





# **Observation Rebate Program**

for eligible commercially insured patients

# Pay \$0 after rebate for observation of each treatment. Maximum program benefit per calendar year and program limits shall apply.

Eligible commercially insured patients pay \$0 after rebate to patient for observation of each treatment. Maximum program benefit per calendar year shall apply.

Terms expire at the end of each calendar year. Offer subject to change or end without notice. Not valid for patients using Medicare, Medicaid, or other government-funded programs to pay for their medication. Restrictions, including monthly maximums, may apply. Not valid for residents of MA, MI, MN, or RI. Participate without sharing your income information. See full program requirements below.

#### Program does not cover SPRAVATO® medication cost.

For medication cost support, we offer the SPRAVATO withMe Savings Program. Learn more at **Spravato.com/SavingsRequirements**.

The support and resources provided by SPRAVATO withMe are not intended to provide medical advice, replace a treatment plan you receive from your doctor or nurse, or serve as a reason for you to start or stay on treatment.

### What is SPRAVATO® (esketamine) CIII nasal spray?

SPRAVATO® is a prescription medicine, used along with an antidepressant taken by mouth to treat:

- Adults with treatment-resistant depression (TRD)
- 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 and dissociation.** SPRAVATO® may cause sleepiness (sedation), fainting, dizziness, spinning sensation, anxiety, or feeling disconnected from yourself, your thoughts, feelings, space and time (dissociation).
  - 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.
- Respiratory depression was observed with the use of SPRAVATO®; additionally, there were rare reports of respiratory arrest.
  - Your healthcare provider must monitor you for serious side effects for at least 2 hours (including pulse oximetry) after taking SPRAVATO®. Your healthcare provider will decide when you are ready to leave the healthcare setting.

(CONTINUED)

# Spravato with Me



# 1

# Enroll in the SPRAVATO withMe Observation Rebate Program



### Am I eligible?

#### You may be eligible for the SPRAVATO withMe Observation Rebate Program if you:

- Are age 18 or older and use commercial or private health insurance for treatment with SPRAVATO®.
- Are enrolled in the SPRAVATO® Risk Evaluation and Mitigation Strategy (REMS). Learn more at **SpravatoREMS.com/Patients**.
- SPRAVATO withMe Observation Rebate Program is based on treatment observation costs only and does not include costs for your medication. To receive a rebate, you must have paid your treatment provider for your out-of-pocket treatment observation costs.

### Other requirements

- This program is only for people age 18 or older using commercial or private health insurance for their SPRAVATO® treatment. This includes plans from the Health Insurance Marketplace. This program is not for people who use any state or federal government-funded healthcare program. Examples of these programs are Medicare, Medicaid, TRICARE, Department of Defense, and Veterans Administration.
- You may not seek payment for the value received from this program from any health plan, patient assistance foundation, flexible spending account, or healthcare savings account.
- You must meet the program requirements at the time of each rebate request.
- Program terms will expire at the end of each calendar year. The program may change or end without notice, including in specific states. Not valid for residents of MA, MI, MN, or RI.
- To use this program, you must follow any health plan requirements, including telling your health plan how much co-payment support you get from this program. By getting an Observation Rebate Program benefit, you confirm that you have read, understood, and agree to the program requirements on this page.
- Before you complete enrollment, you will be asked to provide personal information that may include your name, address, phone number, email address, and information related to your healthcare insurance and treatment. This information is needed for Johnson & Johnson Health Care Systems Inc., the maker of SPRAVATO®, and our service providers to enroll you in the SPRAVATO withMe Observation Rebate Program. We may also use the information you give us to learn more about the people who use SPRAVATO®, and to improve the information we give them. Johnson & Johnson Health Care Systems Inc. will not share your information with anyone else except where legally allowed.
- You are responsible for submitting a completed Rebate Request Form and proof of provider payment to receive payment under the Observation Rebate Program. Rebate requests must be submitted within 270 days of the date of service.
- This program offer may not be used with any other coupon, discount, prescription savings card, free trial, or other offer. Offer good only in the United States and its territories, excluding states noted above. Void where prohibited, taxed, or limited by law.

You may end your participation in SPRAVATO withMe at any time by calling 844-4S-WITHME (844-479-4846).

Please see additional Important Safety Information on page 1 and pages 4–6 and full <u>Prescribing Information</u>, including Boxed WARNINGS, and <u>Medication Guide</u> for SPRAVATO®.

# Spravato with Me





# **Submit Rebate Request**

### How do you know if you need to submit a rebate request?

If you made a payment to your treatment provider to cover costs of the observation period after a SPRAVATO® treatment session, you can submit a rebate request to the SPRAVATO withMe Observation Rebate Program.

#### How it works:

You'll need to submit proof of provider payment (eg, receipt for out-of-pocket treatment observation costs) to receive a rebate check.

- Make sure your receipt includes the treatment date and the amount you paid for your treatment observation (not your medication cost)
- If you are unable to obtain a receipt or need additional information on submitting a rebate request, please see the Step-by-Step Guide on page 2 of the **Rebate Request Form**

### 3 ways for patient to request rebate payment:

Mail, fax, or upload your proof of provider payment and the completed **Rebate Request Form**.



#### Mail:

Observation Rebate Program 2250 Perimeter Park Drive, Suite 300 Morrisville, NC 27560



#### Fax:

833-512-0493



Online:

MyJanssenCarePath.com

If you are eligible for a rebate, you will receive a rebate check typically in about 2 to 3 weeks.



### SPRAVATO withMe Savings Program

You may be able to save on your out-of-pocket medication costs for SPRAVATO® Nasal Spray CIII by enrolling in the SPRAVATO withMe Savings Program.

Learn more at Spravato.com/SavingsRequirements





#### **IMPORTANT SAFETY INFORMATION (CONTINUED)**

- **Abuse and misuse.** There is a risk for abuse and physical and psychological dependence with SPRAVATO® treatment. Your healthcare provider should check you for signs of abuse and dependence before and during treatment with SPRAVATO®.
  - 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 and 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 (e.g., 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.
  - 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 right away if you or your family member have any of the following symptoms, especially if they are new, worse, or worry you:
  - suicide attempts
  - thoughts about suicide or dying

- worsening depression
- 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®.

(CONTINUED)





#### **IMPORTANT SAFETY INFORMATION (CONTINUED)**

#### 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 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-andresearch-programs/pregnancyregistry/antidepressants/.
- are breastfeeding or plan to breastfeed. 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®.

(CONTINUED)





#### **IMPORTANT SAFETY INFORMATION (CONTINUED)**

#### 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® when used along with an antidepressant taken by mouth include:

- feeling disconnected from yourself, your thoughts, feelings and things around you
- dizziness
- nausea
- feeling sleepy
- spinning sensation

- decreased feeling of sensitivity (numbness)
- · feeling anxious
- · lack of energy
- increased blood pressure
- vomiting
- · feeling drunk
- 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 FDA at 1-800-FDA-1088.

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