COMMUNICATIONS TEMPLATE FOR PATIENTS

Disclaimer: At the discretion of your communications leader, the email below may be tailored based on your specific needs and shared with patients. Please share the Consumer Version of the Indications and Important Safety Information (ISI) along with this email.

Spravato® (esketamine) C III
28 mg nasal spray

SUBJECT LINE: [Treatment Center Name] will be there for you through your treatment journey

[Custom Greeting]

[Treatment Center Name] is now able to provide appropriate adult patients with SPRAVATO®. SPRAVATO®, the only FDA-approved nasal spray for adults with treatment-resistant depression (TRD), reduces depression symptoms when two or more oral antidepressants haven't worked. SPRAVATO® can be taken with or without an oral antidepressant.

SPRAVATO® is not for use as a medicine to prevent or relieve pain (anesthetic). It is not known if SPRAVATO® is safe or effective as an anesthetic medicine.

It is not known if SPRAVATO® is safe and effective for use in preventing suicide or in reducing suicidal thoughts or actions. SPRAVATO® is not for use in place of hospitalization if your healthcare provider determines that hospitalization is needed, even if improvement is experienced after the first dose of SPRAVATO®.

It is not known if SPRAVATO® is safe and effective in children.

SPRAVATO® can cause serious side effects, including sleepiness (sedation); fainting; dizziness; spinning sensation; anxiety; or feeling disconnected from yourself, your thoughts, feelings, space and time (dissociation); breathing problems (respiratory depression and respiratory arrest); abuse and misuse; and increased risk of suicidal thoughts and actions. Because of the risks for sedation, dissociation, respiratory depression, and abuse and misuse, SPRAVATO® is only available through a restricted distribution program called the SPRAVATO® Risk Evaluation and Mitigation Strategy (REMS) Program.

Here is an overview of how to get started and what to expect

Before treatment
At [Treatment Center Name], we understand that finding the right treatment for you can be a difficult process. You can schedule a SPRAVATO® consultation directly with us to see if treatment could be an option for you. You can also work with your current doctor to see if SPRAVATO® may be right for you and complete our patient intake form to get started. Our medical staff and care team are committed to partnering with you and your doctor to support you during your treatment journey with SPRAVATO®.

During the SPRAVATO® consultation, a healthcare provider will review your medical history, treatment goals, and insurance to determine if SPRAVATO® is right for you. Treatment is not usually administered on this first visit.

Our doctors and nurses proactively coordinate care and will ensure an open line of communication with your referring doctor to monitor your progress. In addition, our care team will guide you through your journey, clearly explaining what to expect during SPRAVATO® treatment sessions. They will also work with your insurance provider to confirm your coverage and your costs prior to your treatment with SPRAVATO®.

Day of treatment
On treatment days, you will administer SPRAVATO® nasal spray yourself under the supervision of a healthcare provider at the treatment center, followed by a 2-hour monitoring period. Our doctors and nurses will also watch for any changes in respiratory status (including pulse oximetry) and blood pressure.

After treatment
Please keep in mind that you should not drive or operate machinery until the next day after a night of restful sleep. For the first month, you'll take SPRAVATO® twice per week, then once per week for the second month. After that, you and your provider will have the flexibility to decide your treatment frequency. You will not be able to self-administer SPRAVATO® at home.

To learn more about our treatment center and how we can work together to determine if SPRAVATO® is right for you, please contact [designated treatment center contact].

What is SPRAVATO® (esketamine) CIII nasal spray?

SPRAVATO® is a prescription medicine used:

- with or without an antidepressant taken by mouth, to treat adults with treatment-resistant depression (TRD)
- with an antidepressant taken by mouth, to treat depressive symptoms in adults with major depressive disorder (MDD) with suicidal thoughts or actions

SPRAVATO® is not for use as a medicine to prevent or relieve pain (anesthetic). It is not known if SPRAVATO® is safe or effective as an anesthetic medicine.

It is not known if SPRAVATO® is safe and effective for use in preventing suicide or in reducing suicidal thoughts or actions. SPRAVATO® is not for use in place of hospitalization if your healthcare provider determines that hospitalization is needed, even if improvement is experienced after the first dose of SPRAVATO®.

It is not known if SPRAVATO® is safe and effective in children.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about SPRAVATO®?

SPRAVATO® can cause serious side effects, including:

- **Sedation, dissociation, and respiratory depression.** SPRAVATO® may cause sleepiness (sedation), fainting, dizziness, spinning sensation, anxiety, or feeling disconnected from yourself, your thoughts, feelings, space and time (dissociation), breathing problems (respiratory depression and respiratory arrest)
    - Tell your healthcare provider right away if you feel like you cannot stay awake or if you feel like you are going to pass out.
    - Your healthcare provider must monitor you for serious side effects for at least 2 hours after taking SPRAVATO®. Your healthcare provider will decide when you are ready to leave the healthcare setting.
- **Abuse and misuse.** There is a risk for abuse and misuse with SPRAVATO®, which may lead to physical and psychological dependence. Your healthcare provider should check you for signs of abuse, misuse, and dependence before and during treatment.
    - Tell your healthcare provider if you have ever abused or been dependent on alcohol, prescription medicines, or street drugs.
    - Your healthcare provider can tell you more about the differences between physical and psychological dependence in drug addiction.
- **SPRAVATO® Risk Evaluation and Mitigation Strategy (REMS).** Because of the risks for sedation, dissociation, respiratory depression, and abuse and misuse, SPRAVATO® is only available through a restricted program called the SPRAVATO® Risk Evaluation and Mitigation Strategy (REMS) Program. SPRAVATO® can only be administered at healthcare settings certified in the SPRAVATO® REMS Program. Patients treated in outpatient healthcare settings (such as medical offices and clinics) must be enrolled in the program.
- **Increased risk of suicidal thoughts and actions.** Antidepressant medicines may increase suicidal thoughts and actions in some people 24 years of age and younger, **especially within the first few months of treatment or**

when the dose is changed. SPRAVATO® is not for use in children.

- Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Some people may have a higher risk of having suicidal thoughts or actions. These include people who have (or have a family history of) depression or a history of suicidal thoughts or actions.

- **How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member?**
  - Pay close attention to any changes, especially sudden changes, in mood, behavior, thoughts, or feelings, or if you develop suicidal thoughts or actions.
  - Tell your healthcare provider right away if you have any new or sudden changes in mood, behavior, thoughts, or feelings, or if you develop suicidal thoughts or actions.
  - Keep all follow-up visits with your healthcare provider as scheduled. Call your healthcare provider between visits as needed, especially if you have concerns about symptoms.

- **Tell your healthcare provider or get emergency help right away if you or your family member have any of the following symptoms, especially if they are new, worse, or worry you:**
  - thoughts about suicide or dying
  - new or worse depression
  - feeling very agitated or restless
  - trouble sleeping (insomnia)
  - acting aggressive, being angry or violent
  - an extreme increase in activity and talking (mania)
  - suicide attempts
  - new or worse anxiety
  - panic attacks
  - new or worse irritability
  - acting on dangerous impulses
  - other unusual changes in behavior or mood

Do not take SPRAVATO® if you:

- have blood vessel (aneurysmal vascular) disease (including in the brain, chest, abdominal aorta, arms and legs)
- have an abnormal connection between your veins and arteries (arteriovenous malformation)
- have a history of bleeding in the brain
- are allergic to esketamine, ketamine, or any of the other ingredients in SPRAVATO®.

If you are not sure if you have any of the above conditions, talk to your healthcare provider before taking SPRAVATO®.

Before you take SPRAVATO®, tell your healthcare provider about all of your medical conditions, including if you:

- have heart or brain problems, including:
  - high blood pressure (hypertension)
  - slow or fast heartbeats that cause shortness of breath, chest pain, lightheadedness, or fainting
  - history of heart attack
  - history of stroke
  - heart valve disease or heart failure
  - history of brain injury or any condition where there is increased pressure in the brain
- have liver problems
- have ever had a condition called “psychosis” (see, feel, or hear things that are not there, or believe in things that are not true).
- are pregnant or plan to become pregnant. SPRAVATO® may harm your unborn baby. You should not take SPRAVATO® if you are pregnant.
  - Tell your healthcare provider right away if you become pregnant during treatment with SPRAVATO®.

- If you are able to become pregnant, talk to your healthcare provider about methods to prevent pregnancy during treatment with SPRAVATO®.
- There is a pregnancy registry for women who are exposed to SPRAVATO® during pregnancy. The purpose of the registry is to collect information about the health of women exposed to SPRAVATO® and their baby. If you become pregnant during treatment with SPRAVATO®, talk to your healthcare provider about registering with the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or online at https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/antidepressants/.

- are breastfeeding or plan to breastfeed. SPRAVATO® passes into your breast milk. You should not breastfeed during treatment with SPRAVATO®.

Tell your healthcare provider about all the medicines that you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. Taking SPRAVATO® with certain medicine may cause side effects.

Especially tell your healthcare provider if you take central nervous system (CNS) depressants, psychostimulants, or monoamine oxidase inhibitors (MAOIs) medicine. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine.

How will I take SPRAVATO®?

- You will take SPRAVATO® nasal spray yourself, under the supervision of a healthcare provider in a healthcare setting. Your healthcare provider will show you how to use the SPRAVATO® nasal spray device.
- Your healthcare provider will tell you how much SPRAVATO® you will take and when you will take it.
- Follow your SPRAVATO® treatment schedule exactly as your healthcare provider tells you to.
- During and after each use of the SPRAVATO® nasal spray device, you will be checked by a healthcare provider who will decide when you are ready to leave the healthcare setting.
- You will need to plan for a caregiver or family member to drive you home after taking SPRAVATO®.
- If you miss a SPRAVATO® treatment, your healthcare provider may change your dose and treatment schedule.
- Some people taking SPRAVATO® get nausea and vomiting. You should not eat for at least 2 hours before taking SPRAVATO® and not drink liquids at least 30 minutes before taking SPRAVATO®.
- If you take a nasal corticosteroid or nasal decongestant medicine take these medicines at least 1 hour before taking SPRAVATO®.

What should I avoid while taking SPRAVATO®?

Do not drive, operate machinery, or do anything where you need to be completely alert after taking SPRAVATO®. Do not take part in these activities until the next day following a restful sleep. See **"What is the most important information I should know about SPRAVATO®?"**

What are the possible side effects of SPRAVATO®?

SPRAVATO® may cause serious side effects including:

See **"What is the most important information I should know about SPRAVATO®?"**

Increased blood pressure. SPRAVATO® can cause a temporary increase in your blood pressure that may last for about 4 hours after taking a dose. Your healthcare provider will check your blood pressure before taking SPRAVATO® and for at least 2 hours after you take SPRAVATO®. Tell your healthcare provider right away if you get chest pain, shortness of breath, sudden severe headache, change in vision, or seizures after taking SPRAVATO®.

Problems with thinking clearly. Tell your healthcare provider if you have problems thinking or remembering.

Bladder problems. Tell your healthcare provider if you develop trouble urinating, such as a frequent or urgent need to urinate, pain when urinating, or urinating frequently at night.

The most common side effects of SPRAVATO® include:

- feeling disconnected from yourself, your thoughts, feelings and things around you
- feeling anxious
- lack of energy

- dizziness
- nausea
- feeling sleepy
- spinning sensation
- decreased feeling of sensitivity (numbness)
- increased blood pressure
- vomiting
- feeling drunk
- headache
- feeling very happy or excited

If these common side effects occur, they usually happen right after taking SPRAVATO® and go away the same day.

These are not all the possible side effects of SPRAVATO®.

Call your doctor for medical advice about side effects. You may report side effects to Johnson & Johnson at 1-800-526-7736, or to the FDA at 1-800-FDA-1088.

Please see full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO® and discuss any questions you may have with your healthcare provider.

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