



Clozapine Risk Evaluation and Mitigation Strategy Requires Providers and Pharmacies to Re-certify/Re-enroll Patients by November 15, 2021

Effective immediately, all providers and pharmacies that prescribe or dispense clozapine must re-certify in the Clozapine Risk Evaluation and Mitigation Strategy (REMS) by November 15, 2021. Clozapine is FDA-approved for treatment-resistant Schizophrenia and to reduce the risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorder. Clozapine is associated with severe neutropenia (absolute neutrophil count (ANC) less than 500/ μ L), and as part of the REMS, the patient's ANC must be submitted monthly via the Patient Status form.

For prescribers, re-certification is required regardless of outpatient or inpatient setting. Providers and pharmacies that fail to re-certify cannot prescribe or dispense clozapine. Providers/pharmacies must also re-enroll their patients in the Clozapine REMS by November 15, 2021. Patients who are not re-enrolled by their provider into Clozapine REMS cannot receive clozapine.

The modifications to the Clozapine REMS, which include the prescribing, dispensing, and receiving of clozapine into a single-shared program, were approved on July 29, 2021 by the Food and Drug Administration and can be found here: <http://www.fda.gov/drugs/drug-safety-and-availability/clozapine-risk-evaluation-and-mitigation-strategy-rems-requirements-will-change-november-15-2021>. Providers and pharmacies can re-certify or re-enroll their patients into the program by visiting the Clozapine REMS homepage/website at the following link: <https://www.newclozapinerems.com/home>