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News Release

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VA to make new nasal spray drug available for treatment-resistant depression

WASHINGTON — Today the U.S. Department of Veterans Affairs (VA) announced its health care providers will now be able to offer the newly approved Spravato nasal spray for treatment-resistant depression.

The treatment will be made available to Veterans based on their individual medical needs combined with providers' clinical assessments.

The move follows the March 5 Food and Drug Administration (FDA) approval of Spravato (esketamine) nasal spray. Spravato was approved for use in conjunction with an oral antidepressant for the treatment of treatment-resistant depression in adults.

"We're pleased to be able to expand options for Veterans with depression who have not responded to other treatments," said VA Secretary Robert Wilkie. "It reflects our commitment to seek new ways to provide the best health care available for our nation's Veterans."

Spravato will be available through a restricted distribution system under an FDA-approved Risk Evaluation and Mitigation Strategy (REMS). The purpose of the REMS is to mitigate the risks of serious adverse outcomes and the potential abuse and misuse of Spravato.

VA health care providers will monitor Veterans for serious adverse outcomes, such as sedation and difficulty with attention, judgment and thinking (dissociation), abuse and misuse, worsening of depression and suicidal thoughts and behaviors.

Veterans will self-administer Spravato nasal spray under the direct observation of a health care provider in a certified medical facility, and then must be monitored by a health care provider for at least two hours after receiving their dose. Spravato cannot be dispensed directly to Veterans for use at home.

For additional information on access to Mental Health Support for Veterans, visit <u>VA Mental Health</u>. Veterans in immediate crisis may call the Veterans Crisis Line at 800-273-8255 and press 1, text to 838255 or chat online at <u>Veterans Crisis Line</u>.

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