

# TMS TRENDS

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## FAST-ACTING DEPRESSION DRUG, NEWLY APPROVED, COULD HELP MILLIONS

(From 3/6/19 NY Times)

Of the [16 million American adults](#) who live with depression, [as many as one-quarter](#) gain little or no benefit from available treatments, whether drugs or talk therapy. They represent perhaps the greatest unmet need in psychiatry. On Tuesday, the Food and Drug Administration approved a prescription treatment intended to help them, a fast-acting drug derived from an old and widely used anesthetic, ketamine.

The move heralds a shift from the Prozac era of antidepressant drugs. The newly approved treatment, called esketamine, is a nasal spray [developed by Janssen](#) Pharmaceuticals Inc., a branch of Johnson & Johnson, that will be marketed under the name Spravato. It contains an active portion of the ketamine molecule, whose antidepressant properties are not well understood yet.

The generic anesthetic is already increasingly available for depression, at hundreds of clinics around the country that provide a course of intravenous treatments, and studies suggest it can help treatment-resistant people. It often causes out-of-body and hallucinogenic sensations when administered; in the 1980s and 1990s it was popular as a club drug, Special K.

The cost for these treatments typically is out of pocket, as the generic anesthetic is not approved by the F.D.A. for depression. In contrast, esketamine likely would be covered under many insurance plans, and its side effects, though similar to those of generic ketamine, are thought to be less dramatic.

The recommended course of the newly approved drug is twice a week, for four weeks, with boosters as needed, along with one of the commonly used oral antidepressants. F.D.A. approval requires that doses be taken in a doctor's office or clinic, with patients monitored for at least two hours, and their experience entered in a registry; patients should not drive on the day of treatment.

Esketamine, like ketamine, has the potential for abuse, and both drugs can induce psychotic episodes in people who are at high risk for them. The safety monitoring will require doctors to find space for treated patients, which could present a logistical challenge, some psychiatrists said.

The wholesale cost for a course of treatment will be between \$2,360 and \$3,540, said Janssen, and experts said it will give the company a foothold in the \$12 billion global antidepressant market, where most drugs now are generic.

The approval of esketamine marks a new approach to treating serious mood problems, experts said. Prozac and similar drugs enhance the activity of brain messengers such as serotonin; they are mildly effective, but they take weeks or months for their effects to be felt, and for many patients they provide little or no relief from depression. In contrast, the ketamine-based compounds — several others are being developed — work within hours or days, and are effective in some people who are considered “treatment resistant,” meaning they have not benefited from other antidepressants.

One question that will need to be answered is how well esketamine performs in comparison to intravenous or intranasal ketamine.