HEALTHWEST

Policy and Procedure

No. 06-010

Prepared by:

Cyndi Blair, RNBC
Chief Clinical Officer

Effective: June 1, 1989
Revised: March 6, 2018

Approved by:

Subject: Medication Management

Justin Bensinger, Consulting Pharmacist

Julia B. Rupp, Executive Director

I. POLICY

Medications listed on the HealthWest Formulary and deemed medically appropriate for individuals receiving services at this agency will be prescribed and managed in a safe and effective manner.

II. PURPOSE

To establish policies and procedures for prescribing, monitoring, administering, storing, and documenting the use of medications.

III. APPLICATION

All programs operated by the HealthWest Board of Muskegon County or contracted providers as identified in their contract. This policy does not supersede or replace licensing requirements, but rather supplements any state and federal regulations which apply.

IV. DEFINITIONS

A. SERIOUS ADVERSE DRUG REACTION: Any adverse event occurring at any medication dose that results in any of the following outcomes: death, a life-threatening adverse experience, inpatient hospitalization, or prolongation of an existing hospital stay, a persistent or significant disability/incapacity, or a congenital anomaly or birth defect, or requires medical or surgical intervention to prevent permanent impairment or damage to the individual receiving services.

B. INDIVIDUAL RECEIVING SERVICES: Any person receiving mental health services at HealthWest.

C. INVOLUNTARY INDIVIDUAL: An Individual receiving services under Probate Court-ordered treatment.

D. RECORD: The individual's Electronic Clinical Record (ECR).

E. MEDICATION: Prescription medications given for the treatment of psychiatric disorders, or for treatment of side effects of psychotropic medications, or any medications stored or administered by HealthWest staff or kept on HealthWest premises.

F. PHYSICIAN: An M.D. or D.O. licensed in Michigan, and under contract with HealthWest.

G. PA: Physician's Assistant licensed in Michigan and under contract with HealthWest.

H. NP: Nurse Practitioner licensed in Michigan, and employed or under contract with HealthWest.

I. NURSE: Registered Nurse (RN) licensed in Michigan.

J. HP: Health Professional – Physician, PA, NP, or Nurse.

K. PRIMARY WORKER: Supports Coordinator (SC), primary therapist, or other clinical staff person who is assigned primary responsibility for case coordination.

L. PSYCHOTROPHIC DRUG: Any medication administered for the treatment or amelioration of disorders of thought, mood, or behavior.

M. STAT: Immediately.

V. PROCEDURES

Overview of Sections:

A. General
B. Documentation
C. Prescriptions
D. Administration and Storage
E. Medication Teaching Sheets
F. Informed Consent
G. Involuntary Movements
H. Specific Medications
I. Laboratory Monitoring Guidelines for Psychotropic Medications
J. Antidepressant Medication for Children and Adolescents
L. Medications for Behavior Management
M. Serious Adverse Drug Reactions
N. Medical Abbreviations and Symbols
O. Quality Assurance

A. GENERAL

1. Medication shall be prescribed only by a Physician, PA, or NP under the supervision of a physician.

   a. All such HealthWest/IHC Physician/PA/NP shall demonstrate competency with medications through medication utilization studies, peer review, pharmacy and therapeutic reviews, and record pertinence.

   b. Medication regimens must be determined by considering the individual's diagnosis, age, sex, weight, physical condition, other illnesses, other medications, and previous medication history including history of adverse side effects or reactions.

   c. The HealthWest/IHC Physician/PA/NP or nurse must directly assess the individual as frequently as necessary to establish a maintenance dosage, decrease or eliminate target symptoms, and monitor for side effects of medications.

   d. Medications shall be maintained at the minimum dose necessary to decrease or eliminate target symptoms. Once a maintenance dosage is reached, direct contact with a HealthWest/IHC Physician/PA/NP shall be scheduled at least every three months for the purpose of documenting the continued need for medication as well as the presence/absence of side effects. If the individual is treated in a HealthWest residential setting, the individual's medication shall be reviewed at least once every thirty (30) days by a HP to determine the appropriateness of continued use.

   e. All medication reviews shall be documented in the record as a progress note or psychiatric evaluation.

   f. Medications prescribed for an individual shall be given to and used only by that individual.

   g. No psychotropic medication should be prescribed during pregnancy unless it is clearly needed and potential benefits for the individual outweigh potential hazards to the fetus.

   h. A HealthWest/IHC Physician/PA/NP may prescribe an FDA-approved medication for an unlabeled indication when such use is based on sound scientific evidence, sound medical opinion, or anecdotal clinical evidence. When a HealthWest/IHC Physician/PA/NP departs from the FDA's labeling, with regard to indication, a Physician's Progress Note (or Psychiatric Evaluation) must be written and included in the individual's record documenting clinical justification.

   i. The prescribing of only one psychotropic medication from the same medication class is encouraged. *(Practice Guideline No. 12-010, Simultaneous Use of Multiple Psychotropic Medications - Appendix A).*

2. Formulary of Approved Medications (*Appendix B)*

    a. Dosage levels for medications shall not ordinarily exceed those specified in the current Physician Drug Reference (PDR) and listed in the HealthWest Formulary on the HealthWest Intranet.

    b. When dosage levels are prescribed above the range listed in the HealthWest Formulary of Approved Medications (*Appendix B)*, the HealthWest/IHC Physician/PA/NP shall document the medical rationale via each Physician's Progress Note/Psychiatric Evaluation. Specific informed consent shall be obtained per established protocols, but indicating the dosage range is above the normal range listed in the formulary.

    c. The HealthWest Formulary of Approved Medications will be maintained according to Procedure 06-009 – Maintenance of Formulary of Approved Medications (*Appendix C)*.

    d. Request for Changes in the Formulary of Approved Medications (M010) shall be used to request changes to the HealthWest Formulary.

3. Unfilled Schedule II prescriptions expire in sixty (60) days.

4. PRN (as needed) medications:

    a. Orders for PRN medications shall contain precise instructions about dosage and clear descriptions of the intermittent target symptoms for which the medication is to be administered.

    b. The use and benefit of PRN doses must be documented by a HP.

5. When individuals are discharged from residential settings, medication instructions shall be written and explained to the individual and/or guardian.

    a. Only those medications authorized by a HealthWest/IHC Physician/PA/NP are to be given to the individual/guardian at discharge or leave of absence.

    b. Enough medication will be made available to ensure the individual has an adequate supply until he or she can become established with another provider.

B. DOCUMENTATION

1. The following documentation shall appear in the record of any individual receiving medication at HealthWest:

    a. Psychiatric evaluation shall include the individual's:

        1) Psychiatric history, including psychiatric medications within the previous year, if available.

2) Medical history, including significant nonpsychiatric medication history.

3) Mental status examination.

4) Diagnosis by HealthWest/IHC Physician/PA/NP.

b. HealthWest/IHC Physician/PA/NP Progress Note shall include the individual's:

1) Description of target symptoms, their improvement or lack of improvement.

2) Medication side effects.

3) Medication changes.

4) The use and benefits of PRN medication, if prescribed.

5) Lab tests ordered and/or review of results.

c. If more than one psychotropic agent is simultaneously prescribed from the same medication class (i.e., antipsychotic, antidepressant), the rationale for continuation or a plan for discontinuation must be documented in the record via each Physician's Progress Note/Psychiatric Evaluation.

d. Medication dosage, schedule, amount, and refills, with signature of HealthWest/IHC Physician/PA/NP. The history of medications prescribed will be maintained using current electronic format.

e. Individual Plan of Service (IPOS) authorized by HealthWest/IHC Physician/PA/NP: Whenever an individual is prescribed medications by HealthWest, at least one health and safety goal will be written addressing medications by the primary worker responsible for documenting the plan. These goals/objectives may include educating the individual about the medications, eliminating target symptoms, reducing side effects, ensuring adherence, obtaining the minimum effective dosage and/or wellness management and recovery.

f. Laboratory monitoring as appropriate to medication ordered.

1) Only a HealthWest/IHC Physician/PA/NP may order lab work.

2) The Laboratory Telephone Report (M012) allows an HP to obtain lab values over the phone; this should be discarded when the final written lab report is placed in the record.

3) The HealthWest/IHC Physician/PA/NP will review and initial the laboratory report and write or dictate a progress note or make a notation on the lab sheet addressing any significant abnormalities in the results.

4) Nurse will complete Physician's Appointment/Communication (C204) and forward with the lab results to the primary care physician.

g. Informed consent (C148) for each medication prescribed, with documentation that educational materials were given to the individual.

h. Other prescribed medications from non-HealthWest sources and over-the-counter drugs and nutritional supplements using current electronic format. This shall be a nursing responsibility, updated at each HealthWest/IHC Physician/PA/NP contact.

i. List of HealthWest Approved Medical Abbreviations and Symbols (M007) shall be used when documenting.

C. PRESCRIPTIONS

Prescription medication quantity for all individuals receiving services may be up to three months' supply. A Physician's/PA's/NP's Progress Note must describe in detail each prescription written including name of drug, strength, dosage, and target symptoms. Medication requests between appointments will be documented using the Medication Request form (C179). A controlled substance shall not be ordered on the same prescription form as a noncontrolled drug.

1. Electronic Orders

a. Prescriptions shall be completed using the current electronic format.

b. The prescription shall be signed only by a HealthWest/IHC Physician/PA/NP. A Schedule II prescription shall be printed on tamperproof paper and countersigned by a physician.

2. Written Orders: Whenever the current electronic format is not available, prescriptions shall be written only on HealthWest duplicate tamperproof printed forms. HealthWest/IHC Physician/PA/NP will use HealthWest prescription forms only for HealthWest individuals receiving services.

3. Verbal Orders:

a. Only a HP may receive and document a verbal order.

b. When receiving a verbal order, the HP will write down the order and then repeat it back verbatim to the prescriber. The prescriber will then verbally confirm that the order is correct. This should include name of drug, strength, dosage, quantity, and rationale for the medication change.

c. Only a HP may call the prescription in to a pharmacy. The prescription shall be entered into the current electronic format. The HP will notify the individual/care giver/guardian.

d. When current electronic format is not available, the HP will document on the Physician/Physician's Assistant/Nurse Practitioner Verbal Orders (C005). The form will be forwarded promptly to the HealthWest/IHC Physician/PA/NP for signature. The form will be scanned into the client record.

e. Consent for new medications initiated by the Consent for Use of Psychiatric Medications & General Medication Teaching (C148) shall be obtained as outlined in Section F - INFORMED CONSENT - of this Policy and Procedure.

D. ADMINISTRATION AND STORAGE

1. All medication administered in HealthWest programs and HealthWest residential facilities shall be kept in locked cabinets or boxes accessible only to HP/contracted pharmacist, and staff members trained by HealthWest nurses and/or qualified staff.

   a. If medications require refrigeration, they will be stored in a locked box in the refrigerator on site, with the temperature maintained between 36-44 degrees Fahrenheit. Daily temperature will be monitored and recorded.

   b. Medication cabinets or carts shall not be located in areas with excessive heat or moisture.

   c. Medication cabinets or carts shall be used only for medication storage. They shall be kept clean and orderly.

   d. If medication bins are used, each bin shall be labeled with the individual's name and allergies.

   e. Medication storage sites shall be inspected quarterly by a nurse or pharmacist. Monthly repeat inspections will be completed if a deficiency is identified. See Medication Storage Area Inspection (Q001).

2. All prescription medications must be kept in an original pharmacy container with the original label.

   a. Prescription medication containers shall have the following information: the individual for whom they are ordered, pharmacy name and address, medication name, dose and frequency of administration, quantity dispensed, name of prescriber, date filled, and initials of pharmacist filling the prescription.

   b. If a prescription dosage is changed, then a new label must be written and initialed by a HP or obtained from the pharmacy indicating the new regimen, and the new label shall be affixed to the container.

c. If any discrepancy is found between the medication record and pharmacy label, the staff member must consult with the nurse or pharmacist for clarification and complete a HealthWest Incident Report (C260).

3. All nonprescription medications must be kept in the original stock bottles with the original label.

   a. The bottle will be labeled with the individual's name.

   b. The nonprescription medication will only be administered per the HealthWest/IHC Physician/PA/NP orders.

4. Medications may only be administered when the following are in the record:

   a. Current prescription, or Physician/Physician's Assistant/Nurse Practitioner Verbal Orders (C005).

   b. Signed informed consent for medications prescribed by a HealthWest/IHC Physician/Physician's Assistant/Nurse Practitioner Verbal Orders (C005) with documentation that medication teaching sheets were given as outlined in Section F – INFORMED CONSENT - (C148 – Consent for Use of Psychiatric Medications & General Medication Teaching) of this Policy and Procedure.

   c. Identity Verification & Photo Consent for Medication Administration (C154).

   d. Medication brought into a HealthWest or contracted facility by an individual or a significant other will not be administered from containers or prescriptions dated more than thirty (30) days from the date of receipt by staff. Medication with a container/prescription older than thirty (30) days can only be administered after reauthorization by a HP.

5. Medications may be administered only by HealthWest/IHC Physician/PA/NP/ Nurse or by direct-care staff who have taken and passed a HealthWest medications training class and according to the Medication Administration Guidelines *(Appendix D).*

   a. Specific clinical programs will determine which non-HP staff shall be trained and authorized to administer medications.

   b. Training shall be provided for designated staff by a HealthWest nurse and/or qualified staff on an ongoing basis.

   c. Documentation of dates and attendance will be kept by the site supervisor and/or the HealthWest Quality Improvement Project Coordinator.

6. Self-Administration of Oral or Topical Medication: While receiving services from a HealthWest-operated or contracted residential program, an individual may self-administer his/her medication only when approved in a written order (Order for Self-Administration of Oral or Topical Medications, C279) by the HealthWest/IHC

Physician/PA/NP specified in the Individual Plan of Service (IPOS) and monitored by trained staff. The HealthWest/IHC Physician/PA/NP must assess the individual's capacity to self-administer medication and document that an appropriate level of competency exists at the time the order to self-administer medication is written.

7. Medication Compliance Packaging Program:

   a. If it is determined that medication assistance is needed, it must be documented in a psychiatric progress note and incorporated in the IPOS. The nature and duration of HealthWest assistance must be specified. Once sufficient competency is acquired on the part of the individual, assistance in self-administration of medication will be discontinued. Only a HealthWest/IHC Physician/PA/NP can discontinue the order.

      1) HealthWest staff will use Medication Compliance Packaging Evaluation (C349) to inform the appropriate licensed health care provider of the client's needs. The form will be forwarded to the RN for review. RN will complete the form and forward to HealthWest/ IHC Physician/PA/NP.

      2) HealthWest/IHC Physician/NP/PA will write an order on the Order for Medication Compliance Program (C352). This form will also be used to discontinue the order.

      3) Information will be put in the IPOS regarding goals and objectives to be met, utilizing Medication Compliance Packaging Evaluation Registered Nurse Assessment (C358).

      4) Team members will implement the order in coordination with the team RN.

      5) Quarterly reevaluation will consist of a repeat of issuing the Medication Compliance Packaging Evaluation (C349), the Medication Compliance Packaging Evaluation Registered Nurse Assessment (C358), and a medication review with the health care provider.

   b. All medications determined to require assistance with self-administration will be dispensed by Mercy HealthWest Pharmacy.

   c. Medications will be provided in recommended format by the dispensing pharmacy according to the Order for Medication Compliance Program (C352).

   d. Use of the Medication Sheet (C145) will be used for all assistance by HealthWest staff. Completion of form at each medication assistance encounter is required.

e. All medications from the medication storage bin must be signed in and out using the Medication Container Log (M169). This form must be kept in the individual medication storage bin.

f. Scheduled Drugs Count Log (M170) must be completed at each medication assistance encounter when prescribed scheduled medications are used. This form must be kept with the medication storage bin. The completed count log must be scanned into eClinical under "Prescriptions." On medications obtained by Mercy HealthWest Pharmacy that are controlled substances, the prescription number will begin with the number 2 or the number 4.

g. The start and end count is always an actual count of the medication in the container.

h. Transporting of medications into the community by HealthWest staff must be in designated provided containers.

8. Procedure for Insulin Administration and Blood Glucose Monitoring

a. Nurse will assess the clarity of the physician's orders and the individual's ability to self-administer insulin, to monitor blood glucose, to understand the physician's orders, to prepare accurate amount of insulin, and administer the insulin.

b. If a nurse determines the individual is not capable of all or some aspects of self-administration of insulin, a nurse or staff appropriately trained by a nurse will monitor/assist with prescribed orders for insulin administration.

9. Procedure for Administration of Injectable Psychotropics

a. Nurse will verify last HealthWest/IHC Physician/PA/NP progress note and prescription. Current order must be within ninety (90) days.

b. Nurse will note all new orders or changes in orders on the Injection Record (C264) and in the HealthWest Injection Database. Nurse will highlight each prescription entry made on the Injection Record.

c. Medication will be administered with an appropriate 21-guage needle. Medication will be administered IM with the exception of Haldol Decanoate, which will be administered Z-track.

d. A nursing progress note will be completed after each injection.

e. Injection database will be updated after each injection.

10. Procedure for STAT Medications

a. STAT Medications shall be secured from the Mercy HealthWest Pharmacy for use at HealthWest Main Campus.

b. An emergency STAT medication box shall be secured at Brinks' Sample Medication Cabinet.

c. The contents of the STAT medications box as determined by the Doctors Work Group and the Medical Director will include Zyprexa Zydis (Olanzapine) 10 mg #5 tabs, Ativan (Lorazepam) 1 mg #5 tabs, and Adult EpiPen. Additions or deletions will be subject to the approval of the Doctors Work Group.

d. The STAT medications will only be used to fill a STAT order given by a HealthWest/IHC Physician/PA/NP. The only time staff other than an RN will administer the oral medication is when they are given a handwritten prescription or a verbal order from an RN.

e. A log will be kept with the STAT medication box, which will include a list of the contents, medication usage logs, and quarterly inspection records.

f. RN will document STAT orders on a Physician/Physician's Assistant/Nurse Practitioner Verbal Orders form (C005), including all pertinent information if no written order from the HealthWest/IHC Physician/PA/NP is available. All staff involved in administering STAT medication will document on a progress note all instructions received from the nurse and will include a note regarding the effect of the STAT medication administered.

g. An entry must be made on the STAT Medication Inventory and Use log (M083) any time a medication is taken from the box, including:

1) Date
2) Name of medication
3) Dose
4) Name of individual receiving services
5) Case number
6) Name of the person who prescribed the medication
7) Name of the person administering the medication

h. The designated HealthWest RN responsible for the quarterly medication storage inspection will be responsible for inventory of medication in the STAT medication box to ensure that outdated medications are removed, destroyed, and replaced. This will be documented on the STAT Medications Quarterly Inspection Form (M084).

i. Replacement medications will be prescribed by a HealthWest/IHC Physician/NP/PA ordered from the Mercy HealthWest Pharmacy and delivered to Brinks under the supervision of the designated program RN. These medications will be paid for as a program expense since they will not be ordered for a specific individual receiving treatment.

11. Management of Medication Samples

    a. Samples will be received (signed for) from a pharmaceutical representative by a HealthWest/IHC Physician/PA/NP.

    b. The Medication Sample Inventory Database must be maintained of sample medications received, administered, and/or destroyed by a nurse at each location that stores and utilizes sample medications.

        1) The inventory shall document date received, name of drug, strength, quantity, lot number, expiration date, date issued, Recipient ID, and Staff ID Number.
        2) The samples inventory must be checked quarterly by a nurse for expired medications. Outdated samples shall be removed from stock, destroyed appropriately, and removal recorded in the Medication Sample Inventory Database.

    c. Samples must be kept in a locked cabinet accessible only by a nurse.

    d. Medication samples shall be issued on a HealthWest/IHC Physician/PA/NP order (prescription or Physician/Physician's Assistant/Nurse Practitioner Verbal Orders form (C005) in the manufacturer's original packaging.

        1) Instructions for taking each medication will be provided to the individual by a nurse using the Medication Instruction Sheet (C113) produced in duplicate by the Medication Sample Inventory Database and attached to the bag. One copy will be signed by the individual and nurse indicating the individual has received verbal and written instruction. The signed copy will be scanned into the individual's electronic clinical record.

        2) A thirty-four (34)-day supply or less of medication will be issued unless otherwise authorized by a HealthWest/IHC Physician/PA/NP.

        3) An entry must be made in the current electronic format to account for each sample medication issued.

12. Management of Patient Assistance Medications

    a. Patient Assistance forms are obtained from each drug company. Form is completed by the designated HealthWest representative or nurse and signed by the HealthWest/IHC Physician/PA/NP when needed, and submitted as instructed.

    b. The medication received must be given to a nurse. The medication is logged into the Medication Sample Inventory Database and the current electronic format by a nurse, the medication is locked in the storage area with the individual's name on the package.

c. Instructions for taking each medication will be provided to the individual by a nurse using the Medication Instruction Sheet (C113) produced in duplicate by the Medication Sample Inventory Database and attached to the bag. One copy will be signed by the individual and nurse indicating the individual has received verbal and written instruction. The signed copy will be scanned into the individual's electronic clinical record.

13. Refused/Dropped Medications: If medication is refused/dropped or contaminated, staff must complete an IR and forward it to a nurse/their supervisor. Two staff must be present to dispose of or destroy the medication. Two nurses must be present to dispose a Schedule II – V Medication (Q052-Q052A).

14. Individuals Receiving Medications Away From the Usual Facility (e.g., outings or Leaves of Absence [LOA] from residential settings or day programs):

a. Envelopes may be used for providing medication for such individuals. Printed on the envelope shall be the individual's name, medication and strength, time to be administered, and the number of pills included in the envelope. The envelope must then be sealed. Multiples of pills to be taken at the same time may be placed in the same envelope.

b. Such medication shall be recorded in the medication administration record/LOA form.

c. Medication not taken for any reason while away shall be secured in the medication storage area.

1) An Incident Report (IR) shall be completed and sent to the site supervisor.

2) The medication sheet entry for the LOA medications shall be circled in black ink.

3) If authorized by the nurse, the missed medication should be given to the individual, with the time given noted on the medication administration record.

4) If the medication envelope is returned unsealed, the Nurse and staff will verify contents of the envelope prior to administration.

15. Transporting Medications to Individuals in the Community

a. Each program administering and/or delivering medications in the community (e.g., ACT) shall utilize a medication inventory sheet, indicating signature of person receiving medication, the number of doses transported, administered, or returned.

b. If number of doses remaining in original package is inaccurate when monitored, then an Incident Report (IR) shall be completed and sent to the Program Supervisor according to procedures.

c. Medication may be transported using duplicate pharmacy containers.

d. Medication not taken when designated from the mediset (daily medication reminder container) may be left in the mediset to be used for the next period of time, or destroyed. Do not return medication to the original pharmacy container.

16. Discontinuation, Holding, and Disposal of Medication

a. On admission to a HealthWest residential facility, the HealthWest/IHC Physician/PA/NP will review the individual's medication regimen, and will discontinue any medication contraindicated by the individual's treatment plan.

b. An individual's medication(s) can only be held for up to fourteen (14) days if ordered to do so by a HealthWest/IHC Physician/PA/NP for a specific purpose.

c. An HP will document the discontinuation or holding of a medication in the Medication Administration Record/current electronic format.

d. The current supply of an individual's medication must be administered or destroyed before a new supply of the same medication is initiated. Storage of a duplicate supply of the same medication will not be allowed.

e. If an individual is discharged or leaves against medical advice from a residence or program, the individual's currently prescribed medications will be given to the individual or a responsible party, or destroyed.

f. Discontinued or expired medication stored at a HealthWest site will be destroyed or transported by an HP for temporary storage pending disposal with the agency's medical waste within thirty (30) days.

1) Destroyed Schedule II – V Medications will be documented on the Destroyed Schedule II-V Medications Common Schedule II-V Medications that Require Monitoring (Q052-Q052a) by the HP disposing of the medication. The signature of a witness is also required.

2) Non-controlled medications shall be secured in an appropriate container, transported to HealthWest by a HP and secured in the locked metal cabinet in the medication storage room in the Med Pod pending disposal with the agency's biohazard waste at the county's licensed waste disposal site.

E. MEDICATION TEACHING SHEETS

1. Medication teaching sheets shall be available for all medications on the HealthWest Formulary and written and updated with existing medical knowledge of each drug's purpose, benefits, risks, side effects, and approved dosage range.

2. Teaching sheets may be revised or deleted, or new ones added, as needed, without amendment to this Policy and Procedures document.

F. INFORMED CONSENT *(HealthWest Policy 04-003: Consent - Appendix E)*

1. All of the following are elements of informed consent:

a. LEGAL COMPETENCY: An individual shall be presumed to be legally competent. This presumption may be rebutted only by a court appointment of a guardian or exercise by a court of guardianship powers and only to the extent of the scope and duration of the guardianship. An individual shall be presumed legally competent regarding matters that are not within the scope and authority of the guardianship.

b. KNOWLEDGE: To consent, a recipient or legal representative must have basic information about the procedure, risks, other related consequences, and other relevant information. The standard governing required disclosure by a doctor is what a reasonable patient needs to know in order to make an informed decision. Other relevant information includes all of the following:

1) The purpose of the procedures.

2) A description of the attendant discomforts, risks, and benefits than can reasonably be expected.

3) A disclosure of appropriate alternatives advantageous to the recipient.

4) An offer to answer further inquiries.

c. COMPREHENSION: An individual must be able to understand that the personal implications of providing consent will be based on the information provided under Paragraph F.1.b above.

d. VOLUNTARINESS: There shall be free power of choice without the intervention of an element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion, including promises or assurances of privileges or freedom. There shall be an instruction that an individual is free to withdraw consent and to discontinue participation or activity at any time without prejudice to the recipient.

2. All individuals receiving medication prescribed by a HealthWest Physician/PA/NP (or their parent or guardian) shall:

a. Sign a Release to Exchange Information with the individual's primary care physician to minimally include all medications, prescribed lab orders and results, and diagnoses in order to safely and effectively coordinate medical and psychiatric services.

Exchange of information is required and authorized by the individual's signature on the Medicaid application to ensure coordination of care with Medicaid provider.

b. Be informed of the dosage range, purpose, benefits, risks, and side effects of each medication by a HP, as well as alternative medications and viable options to treatment with psychotropic medication. Women of childbearing age shall be informed by a HP about the risks associated with pregnancy.

c. Receive a medication teaching sheet for each medication. This shall be indicated on the consent form.

d. Sign a written voluntary consent form to receive psychotropic drugs, which shall be posted in the record (C148 - Consent for Use of Psychiatric Medications and General Medication Teaching).

e. Be informed that consent for use of medication may be withdrawn at any time.

3. To ensure coordination of care, if a physician outside of HealthWest prescribes medication, HealthWest staff will ensure medication education occurs for client/guardian and direct care staff. Education provided will be documented. Medication education will be included in the treatment plan.

4. An individual under Court Order for continued treatment may be prescribed/ administered outpatient medications without providing informed consent.

5. The HealthWest/IHC Physician/PA/NP Progress Note shall indicate if the individual demonstrated the capacity to understand the information provided. If the individual is deemed competent but intellectually limited, the progress note shall document how the information was given at a level of understanding consistent with individual's functioning.

6. If the individual/guardian declines to sign the Consent for Use of Psychiatric Medications (C148) or Authorization for Exchange of Information with the primary care physician, the HP will document such refusal. Medications will not be prescribed or administered whenever the individual or guardian refuses to give consent or give permission to exchange information with the primary care physician or withdraws consent or Release of Information.

7. If immediate written consent from an individual/guardian is not possible, verbal consent may be obtained and documented by the HP and one witness. A signed consent must then be obtained as soon as possible.

8. A change of dosage within the approved range does not require obtaining a new consent. A change of dosage outside the approved range, or a change of medication within the same class, does require a new consent.

9. Informed consent for use of medication must be obtained at the time a medication is initially prescribed. This is the responsibility of the prescribing

HealthWest/IHC Physician/PA/NP. This consent remains in effect until revoked by the individual or the medication is discontinued by the HealthWest/IHC Physician/PA/NP.

a. HealthWest shall accept as valid, and act upon the consent or refusal of any individual/guardian who is age 18 or over, has not been declared legally incompetent, and who is presumed by the HealthWest/IHC Physician/PA/NP to be clinically capable of providing informed consent.

b. Any individual who is under age 18, or has been declared legally incompetent to make medical treatment decisions, may not give informed consent. Either a parent or guardian with authority to make medical treatment decisions must provide informed consent to take medication.

c. If an individual is legally competent on his/her 18th birthday, previous consent obtained from the parent or guardian expires on that date, and a new consent must be obtained from the individual.

d. If long-term clinical incapacity is determined, the physician will so document and request that a guardian be appointed.

    1) Medication should not be initiated until incapacity is established judicially and a guardian is appointed. If individual meets the legal criteria for involuntary treatment, then involuntary proceedings should take place.

    2) If the individual is already taking the medication and agrees to continue doing so, the medications can be continued if the HealthWest/IHC Physician/PA/NP determines that a discontinuation of medication will have an unfavorable effect. The HealthWest/IHC Physician/PA/NP shall document the circumstances in a progress note.

e. Medication can be prescribed and administered to an individual without informed consent only when the person poses a risk of harm to himself, herself, or others. The circumstances must be clearly documented in the individual's clinical record by the prescribing HealthWest/IHC Physician/PA/NP.

    1) The initial administration of psychotropic medication may not extend beyond forty-eight (48) hours unless informed consent is obtained.

    2) The duration of psychotropic chemotherapy under these circumstances shall be as short as possible and at the lowest dosage that is therapeutically effective.

    3) Psychotropic chemotherapy shall be terminated as soon as there is little likelihood that the individual will pose a risk of harm to self or others.

4) Additional courses of psychotropic chemotherapy may be prescribed and administered if an individual decompensates and poses a risk of harm to self or others.

G. INVOLUNTARY MOVEMENTS

1. The following applies to all individuals receiving antipsychotic medications or Amoxapine (Asendin):

   a. Individual shall be evaluated by a HealthWest/IHC Physician/PA/NP for the presence and extent of involuntary movement disorders prior to treatment with said medications.

   b. While taking such medications, an individual shall be given an Abnormal Involuntary Movement Scale (AIMS) evaluation by a HP, at least quarterly, or more frequently if determined by a HealthWest/IHC Physician/PA/NP, and completed in the current electronic record or Abnormal Involuntary Movement Scale (AIMS) (C210).

2. Any staff person who suspects that an individual may have involuntary movements will promptly refer the individual to the appropriate HP for an AIMS test and medication review.

3. If the AIMS score determines Tardive Dyskinesia is present, the individual or guardian must complete a special consent form annually - Consent Form: Individual with Tardive Dyskinesia (C153).

H. SPECIFIC MEDICATIONS

1. Anticholinergics/Antiparkinsonian

   a. Routine prophylactic use of anticholinergic agents with antipsychotic agents is discouraged. Anticholinergic agents will generally not be prescribed at the initiation of antipsychotic therapy, except for groups at high risk of extrapyramidal side effects (EPSE) or nonadherence, or a history of such side effects from similar medications.

   b. When an individual does experience extrapyramidal side effects anticholinergics may be used, but periodic attempts should be made to discontinue these medications.

   c. The HealthWest/IHC Physician/PA/NP shall provide ongoing documentation of the justification for use of an anticholinergic agent in progress notes.

2. Clozapine (Clozaril): Refer to Procedure 06-016 - Clozaril/Clozapine Treatment System (CTS) Procedures *(Appendix F).*

3. Atypical Antipsychotics

a. Individuals with risk factors for diabetes mellitus who are starting treatment with atypical antipsychotics should undergo baseline screening and routine monitoring throughout treatment.

b. The following risk factors may increase an individual's potential of developing Type 2 Diabetes:
   1) Family history of Diabetes
   2) Age over 45
   3) Race or ethnic background
   4) Being overweight
   5) Hypertension
   6) Abnormal cholesterol levels
   7) History of gestational diabetes
   8) History of polycystic ovarian disease
   9) Sedentary lifestyle
   10) History of vascular disease

c. Before starting an atypical antipsychotic medication:

   1) Assess and document the above risk factors.

   2) Obtain a baseline Hemoglobin A1C and Cardiac Lipid Profile.

d. Following initiation of an atypical antipsychotic medication, the HealthWest/IHC Physician/PA/NP shall minimally:

   1) Monitor individual's weight, Body Mass Index (BMI), waist circumference, and blood pressure regularly.

   2) Follow up with Hemoglobin A1C and Cardiac Lipid Profile at three months and at least annually thereafter.

   3) If any abnormalities in lab results are noted, inform the individual's primary care physician for follow up.

   4) See Laboratory Monitoring Guidelines for Use of Psychotropic Medications (*Appendix G*) for complete laboratory monitoring requirements.

3. Controlled Substances

a. When a prescription for a controlled substance is written by a HealthWest/IHC Physician/PA/NP for an individual responsible for self-administration of medication, or who will soon be responsible for self-administration of medication, he/she will be required to sign the Consent For Use Of Psychiatric Medications & General Medication Teaching (C148) and adhere to the conditions outlined in the Consumer Controlled Substance Standard (M145) if one has not previously been signed.

b. The parent(s)/guardian(s) of a minor child who is prescribed a controlled substance by a HealthWest/IHC Physician/PA/NP will be required to sign the Consent for Use of Psychiatric Medications & General Medication Teaching (C148) and adhere to the conditions outlined in the Consumer Controlled Substance Standard (M145) if one has not previously been signed.

c. HP will provide the individual (if an adult) or parent/guardian (if individual is a minor child) with a Consumer Controlled Substance Education sheet (M145) and review the contents as necessary.

d. A Written Prescription Tracking form (C274) will be attached to the Schedule II prescription. The HealthWest staff person and the person picking up the written prescription will sign and date the form to acknowledge receipt of the prescription. The form will then be placed for priority scanning into the Prescription section of the electronic clinical record.

4. Stimulants

a. Psychiatric Assessment should include a detailed history as well as documentation of medical conditions. If possible, collateral information from parents or significant others should be obtained. Prior to the initiation of stimulant therapy, a baseline blood pressure, pulse, height, and weight should be obtained. Collaboration with the primary care provider or specialist may be necessary if there are comorbid cardiac or neurological issues of concern.

1) Conditions that may benefit from stimulant use include the following:

a) <u>ADHD</u>. The prescriber should document whether the patient has a diagnosis of ADHD based on DSM IV TR criteria.

b) <u>Narcolepsy</u>. If an individual has a confirmed diagnosis of Narcolepsy, stimulants may be part of the treatment plan. If possible, the prescribing for this condition should be through the primary care provider or sleep specialist.

c) <u>Apathy due to general medical condition</u>. Individuals with Traumatic Brain Injury (TBI), stroke, or degenerative neurological illness may at times have a degree of apathy in which stimulant medications may prove to be of assistance in treatment.

d) <u>Treatment refractory depression</u>. In rare cases, low-dose stimulants may be used in cases of treatment refractory depression as an augmentation strategy.

2) Contraindications: Aside from comorbid medical conditions that would preclude the use of stimulant medication, the following conditions should be considered relative contraindications to stimulant use:

a) Substance abuse. If an individual has an Axis I diagnosis of substance abuse or dependence, caution should be exercised in prescribing stimulant medication. If the benefit is thought to outweigh the risk, extreme caution and careful monitoring for misuse should be undertaken. If possible, Strattera or other nonstimulant options should be considered as first-line agents.

b) A member of the individual's household has a history of stimulant abuse. This should be discussed during the Psychiatric Evaluation.

c) Stimulants are not indicated in individuals with an active psychotic disorder.

3) Stimulants in Mood and Anxiety Disorders: Both anxiety and mood disorders may be comorbid with ADHD. Caution and careful clinical judgment should be exercised when prescribing stimulants in this population as they can lead to an increase in either mood fluctuations or an increase in anxiety in certain individuals. In the majority of these cases, the underlying anxiety or mood disorder should be the initial focus of treatment.

5. Medication-Assisted Treatment

a. Vivitrol:
http://www.fda.gov/downloads/Drugs/DrugSafety/UCM206669.pdf

1) Naltrexone/Vivitrol: Positive drug screens will be repeated in seventy-two (72) hours. The drug screen is to be negative prior to the injection being given.

2) Onsite drug screening for opioid use with a negative result to be performed prior to the initial injection and every injection given not within the dosage regimen (every thirty-five (35) days).

3) Vivitrol will be held if the drug test is positive for opioids, and the Individual receiving services will be asked to repeat the test on the following day.

b. Suboxone:
http://www.suboxone.com/content/pdfs/medication-guide.pdf

1) Teaching and consent by HealthWest/IHC Physician/PA/NP at time of prescribing: A medication guide will be given to the

individual receiving services at this time (see link above and HealthWest Formulary of Approved Medications, *Appendix B*).

2) Monthly Michigan Automated Prescription System (MAPS) will be printed by RN and presented to prescribing physician.

3) In-house drug testing for Opioid Panel monthly.

4) Drug results will be documented in a progress note and forwarded to the physician for signature.

I. LABORATORY MONITORING GUIDELINES FOR USE OF PSYCHOTROPIC MEDICATIONS

Baseline and periodic laboratory studies shall be performed in accordance with the pharmacology of the specific drug prescribed. (See Laboratory Monitoring Guidelines for Use of Psychotropic Medications *(Appendix G)* for complete monitoring guidelines.) The exact laboratory tests required depend on clinical judgment, the individual's medical and drug history, the pharmacology of the medication to be used, and the anticipated duration of time it will be prescribed.

J. ANTIDEPRESSANT MEDICATION FOR CHILDREN AND ADOLESCENTS

Upon initiation of prescribing an antidepressant medication to a child or adolescent, the HealthWest/IHC Physician/PA/NP shall follow HealthWest Practice Guideline 12-008 – Monitoring of Children and Adolescents Being Treated with Antidepressants (*Appendix H)*.

K. MEDICATIONS FOR BEHAVIOR MANAGEMENT

1. Medication shall not be used as punishment, for the convenience of staff, or as a substitute for other appropriate treatment.

2. Medications ordered by a HealthWest/IHC Physician/PA/NP may be administered following an individualized protocol in order to prevent physical injury to self or others. It is the intent of HealthWest to have individuals who are determined by assessment to be a danger to self or others due to mental illness or developmental disability admitted (by involuntary commitment if necessary) to an inpatient psychiatric unit or center. Staff will be encouraged to protect themselves and others from injury (e.g., Non Abusive Psychological and Physical Intervention (NAPPI).

L. SERIOUS ADVERSE DRUG REACTIONS *(See Page 1, Definition/Section IV, A.)*

1. In case of a serious adverse drug reaction (ADR), HealthWest staff and/or contracted providers will take action as necessary to assure appropriate medical care for the individual.

2. Any HealthWest staff person or contracted provider may initiate an inquiry regarding a possible serious adverse drug reaction stemming from HealthWest

prescribed medications by filling out Part One of the Report of Serious Adverse Drug Reaction form (C033).

3. If not previously completed, the HealthWest staff person/contracted provider will fill out an IR as soon as possible and forward it to a HealthWest nurse for review. The nurse will note the possible occurrence of an ADR in the Alert section of the individual's electronic clinical record and the Allergy section of the medication database.

4. The ADR (C033) shall be given to the individual's primary worker as soon as possible. If the primary worker is not available, the ADR form should be given to their supervisor.

    a. The HealthWest primary worker/supervisor shall promptly notify the treating HealthWest/IHC Physician/PA/NP of the possible serious adverse drug reaction.

    b. The primary worker/Supervisor will give the ADR form with Part One completed to the HealthWest/IHC Physician/PA/NP as soon as possible.

5. The HealthWest/IHC Physician/PA/NP shall complete Part Two of the ADR form and forward it to the chairperson of the Pharmacy Work Group within seven (7) calendar days of receipt of the form. This may or may not involve a face-to-face examination of the individual, at the discretion of the HealthWest/IHC Physician/ PA/NP.

6. The Pharmacy Work Group, in consultation with the HealthWest Medical Director, shall further review the suspected serious ADR to confirm its occurrence.

    a. The ADR form, with Part Three completed, shall be a permanent part of the Alerts section of the individual's electronic clinical record.

    b. The HealthWest senior nurse will note the final outcome of the ADR review in the Allergy Section of the individual's medication database.

    c. The findings of the Pharmacy Work Group review shall be promptly reported to the HealthWest Recipient Rights Officer and the HealthWest/IHC Physician/PA/NP for follow up with the individual/guardian as appropriate.

    d. The Pharmacy Work Group shall notify the Federal Drug Administration (FDA) via FDA Voluntary Form 3500 (*See Appendix I)* of a confirmed serious ADR.

    e. The Pharmacy Work Group shall monitor all confirmed serious ADRs and note trends and patterns.

M. MEDICAL ABBREVIATIONS AND SYMBOLS

All HealthWest staff shall use only approved abbreviations and symbols (M007).

N. QUALITY ASSURANCE

1. The Pharmacy Work Group will assure that elements of this policy shall be studied and monitored yearly by means of:

   a. Drug use evaluations: indications for prescribing the medication.

   b. Critical path reviews: standards of practice for prescribing and monitoring the medication.

   c. Pharmacy therapeutics reviews: signed orders, etc.

   d. Records pertinence.

   e. Satisfaction of internal and external customers.

2. Emphasis shall be placed on areas of high risk, high volume/frequency, high cost, ease of data collection, and clinical benefit to HealthWest Individuals receiving services.

VI. REFERENCES

J. AM. ACAD. Child Adolescent Psychiatry 41:2 Supplement February 2002

MDHHS Group Home Curriculum

MDHHS Public Mental Health Manual III.7158-R.GL.07
(further references are cited therein)

FORMS

C005	Physician/Physician's Assistant/Nurse Practitioner Verbal Orders
C033	Report of Serious Adverse Drug Reaction
C113	Medication Instruction Sheet
C145	Medication Sheet
C148	Consent for Use of Psychiatric Medications & General Medication Teaching
C153	Consent Form: Individual with Tardive Dyskinesia
C154	Identity Verification & Photo Consent for Medication Administration
C179	Medication Request Form
C204	Physician's Appointment/Communication
C210	Abnormal Involuntary Movement Scale (AIMS)
C260	HealthWest Incident Report

C264	Injection Record
C274	Written Prescription Tracking Form
C279	Order for Self-Administration of Oral or Topical Medications
C349	Medication Compliance Packaging Evaluation
C352	Order for Medication Compliance Program
C358	Medication Compliance Packaging Evaluation Registered Nurse Assessment
M007	List of Approved Medical Abbreviations and Symbols
M010	Request for Changes in the Formulary of Approved Medications
M012	Laboratory Telephone Report
M083	STAT Medications Inventory and Use
M084	STAT Medications Quarterly Inspection Form
M145	Consumer Controlled Substance Standard
M169	Medication Container Log
M170	Scheduled Drugs Count Log
Q001	Medication Storage Area Inspection
Q052-Q052a	Destroyed Schedule II-V Medications Common Schedule II-V Medications that Require Monitoring

VII. APPENDICES

Appendix A	Practice Guideline 12-010: Simultaneous Use of Multiple Psychotropic Medications
Appendix B	HealthWest Formulary of Approved Medications
Appendix C	Procedure 06-009: Maintenance of Formulary of Approved Medications
Appendix D	Medication Administration Guidelines
Appendix E	Policy 04-003: Consent
Appendix F	Procedure 06-016: Clozaril/Clozapine Treatment System (CTS) Procedure
Appendix G	Laboratory Monitoring Guidelines for Use of Psychotropic Medications

Appendix H Practice Guideline 12-008: Monitoring of Children and Adolescents Being Treated with Antidepressants

Appendix I Form FDA 3500: For Voluntary Reporting of Adverse Events, Product Problems, and Product Use Errors

CB/jec

APPENDIX A

HEALTHWEST
PRACTICE GUIDELINE

No. 12-010

Prepared by:

Cyndi Blair, RNBC
Pharmacy Work Group

Effective: February 1, 2006
Revised: August 9, 2016

Approved by:

SUBJECT: Simultaneous Use of Multiple Psychotropic Medications

Justin Bensinger, Consulting Pharmacist

Julia B. Rupp, Executive Director

I. PURPOSE:

To encourage the use of monotherapy with psychotropic agents in a pharmaco-therapeutic regimen.

II. APPLICATION:

Community Mental Health Services of Muskegon County Physicians, Physician Assistants, and Nurse Practitioners.

III. DEFINITIONS:

Psychotropic Medications: Medications listed in the Physician's Desk Reference (PDR) that effect the functioning of brain chemistry.

Simultaneous Use of Multiple Medications: 2 or more medications from the same class being prescribed at the same time. (Exception: Use of a depot antipsychotic agent plus a different oral agent as a PRN [as needed] may in some cases be justified.)

IV. PROTOCOL:

A. Continuous Review of Medications by Prescribers

1. Current medications will be reviewed by the prescriber for individuals seen in outpatient clinics.

2. The prescriber will implement a specific plan to eliminate excess psychotropic agents in cases of prescription of multiple psychotropic medications.

B. Documentation

1. The prescriber will document in each case where simultaneous use of multiple psychotropic medications are in use.

    a. Documentation will be in the Treatment Plan Section of the Psychiatric Evaluation or Medication Review.

    b. Documentation will specify *either:*

        (i) The *rationale* for continuing multiple psychotropic use, or
        (ii) The *specific plan* for eliminating superfluous psychotropic agents through gradual dosage titrations. Reference to published algorithms for psychotropic therapy is suggested.

2. Random peer reviews will occur in cases of simultaneous use of multiple psychotropic uses when 2 or more medications are prescribed from the same class.

HEALTHWEST

FORMULARY OF APPROVED MEDICATIONS

Dosage Range as specified in the drug references.

	Generic Name	Brand Name	Dosage Range In milligrams per day unless otherwise noted.	Teaching Sheet
ANTIANXIETY/SEDATIVES/HYPNOTICS				
Antihistamines				
	Cyproheptadine	Periactin	4-32	Cyproheptadine
	Diphenhydramine	Benadryl	25-300	Diphenhydramine
	Hydroxyzine	Atarax, Vistaril	25-400	Hydroxyzine
Benzodiazepines				
	**Alprazolam	Xanax	0.25-10	Alprazolam
	**Chlordiazepoxide	Librium	5-300	Chlordiazepoxide
	**Clonazepam	Klonopin, Klonopin Wafer	0.5-20	Clonazepam
	**Clorazepate	Tranxene	3.75-90	Clorazepate
	**Diazepam	Valium	2-40	Diazepam
	**Estazolam	ProSom	0.5-2.0	Estazolam
	**Flurazepam	Dalmane	15-30	Flurazepam
	**Lorazepam	Ativan	0.5-10	Lorazepam
	**Oxazepam	Serax	10-120	Oxazepam
	**Quazepam	Doral	7.5-15	Quazepam
	**Temazepam	Restoril	7.5-30	Temazepam
	**Triazolam	Halcion	0.125-0.5	Triazolam
Other Antianxiety/Sedatives/Hypnotics				
	Buspirone	BuSpar	5-90	Buspirone
	**Eszopiclone	Lunesta	1-3	Eszopiclone
	Melatonin		1-5	Melatonin
	Ramelteon	Rozerem	4-8	Ramelteon
	**Zaleplon	Sonata	5-20	Zaleplon
	**Zolpidem	Ambien, Ambien CR	5-10	Zolpidem

Controlled Substances:
* Schedule II
** Schedule IV
*** Schedule V

HEALTHWEST

FORMULARY OF APPROVED MEDICATIONS

Dosage Range as specified in the drug references.

	Generic Name	Brand Name	Dosage Range In milligrams per day unless otherwise noted.	Teaching Sheet
ANTIDEPRESSANTS				
Tricyclics				
	Amitriptyline	Elavil	10-300	Amitriptyline
	Clomipramine	Anafranil	25-250	Clomipramine
	Desipramine	Norpramin	25-300	Desipramine
	Doxepine	Sinequan	25-300	Doxepine
	Imipramine	Tofranil	25-300	Imipramine
	Nortriptyline	Pamelor	10-150	Nortriptyline
	Protriptyline	Vivactil	5-60	Protriptyline
Monoamine Oxidase Inhibitors				
	Phenelzine	Nardil	15 qod-90	Phenelzine
	Tranylcypromine	Parnate	10-60	Tranylcypromine
Serotonin Reuptake Inhibitors				
	Citalopram HBr	Celexa	10-40	Citalopram HBr
	Escitalopram	Lexapro	5-20	Escitalopram
	Fluoxetine	Prozac	10-80	Fluoxetine
	Fluvoxamine	Luvox, Luvox CR	50-300	Fluvoxamine
	Paroxetine	Paxil, Paxil CR	10-60	Paroxetine
	Sertraline	Zoloft	25-200	Sertraline
Other Antidepressants				
	Amoxapine	Asendin	25-400	Amoxapine
	Buproprion	Aplenzin, Wellbutrin, Wellbutrin SR, Wellbutrin XL	150-450	Buproprion
	Desvenlafaxine	Pristiq	50-100	Desvenlafaxine
	Duloxetine	Cymbalta	30-120	Duloxetine
	Maprotiline	Ludiomil	25-225	Maprotiline
	Mirtazapine	Remeron, Remeron Sol-Tab	15-45	Mirtazapine
	Trazodone	Desyrel, Oleptro	50-400	Trazodone
	Venlafaxine	Effexor, Effexor-XR	37.5-375	Venlafaxine
	Vortioxetine	Brintellex	5-20	Vortioxetine

Controlled Substances:
* Schedule II
** Schedule IV
*** Schedule V

HEALTHWEST

FORMULARY OF APPROVED MEDICATIONS

Dosage Range as specified in the drug references.

	Generic Name	Brand Name	Dosage Range In milligrams per day unless otherwise noted.	Teaching Sheet
ANTIDYSKINETICS				
	Amantadine	Symmetrel	100-400	Amantadine
	Benztropine	Cogentin	0.5-6	Benztropine
	Biperiden	Akineton	2-16	Biperiden
	Trihexyphenidyl	Artane	1-15	Trihexyphenidyl
ANTIMANIC AGENTS [Blood Levels]				
	Carbamazepine	Carbatrol, Equetro, Tegretol, Tegretol-XR	200-1600 (4-12)	Carbamazepine
	Divalproex Sodium	Depakote, Depakote ER, Depakote Sprinkles	10-60 mg/kg/day	Divalproex Sodium
	Gabapentin	Neurontin	100-3600	Gabapentin
	Lamotrigine	Lamictal	25-500	Lamotrigine
	Lithium	Eskalith, Lithobid	300-1800 (0.5-1.5)	Lithium
	Oxcarbazepine	Trileptal	600-2400	Oxcarbazepine
	Tiagabine	Gabitril	4-56	Tiagabine
	Topiramate	Topamax, Topamax Sprinkles	25-400	Topiramate
	Valporic Acid	Depakene	10-60 mg/kg/day	Valporic Acid
ANTIPSYCHOTICS				
	Aripiprazole	Abilify	2-30	Aripiprazole
	Aripiprazole Extended Release	Abilify Maintenna	160-400	Aripiprazole Extended Release
	Aripiprazole Lauroxil	Aristada	441-882	Aristada
	Asenapine	Saphris	10-20	Asenapine
	Brexpiprazole	Rexulti	0.5-4	Brexpiprazole
	Chlorpromazine	Thorazine	10-2000	Chlorpromazine
	Clozapine	Clozaril, FazaClo	12.5-900	Clozapine
	Fluphenazine	Prolixin	0.5-40 mg daily	Fluphenazine
	Fluphenazine	Prolixin Decanoate	6.25-100 mg dose (max 100 mg per week)	Fluphenazine decanoate
	Haloperidol	Haldol	0.5-100 mg daily	Haloperidol
	Haloperidol	Haldol Decanoate	12.5 mg/dose 450 mg/month	Haloperidol Decanoate
	Iloperidone	Fanapt	2-24	Iloperidone
	Loxapine	Loxitane	20-250	Loxapine
	Lurasidone	Latuda	20-160	Lurasidone
	Olanzapine	Zyprexa, Zyprexa Zydis	5-20	Olanzapine
	Paliperidone	Invega	3-12	Paliperidone

Controlled Substances:
* Schedule II
** Schedule IV
*** Schedule V

HEALTHWEST

FORMULARY OF APPROVED MEDICATIONS

Dosage Range as specified in the drug references.

	Generic Name	Brand Name	Dosage Range In milligrams per day unless otherwise noted.	Teaching Sheet
	Paliperidone Palmitate Injection	Invega Sustenna	39 -234	Paliperidone Palmitate Injection
	Paliperidone Palmitate	Invega Trinza	273-819	Paliperidone Palmitate
	Perphenazine	Trilafon	2-64 mg daily	Perphenazine
	Pimozide	Orap	1-10 (<0.2 mg/kg/d)	Pimozide
	Quetiapine	Seroquel, Seroquel XR	25-800	Quetiapine
	Risperidone	Risperdal, Risperdal M-Tab	1-16	Risperidone
	Risperidone Injection	Risperdal Consta	25-50 per dose/every 2 wks	Risperidone Injection
	Thioridazine	Mellaril	50-800	Thioridazine
	Thiothixene	Navane	1-60	Thiothixene
	Trifluoperazine	Stelazine	1-50	Trifluoperazine
	Cariprazine	Vraylar	1.5 - 6	Vraylar
	Ziprasidone	Geodon	20-160	Ziprasidone
MISCELLANEOUS				
	Acamprosate	Campral	999-1998	Acamprosate
	Atomoxetine	Strattera	40-100 max 1.4 mg/kg children	Atomoxetine
	Buprenorphine Naloxone	Suboxone		Buprenorphine Naloxone
	Cimetidine	Tagamet	400-2400	Cimetidine
	Clonidine	Catapres, Catapres Patch	0.1-2.4	Clonidine
	Clonidine Extended Release	Kapvay	0.1-0.4	Clonidine Extended Release
	Disulfiram	Antabuse	125-500	Disulfiram
	Donepezil	Aricept	5-23	Donepezil
	Galantamine	Razadyne (formerly Reminyl)	8-32	Galantamine
	Guanfacine	Intuniv, Tenex	1-7	Guanfacine
	Levetiracetam	Keppra	500-300	Levetiracetam
	Levocarnitine	Carnitor	330-2970	Levocarnitine
	Liothyronine	Cytomel	5-100 micrograms	Liothyronine
	Memantine	Namenda	5-20	Memantine
	Naltrexone	Vivitrol		Naltrexone
	Naltrexone	ReVia	25-50 (100 qod, 150 q3d, 50)	Naltrexone
	Nizatidine	Axid	150-300	Nizatidine
	Olanzapine/Fluoxetine	Symbyax	6/25-18/75	Olanzapine/Fluoxetine

Controlled Substances:

* Schedule II

** Schedule IV

*** Schedule V

HEALTHWEST

FORMULARY OF APPROVED MEDICATIONS

Dosage Range as specified in the drug references.

	Generic Name	Brand Name	Dosage Range In milligrams per day unless otherwise noted.	Teaching Sheet
	Omega-3-Acid Ethyl Esters	Lovaza (formerly Omacor)	4 gm	Omega-3-Acid Ethyl Esters
	Pindolol	Visken	5-60	Pindolol
	Prazosin	Minipress	0.5-40	Prazosin
	Propranolol	Inderal, Inderal-LA, Innopran XL	20-320	Propranolol
	Ranitidine	Zantac	150-600	Ranitidine
	Rivastigmine	Exelon	1.5-12	Rivastigmine
	Scopolamine - Transdermal	Transderm-Scop	1.5 q3d	Scopolamine - Transdermal
	Varenicline	Chantix	0.5-2	Varenicline
	Vitamin E		200 IU-2000 IU	Vitamin E
NICOTINE REPLACEMENT PRODUCTS				
	Nicotine Gum		2-4	Nicotine Gum
	Nicotine Inhaler		10 mg per Cartridge	Nicotine Inhaler
	Nicotine Lozenge		2-4	Nicotine Lozenge
	Nicotine Nasal Spray		.5 mg per Ectuation	Nicotine Nasal Spray
	Nicotine Patch		7-21	Nicotine Patch
SIDE EFFECT MEDICATION				
	Bisacodyl	Dulcolax	5-15 (1-3 tabs)	Bisacodyl
	Bromocriptine	Parlodel	2.5-100	Bromocriptine
	Dantrolene	Dantrium	25-400	Dantrolene
	Desmopressin	DDAVP	10-40 mcg	Desmopressin
	***Diphenoxylate HCl	Lomotil	5-20 (2-4 tabs)	***Diphenoxylate HCl
	Discusate Sodium	Colace	50-500	Discusate Sodium
	Hydroclorothiazide	HydroDIURIL	25-100	Hydroclorothiazide
	Hydrochlorthiazide/Triamterene	Dyazide	25/37.5-50/75 (1-2/day)	Hydrochlorthiazide/Triamterene
	Lactulose	Kristalose	10-40 mg, 15-60 ml daily	Lactulose
		Imodium	2-16	Imodium
	**Modafinil	Provigil	100-400	Modafinil
	Oxybutynin	Ditropan	5-30	Oxybutynin
	Polycarbophil	Fibercon	1-4 gm (2-8 tabs)	Polycarbophil
	Polyethylene Glycol	Miralax Powder	17 gm	Polyethylene Glycol
	Ropinirole	Requip	0.25-24	Ropinirole
	Senna	Senokot	187-1496 (1-8 tabs)	Senna
	Sennocides/Docusate	Peri-Colace	2-4 tabs	Sennocides/Docusate
	Sildenafil	Viagra	25-100	Sildenafil

Controlled Substances:

* Schedule II

** Schedule IV

*** Schedule V

HEALTHWEST

FORMULARY OF APPROVED MEDICATIONS

Dosage Range as specified in the drug references.

	Generic Name	Brand Name	Dosage Range In milligrams per day unless otherwise noted.	Teaching Sheet
	Tadalafil	Cialis	5-20	Tadalafil
	Tolterodine	Detrol	2-4	Tolterodine
	Vardenafil	Levitra	5-20	Vardenafil
	Yohimbine	Yocon	5.4-16.2	Yohimbine (Teaching Sheet Not Avail)
	Zolmitriptan	Zomig	1.25-5 (max 10 mg/day)	Zolmitriptan
STIMULANTS				
	*Dextroamphetamine	Dexedrine	5-60	Dextroamphetamine
	*Dextroamphetamine	Dextrostat	5-60	Dextroamphetamine
	*Dexmethylphenidate	Focalin	5-20	Dexmethylphenidate
	*Dextroamphetamine/Amphetamine	Adderall, Adderall XRm Quillivant XR	5-60	Dextroamphetamine/Amphetami
	*Lisdexamfetamine Dimesylate	Vyvanse	30-70	Lisdexamfetamine Dimesylate
	*Methamphetamine	Desoxyn	2.5-25	Methamphetamine
	*Methylphenidate	Concerta	18-72	Methylphenidate
	*Methylphenidate	Daytrana Patch, Focalin, Focalin XR, Methylin, Methylin ER, Metadate CD, Metadate ER, Ritalin, Ritalin LA, Ritalin-SR	5-60	Methylphenidate

Controlled Substances:
* Schedule II
** Schedule IV
*** Schedule V

APPENDIX B

HEALTHWEST FORMULARY

APPENDIX C

HEALTHWEST

POLICIES AND PROCEDURES

No. 06-009

Prepared by:

Cyndi Blair, RNBC
Pharmacy Work Group

Effective: February 26, 1997
Revised: August 3, 2016

SUBJECT: Maintenance of Formulary of Approved Medications

Approved by:

_____
Justin Bensinger, Consulting Pharmacist

_____
Julia B. Rupp, Executive Director

I. PURPOSE:

To assure the maintenance of an approved formulary for all medications prescribed or administered at HealthWest for the treatment of psychiatric disorders or the side effects of psychotropic medications.

II. APPLICATION:

Medications prescribed by HealthWest-contracted Physicians/PA/NP to individuals receiving services for the treatment of psychiatric disorders or the side effects of these medications.

III. DEFINITIONS:

Formulary: A catalogue of the medications approved for agency use in the treatment of psychiatric disorders and the side effects of those medications. The formulary shall include the generic name of the drug, common proprietary name, the normal dosage range, and a hyperlink to the corresponding medication teaching sheet.

IV. PROCEDURE:

A. The HealthWest Formulary of Approved Medications *(Attachment A)* in its entirety shall be reviewed and updated by the Pharmacy Work Group and approved by the Doctors Work Group annually during the first quarter of each calendar year.

B. The formulary may also be revised and approved by the Doctors Work Group as needed throughout the year, without amendment to this procedure.

C. The chairperson of the Pharmacy Work Group shall ensure that a copy of the current formulary is forwarded for attachment to this procedure and kept by contracted Physicians/PA/NP in all areas where medications are prescribed.

D. Physicians/PA/NP shall routinely prescribe for individuals receiving services only medications from the formulary.

1. Medications included on the formulary shall be specifically prescribed in order to treat psychiatric disorders or medication side effects, but not nonpsychiatric medical disorders.

2. In cases where nonpsychiatric medications are indicated and no primary care physician is available, only existing prescriptions may be extended; however, the primary worker shall make every effort to promptly link the individual with a primary care physician.

E. Addition of Nonformulary Medications

1. In cases where nonformulary medications are prescribed, a request for inclusion of the medication in the formulary must be submitted to the chairperson of the Pharmacy Work Group by the physician using the Request for Changes in the HealthWest Formulary of Approved Medications (M010).

2. The Pharmacy Work Group shall review the request for inclusion and ensure that it is placed on the agenda with recommendations for consideration at the next monthly meeting of the Doctors Work Group. Minutes of the Doctors Work Group meeting will include documentation of formulary decisions.

3. Without specific exceptions approved by the Pharmacy Work Group and the Doctors Work Group, nonformulary medications may not be prescribed for a consumer for more than three months without inclusion in the formulary. These exceptions would allow further evaluation of the use of a specific medication.

F. Implementing Additions of Medications to the Formulary

1. Following approval by the Doctors Work Group, the chairperson of the Pharmacy Work Group shall facilitate updating of the formulary by:

a. Providing the recommended dosage range for inclusion in the formulary.

b. Developing a Medication Teaching Sheet.

c. Ensuring prompt distribution of the revised formulary and Teaching Sheet to affected staff.

G. Deletion of Medications from the Formulary

1. A Physician/PA/NP may request that a medication be deleted from the formulary by completing and forwarding a Request for Changes in the HealthWest Formulary of Approved Medications (M010) to the chairperson of the Pharmacy Work Group.

2. The Pharmacy Work Group shall review the request for deletion and ensure that it is placed on the agenda with the recommendations for consideration at the next monthly meeting of the Doctors Work Group. Minutes of the Doctors Work Group meeting will include documentation of formulary decisions.

3. The chairperson of the Pharmacy Work Group shall facilitate updating of the formulary and ensure prompt distribution of the revised formulary to affected staff.

V. REFERENCES:

APPENDIX A: HealthWest Formulary of Approved Medications

APPENDIX B: M010 – Request for Changes in the HealthWest Formulary of Approved Medications

APPENDIX D

HEALTHWEST

MEDICATION ADMINISTRATION GUIDELINES

A. ADMINISTERING

1. Observe the Five Rights:

    a) Right person
        1) Prior to administering medication, staff will confirm the identity of the recipient using at least two approved sources specified on HealthWest Identity Verification & Photo Consent for Medication Administration Form (C154).
    b) Right time
    c) Right route
    d) Right dosage
    e) Right medication

        1) If there is anything unusual about the appearance or smell from the previous supply, do not give the medication until you check with the pharmacist/RN. If the medication must be held, the RN must be notified.

        2) If the wrong medication or dosage is supplied by the pharmacy, the staff member will immediately notify the RN who will then inform the pharmacy of the error, and facilitate securing the right medication. The staff person will promptly complete an incident report.

    f) Right reason – for PRN (as needed) medication

2. Work with adequate light.

3. Always wash hands before preparing medications and between each individual.

4. Provide a clean environment for preparing medications and assemble all supplies needed to administer medications, (water, spoons, applesauce, etc.).

5. Use the monthly medication sheet to prepare medication. Check with the monthly medication sheet:

a) To label on medication card/bottle.
b) When removing medication from card/bottle.
c) Before giving medication to the individual.

6. While preparing or administering medications, concentrate on this alone.

7. Medications shall be prepared at the time of administration for each individual.

8. Medications are never to be left out unattended for any reason.

9. Be knowledgeable about the medications you give:

    a) Why and how it is being given.
    b) Possible side effects and adverse reactions, and what to do if they occur.

10. Administer only medications that you have prepared personally and administer only in designated medication-passing areas.

11. Give medications as prescribed and on time. Medications can be administered 30 minutes before or after the prescribed time. To administer outside of this time frame, the RN must be notified.

12. Persons with known drug allergies must have charts and medication bins labeled with allergy labels. Medication record must have allergies noted in red.

13. Have prescriptions refilled several days before medications run out. (Seven days for group homes).

14. The RN will check any changes to the medication orders, on the medication sheet, made by someone other than the RN, at the earliest feasible time. The staff member making the change will be responsible for alerting the RN of the change.

15. If you find any discrepancy between the medication record or pharmacy label, consult with the RN for clarification.

16. If a documentation error is made on the medication sheet, circle it, notify the home supervisor, document explanation and fill out an incident report.

17. Only approved abbreviations can be used. Abbreviation form (M007) should be posted.

18. All pertinent information must be documented! If it is not documented, it didn't happen!

19. Document medications immediately after you pass them and before starting preparation for the next individual.

20. Avoid interruptions or distractions while preparing or administering medications. Be attentive.

B. SPECIFIC TYPES OF MEDICATIONS

1. Suspensions are to be shaken well and measured into a measuring cup, with care being taken to keep the outside of the container and cap free of medication.

2. Oral medications may be offered with liquids or applesauce followed with a glass of liquid.

C. GIVING THE MEDICATIONS TO THE RECIPIENT

1. Positively identify the recipient using at least two sources of identification.

    a) **NEVER** give anyone any medication that has not been ordered by a licensed provider.
    b) **NEVER** use a medication ordered for one person to treat another.
    c) **NEVER** give a medication to one person from another person's medication bottle.
    d) **NEVER** force an individual's medication.
    e) **NEVER** return an unused dose of medication to the bottle.

2. Provide privacy if appropriate.

3. Give the individual the medication(s) being careful not to handle the medication with fingers.

4. Assure that medications have been swallowed by visually checking the mouth cavity if necessary.

D. STAT MEDICATION ADMINISTRATION FOR BRINKS RESIDENCE, ACT AND COUNTY MENTAL HEALTH CENTER

1. Refer to STAT Medication protocol at each site.

APPENDIX E

HEALTHWEST
POLICY AND PROCEDURE
No. 04-003

Prepared by:

The Office of Recipient Rights

Effective: April 22, 1983
Revised: March 11, 2016
Subject: Consent

Approved by:

_____
Julia B. Rupp, Executive Director

I. POLICY:

HealthWest will provide mental health services only after the recipient, or his/her legal representative, has provided a written consent for treatment. Exceptions may occur where agency services will be provided to persons who meet criteria for involuntary evaluation or treatment.

II. APPLICATION:

All HealthWest programs

III. DEFINITIONS:

A. **Consent:** Written informed consent on the part of a recipient, or his/her legal representative. Informed consent requires:
   1. Legal competency. An individual shall be presumed to be legally competent. This presumption may be rebutted only by a court appointment of a guardian or exercise by a court of guardianship powers and only to the extent of the scope and duration of the guardianship. An individual shall be presumed legally competent regarding matters that are not within the scope and authority of the guardianship.
   2. Knowledge. To consent, a recipient or legal representative must have basic information about the procedure, risks, other related consequences, and other relevant information. The standard governing required disclosure by a doctor is what a reasonable patient needs to know in order to make an informed decision. Other relevant information includes all of the following:
      i. The purpose of the procedures.
      ii. A description of the attendant discomforts, risks, and benefits that can reasonably be expected.
      iii. A disclosure of appropriate alternatives advantageous to the recipient.
      iv. An offer to answer further inquiries.

3. Comprehension. An individual must be able to understand what the personal implications of providing consent will be based upon the information provided under subdivision (2) of this definition.
4. Voluntariness. There shall be free power of choice without the intervention of an element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion, including promises or assurances of privileges or freedom. There shall be an instruction that an individual is free to withdraw consent and to discontinue participation or activity at any time without prejudice to the recipient.

B. **Involuntary Recipient:** An individual who is in police custody under provisions of the Mental Health Code, or is held in a psychiatric inpatient unit or state facility by medical certification or Probate Court petition, or is otherwise under Probate Court order to receive mental health services.

IV. PROCEDURE:

A. The responsible staff person is required to provide full information to the recipient regarding treatment procedures' risks and other consequences and relevant information to the degree that a recipient can benefit from such information, even when a guardian has been appointed.

B. The responsible staff person will inform the recipient or legal representative that consent for mental health services may be withdrawn at any time without prejudice.

C. The responsible staff person must make a determination regarding the ability of a recipient, or legal representative, to give informed consent, as described in HealthWest Policy 06-010 Medication Administration §V.F.

D. Before any guardianship proceedings are initiated, the responsible staff person shall evaluate the recipient's, or legal representative's ability to give consent.

E. The rights of a minor to give consent shall be governed by the following:
1. A minor 14 years of age or older may request and receive mental health services and a mental health professional may provide mental health services on an outpatient basis, excluding pregnancy termination referral services and the use of psychotropic drugs, without the consent or knowledge of the minor's parent, guardian or person in loco parentis.
2. Except as otherwise provided in this section, the minor's parent, guardian or person in loco parentis shall not be informed of the services without the consent of the minor unless the mental health professional treating the minor determines that there is a compelling need for disclosure based on a substantial probability of harm to the minor or to another individual, and if the minor is notified of the mental health professional's intent to inform the minor's parent, guardian or person in loco parentis.
3. Services provided to a minor under this section shall be limited to not more than 12 sessions or four months per request for services. After the twelfth session or fourth month of services, the mental health professional shall terminate the services or, with

the consent of the minor, notify the parent, guardian or person in loco parentis to obtain consent to provide further outpatient services.

4. This section does not relieve a mental health professional from his or her duty to report suspected child abuse or neglect under Section 3 of the Child Protection Law, Act no. 238 of the Public Acts of 1975.

V. REFERENCES

M.C.L. 330.1707
Administrative Rules R 330.7003

LS/los

APPENDIX F

HEALTHWEST

PROCEDURE

No. 06-016

Prepared by:

Effective: October 1, 2002
Revised: February 1, 2009
Revised: May 25, 2016

Cyndi Blair, RNBC
Clozaril Work Group

Approved by:

Subject: Clozaril/Clozapine Treatment System (CTS) Procedures

_____, Consulting Pharmacist

Julia Rupp, Executive Director

I. PURPOSE:

To establish procedures for prescribing, monitoring, administering, and documenting the use of Clozaril/Clozapine as mandated by the FDA Clozapine Risk Evaluation & Mitigation Strategy (REMS) Program, Department of Community Health, and American Psychiatric Association Guidelines and Standards of Practice.

II. APPLICATION:

This procedure applies to all HealthWest employees, programs, contract physicians, physician assistants (PA), and nurse practitioners (NP) who prescribe, monitor, administer, and document Clozaril/Clozapine therapy.

III. DEFINITIONS/BACKGROUND INFORMATION:

A. Clozaril/Clozapine Treatment System (CTS) consists of doctors, PA, NP, pharmacists, medical testing laboratories, the individual's assigned Supports Coordinator (SC) and Registered Nurse Care Manager (RN Care Manager), individual receiving services, and support staff. Together they make sure the necessary weekly/biweekly/monthly blood testing is done, results are checked, and the correct number of Clozaril/Clozapine tablets is provided to the individual for each weekly/biweekly/monthly interval the individual is involved in Clozaril/Clozapine therapy.

B. Clozapine REMS: A strategy to manage known or potential risks associated with a drug or group of drugs, and is required by the FDA for Clozaril/Clozapine to ensure that the benefits of the drug outweigh the risk of severe Neutropenia.

C. Neutropenia: A blood disorder that occurs when a certain type of WBC called Neutrophils is not made or not enough of them are made. This makes it harder for the body to fight infection.

D. 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.

E. Clozapine REMS provides a centralized point of access for prescribers and pharmacies to certify before prescribing or dispensing Clozapine and to manage patients on Clozapine prescriptions.

IV. PROCEDURES

Overview of Sections

A. Clozaril/Clozapine Pretreatment
B. Initiation of Active Clozaril/Clozapine Treatment
C. Transferring Inpatient Clozaril/Clozapine Individuals New to the Outpatient CTS
D. Active Clozaril/Clozapine Treatment
E. Discontinuation of Clozaril/Clozapine Treatment
F. Response to Abnormal WBC and/or ANC Count
G. Changing Clozaril/Clozapine Dosage Midweek
H. Continuation of Clozaril/Clozapine Treatment in Event of Crisis Residential Admission
I. Continuation of Clozaril/Clozapine Treatment in Event of Hospitalization
J. Response to Individual's Failure to Comply with Clozaril/Clozapine Treatment Procedures
K. Individuals Receiving Services Vacations

A. CLOZARIL/CLOZAPINE PRETREATMENT

Prescribers must all get certified. To certify prescribers must:

1. Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers.*

2. Successfully pass the *Knowledge Assessment for Healthcare Providers*.

3. Complete and submit the one-time Clozapine REMS Prescriber Enrollment Form.

    a. Prescribers can allow designees to enroll patients and enter ANCs on their behalf. The term designee refers to any person who has been designated or requested to perform some duty or function on behalf of a prescriber. Designees must be certified in the Clozapine REMS Program before they can perform any duties or functions for their associated prescriber.

b. Prescriber designees must enroll in the Clozapine REMS Program, and a certified prescriber must confirm the designee. Any medical professional prescribing Clozapine must enroll and become certified in the Clozapine REMS Program. A notification will be sent to the prescriber when the designee enrolls. Before a designee can become certified, the prescriber will need to approve the person acting on his/her behalf. Once the designee has been approved, they will be able to engage in patient management through the Clozapine REMS Program website.

c. A designee can perform the following actions on behalf of the prescriber:

1) Enroll patients

2) Report ANC lab results

3) Manage patients and view patient lists

d. Get certified online at www.Clozapinerems.com or call 844-267-8678 for more information or to request materials.

4. Physician/PA/NP determines that the individual meets criteria for Clozaril/ Clozapine treatment listed below:

a. Clozaril/Clozapine is indicated in the treatment of severely ill, treatment-resistant psychotic individuals, i.e., "schizophrenic," "schizoaffective," "bipolar psychotic," or other psychotic conditions, who have had a substantiated diagnosis of psychosis for many years and have been treated with standard antipsychotic medication(s) in the past without positive response, either:

1) Because of insufficient effectiveness of other medications.

2) The inability to achieve an effective dose due to intolerable adverse effects from those drugs.

3) FDA Clozapine REMS Program APA *Guidelines and Standards of Practice* strongly recommend an individual be given at least two trials, each with a different antipsychotic medication, at an adequate dose and for an adequate duration, as defined by the *Guidelines for Pharmacological Treatment*, to establish ineffectiveness prior to starting Clozaril/Clozapine. Well-documented history may be employed to demonstrate this.

4) Individuals with symptoms of psychosis who meet any of the following criteria that are persistent and not amenable to conventional treatment must have such thoroughly documented by the physician/physician assistant/nurse practitioner in the clinical record:

a) Presence of drug-induced chronic abnormal movements

b) Well-documented history of drug-induced chronic abnormal movements

c) Presence of, or well-documented history of, Tardive Dyskinesia

d) Presence of, or well-documented history of, Tardive Dystonia.

a. The physician/PA/NP/RN must inform the individual of their role in the Clozaril/Clozapine Treatment System. The individual must consent to and complete baseline screening as ordered by the physician/PA/ NP.

b. The individual must be able to follow through with the required blood tests. Use the patient counseling tool titled *What You Need to Know about Clozapine & Neutropenia: A Guide for Patients and Caregivers.* Review this information with patients or their caregivers as often as needed to ensure they understand the risk of Neutropenia associated with Clozapine and the importance of ANC monitoring. Refer to Section 17 of the *Clozapine Prescribing Information* for additional important counseling messages for your Clozapine patients.

c. You may choose not to provide *What You Need to Know about Clozapine and Neutropenia: A Guide for Patients and Caregivers* to the patient or caregiver if you do determine that the patient's adherence to Clozapine treatment will be negatively impacted by providing it.

5. Physician/PA/NP/RN notifies SC of recommendation to initiate Clozaril/ Clozapine treatment.

a. If an SC is not assigned, Physician/PA/NP/RN notifies the primary worker who will contact the Access Program requesting authorization of Supports Coordination Services. Every individual who is treated with Clozaril/Clozapine must have a SC or designated support staff.

b. SC required to have Clozaril/Clozapine training by a HealthWest RN Care Manager, to review and familiarize themselves with Clozaril/ Clozapine Treatment System (CTS) procedures.

c. The RN Care Manager will verify insurance provider using Health Plan Benefits search & information, all of which should be sent to the pharmacy and lab with initial orders.

d. The SC will notify RN Care Manager of spend-down information.

e. RN will use ECR data to verify identifiers that are required by Clozapine REMS such as date of birth and zip code.

6. Rechallenge check is completed:

a. Inquire about a patient's Clozaril/Clozapine history before enrolling the patient; please call the Clozapine REMS Program at 844-267-8678 for

assistance or go to the website at www.Clozapinerems.com to view the history profile.

b. Per FDA requirements, if a patient and/or their caregiver or guardian will not provide the required information, the patient will not be able to receive Clozaril/Clozapine therapy.

c. Physician/designee enrolls consumer in the Clozapine REMS via online or Clozapine REMS Patient Enrollment Form or fax. Complete a Clozapine REMS Patient Enrollment Form.

7. Initial labwork is completed (pretreatment begins). Required laboratory testing prior to initiation and during therapy:

a. Prior to initiating treatment with Clozapine, a baseline ANC must be obtained within seven days of anticipated start of Clozaril/Clozapine usage. The baseline ANC must be at least 1500/µL for the General Population, and at least 1000/µL for patients with documented Benign Ethnic Neutropenia (BEN).

b. Case Manager/RN coordinates sending the individual to the lab for the initial blood draw.

c. RN notified the designated clerical person of the individual's pretreatment status.

d. RN sends the Health Plan Benefits report to the pharmacy and lab for all new Clozaril consumers.

e. Lab releases results to HealthWest addressed to physician within 24 hours. They are distributed to RN who reviews and communicates results to physician. The lab report is initialed/commented on by physician and turned in for filing.

f. If the lab report is obtained verbally from the lab, the RN will note the results on Laboratory Telephone Report (Form MO12) and have the physician initial the form.

8. If ANC is above 1500/µL for the General Population and at least 1000/µL for BEN patients, physician/RN may continue with Clozaril/Clozapine pretreatment procedures.

9. If ANC is less than 1499/µL for BEN, physician must document his/her decision to retest and/or evaluate the cause of the condition (Clozaril/Clozapine treatment cannot start).

10. If ANC is less than 999/µL for BEN, obtain at least two baseline ANCs before initiating treatment.

B. INITIATION OF ACTIVE CLOZARIL/CLOZAPINE TREATMENT

1. Physician/designee enrolls consumer in Clozapine REMS.

2. You can enroll a General Population consumer patient one of two ways:

   a. By signing into the Clozapine REMS Program website at www.Clozapinerems.com and enrolling the patient online.

   b. By downloading the Clozapine REMS Patient Enrollment Form from the Clozapine REMS Program website at www.Clozapinerems.com, and faxing the completed form to 844-404-8876. HealthWest has all Clozaril forms in the H-drive for each HealthWest prescriber.

3. For patients with Benign Ethnic Neutropenia (BEN), prescribers would indicate BEN status as part of the enrollment process on the Clozapine Program website. Phone enrollment is only available for the General Population consumers. General population patients and BEN patients can also be enrolled via fax.

4. If another prescriber has previously treated the patient with Clozapine, you must enroll the patient with a HealthWest prescriber by completing and submitting the Clozapine REMS Patient Enrollment Form to the Clozapine REMS Program (online or by fax) to access the patient's ANC History. If you cannot find the patient online, contact the REMS Program at 844-267-8678 for assistance or re-enroll the patient.

5. Certified physicians and designees can add ANC lab values for the enrolled consumer using the following steps:

   a. Sign into the Program website and navigate to your My Dashboard page using the button in the upper right corner of the page.

   b. Within our list of patients, select the "Add Lab" option from the actions drop-down list for the appropriate patient.

   c. Within the lab form, fill in the requested information and submit the form.

6. The patient's treatment status and monitoring frequency will automatically be set by the system.

7. RN/SC has individual receiving treatment/guardian sign an Authorization to Exchange Information allowing HealthWest to communicate with the lab and pharmacy, Clozapine REMS Program, specific brand of Clozaril/Clozapine manufacturer.

8. RN/SC interviews the individual, obtaining a list of all medications he/she is currently taking.

   a. This list, with the individual's name, is forwarded to the pharmacy to be entered into their computer. Medications that will suppress bone marrow function will be identified by the pharmacy.

b. In the event of a potential medication interaction, the pharmacy will notify the RN, by telephone, at the time of review.

c. Physician/PA/NP and RN confer. Clozaril/Clozapine is not to be used with other medications that suppress bone marrow function. The physician/PA/NP must document in a progress note the presence or absence of any contraindicated medications being taken by or prescribed for the individual receiving services.

9. Physician/PA/NP/RN/case manager communicates with the individual/ guardian to complete the following:

a. Briefing of individual/guardian regarding Clozaril/Clozapine procedures.

b. *A Guide for Patients and Caregivers: What do I tell my Patients about Clozapine?* This guide is found on the Clozapine REMS website at www.Clozapinerems.com.

c. Use the patient counseling tool titled "*What You Need to Know about Clozapine and Neutropenia: A Guide for Patients and Caregivers*." Review this information with patients or their caregivers as often as needed to ensure they understand the risk of Neutropenia associated with Clozapine and the importance of ANC monitoring. Refer to Section 17 of the Clozapine prescribing information for additional important counseling messages for your Clozapine patients.

1) You may choose not to provide "*What you Need to Know about Clozapine and Neutropenia: A Guide for Patients and Caregivers"* to the patient or caregiver if you determine that the patient's adherence to Clozapine treatment will be negatively impacted by providing the guide.

d. Clozaril/Clozapine teaching sheet.

e. Consent for Use of Psychotropic Medications (C148).

f. If Tardive Dyskinesia is present, Consent Form: Patient with Tardive Dyskinesia (C153).

g. Prescriptions for starting dose of Clozaril/Clozapine.

10. Physician/PA/NP issues standing order for weekly White Blood Cell and Absolute Neutrophil Count testing by the lab. RN will forward this order to the appropriate lab. Tests must be done weekly for at least six months on all new Clozaril/Clozapine individuals.

11. Physician/PA/NP/RN completes Clozapine REMS ANC Reporting Form. A copy is retained and filed in the individual's chart, and a copy is forwarded to the pharmacy with the current lab results.

12. RN notifies designated HealthWest clerical person that the individual is about to begin active Clozaril/Clozapine treatment. The following information is placed on the Clozaril Master List:

    a. Name

    b. Medicaid recipient ID number or other insurance provider information

    c. Prescribing physician and HealthWest program.

    d. Brand of Clozaril/Clozapine

    e. RN Care Manager and case manager assigned

    f. Date of birth

    g. Clozaril group.

13. The designated clerical staff transmits copies of the revised Clozaril Master List to HealthWest staff, RN Care Managers, Pharmacy, and lab as it is revised.

14. RN/designated HealthWest staff will forward the following to the pharmacy by 3 p.m. the Tuesday of the week due so that the individual's seven-day supply of Clozaril/Clozapine is available for prompt pick up the next morning.

    a. Clozapine REMS ANC Reporting Form with current lab attached.

    b. The prescription for the individual's titration of Clozaril/Clozapine with Health Plan Benefits report attached.

15. The SC prepares and processes a Treatment Plan Addendum to modify the individual's existing PCP to include Clozaril/Clozapine treatment.

16. The RN takes and records vital signs (including weight) weekly for one month and then monthly unless otherwise indicated. Abnormal results will be rechecked in accordance with the Clozapine REMS chart for recommended monitoring frequency and clinical decisions by ANC level.

17. The SC/designated staff person coordinates the individual reporting to the Clozaril/Clozapine clinic or lab and pharmacy as needed.

    a. Blood is drawn at the designated location.

    b. The individual receives a Clozaril/Clozapine Blood Draw Confirmation Slip to present to the pharmacy for medication pick-up to pick up a one-week supply of Clozaril/Clozapine.

C. TRANSFERRING INPATIENT CLOZARIL/CLOZAPINE INDIVIDUALS NEW TO THE OUTPATIENT CTS

1. In the event Clozaril/Clozapine treatment is initiated for an individual while hospitalized, the assigned case manager will facilitate transfer to the HealthWest outpatient CTS. If a SC is not assigned, the HealthWest Hospital Liaison will process a referral for case management and monitor the individual and treatment procedures until a case manager is assigned.

2. The Case Manager/Hospital Liaison arranges for the individual to be seen by the HealthWest physician/PA/NP within the week of discharge and forward discharge information the day of the discharge and the most recent lab to the Care Manager or RN Care Manager. A HealthWest prescription will be obtained for WBC/ANC and Clozaril/Clozapine, and the RN Care Manager will establish protocol in accordance with what was started inpatient.

3. The RN enrolls consumer in the Clozapine REMS Program under HealthWest prescriber and submits online with the most recent lab or fax enrollment form.

D. ACTIVE CLOZARIL/CLOZAPINE TREATMENT

1. The frequency of monitoring WBC and ANC results, per the current FDA (Food and Drug Administration) recommendations, will be followed as is dictated in the *Clozapine & the Risk for Neutropenia: A Guide for Healthcare Providers* found on the website www.clozapinerems.com.

2. The lab ensures delivery and Clozapine REMS Program ANC results for all HealthWest Clozaril/Clozapine individuals to the appropriate HealthWest location on Wednesdays, no later than 2 p.m.

3. ANC results & Clozapine REMS ANC Reporting Form will be reviewed by the RN and initialed by the physician before being submitted for filing.

4. RN completes ANC Reporting Form by the appropriate Tuesday prior to the consumer's Wednesday clinic. A 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 90 days and submitted to the pharmacy.

5. Designated HealthWest staff faxes copy of ANC Reporting Form and copy of lab results to the pharmacy no later than Friday of the clinic date.

6. The physician/PA/NP sees the individual for medication reviews as needed, minimally every 90 days. Clozaril/Clozapine dosage is adjusted as needed.

7. Prescriptions for increases or decreases in Clozaril/Clozapine are phoned or faxed to the pharmacy and documented in the clinical record according to HealthWest policy. The pharmacy is requesting that any time we increase the Clozaril dose in-between dispense dates to do a Clozaril prescription to bridge until the actual dispense due date for the regularly scheduled Clozaril clinic.

8. 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.

9. The RNs that conduct the weekly HealthWest Clozaril Clinic will be responsible for monitoring the individual's vital signs, assessing for medication effectiveness/side effects, and providing support. Monitoring will occur monthly unless otherwise indicated. Any abnormal vital signs will result in repeat monitoring in one week. Generally, Clozapine treatment should be interrupted, as a precautionary measure, in any patient who develops a fever of 101.3 F or greater, and the ANC should be obtained.

10. RN is responsible for communicating changes to the lab and pharmacy. If additional routine laboratory work has been ordered, the RN will notify the lab so the draw can coincide with the scheduled WBC/ANC draw.

11. During the first week of Clozaril/Clozapine treatment, the individual's status is changed from "pretreatment" to "active treatment." The RN communicates status change(s) to the designated clerical person prior to the next Tuesday. Status changes(s) are reflected on the Clozapine REMS ANC Reporting Form.

12. A designated clerical person is responsible for updating of all information on the HealthWest Clozaril/Clozapine list. This list will be used by lab and pharmacy personnel to identify registered individuals who have failed to come in for their blood test or medication.

13. Designated clerical person sends copy of Clozaril/Clozapine list to all direct care HealthWest Staff, and to RN Care Managers to review. They will notify the clerical person if there are any discrepancies.

14. Active Clozaril/Clozapine individuals transferring from programs within HealthWest will require:

    a. A telephone call from the previous program nurse to the new program nurse regarding the transfer.

    b. The current Clozaril/Clozapine order and current labs faxed to the new program nurse.

    c. The new program nurse calling the designated clerical person, laboratory, and pharmacy as needed.

15. The physician/PA/NP will write an order to change the frequency of WBC and ANC monitoring to every two weeks for six months after six months of therapy has been completed if WBC and ANC results have remained normal.

    a. The RN will notify the lab and pharmacy of the change in monitoring frequency.

b. Pharmacy will supply a two-week supply of medication to the individual.

16. The physician/PA/NP will write an order. The Clozapine REMS ANC Reporting Form will reflect change and enter change information online within 12 months of treatment and ANC results have remained normal.

    a. The RN will notify the lab and pharmacy of the change in monitoring frequency.

    b. The pharmacy will supply a one-month supply of medication to the individual.

E. DISCONTINUATION OF CLOZARIL/CLOZAPINE TREATMENT

1. Physician/PA/NP/RN informs the pharmacy of medication discontinuation with an order, and notifies the lab with an order the same day the Clozaril/Clozapine discontinuation is to start.

    a. When termination is planned, a gradual reduction over a one- to two-week period is recommended. The pharmacy will be advised of the last planned dose. The discontinuation order from the HealthWest prescriber will reflect the taper. The RN Care Manager will ensure the order is transmitted to and understood by the entire care team

    b. The method of treatment discontinuation will vary depending on the patient's last ANC. Abrupt treatment discontinuation is necessary for moderate to severe Neutropenia that you suspect is caused by Clozapine.

    c. Remember to report the decision to discontinue Clozapine for a patient to the Clozapine REMS Program. You can do this one of three ways:

        1) By signing into the Clozapine REMS Program website at www.Clozapinerems.com.

        2) By calling the Clozapine REMS Program contact center at 844-267-8678.

        3) By completing the "Patient Update – Change Treatment Status" section of the ANC Lab Reporting Form and faxing it to the Clozapine REMS Program at 844-404-8876.

    d. When the individual's medical condition requires abrupt discontinuation, the RN and the prescribing physician/PA/NP will be notified if there are recurrences of psychiatric symptoms and/or withdrawal symptoms.

    e. For some patients who experience, or have experienced, moderate Clozapine-related Neutropenia (ANC less than 1000/µL) or severe Clozapine-related Neutropenia (ANC less than 500/µL), the risk of serious psychiatric illness from discontinuing Clozapine may be greater than the risk of rechallenge. This may be relevant for patients with severe schizophrenic illness who have no treatment option other than Clozapine. In making the decision to rechallenge a patient, consider:

1) A hematology consultation.

2) The ANC ranges defined in the full prescribing information.

3) A discussion with the patient and his or her caregiver about the benefits and risks of Clozaril/Clozapine rechallenge the severity and characteristics of the neutropenia episode.

f. Prescribers may choose to continue Clozapine treatment in patients with ANCs less than 1000/µL in the General Population; however, the prescribers should follow the treatment recommendations carefully to determine if the benefits of continuing Clozaril/Clozapine treatment outweigh the risks.

g. If treatment is interrupted < 30 days, continue monitoring schedule as before. If treatment is interrupted > 30 days, continue monitoring as if a new patient. This is for General Population & BEN Population patients.

2. The RN sends an order to the lab indicating the four post Clozaril dates that ANC must be done, then discontinue after the last date.

3. The RN continues to see the individual four weeks following discontinuation of Clozaril, whether abrupt or gradual, to monitor and record vitals, monitor for withdrawal symptoms, assess physical and psychiatric condition, and provide support. Monitor patients carefully for the recurrence of psychotic symptoms and symptoms related to cholinergic rebound such as profuse sweating, headache, nausea, vomiting, and diarrhea.

4. For abrupt Clozapine discontinuation for a reason unrelated to Neutropenia, continuation of the existing ANC monitoring is recommended for General Population patients until their ANC is ≥ 1500/µL and for patients with BEN until their ANC is ≥ 1000/µL or above their baseline.

5. The individual continues to go to the lab weekly for four weeks following discontinuation to have blood drawn for WBC/ANC counts. A confirmation slip for the ANC blood draw is not needed. Depending on the individual's ANC, more frequent blood testing may be ordered as outlined in Clozapine REMS treatment recommendations.

6. The lab delivers/faxes the ANC results to the appropriate HealthWest location the day it is drawn. The assigned RN reviews and communicates results to the prescribing physician via the Clozapine REMS ANC Reporting Form, indicating change in treatment status for each of the four weeks following discontinuation. Change in treatment status may also be reported to Clozapine REMS via phone call or online. The Physician/PA/ NP will initial the results before filing.

7. After <u>four weekly ANCs,</u> the RN instructs the designated clerical person to remove the individual's name from the Clozaril/Clozapine list.

8. If the individual is not cooperative in obtaining a blood test after discontinuation, repeated attempts should be made to seek the

individual's cooperation. The danger should be explained and documented. In the case of incompetent individuals, the guardian should be advised of the situation. Individuals may not be forced to comply.

F. RESPONSE TO AN ABNORMAL ANC COUNT (See Attachment A)

1. Mild Neutropenia: If an individual's ANC is between 1000/µL and 1499/µL:

   a. For General Population, the lab is to contact the HealthWest RN involved that working day.

   b. For BEN Population, Mild Neutropenia is normal range. Continue Patient's "Normal BEN Range" for ANC monitoring interval.

   c. For General Population patients the RN and Physician/PA/NP review the ANC results. (See Attachment A)

   d. Continue treatment.

   e. The Physician/PA/NP and RN develop and implement, within 48 hours, a plan for monitoring the individual and document decision to maintain or reduce the dosage of Clozaril/Clozapine.

      1) For General Population patients, physician orders ANC to be done three times weekly until ANC is 1500/µL) or greater. Once the ANC is equal to or greater than 1500/µL, the consumer's last "Normal Range" ANC monitoring interval may be reinstated.

      2) The RN monitors the individual's physical condition and records vitals as ordered by the Physician/PA/NP. Results are reviewed with the Physician/PA/NP.

      3) RN will inform the SC and/or treatment team of the abnormal test results and monitoring plan.

      4) SC/RN communicates this information to the individual and, if necessary, accompanies him/her to the lab for blood draws. The risk and symptoms of infection will be explained to the individual and others (family/care provider). The individual will be instructed to immediately report to the treatment team if they develop any symptoms of infection.

      5) Primary care physician will be kept informed of the individual's status by the RN.

      6) Recommend hematology consultation.

2. Moderate Leukopenia and Moderate Granulocytopenia: If the General Population individual's ANC is 500/µL to 999/µL.

   a. The lab immediately notifies a HealthWest RN.

b. The RN and Physician/PA/NP review the ANC results.

c. Physician/PA/NP and RN develop, implement, and document (within 24 hours) a plan for monitoring the individual.

1) For the General Population recommend hematology consultation.

2) For the General Population interrupt treatment for suspected Clozapine-induced Neutropenia. The RN completes the Clozapine ANC Reporting Form and notifies the pharmacy and Clozapine REMS either online, by fax, or by phone.

"On hold" is checked for the individual's Clozaril/Clozapine status ensuring that the pharmacy will stop dispensing Clozaril/Clozapine to this individual until ordered to resume by the Physician/PA/NP.

3) Daily ANC test must be ordered until the patient's ANC ≥ 1500/µL.

4) Once ANC is ≥ equal to or greater than 1500/µL, return to patient's last "normal range" ANC monitoring interval.

5) Resume Clozaril/Clozapine treatment once ANC normalizes ≥ 1500/µL with titrating order from HealthWest prescriber.

6) For the BEN Population recommend hematology consultation and continue Clozaril/Clozapine treatment.

7) For BEN Population, labs must be done three times weekly until ANC is ≥ 1000/µL or patient's known baseline. Check ANC weekly for 4 weeks, and then return to patient's last "normal BEN range" ANC monitoring interval.

8) RN will inform the SC and/or treatment team of the abnormal test results and monitoring plan.

9) SC/RN notifies the individual of the Clozaril/Clozapine status change and ensures that the individual stops taking his/her Clozaril/Clozapine. The risk and symptoms of infection will be explained to the individual and others (family/care provider) by RN. The individual will be instructed to report immediately to the treatment team if they develop any symptoms of infection.

10) SC/designated staff accompanies the individual to the lab for all prescribed blood draws as necessary.

11) The RN monitors the individual's physical condition, taking and recording vitals as ordered by the Physician/PA/NP. Results are reviewed with the Physician/PA/NP.

12) Primary care physician will be kept informed of the individual's status by the RN.

13) The RN completes the Clozapine ANC Reporting Form and notifies the pharmacy & Clozapine REMS either online, by fax, or by phone.

"On hold" is checked for the individual's Clozaril/Clozapine status ensuring that the pharmacy will stop dispensing Clozaril/Clozapine to this individual until ordered to resume by the Physician/PA/NP.

3. Severe Leukopenia and Severe Granulocytosis: Total ANC count is less than 500/µL for the General Population and less than 500/µL for the BEN Population.

a. Lab notifies HealthWest RN or Physician/PA/NP immediately. The HealthWest Emergency Line, 231-722-4357, is used for contacting the RN on call after hours, on holidays, or weekends.

b. Physician and RN review results and inform SC or designated staff person that Clozaril/Clozapine must be discontinued immediately for suspected Clozapine-induced Neutropenia. The Physician/PA/NP writes an order indicating discontinuation.

c. RN/SC or designated staff person contacts the individual at once and ensures that he/she discontinues Clozaril/Clozapine immediately.

d. The Physician/PA/NP orders appropriate monitoring procedures until ANC are at least four weeks from day of discontinuation as follows:

1) For General Population patients, daily lab until ANC is ≥ 1000/µL.

2) For General Population patients ANC weekly until ANC is ≥ 1500/µL.

3) For the General Population, do not rechallenge unless prescriber determines the benefits outweigh risks. If patient is rechallenged, resume treatment as a NEW patient under "normal range" monitoring once the ANC is ≥ 1500/µL.

4) The physician/PA/NP must request medical consult with primary care physician and appropriate medical referral(s) within 24 hours.

5) Physician/RN/PA/NP monitors the individual's physical/psychiatric condition.

e. RN notifies the pharmacy by telephone within 24 hours that the individual has discontinued Clozaril/Clozapine treatment.

f. RN communicates status change to the designated clerical person. Treatment status is changed from "active" to "discontinued."

g. The RN flags the individual's record with a drug-sensitization warning of Allergic Agranulocytosis secondary to Clozaril/Clozapine.

h. All further steps outlined in Section E above, Discontinuation of Clozaril/ Clozapine Treatment, Paragraphs 1 through 8, are to be followed.

i. Physician/PA/NP/RN must communicate with the individual's primary care physician regarding the risk of infection. Recommend hematology consultation.

1) The physician/PA/NP must request medical consult with primary care physician and appropriate medical referral(s) within 24 hours.

2) Physician/RN/PA/NP monitors individual's physical/psychiatric condition.

4. Authorizing continuation of Clozaril/Clozapine when the ANC is less than 1000/µL for General Population or less than 500/µL for BEN Population.

a. A prescriber may authorize Clozapine treatment to continue.

b. This authorization is called a treatment rationale; it requires the prescriber to confirm that the benefits of continuing Clozaril/Clozapine treatment outweigh the risks of developing severe Neutropenia.

c. For reporting a treatment rationale:

1) The Clozapine REMS Program will alert the prescriber if an ANC is provided that is below the recommended thresholds for a patient. Clozapine will not be dispensed to the patient unless the prescriber provides a treatment rationale to authorize continued treatment.

2) The Clozapine REMS Program will change the treatment status of a patient with a low ANC to "interrupted" or "discontinued," and according to the recommendations in the prescribing information.

3) If the prescriber wishes to continue Clozaril/Clozapine treatment, the prescriber must change the patient's treatment status to "active," and confirm that the benefits of continuing Clozapine treatment outweigh the risks of developing severe Neutropenia (i.e., the treatment rationale).

4) Prescribers must confirm treatment continuation by faxing a signed Clozapine ANC Lab Reporting form to Clozapine REMS with a completed Treatment Rationale section.

5) After the prescriber provides the treatment rationale, the Clozapine REMS Program will issue a Pre-Dispense Authorization (PDA), which allows the outpatient pharmacy to dispense Clozaril/ Clozapine.

6) Information provided in the Clozapine REMS Program is not a substitute for appropriate documentation. Documentation to be in the patient's medical record regarding the prescriber's decision to continue, interrupt, or discontinue Clozapine treatment.

5. Report suspected adverse events directly to the Clozapine REMS Program via phone. You may also report adverse event information to the FDA MedWatch Reporting System by phone at (800) FDA-1088, or by mail using Form 3500A, available at www.fda.gov/medwatch.

6. For Hospice patients (i.e., terminally ill patients with an estimated life expectancy of six months or less), the prescriber may reduce the ANC monitoring frequency to once every six months, after a discussion with the patient and his/her caregiver. The individual treatment decisions should weight the importance of monitoring ANC in the context of the need to control psychiatric symptoms and the patient's terminal illness.

G. CHANGING CLOZARIL/CLOZAPINE DOSAGE MID-WEEK

1. Physician/PA/NP/RN/staff confer.

2. Physician/PA/NP determines that a specific change in dosage is needed.

3. Physician/PA/NP/RN phones in the new prescription to the pharmacy. The verbal order is documented according to HealthWest policy, and prescription copy is faxed to the pharmacy with "new" or "change" written on the fax to alert the pharmacist.

4. The rationale for the change is appropriately documented in the chart by the Physician/PA/NP/RN, signed by the Physician/PA/NP (or verbal order form), in case of a verbal order. [ENTERED IN OC]

5. The SC or designated staff person contacts the individual the same working day and picks up the change in prescription of Clozaril/Clozapine and takes it to the individual with specific instructions on when to take it. (The individual, if able, may pick up the medication once notified by the RN or SC to do so.)

6. The RN communicates with the pharmacy regarding the midweek dosage change. In the event of a decrease, the pharmacy is to be instructed to reduce the individual's next weekly supply of Clozaril/Clozapine by a corresponding number of pills. ******* (The individual is not to accumulate a supply of this medication.)

H. CONTINUATION OF CLOZARIL/CLOZAPINE TREATMENT IN EVENT OF HOSPITALIZATION

1. Psychiatric Hospitalization (Except KPH):

   a. HealthWest Physician/PA/NP/RN/SC/Case Manager alerts hospital staff of the individual's medication needs and communicates relevant information.

b. RN informs lab, pharmacy, and designated HealthWest clerical person of the transfer. The clerical person will update the individual's Clozaril/Clozapine status change to "on hold/interrupted" on the next Clozaril/Clozapine List.

c. Upon discharge, the SC/RN facilitates transfer back to the HealthWest Outpatient CTS. At the time of discharge, the hospital physician will provide a current Clozaril/Clozapine prescription and current WBC/ANC count results. SC responsible for getting information on the day of discharge.

1) If an individual is discharged on a weekday, the individual/ designated staff must report the same day to the pharmacy to pick up the change in his/her weekly prescription which will carry him/her until the following Wednesday.

2) An individual discharged over a weekend will be provided enough Clozaril/Clozapine by the hospital to last until the next working day. The first working day following discharge, the individual or designated staff report to the pharmacy to pick up the remainder of his/her weekly prescription which will carry him/her until the following Wednesday.

3) If an individual was on Clozaril/Clozapine prior to admission to the hospital, the individual will turn in medication to RN/SC for appropriate disposal by a Health Care Professional.

d. SC arranges for the individual to be seen by a HealthWest physician/ PA/NP within seven days of discharge.

e. The RN notifies the designated clerical person of the individual's outpatient status on the day of discharge. The clerical person will update the individual's Clozaril/Clozapine status change to "active treatment" on the next Clozaril/Clozapine List.

2. Kalamazoo Psychiatric Hospital (KPH):

a. Emergency Services (ES) staff alerts HealthWest's Kalamazoo Psychiatric Hospital (KPH) Liaison that the individual is receiving Clozaril/Clozapine.

b. ES notifies the individual's HealthWest RN of the admission, and this information is updated on the "Clozaril List," and the pharmacy is notified.

c. RN consults with the HealthWest KPH Liaison and forwards copies of the previous Clozaril prescribing information to the KPH Liaison.

d. When a Clozaril/Clozapine individual is to be discharged from KPH, the HealthWest Liaison must notify the HealthWest Program that will be responsible for his/her treatment after appropriate placement is found.

e. HealthWest Liaison obtains the results of the current WBC/ANC count from KPH. If a new WBC/ANC is required, HealthWest staff will facilitate arrangements to have the WBC/ANC count completed by the appropriate lab.

f. The HealthWest RN will complete the Clozapine Patient Enrollment Form on the day of discharge and fax it to Clozapine REMS (fax 844-404-8876) or submit data online to Clozapine REMS website at www.Clozapinerems.com.

g. It should be noted that an individual cannot be released from KPH with more than a two-weeks supply of Clozaril/Clozapine. Arrangements by the KPH Liaison for securing this medication in the community will have to be made quickly. The individual must be seen, depending on the amount of medication dispensed, by a HealthWest Physician within 7 to 14 days of discharge.

3. Medical Hospitalization

a. HealthWest Physician/PA/NP/RN consults with the individual's private physician and communicates relevant medication information (with the exception of a life-threatening situation, the SC/RN/ Physician/PA/NP must obtain the individual/guardian's written authorization to release information prior to disclosure).

b. If the treating Physicians/PA/NP elects to continue Clozaril/Clozapine, SC and/or designated HealthWest staff will facilitate a transfer to the Hospital Inpatient CTS.

c. Procedures outlined in Section H.1. (Items b through e) are followed with hospital medical staff.

I. RESPONSE TO INDIVIDUAL FAILURE TO COMPLY WITH CLOZARIL/ CLOZAPINE TREATMENT PROCEDURES

1. The individual fails to see RN for scheduled vital sign monitoring appointments.

a. The RN will notify the SC or designated staff person of the individual's missed appointment.

b. SC/staff person promptly attempts to contact the individual to determine the reason for lack of compliance, and then confers with the Physician/PA/NP/RN.

c. If Clozaril/Clozapine is to be continued, the SC/staff person requests the individual to come in to see the RN and then directs them to the lab and pharmacy, if necessary.

d. If the individual cannot be located within three days after the missed appointment, serious consideration must be given to temporarily suspend Clozaril/Clozapine treatment.

e. If the decision is to discontinue treatment due to lack of compliance, follow the procedures outlined in Section E.

2. Failure to Report to Lab/Clinic for Blood Draw:

a. If the individual fails to show for the clinic blood draw, their Clozaril/ Clozapine should be returned to the pharmacy. Pharmacy will notify RN by 5 p.m. on the day Clozaril refill due.

b. The RN will notify IHC lab of all Clozaril no-shows on the clinic day of the no-show. All delinquent and repeat Clozaril labs will be done at the IHC HealthWest lab. All repeat labs are done after 12 p.m. only, per directive of HealthWest prescribers, at HealthWest IHC lab. All delinquent Clozaril labs are done at the HealthWest IHC lab also.

3. Individual Fails to Pick Up Clozaril/Clozapine from Pharmacy after Blood Draw:

a. After 12 noon Wednesday, pharmacy will contact the RN.

b. Follow Paragraph 1 above (Items b through e) as appropriate.

4. Individual is not Taking Medications as Prescribed

a. RN confers with Physician/PA/NP and SC/staff person.

b. Immediately following consultation, SC/staff person contacts individual to discuss/assess problems with medication compliance.

c. Physician/PA/NP, RN, and SC confer to determine whether to continue or suspend Clozaril/Clozapine treatment. Treatment recommendations are documented in the record.

J. INDIVIDUALS RECEIVING SERVICES VACATIONS

1. If the individual is out of town for 3 weeks or less after the first 6 months of treatment but before 12 months of treatment, RN to contact pharmacy for the appropriate amount of Clozaril/Clozapine.

2. Transfer to an existing Clozaril/Clozapine Treatment System if the individual is not able to appear for more than three weeks and has not been on Clozaril treatment for more than 12 months.

a. The individual/guardian must notify the RN or SC two to four weeks in advance when planning to leave town on vacation greater than three weeks. If the individual must leave town on short notice (one to two days), the individual/guardian must notify the RN or SC as soon as possible, prior to leaving. The individual will need to provide an outline of his/her travel plans, giving destinations and expected arrival times, etc.

b. The RN/SC will need to check with the individual's health plan regarding prior authorization needs. Michigan Medicaid will cover Clozaril/Clozapine costs while an individual is on vacation in other states only when prior authorization from the appropriate health care plan has been obtained. Vacations of less than one month are recommended as the length of time outside of the state may affect Medicaid eligibility.

c. The RN, Physician/PA/NP and SC confer. Consultation and recommendation for ensuring compliance with the Clozaril/Clozapine treatment regimen over vacation are documented by the SC.

d. The RN phones the Clozaril REMS at 844-267-8678.

e. The SC obtains from the individual/guardian separate Authorization to Exchange Information for the participating CTS(s) allowing the RN/SC to communicate specific Clozaril/Clozapine treatment information.

f. To obtain authorization for out-of-state pharmacy coverage, the RN phones appropriate health care plan.

g. The following information will need to be provided to the representative of the health plan:

    1) Out-of-state physician's name and telephone number;

    2) Out-of-state pharmacy's name and telephone number;

    3) The dosage that the individual is taking;

    4) Dates of service while the individual is out-of-state/town;

    5) And, if available, the prescription numbers.

h. The Health Plan's Office of Prior Authorization will call the out-of-state pharmacy directly to authorize coverage.

i. Obtaining out-of-state laboratory services while the individual is covered by Michigan Medicaid does not require prior authorization. The laboratory must be willing to accept Michigan Medicaid as full payment. If not, the individual may need to pay the full amount or the difference of the cost of the required laboratory services. The individual may also attempt to find another laboratory willing to accept Michigan Medicaid. The laboratory bills Michigan Medicaid directly. The contact phone number is 517-335-5477 and the fax number is 517-335-5570.

j. If the individual is indigent, the SC must contact HealthWest Access and obtain authorization for payment of laboratory, pharmacy and HealthWest services.

k. The SC/RN shares the plan for out-of-state/town Clozaril/Clozapine services with the individual. The final plan should be available in writing for the individual.

l. The RN must notify the designated clerical person the Tuesday before vacation starts to change the individual's Clozaril status to "on vacation."

m. The SC/RN is to call the out-of-state/town CTS to confirm that the individual has followed through as arranged. If the individual has not followed through, the SC/RN will attempt to contact the individual.

n. The RN/SC instructs the individual to call the RN or SC immediately if he/she cannot follow through with the plan while on vacation.

o. If appropriate, the RN/SC will assist the individual with developing an alternative plan.

p. Depending on their functioning/compliance level, individuals may be able to set up their own Clozaril/Clozapine travel plans with minimal assistance from staff.

3. Continuing with HealthWest Outpatient CTS while the individual is vacationing (use when this option is easier, or no other CTS is available):

a. Follow Paragraph J above.

b. Locate via long distance phone a medical lab with fax capability in the city in which the individual is going to vacation.

c. Secure the following:

1) Directions to the lab

2) Hours of operation

3) Cost of WBC

4) Fax number

5) Fee for faxing WBC results to HealthWest

d. The SC obtains an Authorization to Exchange Information for the participating lab, allowing the Physician/PA/NP/RN/SC to communicate specific Clozaril/Clozapine information.

e. HealthWest Physician/PA/NP or RN phones in an order for a WBC/ANC, gives lab HealthWest Fax number and name of staff person to receive the results and documents this according to Agency policy.

f. The RN/SC shares the plan for out-of-state/town Clozaril/Clozapine services with the individual; the final plan should be available in writing for the individual.

ATTACHMENTS

ATTACHMENT A **RECOMMENDED MONITORING FREQUENCY AND CLINICAL DECISIONS BY ANC LEVEL**

FORMS

M012 **LABORATORY TELEPHONE REPORT**
C148 **CONSENT FOR USE OF PSYCHOTROPIC MEDICATIONS**
C153 **CONSENT FORM – PATIENT WITH TARDIVE DYSKINESIA**

ATTACHMENT A

From Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers

RECOMMENDED MONITORING FREQUENCY AND CLINICAL DECISIONS BY ANC LEVEL

ANC LEVEL	TREATMENT RECOMMENDATION	ANC MONITORING
Normal Range for a New Patient GENERAL POPULATION ●ANC ≥ 1500/µL BEN POPULATION ●ANC ≥ 1000/µL ●Obtain at least two baseline ANC levels before initialing treatment	●Initiate treatment ●If treatment interrupted: <30 days, continue monitoring as before ≥30 days, monitor as if new patient ●Discontinuation for reasons other than neutropenia	●Weekly from initiation to 6 months ●Every 2 weeks from 6 to 12 months ●Monthly after 12 months ●See Section 2.4 of the full Prescribing information
Mild Neutropenia (1000 – 1499/µL)*	GENERAL POPULATION ●Continue treatment BEN POPULATION ●Mild Neutropenia is normal range for BEN population, continue treatment ●Obtain at least 2 baseline ANC levels before initiating treatment ●Discontinuation for reasons other than Neutropenia	GENERAL POPULATION ●3 times weekly until ANC ≥ 1500/µL ●Once ANC ≥ 1500/µL return to patient's last "Normal Range" ANC monitoring interval** BEN POPULATION ●Weekly from initiation to 6 months ●Every 2 weeks from 6 to 12 months ●See Section 2.4 of the full Prescribing information
Moderate Neutropenia (500 – 999/µL)*	GENERAL POPULATION ●Recommend hematology consultation ●Interrupt treatment for suspected Clozapine-induced Neutropenia ●Resume treatment once ANC normalizes to ≥ 1000/µL	GENERAL POPULATION ●Daily until ANC ≥ 1000µL, then ●3 times weekly until ANC ≥ 1500µL ●Once ANC ≥ 1500µL check ANC weekly for 4 weeks then return to patient's last "Normal Range" ANC monitoring interval**
	BEN POPULATION ●Recommend hematology consultation ●Continue treatment	BEN POPULATION ●3 times weekly until ANC ≥ 1000µL or ≥ patient's known baseline ●Once ANC ≥ 1000µL or patient's known baseline, check ANC weekly for 4 weeks, then return to patient's last "Normal BEN Range" ANC monitoring interval.**
Severe Neutropenia (<500/µL)*	GENERAL POPULATION ●Recommend hematology consultation ●Interrupt treatment for suspected Clozapine-induced Neutropenia ●Do not rechallenge unless prescriber determines benefits outweigh risks	GENERAL POPULATION ●Daily until ANC ≥ 1000µL ●3 times weekly until ANC ≥ 1500µL ●If patient rechallenged, resume treatment as a new patient under "Normal Range* monitoring once ANC ≥ 1500µL
	BEN POPULATION ●Recommend hematology consultation ●Interrupt treatment for suspected Clozapine-induced Neutropenia ●Do not rechallenge unless prescriber determines benefits outweigh risks	BEN POPULATION ●Daily until ANC ≥ 500µL ●3 times weekly until ANC ≥ patients established baseline ●If patient rechallenged, resume treatment as a new patient under "Normal Range" monitoring once ANC ≥ 1000/µL or at patient's baseline

* Confirm all initial reports of ANC less than 1500/µL (ANC < 1000/µL for BEN patients) with a repeat ANC measurement within 24 hours

** If clinically appropriate

APPENDIX G

HEALTHWEST
LABORATORY MONITORING GUIDELINES FOR USE OF PSYCHOTROPIC MEDICATIONS

Mood Stabilizers
Carbamazepine (Carbatrol, Equetro, Tegretol) and Oxcarbazepine (Trileptal)

TESTS	BASELINE	2nd WEEK	1st MONTH	3RD MONTH	6TH MONTH	YEARLY
Pregnancy Test	Every 3 months for women of childbearing age					
CBC (not for Trileptal)	Yes		Yes	If indicated		Yes, or early as indicated
Liver Function Test	Yes		Yes			Yes, or early as indicated
Carbamazepine Level (Tegretol)	1 week		Yes, or early or if meds increase/ decrease			Yes, or early as indicated
Kidney Function Test (BUN and Creatinine)	Yes					If indicated
TSH	Yes					If indicated
Electrolytes, especially with Trileptal (BMP)	Yes		Yes			Yes

Mood Stabilizers
Lithium (Eskalith, Lithobid, and Lithium)

TESTS	BASELINE	WEEK 1	WEEK 2	1ST MONTH	6TH MONTH	ANNUALLY
Pregnancy Test	Every 3 months for women of childbearing age					
Serum Levels		Yes	Yes, if meds increase/ decrease until levels stabilize		Yes	Ye, or early if indicated
Urine Analysis	Yes					If indicated
TSH	Yes		Yes		Yes	Yes, or early if indicated
ECG*	If indicated or if 45 years or older and if pre-existing cardiac disease					If indicated
BUN/Creatinine	Yes		Yes			Yes

Mood Stabilizers

Valproic Acid (Depakene) and Divalproex Sodium (Depakote)

TESTS	BASELINE	2 WEEKS	1 MONTH	3 MONTHS	6 MONTHS	YEARLY	IF SYMPTOMS ARISE
Pregnancy	Every 3 months for women of childbearing age						Yes
CBC with Platelets	Yes	Yes			Yes	Yes	Yes
Liver Function Tests	Yes	Yes				Yes	
Electrolytes (BMP)	Yes						Yes
Drug Levels		Yes, and weekly until stabilized				Yes	Yes
Prothrombin Time							Yes
Androgens							
Amylase							Yes
Bicarb *only for Topamax	Yes		Tes				Yes

Mood Stabilizers

Lamotrigine (Lamictal)

TESTS	BASELINE	IF SYMPTOMS ARISE
Drug Level		Yes (if indicated)
Pregnancy	Every 3 months for women of childbearing age	

*Second Generation Antipsychotic

In addition to Clozapine and Chlorpromazine

TESTS	BASELINE	8 WEEKS OR EARLY AS INDICATED	QUARTERLY	YEARLY	IF SYMPTOMS ARISE
Pregnancy	If indicated				Yes
Weight/BMI	Yes	Yes	Yes	Yes	
Waist Circumference	Yes			Yes	
Blood Pressure	Yes		Yes	Yes	Yes
Fasting Glucose/HbA1C	Yes			Yes	Yes
ECG	If indicated				Yes
Fasting Lipids Panel	Yes			Yes	
Drug Level					If indicated

*Clozapine (Clozaril): Refer to Clozapine/Clozaril Procedures. Use protocol for ANC.

ANTIDEPRESSANTS

A. SNRIs: Venlafaxine (Effexor), Duloxetine (Cymbalta)

	BASELINE	QUARTERLY
BP	Yes	Yes
Hepatic Enzyme (Duloxetine)	If indicated	If indicated

B. MAOIs

	BASELINE	QUARTERLY	YEARLY
Liver Enzymes	Yes		Yearly
BP	Yes		Yearly

C. Tricyclics

	BASELINE	YEARLY
Pregnancy Test	If indicated	
ECG	If indicated	If indicated
Drug Level		If indicated
Liver Function Test		If indicated

D. Serotonin: 2 Antagonist/Reuptake Inhibitors: Nefazodone (Serzone)

	BASELINE	YEARLY
Liver Function Test	Yes	Yes, or earlier if indicated

APPENDIX H

HEALTHWEST

PRACTICE GUIDELINE

No. 12-008

Prepared by:
Cyndi Blair, RNBC
Pharmacy Work Group

Effective: October 1, 2005
Revised: August 9, 2016

Approved by:

SUBJECT: Monitoring of Children and Adolescents Being Treated With Antidepressants

Justin Bensinger, Consulting Pharmacist

Julia B. Rupp, Executive Director

I. PURPOSE: To ensure that all children and adolescents who are prescribed antidepressants from Agency Physicians or Physicians Assistants are monitored for suicidal thoughts and behavior.

II. APPLICATION: All individuals under the age of 18 who are prescribed antidepressants by Agency medical staff.

III. PROTOCOL:

A. The frequency and nature of the monitoring should be individualized to the needs of the family and the individual receiving services. HealthWest staff should enlist the parents/guardians in the responsibility of monitoring the individual at time of the prescription. The primary care worker or program registered nurse will contact the family during the first month of initiation of an antidepressant to monitor progress. If family members become concerned about observed changes, they should contact HealthWest (after hours 724-HELP) if the child:

1) Expresses new or more frequent thoughts of wanting to die, or engages in self-destructive behavior;

2) Shows signs of increased anxiety/panic, agitation, aggressiveness, or impulsivity;

3) Experiences involuntary restlessness (akathisia), or an extreme degree of unwarranted elation or energy accompanied by fast, driven speech and unrealistic plans or goals.

B. Adverse reactions to antidepressants are more likely to occur early in the course of treatment or in changes of the dose. It may become appropriate to adjust the dosage, change to a different medication, or stop using the medication.

C. ***The Physician/PA should warn the parents/guardian of abruptly discontinuing the medication due to possible adverse withdrawal effects such as agitation or increased depression. The Psychiatrist/ PA should convey the importance of consulting with the Provider before changing or terminating their child's antidepressant treatment.***

/jec

APPENDIX I

US DHHS MEDWATCH FORM FDA 3500

HEALTHWEST

PHYSICIAN/PHYSICIAN'S ASSISTANT/NURSE PRACTITIONER VERBAL ORDER

Date: _____ Name: _____ Case **No.:** _____

Physician/Physician's Assistant/Nurse Practitioner: _____

ORDER:

_____ _____

Physician/Physician's Assistant/Nurse Practitioner Date

_____ _____

HealthWest Staff Date

HEALTHWEST
REPORT OF SERIOUS ADVERSE DRUG REACTION

Date: _____ Name: _____ Case No.: _____

A serious adverse drug reaction is any adverse event occurring at any medication dose that results in any of the following outcomes: death, a life-threatening adverse experience, inpatient hospitalization, or prolongation of an existing hospital stay, a persistent or significant disability/incapacity, or a congenital anomaly or birth defect, or requires medical or surgical intervention to prevent permanent impairment or damage to the recipient.

Any HealthWest staff person or contracted provider may initiate an inquiry by filling out Part One of this form. In addition, please complete and forward an Incident Report to a HealthWest RN for review.

PART ONE: INQUIRY

Date symptoms first noticed: _____

Description of Incident: _____

_____

_____

_____

_____

Person completing Part One: _____

Please give this form to the individual's primary worker as soon as possible. If the primary worker is not available, give to the worker's supervisor. Once the primary worker/supervisor has received it, he/she should promptly notify the individual's HealthWest physician/PA/NP of the suspected serious adverse drug reaction. This form should be forwarded to the HealthWest physician/PA/NP as soon as possible.

PART TWO: VERIFICATION
To be completed by the HealthWest physician/PA/NP within 7 calendar days of receipt.

Date of assessment: _____ Was individual seen face-to-face? ☐ Yes ☐ No

Birthdate: _____ Individual's Age: _____ Sex: _____

Etiology: ☐ Allergic reaction ☐ Drug-drug interaction ☐ Idiosyncratic ☐ Other: _____

_____

Clinical findings: _____

_____

_____

_____

_____

Select drug(s). Give name, strength, dosage, route, indication(s) for use/diagnoses, and date of administration (from/to): _____

_____

_____

Was drug discontinued? ☐ Yes ☐ No Did reaction abate after stopping drug? ☐ Yes ☐ No

Did reaction reappear after reintroduction: ☐ Yes ☐ No ☐ Drug was not reintroduced

Other concomitant drugs and dates of administration (exclude those used to treat reaction):

Other relevant history:

Describe any specific permanent or temporary morbidity or disability: ☐ Death

Treatment of incident (describe all medications and other interventions): ☐ Hospitalization

Signature of person completing Part Two **Date**

This form, with Parts One and Two completed, should be sent by the HealthWest physician/PA/NP to the Chairperson of the Pharmacy Work Group within 7 calendar days of receipt.

PART THREE: PHARMACY WORK GROUP

Date of review: _____ Did chart review occur? ☐Yes ☐No Was the event a serious ADR? ☐ Yes ☐ No

Pharmacy Work Group recommendations:

Chairperson, Pharmacy Work Group: **Date:**

Medical Director: **Date:**

MEDICATION INSTRUCTION SHEET

Date: _____ Case No.: _____

Name: _____

Prescriber: _____ Medication: _____

Refills Remaining: _____

Strength: _____ Units: _____ Total Tabs/Caps: _____

Instructions:

_____ _____

Health Professional Signature Date

Please call for refills at least 4 business days before you will be out of medication.

Receiving Information:

_____ _____

Samples Received By Date

_____ _____

HealthWest Staff Date

Distribution: 1 copy to client
1 copy, with receiving information completed, to clinical record

HEALTHWEST
MEDICATION SHEET

NAME: _____ **CASE #:** _____

ALLERGIES:

FREQUENCY OF ISC MEDICATION DROP:

	DATE	DATE	DATE	DATE	DATE	DATE	DATE

NON ISC MEDICATIONS:

	DATE	DATE	DATE	DATE	DATE	DATE	DATE

Staff Initials:							
RN Initials:							

Nurse's Signature: _____ **Nurse Initials:** _____ **Date:** _____

Staff Signature: _____ **Staff Initials:** _____

Staff Signature: _____ **Staff Initials:** _____

Staff Signature: _____ **Staff Initials:** _____

Staff Signature: _____ **Staff Initials:** _____

DATE: ________ CLIENT INITIALS ______ STAFF INITIALS ______
MEDS TAKEN AS DIRECTED: YES ☐ NO ☐

COMMENTS/
OTHER MEDS: ____________________

MED ________ #USED ________ #RETURNED ________
MED ________ #USED ________ #RETURNED ________
MED ________ #USED ________ #RETURNED ________
MED ________ #USED ________ #RETURNED ________

SYMPTOM REPORT COMPLETED: YES ☐ NO ☐
Staff sign-out: ________ Nurse sign-out: ________

DATE: ________ CLIENT INITIALS ______ STAFF INITIALS ______
MEDS TAKEN AS DIRECTED: YES ☐ NO ☐

COMMENTS/
OTHER MEDS: ____________________

MED ________ #USED ________ #RETURNED ________
MED ________ #USED ________ #RETURNED ________
MED ________ #USED ________ #RETURNED ________
MED ________ #USED ________ #RETURNED ________

SYMPTOM REPORT COMPLETED: YES ☐ NO ☐
Staff sign-out: ________ Nurse sign-out: ________

DATE: ________ CLIENT INITIALS ______ STAFF INITIALS ______
MEDS TAKEN AS DIRECTED: YES ☐ NO ☐

COMMENTS/
OTHER MEDS: ____________________

MED ________ #USED ________ #RETURNED ________
MED ________ #USED ________ #RETURNED ________
MED ________ #USED ________ #RETURNED ________
MED ________ #USED ________ #RETURNED ________

SYMPTOM REPORT COMPLETED: YES ☐ NO ☐
Staff sign-out: ________ Nurse sign-out: ________

DATE: ________ CLIENT INITIALS ______ STAFF INITIALS ______
MEDS TAKEN AS DIRECTED: YES ☐ NO ☐

COMMENTS/
OTHER MEDS: ____________________

MED ________ #USED ________ #RETURNED ________
MED ________ #USED ________ #RETURNED ________
MED ________ #USED ________ #RETURNED ________
MED ________ #USED ________ #RETURNED ________

SYMPTOM REPORT COMPLETED: YES ☐ NO ☐
Staff sign-out: ________ Nurse sign-out: ________

DATE: ________ CLIENT INITIALS ______ STAFF INITIALS ______
MEDS TAKEN AS DIRECTED: YES ☐ NO ☐

COMMENTS/
OTHER MEDS: ____________________

MED ________ #USED ________ #RETURNED ________
MED ________ #USED ________ #RETURNED ________
MED ________ #USED ________ #RETURNED ________
MED ________ #USED ________ #RETURNED ________

SYMPTOM REPORT COMPLETED: YES ☐ NO ☐
Staff sign-out: ________ Nurse sign-out: ________

DATE: ________ CLIENT INITIALS ______ STAFF INITIALS ______
MEDS TAKEN AS DIRECTED: YES ☐ NO ☐

COMMENTS/
OTHER MEDS: ____________________

MED ________ #USED ________ #RETURNED ________
MED ________ #USED ________ #RETURNED ________
MED ________ #USED ________ #RETURNED ________
MED ________ #USED ________ #RETURNED ________

SYMPTOM REPORT COMPLETED: YES ☐ NO ☐
Staff sign-out: ________ Nurse sign-out: ________

HEALTHWEST

CONSENT FOR USE OF PSYCHIATRIC MEDICATIONS & GENERAL MEDICATION TEACHING

Name _____ Case Number _____

I have been informed of the benefits, risks, and possible discomforts to be reasonably expected from these medications. These were explained to me verbally by the prescribing physician, physician's assistant, nurse practitioner, or a nurse. A teaching sheet has also been provided to me for each of these medications prescribed by a HealthWest physician/physician's assistant/nurse practitioner. The following information has been explained to me as needed by a health professional:

1. Possible drink and/or food interactions
2. Driving precautions
3. Possibility of Tardive Dyskinesia/Cardiotoxicity
4. Addiction potential
5. Necessity for abstinence from alcohol
6. The need to consult a physician before increasing, decreasing or stopping medication
7. Possible effects on pregnancy, the need to contact a physician before planning pregnancy and that it is my responsibility to notify my physician within 24 hours in the event of an unexpected pregnancy
8. Opportunity for further explanation of the medication(s) offered
9. Usage outside of Federal Drug Administration indications
10. Dosage outside of Physician Desk Reference recommended range
11. Effects of antidepressants and suicidal behaviors
12. Alternative medications and viable options to treatment
13. Consumer signature indicates that the risks, benefits and possible side effects of the prescribed controlled substance were explained and also verifies the consumer received a copy of the Agency standards on controlled substance

I understand that I am free to withdraw my consent for specific medications or discontinue psychiatric services without prejudice.

Date	Drug Name	Client/Legal Rep.	Health Professional	Teaching Sheet Given	Outside Dosage Range	Controlled Substance Standard Given
				☐	☐	☐
				☐	☐	☐
				☐	☐	☐
				☐	☐	☐
				☐	☐	☐
				☐	☐	☐
				☐	☐	☐
				☐	☐	☐
				☐	☐	☐
				☐	☐	☐
				☐	☐	☐
				☐	☐	☐
				☐	☐	☐
				☐	☐	☐
				☐	☐	☐

HEALTHWEST
CONSENT FORM: INDIVIDUAL WITH TARDIVE DYSKINESIA

Date _____ Name _____ Case No. _____

The Physician/PA/NP has explained to me that I have abnormal movements of my (CHECK ALL PRESENT):

- ☐ mouth
- ☐ face
- ☐ extremities
- ☐ tongue
- ☐ body

This is called Tardive Dyskinesia. These movements may be caused by antipsychotic medication that I (CHECK ONE):

- ☐ took
- ☐ am taking

The Physician/PA/NP recommends (CHECK ONE):

- ☐ continue the current antipsychotic medication
- ☐ stop the current antipsychotic medication
- ☐ add an additional medication
- ☐ decrease the current antipsychotic medication
- ☐ change to another antipsychotic medication

I understand that if I continue the current antipsychotic medication the movements may get better, stay the same, or worsen. I also understand that if the current antipsychotic medication is reduced or stopped my psychotic symptoms may worsen.

I hereby give consent to (CHECK ONE):

- ☐ continue the current antipsychotic medication
- ☐ stop the current antipsychotic medication
- ☐ add an additional medication
- ☐ decrease the current antipsychotic medication
- ☐ change to another antipsychotic medication

_____ _____
Individual/Legal Representative Signature Date

_____ _____
Physician/Physician's Assistant/Nurse Practitioner Signature Date

HEALTHWEST
IDENTITY VERIFICATION & PHOTO CONSENT FOR MEDICATION ADMINISTRATION

Date _____ **Name** _____ **Case Number** _____

HealthWest staff must use at least two identifiers listed below before administering medication:

- Ask the person's name
- Verify With person's picture attached below
- Verify the person's birth date (record DOB here) _____
- Verify with a familiar staff member
- Other (significant physical characteristic, i.e., a scar, tattoo, etc.) Specify: _____

(Attach photo below)

I hereby authorize HealthWest staff to photograph the above-named person to use as a means of identity verification for the purpose of medication administration. I have been assured that the photograph will be kept confidential in accordance with Sections 724 and 748 of Public Act 258, Michigan's Mental Health Code.

This consent will expire the date the above-named person is discharged from all HealthWest services, but consent may be withdrawn by the undersigned individual at any time before then. Photographs, together with any copies, will be given to the recipient (if requested) or will be destroyed at that time, and staff will document in the area where the photograph was removed the status of the photograph, i.e. whether it was destroyed or returned. Staff will sign/date the entry and submit the form for scanning.

_____ _____
Signature of Person Receiving Services/Parent/Guardian Date

_____ _____
Witness Date

HEALTHWEST

MEDICATION CONSULT

☐ Med Consult ☐ Prior Authorization ☐ Other _____

Date: _____ Name: _____ Case No.: _____

Time: _____ Prescriber Name: _____

DOB: _____ Name of Caller/Relationship: _____ Phone: _____

Pharmacy: _____ Location: _____

Date of Last Med Review:
(Include no-show and cancel dates) _____ JIT Refill Date: _____

Primary Worker: _____ Form Completed By: _____

REQUEST:

PLEASE FORWARD TO RN WHEN COMPLETED

PLEASE ALLOW UP TO 2 BUSINESS DAYS FOR REQUESTS TO BE PROCESSED

Psychiatrist/Nurse Response:

_____ _____

Signature/Credentials Date

HEALTHWEST
Physician's Appointment / Communication Form

Date _____ Name _____ Case No. _____
Date of Birth _____

☐ Nursing – 376 E. Apple Ave., 724-3699, Fax 724-3327
☐ Brinks Hall, 1890 E. Apple Ave., 724-6040, Fax 724-6042

Appointment Date _____ Time _____ Physician _____
Location _____
Current Medications: ☐ See Attached Medication Sheet

_____
_____
_____

Reason for Appointment / Communication / RN Comments:

_____
_____
_____
_____
_____
_____
_____
_____

_____
Staff / RN Signature Date

Findings / Plan / Restrictions: (Please document findings below)

_____
_____
_____
_____
_____
_____
_____

Follow up Appointment? _____ Keep home from school/work? ☐Y ☐N ☐N/A

_____
Physician Signature Date

HEALTHWEST
ABNORMAL INVOLUNTARY MOVEMENT SCALE (AIMS)

Name _____ Case No. _____

		Date				
		Initials of Rater				
Dental Status	1. Does client usually wear dentures? Yes-1, No-0					
	2. Current problems with teeth or dentures? Yes-1, No-0					
Global Judgments	3. Client's awareness of abnormal movements (rate only client's report). 0 – No awareness 1 – Aware, no distress 2 – Aware, mild distress 3 – Aware, moderate distress 4 – Aware, severe distress					
	4. Incapacitation due to abnormal movements	Rating Scale				
	5. Severity of abnormal movements					
Facial/Oral	6. Muscles of facial expression	0 – None				
	7. Lips and area around mouth	1 – Minimal				
	8. Jaw	2 – Mild				
	9. Tongue	3 - Moderate				
Extremities	10. Upper extremities	4 - Severe				
	11. Lower extremities					
Trunk	12. Neck, shoulder, hips					
Rater Signature	_____	**TOTAL**				

AIMS EXAMINATION PROCEDURE

Before or after completing the exam, observe the patient unobtrusively at rest.
The chair to be used in this examination should be a hard, firm one without arms.

1. Ask client whether there is anything in his/her mouth and to remove it.
2. Ask client about the current condition of his/her teeth. Dentures? Do teeth or dentures bother client?
3. Ask client whether he/she noticed any movements in mouth, face, hands or feet. If yes, ask to describe and to what extent they currently bother patient or interfere with activities.
4. Have client sit in chair with hands on knees, legs slightly apart and feet flat on floor. (Observe entire body)
5. Ask client to sit with hands hanging unsupported. (Observe hands and body)
6. Ask client to open mouth (do it twice). (Observe tongue at rest within mouth)
7. Ask client to protrude tongue (do it twice). (Observe tongue)
8. Ask client to tap thumb with each finger as rapidly as possible for 10-15 seconds; first right hand, then left. (Observe facial and leg movement)
9. Flex and extend client's left and right arms one at a time. (Note any rigidity)
10. Ask client to stand up. (Observe in profile all body areas)
11. Ask client to extend both arms outstretched in front with palms down. (Observe trunk, legs and mouth)*
12. Have client walk a few places, turn and walk back to chair (do this twice). (Observe hands and gait)*

*Activated movements

ADDITIONAL INFORMATION

Severity of movements: Score based on highest single score on Items 6-12.
Muscles of facial expression: Movements of forehead, eyebrows, periorbital area; include frowning, blinking, tics, grimacing of upper face.
Lips and perioral area: Puckering, pouting, smacking, chewing.
Jaw: Biting, clenching, chewing, mouth opening, lateral movement.
Tongue: Rate only increase in movement both in and out of mouth, not inability to sustain movement.
Upper arms, wrists, hands, fingers: Include choreic movements (rapid, objectively purposeless, irregular, spontaneous) and athetoid movements (slow, irregular, complex, serpentine). Do not include tremor (repetitive, regular, rhythmic).
Lower legs, knees, ankles, toes: Later knee movement, foot tapping, heel dropping, foot squirming, inversion and eversion of foot.
Neck, shoulders, hips: Rocking, twisting, squirming, pelvic gyrations; include diaphragmatic movements.

INCIDENT REPORT

REPORT DATE	REPORT TIME	REPORTING AGENCY	REPORTING PROGRAM/ HOME	
CONSUMER NAME		**CASE NUMBER**	**GENDER**	**AGE/DOB**

WHEN DID YOU DISCOVER INCIDENT (Date & Time) ☐AM ☐PM	WHEN DID IT HAPPEN (Date & Time) ☐AM ☐PM	WHERE DID INCIDENT HAPPEN (Specific Location)

CONSUMER(S) INVOLVED: _____

EMPLOYEE(S) INVOLVED AND/OR PRESENT: _____

EXPLAIN WHAT HAPPENED: _____

ACTION TAKEN BY STAFF: _____

PHYSICAL INJURY APPARENT? ☐YES ☐NO	REPORTING PERSON'S SIGNATURE & TITLE:	DATE:

REVIEW/COMMENTS FROM SC/CSM/CC: _____

ASSIGNED SC/CSM/CC NAME: (PRINT CLEARLY)	SIGNATURE:	DATE:

IF RELATED TO BEHAVIOR PROGRAM AND/OR P.I., REVIEW AND COMMENTS BY PSYCHOLOGIST: _____

ASSIGNED PSYCHOLOGIST NAME (PRINT CLEARLY):	SIGNATURE:	DATE:

IF INJURY, DESCRIPTION OF INJURY AND CARE/TREATMENT GIVEN BY PHYSICIAN OR R.N.: _____

DATE & TIME CARE GIVEN ☐AM ☐PM	EXTENT OF INJURY AT THIS TIME ☐SERIOUS ☐NONSERIOUS		
IF SERIOUS INJURY: DATE & TIME DIRECTOR OR DESIGNEE NOTIFIED ☐AM ☐PM	IF SERIOUS INJURY: DATE & TIME RIGHTS OFFICER NOTIFIED ☐AM ☐PM	PHYSICIAN'S OR R.N. SIGNATURE	DATE:

DESIGNATED SUPERVISOR (State program or administrative action to remedy and/or prevent reoccurrence of incident, including disciplinary action):

_____

NAME OF EMPLOYEE ASSIGNED TO CONSUMER AT TIME OF INCIDENT:	DESIGNATED SUPERVISOR'S SIGNATURE:	DATE:

WITHIN 24 HOURS, DISTRIBUTE: WHITE COPY to Provider YELLOW COPY to Office of Recipient Rights

C260 (Rev. 03/04/15)
(Incident Report)

HEALTHWEST

HEALTHWEST
INJECTION RECORD

Name:_____ Case Number:_____

Primary Worker:_____ ☐Medicaid ☐VA
☐Medicare ☐Patient Assistance

Date	Medication	Dosage	Schedule	Prescribed By	Administered By

HEALTHWEST
WRITTEN PRESCRIPTION TRACKING FORM

DATE: _____ NAME: _____ CASE NO. _____

Medication name _____ Dose _____

Medication name _____ Dose _____

Date RX written _____ Start Date _____

Special Instructions: _____

RECEIVED BY_____ DATE_____
Signature

_____
Printed name

STAFF SIGNATURE_____ DATE_____

Please forward this document to the clinical record upon receipt of the prescription by the consumer.

HEALTHWEST
ORDER FOR SELF-ADMINISTRATION OF ORAL OR TOPICAL MEDICATIONS

DATE: _____ NAME: _____ CASE #: _____

I have assessed the above-named individual and determined (please check one):

☐ Individual may self-administer medications for 1 year unless there is evidence of psychiatric decompensation, at which time individual will be reevaluated immediately.

☐ Individual may self-administer the following medications:

_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

PHYSICIAN/PA/NP SIGNATURE: _____ **DATE:** _____

HEALTHWEST

MEDICATION COMPLIANCE PACKAGING EVALUATION

DATE: _____ **NAME:** _____ **CASE NO:** _____

Assigned Team:		**Supports Coordinator:**	
Primary Care Physician/PA/NP:		**Nurse:**	
HealthWest Physician/PA/NP:			

1. Why does the individual require assistance with self-administration of medications?

2. YES ☐ NO ☐ Is there a current order? (Form C352) If **YES**, what is the date?

3. YES ☐ NO ☐ Is the order signed? If **YES**, by who?

4. YES ☐ NO ☐ Are there other significant caregivers that could help assist with medications? If **YES**, who?

5. YES ☐ NO ☐ Is there a release for the person(s) who is assisting in self-administration of medications? If **YES**, who is authorized?

6. YES ☐ NO ☐ Is there a safety issue? If **YES**, was the individual hospitalized? YES ☐ NO ☐ If **YES**, why?

7. YES ☐ NO ☐ Has there been a suicide attempt/threat? If **YES**, when?

8. YES ☐ NO ☐ Does the individual have the ability to self-administer medications? If **NO**, why not?

9. YES ☐ NO ☐ Is the individual adherent with medications? If **NO**, why not?

10. YES ☐ NO ☐ Is the individual using HealthWest pharmacy? If **NO**, which pharmacy is being used?

11. YES ☐ NO ☐ Does the individual require assistance with any medications? If **YES**, which ones?

_____ _____

Supports Coordinator Signature Date

_____ _____

RN Review Signature Date

☐ RN Assessment Attached

HEALTHWEST
ORDER FOR MEDICATION COMPLIANCE PROGRAM

Date: _____ **Name:** _____ **Date of Birth:** _____ **Case No.:** _____

I have assessed the above-named individual and determined:

☐ _____ may fill med box with staff.

Frequency: _____. (Will be reassessed quarterly. Expires in 1 year.)

☐ All prescribed medications

☐ All prescribed medications except:

_____ _____ _____ _____ _____

_____ _____ _____ _____ _____

☐ Medications will be stored at a HealthWest facility.

☐ Medications may be stored at individual's residence.

_____ will assist with administration of medications.
(Obtain Release of Information)

Based on RN assessment, the following packaging is ordered:

☐ Bottle ☐ Punch ☐ Foiler ☐ SD Strip ☐ Multidose Strips

NOTES: _____

Authorized to pick up medications from CMH/Mercy Pharmacy:

☐ Individual or alternative approved person.

☐ Staff/Primary Worker Name: _____ Team: _____

☐ Support Individual: _____ Relationship: _____

☐ Support Individual: _____ Relationship: _____

☐ No longer needs to participate in the medication compliance program at this time.

_____ _____
Physician/PA/NP Signature **Date**

☐ Copy of this document sent to CMH/Mercy CMH Pharmacy Date: _____

☐ PCP _____ has been made aware that patient is receiving medication assistance. By RN: ☐ By SC: ☐ Date: _____ By RN: ☐ By SC: ☐

☐ HealthWest RN has notified PCP, and PCP has agreed to send prescriptions to CMH/Mercy Pharmacy.

_____ _____
RN Signature **Date**

HEALTHWEST
MEDICATION COMPLIANCE PACKAGING EVALUATION
REGISTERED NURSE ASSESSMENT

DATE: _____ **NAME:** _____ **CASE NO:** _____

Assigned Team:		Supports Coordinator:	
Primary Care Physician/PA/NP:		Nurse:	
HealthWest Physician/PA/NP:			

ASSESSMENT OF GOALS TO ATTAIN MORE INDEPENDENT MEDICATION ADHERENCE

		Tasks	Comments
1.	☐	Take medications as prescribed	
2.	☐	Learn how to read a medication bottle label properly	
3.	☐	Learn the names of your medications	
4.	☐	Learn what your medications are for	
5.	☐	Learn how many doses should be taken daily	
6.	☐	Fill the medication box without ANY prompting from staff	
7.	☐	Identify when refills are necessary	
8.	☐	Identify how to obtain refills	
9.	☐	Identify what to do when you miss a dose	
10.	☐	Know when to take/use any PRN medications and what they are for	
11.	☐	Take insulin as prescribed, if applicable	
12.	☐	Check blood sugar as required, if applicable	

Based on this assessment and consultation with CMH/Mercy pharmacist, this RN recommends the following packaging:

☐ Bottle ☐ Punch ☐ Foiler ☐ SD Strip ☐ Multidose Strips

Notes: _____

_____ _____

RN Signature Date

HEALTHWEST
LIST OF APPROVED MEDICAL ABBREVIATIONS AND SYMBOLS

#	pound or number
△	change
@	at
°	degree, hour
=	equal to
a	before
AA	Alcoholics Anonymous
ac	before meals
ad lib	as desired
ADL	activities of daily living
adm	admission
AM	morning
amt	amount
ant	anterior
approx	approximately
appt	appointment
ASA	aspirin
ASAP	as soon as possible
AVH	auditory & visual hallucinations
BID	two times a day
BM	bowel movement
BMI	body mass index
BP	blood pressure
BR	bathroom
$\overline{c}$	with
c/o	complaints of
Ca	calcium
CA	cancer
CAD	coronary artery disease
cap	capsule
cath	catheter, catheterize
✓	checked
CHF	congestive heart failure
cm	centimeter
CNS	central nervous system
Cont	continue, continuous
COPD	chronic obstructive pulmonary disease
CPR	cardiopulmonary resuscitation
CVA	stroke
d/t	due to
DAW	dispense as written
diag/dx	diagnosis
drsg	dressing
DTs	delirium tremens
dx/diag	diagnosis
ECT	electroconvulsive therapy
EENT	eye, ear, nose, throat
elix	elixir
ED	emergency department
ETOH	alcohol
FDLMP	first day last menstrual period
Fe	iron
Fl	fluid
Fx	fracture
GB	gallbladder
GC	gonorrhea
GERD	Gastroesophageal Reflux Disease
GI	gastrointestinal
gr	grain (5 gr = 325 mg)
gtt	drop
GU	genitourinary
gyn	gynecology
H&P	history & physical
h, hr	hour
H_2O	water
H_2O_2	hydrogen peroxide
HA	headache
Hct	hematocrit
Hg	mercury
Hgb	hemoglobin
HI	homicidal ideation
Hosp	hospital
HS	bedtime
Ht	height
HTN	hypertension
hx	history
i	one
ii	two
iii	three
iv	four (etc.)
IM	intramuscularly
↓	increased, down, low
↑	increased, up, elevated
IV	intravenous
K+	potassium
Kg	kilogram
L or lt	left
L	liter
Lat	lateral
LE	lower extremities
→	leads to
lg	large
Li	lithium
max	maximum
mcg	microgram
mEq	milliequivalent
mg	milligram
MI	heart attack
min	minimum
ml	milliliter
mm	millimeter
MR x n	may repeat times n
N&V	nausea and vomiting
N/A	not applicable
NA	Narcotics Anonymous
Na	sodium
neg	negative, minus
NKA	no known allergies
NKDA	no known drug allergies
Noc	night
NP	Nurse Practitioner
NPO	nothing by mouth
occ	occasional
oint	ointment
OT	occupational therapy
OTC	over-the-counter
OU	both eyes
oz	ounce = 30 cc = 2 TBSP
$\overline{p}$	after
PA	physician assistant, prior authorization
pc	after meals
PCP	primary care physician
PERLA	pupils equal, reactive to light and accommodation
PO	by mouth
pos	positive, plus
PPD	packs per day
PRN	as needed
Q	every
QD	daily
QID	four times a day
R or resp	respiration
R or rt	right
R	rectal
R/O	rule out
r/t	related to
ROM	range of motion
RRR	regular rate and rhythm
Rx	prescription, therapy, treatment
$\overline{s}$	without
S/P	status post
SD	subdermally
SI	suicidal ideation
SIB	self-injurious behavior
Sig	let it be marked
SL	sublingually
sm	small
SOB	shortness of breath
stat	immediately
subq, sq	subcutaneous
sx	symptom
TBI	traumatic brain injury
tbsp.	tablespoon = 15cc
TID	three times a day
TO	telephone order
TPR	temp, pulse, resp
tsp	teaspoon = 5cc
tx	treatment
UA	urinalysis
UE	upper extremities
URI	upper respiratory infection
UTI	urinary tract infection
VD	venereal disease
VO	verbal order
VS	vital signs
WC, W/C	wheelchair
WO	written order
WT	weight
Y/O	year old

HEALTHWEST

REQUEST FOR CHANGES IN THE FORMULARY OF APPROVED MEDICATIONS

Please submit this request to the chairperson of the Pharmacy Work Group.

☐ Addition(s) to the current Formulary

☐ Deletion(s) from the current Formulary

Generic Name of Medication: _____

Brand Name of Medication: _____

Dosage Range:
(In milligrams per day unless otherwise noted) _____

Rationale for adding/deleting the medication:

Please provide (or attach, if possible) any supporting reference or articles or other documentation regarding this particular medication and indication.

_____ _____

Physician/PA/NP Name Date:

HEALTHWEST
LABORATORY TELEPHONE REPORT FORM

Client's Name: _____ **Case Number:** _____

Time: _____ **Results Given To:** _____

Lab obtained on: Date: _____ **Time:** _____

CHEMISTRY Profiles		NORMAL
BUN		6 – 20
Na		135 – 144
K		3.5 – 5.0
CL		98 – 111
CO2		21 – 31
Gluc		70 – 106
Creat		0.6 – 1.1
Trig		< 150
Chol		< 200
LDL		< 100
HDL		< 40
SGOT		10 - 42
Alk Pho		32 – 123 (adult)
T Bil		0.0 – 1.3
T Pro		6.4 – 8.2
Albumin		3.4 – 5.0
Phos		2.5 – 4.6
Ca		8.4 – 10.2
Mg		1.8 – 2.5
Amylase		21 – 101
Lipase		22 - 51
CPK		44 - 196
HBA1C		4.0 – 6.0

TSH		(0.34 – 5.6)
Lithium		(0.6 – 1.2)
Tegretol		(4 – 12)
Dilantin		(10 – 20)
Valporic Acid		(50 – 100)

HEMATOLOGY CBC		NORMAL Male	Female
WBC		4.0 – 10.0	4.0 – 10.0
RBC		4.60 – 6.20	4.20 – 5.40
Hgb		12.5 – 17.0	11.5 – 15.5
Hct		36 – 50	34 – 45
MCV		82 – 100	82 – 100
MCH		27 – 31	27 – 31
MCHC		32 – 36	32 – 36
Plt Ct		140 – 450	140 – 450

Differential Path Rev.		Male	Female
Neu %		45 – 75	45 – 75
Lym %		15 – 44	15 – 44
Mono %		4 – 12	4 – 12
EOS %		0 – 5	0 – 5
Baso %		0 – 2	0 – 2
New (ABS)		1.9 – 6.5	1.9 – 6.5
Lym (ABS)		0.8 – 5.0	0.9 – 3.2
Mono (ABS)		0.0 – 0.8	0.2 – 0.8
EOS (ABS)		0.0 – 0.4	0.0 – 0.4
Baso (ABS)		0.0 – 0.2	0.0 – 0.2

Urinalysis			OTHER
Color			
Appearance			
Sp. Gr.		(1.005 – 1.030)	
WBC Estrase		(neg)	
Nitrite		(neg)	
Ph		(4.8 – 8.0)	
Protein		(neg)	
Glucose		(neg)	
Ketone		(neg)	
Urobilinogen		(neg)	
Bili Qual		(neg)	
Blood		(neg)	

HEALTHWEST
STAT MEDICATIONS INVENTORY AND USE

Date Received	Staff Initials Logging in Med	Medication Name	Dose	Amount Received	Rx/ Lot Number	Expiration Date	Date Administered	Client Case Number	Signature of Staff Administering

HEALTHWEST
STAT MEDICATIONS QUARTERLY INSPECTION

DATE	INSPECTED BY	MEDICATION REPLACED

HEALTHWEST
CONSUMER CONTROLLED SUBSTANCE STANDARD

You have been prescribed a controlled substance. Your health care provider has decided that this medication will be used to treat your mental health concerns. The purpose of this standard is to maintain a safe, controlled treatment plan. In order for this treatment to work, you have a responsibility to participate in this treatment.

Agency standards for the prescribing of controlled substances are as follows:

1) We ask that you pick one pharmacy to obtain your controlled substance medication.

2) If it is found that you receive a prescription for controlled substance medication from a source other than HealthWest, controlled substances may no longer be prescribed for you by a HealthWest prescriber.

3) HealthWest will not accept telephone requests for controlled substance medication refills from anyone other than yourself/legal representative.

4) It is necessary to call HealthWest during hours of operation on Monday through Friday from 8AM to 5PM (except holidays) to refill controlled substance medications. It is important to have enough medications to get you through the next 7 days. This is your responsibility. No controlled substance medication will be refilled after hours, on weekends or holidays. You must allow seven (7) days for a prescription to be authorized and arrange to have it picked up.

5) All prescriptions for medication refills will be picked up within four (4) days of your request being completed. If you are too disabled or sick to pick them up, the decision to allow another person to pick up your prescription will be determined at HealthWest discretion. No minor can pick up the prescription.

6) You must agree to allow the HealthWest providers to communicate with other healthcare providers involved with your care and with the pharmacies regarding your use of medications.

7) You must agree to sign a release of information for all other health care providers, including pharmacies, primary care physicians, urgent care, and emergency rooms, regarding your health care.

8) You will inform the health care providers at HealthWest of any medication related side effects as listed in the education section. If any significant side effects occur after hours or on weekends or holidays, you will call or go to the closest emergency room.

9) You will take the medication as prescribed exactly as instructed by HealthWest health professional. You are not allowed to change the dose amounts or to change the time schedule of taking the medication or discontinue taking it without talking to a HealthWest health professional.

10) You must keep all regular follow-up appointments as recommended by HealthWest guidelines. Consumers must be seen at least every three (3) months by a HealthWest health care provider. Failure to do so may result in discontinuation of controlled substance prescriptions and discharge from HealthWest.

11) Please understand that it is a federal offense to alter a prescription in any way. HealthWest will take legal action as required.

12) You may be required to submit random urine or blood samples for drug screens.

13) You are responsible for your prescription and for your medication once filled. HealthWest has a **no replacement policy**. This includes lost or destroyed prescriptions or lost, damaged or stolen medications.

14) *For Women only:* You agree that you are not pregnant and that you will inform the health care provider if you become pregnant or believe that you may be pregnant, or breast feeding. If you become

pregnant, the baby may become addicted to the medication or experience other unknown risks to the baby.

15) *For Stimulant Medications only:*
    1. Prescriptions can only be hand written- HealthWest cannot "call-in" a prescription.
    2. Refills cannot be listed on the prescription.
    3. The person picking up the written prescription for a stimulant will sign and date a form to acknowledge receipt of the written prescription.

CONTROLLED SUBSTANCE EDUCATION

There are possible adverse reactions and conditions that may develop with the use of controlled substances. We have listed a few of these for your information. Please refer to your medication teaching sheet for a more complete list.

Possible Adverse Reactions:

- Allergy
- Overdose (can lead to respiratory arrest and/or death)
- Constipation
- Itching
- Difficulty with urination
- Nausea or vomiting
- Change in mental status or thinking ability
- Increased sleepiness
- Problems with balance or coordination (use caution when operating a motor vehicle or dangerous equipment)
- Decreased sexual function
- Other less common side effects are possible
- Children born to mothers on controlled substances (narcotics) are usually physically dependent at birth

Conditions That May Develop:

- Physical Dependence – After stopping the medication you can experience withdrawal symptoms. These may include:
    - Nausea / vomiting
    - Sweating
    - Shaking
    - General bad feeling / anxiety
    - Runny nose
    - Diarrhea and/or abdominal cramping
    - Achiness

- Psychological Dependence or Addiction – The risk is low when used appropriately. After stopping the medication, you may go through withdrawal- this is related to physical dependence. If you psychologically or mentally become dependent on the medication, you may exhibit addiction behavior.

- Tolerance – The medication may become less effective.

HEALTHWEST
MEDICATION CONTAINER LOG

CLIENT NAME: _____ **CASE NO.:** _____

DATE	TIME OUT	STAFF NAME	TIME IN	STAFF NAME

HEALTHWEST
SCHEDULED DRUGS COUNT LOG

NAME _____ **CASE NO.:** _____

DATE	NEW MED SUPPLY?	DRUG/MED NAME	STRENGTH, i.e. mg	START COUNT	END COUNT	STAFF INITIALS

Staff Signature: _____ **Staff Initials:** _____

Staff Signature: _____ **Staff Initials:** _____

Staff Signature: _____ **Staff Initials:** _____

HEALTHWEST

COMMON SCHEDULE II-V MEDICATIONS THAT REQUIRE MONITORING

SCHEDULE II DRUGS		SCHEDULE III – V DRUGS		
Adderall	Methadose	Acetaminophen + Codeine	Limbitrol	Xanax
Adzenys	Methylin	Alprazolam	Lorazepam	Zaleplon
Amphetamine	Methylphenidate	Ambien	Lunesta	Zolpidem
Concerta	Morphine	ASA/Cod Phosphate	Lyrica	
Daytrana	MS Contin	Ativan	Mebaral Oral	
Dexedrine	Norco	Buprenorphine Sublingual	Mephobarbital	
Dexmethylphenidate	Nucynta	Butalbital/ASA/Caffeine	Mytussin DAC	
Dextroamphetamine	Oramorph SR	Carisoprodol	Noctec	
DextroStat	Oxy IR	Cheratussin AC Syrup	Nucofed	
Dilaudid	Oxycodone	Chlordiazepoxide	Oxazepam	
Dolophine	OxyContin	Clonazepam	Pentazocine	
Duragesic Patch	Percocet	Clorazepate	Phenobarbital	
Duramorph	Percodan	Codeine/Guaifenesin/Pseudoephedrine	Pregabalin	
Endocet	Quillivant/Quillachew	Codeine/Pseudoephedrine	Promethazine w/Codeine Syrup	
Fentanyl Transdermal	Ritalin	Depo-Testosterone Vial	Restoril	
Focalin	RMS Suppository	Diastat Rectal Gel	Robitussin DAC	
H-C Tussive Syrup	Roxanol	Diazepam	Soma	
Hycet	Roxicet	Dihistine Elixir	Sonata	
Hydrocodone Products	Roxicodone	Dihydrocodeinone	Suboxone	
Hydromet	TussiCaps, Tussionex	Duradrin	Talwin	
Hydromorphone	Tylox	Epidrin	Temazepam	
Hydrostat	Vicodin	Eszopiclone	Tramadol	
Kadian	Vyvanse	Fiorinal	Tranxene	
Lisdexamfetamine	Zohydro	Flurazepam	Tylenol w/Codeine, #2, #3, #4	
Metadate		Guaifenesin/Codeine - Oral	Valium	
Methadone		Klonopin	Valrelease	

HEALTHWEST

MEDICATION STORAGE AREA INSPECTION

Location:	Yes	No*	N/A
1) All medications are locked **Comments**:	☐	☐	☐
2) The medication storage site key is inaccessible to unauthorized staff **Comments:**	☐	☐	☐
3) Medications intended for external use are stored separately from oral meds** **Comments:**	☐	☐	☐
4) Medication cabinets/carts are clean and orderly **Comments:**	☐	☐	☐
5) Medication cabinets/carts are used only for medication storage **Comments:**	☐	☐	☐
6) Each medication bin is labeled with the consumer's name **Comments:**	☐	☐	☐
7) Each medication bin is labeled with the consumer's allergies **Comments:**	☐	☐	☐
8) Prescription medications have a current pharmacy label with specific directions for the client **Comments:**	☐	☐	☐
9) Unissued sample medications are kept separate from routine medications **Comments:**	☐	☐	☐
10) Monitoring of med inventory for expired medications is documented below in "Comments" **Comments:**	☐	☐	☐
11) List of expired medications found/destroyed is documented below in "Comments" **Comments:**	☐	☐	☐
12) A sharps container is available and properly utilized if sharps are being used **Comments:**	☐	☐	☐
13) All refrigerated medications are maintained at the proper temperature (36-46 degrees Fahrenheit) **Comments:**	☐	☐	☐
14) Disposal of Schedule II-V drugs is documented **Comments:**	☐	☐	☐

Comments: _____

_____

Inspected by:

_____ _____

Health Care Professional **Date**

* **A "NO" answer requires an explanatory note in the "Comments" section and follow up the next month. All answers must reflect the status of the site upon arrival, not after corrections have been made.**

** **Oral meds (tablets, capsules, etc) must be stored separately. Eye, ear, nasal medications must be stored separately from the oral meds, in a separate bin or basket but ok in the same drawer or shelf as the oral meds. Topicals (creams, ointments, patches) cannot be stored in the same drawer or shelf as oral meds, even if in a separate bin/basket.**

HEALTHWEST
DESTROYED SCHEDULE II-V MEDICATIONS

SITE LOCATION: _____

DATE DESTROYED	CASE NUMBER	MEDICATION NAME/STRENGTH	QUANTITY DESTROYED	REASON DESTROYED		SIGNATURES	
				CODE #	SPECIFY USE OF CODE #6	HEALTH CARE PROFESSIONAL	WITNESS

CODE: REASON MED DESTROYED: 1 = CASE CLOSED 2 = MEDICATION CHANGED 3 = MEDICATION DISCONTINUED 4 = NONCOMPLIANCE 5 = EXPIRED MED 6 = OTHER

HEALTHWEST

COMMON SCHEDULE II-V MEDICATIONS THAT REQUIRE MONITORING

SCHEDULE II DRUGS		SCHEDULE III – V DRUGS		
Adderall	Methadose	Acetaminophen + Codeine	Limbitrol	Xanax
Adzenys	Methylin	Alprazolam	Lorazepam	Zaleplon
Amphetamine	Methylphenidate	Ambien	Lunesta	Zolpidem
Concerta	Morphine	ASA/Cod Phosphate	Lyrica	
Daytrana	MS Contin	Ativan	Mebaral Oral	
Dexedrine	Norco	Buprenorphine Sublingual	Mephobarbital	
Dexmethylphenidate	Nucynta	Butalbital/ASA/Caffeine	Mytussin DAC	
Dextroamphetamine	Oramorph SR	Carisoprodol	Noctec	
DextroStat	Oxy IR	Cheratussin AC Syrup	Nucofed	
Dilaudid	Oxycodone	Chlordiazepoxide	Oxazepam	
Dolophine	OxyContin	Clonazepam	Pentazocine	
Duragesic Patch	Percocet	Clorazepate	Phenobarbital	
Duramorph	Percodan	Codeine/Guaifenesin/Pseudoephedrine	Pregabalin	
Endocet	Quillivant/Quillachew	Codeine/Pseudoephedrine	Promethazine w/Codeine Syrup	
Fentanyl Transdermal	Ritalin	Depo-Testosterone Vial	Restoril	
Focalin	RMS Suppository	Diastat Rectal Gel	Robitussin DAC	
H-C Tussive Syrup	Roxanol	Diazepam	Soma	
Hycet	Roxicet	Dihistine Elixir	Sonata	
Hydrocodone Products	Roxicodone	Dihydrocodeinone	Suboxone	
Hydromet	TussiCaps, Tussionex	Duradrin	Talwin	
Hydromorphone	Tylox	Epidrin	Temazepam	
Hydrostat	Vicodin	Eszopiclone	Tramadol	
Kadian	Vyvanse	Fiorinal	Tranxene	
Lisdexamfetamine	Zohydro	Flurazepam	Tylenol w/Codeine, #2, #3, #4	
Metadate		Guaifenesin/Codeine - Oral	Valium	
Methadone		Klonopin	Valrelease	