Date: March 4, 2025

To: MCO Contractor Pharmacy Directors

MCO Contractor Medical Directors

MCO Contractor Compliance Officers

AHCCCS Fee-For-Service Staff

AHCCCS Medical Services, Clinical & MCO Operations Staff

Optum PBM Staff

From: Suzi Berman, RPH

Subject: Clozapine REMS Program Update

Effective February 24th, the FDA issued a statement effectively ending the requirements of the Clozapine REMS Program. The FDA statement is as follows:

February 24, 2025 *- Beginning today, FDA does not expect prescribers, pharmacies, and patients to participate in the risk evaluation and mitigation strategies (REMS) program for clozapine or to report results of absolute neutrophil count (ANC) blood tests before pharmacies dispense clozapine. FDA still recommends that prescribers monitor patients' ANC according to the monitoring frequencies described in the prescribing information. Information about severe neutropenia will remain in the prescribing information for all clozapine medicines, including in the existing Boxed Warnings.*

Although the risk of severe neutropenia with clozapine still exists, FDA has determined that the REMS program for clozapine is no longer necessary to ensure the benefits of the medicine outweigh that risk. Eliminating the REMS is expected to decrease the burden on the health care delivery system and improve access to clozapine. FDA has notified the manufacturers that the clozapine REMS must be eliminated. FDA has instructed the clozapine manufacturers to formally submit a modification to eliminate the Clozapine REMS and to update the prescribing information, including removing mandatory reporting of ANC blood tests to the REMS program.

In the coming months, FDA will work with the clozapine manufacturers to update the prescribing information and eliminate the Clozapine REMS.

The FDA no longer expects prescribing clinicians and pharmacies to upload patient data, including registration and ANC lab results, to the clozapine REMS program. If you have any questions regarding the clozapine REMS program, they can be contacted at https://www.newclozapinerems.com/Public/home/Contact or 1-888-586-0758. information.

With the FDA changes to the REMS program, prescribing clinicians are still expected to monitor clozapine patients' ANC. The monitoring requirements are not changing at this time and prescribing clinicians should continue the same ANC monitoring schedule until further notice.

There may be individual pharmacies that are still adhering to the REMS requirements, please maintain business as usual to minimize and avoid the likelihood of a treatment disruption.

The Arizona State Board of Pharmacy will be posting the FDA notice on their website and expects to include this information in their quarterly newsletter.

Please inform your stakeholders of the FDA clozapine REMS changes including but not limited to the following:

- Members & Network Pharmacies
- Prescribing Clinicians & Clinic Facilities
- Behavioral Health Organizations
- Hospitals

If you have questions, please contact me at Suzanne.Berman@azahcccs.gov or at the general pharmacy mailbox, AHCCCSPharmacyDept@azahcccs.gov.

C: Dr. Theresa Costales, MD, CMO AHCCCS
CJ Loiselle, Assistant Director - DBHH
Alisa Randall, Assistant Deputy Director, Clinical Operations
Lynne Emmons, Assistant Deputy Director, DFSM