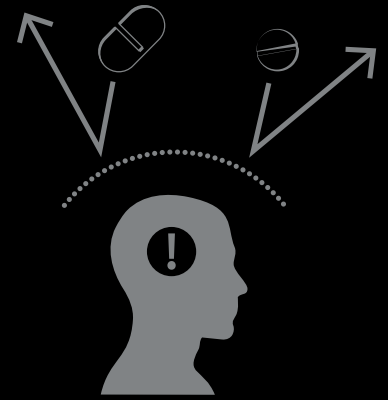


# Mental Health and Ketamine

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Mental health conditions desperately need novel treatment options. **Depression** alone has a tremendous impact on population health, accounting for the **largest share** of disability-adjusted life years lost globally. Furthermore, estimates suggest that **nearly 50 percent** of people diagnosed with depression classify as treatment-resistant, meaning they did not respond to at least two antidepressant medications. Studies suggest that **ketamine**, a medication used in anesthesia and to treat pain, has **antidepressant effects** and may also effectively treat **substance use disorders and post-traumatic stress disorder (PTSD)**.



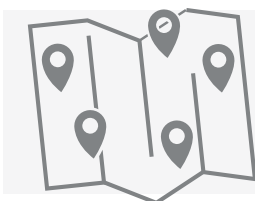
## About Ketamine

There are two versions of ketamine used to treat mental health conditions: esketamine and racemic ketamine. Marketed under the brand name **Spravato** and administered as a nasal spray, esketamine is **approved** to treat treatment-resistant depression and major depressive disorder with suicidal ideation. Patients must receive esketamine at a medical provider's office and remain under clinical observation for **at least two hours**. It is also subject to stringent **risk and evaluation reporting requirements** as part of its Food and Drug Administration (FDA) approval.

Racemic ketamine (hereafter, "ketamine") is **no longer under patent**. It is FDA-approved as an **anesthetic** and classified as a **Schedule III** controlled substance by the Drug Enforcement Administration (DEA), meaning it has a low to moderate risk of causing **physical dependence**. Although ketamine is **not FDA-approved** to treat any mental health conditions, medical providers can **prescribe** it "off label" (i.e., for conditions other than those it is approved to treat) if deemed **medically appropriate**—for example, if there is no approved drug for the condition or if approved drugs have not benefited the patient. Ketamine does not require patient monitoring or **risk and evaluation reporting** like esketamine does; however, because off-label prescribing affects insurance coverage, ketamine treatment is **not typically eligible**.

## The Ketamine Treatment Environment

More than **1,500 clinics** offering **ketamine infusions** have opened since the 2010s. These brick-and-mortar clinics typically serve patients with **depression and neuropathic pain**, although some offer ketamine treatment for other conditions where evidence of its benefit is unclear. Some of these clinics only provide ketamine infusions, while others offer psychotherapy to patients while they receive ketamine.



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Changes to prescribing requirements for controlled substances during the COVID-19 pandemic allowed companies to offer at-home ketamine therapy via telehealth. Prior to that, providers had to **examine a patient in person** at least once before prescribing a controlled substance. During the pandemic, the DEA and the Department of Health and Human Services issued

temporary rules waiving the in-person exam requirement. Renewed four times since, these [flexibilities](#) will remain in effect [until the end of 2026](#)— unless they become permanent. Removing the requirement for in-person medical evaluation before prescribing a controlled substance has allowed online ketamine treatment providers to [proliferate](#).

Telehealth companies that provide at-home ketamine treatment [vary widely](#) in how they deliver patient care. For one thing, dosing regimens vary considerably. Some telehealth companies prescribe ketamine for [daily use](#), while others have patients dose less frequently. [Dosing itself](#) varies as well, with some companies prescribing lower doses than others. Companies also differ in how they evaluate whether ketamine is an [appropriate treatment](#) for each patient. Another concern about at-home ketamine treatment is that most telehealth providers [do not monitor patients](#) when they are under the influence of ketamine. Some companies have the patient attest that a [trusted friend or family member](#) will stay with them during their ketamine experience, but the safety and appropriateness of this arrangement is debatable. At-home ketamine treatment is generally more [affordable and accessible](#) than in-clinic infusions; however, serious safety and efficacy questions remain about unsupervised, at-home ketamine treatment.

## Questions Remain About Ketamine Treatment

While ketamine has been shown to produce [rapid improvements](#) in depressive symptoms, some components of the current prescribing environment warrant continued monitoring and attention. First, there is no consistent dosing protocol for ketamine. Intravenously injected ketamine has the [most research](#) supporting dosing, while other formulations lack an established evidence base. Whether or not (and if so, at what point) [psychotherapy](#) should accompany ketamine treatment is also [debated](#). Although [about 47 percent](#) of people prescribed ketamine use it unsupervised at home, most studies of ketamine's use for mental health conditions show [improved effectiveness](#) when combined with psychotherapy.

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There is also uncertainty about how long ketamine treatment remains effective. Studies of ketamine's effectiveness use different dosing protocols and follow patients for different lengths of time after treatment, making it difficult to assess the [longevity](#) of ketamine's effects after [stopping treatment](#). One study found [sustained decreases in depression symptoms](#) 30 days after a single ketamine infusion, while another found that [symptom relapse](#) occurred a median of 20 days after the end of treatment for depression and 41 days for PTSD. Literature reviews have found that [regular dosing](#) (as opposed to a single dose) and [higher doses](#) are more effective for treatment-resistant depression.

While ketamine is administered only occasionally when used for its approved purpose as an anesthetic, people using it as a mental health treatment may use it much more frequently. The [long-term safety](#) of frequent ketamine use is not well established. There are [reports of bladder problems](#) occurring from frequent ketamine use, as well as [side effects](#) like anxiety and vomiting. As a Schedule III substance, ketamine has the potential to [cause dependence](#) and [lead to abuse](#). One survey of people prescribed ketamine for at-home use found that [55 percent](#) took more than prescribed. It is possible to [overdose](#) from ketamine use, and the drug is known to cause [slowed breathing and elevated blood pressure](#).

## Conclusion

Ketamine is a promising treatment for some mental health conditions; however, treatment challenges and risks remain in the current prescribing environment. Continued research and regulatory adjustments are essential to establish best practices, ensure the best patient outcomes, navigate questions about insurance coverage, and ensure equitable treatment access.