

Dear Pharmacy Manager:

This letter is intended to inform outpatient pharmacies who must obtain a "Predispense Authorization" (PDA) electronically via their pharmacy management system (i.e., "the switch") of changes to the Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program that will occur in the 02/2019 REMS Modification.

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

- Only pharmacies certified in the Clozapine REMS Program will be able to receive and dispense clozapine.**
 - Only pharmacies certified in the Clozapine REMS Program will be able 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.
 - If your pharmacy is part of a pharmacy chain, contact your chain's authorized representative to complete enrollment and certification. If you need assistance, call the Clozapine REMS Program Contact Center at 844-267-8678.
- Prescribing clozapine for patients in an outpatient setting¹ requires certification in the Clozapine REMS Program.**

If the prescriber is not certified in the Clozapine REMS Program, the outpatient pharmacy will not receive authorization to dispense clozapine.
- 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 information provided below, the *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* or *Clozapine REMS Frequently Asked Questions (FAQ's)* available at www.clozapinerems.com; or, call the Clozapine REMS Program Contact Center at 844-267-8678.

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
 - The last ANC on file indicates moderate or severe neutropenia, and has a "Treatment Rationale" on file.
- Dispense Rationales* are valid for 72 hours (3 calendar days) and are 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 web instructions provided in the enclosed *Clozapine REMS Predispense Authorization Fact Sheet*.

¹An 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.

The products covered under the Clozapine REMS Program are: Clozari® (clozapine) tablets, for oral use • Versacloz® (clozapine, USP) oral suspension • Fazaclor® (clozapine USP) orally disintegrating tablets • Approved generic equivalents of these products

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;
 - A *Treatment Rationale* is on file if the last ANC submitted to the Clozapine REMS Program indicates moderate to 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, 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 last 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 that 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 or use of the REMS Pharmacy Network, 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

The products covered under the Clozapine REMS Program are: Clozaril® (clozapine) tablets, for oral use • Versacloz® (clozapine, USP) oral suspension • Fazaclo® (clozapine USP) orally disintegrating tablets • Approved generic equivalents of these products