

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.

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
- 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

Dosing Recommendations

Spravato is administered intranasally under the supervision of a healthcare provider.

The recommended dosage for Spravato is 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

Dosage adjustments should be made based on efficacy and tolerability. Evidence of therapeutic benefit should be evaluated at the end of the induction phase to determine need for continued treatment.

References

1. Spravato™ nasal spray [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; March 2019.
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/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PsychopharmacologicDrugsAdvisoryCommittee/ucm630969.htm>. Accessed on March 7, 2019.
3. National Institute of Mental Health. Major Depression. Last updated: November 2017. Available at: <https://www.nimh.nih.gov/health/statistics/major-depression.shtml>. Accessed on March 7, 2019.
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 March 7, 2019.
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 March 7, 2019.
7. Symbyax® capsules [prescribing information]. Indianapolis, IN: Lilly USA, LLC; March 2018.