

Spravato™ (esketamine nasal spray)

When requesting Spravato™ (esketamine nasal spray), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indications

Spravato is indicated, in conjunction with an oral antidepressant, for the treatment of:

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

Coverage Guidelines

Treatment-resistant depression

An individual must meet **ALL** of the following criteria for approval:

- Has demonstrated nonresponse ($\leq$ 25% improvement in depression symptoms or scores) to at least TWO different antidepressants, each from a different pharmacologic class (e.g., selective serotonin reuptake inhibitors [SSRIs], serotonin-norepinephrine reuptake inhibitors [SNRIs], tricyclic antidepressants [TCAs], bupropion, mirtazapine, etc.);
- Has used each antidepressant at therapeutic dosages for at least 6 weeks in the current episode of depression;
- Is currently receiving at least one oral antidepressant;
- Has no history of psychosis OR has a history of psychosis and the prescriber believes that the benefits of Spravato outweigh the risks;
- Is 18 years of age or older;
- Spravato is prescribed by a psychiatrist;
- History of controlled substance prescriptions has been checked using the state prescription drug monitoring program (PDMP).

Approval duration: 6 months

Major depressive disorder with acute suicidal ideation or behavior

An individual must meet **ALL** of the following criteria for approval:

- Has severe major depressive disorder;
- Is currently receiving at least one oral antidepressant (e.g., selective serotonin reuptake inhibitors [SSRIs], serotonin-norepinephrine reuptake inhibitors [SNRIs], tricyclic antidepressants [TCAs], bupropion, mirtazapine, etc.);
- Has no history of psychosis OR has a history of psychosis and the prescriber believes that the benefits of Spravato outweigh the risks;
- Is 18 years of age or older; AND
- Spravato is prescribed by a psychiatrist.

Approval duration: 2 months

Dosing Recommendations

Major depressive disorder with acute suicidal ideation or behavior

Administer 84 mg intranasally twice weekly for 4 weeks. Dosage may be reduced to 56 mg twice weekly based on tolerability.

Treatment-resistant depression

The recommended dosage for Spravato is administered intranasally as follows:

Induction phase	Weeks 1 to 4: Administer twice per week	Day 1 starting dose: 56 mg Subsequent doses: 56 mg or 84 mg
Maintenance phase	Weeks 5 to 8: Administer once weekly Week 9 and after: Administer every 2 weeks or once weekly	56 mg or 84 mg

References

1. Spravato® nasal spray [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; November 2024.
2. FDA news release. FDA approves new nasal spray medication for treatment-resistant depression; available only at a certified doctor's office or clinic. March 5, 2019. Available at: <https://www.fda.gov/news-events/press-announcements/fda-approves-new-nasal-spray-medication-treatment-resistant-depression-available-only-certified>. Accessed on January 3, 2024.
3. National Institute of Mental Health. Major Depression. Last updated: July 2023. Available at: <https://www.nimh.nih.gov/health/statistics/major-depression.shtml>. Accessed on January 3, 2024.
4. World Health Organization. Depressive disorder (depression). Available at: [Depressive disorder \(depression\)](https://www.who.int/mental-health/prevention/depression) ([who.int](https://www.who.int/mental-health/prevention/depression)). Accessed on May 20, 2024.
5. Rush AJ, Trivedi MH, Wisniewski SR, et al. Acute and longer-term outcomes in depressed outpatients requiring one or several treatment steps: a STAR*D report. *Am J Psychiatry*. 2006;163(11):1905-17.
6. McQuaid JR, Buelt A, Capaldi V, et al. The management of major depressive disorder: synopsis of the 2022 U.S. Department of Veterans Affairs and U.S. Department of Defense clinical practice guideline. *Ann Intern Med*. 2022;175(10):1440-1451.
7. Symbyax® capsules [prescribing information]. Indianapolis, IN: Lilly USA, LLC; August 2023.