

**FDA REQUIRED
UPDATED REMS
SAFETY
INFORMATION**

Re-certify and Re-enroll Patients Now

Dear Healthcare Provider,

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**:
 - o Go to www.clozapinerems.com.
 - o Click on the link in the **Important Program Update**. You will be taken to the modified Clozapine REMS website.
 - o Prescribers must create new login credentials.
 - o Click on Log-in | Register tab. These credentials will only work on the modified Clozapine REMS.
 - o Prescribers must first review the Prescriber Training, complete and submit the Knowledge Assessment and Prescriber Enrollment Form to become re-certified
 - o 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.

- o 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.
- o 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**.