

Clozapine REMS

Pharmacy Outreach

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Agenda

Clozapine REMS

- Overview of the REMS modifications – FDA
- Overview of the implementation of the REMS modification – Clozapine Products Manufacturer Group (CPMG)
- Questions and Answers



Why did the FDA approve this modification?

Clozapine REMS

- The Clozapine Manufacturers proposed a modification to the Clozapine REMS that included changing their REMS vendor and developing a new REMS web platform
- Changes were also made to:
 - Address issues with potential patient access issues due to the requirements for reporting the absolute neutrophil count (ANC)

The modification to the Clozapine REMS was approved on July 29, 2021.
The modification will be fully implemented on Nov 15, 2021

Who is impacted by the modification?

Clozapine REMS

Stakeholders that are impacted

- Prescribers
- Pharmacists

Patients do not need to take any actions

- Prescribers will need to enroll their patients in the new REMS



The *new* Patient Status Form is used to document monitoring of the ANC

The **form** is used to document the monitoring frequency, ANC values, adverse events related to clozapine-induced neutropenia, and appropriateness to continue treatment.

Intended to:

- Prevent unintended interruptions in treatment for patients due to clerical delays with the requirement to document ANCs.

Due to these changes all prescribers will need to certify in the new REMS

Continue to monitor the patient's ANC as described in the Prescribing Information



Clozapine will only be dispensed with a PSF

Clozapine REMS

- The *PSF* must be submitted monthly in order for the pharmacist to dispense clozapine
- At day 31, the prescriber will be reminded that the form is overdue.
- At day 37, the patient will not be able to receive clozapine from the pharmacy until a PSF is received.

Important Changes for Pharmacies

Clozapine REMS

Changes for pharmacies include:

- **Removal of the switch system** to verify the safe use conditions
- The pre-dispense authorization is now called the **REMS Dispense Authorization** and verifies all the safe use conditions have been met.
- The pharmacist will need to access the new REMS website or the contact center to obtain a **REMS Dispense Authorization**, prior to dispensing clozapine.



Changes to the Verification of Safe Use Conditions

Clozapine REMS

RDA includes:

- Patient is enrolled in the REMS by a certified prescriber
- Pharmacy is certified in the REMS
- Monthly Patient Status Form completed by a certified prescriber is on file
- Patient's treatment is not interrupted or discontinued

REMS Dispense Authorization (RDA)

Must be obtained prior to dispensing clozapine

Dispense Rationale

Clozapine REMS

- If an RDA is rejected there will be an option to request a **Dispense Rationale** through the website or contact center.
- To obtain a **Dispense Rationale**, the pharmacist must have an ANC that was obtained in the last 30 days within the acceptable range.
- The pharmacist will need to provide the following to the REMS:
 - Prescriber's NPI number
 - Blood draw date
 - ANC value
- Dispense Rationales are limited to 3 per patient per year.

What do pharmacies need to do for patients treated in an inpatient setting?



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REMS program requirements for inpatients are not changing.

- For patients initiating clozapine in an inpatient setting, the initial prescription must be from a certified prescriber and the patient must be enrolled in the Clozapine REMS.
- For a patient continuing treatment in an inpatient setting, the pharmacist needs to obtain an RDA.
 - If the patient is enrolled but not authorized, the pharmacist will need to obtain a Dispense Rationale verifying there is a current ANC within the acceptable range.
- The PSF is not required in the inpatient setting as patients will be under the care of a health care provider.

Impact of the changes on patients

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- There are no changes to the requirements for patients.
- Patients need to continue to have their ANCs monitored as described in labeling.
- Prescribers will need to **enroll** all patients in the new program by **November 15, 2021**.

Patients should contact their prescriber if they have any questions.

What do Pharmacies need to do?

Clozapine REMS

- **Before November 15, 2021**
 - Authorized Representative must re-certify in the new REMS
 - Visit www.clozapinerems.com
 - Click on the **Important Program Update**
 - Follow the link to the new website

Where to find more information?

Clozapine REMS



Pharmacy outreach communications

- Authorized representatives for inpatient and outpatient pharmacies certified in the REMS will receive an email or letter
- Professional societies will be asked to disseminate information

Clozapine REMS Website

www.clozapinerems.com

What's Changed in the Clozapine REMS for Pharmacies? Factsheet

FDA Clozapine Website

<https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-clozapine>

Clozapine REMS Contact Center

1-888-586-0758