



Clozapine REMS Program

Pharmacy Professional Society Meeting

August 19, 2021



Table of Contents

Demonstration of REMS Website	3
How to Certify	5
How to Obtain an RDA	16
How to Troubleshoot Common Issues	27
Closing	29

Demonstration of REMS Website

The screenshot shows the Clozapine REMS website homepage. At the top, there is a navigation bar with the logo "CLOZAPINE REMS" and the tagline "The Single Shared System for Clozapine No Blood, No Drug™". Below the logo is a navigation menu with links for Home, Prescriber, Pharmacy, Patient, Resources, and Support. A login form is visible with fields for Username and Password, and a Sign in button. A yellow banner in the center of the page reads: "***Important Program Update (as of 07/28/2021)*** Please click to open the IPU". Below this banner is a detailed update notification box with a yellow border. The box contains the following text: "Update: New Clozapine REMS Coming November 15, 2021", "Re-Certification and Re-Enrollment Required at www.newclozapinerems.com.", and a list of bullet points: "ALL Prescribers and Pharmacies must re-certify to continue to prescribe or dispense clozapine.", "ALL Patients continuing on clozapine must be re-enrolled by a certified prescriber or prescriber designee.", and "Start re-certification and re-enrollment on August 16, 2021 to avoid interruption in patient treatment". Below the notification box, there is a link "Go to www.newclozapinerems.com" and a list of instructions: "Click on Log-in | Register tab. You need to create new login credentials before re-certifying by clicking on Register." Red circles with numbers 1 and 2 are overlaid on the notification box to highlight specific parts of the update.

Until November 15, 2021, continue to use the ClozapineREMS.com website to ensure safe use conditions are met.

1 Pharmacies should certify in the new program as soon as possible and no later than November 15.

2 To certify in the modified program, go to NewClozapineREMS.com, as noted on the Important Program Update on the homepage of ClozapineREMS.com.

What is the Clozapine REMS Program?

Clozapine is associated with severe neutropenia (absolute neutrophil count (ANC) less than 500/ μ L), which can lead to serious and fatal infections. The requirements to prescribe, dispense, and receive clozapine are incorporated into a single shared program called the Clozapine Risk Evaluation and Mitigation Strategy (REMS). A REMS is a strategy to manage known or potential risks associated with a drug or group of drugs, and is required by the Food and Drug Administration (FDA) for clozapine to ensure that the benefits of the drug outweigh the risk of severe neutropenia. The Clozapine REMS Program replaces the individual clozapine patient registries and the National Non-Rechallenge Master File (NNRMF).



Demonstration of REMS Website (Continued)

Clozapine REMS

Home Find Pharmacy Patients Prescriber Login | Register

What is the Clozapine REMS?

The Clozapine REMS (Risk Evaluation and Mitigation Strategy) is a safety program required by the Food and Drug Administration (FDA) to manage the risk of severe neutropenia associated with clozapine treatment.

Severe neutropenia (absolute neutrophil count (ANC) less than 500/µL), can lead to serious and fatal infections.

To facilitate a smooth transition to the modified Clozapine REMS program on November 15, we encourage pharmacies to certify in the modified program now via

- The transition website, [NewClozapineREMS.com](https://www.newclozapinerems.com/), or
- The transition Contact Center at **1-888-586-0758**.

Patient

To receive treatment, a patient must be enrolled in the Clozapine REMS program by a certified doctor.

[Enrollment Information](#)

Pharmacy

Pharmacies must be certified in the Clozapine REMS to receive and dispense clozapine.

If you are the designated authorized representative of a pharmacy, you can certify below.

[Certify Pharmacy](#)

Prescriber

Healthcare Providers must be certified in the Clozapine REMS to prescribe clozapine for outpatient use.

If you are a clozapine prescriber, you can certify below.

[Certify Prescriber](#)

Click Certify Pharmacy on the homepage to start the certification process.

How to Certify: Introduction

All inpatient and outpatient pharmacies must certify in the Clozapine REMS to purchase and dispense clozapine. The requirements for outpatient pharmacies are different from the requirements for inpatient pharmacies.

An **inpatient pharmacy** is a pharmacy within a facility dispensing clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions, or injuries (usually for a short-term illness or condition).



An **outpatient pharmacy** is a pharmacy that dispenses clozapine only to patients treated on an outpatient or chronic basis including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities, and prison systems.



- The designated authorized representative for the pharmacy will complete the *Inpatient Pharmacy Enrollment Form* and/or the *Outpatient Pharmacy Enrollment Form*. This form is to certify a single inpatient or a single outpatient pharmacy location.
- The authorized representative for the pharmacy or pharmacies can certify the pharmacy online or by fax.
- Certifying multiple pharmacy locations must be completed online.

How to Certify: Introduction (Continued)



A pharmacy's certification **does not expire**. However, if a pharmacy's **Authorized Representative changes**, the new **Authorized Representative must certify the pharmacy** in the REMS Program.



For a pharmacy with a **single location**, the authorized representative may be a **Pharmacy Manager or Staff Pharmacist**.



If your pharmacy has **more than one pharmacy location** and your organization would like to **coordinate staff training and implement processes for all the pharmacies in your organization**, the Authorized Representative may be a **director of pharmacy services or corporate executive overseeing pharmacy services**.

How to Certify: Register

All users must create new REMS login credentials. Legacy system credentials will not work in the new system.



Click Register at the top of the home page to create your account.

Create Account
Pharmacy Authorized Representative

Username and Password

Username (email address)
RxAuthRep333@examoto.net

First Name Last Name
RxAuth Representative

Password
Confirm Password

Cancel Next 3

Type in the Authorized Representative's username, first and last name, and password, noting that the username must be an email address.

Then Click Next.

Create Account
Verify Identity

Choose verification method

We will send you a code to verify your identity. The code may only be used once and is time sensitive.

Email me the code
verifytest74839@examoto.net

After logging in, use preferences to add password reset options and/or enable multi-factor authentication.

Cancel Next 4

You will need to verify your account on the next screen by requesting a code via email and clicking Next.

On the account confirmation page, click Login to use your new credentials to continue certification.

Create Account
Complete

verifytest74839@examoto.net, your account has been created.

You may now login to perform REMS functions online.

Login 6

Create Account
Verify Identity

Enter Verification Code

Please enter your code.

472795

Cancel Next 5

On the next screen, enter the code received via email and click Next to proceed with certification.

How to Certify: Knowledge Assessment

Wholesaler Prescribing Information Contact Us

CLOZAPINE REMS

Home Find Pharmacy 1 Prescriber Login Register

Pharmacy

Pharmacies must be certified in the Clozapine REMS to receive and dispense.

To certify your pharmacy:

- 1 Designate an Authorized Representative**
Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the Clozapine REMS on behalf of the pharmacy.
- 2 Review the Pharmacy Information**
Have the authorized representative review the Clozapine and the Risk of Neutropenia: A Guide for Pharmacists.
- 3 Complete the Knowledge Assessment for Pharmacies**
Have the authorized representative successfully complete the Knowledge Assessment for Pharmacy and submit it to the Clozapine REMS.
[Online](#) or [Print](#)
- 4 Establish Processes and Procedures**
Establish processes and procedures to verify an available, current ANC is within the acceptable range for patients enrolled but not authorized to receive the drug.
- 5 Enroll Pharmacy**
Have the authorized representative enroll in the Clozapine REMS by completing the Pharmacy Enrollment Form and submitting it to the Clozapine REMS.
[Online](#) or [Print Inpatient](#) or [Print Outpatient](#)
- 6 Train All Relevant Staff**
Train all relevant staff involved in dispensing clozapine on the requirements of the REMS program using the Clozapine and the Risk of Neutropenia: A Guide for Pharmacists.

Pharmacy Materials

- Clozapine and the Risk of Neutropenia: A Guide for Pharmacists
- Knowledge Assessment for Pharmacies
- Inpatient Pharmacy Enrollment Form
- Outpatient Pharmacy Enrollment Form
- ANC Lab Reporting Form
- RDA Factsheet for Inpatient Pharmacies
- RDA Factsheet for Outpatient Pharmacies
- What's Changed in the Clozapine REMS for Pharmacies?

1 Click Pharmacy at the top of the home screen to access the certification screen.

2 Following completion of Steps 1 and 2, complete the Knowledge Assessment by clicking Online under Step 3.

How to Certify: Knowledge Assessment (Continued)

Pharmacy - Knowledge Assessment

Knowledge Assessment for Pharmacies

You may leave and return to the Knowledge Assessment at any time, your progress will be saved.

0 of 13 questions in progress

1. All clozapine products are only available under the single shared Clozapine REMS.

- True
- False

2. Clozapine is associated with severe neutropenia, which can lead to serious infection and death.

- True
- False

3. Severe neutropenia is defined as:

- A. A white blood cell count (WBC) less than 2000/ μ L
- B. An absolute neutrophil count (ANC) less than 1000/ μ L

The Authorized Representative must successfully complete a 13-question Knowledge Assessment.

Three attempts are allowed. If you exceed this number, then call the Contact Center.

Following successful completion of the Knowledge Assessment, the Authorized Representative can continue the certification process.

How to Certify: Enrollment

Wholesaler Prescribing Information Contact Us

CLOZAPINE REMS Home Find Pharmacy Patient Prescriber Login | Register

Pharmacy

Pharmacies must be certified in the Clozapine REMS to receive and dispense .

To certify your pharmacy:

- 1 Designate an Authorized Representative**
Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the Clozapine REMS on behalf of the pharmacy.
- 2 Review the Pharmacy Information**
Have the authorized representative review the Clozapine and the Risk of Neutropenia: A Guide for Pharmacists.
- 3 Complete the Knowledge Assessment for Pharmacies**
Have the authorized representative successfully complete the Knowledge Assessment for Pharmacy and submit it to the Clozapine REMS.
[Online](#) or [Print](#)
- 4 Establish Processes and Procedures**
Establish processes and procedures to verify an available, current ANC is within the acceptable range for patients enrolled but not authorized to receive the drug.
- 5 Enroll Pharmacy**
Have the authorized representative enroll in the Clozapine REMS by completing the Pharmacy Enrollment Form and submitting it to the Clozapine REMS.
[Online](#) or [Print Inpatient](#) or [Print Outpatient](#)
- 6 Train All Relevant Staff**
Train all relevant staff involved in dispensing clozapine on the requirements of the REMS program using the Clozapine and the Risk of Neutropenia: A Guide for Pharmacists.

Pharmacy Materials

- Clozapine and the Risk of Neutropenia: A Guide for Pharmacists
- Knowledge Assessment for Pharmacies
- Inpatient Pharmacy Enrollment Form
- Outpatient Pharmacy Enrollment Form
- ANC Lab Reporting Form
- RDA Factsheet for Inpatient Pharmacies
- RDA Factsheet for Outpatient Pharmacies
- What's Changed in the Clozapine REMS for Pharmacies?

After completing Step 4, the Authorized Representative needs to complete enrollment by clicking Online under Step 5.

How to Certify: Enrollment (Continued)

Pharmacy Enrollment

The authorized representative for the pharmacy must:

1. Review the REMS materials
2. Successfully complete the *Knowledge Assessment for Pharmacies*
3. Complete and submit this Pharmacy Enrollment, along with the completed *Knowledge Assessment for Pharmacies*
4. Implement the necessary staff training and processes to comply with the REMS requirements

Pharmacy Information

Organizational NPI Number (Select address type to populate form)

Use organizational NPI to populate form: Office Address Mailing Address

Pharmacy Name DEA Number

Address Line 1 Address Line 2

City State Zip Code

Number Extension Fax

The name, location, and phone number of your pharmacy will be publicly available on ClozapineREMS.com. If you do not want your information available, please call the Clozapine REMS Contact Center at 1-888-586-0758.

Allow this pharmacy to be found on the Clozapine REMS website as a: Specialty Pharmacy Retail Pharmacy

The Authorized Representative completes the Pharmacy Enrollment form online by filling in pharmacy information (e.g., NPI, pharmacy contact information),...

Authorized Representative Information

First Name Last Name

Credentials RPh PharmD BCPS Other Position or Title

Number Extension Fax Email

Preferred Method of Contact Email Text Call

...information about themselves (e.g., individual contact information and preferences),...

How to Certify: Enrollment (Continued)

Pharmacy Authorized Representative Responsibilities

Pharmacy Type (Please pick a Pharmacy Type. Pharmacies have different REMS requirements.)

Inpatient Pharmacy Outpatient Pharmacy

As the Authorized Representative, I must:

- Review Clozapine and the Risk of Neutropenia: A Guide for Pharmacist.
- Successfully complete the Knowledge Assessment for Pharmacies and submit it to the Clozapine REMS.
- Establish processes and procedures to verify an available, current ANC is within the acceptable range for patients enrolled but not authorized to receive the drug.
- Train all relevant staff involved in dispensing clozapine on the requirements of the Clozapine REMS using the Clozapine and the Risk of Neutropenia: A Guide for Pharmacists.

Before dispensing, all pharmacy staff must:

- Obtain authorization to dispense each prescription by contacting the Clozapine REMS to verify that the patient is enrolled and authorized to receive drug.
- For patients enrolled but not authorized to receive clozapine:
 - Verify an available, current ANC is within the acceptable range through the processes and procedures established as a requirement of the Clozapine REMS.
 - Document and submit the ANC and the prescriber's NPI to the Clozapine REMS and
 - Obtain authorization to dispense each prescription by contacting the Clozapine REMS to verify the patient is now authorized to receive clozapine.
- Report dosing information to the Clozapine REMS.

All pharmacy staff must

- Not distribute, transfer, loan, or sell clozapine except to certified dispensers.
- Maintain records of staff training and that all processes and procedures are in place and are being followed.
- Comply with audits carried out by the manufacturers or a third party acting on behalf of the manufacturers, to ensure that all processes and procedures are in place and are being followed.

To maintain certification to dispense, any new Authorized Representative must:

- Enroll in the Clozapine REMS by reviewing Clozapine and the Risk of Neutropenia: A Guide for Pharmacists, successfully complete the Knowledge Assessment for Pharmacies and the Outpatient Pharmacy Enrollment Form and submit both to the Clozapine REMS.

...and pharmacy type and understanding of Authorized Representative responsibilities associated with that pharmacy type.

Sign Type Signature

screen printx: Please use your mouse or stylus to sign below

I authorize the above signature to be the legally binding equivalent of my handwritten signature.

The final step is to sign and submit the form.

How to Certify: Certification Completion

The screenshot displays the 'Pharmacy' dashboard for an 'Outpatient Pharmacy Group'. The main header is purple with the text 'Pharmacy' and 'Outpatient Pharmacy Group'. Below the header, there are several sections:

- To certify your pharmacy:** A purple box with a bookmark icon and a green checkmark. The text reads: 'To certify your pharmacy: Your pharmacy is currently certified.' This box is highlighted with a red border.
- Obtain a Patient's REMS Dispense Authorization (RDA):** A white box with a document icon. The text reads: 'An RDA is a receipt from the Clozapine REMS signifying that the REMS requirements to dispense for this patient are currently met.' Below the text is a blue button labeled 'Obtain Patient RDA'.
- Submit a Patient's REMS Dispense Authorization (RDA):** A white box with a document icon. The text reads: 'Pharmacists in possession of a valid RDA are authorized to dispense Clozapine REMS. A submission by pharmacy personnel is required for each patient.' Below the text is a blue button labeled 'Submit Patient RDA'.
- Pharmacy Personnel:** A white box with a group of people icon. The text reads: 'A pharmacy can have multiple personnel with online accounts. You may invite personnel or remove them.' Below the text is a purple button labeled 'Manage Personnel'.
- Pharmacies:** A white box with a group of buildings icon. The text reads: 'A pharmacy can have multiple pharmacies grouped together under the responsibility of a Pharmacy Authorized Representative.' Below the text is a purple button labeled 'Manage Pharmacies'.
- Pharmacy Materials:** A purple box with a download icon. The text reads: 'Pharmacy Materials'. Below the text is a list of materials with download icons: 'Clozapine and the Risk of Neutropenia: A Guide for Pharmacists', 'RDA Factsheet for Inpatient Pharmacies', 'RDA Factsheet for Outpatient Pharmacies', and 'What's Changed in the Clozapine REMS for Pharmacies?'. This section is also highlighted with a red border.
- Upload Form:** A purple box with an upload icon. The text reads: 'Upload Form'. Below the text is a white box with the text 'Uploads must be in PDF format.' and a purple button labeled 'Browse' next to the text 'or drop files here'.

Successful completion of Enrollment and the Knowledge Assessment result in a pharmacy being marked as certified on the Pharmacy dashboard.

How to Certify: Adding Pharmacy Staff

The screenshot displays the 'Pharmacy' dashboard with several action items and a 'Pharmacy Personnel' section. A red box highlights the 'Pharmacy Personnel' section, which includes a description and a 'Manage Personnel' button. A larger red box below it shows a magnified view of the 'Pharmacy Personnel' section, detailing the text and the 'Manage Personnel' button.

Pharmacy
Outpatient Pharmacy Group

To certify your pharmacy:
Your pharmacy is currently certified.

Obtain a Patient's REMS Dispense Authorization (RDA)
An RDA is a receipt from the Clozapine REMS signifying that the REMS requirements to dispense for this patient are currently met.
→ Obtain Patient RDA

Submit a Patient's ANC Lab Value
Pharmacists in possession of a patient's ANC lab value are encouraged to enter it into the Clozapine REMS. A submitted ANC lab will be visible to the patient's prescriber and pharmacy personnel attempting to obtain an RDA.
→ Submit ANC Lab

Pharmacy Personnel
A pharmacy can have multiple personnel with online accounts. You may invite personnel or remove them.
→ Manage Personnel

Pharmacies
A pharmacy can have multiple pharmacies grouped together under the responsibility of a Pharmacy Authorized Representative.

Pharmacy Personnel
A pharmacy can have multiple personnel with online accounts. You may invite personnel or remove them.
→ Manage Personnel

Pharmacy Materials

- Clozapine and the Risk of Neutropenia: A Guide for Pharmacists
- Knowledge Assessment for Pharmacies
- Inpatient Pharmacy Enrollment Form
- Outpatient Pharmacy Enrollment Form
- ANC Lab Reporting Form
- RDA Factsheet for Inpatient Pharmacies
- RDA Factsheet for Outpatient Pharmacies
- What's Changed in the Clozapine REMS for Pharmacies?

The certified Authorized Representative can then train staff and add them to their pharmacy in the REMS system.

To add staff in your store(s), the Authorized Representative should click the Manage Personnel button under Pharmacy Personnel.

How to Certify: Adding Pharmacy Staff (Continued)

Pharmacy
Outpatient Pharmacy

Additional Staff

Personnel Type:

Authorized Representative

Pharmacy Staff

Pharmacy Staff Information

Email

First Name Last Name Title

Phone Ext. Fax

Cancel Send Invite

1 On the next screen, the certified Authorized Representative can add Pharmacy Staff by entering the staff member's contact information and clicking Send Invite.

This screen can also be used to add a second Authorized Representative (maximum of two).

2 The REMS system will email the staff member a message that includes a link to establish their own user credentials for login.

How to Obtain an RDA: Introduction



Starting on November 15, 2021, before any pharmacy dispenses clozapine to a patient, you must obtain authorization from the new Clozapine REMS in the form of a REMS Dispense Authorization (RDA).

Until November 15, continue to use the legacy REMS system.

How to Obtain an RDA: Introduction (Continued)

An RDA is an electronic code that indicates the Clozapine REMS has verified that all safe use conditions have been met.

- For the first dispensing, the RDA will verify that:
 - the pharmacy is certified
 - the patient is enrolled
 - the patient's treatment is not interrupted or discontinued
- For a subsequent dispensing, the RDA will verify that:
 - the pharmacy is certified
 - the patient is enrolled
 - a Patient Status Form has been completed in the last 37 days
 - The prescriber has authorized the continuation of treatment if one or more labs are missing
 - The prescriber has provided a Treatment Rationale if the most current ANC lab value is below the acceptable range
 - The patient's treatment is not interrupted or discontinued

Obtain an RDA in one of two ways:

 By using the Clozapine REMS website at www.clozapinerems.com

 By calling the Clozapine REMS Contact Center at 888-586-0758

How to Obtain an RDA: Pharmacy Dashboard

The screenshot shows the Clozapine REMS Pharmacy Dashboard. The top navigation bar includes 'Wholesaler', 'Prescribing Information', and 'Contact Us'. The main header identifies the user as a 'Pharmacy' and shows the 'Outpatient Pharmacy Group'. The dashboard features several cards: 'To certify your pharmacy', 'Obtain a Patient's REMS Dispense Authorization (RDA)', 'Submit a Patient's ANC Lab Value', 'Pharmacy Personnel', and 'Pharmacies'. The 'Obtain a Patient's REMS Dispense Authorization (RDA)' card is highlighted with a red box. A red arrow points from this box to a larger, detailed view of the RDA card on the right.

Obtain a Patient's REMS Dispense Authorization (RDA)
An RDA is a receipt from the Clozapine REMS signifying that the REMS requirements to dispense for this patient are currently met.

[→ Obtain Patient RDA](#)

To obtain an RDA, log into the Clozapine REMS website and click Obtain a Patient's RDA from your pharmacy dashboard.

How to Obtain an RDA: Find Patient

Pharmacy

Outpatient Pharmacy



Obtain a Patient's REMS Dispense Authorization (RDA)

An RDA is a receipt from the Clozapine REMS signifying that the REMS requirements to dispense for this patient are currently met.
Find an enrolled patient:

1

1 Find a patient by entering the patient's information below:

First Name

Last Name

Date of Birth

First Name

Last Name

mm/dd/yyyy

REMS Patient ID

Phone Or Email

REMS Patient ID

Phone Or Email

After entering available patient identifiers, click Find.

2

Clear

Find

The first step in obtaining an RDA is to identify the patient in the REMS system. Enter as much patient information as you have.

Cancel

Continue

How to Obtain an RDA: Find Patient (Continued)

Pharmacy
Outpatient Pharmacy

Obtain a Patient's REMS Dispense Authorization (RDA)
An RDA is a receipt from the Clozapine REMS signifying that the REMS requirements to dispense for this patient are currently met.
Find an enrolled patient:

1 Find a patient by entering the patient's information below:

First Name Last Name Date of Birth
First Name Smith mm/dd/yyyy

REMS Patient ID Phone Or Email
REMS Patient ID Phone Or Email

There are errors, please correct the items below:
• The search result returned too many rows. Please enter additional data to narrow the search.

Clear Find

Cancel Continue

The patient search may return error messages, like those seen below.

If a patient cannot be found or there are too many possible matches, then try entering additional data and searching again.

You can also call the REMS Contact Center for assistance.

There are errors, please correct the items below:
• The patient cannot be found with the data entered. Enter additional data or contact the Clozapine REMS Contact Center at 1-888-586-0758

There are errors, please correct the items below:
• The search result returned too many rows. Please enter additional data to narrow the search.

How to Obtain an RDA: Find Patient (Continued)

1

2 results found

- PatientTerri Smitt (DOB:2/19/1970)
- PatientTerry Smitt (DOB:9/22/1989)

When the REMS system can identify a reasonable number of patient options, you will select the radio button next to the appropriate patient.

2

Click Continue to move forward in the RDA process.

Pharmacy
Outpatient Pharmacy

Obtain a Patient's REMS Dispense Authorization (RDA)
An RDA is a receipt from the Clozapine REMS signifying that the REMS requirements to dispense for this patient are currently met.
Find an enrolled patient:

Find a patient by entering the patient's information below:

1

First Name Last Name Date of Birth

First Name Smit mm/dd/yyyy

REMS Patient ID Phone Or Email

REMS Patient ID Phone Or Email

2 results found

- PatientTerri Smitt (DOB:2/19/1970)
- PatientTerry Smitt (DOB:9/22/1989)

Clear

Cancel Continue

Clear

Cancel Continue

How to Obtain an RDA: Obtain RDA



Pharmacy

Outpatient Pharmacy



Obtain a Patient's REMS Dispense Authorization (RDA)

An RDA is a receipt from the Clozapine REMS signifying that the REMS requirements to dispense for this patient are currently met.



Patient

Enrolled as of 11/23/2020

Name:	PatientTerry Smitt	Zip Code:	28601
Date of Birth:	9/22/1989	Phone:	920-723-6334
REMS Patient ID:	CP1378924	Email:	CPPatientGE01@examoto.net



REMS Dispense Authorization (RDA)

A REMS Dispense Authorization is a receipt from the Clozapine REMS indicating that the safe use conditions managed by the REMS are currently in place. After obtaining an RDA, retain it as your receipt.

Obtain RDA

On the next screen, you can confirm that you have the correct patient and click the Obtain RDA button to request an RDA for that patient.

How to Obtain an RDA: Obtain RDA—Safe Use Conditions Met

Pharmacy

Outpatient Pharmacy

Obtain a Patient's REMS Dispense Authorization (RDA)

An RDA is a receipt from the Clozapine REMS signifying that the REMS requirements to dispense for this patient are currently met.

Patient (Population: General) Enrolled as of 3/23/2021

Name: Patient Terry Smitt Zip Code: 28601
Date of Birth: 9/22/1989 Phone: 920-723-6334
REMS Patient ID: CPPatEI130NoC Email: CPPatEI30NoC@examoto.net

REMS Dispense Authorization (RDA)

A REMS Dispense Authorization is a receipt from the Clozapine REMS indicating that the safe use conditions managed by the REMS are currently in place. After obtaining an RDA, retain it as your receipt.

RDA:

Obtained by RxOutPatJane AuthRepDoe on 04/13/2021 at 11:57 AM Coordinated Universal Time

Detail

- ✓ **Safe Use Conditions:**
- ✓ Patient is Enrolled: Patient Terry Smitt
- ✓ Pharmacy is Certified

Dispensing Information

Outpatients should be dispensed a days' supply in accordance with their monitoring frequency.

Date	Manufacturer	NDC Code	Days' Supply	Quantity
<input type="text" value="mm/dd/yyyy"/>	<input type="text" value="Manufacturers"/>	<input type="text" value="NDC Codes"/>	<input type="text"/>	<input type="text"/>

1 If all REMS elements to assure safe use are met, then the next screen will display an alphanumeric RDA code, which the pharmacy should retain in its records for each fill.

2 You can click Detail to see more information about the conditions satisfied.

3 On the RDA screen, you should enter the dispensing information.

4 Upon entry of the dispensing information, click Save.

How to Obtain an RDA: Obtain RDA—Safe Use Conditions NOT Met

Pharmacy
Outpatient Pharmacy

Obtain a Patient's REMS Dispense Authorization (RDA)
An RDA is a receipt from the Clozapine REMS signifying that the REMS requirements to dispense for this patient are currently met.

Patient (Population: General) Enrolled as of 2/11/2021

Name:	PatientPat Smithe	Zip Code:	44145
Date of Birth:	6/27/1954	Phone:	204-896-7543
REMS Patient ID:	CPDemoPatDiscont	Email:	CPPatDiscont@examoto.net

REMS Dispense Authorization (RDA)

A REMS Dispense Authorization is a receipt from the Clozapine REMS indicating that the safe use conditions managed by the REMS are currently in place. After obtaining an RDA, retain it as your receipt.

⚠ DO NOT DISPENSE

Detail

Safe Use Conditions:

- ✓ Patient is Enrolled: PatientPat Smithe
- ✗ Patient, PatientPat Smithe, most recent Patient Status Form (PSF) on file indicates the patient has discontinued treatment. Let the patient know that their prescriber has not authorized a refill and to contact their prescriber if necessary.
- ✓ Pharmacy is Certified

[Cancel](#)

1

If all REMS elements to assure safe use are NOT met, then the next screen will display a message to not dispense.

You can click Detail to see why the RDA was not issued, such as the examples shown here.

2

Safe Use Conditions:

- ✓ Patient is Enrolled: PatientAli Smithson
- ✗ Patient, PatientAli Smithson, most recent Patient Status Form (PSF) on file indicates the patient has interrupted treatment. Let the patient know that their prescriber has not authorized a refill and to contact their prescriber if necessary.
- ✓ Pharmacy is Certified

Safe Use Conditions:

- ✓ Patient is Enrolled: PatientHospPat Smith
- ✓ General population Patient, PatientHospPat Smith, has a Dispense Rationale with an ANC greater than 999 per µl.
- ✓ Pharmacy is Certified
- ✗ Patient, PatientHospPat Smith, has a reached the Dispense Rationale limit. Please contact the patient's prescriber, the prescriber is required to submit a Patient Status Form (PSF) for this patient to receive drug.
- ✓ Prescriber is Certified: PRJane PRDoe

How to Obtain an RDA: Reverse RDA

If a prescription is not dispensed to the patient and is returned to stock, the RDA must be reversed. To reverse an RDA, log into your account at www.clozapinerems.com and select the Reverse RDA button.

Find the patient and follow the directions.

You may also reverse an RDA by calling the Clozapine REMS Contact Center at 888-586-0758.

How to Obtain an RDA: Reverse RDA (Continued)

Pharmacy
Outpatient Pharmacy

Obtain a Patient's REMS Dispense Authorization (RDA)
An RDA is a receipt from the Clozapine REMS signifying that the REMS requirements to dispense for this patient are currently met.

Patient (Population: General) Enrolled as of 3/23/2021

Name: Patient Terry Smitt Zip Code: 28601
Date of Birth: 9/22/1989 Phone: 920-723-6334
REMS Patient ID: CPPatE130NoC Email: CPPatE130NoC@examoto.net

REMS Dispense Authorization (RDA)

A REMS Dispense Authorization is a receipt from the Clozapine REMS indicating that the safe use conditions managed by the REMS are currently in place. After obtaining an RDA, retain it as your receipt.

RDA: a620091f Copy Print Reverse

Obtained by RxOutPatJane AuthRepDoe on 04/13/2021 at 11:57 AM Coordinated Universal Time

Detail

Safe Use Conditions:

- ✓ Patient is Enrolled: Patient Terry Smitt
- ✓ Pharmacy is Certified

Dispensing Information

Outpatients should be dispensed a days' supply in accordance with their monitoring frequency.

Date	Manufacturer	NDC Code	Days' Supply	Quantity
mm/dd/yyyy	Manufacturers	NDC Codes		

If you need to reverse an RDA, then look up the patient in the REMS. Their latest RDA will be listed on their patient record, and you can click the Reverse button to request a reverse.

The following screen will display a confirmation that the RDA was reversed.

Patient (Population: General) Enrolled as of 3/23/2021

Name: Patient Terry Smitt Zip Code: 28601
Date of Birth: 9/22/1989 Phone: 920-723-6334
REMS Patient ID: CPPatE130NoC Email: CPPatE130NoC@examoto.net

REMS Dispense Authorization (RDA)

A REMS Dispense Authorization is a receipt from the Clozapine REMS indicating that the safe use conditions managed by the REMS are currently in place. After obtaining an RDA, retain it as your receipt.

✘ RDA Reversed.

How to Troubleshoot Common Issues: Incomplete Certification

Authorized Representatives must successfully complete the Knowledge Assessment AND enrollment process to be certified; if a user stops in the middle of certification, then one of these elements may be incomplete. In this case, the Pharmacy Dashboard will only show a check mark next to one of the two activities.

CLOZAPINE REMS Home Pharmacy RxOutPatJane AuthRepDoe

Pharmacy
Outpatient Pharmacy

To certify your pharmacy:
Your pharmacy must certify in the Clozapine REMS to dispense clozapine. To certify please complete the following:

- 1 Review the Pharmacy Information
- 2 **Complete the Knowledge Assessment for Pharmacies**
Have the authorized representative successfully complete the Knowledge Assessment for Pharmacy and submit it to the Clozapine REMS.
Online or Print
- 3 Enroll Pharmacy
Have the authorized representative enroll in the Clozapine REMS by completing the Pharmacy Enrollment Form and submitting it to the Clozapine REMS.

Obtain a Patient's REMS Dispense Authorization (RDA)
An RDA is a receipt from the Clozapine REMS signifying that the REMS requirements to

Pharmacies
Inpatient Pharmacy Enrollment Form
Outpatient Pharmacy Enrollment Form
ANC Lab Reporting Form
RDA Factsheet for inpatient

Incomplete Knowledge Assessment with Complete Enrollment

2 **Complete the Knowledge Assessment for Pharmacies**
Have the authorized representative successfully complete the Knowledge Assessment for Pharmacy and submit it to the Clozapine REMS.

3 Enroll Pharmacy

→ Sign and Submit

Incomplete Enrollment with Complete Knowledge Assessment

CLOZAPINE REMS Home Pharmacy RxOutPatJane AuthRepDoe

Pharmacy
Outpatient Pharmacy

To certify your pharmacy:
Your pharmacy must certify in the Clozapine REMS to dispense clozapine. To certify please complete the following:

- 1 Review the Pharmacy Information
- 2 Complete the Knowledge Assessment for Pharmacies
Have the authorized representative successfully complete the Knowledge Assessment for Pharmacy and submit it to the Clozapine REMS.
- 3 **Enroll Pharmacy**

→ Sign and Submit

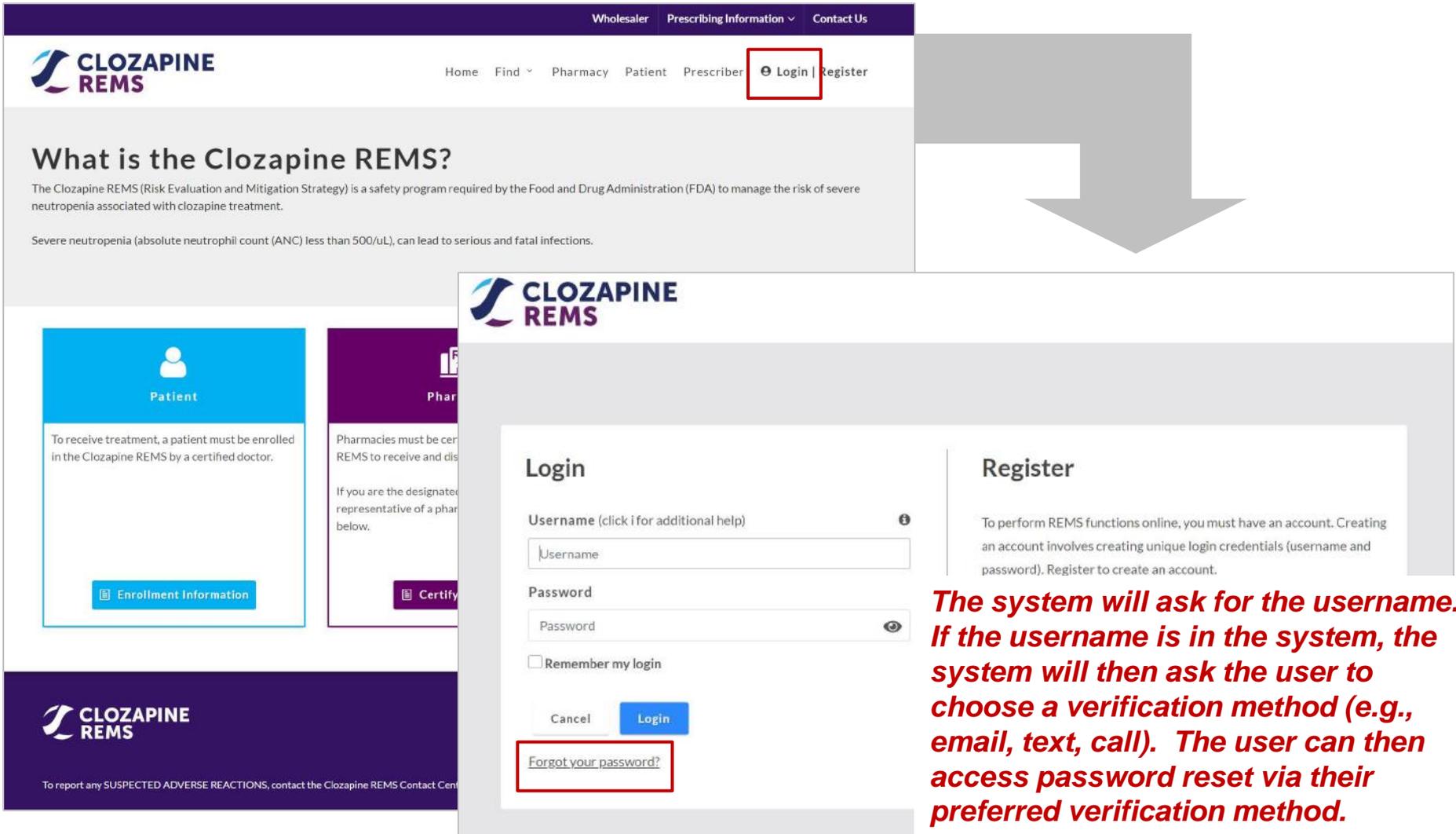
Pharmacy Materials

- Clozapine and the Risk of Neutropenia: A Guide for Pharmacists
- Knowledge Assessment for Pharmacies
- Inpatient Pharmacy Enrollment Form
- Outpatient Pharmacy Enrollment Form

Obtain a Patient's REMS Dispense Authorization (RDA)

How to Troubleshoot Common Issues: Lost/Forgotten Password

Authorized Representatives are not responsible for staff passwords. Staff members can reset their own password from the Login screen.



The image shows a sequence of screenshots from the Clozapine REMS website. The top screenshot shows the website's navigation menu with the 'Login' link highlighted in a red box. A large grey arrow points down to the next screenshot, which shows the 'Login' and 'Register' forms. In the 'Login' form, the 'Forgot your password?' link is highlighted in a red box. The 'Register' form is also visible on the right side of the login screen.

Login

Username (click i for additional help) ?

Password ?

Remember my login

Cancel

[Forgot your password?](#)

Register

To perform REMS functions online, you must have an account. Creating an account involves creating unique login credentials (username and password). Register to create an account.

The system will ask for the username. If the username is in the system, the system will then ask the user to choose a verification method (e.g., email, text, call). The user can then access password reset via their preferred verification method.

Closing

The screenshot shows a web browser window with the address bar displaying <https://www.newclozapinerems.com/>. The website header includes the Clozapine REMS logo and a navigation menu with links for Home, Find, Pharmacy, Patients, Prescriber, and Login | Register. The main content area features a large heading "What is the Clozapine REMS?" followed by a paragraph explaining that the Clozapine REMS is a safety program required by the FDA to manage the risk of severe neutropenia. Below this, a sub-section states that severe neutropenia (ANC less than 500/ μ L) can lead to serious and fatal infections.

Pharmacies must certify in the modified program prior to November 15.

- The transition website, [NewClozapineREMS.com](https://www.newclozapinerems.com), or
- The transition Contact Center at 1-888-586-0758.

Patient

To receive treatment, a patient must be enrolled in the Clozapine REMS program by a certified doctor.

[Enrollment Information](#)

Pharmacy

Pharmacies must be certified in the Clozapine REMS to receive and dispense clozapine.

If you are the designated authorized representative of a pharmacy, you can certify below.

[Certify Pharmacy](#)

Prescriber

Healthcare Providers must be certified in the Clozapine REMS to prescribe clozapine for outpatient use.

If you are a clozapine prescriber, you can certify below.

[Certify Prescriber](#)