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HealthWest
Muskegon's Behavioral Wellness Connection

Procedure Title: Clozaril/Clozapine Treatment System (CTS)	**Procedure#:** 06-016	**Review Dates**	
Category: Medical **Subject:** To establish procedures for prescribing, monitoring, administering, and documenting Clozaril/Clozapine in compliance with FDA and clinical standards.	**Prepared by**: Name: Greg Green MD Title: Medical Director **Approved by:** DocuSigned by: Rich Francisco AA7EBD48ABB04A3... Rich Francisco, Executive Director		
	Effective Date: 10/01/2002	**Last Revised Date:** 06/24/2026	

I. PURPOSE/POLICY

To ensure safe, compliant prescribing, monitoring, dispensing, and documentation of Clozaril/Clozapine in accordance with FDA Clozapine requirements and clinical standards.

II. APPLICATION

Applies to all staff involved in Clozaril/Clozapine treatment, including prescribers (physicians, PAs, NPs), nursing staff, case/support coordinators, pharmacy, laboratory personnel, and support staff.

III. DEFINITIONS

1. **ANC**: Absolute Neutrophil Count used to assess risk of neutropenia.
2. **Clozaril/Clozapine Treatment System (CTS):** A coordinated system of care that includes the prescriber, RN Care Manager, Supports Coordinator, pharmacy, laboratory, and other support staff responsible for ensuring safe Clozapine therapy through required ANC monitoring, medication management, communication, and documentation throughout treatment.
3. **HealthWest Clozaril/Clozapine Clinic**: A clinic occurring at a HealthWest location that the individual attends to receive medication monitoring by an RN, ANC draw by the laboratory, and Clozaril/Clozapine dispensing by the pharmacy.
4. **Neutropenia**: A medical condition characterized by a reduced number of neutrophils (a type of white blood cell) in the blood, which impairs the body's ability to fight infection.
5. **BEN (Benign Ethnic Neutropenia):** Lower baseline ANC in certain populations requiring adjusted monitoring thresholds.

IV. PROCEDURE

1. Pretreatment Requirements
    a. Prescriber confirms clinical indication and prior treatment failure.
    b. Obtain informed consent and provide education on risks and monitoring requirements.
    c. Baseline ANC within 7 days prior to initiation:
        i. ≥1500/μL (general population)
        ii. ≥1000/μL (BEN population)
    d. RN coordinates lab work and communicates results to prescriber.
    e. Case Manager ensures individual readiness and coordination of care.

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2. Initiation of Treatment
    a. Prescriber issues prescription and standing ANC monitoring orders.
    b. RN documents baseline assessment, vital signs, and medication reconciliation.
    c. Pharmacy reviews for drug interactions.
    d. Individual is enrolled in monitoring schedule per guidelines:
        i. Weekly (first 6 months)
        ii. Every 2 weeks (6–12 months)
        iii. Monthly (after 12 months)

3. Active Treatment Monitoring
    a. The frequency of monitoring WBC and ANC results, per the current FDA (Food and Drug Administration) recommendations, will be followed.
    b. RN ensures labs are being drawn as required. A ninety (90)-day order for Clozaril/Clozapine may be submitted to the pharmacy for a one, two or four week supply if no change in dosage is anticipated. A new prescription must be written minimally every ninety (90) days and submitted to the pharmacy.
    c. The Physician/PA/NP sees the individual for medication reviews as needed, minimally every ninety (90) days. Clozaril/Clozapine dosage is adjusted as needed.
    d. Prescriptions for increases or decreases in Clozaril/Clozapine are sent to the pharmacy utilizing the electronic health record. The pharmacy is requesting that any time we increase the Clozaril dose in between dispense dates, we are to do a Clozaril prescription to bridge until the actual dispense due date for the regularly scheduled Clozaril clinic.
    e. On the appropriate Wednesday, the individual proceeds to the designated lab and pharmacy or clinic location for blood draw and medication. If the individual is not capable of doing this independently, they will be escorted by a HealthWest staff or home staff person.
    f. The assigned RN will be responsible for monitoring the individual's vital signs, assessing for medication effectiveness/side effects, and providing support. Monitoring will occur weekly during the first month of initiation and every 90 days thereafter. Generally, Clozapine treatment should be interrupted, as a precautionary measure, in any patient who develops a fever of 101.3 degree F or greater, and the ANC should be obtained.
    g. RN is responsible for communicating changes to the Medical Technician and pharmacy. If additional routine laboratory work has been ordered, the RN will notify the Medical Technician so the draw can coincide with the scheduled WBC/ANC draw.
    h. The team RN is responsible for the updating of all information on the HealthWest Clozaril/Clozapine list. This list will be used to identify individuals who have failed to come in for their blood test or medication.
    i. The Medical Technician or designee sends a copy of the Clozaril/Clozapine list to all RN's and front desk staff.
    j. The Physician/PA/NP will write an order to change the frequency of WBC and ANC monitoring to every two (2) weeks for six (6) months after six (6) months of therapy has been completed if WBC and ANC results have remained normal.
        i. The RN will notify the Medical Technician or designee and pharmacy of the change in monitoring frequency.
        ii. Pharmacy will provide a two-week supply of medication to the individual.
    k. The Physician/PA/NP will write an order to change the frequency of WBC and ANC monitoring to monthly after twelve (12) months of therapy has been completed if WBC and ANC results have remained normal.
        i. The RN will notify the lab and pharmacy of the change in monitoring frequency.

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ii. The pharmacy will supply a one (1)-month supply of medication to the individual.

4. Response to Abnormal ANC Count
    a. General Requirements
        i. All abnormal ANC results must be reviewed by the RN and prescriber immediately upon receipt.
        ii. The RN ensures timely communication to the prescriber, SC, pharmacy, and lab as appropriate.
        iii. All actions, decisions, and communications must be documented in the clinical record.

5. Mild Neutropenia (ANC 1000–1499/uL)
    a. General Population:
        i. Continue Clozapine treatment.
        ii. Increase monitoring frequency to three (3) times weekly until ANC ≥1500/uL.
        iii. Upon normalization, resume prior monitoring schedule.
    b. RN Responsibilities:
        i. Notify prescriber and SC within the same business day.
        ii. Educate individual on infection risk and symptoms.
        iii. Monitor vital signs and overall condition as ordered.
    c. Prescriber Responsibilities:
        i. Evaluate need for dosage adjustment.
        ii. Consider hematology consultation based on clinical presentation.

6. Moderate Neutropenia (ANC 500–999/uL)
    a. General Population:
        i. Interrupt treatment immediately for suspected Clozapine-induced neutropenia.
        ii. Order daily ANC testing until ≥1000/uL, then 3x weekly until ≥1500/uL.
        iii. Resume treatment only after normalization and clinical reassessment.
    b. RN Responsibilities:
        i. Notify pharmacy to place medication “on hold.”
        ii. Ensure individual stops medication immediately.
        iii. Coordinate daily lab monitoring and follow-up.
        iv. Communicate status to SC and care team.
    c. Prescriber Responsibilities:
        i. Document treatment interruption and rationale.
        ii. Determine plan for re-initiation.
        iii. Recommend hematology consultation.

7. Severe Neutropenia (ANC <500/uL)
    a. Immediate discontinuation of Clozapine is required.
    b. RN or prescriber must contact the individual immediately to stop medication.
    c. Monitoring and Care:
        i. Daily ANC until ≥1000/uL, then follow stepwise recovery monitoring.
        ii. Initiate appropriate medical evaluation and referral within 24 hours.
    d. Key Actions:
        i. Notify pharmacy, lab, and internal staff within 24 hours.
        ii. Flag record for Clozapine-related agranulocytosis risk.
        iii. Rechallenge only if prescriber determines benefits outweigh risks, with full documentation.

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8. Communication & Documentation
    a. RN ensures all abnormal ANC results are:
        i. Communicated to pharmacy and care team
    b. Case Management (CSM) ensures individual understanding and adherence to updated plan.

9. Continuation of Clozapine Treatment During Hospitalization
    a. General Requirements
        i. All hospitalizations must be communicated immediately to:
            1. RN Care Manager
            2. Prescriber
            3. Pharmacy
            4. Lab
            5. Clerical staff (for status updates)
        ii. Patient status must be updated to:
            1. “On Hold” or “Interrupted” during admission
            2. “Active” upon return to outpatient CTS

10. Psychiatric Hospitalization
    a. Before/At Admission:
        i. HealthWest staff communicate:
            1. Current Clozapine dose
            2. Recent ANC results
            3. Monitoring requirements
    b. During Hospitalization:
        i. Coordination occurs between inpatient team and HealthWest as needed.
    c. At Discharge:
        i. CSM/RN ensures:
            1. Current WBC/ANC results obtained
            2. Updated prescription secured
            3. Discharge summary received same day
    d. Post-Discharge Requirements:
        i. Individuals seen by HealthWest prescriber/RN within 14 days.
        ii. RN resumes outpatient monitoring schedule.
        iii. Pharmacy dispensing resumes requirements.

11. Medical Hospitalization
    a. Prescriber/RN consult with treating medical team regarding:
        i. Medication continuation or interruption
        ii. Risk of neutropenia and infection
        iii. Written authorization required for information sharing (unless emergent).
    b. If Clozapine is Continued:
        i. Coordinate lab monitoring with hospital team.
    c. If Interrupted:
        i. Follow clinical guidance for re-initiation timing and monitoring.

12. Transition Back to Outpatient CTS
    a. RN confirms:
        i. Updated ANC status
        ii. Documentation Complete
        iii. Pharmacy has current prescription
    b. Clerical staff updates Clozapine tracking list
    c. CSM ensures continuity of care and appointment scheduling.

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13. Medication Handling
    a. Any pre-admission Clozapine must be:
        i. Returned to RN/SC
        ii. Disposed of per policy
    b. Ensure no duplication of supply occurs during transitions.

14. Non-Compliance
    a. Missed labs or appointments require immediate outreach.
    b. If unresolved within 3 days, consider treatment suspension.
    c. Document all attempts and decisions.

Authors Initials HD/hb