1114.0 Laboratory Protocol and Monitoring Medication Side Effects

1114.1 Policy Approval Clearance Record

☐ Rural Services Policy ☒ Rural Clinics Policy ☐ Rural Regional Center Policy	This policy supersedes:	Number of pages in Policy: 13
Review by Representative from the Office of the Attorney General: n/a	Date: n/a	Date Policy Effective: 08/2012
Rural Services Director Approval Signature: *Barbara Legier*	Date: 8/23/12	Policy Lead: Sally Mitchell, RN, DON

1114.2 Statement of Purpose

1114.2.1 **Policy Statement:** Rural Clinics will monitor the appropriate laboratory evaluation of consumers who are receiving medications prescribed by Rural Clinics medical providers.

1114.2.2 **Purpose:** To establish the minimal protocols for laboratory testing on Rural Service mental health consumers.

1114.3 Authority

NRS Chapter 652, Medical Laboratory Procedures
NAC Chapter 652, Medical Laboratory Procedures
Division Policy 4.033, Laboratory Reporting
Division Policy 4.032, Laboratory Protocols

1114.4 Unique Definitions and Acronyms

1114.4.1 **Refer to Standard Definitions Policy**

1114.4.2 **Cardiovascular Disease:** History of heart murmurs, arrhythmia, angina, myocardial infarction, or congestive heart failure, diabetes mellitus, hypertension, stroke, valvular disease.

1114.4.3 **Comprehensive Metabolic Panel (also called Chemistry Panel, Metabolic Panel):** Includes Glucose test, alkaline phosphatase, ALT (SGOT), AST (SGPT), BUN, Creatinine, Sodium, Potassium, Chloride, Calcium, Carbon Dioxide, Total Protein, Total Bilirubin, Albumin, and Direct Bilirubin.

1114.4.4 **Hepatic and Pancreatic Disease:** History of hepatitis, jaundice, intravenous drug use, pancreatitis and alcohol dependence.

1114.4.5 **Impaired Renal Function:** Elevated creatinine, reduced creatinine clearance, or gross proteninuria.

1114.4.6 **Lipid Panel:** Includes Total Cholesterol, Triglycerides, HDL Cholesterol, VLDL, Cholesterol calculated, and LDL Cholesterol calculated.

1114.4.7 **Liver Function Test:** Includes albumin, Alkaline Phosphatase, ALT (SGOT), AST (SGPT), Total Bilirubin, Direct Bilirubin, and Total Protein.

1114.4.8 **Metabolic Syndrome:** This condition includes hyperglycemia/diabetes type II, weight gain (at least 3 pounds per month), and increased lipids.

1114.4.9 **Renal Disease:** History of pyelonephritis, reduced Creatinine clearance, or diabetes.

1114.4.10 **Thyroid Function Tests:** Blood tests including a minimum of thyroid stimulating hormone. Tests include Thyroxine (T4) Free, Direct Triiodothyronine (T3), and Thyroid Stimulating Hormone (TSH).

1114.4.11 Acronyms:

A. BUN = Blood Urea Nitrogen

B. CBC = Complete Blood Count

C. Chem Panel, CMP = Chemistry Panel

D. CR = Creatinine

E. EKG = Electrocardiogram

F. FBS = Fasting Blood Sugar

G. LFT = Liver Function Test

H. PT/PTT = Prothrombin time/Partial Prothrombin Time

1114.5 Procedures

1114.5.1 All consumers on pharmacotherapy for psychiatric or related conditions shall have laboratory monitoring that is clinically indicated and recommended by the guidelines of the American Psychiatric Association and American Diabetes Association.

A. The psychiatrist or APN is responsible for reviewing the consumer's chart at least quarterly or when clinically indicated to assess whether appropriate laboratory tests have been completed as required and take all necessary action to order laboratory tests.

B. At the time of each prescription change or renewal, the psychiatrist/APN will determine whether or not appropriate laboratory tests have been completed, and as determined necessary, immediately communicate orders to the medication clinic nurse.

C. The nurse will maintain a tracking sheet, updated on an ongoing basis, for each consumer in the Medication Maintenance program so that: 1) laboratory needs are tracked timely and routinely; 2) labs are completed timely; 3) the lab results are filed in the consumer's physical chart timely; 4) the psychiatrist/APN is informed if laboratory tests are indicated; and 5) the psychiatrist/APN is informed of abnormal laboratory results.

D. The nurse, within one (1) working day of notification by the consumer, will obtain recent laboratory results that may be available from the consumer's Primary Care Physician (PCP) or the result of a recent hospitalization prior to referring the consumer for laboratory tests, and triage with referral to community service providers when clinically indicated as related to out of range or abnormal laboratory results.

E. The nurse will refer the consumer for laboratory tests as ordered by the psychiatrist/ APN within one (1) working day.

F. All the above interactions require an electronic progress note, completed within one (1) working day by the psychiatrist/APN and psychiatric nurse.

G. EKG: Consumers at risk for cardiovascular disease will require a baseline EKG and when clinically indicated. An EKG is not required if a consumer's PCP has performed an EKG within the last six (6) months and the results can be obtained for the clinical record. All consumers starting tricyclic antidepressants will have an EKG prior to beginning any of these medications.

H. Baseline labs will be ordered when the consumer is initially prescribed medication as follows: Chemistry Panel, CBC with differential, ultra sensitive TSH, and T4, lipids

I. Urinalysis and Urine Drug Screen will be ordered as clinically indicated.

J. Annually a chemistry panel and CBC with differential will be ordered.

K. The treating psychiatrist/APN will take every precaution to avoid treating females of childbearing age with teratogenic medication until a pregnancy test has been completed.

L. Tests will be concurrently ordered with the psychotropic medication, if the treating psychiatrist deems it clinically appropriate and is documented in the electronic file within one (1) working day.

M. Additional Lab Work: The following lab work is indicated for specific conditions or for specific medication or groups of medication:

1. Lithium:

- Will be used with caution in consumers with impaired renal function and appropriate nephrology consults will be done.
- Pre-treatment baseline EKG/laboratory work-up, as deemed clinically appropriate by the treating psychiatrist/APN which will include, at a minimum, a Complete Metabolic Panel and CBC with differential.
- Thyroid function tests will be ordered before initiation of treatment and yearly thereafter, as clinically indicated. If thyroid function tests are abnormal, appropriate referrals will be made yearly thereafter and sooner if thyroid values indicate a pathological trend.
- Serum Lithium Levels
  - Within two (2) weeks after initiation of medication.
  - Recheck within 6 to 12 weeks and every six (6) months thereafter.
  - Within two (2) weeks after each change in dose.
- Blood Urea Nitrogen and Creatinine every six (6) months.
- Pretreatment EKGs will be ordered for consumers over 40 years of age or as clinically indicated.
- If Lithium toxicity is suspected, such as drowsiness, muscular weakness, ataxia, nausea, vomiting, diarrhea, or fever over 100 degrees:
  - Hold Lithium until the physician is consulted.
  - Check Lithium level, BUN and CR.
  - Treat clinically and restart Lithium if clinically indicated.

2. Carbamazepine:

- Pre-treatment baseline EKG/laboratory work-up, as deemed clinically appropriate by the treating psychiatrist/APN which will include, at a minimum, a Complete Metabolic Panel and CBC with differential.
- Carbamazepine level and CBC with differential within two (2) weeks after initiation of treatment then one (1) month later and every six (6) months thereafter or if clinically indicated.
- Order a Carbamazepine level and CBC with differential within two (2) to three (3) weeks after each change in dose.

- If blood abnormality is suspected, CBC with differential, PT/PTT, INR and LFTs will be rechecked as deemed clinically appropriate by the treating Psychiatrist/APN.
- Levels of other concurrent and anti-epileptic drugs will be obtained along with the Carbamazepine level.

3. Valproic Acid:

- Pre-treatment baseline EKG/laboratory work-up, as deemed clinically appropriate by the treating psychiatrist/APN which will include, at a minimum, a Complete Metabolic Panel and CBC with differential.
- Follow-up treatment work-up:
    - Valproic Acid level within one (1) month after initiation of treatment and six (6) months thereafter.
    - Within two (2) to three (3) weeks after each change in dose.
    - CBC with differential ,and Complete Metabolic Panel level every six (6) months thereafter
- Levels of other concurrent and anti-epileptic drugs will be obtained along with the Valproic Acid level.
- If the psychiatrist/APN has reason to suspect pancreatitis, appropriate labs will be ordered and referrals will be made.

4. Clozapine:

- Clozapine is an atypical anti-psychotic medication indicated for the management of severely ill consumers with schizophrenia or schizoaffective disorder. Because of the serious side effects with a black box warning of agranulocytosis, seizure, myocarditis, cardiovascular and respiratory collapse associated with its use, Clozapine is usually a medication initiated while the client is in an inpatient facility and should be reserved for:
    - Treating severely ill consumers who have failed to respond adequately to treatment with two appropriate trails of a Class I anti-psychotic drug, either because of lack of efficacy, the inability to obtain an effective dose due to intolerable adverse effects from those drugs or the presence of tardive dyskinesia; or
    - Reducing the risk of recurrent suicidal behavior in consumers with schizophrenia or schizoaffective disorder who are judged to be at risk of re-experiencing suicidal behavior.
- All consumers to be given a trial on Clozapine will have the following forms completed, usually in an inpatient setting. This information is noted here for reference for inpatient procedures.
    - Clozapine Protocol Form (Attachment RC1114C) completed by the prescribing physician and the pharmacy staff, and signed consumer consent for treatment form. A copy of each will be kept in the consumer's chart and on file in the pharmacy.
    - Clozapine Checklist (Attachment RS1114D) completed by the inpatient Nurse assigned to the consumer by Service

Coordination Supervisor or the assigned outpatient nurse when notified of pending Clozapine candidate. Original will be sent to the Pharmacy after completion and prior to any Clozapine being filled. A copy will be placed in the chart.

- Prior to the administration of Clozapine, the following screens must be performed:
    - A complete blood count within seven (7) days of the first admission of Clozapine with a white blood cell count (WBC) >3,500 and an absolute neutrophil (ANC) >2,000.
    - Metabolic pre-screening within the previous week that shows no contraindication for Clozapine therapy.
    - The prescriber will ensure the consumer has been assigned to a service coordinator (Service Coordination, Mental Health Court, or PACT), has stable housing and regular transportation to the laboratory before prescribing Clozapine.
    - CBC must be obtained within seven (7) days of the first administration of Clozapine with a WBC >3,500 and an absolute neutrophil (ANC)>2000.initially
- The inpatient Pharmacist or local community pharmacy will complete the Clozapine Registration Form (Attachment RC1114E) on all authorized prescribers and will transmit the information to the Clozapine Registry or equivalent registry.
- After the above conditions have been met, the inpatient or outpatient pharmacy staff as determined will transmit the information to the Clozapine Registry, complete Clozapine WBC Monitoring Form or its equivalent. An “Authorization Code Number” will be obtained and entered on the Clozapine Protocol Form (Attachment RC1114F). A copy of the completed form will be returned to the prescriber who will then write a maximum seven (7) days prescription order.
- After six (6) months of continuous Clozapine treatment and acceptable WBC levels, the prescriber may elect to order laboratory testing for WBC at biweekly intervals. The prescriber may elect to order laboratory testing monthly after one (1) year of stable WBC counts. The laboratory and the pharmacy staff should be notified if this is to occur to prevent delays in dispensing.
- The prescriber will review the weekly WBC and a copy of this review will be transmitted directly to the pharmacy staff. The designated pharmacy staff will transmit the WBC to the Registry. The National Registry Reporting Form may be used for this function but other means are acceptable. An acceptable WBC count will permit the consumer to receive a maximum seven (7) day prescription order for the first six (6) months, fourteen (14) day prescription order after the first six (6) months, and 30 day prescription order after one (1) full year.
    - An “acceptable WBC” value for a consumer on Clozapine is a total WBC greater than 3,500 with a neutrophil (ANC) count over 2,000.
    - If the WBC falls below 3,500 or three (3) successive WBCs show consistent decline of 3,000 (total) with a WBC remaining above 3,500, the prescriber must reconsider the

Clozapine therapy and document in the chart this change in WBCs, along with the rationale for the decision to continue or discontinue theraphy. These parameters do not necessarily represent an absolute indication for stopping Clozapine therapy.

- If the total WBC falls below 3,000 or the neutrophil (ANC) count falls below 2,000, Clozapine therapy should be interrupted. WBC and the differential counts should be carefully monitored for flu-like symptoms or other symptoms suggestive of infection.
- Therapy may be resumed if no symptoms of infection develop and the WBC returns to levels above 3,000 and the neutrophil (ANC) count returns to levels above 2,000. However, in this event, twice weekly WBCs and differential counts should continue until the total WBC returns to levels above 3,500. The Algorithm should be utilized to restart the medication.
- Any WBC value of less than 2,000 or neutrophil (ANC) count below 1,000 while on Clozapine is “unacceptable” and Clozapine therapy must be discontinued immediately and permanently. The consumer should never again be re-tried on Clozapine. A hematology consultation is to obtained immediately for further treatment recommendations.

- Upon approval of Clozapine for therapy, the designated pharmacy staff will dispense the medication according to the following protocols:
  - Inpatients will have their medication supplied in the usual manner, except that a consumer must have an acceptable WBC result drawn within the seven (7) days preceding the current day’s dosing. No medication will be dispensed to a consumer with an unacceptable WBC.
  - Outpatients will have their prescriptions filled in weekly, biweekly, or monthly installments, according to the above protocol. The consumer must have an acceptable WBC result drawn within the preceding seven (7) days or 14 days. No medication will be dispensed to a consumer with an unacceptable WBC.
  - The designated pharmacy staff will transmit the information required weekly to the Registry.
- When Clozapine is discontinued, the psychiatrist will complete the top half of the Discontinuation Form, or equivalent (Attachment RC1114E), and forward it to the Pharmacy and Therapeutics (P&T) Committee. The committee will send the form to the Medical Director, who will sign it and send it to the pharmacy staff. The pharmacy staff will inform the Registry and send the original for filing in the consumer’s chart and retain a copy in the pharmacy.
- When Clozapine is discontinued, four (4) weekly WBCs will be obtained after the drug is stopped and these will be reported to the psychiatrist/APN.

5. Antipsychotic Monitoring Protocol for Obesity, Hyperlipidemia and Diabetes (Metabolic Syndrome)**:**

- Pre-treatment baseline EKG/laboratory work-up, as deemed clinically appropriate by the treating Psychiatrist/APN which will include, at a minimum, a Complete Metabolic Panel, fasting lipid panel, and CBC with differential.
- At baseline, obtain personal/family history, weight (BMI), waist circumference, blood pressure, fasting glucose, hemoglobin A1C, and fasting lipid profile, as deemed clinically appropriate by the treating Psychiatrist/APN.
- Thereafter, the medical history is done annually by the Psychiatrist/ APN.
- Waist circumference, weight, and blood pressure are done quarterly by the nurse or designee.
- Fasting glucose and hemoglobin A1C is done quarterly for the first year and then annually
- The fasting lipid profile is done one time at the end of the first quarter and every year thereafter.

N. Rural Services will develop and maintain a quality assurance program to ensure ongoing compliance with this policy.

1114.5.2 Timelines

Requirement	Deadline	Starting Date	Responsible Party	Actions to be Taken
1114.5.1	Quarterly	On admission	Psychiatrist or APN	Review chart for appropriate lab tests and required action
1114.5.1	Each time a prescription is renewed or changed	On admission	Psychiatrist or APN	Determine whether appropriate lab tests have been completed
1114.5.1	Immediately	On admission	Psychiatrist, APN, Nurse	Communicate lab orders to the medication clinic nurse
1114.5.1	Updated on an ongoing basis	On admission	Nurse	Tracking sheet for labs: 1. Lab needs are tracked timely and routinely 2. Labs are ordered timely 3. Labs are filed in consumer's physical chart timely 4. Psychiatrist/APN is informed if lab tests are indicated 5. Nurse advises the Psychiatrist/APN of abnormal lab results

Requirement	Deadline	Starting Date	Responsible Party	Actions to be Taken
1114.5.1	Within one (1) working day	Upon consumer notification	Nurse	1. Obtain recent lab result as available from PCP or outside medical provider prior to referring the consumer for lab test 2. Triage with referral to community service providers when clinically indicated as related to out of range or abnormal lab results
Baseline EKG 1114.5.1	Within one (1) working day	With receipt of Psychiatrist/APN orders, completion of ordered labs, and filed in consumer's physical chart	Nurse	Refer the consumer for lab tests as ordered
Baseline labs, includes Chemistry Panel, CBC with differential, ultra sensitive TSH, T4, lipids 1114.5.1	Within one (1) working day	On admission	Psychiatrist/APN or Nurse	1. Order for consumers at risk for cardiovascular disease and when clinically indicated 2. Not required if a consumer's PCP has performed an EKG in the last six (6) months and the results can be obtained and placed in the physical chart 3. All consumers starting tricyclic antidepressants prior to beginning any of these medications
1114.5.1	Within one (1) working day	On admission	Psychiatrist/APN	Baseline labs will be ordered when medication is initially prescribed
Urinalysis and Urine Drug Screens	Within one (1) working day	On admission and on-going based on assessment	Psychiatrist/APN	When clinically indicated
Chemistry Panel and CBC with differential	Within one (1) working day	Annually	Psychiatrist/aPN	Order labs
Lithium	Within one (1) working day	Initiating Lithium	Psychiatrist/APN	Pre-treatment EKG/labs with a minimum of a Complete Metabolic Panel and CBC with differential
Lithium	Within one (1) working day	Before initiating Lithium and yearly thereafter or with any abnormality	Psychiatrist/APN	Thyroid function tests
Lithium	Within two (2) weeks	After initiating Lithium	Psychiatrist/APN	Order Serum Lithium level

Requirement	Deadline	Starting Date	Responsible Party	Actions to be Taken
Lithium	Recheck within 6 to 12 weeks and every six (6) months thereafter	After initiating Lithium	Psychiatrist/APN	Order Serum Lithium level
Lithium	Within two (2) weeks after each change in Lithium dose	After changing Lithium dose	Psychiatrist/APN	Order Serum Lithium level
Lithium	Every six (6) months	After initiating Lithium	Psychiatrist/APN	Order Blood Urea Nitrogen and Creatinine
Requirement	Deadline	Starting Date	Responsible Party	Actions to be Taken
Lithium	Consumer 40 years of age or over or as clinically indicated	With Lithium initial order	Psychiatrist/APN	Pre-treatment EKG
Lithium	Suspected Lithium toxicity	After initiating Lithium	Psychiatrist/APN	Lithium Level, BUN, and Creatinine ordered
Carbamazepine	Within one (1) working day	Before starting Carbamazepine	Psychiatrist/APN	Pre-treatment EKG/lab work up with a minimum of a Complete Metabolic Panel and CBC with differential
Carbamazepine	Within two (2) weeks after initiation	On initiating Carbamazepine	Psychiatrist/APN	Serum Carbamazepine level and CBC with differential
Carbamazepine	One (1) month	After initiating Carbamazepine	Psychiatrist/APN	Serum Carbamazepine and CBC with differential ordered
Carbamazepine	Every six (6) months or if clinically indicated	After initiating Carbamazepine	Psychiatrist/APN	Carbamazepine level and CBC with differential ordered
Carbamazepine	Within two (2) to three (3) weeks after each change in dose	After initiating Carbamazepine	Psychiatrist/APN	Carbamazepine level and CBC with differential
Carbamazepine	If blood abnormality is suspected and rechecked as clinically appropriate	After initiating Carbamazepine	Psychiatrist/APN	CBC with differential, PT/PTT, INT and LFTs rechecked
Carbamazepine	Levels of other concurrent and anti-epileptic drugs	After initiating Carbamazepine and with Carbamazepine serum levels	Psychiatrist/APN	Serum levels for identified drugs ordered

Requirement	Deadline	Starting Date	Responsible Party	Actions to be Taken
Valproic Acid	Within one (1) working day	Before starting Valproic Acid	Psychiatrist/APN	Pre-treatment baseline EKG/lab work up, with a minimum of a Complete Metabolic Panel and CBC with differential
Valproic Acid	Within one (1) month	After initiating Valproic Acid	Psychiatrist/APN	Valproic Acid serum ordered
Valproic Acid	In six (6) months	After initiating Valproic Acid	Psychiatrist/APN	Valproic Acid level ordered, along with a CBC with differential and Complete Metabolic Panel
Valproic Acid	Within two (2) to three (3) weeks	With each change in Valproic Acid level	Psychiatrist/APN	Valproic Acid ordered
Valproic Acid	Levels of other concurrent and anti-epileptic drugs	With each Valproic Acid level	Psychiatrist/APN	Serum levels for identified drugs ordered
Clozapine	Before starting Clozapine therapy	With decision to start Clozapine	Psychiatrist/APN	Order Metabolic pre-screen and obtain results that do not indicate contraindications
Clozapine	Within seven (7) days of the first dose of Clozapine	On initiating Clozapine	Psychiatrist/APN	Order CBC with a WBC >3500 and an absolute neutrophil (ANC) >2000 initially
Clozapine	PRN: within one (1) working day	With ongoing Clozapine therapy	Psychiatrist/APN	Order CBC PRN in response to decreased WBC
Clozapine	Six (6) months, within one (1) working day	With ongoing Clozapine therapy	Psychiatrist/APN	Order standing order for weekly WBC for six (6) months
Clozapine	After six (6) months, within one (1) working day	With ongoing Clozapine therapy	Psychiatrist/APN	Order standing order of bi-weekly WBC if lab testing in acceptable range per medical provider decision
Clozapine	After one (1) year, within one (1) working day	With ongoing Clozapine therapy	Psychiatrist/APN	Psychiatrist/APN may elect to order lab testing monthly after one (1) year of stable WBC counts
Clozapine	Within one (1) working day	If Clozpine is discontinued	Psychiatrist/APN	Order four (4) weekly WBCs
Lab Protocol for Obesity, Hyperlipidemia, and Diabetes	Within one (1) working day	Identified diagnosis of obesity, hyperlipidemia, and/or diabetes with antipsychotic medications	Psychiatrist/APN	Order pre-treatment baseline EKG/laboratory workup, which will include a minimum of a complete Metabolic Panel, testing lipid panel, and CBC with differential

1114.5.3 Documentation

A. Case File Documentation (paper):

File Location	Data Required
1114.5.1 Laboratory results	Within one (1) working day

B. Electronic Documentation (AVATAR):

Applicable UNITY Screen	Data Required
1114.5.1 Progress Note	Within one (1) working day

1114.5.4 **Supervisory Responsibilities:** Supervisors will provide in-service training to ensure all staff understands the requirements of this policy and its procedures. Supervisors will revisit this policy periodically, but no less than annually to identify recommendations for improvement.

1114.6 Policy Cross Reference

1114.6.1 Rural Services 902, Referral to Primary Care Physician

1114.6.2 Rural Services 1101, Indigent Drug Program and Exceptions

1114.6.3 Rural Services 1109, Mental Health Services Medication Policy

1114.6.4 Rural Services 1120, Medication Maintenance

1114.6.5 MHDS 4.015 – Obtaining, Use, and Documentation of Formulary Approved Medication including Clozapine (Clozaril**)**

1114.6.6 NN-MM-29 Clozapine Protocols

1114.7 References

1114.7.1 National Institute of Health, "Frequency of Laboratory Monitoring of Chronic Medications Administered to Nursing Facility Residents: Results of a National Internet-Based Study, "by Steven M. Handler, MD, MS, CMD, assistant professor, Brian H. Shirts, PhD, medical student, Subashan Perera, PhD, assistant professor, Stephanie A. Studenski, MD, MPH, professor, Michael J. Becich, MD, PhD, professor, Nicholas. G. Castle, PhD, associate professor, and Joseph T. Hanlon, PharmD, MS, BCPS, FASCP, FASHP, professor

1114.7.2 Physician's Desk Reference, 2012, www.PDR.net and www.PDRbooks.com/updates

1114.7.3 American Psychiatric Association Laboratory Guidelines

1114.7.4 American Diabetes Association Laboratory Guidelines

1114.8 Attachments

1114.8.1 RC1114A Laboratory Protocols and Monitoring Medication Side Effects Worksheet

1114.8.2 RC1114B Metabolic Syndrome Teaching Tool

1114.8.3 RC1114C Clozapine Protocol Form

1114.8.4 RC1114D Clozapine Registration Form

1114.8.5 RC1114E Clozapine Discontinuation Form

1114.8.6 RC1114F Clozapine WBC Monitoring Form

1114.8.7 RC1114G Interrupted Therapy Algorithm Form

1114.8.8 RC1114H Decision Matrix in the Use of Atypical Antipsychotic and Decision Matrix in the USE of SSRIs

1114.8.1
RC1114A:
LABORATORY PROTOCOLS
AND
MONITORING MEDICATION SIDE EFFECTS
WORKSHEET

Laboratory Protocols Guidelines Rural Clinics #1114		
Client Population	**Laboratory**	**Frequency**
Baseline Labs	Chemistry Panel CBC w/ differential Ultrasensitive TSH and T4 Lipid panel Urine Analysis and Urine drug screen PRN	Baseline and Annual Baseline
Consumers at risk for Cardiovascular Disease	EKG	Baseline and PRN Prior to starting tricyclic antidepressants.
Psychiatric medication with Obesity, Hyperlipidemia, and/or Diabetes	EKG PRN Chem Panel CBC with Differential Thyroid Panel Urine Analysis and Urine drug screen PRN Fasting glucose and hemoglobin A1C Fasting Lipids	Pre-Treatment Baseline Baseline Quarterly the first year; then Annual Baseline First Quarter ; then Annual
All Clients prescribed Lithium	Chemistry Panel CBC with Differential Thyroid Panel EKG PRN Urine Analysis and Urine drug screen PRN	Pre-Treatment Baseline Annual
	BUN and Creatinine	Every Six Months
	Serum Lithium	Within 2 weeks of initiating treatment Within 6-12 weeks of initiation Recheck every six months Within two weeks after each dosage change
Carbamazepine	EKG and Baseline Labs Carbamazepine and CBC with differential	Pre-Treatment Baseline Within two weeks of initiation One month after first level drawn Every six months Within 2-3 weeks after change in dose
	Complete Metabolic Panel	Every Six Months
	CBC with differential PT/PTT/INR LFTs	If Blood abnormality is suspected and PRN
Valproic Acid	Valproic Acid Level	Within one month of initiation In six(6) months Within 2-3 weeks after change in dose
	EKG and Baseline Labs	Pre-treatment
	CBC with differential Complete metabolic panel	Every 6 months
Clozapine	Complete Metabolic Panel	Baseline Pre-treatment
	CBC	Within seven (7) days of first dose of Clozapine PRN in response to decreased WBC
*****When discontinued, four (4) weekly WBC's will be obtained after the drug is stopped. Report results to APN/ MD.****	WBC	Weekly as a standing order for 6 mo After 6 months of acceptable WBC levels, WBC may be ordered bi-weekly Monthly after one year of stable WBC

Approved by MARS: 8/23/12

1114.8.2

RC1114B:

METABOLIC SYNDROME TEACHING TOOL

METABOLIC SYNDROME
TEACHING TOOL

What is metabolic syndrome? It is a cluster of conditions –increased blood pressure, a high blood sugar, excess body fat around the waist or abnormal cholesterol levels – that occur together, increasing your risk of heart disease or, stroke, and diabetes. The more of these symptoms you have, the greater are your health risks. Aggressive lifestyle changes can delay or even prevent the development of serious health problems.

What are the symptoms? Having metabolic syndrome means you have three or more disorders related to your metabolism at the same time. They include:

- Obesity (having an apple shape) where most of your body fat is around your waist. For women, if your waist is greater than 35 inches, or for men if you waist is greater than 40 inches, then you are considered to be obese. (This can vary by race).
- High blood pressure – meaning systolic (top number) is above 130 and diastolic (bottom number) is above 85 or more.
- High blood sugar level if your fasting blood glucose is above 100.
- High cholesterol if your triglycerides are150 or more; HDL cholesterol less than 40 for men and less than 50 for women.

The goal of **treating metabolic syndrome** is to reduce the risks associated with this condition, which include heart diseases and diabetes. Some things that are highly recommended for treatment include:

- Lose weight. Initial goal is to lose between 7 and 10% of your current weight. This usually means that you need to eat between 500-1000 less calories per day.
- Exercise. Get 30 minutes of moderate intensity exercise such as walking 5-7 times per week, seeking to lower your BMI, (Body Mass Index).
- Lower your cholesterol, using weight loss and exercise, and cholesterol lowering medications, if needed.
- Lower your blood pressure, using weight loss, exercise, and medications, if needed.
- Some people may need daily low-dose aspirin.
- If you smoke, then QUIT.

PREVENTION

Preventing (and managing) the condition involves:

- Eating a diet low in fat, with a variety of fruits, vegetables, and whole grain products
- Getting regular exercise, at least 30 minutes of moderate activity almost every day
- Losing weight so that you body mass index (BMI) is less than 25
- Managing blood pressure and blood sugar
- Not smoking
- Trying to include fish, preferably oily fish, in your diet at least twice a week.

Source: http://www.ask.com, Reviewed by Deborah Wexler, MD, Assistant Professor of Medicine, Harvard Medical School, Endocrinology.

Approved by MARS: 8/23/12

1114.8.3

RC1114C:

CLOZAPINE PROTOCOL FORM

CLOZARIL PROTOCOL FORM

Agency: _____

1. Psychiatrist

I request that Clozaril (Clozapine) be approved for therapeutic trial on _____ for the following clinical indications:

☐ Patient is a severely ill schizophrenic who has experienced intolerable side effects and/or adverse reactions to:

☐ Haldol	☐ Thorazine	☐ _____
☐ Mellaril	☐ Navane	☐ _____
☐ Stelazine	☐ Prolixin	☐ _____

☐Patient is a severely ill schizophrenic whose symptoms have not been controlled adequately on a therapeutic regimen equivalent to six weeks of chlorpromazine at 1,000 mg. daily:

☐ Haldol	☐ Thorazine	☐ _____
☐ Mellaril	☐ Navane	☐ _____
☐ Stelazine	☐ Prolixin	☐ _____

☐ Patient is currently receiving Clozaril per accepted standards.
☐ Patient has Tardive Dyskinesia.
☐ The above named patient has been screened through the Clozaril National Registry using the Sandoz Clozaril Patient Safety Assurance Form and has been issued a "Rechallenge Clearance Authorization Code Number."

Authorization Code Number: Signature Date

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2. Medical Clearance

☐ Patient has been screened:

☐ White Blood Cell Count is greater than 3,500
☐ White Blood Cell Count is less than 3,500
☐ Medical History shows no absolute contraindication
☐ Medical History is significant for _____

Signature Date

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3. Authorization

The Agency Clozaril Advisory Panel has reviewed the above information and patient record and

☐ Treatment with Clozaril per Agency Protocol is **AUTHORIZED**
☐ Treatment with Clozaril is **NOT AUTHORIZED**

Medical Director Signature Date

Approved by MARS: 8/23/12

1114.8.4

RC1114D:

CLOZAPINE REGISTRATION FORM

REGISTRATION FORM B

The Mylan Brand
CLOZAPINE

CLOZAPINE *Prescription Access System*™

P.O. Box 4649, Star City, WV 26504-4649 • Toll-free Phone: 800-843-9915 • Toll-free Fax: 800-843-9916

A. I am completely familiar with the Clozapine Prescribing Information, including WARNINGS concerning the risk of death associated with agranulocytosis and granulocytopenia.

B. I understand that each of my patients must be enrolled in the CLOZAPINE *Prescription Access System* (CPAS) to reduce the potential of rechallenging patients at risk. Clozapine should not be prescribed before receiving a patient reclearance from the CLOZAPINE *Prescription Access System*. I agree to report all White Blood Cell (WBC) counts (normal and abnormal) to the pharmacy for submission to the CLOZAPINE *Prescription Access System* within 7 days of collection for weekly patients and within 14 days of collection for biweekly patients. Finally, I agree to notify the CLOZAPINE *Prescription Access System* promptly of all discontinued patients and submit the results of the 4 required weekly WBC counts after discontinuation of therapy.

C. I understand that the CLOZAPINE *Prescription Access System* strongly recommends my enrollment of a local quality assurance committee to help ensure compliance with the Clozapine Prescribing Information requirements. The CLOZAPINE *Prescription Access System* will notify the physician and pharmacist of all issues regarding noncompliance.

The completion of this document demonstrates my intention to participate in the CLOZAPINE *Prescription Access System*. I have devised a plan for a Clozapine access group which meets the requirements of the Prescribing Information. Signing this form constitutes commitment on my part to ensure drug dispensing will be contingent upon receipt of WBC count test results and will be performed in compliance with the guidelines of the CLOZAPINE *Prescription Access System*.

Physician's Signature _____ Date ___/___/___ (M D Y)

Pharmacist's Signature _____ Date ___/___/___ (M D Y)

PHYSICIAN (If registered with CLOZAPINE *Prescription Access System*, only DEA/ID number is required.)

Physician's DEA/ID Number

Physician's Name (Type or Print) & Title

Address | City | State | Zip Code

( ) Phone Number | ( ) Fax Number

Associated Institution

PHARMACIST (If registered with CLOZAPINE *Prescription Access System*, only DEA/ID number is required.)

Pharmacy DEA/ID Number

Pharmacist's Name (Type or Print) & Title

Pharmacy Name

Address | City | State | Zip Code

( ) Phone Number | ( ) Fax Number

Wholesaler | Fax Number

Address | City | State | Zip Code

PATIENT

Initials (First Last)

Date of Birth (M D Y)

Sex (M/F)

Zip Code

Today's Date (M D Y)

Race (W Afr/A Hisp Asian Other)

Patient's Social Security #

☐ New Patient?

☐ Patient With Interrupted Treatment?

Patient Continuing Treatment? Y ☐ N ☐

If yes, Biweekly testing? Y ☐ N ☐

☐ If weekly testing, how many weeks without interruption or a treatment break >1 month?

☐ Check here to receive preprinted Patient-Specific WBC Count Reporting Forms (Form D).

PATIENT RECLEARANCE CODE IS
(Provided by CLOZAPINE *Prescription Access System*)

Confirmed by: _____ Date: _____

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White: CPAS

Approved by MARS: 8/23/12

1114.8.5

RC1114E:

CLOZAPINE DISCONTINUATION FORM

CLOZARIL DISCONTINUATION FORM

Agency: _____

1. Psychiatrist

Patient Name: _____

Clozaril Start Date: _____

This patient has been on treatment with Clozaril (Clozapine) and therapy is now being terminated for the following reason(s):

- ☐ Noncompliance with medication
- ☐ Noncompliance with phlebotomy schedule
- ☐ Patient withdrew consent for treatment
- ☐ White Blood Cell Count less than 3,500
- ☐ White Blood Cell Count less than 2,000
- ☐ Clozapine related seizures
- ☐ Death (specify cause): _____
- ☐ Other (please specify): _____

Signature Date

2. Agency Advisory Panel

The Agency Clozaril Advisory Panel has reviewed the above information and patient record.

- ☐ Authorization for treatment with Clozaril is **REVOKED**
- ☐ Clozaril National Registry has been notified of discontinuation.

Medical Director Signature Date

Approved by MARS: 8/23/12

1114.8.6

RC1114F:

CLOZAPINE WBC MONITORING FORM

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The completion of this document demonstrates my intention to participate in the CLOZAPINE *Prescription Access System* (CPAS) and to participate in a plan that ensures that drug dispensing will be contingent upon receipt of White Blood Cell (WBC) count test results. Completion of this form constitutes a continuing commitment to adhere to the guidelines outlined in the Clozapine Prescribing Information and the parameters of the CLOZAPINE *Prescription Access System*.

Please mark appropriate box ☐ **WEEKLY WBC MONITORING** ☐ **BIWEEKLY WBC MONITORING**

PATIENT

First Last
Initials ☐☐

Patient's Reclearance Code ☐☐☐ ☐☐☐☐

Patient's Social Security # ☐☐☐-☐☐-☐☐☐☐

Patient's Treatment ☐ Pretreatment ☐ Active ☐ Interrupted ☐ Discontinued

Blood Draw Date ☐☐ ☐☐ ☐☐
M D Y

Total WBC Count (per mm³) x 10³ ☐☐.☐ x 10³

Total ANC (per mm³) ☐☐☐☐ (Optional)

Is WBC Count Acceptable for Dispensing? ☐ Yes ☐ No

Today's Clozapine Dosage: ☐☐☐ Total Mg/Day

Dispensed From: ☐ Bottle ☐ Unit Dose

Today's Date: ☐☐ ☐☐ ☐☐
M D Y

PRESCRIBING REMINDERS:

Treatment should not be initiated if WBC count is <3500 (3.5 x 10³) per mm³	Please see full prescribing information for patients with interruption of Clozapine treatment	If subsequent WBC counts are <3500 (3.5 x 10³) per mm³ and ≥3000 (3.0 x 10³) per mm³ and ANC ≥1500/mm³, twice-weekly WBC counts with differential should be performed	If total WBC count is <3000 (3.0 x 10³) per mm³ and ≥2000 (2.0 x 10³) per mm³ or ANC <1500/mm³ and ≥1000/mm³, therapy should be interrupted and **patient closely monitored**	If total WBC count is <2000 (2.0 x 10³) per mm³ or ANC <1000/mm³, therapy should be discontinued and patient should never be rechallenged with Clozapine

PHYSICIAN (If registered with CLOZAPINE *Prescription Access System*, only DEA/ID number is required.)

Registered Physician ☐ Covering Physician ☐

Physician's DEA/ID Number ☐☐ ☐☐☐☐☐☐☐

Physician's Signature

Registered Physician's Name (Type or Print) & Title

Covering Physician's Name

Address City State Zip Code

( ) Phone Number

( ) Fax Number

PHARMACIST (If registered with CLOZAPINE *Prescription Access System*, only DEA/ID number is required.)

Pharmacy DEA/ID Number ☐☐ ☐☐☐☐☐☐☐

Pharmacist's Name (Type or Print) & Title

Pharmacy Name

Address City State Zip Code

( ) Phone Number

( ) Fax Number

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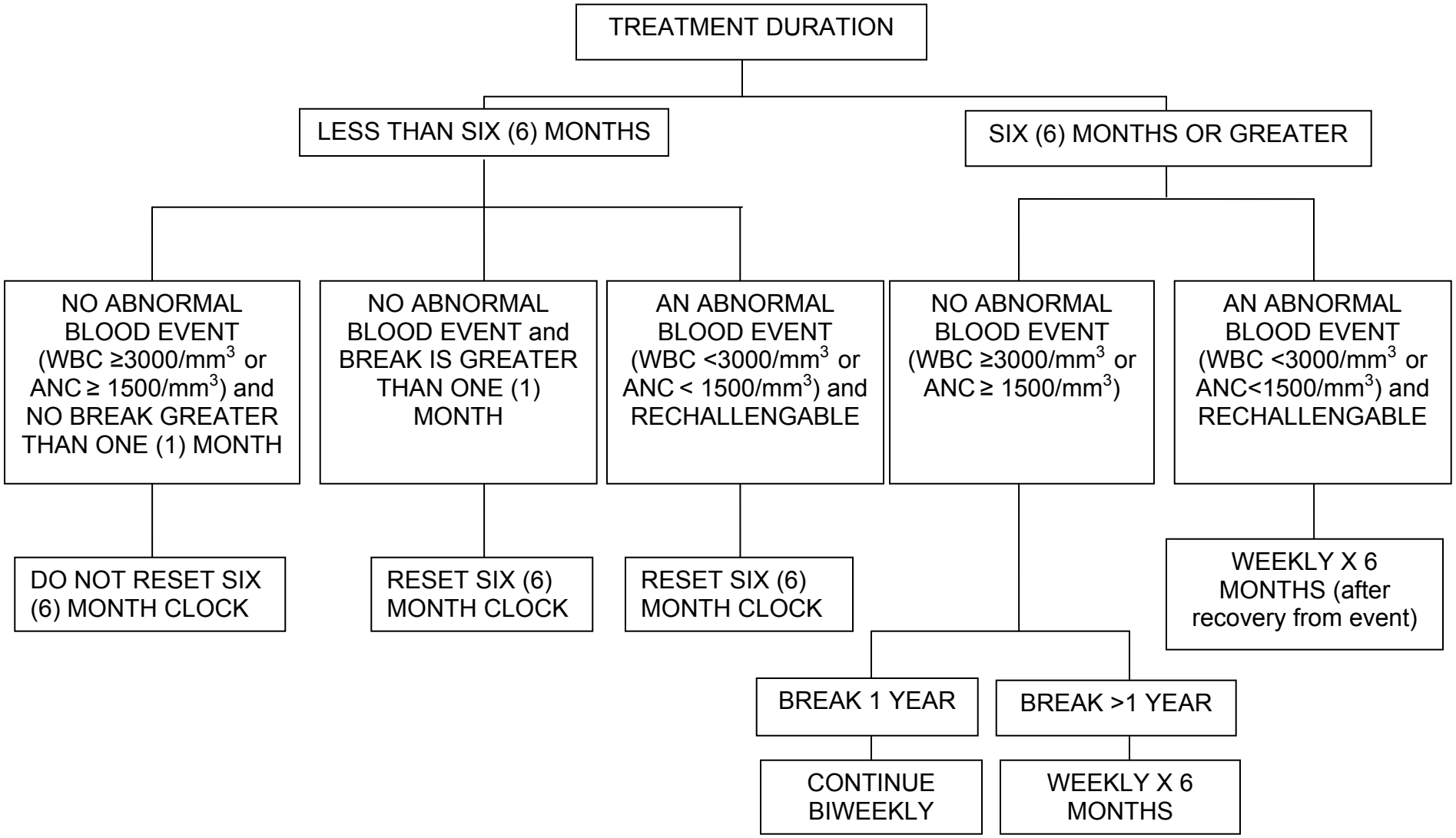
Approved by MARS: 8/23/12

1114.8.7

RC1114G:

INTERRUPTED THERAPY ALGORITHM FORM

INTERRUPTED THERAPY (WBC < 3000/mm^3 ANC < 1500/mm^3 FOR BI-WEEKLY MONITORING



Approved by MARS: 8/23/12

1114.8.8

RC1114H:

DECISION MATRIX IN THE USE OF ATYPICAL ANTIPSYCHOTIC

AND

DECISION MATRIX IN THE USE OF SSRIs

MHDS DECISION MATRIX IN THE USE OF ATYPICAL ANTIPSYCHOTICS

We are still in the process of completely adopting the NMAP (Nevada Medication Algorithm Project) in Schizophrenia, a variation of the TMAP. The TMAP (Texas Medication Algorithm Project) guidelines (algorithm) reflect the state of current knowledge on effective and appropriate care, as well as clinical consensus judgments. The TMAP authors further caution that the guidelines may not apply to all patients, but must be adapted and tailored to each individual patient. Proper use, adaptation modifications or decisions to disregard, in whole or in part, are entirely the responsibility of the clinician. The decision matrix denoted below follows the TMAP model, but with the incorporation of fiscal responsibility requirement. Fiscal responsibility is not a new concept in the optimal treatment of patients. It has always been implicit in the overall clinical responsibility of the clinician. Unfortunately it has not received as much attention as it merits. Because of the inevitable changes in scientific information and technology including the future availability of single source drugs in generic forms, it is imperative that periodic review resulting in the updating and revisions of the decision matrix be needed from time to time. Thus, the decision matrix will become a very dynamic concept that seeks to maximize and stabilize the clinical and fiscal positions of our patients and our organization. The medical staff will be involved in developing new decision matrices as they apply to different classes of drugs.

In the attached TMAP Antipsychotic Algorithm, the atypical antipsychotics referenced in Stages 1 to 3 are Olanzapine, Quetiapine and Risperidone. This was developed prior to the release of Ziprasidone. The modification in the MHDS system is as follows:

Stage 1: Risperidone or Ziprasidone (Use in any order)

Stage 2: Use the other in above

Stage 3: Use Quetiapine or Olanzapine (Use in any order)

Stage 4: Use the other in above

Stage 5: Typical Antipsychotic

Stage 6: Clozapine

Stage 7: Augmentations

MHDS DECISION MATRIX IN THE USE OF SSRIs

We have not yet started orientation for the implementation of the NMAP (Nevada Medication Algorithm Project) Depression Algorithm. We are on schedule to adopt the principles of the guidelines. And, like in the use of atypical antipsychotics, we shall make modifications in the interest of our clinical and fiscal goals. Review the clinician's responsibility as denoted in the decision matrix for the use of atypical antipsychotics.

However, our establishment of a decision matrix in the class of SSRIs prepares us for such an implementation. In the TMAP (Texas Medication Algorithm Project) SSRIs feature in Stages 1, 2, and 3 of the algorithm. Monotherapy is recommended in those first 3 stages.

The modification in the MHDS (NMAP) system is as follows:

In considering the use of SSRIs, regardless of the Stage, the decision matrix is:

Step 1: Fluoxetine

Step 2: Lexapro

Step 3: Celexa or Paxil or Zoloft