

Spravato™ (esketamine nasal spray)

When requesting Spravato™ (esketamine nasal spray), the individual requiring treatment must be diagnosed with an FDA-approved indication 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 [SSRI], serotonin-norepinephrine reuptake inhibitors [SNRI], 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 [SSRI], serotonin-norepinephrine reuptake inhibitors [SNRI], 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.;October 2023.
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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 onDecember 19, 2023.
4. Depression and Other Common Mental Disorders: Global Health Estimates. Geneva: World Health Organization; 2017. Available at: <https://apps.who.int/iris/bitstream/handle/10665/254610/WHO-MSD-MER-2017.2-eng.pdf;jsessionid=A566BCE2138CF7D2CA9F1E283F2F4E71?sequence=1>.December 19, 2023.
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. Gelenberg A, Freeman MP, Markowitz JC, et al. Practice guideline for the treatment of patients with major depressive disorder, third edition. American Psychiatric Association, November 2010. Available at: http://www.psychiatryonline.com/pracGuide/pracGuideTopic_7.aspx. Accessed onDecember 19, 2023.
7. Symbyax® capsules [prescribing information]. Indianapolis, IN: Lilly USA, LLC;August 2023.