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Immediate Release:
New Drug for Depression

On March 5, 2019, the U.S. Food and Drug Administration (FDA) approved Spravato® (esketamine) for the treatment of depression in adults. It is a nasal spray and is to be used along with an oral anti-depressant medication. Spravato is indicated for use only in adults who have not received a benefit from other anti-depressant medications.

Spravato is a schedule III controlled substance and carries a black box warning for sedation, dissociated thoughts, abuse and misuse, and suicidal ideation. Due to these risks, it is only available through a restricted distribution system which requires healthcare settings, pharmacies and patients to be enrolled in a special program called the Spravato Risk Evaluation and Mitigation Strategy (REMS).

Additional requirements of the REMS program include:

- Pharmacies that dispense Spravato are required to enroll in the program and can only dispense it to certified doctors' offices or clinics.
- Patients are required to enroll in the program and self-administer the nasal spray under direct supervision of a healthcare provider at an enrolled healthcare facility. Patients are not allowed to take the nasal spray home.
- Patients must be monitored by a healthcare professional for at least 2 hours following administration. Patients are not allowed to drive or use heavy machinery for the rest of the day on which the drug is administered.

During the first 4 weeks of use, Spravato is administered twice weekly. At the end of these 4 weeks, the efficacy of treatment is assessed to determine if use should be continued. During weeks 5 through 8, it is administered once weekly. Thereafter, it can be administered every 2 weeks or once weekly with dosing frequency individualized. The initial dose is 56 mg with subsequent doses of either 56 mg or 84 mg depending on efficacy and tolerability.

Spravato provides a novel therapy for the management of treatment-resistant depression and received priority review from the FDA. It is supplied as a nasal spray device that delivers 28 mg per device. To achieve the 56 mg or 84 mg dose, use of two or three devices, respectively, is required. The average wholesale price (AWP) per device is $354.00.

For additional details on this new therapy for treatment-resistant depression, view the FDA's press release or visit the manufacturer's website.

References

1. FDA approves new nasal spray medication for treatment-resistant depression; available only at a certified doctor's office or clinic. FDA News Release. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm632761. Updated March 5, 2019. Accessed March 9, 2019.

2. Spravato [package insert]. Lakewood, NJ: Janssen Pharmaceuticals, Inc.; March 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/211243lbl.pdf. Accessed March 9, 2019.