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New Clozapine REMS program changes monitoring, dispensing requirements

September 18, 2015 | By Julia Talsma, Content Channel Director

FDA announced new requirements for the monitoring, prescribing, and dispensing of clozapine, an atypical antipsychotic for treatment-resistant schizophrenia, due to the continued risk of severe neutropenia, which can be life-threatening.

A new Clozapine REMS Program has been established and includes revised prescribing information for all clozapine products for the safe monitoring of patients for neutropenia and management of clozapine treatment. The REMS program, which will replace the six clozapine registries that were established by the manufacturers of the drug, requires prescribers, pharmacies, and patients to enroll in one centralized place.

Psychiatric pharmacists help optimize patient care

"Centralizing those registries under one REMS program will allow pharmacies, prescribers, and patients to have one destination for the vital clinical information needed to safely manage their clozapine therapy," according to Tim Gentilcore, PharmD, director of Retail Pharmacy, Mission Health System, Asheville, N.C.


Tim Gentilcore

A centralized, shared REMS program is a great improvement compared with the current system of several different registries managed by the individual manufacturers, said Megan Maroney, PharmD, clinical assistant professor at Ernest Mario College of Pharmacy and a board-certified clinical pharmacy specialist in psychiatry at Monmouth Medical Center, Long Branch, N.J.

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Megan Maroney

"When coordinating care for a patient starting on clozapine in the inpatient setting, one of the challenges I face as a pharmacist, is ensuring continuity of care into the outpatient setting," Maroney continued. "If a patient is started on the Mylan brand of clozapine in the inpatient setting and is originally registered in the Mylan registry, and then after discharge the patient goes to an outpatient pharmacy that supplies clozapine manufactured by Teva, the pharmacist will need to obtain the physician's signature and required bloodwork to enroll them all over again in the TEVA registry. [With the new REMS program], transition from one provider to another and from one pharmacy to another will be much smoother."

New REMS start date

On October 12, 2015, all clozapine products will only be available through the new Clozapine REMS Program. Patients who are currently enrolled in the six separate registries will be automatically transferred into the new centralized program.

"In order to prescribe and dispense clozapine, prescribers and pharmacies will be required to be certified in the Clozapine REMS Program according to a specific transition schedule starting October 12, 2015," FDA wrote in its drug safety communication.

Prescribers and pharmacies can obtain certification online at the Clozapine REMS Program website, www.clozapinerems.com, or call for more information about the program, 844-267-8678. Prescribers can designate a representative to enroll patients in the REMS program and enter the patients' absolute neutrophil counts (ANC). The designated individual also must enroll in the REMS program and be confirmed by the prescriber. Pharmacies also must appoint an authorized representative to become certified. Pharmacies with multiple locations will need to complete staff training and then can enter each location online.

The REMS program also requires that only prescribers or their designated representatives can enroll patients in the REMS program. "Unless a pharmacist is a prescriber designee, a pharmacist is no longer permitted to enroll patients in the Clozapine REMS Program or view a list of patients on clozapine," according to the document, *What's New with Clozapine: An Overview*.

PDA requirement for outpatient pharmacies

Before dispensing clozapine, outpatient pharmacies must obtain a predispense authorization (PDA) from the REMS Program by December 14, 2015. The PDA is an electronic code that ensures that the prescriber and pharmacy are certified in the Clozapine REMS Program and that the patient is enrolled in the program. Also, the PDA confirms that the ANC is up to date and within the acceptable guidelines to continue clozapine treatment or the prescriber has authorized the continued treatment of the atypical antipsychotic.

Inpatient pharmacies are not required to obtain a PDA from the Clozapine REMS Program before dispensing the drug. However, inpatient pharmacies need to verify patient enrollment, provider certification, and the patient's ANC and prescriber authorization by signing into the website, www.clozapinerems.com or calling the Clozapine REMS Program contact center at 844-267-8678. The patient's ANC and prescriber authorization can also be verified by reviewing the patient's electronic medical record.

Changes to neutropenia monitoring

Patients taking clozapine must now be monitored for neutropenia using absolute neutrophil count (ANC) only. Monitoring using white blood cell (WBC) counts is no longer acceptable, FDA stated.

In addition, the ANC thresholds for continued treatment of clozapine are now lower, allowing more patients to be treated with the drug. For patients in the general population, clozapine treatment should be interrupted if neutropenia is suspected and the ANC drops below 1000 cells/µL. For individuals with benign ethnic neutropenia (BEN), clozapine treatment should be stopped if neutropenia is suspected and the ANC is less than 500 cells/µL.

"The requirements for ANC are being modified so that patients will be able to continue on clozapine treatment with a lower ANC, a change that will allow continued treatment for a greater number of patients. In addition, patients with benign ethnic neutropenia (BEN), who were not eligible for clozapine treatment, will now be able to receive the medicine," according to the Agency.

With these new recommendations, FDA stated that prescribers can continue treatment with clozapine even though the ANC is less than 1000 cells/µL if it is determined that the benefits of the drug outweigh the risk of severe neutropenia.

"Patients may be re-challenged if the prescriber determines the risk of psychiatric illness is greater than the risk of severe neutropenia," FDA noted in its drug safety communication.

FDA plans to discontinue the National Non-Rechallenge Master File on October 12, 2015. This file included patients whose WBC count dropped below 2,000 cells/µL or had an ANC less than 1,000 cells/µL. All patients that were in the master file will be transferred to the Clozapine REMS Program.

For more information, visit the Clozapine REMS Program website, www.clozapinerems.com, or call for more information about the program, 844-267-8678.

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