



Clozapine Risk Evaluation and Mitigation Strategy Requires Providers and Pharmacies to Re-certify and 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. For prescribers, re-certification is required regardless of practice setting (e.g., outpatient, inpatient). Prescribers and pharmacies that fail to re-certify cannot prescribe or dispense clozapine. Prescribers 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 were approved on July 29, 2021 by the [Food and Drug Administration](#). The Clozapine REMS now incorporates the prescribing, dispensing, and receiving of clozapine into a single-shared program.

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 absolute neutrophil count (ANC) must be submitted monthly via the Patient Status form. Providers and pharmacies can re-certify or re-enroll patients into the program at the [Clozapine REMS Home](#). Re-certification and re-enrollment must be completed before November 15, 2021, to avoid disruption in care.