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What are the important changes for how clozapine is prescribed and dispensed?



Starting October 12, 2015, ALL clozapine products are only available through the Clozapine REMS Program

The Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program replaces all individual clozapine patient registries. It includes all clozapine products under one shared program and provides a centralized point of access to minimize the risk of severe neutropenia associated with the use of clozapine.



STARTING OCTOBER 12, 2015

- **Prescribers** and **pharmacies** must certify in the shared Clozapine REMS Program. You can no longer enroll or manage patients through the other clozapine patient registries.
- All other clozapine **patient** registries are discontinued.



Key changes to neutropenia monitoring recommendations and treatment algorithm

- **Absolute neutrophil count (ANC) is used exclusively for patient monitoring**
 - White blood cell (WBC) counts are no longer accepted
- **Patients with Benign Ethnic Neutropenia (BEN) can be treated with clozapine and have a separate ANC monitoring algorithm**
- **ANC thresholds to continue clozapine treatment are lower**
 - For General Population patients, interrupt treatment if neutropenia is suspected to be clozapine-induced for ANC less than 1000/ μ L
 - For patients with BEN, interrupt treatment if neutropenia is suspected to be clozapine-induced for ANC less than 500/ μ L
- **Substantial drops in ANC do not require action unless the patient experiences neutropenia**
- **Prescribers have greater flexibility to make patient-specific decisions** about continuing and resuming treatment in patients who experience moderate and severe neutropenia
 - Prescribers can continue clozapine treatment for patients with an ANC less than 1000/ μ L if the prescriber believes the benefits of clozapine therapy outweigh the risk of severe neutropenia
 - **The National Non-Rechallenge Master File (NNRMF) is discontinued.** Patients may be re-challenged if the prescriber determines the risk of psychiatric illness is greater than the risk of severe neutropenia.



Key operational changes in the Clozapine REMS Program

- Social Security numbers are no longer used to identify patients
- Starting December 14, 2015, outpatient pharmacies are required to obtain a predispose authorization (PDA) from the Clozapine REMS Program before clozapine can be dispensed



Prescribers have new requirements to prescribe clozapine

- Prescribers or prescriber designees are responsible for enrolling patients and submitting ANC's
- When you must submit an ANC depends if your patient is an outpatient or an inpatient (see below)

OUTPATIENT

ANC must be reported to the shared Clozapine REMS Program before clozapine can be dispensed

INPATIENT

ANC must be reported to the Clozapine REMS Program within 7 days of the most recent blood draw



Pharmacies have new requirements to dispense clozapine

- Unless they are 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

For Outpatient Pharmacies

- Outpatient pharmacies must obtain a Predispose Authorization (PDA) from the Clozapine REMS Program before clozapine can be dispensed
- A PDA is an electronic code that indicates the Clozapine REMS Program has verified:
 - The prescriber is certified in the Clozapine REMS Program
 - The pharmacy is certified in the Clozapine REMS Program
 - The patient is enrolled in the Clozapine REMS Program
 - The ANC is current and acceptable according to the patient's monitoring schedule, or the prescriber has authorized the continuation of clozapine treatment

OUTPATIENT PHARMACIES

PDA REQUIRED?

Starting on December 14, 2015, outpatient pharmacies must obtain a PDA from the Clozapine REMS Program before clozapine can be dispensed

To VERIFY PATIENT ENROLLMENT and PRESCRIBER CERTIFICATION

Obtain a PDA one of three ways:

1. By enabling your pharmacy management system to support electronic communication with the Clozapine REMS Program
2. By signing into Clozapine REMS Program website at www.clozapinerems.com
3. By calling the Clozapine REMS Program contact center at 844-267-8678

To VERIFY ANC or prescriber authorization to continue clozapine

For Inpatient Pharmacies

- Inpatient pharmacies do not obtain a PDA from the Clozapine REMS Program before dispensing clozapine.

INPATIENT PHARMACIES	PDA REQUIRED?	To VERIFY PATIENT ENROLLMENT and PRESCRIBER CERTIFICATION	To VERIFY ANC or prescriber authorization to continue clozapine
	No.	<p>Before dispensing clozapine, verify this information in one of two ways:</p> <ol style="list-style-type: none"> By signing into the Clozapine REMS Program website at www.clozapinerems.com By calling the Clozapine REMS Program contact center at 844-267-8678 	<p>Verify this information in one of three ways:</p> <ol style="list-style-type: none"> By signing into the Clozapine REMS Program website at www.clozapinerems.com By calling the Clozapine REMS Program contact center at 844-267-8678 By reviewing the patient's medical record in their hospital's medical record

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What about my patients who are currently on clozapine?

If you are a prescriber currently treating patients with clozapine, you will have access to the Clozapine REMS program website for a grace period ending **November 2, 2015**. This will allow you to manage your current patients and minimize disruption. The Clozapine REMS Program will contact you to provide instructions of how to access the website.

Your patients' information was transferred into the Clozapine REMS Program. Once you create an account at www.clozapinerems.com, all patients you currently treat will be available through your prescriber dashboard on the website. After the end of the grace period, you must certify in the Clozapine REMS Program to continue accessing the information for your current patients through your prescriber dashboard. You do not need to reenroll your patients to continue clozapine treatment.

- Patient information before **October 1, 2012** was not transferred into the Clozapine REMS Program unless the patient was listed in the NNRMF
 - If another practitioner has treated the patient with clozapine in the past, you must enroll the patient one of two ways:
 - By signing in to the Clozapine REMS Program website at www.clozapinerems.com and enrolling the patient online
 - By downloading a *Clozapine REMS Patient Enrollment Form* from the Clozapine REMS Program website at www.clozapinerems.com and faxing the completed form to 844-404-8876

If you would like to inquire about a patient's clozapine history before enrolling the patient, please call the Clozapine REMS Program at 844-267-8678 for assistance.

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What do I need to do?

Prescribers - Get certified!

To certify, prescribers must:

1. Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
2. Successfully pass the *Knowledge Assessment for Healthcare Providers*
3. Complete and submit the one-time *Clozapine REMS Prescriber Enrollment Form*

Prescribers can allow designees to enroll patients and enter ANC's on their behalf.

Prescriber designees must enroll in the Clozapine REMS Program and a certified prescriber must confirm the designee.

Get certified online at www.clozapinerems.com or call 844-267-8678 for more information or to request materials.

Pharmacies - Get certified!

To certify a pharmacy, designate an authorized representative to:

1. Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
2. Successfully pass the *Knowledge Assessment for Healthcare Providers*
3. Complete and submit the appropriate pharmacy enrollment form (*Clozapine REMS Pharmacy Enrollment Form* or *Clozapine REMS Chain Headquarters Pharmacy Enrollment Form*)
4. Implement the necessary staff training and processes to comply with the Clozapine REMS Program requirements

Pharmacies with multiple locations must certify online and add each pharmacy location after training is completed for each location. Pharmacies certify through the Clozapine REMS Program website (www.clozapinerems.com) or call the Clozapine REMS Program at 844-267-8678 for more information.

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Where can I find more information?

Information about the Clozapine REMS Program, prescriber certification, pharmacy certification, patient enrollment, other Clozapine REMS Program requirements and tools are available online at www.clozapinerems.com or by contacting the Clozapine REMS Program at 844-267-8678.

Visit www.clozapinerems.com to view the new Clozapine REMS Program patient management portal, resource pages, and specific requirements and instructions for prescribers and pharmacies who wish to prescribe or dispense clozapine.