

Access Considerations for Starting a Patient on SPRAVATO[®]

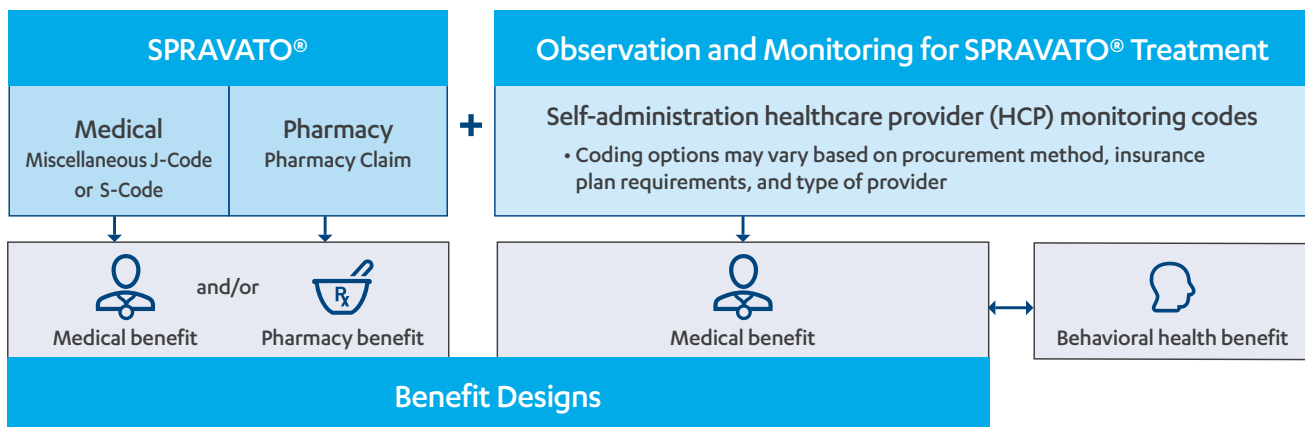
We are pleased to share helpful access considerations when prescribing and administering SPRAVATO[®] for your patients.

Review your patient's insurance coverage

For medication and observation, make sure you understand your patient's health plan benefits. Some key considerations are:

- What type of health insurance does the patient have: Commercial or Medicare?
- For both commercial insurance and Medicare: Is the patient covered under medical benefit or pharmacy benefit for the product?
 - If the patient has coverage under the medical benefit, the treatment center may be able to buy and bill for the product. If the treatment center is not able to buy and bill for the product, does the patient's health insurance allow for Medical Assignment of Benefits (AOB) (pharmacy to bill insurance under patient's medical benefits)?
 - If the patient has a pharmacy benefit and/or allowable coverage under AOB, the treatment center should consider how to obtain the product from a REMS-certified pharmacy covered under the patient's plan. The pharmacy should be able to process the patient's prescription under the patient's medical benefit, pharmacy benefit, or both.
- For Medicare specifically: the coverage of SPRAVATO[®] is defined by the patient's Medicare coverage, such as Part B and/or Part D.
 - If Medicare Part B: the treatment center may buy and bill for the product.
 - If Medicare Part D: identify a REMS-certified pharmacy that is covered under the patient's plan to process the prescription.
 - Medicare has implemented G-codes (2082 and 2083) for SPRAVATO[®], effective 1/1/2020.
- Is a Specialist referral or prior authorization required by the patient's plan? Failing to obtain appropriate referrals or pre-authorization can result in nonpayment by the plan.
- Does the patient's plan indicate the sites of care that may bill for the drug and its administration? For example, does the plan require that the drug be administered only in a healthcare provider practice setting and restrict coverage if provided in a hospital outpatient setting?
- What are the plan's guidelines for determining medical necessity of the therapy? Supporting evidence may be required, including:
 - Information about the patient's medical condition and history
 - Prescribing Information
 - A healthcare provider's statement or Letter of Medical Necessity
 - Availability of other treatment alternatives
 - Supporting literature (eg, peer-reviewed studies and compendia monographs)

Coverage, coding, and reimbursement for SPRAVATO[®] and associated observation and monitoring



Identify a certified SPRAVATO[®] treatment center

Visit [Spravato.com/Find-a-Center](https://spravato.com/Find-a-Center) or call Janssen CarePath at 877-CarePath (877-227-3728), Monday–Friday, 8:00 AM–8:00 PM ET. If you'd like to become a certified SPRAVATO[®] treatment center, visit [SpravatoTreatmentCenter.com](https://spravatoTreatmentCenter.com).

- Certified healthcare providers can also register at [SpravatoREMS.com](https://spravatoREMS.com) for a list of the latest up-to-date REMS-certified treatment centers and pharmacies.

Please see full [Prescribing Information](#), including **Boxed WARNINGS** and [Medication Guide](#) for SPRAVATO[®]. Provide the [Medication Guide](#) to your patients and encourage discussion.



Coordinate with the treatment center

Healthcare provider needs to coordinate with the treatment center before referring patients. Once treatment center is identified, provide critical patient information such as the patient’s insurance information. Some questions to ask when coordinating with the treatment center:

- Are they taking new patients?
- Are they in-network or out-of-network based on the patient’s insurance coverage? You will need treatment center NPI in order to verify the network status of the patient’s benefits.
 - Please note treatment center NPI is important to verify patient’s benefits for evaluation and management and/or for SPRAVATO[®].
- Can treatment for SPRAVATO[®] be covered at the treatment center based on the patient’s insurance coverage? If not sure: Janssen CarePath will be able to assist if a treatment center has been identified.
- Does the patient’s insurance cover the observation and monitoring of SPRAVATO[®] at the treatment center?



Help facilitate effective patient referrals

Provide the treatment center with the following information:

- Any payer requirements, such as prior authorization and/or letters of medical necessity
- Verification of Benefits results
- Patient- and practice-related information to ensure coordination of care:
 - Patient demographic information
 - Patient insurance information
 - Referring healthcare provider information
 - Clinical information



Be sure to tell your patient:

- SPRAVATO[®] must be administered under the direct supervision of a healthcare provider at a REMS-certified treatment center. For more information, visit [SpravatoHCP.com/Dosing-and-Administration](https://www.SpravatoHCP.com/Dosing-and-Administration).
- Patient must be enrolled in the SPRAVATO[®] REMS; they can download the REMS Patient Enrollment Form from [SpravatoREMS.com](https://www.SpravatoREMS.com).
 - Patients should work with their healthcare provider to complete and sign the form.
- Patient will need transportation; they should not drive for 24 hours after treatment.
- Prior to starting treatment, visit [JanssenCarePath.com](https://www.JanssenCarePath.com) to learn about resources that may be able to help your patients with their out-of-pocket medication costs.

SPRAVATO[®] Risk Evaluation and Mitigation Strategy (REMS)

A REMS is a strategy to manage known or potential risks associated with a drug and is required by the U.S. Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks.

SPRAVATO[®] is available only through a restricted distribution program called the SPRAVATO[®] REMS because of the risks of serious adverse outcomes resulting from sedation and dissociation caused by SPRAVATO[®] administration, and abuse and misuse of SPRAVATO[®]. SPRAVATO[®] is intended for use only in a certified healthcare setting.

SPRAVATO[®] is intended for patient administration under the direct observation of healthcare provider, and patients are required to be monitored by a healthcare provider for at least 2 hours. SPRAVATO[®] must never be dispensed directly to a patient for home use.

What are the REMS requirements?

- 1) **Healthcare setting certification:** All healthcare settings must be certified in the REMS in order to receive, dispense, and/or treat patients with SPRAVATO[®].
- 2) **Pharmacy certification:** All pharmacies must be certified in the REMS in order to receive and dispense SPRAVATO[®].
- 3) **Patient enrollment:** Patients in an **outpatient** setting must be enrolled in the REMS with their prescriber in order to receive SPRAVATO[®] treatment.

For more information, or for assistance finding a REMS-certified treatment center and/or pharmacy, visit [SpravatoREMS.com](https://www.SpravatoREMS.com).

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