

CLOZAPINE (CLOZARIL) & CURRENT REGULATIONS

“NO BLOOD, NO DRUG”

- Clozapine is an atypical antipsychotic used for the treatment of schizophrenia or schizoaffective disorder. Since clozapine can cause severe neutropenia (absolute neutrophil count (ANC) <500 µL) which can lead to infection and death, specific guidelines must be followed if a person is to initiate and be maintained on the medication.
- Regulatory updates:
 - All prescribers AND pharmacies must certify in the Clozapine REMS program. The Clozapine REMS program is a shared program that incorporates all of the requirements to prescribe, dispense, and receive clozapine. Link to certification and more information on the requirements : www.clozapinerems.com

Prescriber Duties	Pharmacy Duties
Enroll: requires name, address, NPI, DEA numbers	Enroll
Educate: review the Clozapine & Risk of Neutropenia: A Guide of HealthCare Providers	Educate
Assess: complete the Knowledge Assessment	Assess
Enroll all patients in the Clozapine REMS Program	Implement: the necessary staff training and processes to comply with the program
Report patient ANC to the REMS Program for EVERY prescription of Clozapine	Must verify the prescriber is certified and the patient is enrolled, prior to dispensing clozapine
	Must verify ANC is current and acceptable for each patient prior to dispensing clozapine

**The Clozapine REMS Program replaces the individual clozapine patient registries and the National Non-Rechallenge Master File (NNRMF).

- The ANC (absolute neutrophil count) is used to monitor for clozapine-induced neutropenia. The prescriber **MUST** check and report the ANC prior to initiating therapy, and for the treatment duration. **NO BLOOD, NO DRUG!!!** For the general population with an ANC >1500 µL, the following frequency of ANC checks are required:
 - Weekly from initiation to 6 months
 - Every 2 weeks from 6-12 months
 - Monthly after 12 months
 - See specific guidelines for other populations and for treatment interruptions due to missed doses, fever, or low ANC.
 - The program will alert prescribers when a patient qualifies for a change in ANC monitoring frequency.
 - **NO BLOOD, NO DRUG**---a few doses to hold a patient over until the next blood draw are **NOT** allowed. If an ANC is not done and in the system, the drug will **NOT** be dispensed, per regulation. Ensuring the ANC is done and in the system in a timely manner, will ensure the patient receives the medication on time and does not incur a treatment interruption. The ANC bloodwork is good for 7 days, after which, a new level will need to be drawn.

Show What You Know

Clozapine (Clozaril) & Current Regulations

1) TRUE OR FALSE

You can refill a prescription for Clozaril without obtaining an ANC (absolute neutrophil count) first.

2) TRUE OR FALSE

A physician can order a prescription for Clozaril without being registered in the REMS system. Only the pharmacy needs to be registered.

3) HOW OFTEN SHOULD AN ANC BE OBTAINED DURING THE FIRST 6 MONTHS OF CLOZARIL THERAPY?

- a. An ANC only needs to be obtained once. As long as it's normal, it doesn't need to be rechecked.
- b. Weekly
- c. Monthly
- d. Every other month

4) TRUE OR FALSE

A patient's ANC is obtained on 9/1/17 and is uploaded to the REMS system. Level returned normal. A prescriber sends over an electronic prescription for Clozaril on 9/14/17. The pharmacy can go ahead and fill the prescription using the ANC level from 9/1/17.

5) WHO NEEDS TO BE ENROLLED IN THE CLOZARIL REMS PROGRAM?

- a. Patient
- b. Prescriber
- c. Pharmacy
- d. All of the above

How did you do?

ANSWERS:

1. False

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2. False

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3. B

For the general population with an ANC $>1500 \mu\text{L}$, ANC checks are required weekly from initiation to 6 months.

4. False

If an ANC is not done and in the system, the drug will **NOT** be dispensed, per regulation. The ANC bloodwork is good for 7 days, after which, a new level will need to be drawn.

5. D

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