

OUR LADY OF THE LAKE REGIONAL MEDICAL CENTER			
Policy Manual:	Pharmacy	Section:	Patient Care Services
Title:	Clozapine Dispensing & Monitoring	Policy Reference #:	PH-02-20
		Supersedes #:	
Date of Origination:	April 24, 2014	Last Date Reviewed:	February 24, 2019
Last Date Revised:	December 10, 2017		

PURPOSE:

To ensure Our Lady of the Lake Regional Medical Center is compliant with the monitoring and reporting requirements outlined by the Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program as required by the Food and Drug Administration (FDA).

DEFINITIONS:

The Clozapine REMS Program provides a centralized point of access for prescribers and pharmacies to enroll and manage patients on clozapine as well as certify before prescribing and dispensing clozapine. The purpose of the Clozapine REMS Program is to minimize the risk of severe neutropenia associated with the use of clozapine.

POLICY:

- I. The inpatient pharmacy is enrolled in the Clozapine REMS Program which allows the pharmacy to purchase and dispense clozapine. In compliance with the Clozapine REMS program, the pharmacy staff must enroll in the program in order to complete required eligibility checks before dispensing clozapine.
- II. Psychiatrists with privileges at the hospital must be certified with the Clozapine REMS Program in order to prescribe clozapine.
- III. Patients must be enrolled in the Clozapine REMS Program in order to receive clozapine while inpatient.
 - A. If a patient is not enrolled, a consult to psychiatry or a certified prescriber must be initiated in order to enroll the patient before they are eligible to receive clozapine.
- IV. Pharmacist must complete an eligibility check through the program website or by calling the contact center prior to dispensing clozapine. Patients prescribed clozapine as a continuation of home therapy must be registered in the Clozapine REMS Program.
 - A. Prescribers ordering clozapine for the continuation of patient's home therapy while receiving inpatient care will not be required to become certified with the Clozapine REMS program if the patient is already enrolled in the program.

- B. If the eligibility check is not successful, the pharmacist must contact the prescriber and/or psychiatrist. A certified prescriber must then enroll the patient in the Clozapine REMS program using the Clozapine REMS Program website in order to continue with therapy.
- V. A baseline complete blood count (CBC) with differential must be ordered prior to dispensing clozapine. If a baseline CBC with differential is not ordered, a pharmacist will order one that will be obtained within 24 hours from when clozapine was ordered.
- VI. Pharmacy will monitor the absolute neutrophil count (ANC) in accordance with the ANC monitoring schedule as outlined by the Clozapine REMS Program. (See appendix). Pharmacy can report the results by using the program website or calling the contact center.
- VII. The inpatient pharmacy will maintain an appropriate filing system of monitoring forms for all patients receiving clozapine therapy. Forms will be kept on file for three years.

REFERENCES:

Clozapine REMS Program. www.clozapinerems.com. Accessed February 24, 2019