

What Psychiatrists Need to Know About...

Clozapine REMS Program

Beginning in October, all clozapine products have been available only through the Clozapine REMS (Risk Evaluation and Mitigation Strategy) Program. The REMS Program has replaced all the individual patient registries and combines them into a shared program to provide a centralized point of access. The goal is to minimize the risk of severe neutropenia associated with the use of clozapine. Clozapine prescribers and pharmacies must be certified through the REMS Program, and the FDA has indefinitely extended the certification deadline due to ongoing technical problems.

Several key operational changes are addressed in the Clozapine REMS Program, including: 1) Social Security numbers are no longer used to identify patients, and 2) starting December 14, 2015, outpatient pharmacies are required to obtain a predispose authorization (PDA) from the Clozapine REMS Program before clozapine can be dispensed.

Further, prescribers have new requirements to prescribe clozapine. Prescribers or prescriber designees are responsible for enrolling patients and submitting ANC. And when ANCs are submitted depends on the patient inpatient or outpatient status. For outpatient patients, ANC must be reported to the shared Clozapine REMS Program before clozapine can be dispensed. For inpatient patients, ANC must be reported to the Clozapine REMS Program within 7 days of the most recent blood draw.

The Clozapine REMS Program website has a listing of Frequently Asked Questions, and we have included several of them following this article. One question our office received is about designee certification. REMS does allow prescribers to designate a member of their office staff to assist with patient management. Certified designees can enroll patients, report ANC lab results, and manage patients and view patient lists on behalf of the prescriber. The designee must complete a designee certification online. To do this, visit www.clozapinerems.com and access the Prescriber menu along the top. Under that menu there is a Designee Certification

drop-down menu that will take your designee through the steps of becoming certified (see graphic). Similarly, nurse practitioners and physicians assistants in your office who prescribe clozapine must be registered with the REMS Program.



NCPA members began reporting problems getting certified early on in the process, and the APA met directly with FDA officials in October. This meeting prompted the FDA to issue an alert, and later a deadline extension. In one of its alerts prior to the certification deadline, the FDA stated if "prescribers and pharmacists continue to experience any issues, they should use clinical judgment and consider the best interests of the patient. Continue prescribing and dispensing clozapine to patients with an absolute neutrophil count (ANC) within the acceptable ranges while the issues are being resolved." While the FDA reports that technical issues have been resolved, members are still facing long hold times when contacting REMS customer service and extra steps in their workflow related to REMS.

NCPA continues to work with the APA to identify problems related to REMS certification. Please contact us if you experience any issues (large or small) during the process. Call the NCPA office at 919-859-3370 or email info@ncpsychiatry.org.

Clozapine REMS Certification Frequently Asked Questions

How can a prescriber enroll in the single shared Clozapine REMS Program?

Prescribers can enroll online through the Clozapine REMS Program website or by submitting the Prescriber Enrollment forms via fax to the program contact center at 1-844-404-8876.

To complete certification on the program website:

- From the Home page you will use the “Start Prescriber Certification” button. You will be taken to the applicable stakeholder certification page, which will explain what is expected and required of you from the Clozapine REMS Program.
- From that certification page, you can use the “Begin Now” button to begin your certification in the program.
- Stakeholders that have completed the Clozapine REMS Program enrollment requirements will receive notification that they are certified in the program.
- For a faxed copy of the forms, contact 1-844-267-8678

Do my patients need to enroll in the Clozapine REMS Program?

Yes. Any patient prescribed clozapine must be enrolled in the Clozapine REMS Program by the patient’s prescriber or the prescriber’s certified designee. For immediate patient enrollment please visit www.clozapinerems.com or fax the completed enrollment forms to the Clozapine REMS Program contact center at 844-404-8876.

I am going to be out of the office for an extended period of time. Can I send my patients to one of my colleagues?

Yes, however, the covering prescriber must be certified in the Clozapine REMS Program and the new prescriber must enroll those patients into the program to continue the patient’s clozapine therapy or contact Clozapine REMS Program to have the patient assigned to the covering prescriber.

Can I have a member of my office staff manage my patients?

Yes. The Clozapine REMS Program allows a prescriber to identify a prescriber designee to perform some duties or functions on behalf of the prescriber. The prescriber’s designee(s) will need to become certified in the Clozapine REMS Program before they can perform any duties or functions for their prescriber(s).

A notification will be sent to the prescriber when the designee enrolls. Before a designee can become certified, the prescriber will need to approve the person acting on his/her behalf. Once the designee has been approved, they will be able to engage in patient management through the Clozapine REMS Program website.

What role can my designees play in the Clozapine REMS Program?

A designee can perform the following actions on behalf of the prescriber:

- Enroll Patients
- Report ANC lab results
- Manage patients and view patient lists

Do prescribers need to re-enroll in the Clozapine REMS Program?

No. Prescribers do not need to re-enroll in the Clozapine REMS Program. There is a one-time, initial enrollment into the program. However, prescribers must enroll every patient that is prescribed clozapine, even if the patient was enrolled by another prescriber previously.

My patient will not provide the required information to complete the patient enrollment. Can they still receive clozapine?

Per FDA requirements, these fields must be completed for prescribers and pharmacies to identify the patient in the system to submit ANC values and provide authorization to receive clozapine. If a patient and/or their caregiver will not provide the required information, the patient will not be able to receive clozapine therapy.