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IN BRIEF

REMS Removal for Clozapine

The FDA has announced that prescribers, pharmacies, and patients are no longer required to participate in a Risk Evaluation and Mitigation Strategy (REMS) program for the second-generation antipsychotic drug clozapine (*Clozaril*, and others).¹

Clozapine is generally considered the most effective antipsychotic drug for treatment of schizophrenia. It has been effective for treatment of psychotic symptoms that have not responded to other drugs and has been more effective than other antipsychotics in decreasing the risk of suicide.²

The REMS program for clozapine was instituted by the FDA in 2015 because of the risk of severe neutropenia associated with its use. Although absolute neutrophil count (ANC) monitoring is still recommended and a boxed warning about severe neutropenia will remain in the labels of all clozapine products, reporting ANC results will no longer be required for pharmacists to dispense the drug.

Elimination of the REMS program is expected to minimize the burden on the healthcare system and improve access to the drug. ■

1. FDA. Information on clozapine. February 25, 2025. Available at: <https://bit.ly/4iHjvcu>. Accessed May 16, 2025.
2. Drugs for psychotic disorders. *Med Lett Drugs Ther* 2016; 58:160.

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