

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 Indication

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], tricyclic antidepressants [TCAs], bupropion, mirtazapine, etc.);
- Has used each drug 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; AND
- History of controlled substance prescriptions have been checked using the state prescription drug monitoring program (PDMP), unless unavailable in the state (i.e., Missouri).

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], 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

Approve up to maximum dose of 84 mg administered intranasally twice weekly for 4 weeks.

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.; July 2020.
2. FDA briefing document for Spravato. Psychopharmacologic Drugs Advisory Committee (PDAC) and Drug Safety and Risk Management (DSaRM) Advisory Committee Meeting on February 12, 2019. Available at: <https://www.fda.gov/advisory-committees/february-12-2019-joint-meeting-psychopharmacologic-drugs-advisory-committee-pdac-and-drug-safety-and>. Accessed on April 14, 2020.
3. National Institute of Mental Health. Major Depression. Last updated: February 2019. Available at: <https://www.nimh.nih.gov/health/statistics/major-depression.shtml>. Accessed on April 14, 2020.
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>. Accessed on April 14, 2020.
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 on April 14, 2020.
7. Symbyax® capsules [prescribing information]. Indianapolis, IN: Lilly USA, LLC; March 2018.