

NORTHERN NEVADA ADULT MENTAL HEALTH SERVICES
POLICY AND PROCEDURE

SUBJECT: CLOZAPINE PROTOCOL

NUMBER: NN-MM-29

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APPROVAL- Cody L. Phinney, Agency Director

I. PURPOSE

To establish a procedure for the administration and management of Clozapine at Northern Nevada Adult Mental Health Services (NNAMHS)

II. POLICY

Due to the serious side effects of Clozapine, it's use, shall be reserved for the treatment of severely ill consumers with schizophrenia or schizoaffective disorder who have failed to respond adequately to treatment with two appropriate trials of a class I anti-psychotic drug, either because of lack of efficacy or the inability to obtain an effective dose due to intolerable adverse effects from those drugs or the presence of Tardive Dyskinesia.

III. REFERENCES

1. Northern Nevada Adult Mental Health Services Policy
NN-RI-10 Informed Consent for Medication

2. Division of Mental Health and Mental Developmental Services policy
 - 4.015 Obtaining, Use and Documentation of Formulary
Approved Medication including Clozapine

IV. PROCEDURE

1. Clozapine is an atypical anti-psychotic medication indicated for the management of severely ill consumers.
2. Clozapine carries five black box warnings.
 - a. Agranulocytosis
 - b. seizures
 - c. Myocarditis
 - d. other adverse cardiovascular and respiratory effects
 - e. an increase in mortality in elderly patients with dementia
3. Clozapine is contraindicated for consumers with Myeloproliferative disorders, a history of Clozapine induced Agranulocytosis, severe Granulocytopenia, or consumers receiving other marrow suppressing medication, particularly Carbamazepine, or severe central nervous system depression.
4. All consumers to be given a trial on Clozapine will have the following forms completed:
 - a. Clozapine Protocol Form, (See Clozapine Protocol forms) completed by the prescribing physician and the pharmacy staff, and a signed consumer consent form for treatment. A copy of each will be kept in the consumer's chart and on file in the pharmacy.
 - b. Clozapine checklist to be completed by the Service Coordination Nurse assigned to the consumer by Service Coordination Supervisor when notified of pending Clozapine candidate. Original will be sent to the pharmacy after completed

prior to any Clozapine being filled. A copy will be placed into the chart.

5. Prior to the administration of Clozapine, the following screens must be performed:
 - a) A complete blood count must be obtained within seven (7) days of the first administration of Clozapine with a white blood cell count (WBC) >3,500 and an absolute neutrophil count (ANC) >2000.
 - b) A metabolic pre-screening within the previous week that shows no contraindication for Clozapine therapy.
 - c) The prescriber will ensure the consumer has been assigned to a service coordinator (Service Coordination, Mental Health Court, or PACT), and has stable housing and regular transportation to the laboratory before prescribing Clozapine.
 - d) The Pharmacist will complete the Clozapine Registration Form (see Clozapine Forms) or all authorized prescribers and will transmit the information to the Clozapine Registry or equivalent registry.
 - e) The pharmacy staff will transmit information to the Clozapine registry, and complete the Clozapine WBC Monitoring Form - An "Authorization Code Number" will be obtained and entered on the Clozapine Protocol Form (See Clozapine Forms) a copy of the completed form will be returned to the prescriber who will then write a maximum seven (7) days prescription or order.
6. Physician's orders for weekly white blood cell counts must be sent to the lab before a prescription or order is sent to the pharmacy staff. Outpatients prescribed Clozapine will be registered with the agency laboratory or agency approved laboratory and the initial order for WBC will be written to cover weekly WBC's at the laboratory for six months.
7. After six months of continuous Clozapine treatment and acceptable

WBC levels, the prescriber may elect to order laboratory testing for WBC at Bi- monthly intervals. The prescriber may elect to order laboratory testing monthly after one year of stable WBC counts. The laboratory and the pharmacy staff should both be notified if this is to occur, to prevent delays in dispensing.

8. The prescriber will review the weekly WBC and a copy of this review will be transmitted directly to the pharmacy staff. The pharmacy staff will transmit the WBC to the “Registry”. The National Registry Reporting Form may be used for this function but other means are acceptable. An acceptable WBC count will permit the consumer to receive a maximum seven (7) day prescription or order for the first 6 months of treatment. Fourteen (14) day prescription or order after the first six (6) months and thirty (30) day prescription or order after one full year.
 - a) An “acceptable WBC” value for a consumer on Clozapine is a total WBC greater than 3,500 with an ANC count over 2,000.
 - b) If the WBC falls below 3,500, or three successive WBCs show consistent decline of 3,000 (total) with a WBC remaining above 3,500, the prescriber must reconsider the Clozapine therapy and document in the chart this change in WBCs, along with the rationale for the decision to continue or discontinue therapy; these parameters do not necessarily represent an indication for stopping Clozapine therapy.
 - c) If the total WBC falls below 3,000 or the ANC falls below 2,000, Clozapine therapy should be interrupted. WBC and differential counts should be performed daily and the consumer should be carefully monitored for flu-like symptoms or other symptoms suggestive of infection.
 - d) d). Therapy may be resumed if no symptoms of infection develop and the WBC returns to levels above 3,000 and the

ANC returns to levels above 2,000. However, in this event, twice-weekly WBCs and differential counts should continue until the total WBC returns to levels above 3,500. Algorithm should be utilized to restart the medication.

- e) Any WBC value of less than 2,000 or ANC below 1,000 while on Clozapine is “unacceptable” and Clozapine therapy must be discontinued immediately and permanently. The consumer should never again be re-tried on Clozapine. A hematology consultation is to be obtained immediately for further treatment recommendations.
9. Upon approval of Clozapine for therapy, the pharmacy staff will dispense the medication according to the following protocols.
- a) Inpatients will have their medication supplied in the usual manner, except that a consumer must have an acceptable WBC result drawn within the seven days preceding the current day’s dosing. No medication will be dispensed to a consumer with an unacceptable WBC.
 - b) Outpatients will have their prescriptions filled in weekly, biweekly or monthly installments, according to the above protocol. The consumer must have a WBC result drawn within the preceding seven (7) days or fourteen (14) days. No medication will be dispensed to a consumer with an unacceptable WBC.
 - c) The pharmacy staff will transmit the information required weekly to the Registry.
10. When Clozapine is discontinued, four (4) weekly WBCs will be obtained after the drug is stopped and these will be reported to the prescriber. The information will also be sent weekly to the Registry.
11. When Clozapine is discontinued, the psychiatrist will complete the top half of the Discontinuation Form, or equivalent (See Clozapine Protocol

Forms) and forward it to the Pharmacy and Therapeutics (P & T) Committee. The committee will send the form to the Medical Director who will sign it and send it to the pharmacy staff. The pharmacy staff will inform the Registry and send the original to Medical Records for filing in the consumer's chart and retain a copy in the pharmacy staff.

12. See the following in the Clozapine Protocol Form folder on the

NNAMHS Desktop links:

- a. MR226 Clozapine Protocol Form
- b. MR227 Discontinuation Form
- c. Clozapine Registration Form
- d. Clozapine Checklist