

FDA Approves Fast-Acting Esketamine for Treatment-Resistant Depression: Clinicians and Researchers are Cautiously Optimistic

ADAA Statement – March 6, 2019

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On March 5, 2019 the <u>FDA approved a new nasal spray medication- Spravato</u> (esketamine) for treatment-resistant depression, available only at a certified doctor's office or clinic.

Ketamine represents a major step forward in the treatment of depression and suicide prevention. ADAA recognizes that clinicians want to offer their patients evidence-based options which have passed through the numerous stages of FDA testing, and this marks the first FDA approval of a ketamine product for a psychiatric indication. This is also the first antidepressant with a novel mechanism of action that we have had in decades.

The development of the intranasal esketamine formulation with an intermittent dosing strategy offers a new approach to the treatment of refractory depression that could also impact greatly the care of patients with suicidal activity.

While this newly approved treatment offers hope as a fast acting and durable antidepressant option for patients who have not responded adequately to conventional SSRI or SNRI medications, it is important to be cautious. Many patients seek ketamine who have not received trials with other evidence-based treatments including pharmacotherapy and psychotherapy or rTMS or ECT.

It is also important to note that the long-term efficacy of ketamine is not established and there is also concern about the potential abuse liability factor which will be highlighted by the FDA on the drug's label.

Patients considering the use of Spravato should ask their doctor what the long-term follow up strategy should be and whether there are any potential negative consequences over time with continued use.