Addendum to "Patient Safety Alert: Serious Harm Associated With Failure to Adjust Clozapine Dosing"

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This addendum updates our "Patient Safety Alert: Serious Harm Associated With Failure to Adjust Clozapine Dosing" published on December 15, 2023.

On February 24, 2025, the U.S. Food and Drug Administration (FDA) removed the risk evaluation and mitigation strategy (REMS) program for clozapine. This change eliminated the requirement for prescribers, pharmacies, and patients to participate in REMS and report absolute neutrophil count (ANC) results before clozapine is dispensed. Despite the discontinuation of the Clozapine REMS, the FDA still advises adherence to ANC monitoring frequencies specified in the clozapine prescribing information, and the existing boxed warnings regarding severe neutropenia remain in effect.

Reference

U.S. Food and Drug Administration. Information on Clozapine. FDA. https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-clozapine. Published February 25, 2025. Accessed February 26, 2025.

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