IMPORTANT INFORMATION REGARDING FDA RELEASE OF CLOZAPINE REMS:

- **On 2/24/2025, FDA announced that they do not expect prescribers, pharmacies, and patients to participate in the risk evaluation and mitigation strategy (REMS) for clozapine or report results of absolute neutrophil count (ANC) blood tests before pharmacies dispense clozapine.**
- **FDA is presently working with the clozapine manufacturers to update the prescribing information and eliminate the Clozapine REMS, anticipated to take place in mid-June 2025.**

Although the risk of severe neutropenia with clozapine still exists, FDA has determined that the Clozapine REMS 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 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, and ANC monitoring frequencies will not change.

Per FDA's instruction, clozapine manufacturers have formally submitted a modification to eliminate the Clozapine REMS and to update the prescribing information. **It is anticipated that FDA will approve this modification and officially release (eliminate) the Clozapine REMS in mid-June 2025.**

In preparation for the Clozapine REMS release, clozapine manufacturers wish to provide pharmacies with the following important information / notice.

- FDA does not expect that pharmacies continue to obtain a REMS Dispense Authorization (RDA) before dispensing clozapine.
- Pharmacies that have implemented internal checks within their systems to require entry of an RDA number before dispensing should ensure they have a plan in place to remove those requirements as soon as possible.
    - **Patients should not be denied clozapine due to a pharmacy's inability to obtain an RDA from the Clozapine REMS.**
- At the direction of FDA, clozapine manufacturers have developed a Medication Guide for patients, which FDA has determined is necessary for patients' safe and effective use of clozapine.
    - Pending FDA approval, clozapine manufacturers will make the Medication Guide publicly available.
- **Upon FDA's release of the Clozapine REMS, current features of the Clozapine REMS website (newclozapinerems.com) shall cease.**
    - **Following release of the Clozapine REMS, stakeholders will no longer have access to information within the Clozapine REMS system.**