

Provider Notice

To: **MH OP Clinic Providers, Psychiatrists and CRNPS**
From: **PerformCare**
Date: **May 30, 2025**
Subject: **MH 25 104: Clozapine REMS discontinued**

Effective February 24, 2025, the FDA eliminated the Risk Evaluation and Mitigation Strategies (REMS) program for clozapine, meaning prescribers, pharmacies, and patients are no longer required to participate in the program or report absolute neutrophil count (ANC) results. Elimination of the REMS requirement is expected to increase access to receiving clozapine.

However, the elimination of the REMS program does not indicate that there is a change in the risks associated with clozapine, but rather the FDA determined that the barriers of the REMS outweigh the risk. Therefore, PerformCare is issuing this notice with best practice information about the monitoring of persons receiving clozapine.

While these changes may affect certain prescribing and dispensing requirements, we want to reinforce that it remains essential to adhere to established clinical guidelines for the safe use of Clozaril.

As a reminder, best practices for monitoring include:

- 1) **Absolute Neutrophil Count (ANC) Monitoring:** Regular ANC testing remains critical to mitigate the risk of severe neutropenia. Providers should continue to follow the most current monitoring guidelines, including:
 - Weekly ANC monitoring for the first 6 months of treatment
 - Every two weeks for the next 6 months
 - Monthly monitoring thereafter, if ANC remains stable
- 2) **Ongoing Metabolic and Cardiovascular Monitoring:** Due to the potential metabolic side effects of Clozaril, ongoing screening for weight, lipid profile, and glucose levels is strongly recommended.
- 3) **Patient Education & Adherence Support:** Ensuring patients understand the importance of routine bloodwork and adherence to treatment plans is essential for optimizing outcomes and minimizing risks.

OMHSAS has confirmed that activities conducted by providers that are reimbursable per the OMAP “Clozapine Support Services” bulletin (attached) can continue to be billed to PerformCare.

cc: Scott Suhring, Capital Area Behavioral Health Collaborative
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