RESTRICTIONS for Inpatient Ordering & Dispensing of CLOZAPINE
ALL DISPENSING MUST BE CLOSELY MONITORED AND DOCUMENTED
THERE WILL BE NO EXCEPTIONS

- Due to a black box warning regarding a significant risk of agranulocytosis, the FDA has mandated the use of a National Registry for all prescribers of clozapine and for all patients receiving clozapine.
- All patients must have a baseline WBC and ANC before initiation of therapy and regularly until 4 weeks after stopping therapy.
- The dispensing of clozapine is also controlled by the FDA -- via a distribution system that ensures monitoring of the WBC / ANC prior to delivery of the next supply of medication.
- The Pharmacy & Therapeutics Committee has added an additional restriction -- that only psychiatry faculty are authorized to prescribe or order clozapine for a University Health System patient.
- These FDA mandates and P&T restrictions have resulted in the following Pharmacy policies and procedures:

1. Orders in Sunrise must be ordered on behalf of the Psychiatry Faculty Attending Physician who approved the use of the drug.

2. If patient is not on the Psychiatry Service, a consult must be obtained.

3. Each prescribing Faculty Physician must be registered with the national registry for the brand being prescribed.

4. The prescribing physician must also register the patient with the National Registry. A member of the clinical team may register the patient on behalf of the faculty – if the faculty gives that person their DEA number.

5. During the registration process, the patient must be assigned to a dispensing pharmacy using the pharmacy’s DEA number. The prescribing physician may call pharmacy to get the Inpatient Pharmacy DEA number (AM1472579-IP). Or the prescriber may choose to get the DEA from the registry. The name used in the registry is University Hospital Inpatient Pharmacy

6. Staff Pharmacists will not register the patient nor will they give a faculty DEA number to a resident. (Rare exceptions are discussed below)

7. The prescribing physician is also responsible for entering the WBC / ANC lab results or assigning a member of the clinical team to do so. The drug cannot be dispensed without this information being entered in the registry.

8. Treatment should not be initiated if WBC < 3.5 k/µL. Clozapine cannot be dispensed if the WBC < 3 k/µL or if the ANC < 0.5 k/µL.
9. It is preferred that the WBC / ANC be entered on-line by the physician or a member of the clinical team. However, a WBC form (downloaded from the registry) will still be accepted via FAX until everyone becomes experienced with the on-line registry.

10. If patient is being titrated up or down, a WBC / ANC is required every week, and the amount dispensed will allow doses to be given up to one week after the last WBC / ANC result entered into the registry.

11. Preferred Pharmacy dispensing will be between the hours of 0800 and 1600 Monday thru Friday because the Teva clozapine registry is readily available by phone during those hours.

12. To register patients by phone after hours the provider can page a Registry Case Manager 24 hours a day | 7 days a week | 365 days per year by calling 800-507-8334.

13. If there is a true emergency that requires dispensing after hours and on weekends without all the requirements specified above, the on-call Psychiatry attending must call the inpatient pharmacist at 358-2902 to explain the circumstances.

14. Only a 7-day supply can be dispensed (unless patient is stable for 6 months)

15. All dispensing must be recorded in notebook next to the drug supply (in the investigational drug room). There are two dispensing logs [May change later]:
   - CLOZAPINE 25 mg unit dose
   - CLOZAPINE 100 mg unit dose

16. The dispensing pharmacist must check the website before dispensing to assure that the MD and the patient are registered and that the WBC / ANC data is entered and up to date. If the website is down, or access to the Internet is down, the dispensing pharmacist must call the registry.

17. When recording dispensed amount in logbook, enter the WBC and result date.

Revised December 7, 2011
Important Information about TEVA CLOZAPINE

PHONE NUMBER: 1-800 507-8334
(8 AM – 5 PM Eastern Time – located in Miami, Florida)
To register patients by phone after hours you can page a Case Manager 24 / 7 / 365 by calling 800-507-8334.

WEBSITE:  https://www.clozapineregistry.com/

Inpatient Pharmacy DEA number: AM1472579-IP

Login ID for Pharmacists:    ippharm
Password:                    ippharm1