

3-24-20 Clozapine REMS Program to Allow Pharmacists to Use Discretion:

Summary - The Clozapine Risk Evaluation and Mitigation Strategy (REMS) is an FDA-mandated program implemented by the manufacturers of clozapine which includes a patient registry and requirements for prescribers, pharmacists, patients, and distributors. Until today, it has required patients to have their blood drawn and tested each time by their pharmacist *before* they receive Clozapine. ***As a result of the COVID-19 pandemic and recent medical evidence, the Clozapine REMS program will now allow pharmacists to use their discretion and not require blood draws to before providing Clozapine.***

Requested Action - Please share this information with the pharmacy association in your state ASAP and ask them to share it with their pharmacist members.

Background - As you may know, Clozapine is the most effective antipsychotic and used for treating people who of not done well on any of the other antipsychotic medications. It has a rare side effect called neutropenia where your body stops making white cells which makes it highly susceptible to infection. As a result of this there is been a requirement that people get periodic neutrophil counts as often as every week and nevertheless often than every month and that the lab result has to be presented to the pharmacy before they will give you your medication refill. People who did well on clozapine and stop taking it usually rapidly become quite psychotic often sicker than they were before and almost always require hospitalization. In the current coronavirus environment there is clearly a substantially increased risk of infection if you have to get your blood drawn and your medication filled every week. Blood draw stations and pharmacies are full of sick people so we don't want our patients going there during the epidemic unless absolutely necessary. Also, often the patients requiring this kind of medication need assistance with transportation from CMHC staff. Allowing longer clozapine refills without the frequent blood draws is a huge advantage and relief. And the requirement for this monitoring was much more stringent than was necessary given how extremely rare the side effect is.

See review article at <https://www.ncbi.nlm.nih.gov/pubmed/16595571> - IT'S CONCLUSIONS:

After at least 6 months' treatment with clozapine, the mortality involved in stopping white blood cell monitoring is about the same as the mortality associated with other medications, such as mianserin or phenylbutazone, and with life in general (traffic or occupational accident). If the patient has been well informed and wishes to stop the monitoring, it is a medically justifiable option to do so and is preferable to stopping treatment with clozapine since this drug reduces overall mortality. See also below for additional information.