

SUBJECT: USE OF CLOZAPINE

EFFECTIVE
DATE: 03-22-11 (replaces 08-29-05)

APPROVED BY:

Executive Director

Medical Director

Pharmacist

Reviewed (no changes): _____

POLICY

It is the policy of McIntosh Trail MH/DD/AD Physicians to provide appropriate anti-psychotic medications to those consumers who have mental disorders which require this type of medication. Clozapine has been shown to be effective in some people who have not responded to other medications. However, potential serious adverse side effects are associated with this medication with the most serious one being agranulocytosis. As such, consumers must be carefully screened and will need to meet minimum criteria before a trial of Clozapine may begin. Also, regular monitoring of the consumers' white blood count will be a requirement of consumers on this medication. Due to the complications possible with Clozapine, it is not intended to be used as a first line treatment modality.

PROCEDURE

1. To be eligible for Clozapine, the consumer must meet the following criteria with any exceptions clearly and fully documented:
 - a. Diagnosis: Consumer will have a DSM-IV diagnosis of Schizophrenia, Schizoaffective Disorder, or Bipolar Disorder.
 - b. Demonstrated Treatment Resistance: As shown by:
 1. Consumers, who despite the use of adequate doses of at least two marketed antipsychotic drugs for adequate durations of time (at least 6 week trial), have not had a satisfactory clinical response and remain substantially psychotic, or
 2. Consumers with severe tardive dyskinesia who require antipsychotic medication and develop worsening of the dyskinesia when anti-psychotics are administered, or
 3. Consumers for whom it is not possible to achieve adequate doses of standard antipsychotic drugs because of severe extrapyramidal symptoms (with at least two such drugs) that are intolerable to the consumer and not treatable using standard medications (i.e. Antiparkinson drugs).
 - c. Consumer must not have a medical condition that causes low white blood count or be on any other medication which can lower white blood count (i.e. Tegretol). Consumer must not have an uncontrolled seizure disorder, active substance abuse, or significant mental retardation or a developmental disability.
 - d. Consumer must be willing to submit to required blood tests for white blood counts.
 - e. Be between the ages of 18 to 65, exceptions approved by Medical Director.

SUBJECT: USE OF CLOZAPINE

EFFECTIVE
DATE: 03-22-11 (replaces 08-29-05)

APPROVED BY:

Executive Director

Medical Director

Pharmacist

Reviewed (no changes): _____

PROCEDURE (Continued)

2. The treating physician shall discuss and educate the consumer and his/her significant others regarding the benefits, side effects, and potential risks. This discussion and education shall be documented by appropriate signatures on the Clozapine Consent Form. (See Attachment 1.)
3. The medication shall be prescribed and monitored as per the pharmaceutical company recommendations.
Consumer and Treatment Team (physician and pharmacist) must be registered with the manufacturer by completing the registration forms (Attach. 2.)
4. Baseline serum creatinine, BUN, liver profile, and CBC with differential shall be obtained prior to initiating drug therapy. Baseline EKG and current medical history and physical examination should be obtained prior to initiating Clozapine.
5. The consumer must see the physician face-to-face at least once a month for the first two months of treatment; then the frequency of return visits will be at the discretion of the treating Psychiatrist, at least every 90 days. Treatment initiated by Clinical Nurse Specialist will be monitored closely by the supervising physician.
6. Consumer must have prior arrangements with a Family Practice Physician, General Practitioner, or Internist who would provide medical treatment of agranulocytosis should this condition arise. The doctor's name will be contained within the Clozapine consent form and clearly identified on the consumer's chart.
7. Clozapine is discontinued upon suspicion of myocarditis. Consumers with Clozapine induced myocarditis will not be rechallenged with Clozapine.
8. Serum creatinine, BUN, and liver profile shall be repeated after the initial six weeks of treatment. For those consumers continuing on the medication, these tests will be repeated at six months, twelve months, and then annually. WBC counts must be completed for four weeks after discontinuation of the medication.
9. For consumers who started Clozapine in a hospital and are discharged on Clozapine to a community program, a Clozapine Rechallenge number must be obtained by using Patient Safety Assurance Form (Attachment 2) or calling the Clozapine National Registry (generic Clozapine guidelines substituted, if appropriate). The procedures established by any regional hospital will apply for those consumers on Clozapine who are on temporary leave from the regional hospital.
10. The most current Clozapine Treatment Systems Requirements will be followed (Attachments 3 and 4).

Attachments:

- No. 1 - Informed Consent for Clozapine
- No. 2 - Patient Safety Assurance Forms (page 1-6)
- No. 3 - Frequency of Monitoring
- No. 4 - Interrupted Therapy for Bi-Weekly Monitoring

MCINTOSH TRAIL MH/DD/AD SERVICES

Informed Consent for Clozapine

Clozapine is an antipsychotic medication which has been approved by the Federal Drug Administration for treatment of some psychiatric conditions. Clozapine has been used for years in many countries around the world, and has been found to be an effective drug for the treatment of my type of psychiatric condition. However, because of potentially serious adverse reactions, there are restrictions on the drug's use in all major countries where it is available.

I understand that the possible benefits of my taking this drug are that Clozapine may prove to be more effective in controlling my psychiatric condition than any previous drug I have received and might produce fewer neurological side effects than other drugs which I might receive. In addition, if I am suffering from any abnormal movements related to my past use of antipsychotic medications, it is likely that Clozapine will help to control or eliminate these movements. If I do not have such movements, Clozapine may be less likely to cause them to develop than other medications I have had prescribed.

I have been informed of possible side effects associated with this drug. Clozapine, like other drugs used to treat my condition, may produce drowsiness, fainting, decreased blood pressure, increased salivation, blurring of vision, rapid heart beat, convulsive seizure (fits), nausea and constipation. There is also a possibility of sudden death which can occur with any antipsychotic medication. Clozapine is less likely than other drugs to produce certain common side effects frequently troublesome to patients, such as stiffness, tremor, and restlessness, and may be far less likely to cause or worsen abnormal movements (tardive dyskinesia) than standard treatments. I understand that it is impossible to predict which side effects, if any, will actually occur.

I have been told that taking this medication involves the risk that this medicine may interfere with my body's ability to make white blood cells. (These are the blood cells that fight infection.) This condition is called agranulocytosis. This is not a common reaction but is a serious condition which can develop with many drugs but is considered a higher risk with Clozapine. One or two out of a hundred people may develop some form of this problem, and most will get better with proper medical treatment. Two out of a thousand patients may actually die from it. I understand that I am taking this greater potential risk with Clozapine because it may help me with psychiatric symptoms that other medicines have not helped me with in the past. The early warning signs of this reaction include feeling tired, getting a fever, having a sore throat, or getting sores that do not heal. I understand that my doctors will monitor the condition of my blood regularly with frequent bloodtests. I agree to having my blood tested regularly for the duration of Clozapine treatment. I will report to my doctors immediately if I develop any signs of illness.

Should I develop the condition known as agranulocytosis as a direct result of the administration of Clozapine, I understand that my primary care physician will provide for acute medical care, including hospitalization. I also understand that this would require that I immediately stop taking Clozapine, and that it is unlikely that it would be safe for me to take this drug again.

I understand that Clozapine should not be taken by pregnant or nursing women or those planning to become pregnant while on the drug.

I agree to tell any health care professional with whom I come in contact that I am taking Clozapine.

I understand that my psychiatric condition could be treated with other medications that are currently used in standard medical practice, although I have been treated with several such medications in the past and they have not been effective for me. Another possibility is that I could stop taking medication altogether. However, if I do this, it is likely that I will become sicker.

If I agree to take Clozapine, I will participate in interviews to assess my psychiatric condition and history, as well as my medical condition and history. Small samples of my blood will be taken for laboratory tests.

I understand that while I am on this medication I must have weekly blood tests for six months and then every other week and pulse, blood pressure, and temperature checks in order to evaluate any effects that the drug might have on me. If I do not have a blood test, I cannot get the medication.

Prior to beginning treatment with Clozapine, I will have an EKG, and a physical examination by my primary care physician.

Hospital facilities and professional attention at _____ Hospital will be made available if I suffer physical injury resulting directly from this treatment, and that the physician supervising my treatment, if this is necessary, will be Dr. _____ or one of his/her associates. *(Enter name of local primary care physician and hospital.)*

I understand that I am under no obligation to take this medication. If I choose not to take this treatment, I will continue to have available other services which my physician and I agree that I need. If I do begin this treatment, I am also aware that I may withdraw my participation at any time without prejudice to my continued medical treatment. If I withdraw my participation, my symptoms will probably reappear.

I have been given an opportunity to ask further questions and understand that I can do so at any time during the course of my treatment with Clozapine.

I further understand that should I have any questions about my treatment, I may call _____ at _____ (name of person) is knowledgeable about treatment with Clozapine, but may not be directly involved in my care. I will also be given an opportunity to discuss, in confidence, any questions I may have with a member of the Consumer Rights Committee. This is an independent committee which monitors consumers' rights under Federal and State regulations, composed of professional staff, as well as lay members of the community not affiliated with this treatment center.

Consumer Name: _____ CID No. _____

CONSENT FORM - CLOZAPINE

I have read the information provided above, and I am willing to take Clozapine.

Consumer's Name _____
(Please Print) (Date)

Consumer's Signature _____

Family Member/Significant Other Signature _____

Relationship to Consumer _____

Clinical Staff _____

I have fully defined and explained the treatment involved to the above consumer.

Physician's Signature Date