

**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 μ L. Clozapine cannot be dispensed if the WBC < 3 k μ L or if the ANC < 0.5 k μ L.**

- 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