous trials with a minimal risk for weight gain and sexual dysfunction compared to placebo plus oral antidepressant.

Weight gain observed in patients using Spravato plus oral antidepressant was similar to patients taking placebo plus oral antidepressant.

Sexual dysfunction was not seen in more than 2% of patients in the Spravato clinical trials.

Drug Interactions

CNS depressants: closely monitor for sedation with concomitant use of Spravato with CNS depressants, including benzodiazepines (e.g., diazepam, alprazolam, lorazepam, clonazepam), opioids, and alcohol.

Psychostimulants and monoamine oxidase inhibitors (MAOIs): closely monitor blood pressure with concomitant use of Spravato with psychostimulants (e.g., amphetamines, methylphenidate, modafinil, and armodafinil) and MAOIs.

Spravato REMS (Risk Evaluation and Mitigation Strategy)

To help ensure your safety, Spravato has a program called the Spravato REMS (Risk Evaluation and Mitigation Strategy), which requires close monitoring of safety.

Because of the risks for sedation or loss of consciousness, dissociation, respiratory depression, and abuse and misuse, Spravato is only available through a restricted program called the Spravato Risk Evaluation and Mitigation Strategy (REMS) Program.

Spravato can only be administered at healthcare settings certified in the Spravato REMS Program. Patients treated in outpatient healthcare settings (e.g., medical offices and clinics) must be enrolled in the program.

Spravato is intended for patient administration under the direct observation of a healthcare provider, and patients are required to be monitored by a healthcare provider for at least 2 hours. Spravato will never be dispensed directly to a patient for home use.

Spravato Savings Program

Eligible commercially insured patients pay $10 per treatment for Spravato medication costs, with a $7,150 maximum program benefit per calendar year.

Insurance Coverage

Although it is an FDA-approved treatment, insurance providers require a pre-authorization to determine medical necessity. Coverage criteria varies between insurance providers and your specific plan's policy, and we cannot guarantee how insurance will decide your case.

Specialty drug coverage and preferred pharmacies varies between health plans' medical and pharmacy benefit policies.

Indications for Coverage

Treatment Resistant Depression

- Adults 18 years of age or older.
- Diagnosis of major depressive disorder (treatment-resistant), according to the current DSM (Diagnostic and Statistical Manual of Mental Disorders).
- History of a trial, failure, and/or contraindication of at least two different antidepressants, each from a different pharmacologic class, for at least six weeks at the therapeutic dose.
    - An antidepressant or treatment regimen would include any of the following classes or combinations:
        - Selective Serotonin Reuptake Inhibitors (e.g., citalopram, fluoxetine, paroxetine, sertraline)
        - Serotonin Norepinephrine Reuptake Inhibitors (e.g., duloxetine, venlafaxine, desvenlafaxine, levomilnacipran)
        - Atypical Agents (e.g., bupropion, mirtazapine)
        - Tricyclic Antidepressants (e.g., amitriptyline, clomipramine, doxepin, imipramine)
        - Serotonin Modulators (e.g., trazodone, vilazodone, vortioxetine)
        - Monoamine Oxidase Inhibitors (e.g., selegiline, tranylcypromine, phenelzine)
        - Augmentation with Lithium, Cytomel, Atypical Antipsychotics, or anticonvulsants
- Patient has experienced an inadequate response with an adequate trial of augmentation therapy or evidenced based psychotherapy (e.g., cognitive behavioral therapy) during the current depressive episode.
- Patient does not have current substance use disorder unless in remission (complete abstinence for a month).
- Spravato will be used in combination with an oral antidepressant.

Major Depressive Disorder with Acute Suicidal Ideation or Behavior

- Adults 18 years of age or older
- Diagnosis of major depressive disorder according to the current DSM (Diagnostic and Statistical Manual of Mental Disorders).
- Patient is experiencing an acute suicidal ideation or behavior.
- Spravato will be used with an oral antidepressant.

If you have not done so already, please have your referring provider fax copies of your medical record to our office at (214) 613-1667 to help expedite the insurance pre-authorization.

Spravato Treatment Protocol

Treatment-Resistant Depression

Month 1: Two treatments per week for a total of eight treatments

Month 2: One treatment per week for a total of four treatments

Month 3+: Continue weekly treatment OR Treatment once every 2 weeks

Major Depressive Disorder with Acute Suicidal Ideation or Behavior

Twice weekly treatment for four weeks for a total of eight treatments.

Preparing for Your First Spravato Appointment

Arrange for Rides

You will need to arrange for rides to and from your Spravato treatments. Because of possible side effects affecting mental alertness and motor coordination, you will not be able to drive, operate machinery or do anything where you need to be completely alert until the day after a treatment session, following a restful sleep, even if you think you feel well enough to do so.

Dress Comfortably

Dress comfortably for your Spravato treatments so you can relax during and after treatment.

Avoid Eating or Drinking

Because some patients may experience nausea or vomiting, you should avoid eating for at least 2 hours and drinking for 30 minutes prior to your Spravato treatment.

Cancellation Policy

We will always do our best to accommodate the scheduling changes that you may have, but there will be instances where we are not always able to accommodate these changes.

If we do not receive a request to change the appointment time 24 hours prior to the appointment, or if you are running 20-30 minutes late to the appointment, we may not be able to provide treatment that day. If we are unable to reschedule your session, you may be responsible for payment of the missed appointment.

Financial Policy

Administration and Observation, 120 minutes	$475

Frequently Asked Questions

How is Spravato nasal spray different than ketamine infusion?

Spravato (esketamine) CIII nasal spray is a derivative of ketamine. Spravato is an FDA-approved nasal spray for treatment-resistant depression; it is also approved to treat depressive symptoms in adults with major depressive disorder with suicidal thoughts or actions. Ketamine has not been approved by the FDA to treat depression. Both Spravato and ketamine are Schedule III controlled substances under the US Controlled Substances Act.

What personal items can I bring to my treatment session?

You can bring personal items that make you feel comfortable which may include headphones, a tablet, crossword puzzles or a book to pass the time.

What happens during the observation period after taking Spravato?

The observation period begins right after the treatment is administered. During this time patients will be allowed to rest comfortably and will be monitored by a healthcare provider for any side effects you may experience. You should expect your healthcare provider to ask you about the side effects and have your blood pressure taken periodically during the observation period.

How quickly might I see improvements of depressive symptoms with Spravato for treatment-resistant depression?

In clinical studies, improvement of depressive symptoms was demonstrated at four weeks by Spravato plus an oral antidepressant, compared with placebo nasal spray plus an oral antidepressant. Not all patients will respond to Spravato.

Further Questions

Please feel to write down any questions you may have regarding treatment with Spravato.