

Clozapine REMS

Prescriber 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 CPMG 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) and
 - Decrease burden on prescribers

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





Summary of important changes for prescribers and pharmacies

Stakeholder	Current REMS	New REMS Program Effective November 15, 2021
Prescribers	<p>Report ANC via the website or ANC lab reporting form</p> <p>ANC reporting frequency is dependent on patient's monitoring frequency (e.g., weekly, biweekly, monthly)</p>	<p>Report ANC using a <i>new</i> Patient Status Form (PSF)</p> <p>Document all the ANCs monthly in the PSF</p>
Pharmacies	<p>Dispensing based on timely reporting of ANC to the Clozapine REMS Program</p>	<p>Dispensing based on PSF being submitted</p>

The *new* Patient Status 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 interruptions in treatment for patients due to clerical delays with the requirement to document ANCs and
- Decrease burden on prescribers

Due to these changes all prescribers will need to enroll 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



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- 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.

In rare cases, to prevent treatment disruption, if the pharmacist has a current ANC within the acceptable range, they can use that to dispense clozapine to the patient no more than 3 times per year

What do prescribers 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 authorization.
- The PSF is not required in the inpatient setting as patients will be under the care of a health care provider.

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

The role of the prescriber designee

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A prescriber designee **may**

- Enroll patients
- Report ANCs,
- Complete the Patient Status Form that doesn't require a prescriber's signature

A prescriber designee **may not**

- Designate a patient as a Hospice Care patient
- Designate a patient as a Benign Ethnic Neutropenia patient
- Authorize the continuation of therapy if one or more required labs are missing
- Create a Treatment Rationale for a patient

What do prescribers need to do?

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Before November 15, 2021

- 1) Certify in the new REMS
- 2) Enroll all patients continuing clozapine in the new REMS
 - Visit www.clozapinerems.com
 - Click on the **Important Program Update**
 - Follow the link to the new website

Patient Management

- Continue to use the current program until November 15, 2021
- All **new patients starting clozapine** between now and November 15, 2021, must be enrolled in both the current program and the new program.

Where to Find More Information

Prescriber communications

- All certified prescribers 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 Prescribers?* 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