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Demonstration of REMS Website

Until November 15, 2021, continue to use the ClozapineREMS.com website to manage patients in the REMS.

1. Prescribers should certify in the new program and enroll their patients 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/µL), 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 (NNRMM).
To facilitate a smooth transition to the modified Clozapine REMS program on November 15, we encourage Prescribers to certify in the modified program now via

- The transition website, NewClozapineREMS.com, or
- The transition Contact Center at 1-888-586-0758.

Click Certify Pharmacy on the homepage to start the certification process.
How to Certify: Register

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

1. Type in the Prescriber’s Individual NPI Number and password.
2. Then Click Next.
3. On the account confirmation page, click Login to use your new credentials to continue certification.
4. You will need to request a code via email and clicking Next.
5. On the next screen, enter the code received via email and click Next to proceed with certification.
6. All users must create new REMS login credentials. Legacy system credentials will not work in the new system.
How to Certify: Knowledge Assessment

1. Click Prescriber 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.
Prescribers must successfully complete a 12-question Knowledge Assessment.

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

Following successful completion of the Knowledge Assessment, Prescribers can continue the certification process.
How to Certify: Enrollment

After completing Step 3, Prescribers need to complete enrollment by clicking Online under Step 4.
How to Certify: Enrollment (Continued)

The Prescriber starts the Prescriber Enrollment form online by filling in information about themselves (e.g., NPI, practice name, credentials, contact information).

Prescribers should also enter their contact preferences.
Next the Prescriber must review their responsibilities in the REMS.

The last step is to sign the enrollment form and submit it by clicking Sign and Submit.
How to Certify: Certification Completion

Successful completion of Enrollment and the Knowledge Assessment result in a Prescriber being marked as certified on the Prescriber Dashboard.
How to Certify: Adding Prescriber Designees

Certified Prescribers can designate individuals, known as Prescriber Designees, to conduct certain activities in the REMS on their behalf.

Under Edit Personnel on the Prescriber Dashboard, click Manage to add Prescriber Designee(s).

Follow instructions on the screens that follow to invite a designee to act on your behalf either via the REMS website and the Contact Center or by via the Contact Center only.
How to Enroll Patients

Under Enroll Patients in the Clozapine REMS on the Prescriber Dashboard, click Enroll Patient to add patients managed by the Prescriber.
How to Enroll Patients (Continued)

The Prescriber completes the Patient Enrollment form online by filling in information about the patient (e.g., name, DOB, demographics),...

...contact information (e.g., phone, email),...
How to Enroll Patients (Continued)

- ...information about clozapine therapy (e.g., therapy status, monitoring frequency), ...
- ...baseline lab information (e.g., draw date, ANC), ...
- ...BEN status (if applicable), ...
- ...and hospice status (if applicable).

Then click Enroll Patient.
How to Use the Patient Status Form

To complete and submit a Patient Status Form, click the Manage Patients button on the Prescriber Dashboard.
How to Use the Patient Status Form (Continued)

On your Manage Patients screen, you can sort by any column (e.g., name, REMS patient ID number) to help you identify the patient you need.

To add a Patient Status Form, click the Add PSF button on the appropriate patient’s row.
How to Use the Patient Status Form (Continued)

Beginning November 15, 2021, Prescribers must complete and submit the Patient Status Form to the REMS for each enrolled patient who is continuing treatment with clozapine.

Confirm the patient information,…

…indicate the patient’s status (e.g., monitoring frequency, hospice),…

…mark whether the patient had an adverse event and update their status, if necessary,…

…and note that the patient has benign ethnic neutropenia (BEN), if appropriate.
How to Use the Patient Status Form (Continued)

5. Report ANC lab data or reason for missing lab.

6. Note that the system will provide the number of entry lines necessary based on the patient’s monitoring frequency.

After entering all required information, click Save to submit the Patient Status Form to the REMS.
How to Use the Patient Status Form (Continued)

Note that if you provide a lab on the Patient Status Form that indicates moderate or severe neutropenia, the REMS System will alert the Prescriber that action is required relative to the Patient Treatment Status.

In this scenario, the Prescriber should select one of the following: Interrupt Treatment, Treatment Rationale, or Discontinue Treatment before saving the Patient Status Form.
How to Troubleshoot Common Issues: Incomplete Certification

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

1. Incomplete Enrollment with Complete Knowledge Assessment

2. Incomplete Knowledge Assessment with Complete Enrollment
How to Troubleshoot Common Issues: Lost/Forgotten Password

Prescribers and Prescriber Designees can reset their own password from the Login screen.

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.
Prescribers must certify in the modified program and enroll their patients prior to November 15.

- The transition website, NewClozapineREMS.com, or
- The transition Contact Center at 1-888-586-0758.