From: **SPRAVATOREMS** SPRAVATOREMS@ubc.com
Subject: SPRAVATO® REMS – Notice Based on FDA COVID-19 Communication
Date: May 28, 2020 at 10:16 AM
To: Undisclosed recipients:;

Dear REMS Stakeholder,

We recognize the importance of treatment continuity to avoid depression symptom relapse in adult patients with treatment-resistant depression. During the COVID-19 public health emergency, treatment continuity considerations are even more critical. Healthcare providers are therefore encouraged to use their best clinical judgment regarding timing of new patient treatment initiation with SPRAVATO® (esketamine) CIII nasal spray treatment.

Should you have patients enrolled in the SPRAVATO® REMS, but not yet treated, please consider the risks of potential therapy interruption caused by patient or healthcare provider isolation and/or quarantine during the COVID-19 public health emergency compared with the potential benefits of treatment at this time.

Given the COVID-19 public health emergency, Janssen explored with the Food and Drug Administration (FDA) the possibility of REMS enrolled patients receiving SPRAVATO® (esketamine) CIII nasal spray treatment in their homes, under the direct supervision of a healthcare provider for both administration and the REMS mandated monitoring period.

FDA's RESPONSE[1]

> "FDA recognizes that during the COVID-19 public health emergency, completion of certain REMS-required patient monitoring may be difficult because patients suspected of having COVID-19 may be self-isolating and/or subject to quarantine. During this time, FDA does not intend to object to healthcare providers from REMS-certified health care facilities administering SPRAVATO® and monitoring patient's post-administration at the patient home through the end of the COVID-19 Public Health Emergency declared on January 31, 2020[2], by the Department of Health and Human Services (HHS) (https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx)".

Thus, until the end of this Public Health Emergency, healthcare providers from REMS-certified health care centers are permitted to supervise the self-administration of SPRAVATO® and monitor the patients for at least two hours in the patients' homes.

Healthcare providers from REMS-certified health care centers who administer SPRAVATO® and monitor patients treated in patients' homes must abide by the government health instruction in place in his/her health care center, county, and state related to the COVID-19 Public Health Emergency.

REMS REMINDERS FOR IN HOME TREATMENT AND MONITORING

Healthcare providers from REMS-certified healthcare centers administering SPRAVATO® and monitoring patients in patients' homes are expected to follow all applicable SPRAVATO® REMS requirements as described on the healthcare setting enrollment form, including, but not limited to:

- Maintain records demonstrating processes/procedures are in place and being followed
    - Including those regarding treatment of patients in their home
    - Compliance with all state and local regulations regarding guidelines for Home Visits, including those related to providing care in the home setting
- Verify enrollment in the REMS before dispensing SPRAVATO®
- Healthcare provider monitors every patient for at least 2 hours after every dose
- Submit ***Patient Monitoring Form*** to SPRAVATO® REMS for every patient within 7 calendar days following administration of every dose

INSTRUCTIONS FOR HEALTHCARE PROVIDER GOING TO PATIENTS HOME

- Must be from a REMS-certified healthcare setting
- Must have completed all REMS training
- Must bring only the applicable dose of SPRAVATO® required for that day's treatment.

SPRAVATO® will not be dispensed directly to patients' homes by the pharmacy.

- Must:
  - Follow all REMS instructions including medication provision, requirements for documentation of patient administration/monitoring, REMS required assessments, and reporting of safety measures on the SPRAVATO® REMS Patient Monitoring Form

  - Follow DEA and state-controlled substance laws and regulations on collection and disposal of used and partially used controlled substance containing devices (www.deadiversion.usdoj.gov/drug_disposal/)

    - The healthcare provider conducting in home medical supervision and monitoring **will collect and dispose of** all used devices consistent with local and state guidance for disposal of controlled substances.

- Notify the SPRAVATO® REMS coordinating center of their intent to treat patient in the home in advance and document location by writing "patient treated in home" in the upper right-hand corner of the ***SPRAVATO® REMS Patient Monitoring Form***

    - Fax the form to the REMS coordinating center

- Must complete the Healthcare Setting and Provider Information section of the ***SPRAVATO® REMS Patient Monitoring Form*** using the REMS-certified healthcare setting authorized provider name and address.

  The patient's home address should NOT be placed on this form

CONSIDERATIONS REGARDING PATIENTS:

Healthcare providers are encouraged to use their best clinical judgment regarding the appropriateness of in-home administration and monitoring for each individual patient and are asked to consider the following:

- Is this an established patient enrolled in the SPRAVATO® REMS?

- Has informed consent to treat in the home been obtained and documented by the healthcare provider?

- Does the patient have a history of adverse events requiring intervention?

- Are there household members (adult or children) who will be present for the treatment?

treatment?

- Are there household members with current or history of substance use disorder?
- Has the patient agreed to notify their healthcare provider of any change in health status prior to treatment or following monitoring period?
    - The patient should notify the healthcare provider in advance if they have a fever or other symptoms of infection or illness
    - The patient should notify the healthcare provider of any adverse events occurring after the in-home monitoring period ends
- Has the patient agreed not to drive or use heavy machinery until the next day, following a restful sleep?

Janssen CarePath for Benefit Investigation Questions

Janssen CarePath can assist patients and providers who may need support with finding alternative treatment sites for SPRAVATO® and with determining insurance coverage. If you or your patients need treatment site support and/or have questions regarding the coverage of home administration and monitoring, please contact Janssen CarePath at (844-777-2828) Monday – Friday, 8 AM to 8 PM ET for assistance. Additional information can be found at https://www.spravatotreatmentcenter.com/ .

SPRAVATO® REMS Questions

In the event an existing SPRAVATO® REMS-enrolled patient needs to change the location of SPRAVATO® treatment, the provider must contact the REMS Coordinating Center to share information about the change.

If you have any questions about the SPRAVATO® REMS or need help with certification or enrollment, call 1-855-382-6022 Monday – Friday 8AM – 8PM ET.

For information on SPRAVATO®, please review the full prescribing information[3].

Sincerely,

The SPRAVATO® REMS
Phone:1-855-382-6022
Fax: 1-877-778-0091
www.SPRAVATOrems.com

References:

1. Food and Drug Administration (FDA) COVID-19 National Emergency Correspondence Letter to Janssen for SPRAVATO®. March 23, 2020

2. Determination that a Public Health Emergency Exists. US Department of Health & Human Services, Office of the Assistant Secretary for Preparedness and Response - Public Health Emergency website https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx. Published January 31, 2020. Accessed March 27, 2020.
3. SPRAVATO® (esketamine nasal spray, CIII) [Prescribing information]. Titusville, NJ; Janssen Pharmaceuticals, Inc; http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/SPRAVATO-pi.pdf

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