

Ventura County Medical Center & Ventura County Behavioral Health Clinical Practice Guideline for Prescribing and Monitoring Clozapine

The contents of this clinical practice guideline are to be used as a guide. Healthcare professionals should use sound clinical judgment and individualize patient care. The CPG is not meant to be a replacement for training, experience, CME or studying the latest literature and drug information.

All patients prescribed clozapine are treated and monitored in a manner consistent with the Food and Drug Administration (FDA) requirements.

1. Indications for clozapine treatment.

- a) Treatment refractory schizophrenia-meets current edition of DSM criteria of schizophrenia or schizoaffective disorder.
 - i) The patient has had at least two drug treatment trials with other antipsychotic agents.
 - ii) The patient has risk of or evidence of recurrent suicidal behavior in schizophrenia or schizoaffective disorder.
 - iii) Patients with tardive dyskinesia who require treatment with antipsychotics.

2. Relative contraindications for use of clozapine.

The Medical Director or Physician Coordinator (VCBH outpatient) is consulted if necessary.

- a) Previous hypersensitivity to clozapine.
- b) History of clozapine-induced agranulocytosis or severe granulocytopenia.
- c) Medical condition or drug associated with myeloproliferative disease or immunosuppression.
- d) Severe medical condition or other illnesses causing central nervous system depression or comatose states from any cause.
- e) Seizure Disorder
- f) History of Paralytic Ileus

3. Procedures completed by the prescriber in order to be able to prescribe clozapine.

Complete procedures as required by FDA (see link to website).

4. Prescribing of clozapine

Complete procedures as required by FDA (see link to website)

- b) All clozapine prescriptions are written for a weekly, biweekly or 28-30 day supply of medication; quantity of medication prescribed is based upon lab review schedule.
- b). ALL prescriptions written for clozapine will be written for **NO REFILLS**.
- c). (VCBH Outpatient) All individuals prescribed clozapine will be informed of the lab work (blood draw) requirements while on clozapine. All individuals prescribed clozapine, along with their treating psychiatrist, will sign the "Acknowledgment of Required Lab Work" form (See *Acknowledgment Form*).

5. Outpatient New Starts

- a. Obtain baseline ANC, baseline metabolic panel, baseline vital signs.
- b. Consider baseline EKG or obtain a copy of one completed within the last year.
- c. Consider daily or routine contact with nursing staff to obtain vitals (BP, pulse) during dose titration.
- d. Regular contact with prescriber and clozapine team during dose titration. After this, face-to-face contact is at discretion of prescriber.

5. Use of clozapine serum level-Routine ordering of clozapine serum level is not generally recommended. Considerations for ordering a level may include:

- e. Poor clinical response at typical/therapeutic dose.

- f. When on concomitant agents (e.g. Enzyme inducers, enzyme inhibitors, etc.) that can potentially alter clozapine serum levels.
 - g. In new starts, to help guide dosing adjustments and establish a serum level that is expected to result in a therapeutic response.
 - h. When a patient is having intolerable adverse effects at usual therapeutic doses.
 - i.
6. Coordination with VCMC Inpatient Psychiatric, Medical and Surgical Units, Crisis Residential Treatment Center (CRT) and in-County Mental Health Rehabilitation Centers (MHRC)
- a). At the time of discharge the staff at these facilities will contact the clozapine physician at the receiving facility.
 - b) In the event that a clozapine client is admitted at one of these facilities, designated staff at these units will contact the outpatient psychiatrist by the next working day and confer with the outpatient team.
 - c) Patients are referred for clozapine treatment to the Clozapine Treatment Team (CTT) at the facility where the patient will receive follow up.
 - d) At discharge staff communicates with the outpatient clinic and provides information on the results of the last lab test completed and ensures patient receives an adequate supply of medication to last until the patient is able to be seen at the outpatient clinic. (See attached document-Clozapine History)
7. VCBH Outpatient Clozapine Team Responsibilities
- a) Each Outpatient Adult Behavioral Health Clinic will adhere to the procedures described in the Clozapine Team Responsibilities - (VCBH Policy PH48.)

Links to website: www.clozapinerems.com

Approvals:
Psychiatry: 09/2014; 11/2015; 03/2017
MEC: 12/2014; 12/2015; 04/2017
Oversight: 05/2017

Ventura County Behavioral Health

CLOZAPINE HISTORY

(Required on all transferring clozapine patients)

1. Current dosage and dose form (dissolving or regular tablets);
2. How long on this dose?
3. Is this the maintenance dose, or is the patient undergoing titration?
4. What is the interval of ANCs (7, 14, or 28 days)?
5. How long on this schedule?
6. Has there been any neutropenia as defined by the Clozapine REMS or untoward events during the previous 12 months?
7. Is there evidence that clozapine is effective, and more effective than other antipsychotics?
8. Are copies of AT LEAST the last 4 ANCs sent? As well as copies of the most recent general labs (metabolic, thyroid, and lipids)?
9. Is the patient taking any other antipsychotics? If so, why?
10. If clozapine serum level was obtained-indicate rationale for ordering level, date ordered, result and any action taken.
11. How much medication is client being discharged with?

Approvals:

Psychiatry: 2014; 11/2015; 03/2017

MEC: 2014; 12/2015; 04/2017

Oversight: 05/2017