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Monitoring Clozaril Use in Your Consumers

GENERIC NAME= Clozapine

BRAND NAME= Clozaril or FazaClo

Clozapine is an anti-psychotic medication that works by blocking receptors in the brain for several neurotransmitters including dopamine, serotonin, norepinephrine, acetylcholine, and histamine.

Neurotransmitters-chemical messengers that nerves use to communicate with each other

Psychotic or Psychosis-mental state described as involving "lack of contact with reality"

Clozapine is used in the management of psychotic disorders (schizophrenia). Because of concern for serious side effects, Clozapine is reserved for patients who have failed to respond to other standard medications or who are at risk for recurring suicidal behavior.

Schizophrenia-abnormality in the perception or expression of reality (delusions, hallucinations, disorganized speech and behavior) which may affect any or all of the five senses (sight, hearing, taste, smell, and touch).

Clozapine is typically given 1-3 times a day with a starting dose of 12.5 mg 1-2 times a day. The dose is increased slowly over 2 weeks until the person's optimal dose is found. Observing the person for signs and symptoms of respiratory or cardiac distress during dose increases is vital. It may take several weeks for the full effects and benefits of Clozapine to be observed. The average dose is usually 300-450 mg per day with a maximum dose of up to 900 mg per day.

SO WHY DO WE NEED TO HAVE LABS DONE FOR A CONSUMER BEFORE THE CLOZAPINE CAN BE REFILLED?

To begin with, it's the law. Federal Clozapine monitoring guidelines approved by the FDA state that satisfactory lab results must be obtained prior to dispensing this medication. Clozapine can cause significant bone marrow suppression, leading to agranulocytosis, a dangerous condition that can lead to death. In some people, use of

Clozapine, Clozaril, or FazaClo can cause a decrease in the white blood cell count (WBC), leaving a person open to serious infection. Blood tests should be done before starting Clozapine treatment, then:

- Weekly for 6 months,
- Every 2 weeks for 6 more months,
- Monthly labs thereafter if labs are normal
- If Clozapine is stopped for any reason, labs must be done for at least 4 weeks after

The Doctor will order how often lab results are needed based on several factors like; how long has the person been on OR OFF the Clozapine and what are the blood levels today and on a given day. The lab results are then reported by the pharmacy to the drug manufacturers who, in turn, are responsible to the FDA for the safety of the drug.

The CBC, or Complete Blood Count, is the blood test used to measure major blood components like red blood cells and white blood cells. There are also subgroups of white blood cells and each one has a different role in fighting infection. The Differential, often referred to as a "Diff" is a blood test that measures the types of white blood cells and is often done at the same time as the CBC (called a CBC with Diff). An important part of the Diff is the neutrophil count, allowing the physician to calculate an ANC (Absolute Neutrophil Count). If this specific white cell count is low, severe infection could take over. A person taking Clozapine with an ANC of less than 500 would be stopped from taking more of the medication and he may need to be hospitalized. It is also imperative to watch the person on Clozapine for any signs of infection such as tiredness, weakness, fever, or sore throat and to report these to the physician immediately. *Written by Khalil Rahman R.Ph.*

Consumer Change of Status Notification

Having good communication between the Pharmacy and our customers is imperative to providing quality service. One of the ways Pharmacy Alternatives insures that we have great service to our customers in the community is through our Change of Status Notification form. This is a form that you complete in your facility for any consumers who would have a change that would affect medication delivery. It could be circumstances such as:

- **New Admission**—this form would be used to provide all new consumer information (demographics, insurance, allergies, doctor) in addition, you would need to send signed & dated physician and nursing orders
- **Discharged Consumer**—lets us know not to send you medications or medical records any longer
- **Deceased Consumer**—lets us know to stop sending all meds and records
- **Transfer Within Facility**—informs us of a new address so medications and medical records will automatically go to the correct location
- **Return from Another Facility** (hospital, skilled nursing care, rehab, etc.)—lets us know that the consumer is home and to begin sending meds and records again. Often there are **NEW PHYSICIAN ORDERS** so we would also need to have **ALL ORDERS** signed/dated by the physician at this time. If the consumer is to stay on all previous medications **EXACTLY** as written prior to hospitalization, we need a physician's order stating this. To avoid error, it is always **BEST** to send all orders the consumer will be

on.... signed by the physician.

- **Change to Day Programming Schedule** that affects Medications—if the consumer was on a schedule of going to Day Programming Monday through Friday and changes to a schedule of only going Monday and Wednesday, **AND** they get meds there.....we would need to be notified of the change of schedule so that meds packaged separately for this can be adapted to the new schedule.
- **FAX this form to your Pharmacy** and it will be put into the system so all areas (pharmacy, medical records, billing, etc.) can see the consumer's status

Remembering to have good communication on your end means we will have better service to the consumers and you from our end!

Need to find the Change of Status form? Go to the PAL website at www.palrx.com, click on Resources, click on Forms. All Pharmacy forms are listed and ready to download whenever needed.



NEW ALZHEIMER'S DISEASE DRUGS

There are several new therapies coming down the pike in 2010 for the treatment of Alzheimer's Disease. At the top of the list is immunoglobulin which is now in Phase 3 trials and it's looking good that efficacy and tolerability will put it in the lead for FDA approval soon. Other medications still in the trial phase that are prime are: bapineuzumab (Wyeth), solanezumab (Lilly), dimebon (Pfizer) and LY450139 (Lilly). We are seeing new agents being developed that have at least 6 different mechanisms of action which should tell us that Alzheimer's

research has taken off in some new and different directions. Researchers are looking at ways to treat pre-Alzheimer's and earlier stages of Alzheimer's in patients so that the disease does not progress as quickly or does not progress beyond a certain point. This is very exciting for our consumers especially the many individuals with Down Syndrome who have Alzheimer's at a very high incidence. It looks like the next 2-3 years in Alzheimer's research may reward us with much more effective treatments.

Side Effects Monitoring

Your cold medicine relieves the stuffy nose and sore throat, but it makes you feel sleepy. Your inhaler makes it easier for you to breathe, but it makes your heart race. And the anticonvulsant you take keeps the seizures under control, but it causes terrible constipation and makes your bones brittle. The sleepiness, heart racing, constipation, and osteoporosis in these examples are **Side Effects** of the medications. ALL medications have **POTENTIAL Side Effects....But NOT ALL Side Effects** show up in every person taking a certain medication. Why is that?

Your body is controlled by many chemical reactions. Exercising, digesting your lunch, hearing a song on the radio, and even thinking....are processes involving chemicals. Everything that happens in your body has a chemical action or interaction that is connected to it. When the chemicals in your body get out of balance for some reason, this can cause some body functions to go haywire. When we take medication for that problem, the chemical in the medication helps to stabilize the chemical that is out of balance in the body (generally). When the balance is restored, the function is restored and we feel better.

Everyone has a unique body chemistry. Being thin, heavy, elderly, young, having Diabetes, having Hypothyroidism, or having allergies.....each of these can alter how a medication acts in someone's body. A person's genetics that they inherit from their parents also has a great influence in predisposing that person to being more susceptible to certain diseases or conditions.

People who take several medications, such as the elderly or individuals with DD are at high risk for Medication **Side Effects** or Adverse Drug Reactions due

to a variety of reasons:

- They often take several medications
- They take medications that have a higher potential to cause serious Side Effects or Adverse Drug Reactions (anticonvulsants, cardiac pills, anticoagulants, diuretics, psychiatric meds)
- They take these multiple meds on complex dosing schedules which increases the risk of mistakes
- They have more problems with liver function and kidney function (meds are absorbed and filtered through these organs, so any problems in their function can slow down a med's effect, OR cause toxicity in the body)
- Both of these populations are at risk for dehydration which also can cause drugs to become more concentrated, possibly causing an overdose even at normal prescribing amounts
- Current research is finding that people with IDD have more genetic influences on the medications they take than the non-IDD population. These influences may alter the way a particular medication acts in a specific person's body. This takes monitoring for Side Effects to a whole new level for individuals with IDD...it makes it harder and less straightforward.

When these events occur, certain medications can cause an increase in Medication **Side Effects** to occur. Some of these are not observable right away and may be hard to detect for Direct Support Professionals, for Nurses, or for Physicians.

Common Side Effects of medications are upset stomach, dizziness, dry mouth, unsteady gait, trouble standing from a sitting position, increased falls, and constipation. But, every medication has certain **Side Effects** that are most common for that med. You can find the most common Side

Effects for the medications you are giving listed on the MAR with each medication. If your MARs do not have this, you can request it be added. For more information on Side Effects of ANY medication, you can go to the PAL website at www.palrx.com and use the Informational Links.

RULES FOR SIDE EFFECT MONITORING:

1. Be aware if a consumer is on a new medication and know what it's most common **Side Effects** are
2. OBSERVE and document ANY behavior or changes that are different than normal behavior for that consumer
3. Contact the Nurse or Supervisor for minor OR more serious **Side Effects**
4. The Nurse/Supervisor needs to be aware of changes in eating, sleeping, fluid intake, activity level, toileting habits, and behavior.
5. In addition, follow your system for ongoing **Side Effects** monitoring which should be in place for long term observation of all medications
6. Having **Side Effects** does NOT mean a medication should be stopped or changed. It is important to weigh risks vs. benefits to determine the best action. Some Side Effects may have to be tolerated to some point, because the benefits of taking the medication outweigh the discomfort. This is for the physician, consumer, family, and other team members to determine.

Monitoring for Side Effects of medications is imperative. Any consumer on even ONE MEDICATION can be having Side Effects.



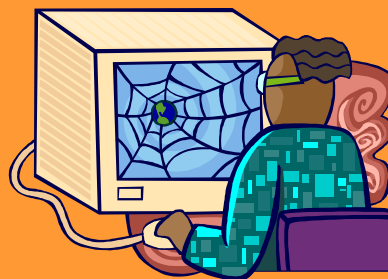
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We would love to earn your business.