Phone: 844-267-8678
Fax: 844-404-8876
www.clozapinerems.com

Dear Pharmacy Manager:

This letter is intended to inform outpatient pharmacies who must obtain a "Predispense Authorization" (PDA) via the Clozapine REMS Program Website or who obtain a PDA by calling the Clozapine REMS Program Contact Center of changes to the Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program occurring in the 02/2019 REMS Modification. If your pharmacy is part of a pharmacy chain, contact your chain's authorized representative to complete enrollment and certification. If you need assistance, please call the Clozapine REMS Program Contact Center at 844-267-8678.

Changes to the Clozapine REMS Program in 02/2019 may affect your ability to dispense clozapine.

1. **Only pharmacies certified in the Clozapine REMS Program will be able to receive and dispense clozapine.**
   - All pharmacies that dispense clozapine must be certified in the Clozapine REMS Program to purchase or receive clozapine from a wholesaler or distributor.
   - If your pharmacy dispenses clozapine and *is not yet* certified in the Clozapine REMS Program, certify online at **www.clozapinerems.com** or download the *Clozapine REMS Outpatient Pharmacy Enrollment Form* and fax the completed form to 844-404-8876.

2. **Pharmacy Classification and program requirements may have changed.**
   Pharmacies previously certified in the Clozapine REMS Program may be reclassified using the following definitions:
   - **Inpatient pharmacy:** a facility dispensing clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition)
   - **Outpatient pharmacy:** a facility that dispenses clozapine only to patients treated on an outpatient or chronic basis including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems

   This pharmacy reclassification, if necessary, will occur at your next scheduled pharmacy recertification. Requirements of pharmacy types differ so if you were an inpatient pharmacy now reclassified as an outpatient pharmacy, please review additional information on outpatient pharmacy requirements available in the *Clozapine REMS PDA Fact Sheet* attached to this letter; in the *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*, in the *Clozapine REMS Frequently Asked Questions (FAQ's)* available at **www.clozapinerems.com**; or, call the Clozapine REMS Program Contact Center at 844-267-8678.

   You may call the Clozapine REMS Program Contact Center at 844-267-8678 if you are unsure whether your pharmacy type is inpatient or outpatient (based on the definitions above) or if your pharmacy provides both inpatient and outpatient pharmacy services to patients being treated with clozapine.

3. **Prescribing clozapine for patients in an outpatient setting[1] requires certification in the Clozapine REMS Program.**
   If the prescriber is not certified in the Clozapine REMS Program, an outpatient pharmacy will not receive authorization to dispense clozapine.

4. **Certified pharmacies may apply clinical judgment and continue to dispense clozapine to enrolled patients if the prescriber is not certified in the Clozapine REMS Program by utilizing a new function, the "Dispense Rationale."**
   The use of a *Dispense Rationale* is limited. Refer to the *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* or the *Clozapine REMS FAQ's* available at **www.clozapinerems.com**; or, call the Clozapine REMS Program Contact Center at 844-267-8678.

[1]An outpatient pharmacy dispenses clozapine only to patients treated on an outpatient or chronic basis including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

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What is a *Dispense Rationale*?

- The Clozapine REMS Program will alert the pharmacy when the prescriber is not certified in the Clozapine REMS Program via a reject message of the PDA request. The pharmacy may then exercise clinical judgement to provide a *Dispense Rationale* to authorize the dispense ***if***:
  - The patient is enrolled in the Clozapine REMS Program; and,
  - Has an acceptable absolute neutrophil count (ANC) value on file; or,
  - If the last ANC on file indicates moderate or severe neutropenia, has a "Treatment Rationale" on file.
- *Dispense Rationales* are valid for 72 hours (3 calendar days) and limited to no more than three (3) occurrences for an individual patient within a rolling six (6) month period.

How can I provide a *Dispense Rationale*?

- Certified pharmacies can provide a *Dispense Rationale*:
  - Via the Clozapine REMS Program Website at **www.clozapinerems.com**, or
  - By calling the Clozapine REMS Program Contact Center at 844-267-8678, or
  - By following the step-by-step instructions provided in the enclosed *Clozapine REMS Predispense Authorization Fact Sheet*.

Patient dispensing

- A PDA will be issued if the patient meets the following program Elements to Assure Safe Use:
  - The patient must be enrolled in the Clozapine REMS Program; and,
  - An acceptable ANC value is on file; or,
  - Has a *Treatment Rationale* on file if the last ANC submitted to the Clozapine REMS Program indicates moderate or severe neutropenia.
- Pharmacies should dispense no more than the amount of clozapine necessary to treat the patient until the next blood draw/ANC or as directed by the prescriber.
- All PDA responses will provide the dispensing pharmacy with the most recent ANC value and the associated blood draw date, and patient's monitoring frequency (MF) on file with the Clozapine REMS Program.

Pharmacies are encouraged to submit the ANC to the Clozapine REMS Program when:

- The pharmacist is made aware of a more current ANC than the most recent lab value reported in the PDA response.
- The most recent ANC indicates moderate or severe neutropenia. The prescriber must provide a *Treatment Rationale* to the Clozapine REMS Program to allow the pharmacy to receive a PDA and dispense clozapine to the patient. The pharmacy may contact the prescriber to remind them of the need for a *Treatment Rationale*.
- Pharmacies may submit ANCs to the Clozapine REMS Program at **www.clozapinerems.com**, by calling the Clozapine REMS Program Contact Center at 844-267-8678; or, faxing a completed *Clozapine REMS ANC Lab Reporting Form* (available from the website) to the Clozapine REMS Program.
- If the ANC result on file with the Clozapine REMS Program is not current according to the patient's MF (within 7 days of the PDA transaction date for weekly monitoring, 15 days for every two weeks monitoring and 31 days for monthly monitoring), a PDA will still be issued, but the pharmacist will receive a warning message regarding the need to ensure the ANC is current.

The pharmacy's authorized representative must ensure that all pharmacy staff are aware of these modifications to the Clozapine REMS Program effective 02/2019.

For additional information related to the Clozapine REMS Program, please call the Clozapine REMS Program Contact Center at 844-267-8678.

Sincerely,

The Clozapine REMS Program

Enclosures: *Clozapine REMS Predispense Authorization Fact Sheet*
How to Start Clozapine and Monitor Patients Fact Sheet