

IREDELL HEALTH SYSTEM

Clozapine Dispensing Policy	
Approved by: Justin Beck, PharmD Laura Rollings, PharmD, BCPS, BCGP	Last Revised/Reviewed Date: 11/2021
P&T Committee	Date: 02/2019

Purpose:

To ensure that each patient who receives clozapine will be properly enrolled and monitored in the clozapine Risk Evaluation and Mitigation Strategy (REMS) program as per the requirements of the Food and Drug Administration (FDA).

Policy:

A pharmacist will monitor any patient receiving clozapine upon initiation of therapy and on weekly basis thereafter, or more frequently if necessary, as set forth by the FDA and Clozapine REMS Program.

Prior to dispensing clozapine, the pharmacist must verify that:

1. The patient is enrolled in the Clozapine REMS Program and eligible for clozapine dispensing
2. The ANC is current (reported within 7 days of blood draw) and acceptable according to the patient's monitoring schedule, or the prescriber has provided treatment rationale to authorize the continuation of clozapine treatment

Procedure:

To complete the above requirements, the pharmacist must:

1. Access the Clozapine REMS Program and verify the patient's eligibility via online or by phone.
 - a. Online at www.newclozapinerems.com
 - b. Phone at 1-888-568-0758

Prescribers who continue clozapine for patients during inpatient medical care and other related services for surgery, acute medical conditions, or injuries (usually for a short-term illness or condition) *will not* be required to become certified in the Clozapine REMS Program if the patient is already enrolled in the Clozapine REMS Program.

2. Verify that the ANC is current and acceptable according to the patient's ANC monitoring schedule, or the prescriber has authorized the continuation of clozapine treatment by entering ANC into the clozapine REMS. The pharmacist will contact the prescriber if the ANC is not acceptable according to the REMS protocol
3. All the patients receiving clozapine therapy at IMH will have weekly CBC with differential monitoring.
4. Pharmacists have the authority to write orders for laboratory tests related to clozapine monitoring which includes a CBC with differential. Upon initiation of therapy, orders will be entered for a CBC with differential STAT (if no labs currently available). These orders will be entered using the communication type "Protocol/Standing Order."
5. In order to aid the pharmacist in monitoring patients on clozapine a "Pharmacy Communication Order" should be entered in PowerChart with a frequency of "q week" and special instructions explaining that the patient is on clozapine and must have a weekly ANC ordered and evaluated. This communication order should be started 6 days after the initial ANC is drawn.
6. Each week a pharmacist will verify that each patient on clozapine has a current and acceptable ANC (or the prescriber has authorized the continuation of clozapine treatment). The pharmacist may enter the ANC if not already entered by the prescriber, and the pharmacist will verify

continued eligibility in the Clozapine REMS Program. The pharmacist will contact the prescriber if the ANC is not acceptable. The pharmacist will also enter an intervention in Pharmacy Medication Manager after the review is complete.

7. If the patient is either not enrolled or not eligible in the Clozapine REMS Program, the pharmacist must contact the prescriber and/or their clozapine REMS designee to determine the next course of action. The pharmacist will not dispense clozapine until the enrollment and eligibility are acceptable in accordance with the Clozapine REMS Program.

INITIAL EFFECTIVE DATE: 12/2015

DATES REVISIONS EFFECTIVE: 02/2019, 11/2021

DATES REVIEWED (no changes): 09/2018