

- Starting October 12, 2015, ALL clozapine products are only available through the Clozapine REMS Program
- There are important changes to neutropenia monitoring recommendations and treatment algorithm for clozapine

Dear [Professional Society]:

Please distribute this notice to your membership, and direct them to the Clozapine REMS Program with any questions and for additional information.

The FDA has required this safety notice to inform healthcare providers about:

1. The new Risk Evaluation and Mitigation Strategy (REMS) Program for all clozapine products
2. Changes to neutropenia monitoring requirements and treatment algorithm for clozapine

### What is the shared Clozapine REMS Program?

The Clozapine REMS Program replaces all individual clozapine registries. It includes all clozapine products under one shared program to minimize the risk of neutropenia and provides a new, **centralized point** of access:

- For **prescribers and pharmacists** to receive training, complete the knowledge assessment, and certify for access to all clozapine products
- To **enroll and manage patients** on clozapine treatment.

### When do pharmacies need to implement the shared Clozapine REMS Program?

- Starting **October 12, 2015**, Pharmacies must be certified in the Clozapine REMS Program to check absolute neutrophil count (ANC) values and fulfill program requirements. The existing clozapine patient registries will no longer be active.
- Starting **December 14, 2015**, pharmacies must:
  - Be certified in the Clozapine REMS Program to purchase clozapine
  - Obtain a Predispose Authorization (PDA) from the Clozapine REMS Program to dispense clozapine (for outpatient dispensing only).

### How do pharmacies participate in the Clozapine REMS Program?

- Starting **October 12, 2015**: Get certified! For your pharmacy to certify, you must designate an Authorized Representative
- The Authorized Representative must:
  1. Review the *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
  2. Successfully pass the Knowledge Assessment

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

3. Complete and submit the appropriate Clozapine REMS Pharmacy Enrollment Form
4. Implement the necessary staff training and processes to comply with the Clozapine REMS requirements

- **Both in-patient and out-patient pharmacies must be certified.** The requirements and responsibilities for dispensing clozapine in-patient and out-patient are different. Pharmacies with multiple pharmacy locations must certify online and add each pharmacy location after training is completed for each location.
- Pharmacies can certify through the Clozapine REMS Program website [www.clozapinerems.com](http://www.clozapinerems.com), by fax 844-404-8876, or by calling the Clozapine REMS Program at 844-267-8678 for more information.

### What are the key changes to the neutropenia monitoring recommendations and treatment algorithm for clozapine?

- Absolute neutrophil count (ANC) is the only test result accepted in the shared Clozapine REMS Program to monitor for neutropenia
- Patients with Benign Ethnic Neutropenia (BEN) can be treated with clozapine and have a separate ANC monitoring algorithm
- ANC thresholds to start and continue clozapine treatment are lower
- Prescribers have greater flexibility to make patient-specific decisions about continuing and resuming treatment in patients who experience moderate and/or severe neutropenia

Please review *What's New with Clozapine* [embed link for email,] [included (for mailed version)] for additional information about changes related to clozapine treatment and monitoring.

Sincerely,  
The Clozapine REMS Program

Please review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* [embed link for email] available at [www.clozapinerems.com](http://www.clozapinerems.com) for more detailed information about the Clozapine REMS Program requirements, and additional information about changes related to clozapine treatment and monitoring. This letter does not contain the complete safety profile for clozapine. Visit [www.clozapinerems.com](http://www.clozapinerems.com) to review the complete Prescribing Information [embed link for email].

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