

**FDA REQUIRED
UPDATED REMS
SAFETY
INFORMATION**



Prescriber Re-certification, Designee and Patient Re-enrollment — Take Action Now

Dear Prescriber Designee,

The information below has been provided to your prescriber. To continue as a prescriber designee, you will also need to be re-enrolled in the new Clozapine REMS. To be re-enrolled, your prescriber must first re-certify in the new Clozapine REMS. Once your prescriber is re-certified, he/she may log into the new Clozapine REMS website and select the Manage Designees button. On the next page, the prescriber will select the Add Designee button and follow the prompts in the system. The prescriber may also fax a completed Prescriber Designee Enrollment Form to the Clozapine REMS Contact Center.

The Clozapine REMS requirements are changing due to a recently approved modification. New Clozapine Requirements will be implemented **November 15, 2021**. Prescribers and patients who are not re-certified or re-enrolled after this time will not have access to clozapine.

- **Re-certify in the Clozapine REMS** in order to prescribe clozapine for outpatient use and/or initiate treatment for inpatients.
- **Re-enroll patients** continuing on clozapine treatment to avoid a break in patient treatment.
- **Re-certification of prescribers and their designees, and re-enrollment of patients must be done with the revised materials.** To do this, you may access the new Clozapine REMS website **beginning August 16, 2021**:
 - Go to www.clozapinerems.com.
 - Click on the link in the **Important Program Update**. You will be taken to the modified Clozapine REMS website.
 - Prescribers must create new login credentials.
 - Click on Log-in | Register tab. These credentials will only work on the modified Clozapine REMS.
 - Prescribers must first review the Prescriber Training, complete and submit the Knowledge Assessment and Prescriber Enrollment Form to become re-certified
 - Then re-enroll your patients using the Patient Enrollment Form.
- A **Transition Contact Center** is available at 888-586-0758 to support re-certification, re-enrollment activities and to answer questions.
- After launch of the modified Clozapine REMS on November 15, 2021, a **NEW Patient Status Form** must be submitted monthly. The Patient Status Form documents the patient's ANC results, monitoring frequency, and appropriateness to continue treatment.
 - Continue monitoring **existing patients** according to their current monitoring schedule using the ANC Lab Reporting Form prior to November 15, 2021. All existing patients will need to be re-enrolled in the new program by November 15, 2021.
 - All **new patients starting clozapine** between now and November 15, 2021 must be enrolled in both the current program and the new program.
- See [Fact Sheet: What's Changed in the Clozapine REMS for Prescribers](#) for more details on these and other changes to the program.

Re-certify and re-enroll your patients prior to November 15th to avoid delays in patient treatment!

Questions? Contact the [Clozapine REMS Transition Call Center](#) at **1-888-586-0758**.