

Subject: FDA Approves Spravato® for Treatment-Resistant Depression

On March 5, 2019, the U.S. Food and Drug Administration (FDA) approved Spravato® (esketamine) nasal spray for adult patients with treatment-resistant major depression (TRD), which refers to patients who have tried and failed to respond adequately to at least two other drugs. Spravato will not be available through retail pharmacies and is only approved to be administered by certified medical providers, due to the need for close patient observation in the immediate post-administration period.

The approval of Spravato is being met with a mixture of enthusiasm and concern.¹ Enthusiasm, in part, for being the first novel antidepressant medication introduced into the U.S. market in many years and its “more rapid” onset of action. Concern, due to its close relation to the drug ketamine, which is known as a recreational substance of abuse, commonly referred to as “Special K,” which in high doses can cause sedation and “out-of-body” experiences.

Despite concerns, "There has been a long-standing need for additional effective treatments for treatment-resistant depression, a serious and life-threatening condition," said Dr. Tiffany Farchione, acting director of the Division of Psychiatry Products in the FDA's Center for Drug Evaluation and Research.²

Drug maker Johnson & Johnson has stated that the Average Wholesale Price (AWP) for each treatment of esketamine would range from \$590 to \$885, depending on dosage and excluding administration and observation costs.³ This implies a twice-weekly treatment during the first month would cost medical treatment centers offering the drug at least \$4,720 to \$6,785. Subsequent weekly treatments would cost about half as much.

The Impact

Antidepressants are frequently prescribed in workers' compensation treatment settings and are included in the top 10 drug categories for spend at First Script. We will continue monitoring and reporting on the impact of Spravato's approval. For more information, please contact your Account Manager or Account Pharmacist.

¹ <https://www.statnews.com/2019/02/20/psychiatry-awaits-esketamine-with-excitement-hesitation>

² <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm632761.htm>

³ <http://fortune.com/2019/03/06/depression-spravato-ketamine>