Spravato withMe | Spravato® (esketamine) CIII
28 mg nasal spray

Once a decision has been made to prescribe SPRAVATO®, enroll your patients in the SPRAVATO withMe program and learn how to minimize delays in the access process so your patients can start treatment quickly.

SPRAVATO withMe
Provider Portal User Guide

Please see additional Important Safety Information on pages 28 and 29, and full **Prescribing Information**, including Boxed WARNINGS, and **Medication Guide** for SPRAVATO®, also available at spravatohcp.com.

INDICATIONS AND IMPORTANT SAFETY INFORMATION:

INDICATIONS:
SPRAVATO® (esketamine) CIII Nasal Spray is indicated, in conjunction with an oral antidepressant, for the treatment of:
- Treatment-resistant depression (TRD) in adults.
- Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior.

LIMITATIONS OF USE:
- The effectiveness of SPRAVATO® in preventing suicide or in reducing suicidal ideation or behavior has not been demonstrated. Use of SPRAVATO® does not preclude the need for hospitalization if clinically warranted, even if patients experience improvement after an initial dose of SPRAVATO®.
- SPRAVATO® is not approved as an anesthetic agent. The safety and effectiveness of SPRAVATO® as an anesthetic agent have not been established.

IMPORTANT SAFETY INFORMATION

WARNING: SEDATION; DISSOCIATION; RESPIRATORY DEPRESSION; ABUSE AND MISUSE; and SUICIDAL THOUGHTS AND BEHAVIORS

See full prescribing information for complete boxed warning

- **Risk for sedation, dissociation, and respiratory depression after administration. Monitor patients for at least two hours after administration (5.1, 5.2, 5.3).**
- **Potential for abuse and misuse. Consider the risks and benefits of using SPRAVATO® prior to use in patients at higher risk of abuse. Monitor for signs and symptoms of abuse and misuse (5.4).**
- **SPRAVATO® is only available through a restricted program called the SPRAVATO® REMS (5.5).**
- **Increased risk of suicidal thoughts and behaviors in pediatric and young adult patients taking antidepressants. Closely monitor all antidepressant-treated patients for clinical worsening and emergence of suicidal thoughts and behaviors. SPRAVATO® is not approved for use in pediatric patients (5.6).**

Table of Contents

Introduction

Welcome to the SPRAVATO withMe Provider Portal, your online resource for patient-level visibility into activity progress on benefits investigations, prior authorizations, appeals, coding, reimbursement, and other SPRAVATO withMe resources.

This User Guide will show you what the SPRAVATO withMe Provider Portal provides and how to navigate the site.

Provider Portal Structure
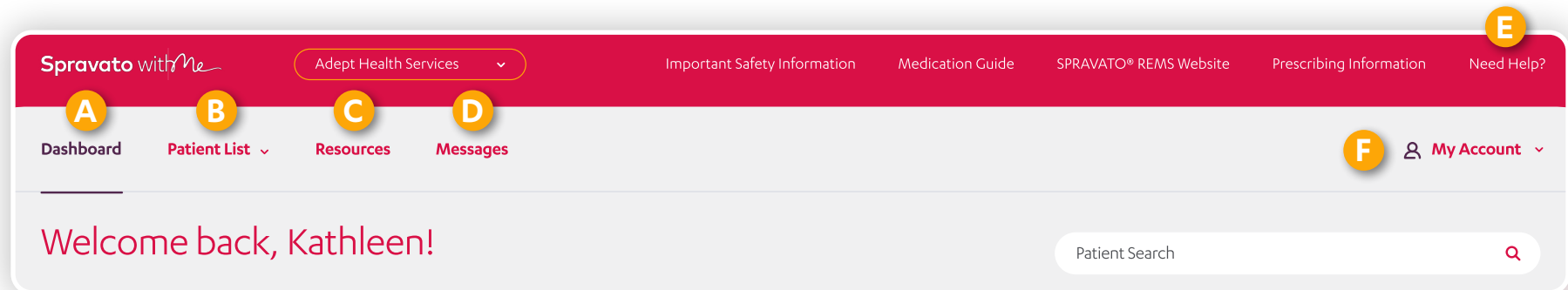
A **DASHBOARD:** A list of actions needed, status updates, and most recent messages

For more information on the Dashboard, *please see page 10*

B **PATIENT LIST:** At-a-glance view of topical patient lists, with extensive filters and sorting options

For more information on the Patient List, *please see page 22*

C **RESOURCES:** Helpful reference materials and templates

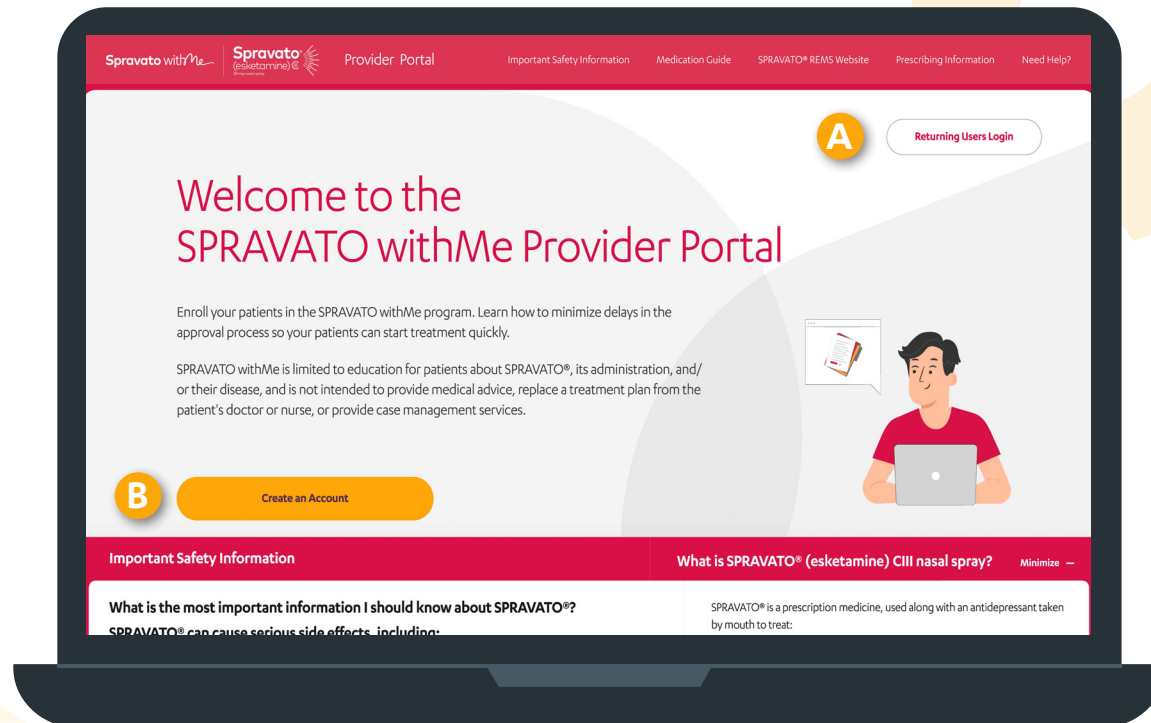**D** **MESSAGES:** Your inbox for all SPRAVATO withMe communications

E **NEED HELP?:** Support and guidance when you need it.

For more information on the Need Help? button, *please see page 24*

F **MY ACCOUNT**
For more information on the My Account page, *please see page 11*

Creating a Portal Account

This is the portal landing page.

(A) RETURNING USERS LOGIN: If you've already registered for the portal, you can log in to your account by clicking here and entering your login information

[Returning Users Login]

(B) CREATE AN ACCOUNT: If you have not already registered for the portal, you can begin the process of creating your account by clicking here

[Create an Account]

Creating a Portal Account (Cont'd)

This is the start of the account registration process. You will see this screen when you click **Create an Account**. All users are considered Site Staff when their account is created. Users will be further designated as one of the following roles: "Educator," "Physician," "Nurse," "Physician Assistant," "Medical Assistant," "Office Manager," "Nurse Practitioner," "Office Staff," "Pharmacist," or "Other."

Users can also be granted Admin permissions. Admin permissions are limited to managing Site information and Staff profiles and access. All other privileges are the same.

Please note: The user that creates the Site is automatically designated as Site Admin.

Network Admins get access to all Sites on the network. They can edit all Site information and all Staff profiles, including approving/rejecting Staff access, across all Sites.
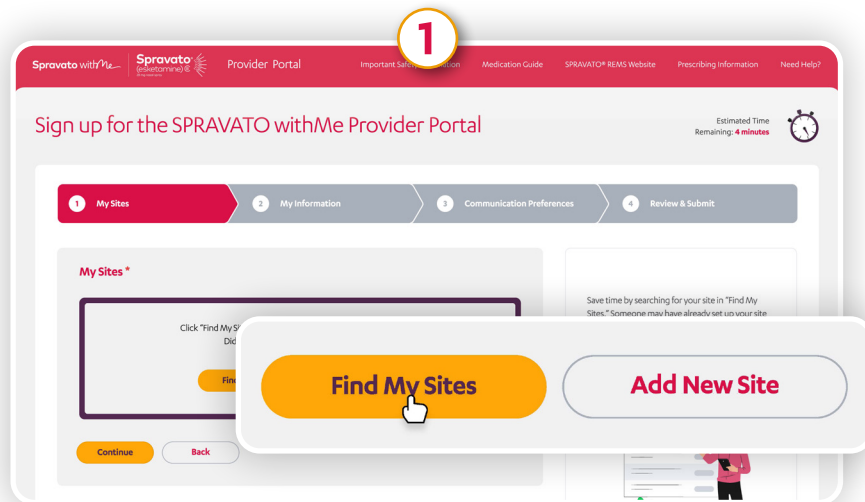
Site Admins can edit Site information and Staff profiles, including approving/rejecting Staff access, for their Site(s) only.
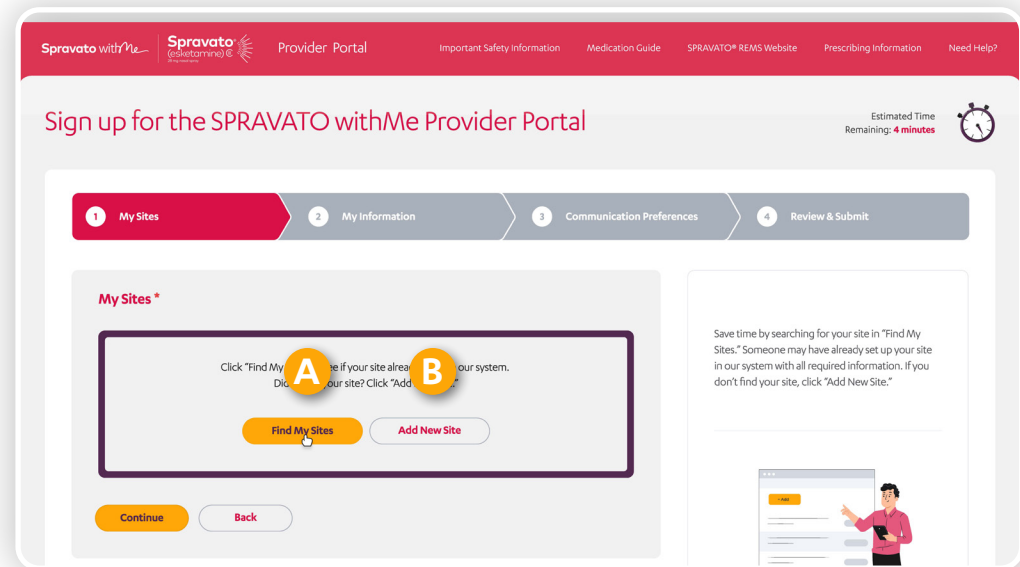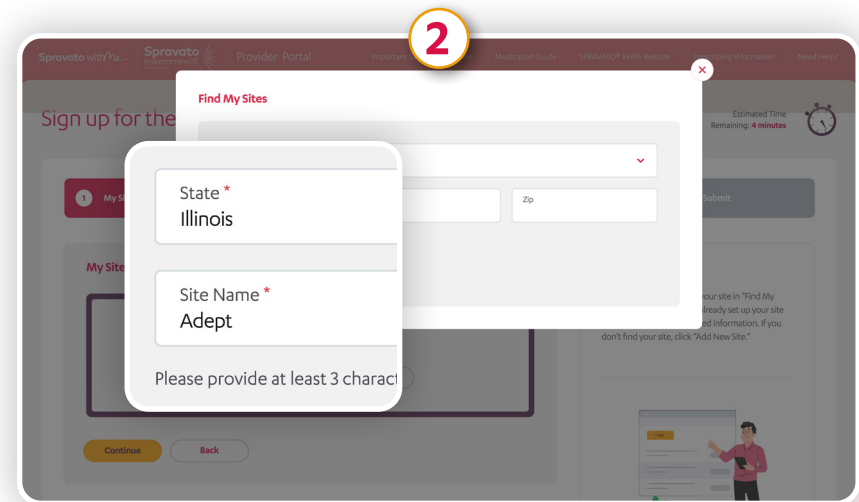

Ⓐ **FIND MY SITES:** If your Site(s) already exist in the system, you will be able to search for them by clicking here

Ⓑ **ADD NEW SITE:** If your Site is not already in the system, you can begin the process of adding it by clicking here
- Sites can be added at a later time from the Site Management section of the My Account screen
- Only users with Network Admin permissions may add affiliated Sites – other users should call **844-4S-WITH-ME (844-479-4846)** so a Case Manager can add the Site

If your Site is part of a Multi-Site Network, you will be able to view all patients across the different Sites from the portal.

Please see Indications and Important Safety Information on pages 1 and 28-29, and full <u>Prescribing Information</u>, including Boxed WARNINGS, and <u>Medication Guide</u> for SPRAVATO®, also available at spravatohcp.com.
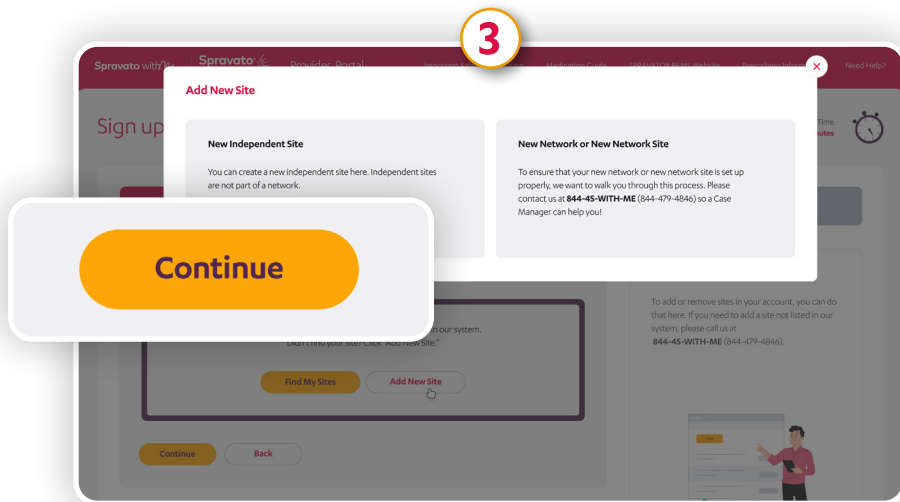
Adding a New Site

At the beginning of the sign-up process, you will be given the option to **Find My Sites** or **Add New Site**.

Click **Find My Sites** to search existing Sites by State and Site Name.

Continued >

Please see Indications and Important Safety Information on pages 1 and 28-29, and full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO®, also available at spravatohcp.com.

Adding a New Site (Cont'd)

Click Add New Site if your Site hasn't already been enrolled. If you are creating a New Independent Site, click Continue to proceed.

If you are creating a New Network or New Network Site, you will need to call **844-4S-WITH-ME (844-479-4846)** so that a Case Manager can help facilitate.

Next, add all the information requested about the Site, and the Prescriber associated with the Site.

Please see Indications and Important Safety Information on pages 1 and 28-29, and full <u>Prescribing Information</u>, including Boxed WARNINGS, and <u>Medication Guide</u> for SPRAVATO®, also available at spravatohcp.com.

Adding a New Site (Cont'd)

5

Sign up for the SPRAVATO withMe Provider Portal

Estimated Time Remaining: **1 minute**

1 My Sites 2 My Information 3 Communication Preferences 4 Review & Submit

Summary

Medication(s)

SPRAVATO® (esketamine)

My Information ✎ Edit

Full Name: **Collins, Kathleen**
Role: **Physician**
Phone (Office): **(555) 833-2596**
Email: **kathleencollins@mail.net**

My Sites ✎ Edit

Site Name	Address	Phone / Fax
Adept Health Services	200 E Cermak Rd, Chicago, IL 60616	Phone: (555) 925-8338 Fax: (555) 285-7634

Last step!

Please take a minute to make sure the information you provided is correct before completing the sign up process.

Submit

Once you have finished adding information about the Site, complete the sign-up process by adding your personal information and communication preferences, then reviewing your information and clicking Submit. You will see a confirmation message with a green check mark once the Site has been submitted.

6

Welcome back, Kathleen!

My Actions Other Updates

Smith, Patricia 08 / 15 / 1955 · SPRAVATO® ⚠ PA Denied Nov 1, 2023
Johnson, James 07 / 01 / 1958 · SPRAVATO® ⚠ PA Denied Nov 1, 2023
Miller, Mary 12 / 10 / 1957 · SPRAVATO® ⚠ BI in Progress—Missing Info Nov 1, 2023
Wilson, Robert 05 / 28 / 1969 · SPRAVATO® ⚠ BI in Progress—Missing Info Nov 1, 2023
Davis, Christopher 09 / 05 / 1978 · SPRAVATO® ⚠ PA in Progress—Unable to Contact HCP Nov 1, 2023

My Account

Account Management
Communication Preferences
Site Management
Staff Management

VOB Delayed: White, Donald
White, Donald 03/03/1956 ID: 1234567890
Justin Reed Nov 1, 2023
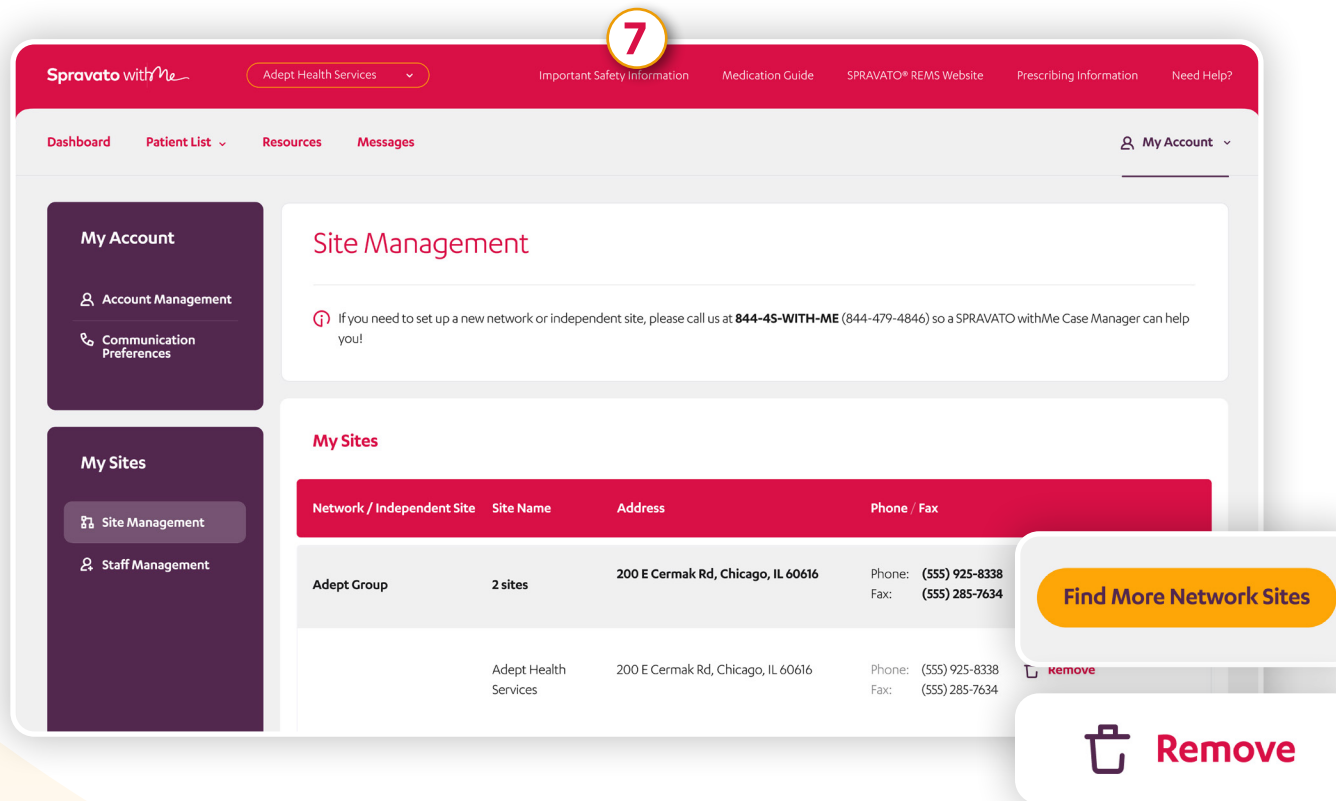VOB Delayed: Rodriguez, Lisa
Rodriguez, Lisa 11-13-1958 ID: 1234567890

If you need to add a Site later on, navigate to the Dashboard and use the My Account dropdown menu to click Site Management.

Please see Indications and Important Safety Information on pages 1 and 28-29, and full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO®, also available at spravatohcp.com.

Adding a New Site (Cont'd)

From this screen you can initiate the process described above using the **Find More Network Sites** button. You can also use the **Remove** button to remove a Site. Only Network Admins and Site Admins may remove a Site.

Please note: Removing the Site will also remove all Patients associated with that Site. If you want to transfer Patients to another Network Site prior to removing a Site, please call your Case Manager.

Please see Indications and Important Safety Information on pages 1 and 28-29, and full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO®, also available at spravatohcp.com.

Dashboard

The SPRAVATO withMe Provider Portal is a consolidated overview of your day-to-day actions and updates. This will be your landing page when you log in to the Provider Portal, giving you immediate access to priority actions and relevant updates based on recent activity.

(A) CURRENT SITE: Sites that the user has access to can be selected using this dropdown menu
- Patients displayed in the Dashboard are associated with the currently selected Site

(B) MY ACTIONS: A list of actions needed by you for your patients
- As actions are performed and the system is updated with changes, completed actions will be removed, and new actions will be added as needed

(C) OTHER UPDATES: A list of the most recent status updates for your patients
- Updates shown in this section are included only to record progress and do not currently require action from you
- As the system is updated with changes, only the latest status will be shown

(D) MOST RECENT BOOKMARKED PATIENTS: Quick access to patients you've bookmarked
- You can bookmark patients anywhere on the provider portal by clicking the **star** displayed next to the patient's name

**(E) LATEST MESSAGES:** Preview of the most recent messages received in your SPRAVATO withMe inbox

(F) MY ACCOUNT: Options related to your user account, site management, and staff management

Please see Indications and Important Safety Information on pages 1 and 28-29, and full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO®, also available at spravatohcp.com.
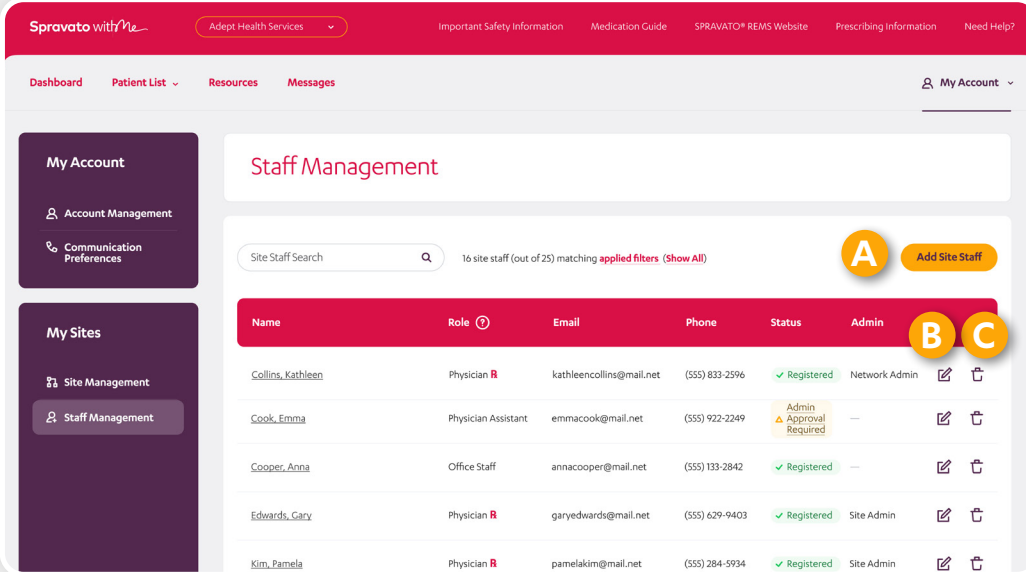
My Account

Clicking on My Account from anywhere in the portal will allow you to navigate to the various pages of the My Account tab. The My Account tab allows you to manage your account, including details and options related to your Sites and Staff.
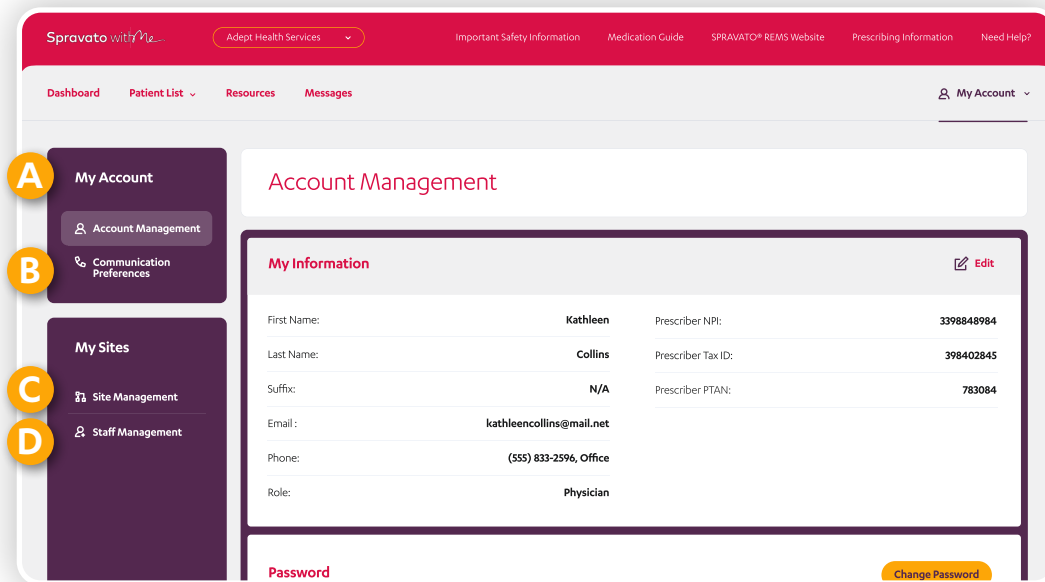
A **ACCOUNT MANAGEMENT:** Make any changes to your personal information, or change your password

B **COMMUNICATION PREFERENCES:** Control how you would like to see communications from SPRAVATO withMe

C **SITE MANAGEMENT:** Add affiliate sites, find more network sites, and remove sites

D **STAFF MANAGEMENT:** Review all staff on record, including current status and any required actions or approvals

Please see Indications and Important Safety Information on pages 1 and 28-29, and full <u>Prescribing Information</u>, **including Boxed WARNINGS, and** <u>Medication Guide</u> **for SPRAVATO®, also available at spravatohcp.com.**

Staff Management

Network Admins and Site Admins may add, remove, and edit Site Staff from the Staff Management screen.

A **ADD SITE STAFF:** Add a new Staff member to a Site

B **EDIT:** Make changes to a Staff member's information

C **REMOVE:** Remove a Staff member from a Site – once a staff member is removed, they will no longer have access to patient records and data.

Please see Indications and Important Safety Information on pages 1 and 28-29, and full Prescribing Information, **including Boxed WARNINGS, and** Medication Guide **for SPRAVATO®, also available at spravatohcp.com.**
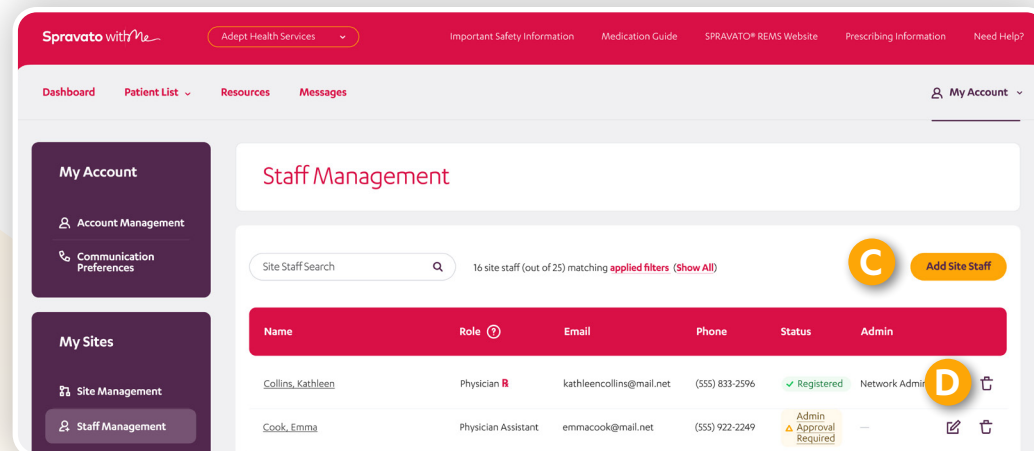
Adding New Site Staff and Patients

To begin the process of adding new staff and patients to your site, begin at the Dashboard.
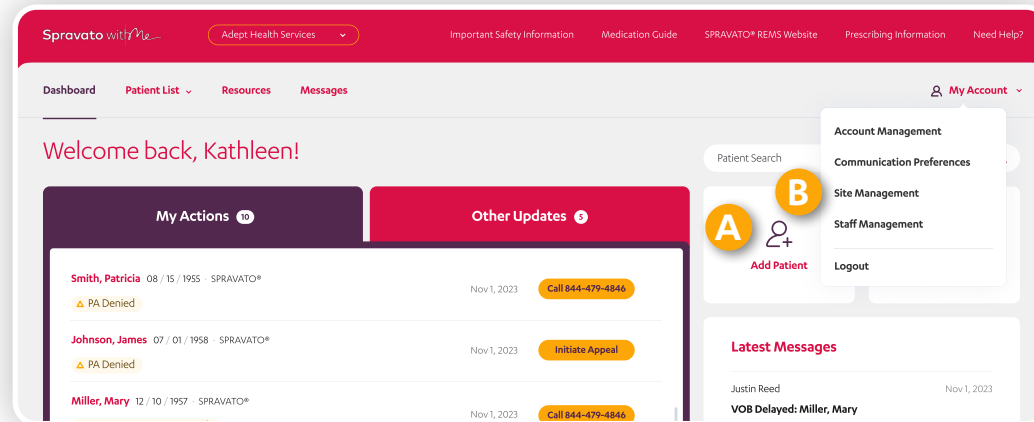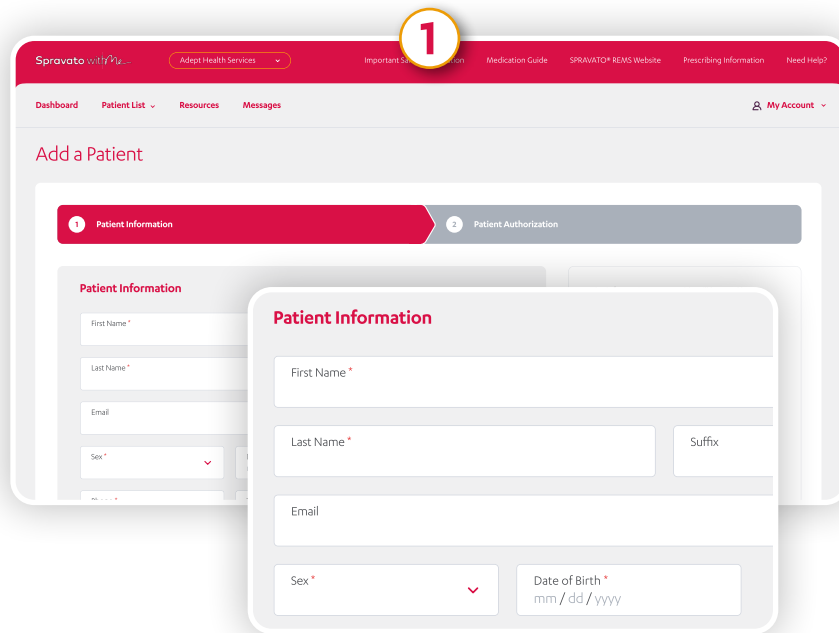
(A) ADD PATIENT: You can begin the process of adding a Patient by clicking here

(B) STAFF MANAGEMENT: You can begin the process of adding a new Staff member by clicking **My Account**, then clicking **Staff Management** from the dropdown menu

(C) ADD SITE STAFF: Add a Staff member to a Site

(D) REMOVE SITE STAFF: Remove a Staff member from a Site

Please see Indications and Important Safety Information on pages 1 and 28-29, and full <u>**Prescribing Information**</u>**, including Boxed WARNINGS, and** <u>**Medication Guide**</u> **for SPRAVATO®, also available at spravatohcp.com.**

Adding New Site Staff and Patients (Cont'd)

To add a Patient, first click Add Patient from the Dashboard and then fill out all the required information – required fields are marked with a red asterisk.

Next, you will need to upload a signed patient enrollment and authorization form (PEF). Please upload pages 3-6 from the patient section of the PEF.

If you already have a printed and signed document, it can be scanned and uploaded to the provider portal here. If the patient or their legally authorized representative are in the office with you, they can e-sign the PEF digitally.
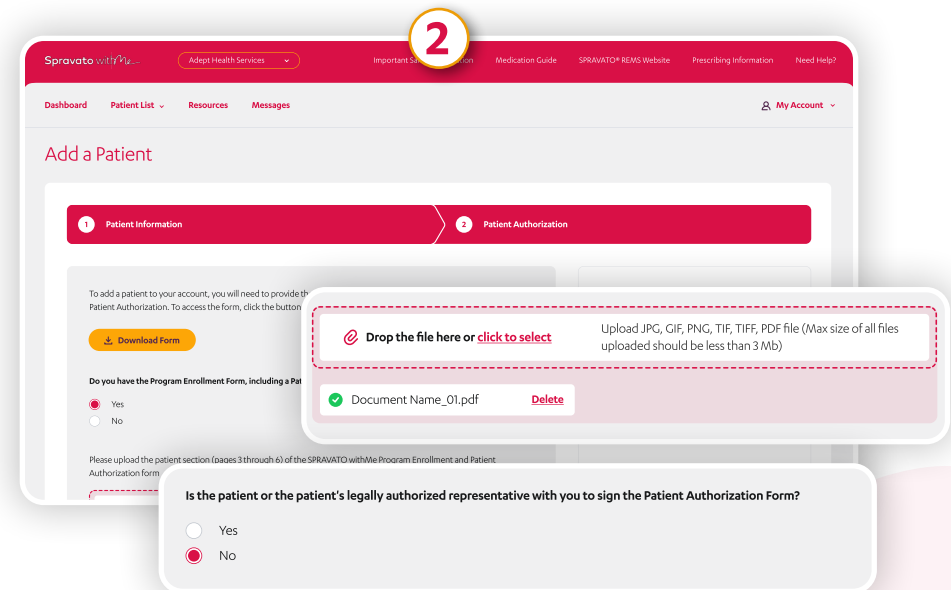
Please see Indications and Important Safety Information on pages 1 and 28-29, and full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO®, also available at spravatohcp.com.

Adding New Site Staff and Patients (Cont'd)

You can also send the patient a link to the program enrollment and patient authorization site via an e-mail sent from no-reply@swmpatientsupport.com.

Alternatively, the patient can scan the QR code, which can be found in the SPRAVATO withMe patient brochure or in the patient section of the PEF, which will direct them to a website where they can e-sign and submit the patient authorization.

When the patient authorization has been submitted and the Patient has been added successfully, you will be given the option to initiate a benefits investigation or enroll the patient in the Savings Program. A benefits investigation will not be automatically conducted after enrolling a Patient – it must be initiated via the portal.

Please note: Click Enroll Patient in Savings Program only if you need the Savings Card right away. Alternatively, if your patient has self-attested on the enrollment form for the Savings Program and Observation Rebate Program and is eligible for the programs, they will be enrolled by the Case Manager within 24 hours, provided there is no missing or incomplete information. Their downloadable Savings Program card will then be available in the portal.

Please see Indications and Important Safety Information on pages 1 and 28-29, and full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO®, also available at spravatohcp.com.

Patient Card

Clicking on a patient's name will open their Patient Card as an overlay to the current tab. The Patient Card provides details and functionality regarding the patient's demographics, Savings Program enrollment, insurance coverage, and other related treatment support.

Please see Indications and Important Safety Information on pages 1 and 28-29, and full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO®, also available at spravatohcp.com.

16

Patient Card (Cont'd)

Smith, Patricia 08 / 15 / 1955 ✕

SPRAVATO® (esketamine) CIII Nasal Spray

Action Needed Case #0024835160 ✕
Patient's PA returned not covered Oct 29, 2023

📋 **Begin Appeal**

Patient Summary ⌄

Savings Program ⌄

Insurance Coverage ⌃

View Case History

Benefits Investigation
Status Not started
Outcome N/A

Run New BI

Treatment Support ⌃

Patient Journey Tracker

━━━━━━━━ 66*

✓ Program Enrollment ❓
  Complete
✓ Benefits Verification ❓
  Complete
⊖ Prior Authorization ❓
  Not Started

A **ACTION NEEDED:** Actions that are needed by you for your patient will appear at the top of the Patient Card

- These are the same actions as those displayed on the My Actions tab on the landing page and the Patient List. They will be removed as the action is taken and the system updates.

  If there are no actions needed for the patient, nothing will show here on the Patient Card

B **PATIENT SUMMARY:** Overview of patient information, including address, contact information, medical insurance details, pharmacy insurance details, and information about their caregiver(s)

- All of the above can be edited from the Patient Card
- This section also contains a record of all recent updates pertaining to this patient

C **SAVINGS PROGRAM:** Overview of the patient's Savings Program enrollment

For Medical Benefit
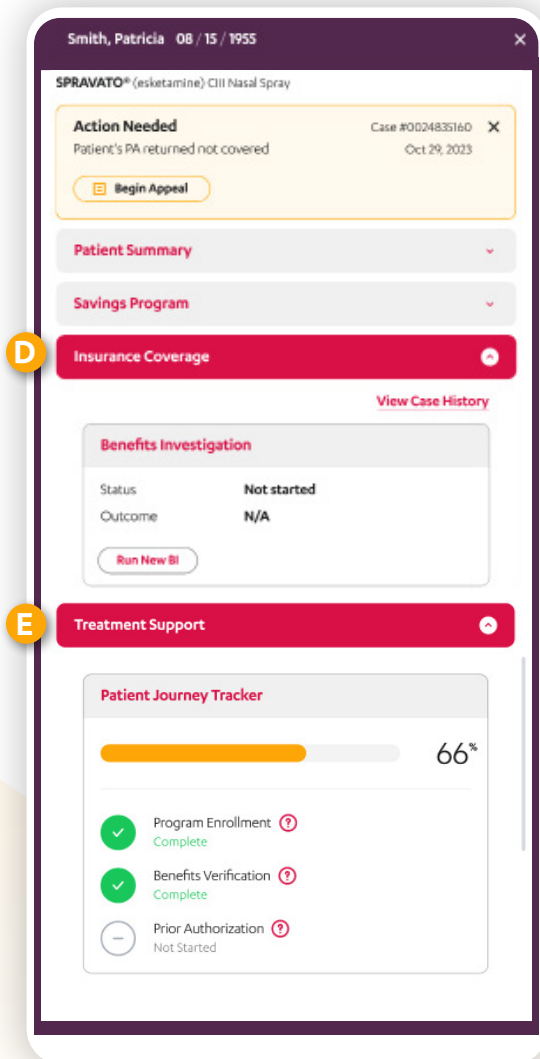
- Details include enrollment status, program year, total benefit, remaining benefit, funds on card, AOB status, and rebate preference
- Ability to submit a rebate and view all Savings Program transactions

For Pharmacy Benefit

- Details include enrollment status, member ID, BIN and group number, total benefit, and remaining benefit
- Ability to view all Savings Program transactions

Continued >

Please see Indications and Important Safety Information on pages 1 and 28-29, and full <u>Prescribing Information</u>, including Boxed WARNINGS, and <u>Medication Guide</u> for SPRAVATO®, also available at spravatohcp.com.

Patient Card (Cont'd)

D **INSURANCE COVERAGE:** Overview of information related to the patient's insurance

Benefits Investigation (BI)
- Status and Outcome readouts
- Ability to Run New BI

Prior Authorization (PA)
- Status and Outcome readouts
- Ability to Run New PA

Appeal
- Status and Outcome readouts
- Ability to Begin Appeal

Exception
- Status and Outcome readouts
- Ability to Begin Exception

E **TREATMENT SUPPORT:** Overview of the Patient Journey

Please see Indications and Important Safety Information on pages 1 and 28-29, and full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO®, also available at spravatohcp.com.

Savings Program

The Savings Program section of the Patient Card allows you to view the Patient's Savings Program card, submit a rebate, and view all transactions for this patient. Click **Download Card** to view a card with the patient's member number for the patient to download and print out.

A **DOWNLOAD CARD:** View a card with the patient's member number for the patient to download and print out

B **SUBMIT REBATE:** Initiate the process of submitting a rebate via the provider portal

C **VIEW ALL TRANSACTIONS:** See a history of all recorded Savings Program transactions, submitted rebate requests, and other related communications

Please see Indications and Important Safety Information on pages 1 and 28-29, and full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO®, also available at spravatohcp.com.
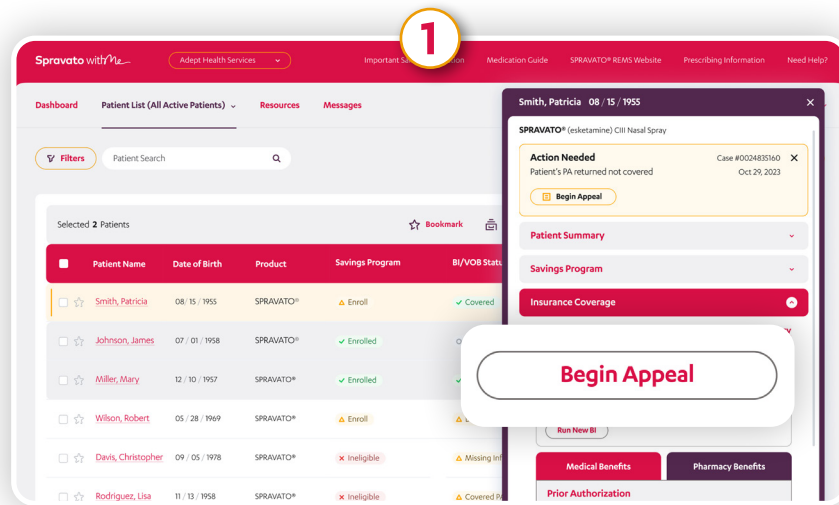
Request an Appeal

To begin an Appeal, navigate to the Insurance Coverage dropdown of the patient's Patient Card. Find the Appeal section and click **Begin Appeal**.
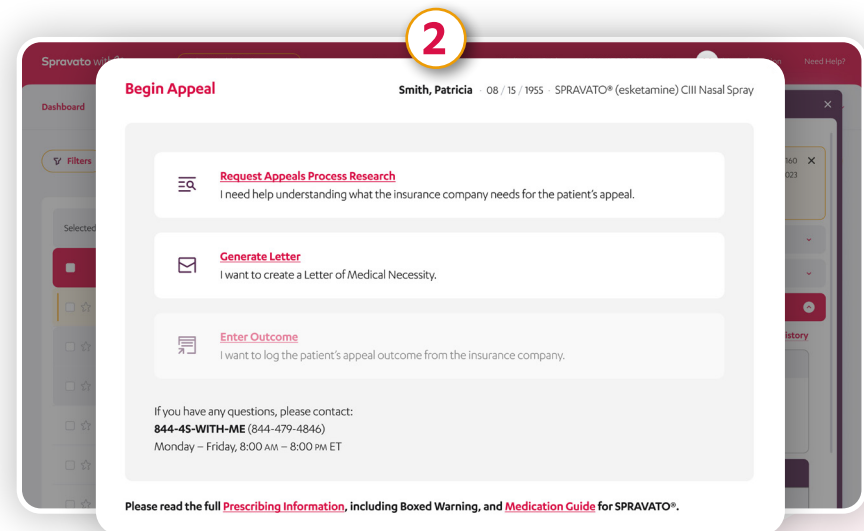
To proceed, select one of the options shown here.

Please see Indications and Important Safety Information on pages 1 and 28-29, and full Prescribing Information, **including Boxed WARNINGS, and** Medication Guide **for SPRAVATO®, also available at spravatohcp.com.**

Request an Appeal (Cont'd)

③

Letter of Medical Necessity

Smith, Patricia 08 / 15 / 1955 · SPRAVATO® (esketamine) CIII Nasal Spray

1 Letter Details **2** Review

The information you enter will be used to assemble the Letter of Medical Necessity (LMN). Enter the recipient's information. Add the patient's information as provided in the Benefits Investigation form for this Janssen medication.

Patient Information | **Prescriber Information** ✎ Edit

First Name * Patricia | Last Name * Smith | Prescriber Name: Collins, Kathleen
Date of Birth * 08/15/1955 | Member ID / Policy Number * 12341234 | Practice Name: Adept Health Services
Group # * 23452345

Request Details

Primary Diagnosis Code *

Primary Diagnosis Indication *

☐ Add Secondary Diagnosis

Fill out this form with any missing information about the Patient or Prescriber, or make edits to the existing information, then add details of the request.

④

Letter of Medical Necessity

Smith, Patricia 08 / 15 / 1955 · SPRAVATO® (esketamine) CIII Nasal Spray

✓ Letter of Medical Necessity has been successfully generated

📄 [Download Letter of Medical Necessity (pdf)](#)

📄 [Download Letter of Medical Necessity (doc)](#)

If you h...
844-4...
Monda...

OK

Please read the full Prescribing Information, including Boxed Warning, and Medication Guide for SPRAVATO®.

☐ Rodriguez, Lisa 11 / 13 / 1958 SPRAVATO® ✗ Ineligible — Savings Program
☐ Williams, Daniel 07 / 04 / 1963 SPRAVATO® ✓ Enrolled Treatment Support

Once all the necessary information has been added and you have reviewed your request, the Letter of Medical Necessity will be generated in PDF and Word document formats.

Patient Lists

The Patient List tab provides access to lists of patients grouped by patient type or by resources, with contextual links that allow you to perform any required actions efficiently.
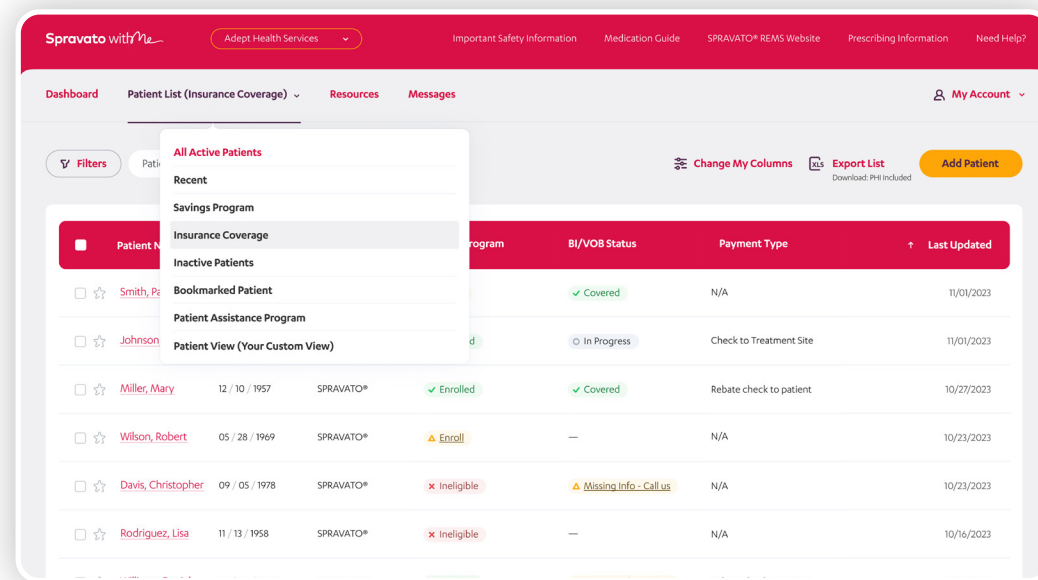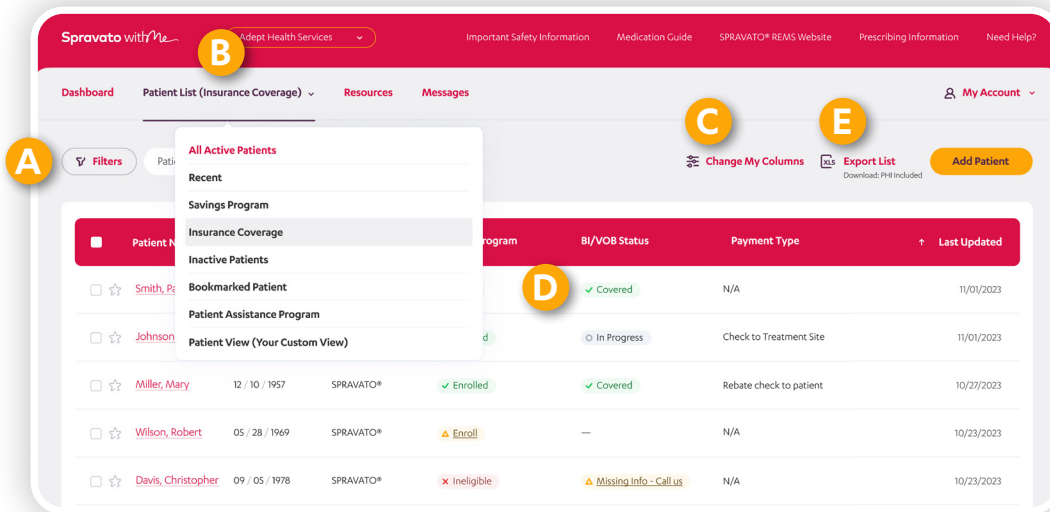
The following lists are available:

- **All Active Patients:** Displayed by default when you visit the Patient List tab, and includes all patients who have had activity in the last 18 months
- **Recent:** Includes all patients who have been accessed in the last 30 days
- **Savings Program:** Displays patient information relevant to the Savings Program, such as enrollment status, assignment of benefit information, and most recent transaction
- **Insurance Coverage:** Displays patient information relevant to insurance coverage, such as VOB status, BI outcome, and PA outcome
- **Pending Patients:** Displays patients who are enrolled but are yet to be approved into the Site by a Site Admin
- **Inactive Patients:** Displays patients who have had no activity for 18 months or have been deactivated by the user
- **Bookmarked Patients:** Displays patient information for those patients who you have bookmarked
- **Patient Assistance Program:** Displays patient information for patients who are enrolled in the Janssen Patient Assistance Program
- **Patient View (Your Custom View):** A customizable patient list that you can tailor to your own needs

Please see Indications and Important Safety Information on pages 1 and 28-29, and full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO®, also available at spravatohcp.com.

Patient Lists (Cont'd)

A **FILTERS:** Restrict the Patient List to only include patients based on criteria including enrollment in the Savings Program, BI outcome, and more

B **PATIENT LIST DROPDOWN:** Click to select which list is displayed
- You can hover your mouse cursor over a list to see a description of what it includes

C **CHANGE MY COLUMNS:** Modify which columns are visible on screen

D **CONTEXTUAL ACTIONS:** Clickable links to take action within the Patient List tab. Status updates are color-coded:
- **Green:** Process is finished with a positive outcome
- **Yellow:** Action is required to complete process – click on the hyperlink to take the action where appropriate
- **Red:** Process is finished with a negative outcome, such as a denial
- **Gray:** Process is in progress

E **EXPORT LIST:** Export the current Patient List as an Excel spreadsheet

Need Help?

Clicking the **Need Help?** button – displayed throughout the portal in the top-right corner of the page – gives you access to assistive features.

Need Help

Call SPRAVATO withMe

Have questions about the SPRAVATO withMe Provider Portal?
A SPRAVATO withMe Case Manager can help you navigate the Provider Portal and find the resources you need.

844-4S-WITH-ME (844-479-4846)
Monday – Friday, 8:00 AM – 8:00 PM ET

User Guide

Check out the User Guide to get an overview of the main components of the SPRAVATO withMe Provider Portal.

FAQs

How do I create an account in the SPRAVATO withMe Provider Portal?

You can access the portal directly at SpravatoProviderPortal.com. On the landing page, you will click "create an account" and then be prompted to identify your treatment site location, contact information, and communication preferences. Upon submission, an email will be sent to the email address entered to verify your account set up. If you currently have a Janssen CarePath account for another brand, you will need to provide a new email address in order to create an account with SPRAVATO withMe. If you have questions, a SPRAVATO withMe Case Manager is available at **844-4S-WITHME** (844-479-4846), Monday-Friday, from 8 AM to 8 PM ET.

How do I add a new provider or site staff?

You can go into "My Account," scroll down the drop-down menu, click on "Staff Management" and then click on the orange button, "Add Site Staff". After you add site staff you can select their role - such as Prescriber, Nurse, Office Manager, etc., from the dropdown menu. Remember to click "SUBMIT" at the end. From this page, you can also remove staff by clicking the trash can button or by

A **CONTACT US:** Contact information for support

B **USER GUIDE:** This guide, always available for easy access

C **FREQUENTLY ASKED QUESTIONS:** Common questions about using the provider portal and resources provided

Please see Indications and Important Safety Information on pages 1 and 28-29, and full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO®, also available at spravatohcp.com.

Frequently Asked Questions

❯ How do I create an account in the SPRAVATO withMe Provider Portal?

You can access the site directly at spravatoproviderportal.com. On the landing page, you will click **"create an account"** and then be prompted to identify your treatment site location, contact information, and communication preferences. Upon submission, an e-mail from no-reply@swmpatientsupport.com will be sent to the e-mail address entered to verify your account set-up. **Please note:** if you already have a Janssen CarePath Provider Portal account, or a Janssen CarePath account for another brand, you will need to provide a different e-mail address to create a SPRAVATO withMe Provider Portal account – any kind of e-mail address, i.e. Gmail or Yahoo, can be used. If you are already a SPRAVATO withMe user, you only need to reset your password, and you can use your existing e-mail address. If you have questions, please contact SPRAVATO withMe at **844-4S-WITHME (844-479-4846),** Monday-Friday, from 8 AM to 8 PM ET.

❯ Can I add multiple sites to my profile?

Yes, multiple sites can be added to your profile. If the site already exists in the system, you can add more than one site during initial account set-up or, once the account has been created, you can click **My Account** at the top right of the dashboard and add or remove site associations from the Site Management section. If it is a new site that does not exist in the system, please call SPRAVATO withMe so that a Case Manager can provide assistance adding the site. Alternatively, a user with Network Admin permissions may add the site.

Please see Indications and Important Safety Information on pages 1 and 28-29, and full Prescribing Information, **including Boxed WARNINGS, and** Medication Guide **for SPRAVATO®, also available at spravatohcp.com.**

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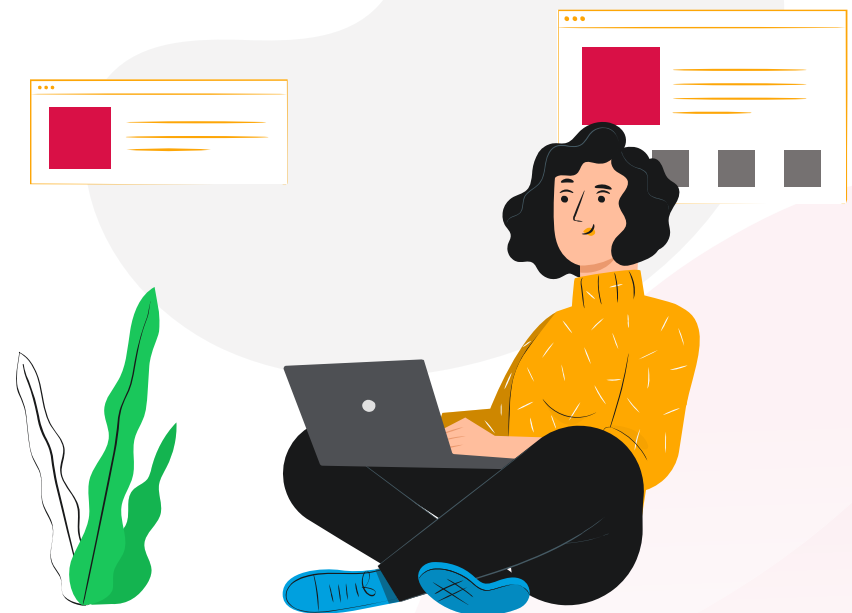
Frequently Asked Questions (Cont'd)

› How do I add a new provider/office staff?

Click **My Account** at the top right of the dashboard and navigate to Staff Management. Click the **Add Site Staff** button to add a new staff member – remember to click **Submit** to complete the process. From this screen, you can also remove staff by clicking the **trash can** button or by editing their information. Once removed, the user will no longer be able to access site data.

› How do I submit a Program Enrollment Form (PEF)?

You can submit the fully completed PEF by using the provider portal directly (spravatoproviderportal.com) or using the hard copy PEF. Hard Copy signature from PEF can be uploaded in the provider portal (spravatoproviderportal.com) or sent by fax (844-577-7282).

› How do I enroll a patient in the Savings Program within the portal?

There are two ways to enroll a commercially insured patient into the Savings Program in the provider portal.

- The patient can select the option for Savings Program enrollment in the patient section of the Program Enrollment and Patient Authorization Form and, if eligible, they will be enrolled in the Savings Program by the SPRAVATO withMe Case Manager.
- If the patient needs a Savings Card immediately, you can click **Enroll Patient in Savings Program** immediately after they enroll the patient and then answer the eligibility questions. Once you have added the patient, this prompt will also be available

in the provider portal, from the Patient Summary section of the Patient Card. You will be able to print/download the Savings Card by going into Savings Program section of the Patient Card, and clicking **Download Card**.

› How do I submit a claim?

Providers or Site Staff can submit a request via the Patient Card in the portal – rebate activity may be reviewed using the Patient List. Documents can be submitted via the provider portal, via fax (844-584-1453) or via mail (2250 Perimeter Park Drive, Suite 300, Morrisville, NC, 27560). The documents required to submit a claim are:

- Savings Card number
- Receipt from the treatment provider
- Medical/Pharmacy Rebate Form
- Assignment of Benefits (AOB)
- CMS-1500 form
- Explanation of Benefits (EOB)

› Where do I find claim documents?

Navigate to the Savings Program section of the Patient Card and click **View All Transactions** link. Here, you will find a history of transactions and can generate a report of these claims at a patient level. Click on an individual claim to view any claims documents that have been uploaded.

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Frequently Asked Questions (Cont'd)

❯ I am having technical problems with the provider portal. Can I call someone for assistance?

Call **844-4S-WITHME (844-479-4846),** Monday through Friday, from 8:00 AM to 8:00 PM ET. The Case Manager can help assist you or open a ticket to resolve technical issues.

❯ How do I upload insurance information in the portal?

You can manually add information about the patient's primary medical insurance and any additional insurances in the portal when completing the benefits investigation form. Alternatively, you can upload pictures of the insurance card in the Treatment Support section of the Patient Card. Please ensure you upload pictures of the front and back of the insurance card.

❯ What does the color coding on the Dashboard mean?

The color coding meanings are as follows:

- **Green:** Positive outcome
- **Gray:** In progress
- **Yellow:** Action needed
- **Red:** Denial/blocker

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IMPORTANT SAFETY INFORMATION (Cont'd)

CONTRAINDICATIONS
SPRAVATO® is contraindicated in patients with:

• Aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial and peripheral arterial vessels) or arteriovenous malformation.

• History of intracerebral hemorrhage.

• Hypersensitivity to esketamine, ketamine, or any of the excipients.

WARNINGS AND PRECAUTIONS
Sedation: SPRAVATO® may cause sedation or loss of consciousness. In some cases, patients may display diminished or less apparent breathing. In clinical trials, 48% to 61% of SPRAVATO®-treated patients developed sedation and 0.3% to 0.4% of SPRAVATO®-treated patients experienced loss of consciousness.

Because of the possibility of delayed or prolonged sedation, patients must be monitored by a healthcare provider for at least 2 hours at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave the healthcare setting.

Closely monitor for sedation with concomitant use of SPRAVATO® with CNS depressants (e.g., benzodiazepines, opioids, alcohol).

Dissociation: The most common psychological effects of SPRAVATO® were dissociative or perceptual changes (including distortion of time, space and illusions), derealization and depersonalization (61% to 84% of SPRAVATO®-treated patients developed dissociative or perceptual changes). Given its potential to induce dissociative effects, carefully assess patients with psychosis before administering SPRAVATO®; treatment should be initiated only if the benefit outweighs the risk.

Because of the risks of dissociation, patients must be monitored by a healthcare provider for at least 2 hours at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave the healthcare setting.

Respiratory Depression: In postmarketing experience, respiratory depression was observed with the use of SPRAVATO®. In addition, there were rare reports of respiratory arrest.

Because of the risks of respiratory depression, patients must be monitored for changes in respiratory status by a healthcare provider for at least 2 hours (including pulse oximetry) at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave the healthcare setting.

Abuse and Misuse: SPRAVATO® contains esketamine, a Schedule III controlled substance (CIII), and may be subject to abuse and diversion. Assess each patient's risk for abuse or misuse prior to prescribing and monitor all patients for the development of these behaviors or conditions, including drug-seeking behavior, while on therapy. Individuals with a history of drug abuse or dependence are at greater risk; therefore, use careful consideration prior to treatment of individuals with a history of substance use disorder and monitor for signs of abuse or dependence.

SPRAVATO® Risk Evaluation and Mitigation Strategy (REMS): SPRAVATO® is available only through a restricted program called the SPRAVATO® REMS because of the risks of serious adverse outcomes from sedation, dissociation, respiratory depression, and abuse and misuse.

Important requirements of the SPRAVATO® REMS include the following:

• Healthcare settings must be certified in the program and ensure that SPRAVATO® is:

  – Only dispensed and administered in healthcare settings.

  – Patients treated in outpatient settings (e.g., medical offices and clinics) must be enrolled in the program.

  – Administered by patients under the direct observation of a healthcare provider and that patients are monitored by a healthcare provider for at least 2 hours after administration of SPRAVATO®.

• Pharmacies must be certified in the REMS and must only dispense SPRAVATO® to healthcare settings that are certified in the program.

Further information, including a list of certified pharmacies, is available at www.SPRAVATOrems.com/ or 1-855-382-6022.

Suicidal Thoughts and Behaviors in Adolescents and Young Adults: In pooled analyses of placebo-controlled trials of antidepressant drugs (SSRIs and other antidepressant classes) that included adult and pediatric patients, the incidence of suicidal thoughts and behaviors in patients age 24 years and younger was greater than in placebo- treated patients. SPRAVATO® is not approved in pediatric (<18 years of age) patients.

There was considerable variation in risk of suicidal thoughts and behaviors among drugs, but there was an increased risk identified in young patients for most drugs studied.

Monitor all antidepressant-treated patients for clinical worsening and emergence of suicidal thoughts and behaviors, especially during the initial few months of drug therapy and at times of dosage changes. Counsel family members or caregivers of patients to monitor for changes in behavior and to alert the healthcare provider. Consider changing the therapeutic regimen, including possibly discontinuing SPRAVATO® and/or the concomitant oral antidepressant, in patients whose depression is persistently worse, or who are experiencing emergent suicidal thoughts or behaviors.

Increase in Blood Pressure: SPRAVATO® causes increases in systolic and/or diastolic blood pressure (BP) at all recommended doses. Increases in BP peak approximately 40 minutes after SPRAVATO® administration and last approximately 4 hours.

Approximately 8% to 19% of SPRAVATO®-treated patients experienced an increase of more than 40 mmHg in systolic BP and/or 25 mmHg in diastolic BP in the first 1.5 hours after administration at least once during the first 4 weeks of treatment. A substantial increase in blood pressure could occur after any dose administered even if smaller blood pressure effects were observed with previous administrations. SPRAVATO® is contraindicated in patients for whom an increase in BP or intracranial pressure poses a serious risk (e.g., aneurysmal vascular disease, arteriovenous malformation, history

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IMPORTANT SAFETY INFORMATION (Cont'd)

of intracerebral hemorrhage). Before prescribing SPRAVATO®, patients with other cardiovascular and cerebrovascular conditions should be carefully assessed to determine whether the potential benefits of SPRAVATO® outweigh its risk.

Assess BP prior to administration of SPRAVATO®. In patients whose BP is elevated prior to SPRAVATO® administration (as a general guide: >140/90 mmHg), a decision to delay SPRAVATO® therapy should take into account the balance of benefit and risk in individual patients.

BP should be monitored for at least 2 hours after SPRAVATO® administration. Measure blood pressure around 40 minutes post-dose and subsequently as clinically warranted until values decline. If BP remains high, promptly seek assistance from practitioners experienced in BP management. Refer patients experiencing symptoms of a hypertensive crisis (e.g., chest pain, shortness of breath) or hypertensive encephalopathy (e.g., sudden severe headache, visual disturbances, seizures, diminished consciousness, or focal neurological deficits) immediately for emergency care.

Closely monitor blood pressure with concomitant use of SPRAVATO® with psychostimulants (e.g., amphetamines, methylphenidate, modafinil, armodafinil) or monoamine oxidase inhibitors (MAOIs).

In patients with a history of hypertensive encephalopathy, more intensive monitoring, including more frequent blood pressure and symptom assessment, is warranted because these patients are at increased risk for developing encephalopathy with even small increases in blood pressure.

Cognitive Impairment

Short-Term Cognitive Impairment: In a study in healthy volunteers, a single dose of SPRAVATO® caused cognitive performance decline 40 minutes post-dose. Compared to placebo-treated subjects, SPRAVATO®-treated subjects required a greater effort to complete the cognitive tests at 40 minutes post-dose. Cognitive performance and mental effort were comparable between SPRAVATO® and placebo at 2 hours post-dose. Sleepiness was comparable after 4 hours post-dose.

Long-Term Cognitive Impairment: Long-term cognitive and memory impairment have been reported with repeated ketamine misuse or abuse. No adverse effects of SPRAVATO® nasal spray on cognitive functioning were observed in a one-year open-label safety study; however, the long-term cognitive effects of SPRAVATO® have not been evaluated beyond one year.

Impaired Ability to Drive and Operate Machinery: Before SPRAVATO® administration, instruct patients not to engage in potentially hazardous activities requiring complete mental alertness and motor coordination, such as driving a motor vehicle or operating machinery, until the next day following a restful sleep. Patients will need to arrange transportation home following treatment with SPRAVATO®.

Ulcerative or Interstitial Cystitis: Cases of ulcerative or interstitial cystitis have been reported in individuals with long-term off-label use or misuse/abuse of ketamine. In clinical studies with SPRAVATO® nasal spray, there was a higher rate of lower urinary tract symptoms (pollakiuria, dysuria, micturition urgency, nocturia, and cystitis) in

SPRAVATO®-treated patients than in placebo-treated patients. No cases of esketamine-related interstitial cystitis were observed in any of the studies, which involved treatment for up to a year.

Monitor for urinary tract and bladder symptoms during the course of treatment with SPRAVATO® and refer to an appropriate healthcare provider as clinically warranted.

PREGNANCY, EMBRYO-FETAL TOXICITY, AND LACTATION

SPRAVATO® is not recommended during pregnancy. SPRAVATO® may cause fetal harm when administered to pregnant women. Advise pregnant women of the potential risk to an infant exposed to SPRAVATO® in utero. Advise women of reproductive potential to consider pregnancy planning and prevention.

There are risks to the mother associated with untreated depression in pregnancy. If a woman becomes pregnant while being treated with SPRAVATO®, treatment with SPRAVATO® should be discontinued and the patient should be counseled about the potential risk to the fetus.

Pregnancy Exposure Registry: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to antidepressants, including SPRAVATO®, during pregnancy. Healthcare providers are encouraged to register patients by contacting the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or online at https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/antidepressants/.

SPRAVATO® is present in human milk. Because of the potential for neurotoxicity, advise patients that breastfeeding is not recommended during treatment with SPRAVATO®.

SELECT USE IN SPECIFIC POPULATIONS

Geriatric Use: No overall differences in the safety profile were observed between patients 65 years of age and older and patients younger than 65 years of age. At the end of a 4-week, randomized, double-blind study, there was no statistically significant difference between groups on the primary efficacy endpoint.

Hepatic Impairment: SPRAVATO®-treated patients with moderate hepatic impairment may need to be monitored for adverse reactions for a longer period of time.

SPRAVATO® has not been studied in patients with severe hepatic impairment (Child-Pugh class C). Use in this population is not recommended.

ADVERSE REACTIONS

The most common adverse reactions with SPRAVATO® plus oral antidepressant (incidence ≥5% and at least twice that of placebo nasal spray plus oral antidepressant) were:

TRD: dissociation, dizziness, nausea, sedation, vertigo, hypoesthesia, anxiety, lethargy, blood pressure increased, vomiting, and feeling drunk.

Treatment of depressive symptoms in adults with MDD with acute suicidal ideation or behavior: dissociation, dizziness, sedation, blood pressure increased, hypoesthesia, vomiting, euphoric mood, and vertigo.

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Spravato with Me | Spravato® (esketamine) CIII 28 mg nasal spray