



March 31st, 2020

RE: COVID-19 & adjusted Clozapine Blood Monitoring Protocol

Dear Health Care Partner,

The COVID-19 Pandemic has forced all Canadians to adjust to a new reality of working, living, and interacting with one another. To that end we must also adjust, if possible but without compromising patient safety, our current treatment and monitoring protocol for patients prescribed Clozapine, to align with the current realities of daily life in Canada.

Health Canada has advised all Market Authorization holders and Health Care Professionals of the following changes regarding collection of bloodwork for patient prescribed Clozapine:

Given the current COVID-19 situation, Health Canada is aware that there may be situations in which patients receiving clozapine are unable to get safely tested in a timely fashion for their white blood cell (WBC) counts and absolute neutrophil counts (ANC) as part of the mandatory testing prior to renewal and/or the dispensing of their clozapine prescription. Health Canada recommends that, if possible, patients should continue to have WBC/ANC testing as per their regular schedule for hematologic monitoring.

As an interim measure during the COVID-19 crisis, a public health emergency, it would be reasonable for Healthcare Providers to use their best medical judgement to allow continued dispensing of clozapine even if patients are late in getting or unable to get their blood tested.

In addition Health Canada has asked all Market Authorization Holders to commit to the following enhanced reporting:

If there is a missing or delayed laboratory test, the reason should be properly documented and reported to Health Canada on a biweekly basis. The reports should be provided via e-mail as an MS-Word document and follow-up with an e-CTD sequence as per usual procedure. It is important that you continue to monitor for missing or late WBC/ANC testing. Also, any new safety issues or change in the safety profile of your product needs to be reported to Health Canada in a timely fashion.

Lastly, Health Canada will reevaluate the current monitoring and reporting requirements as follows:

This change in requirement for blood testing will be reassessed in three months or sooner. It is expected that once the COVID-19 related pressures are over, then blood testing requirements will go back to what they were prior to this situation.

In light of these changes AA Pharma encourages HCP's to assess each patient individually and to always weigh the known risks and blood monitoring recommendations as found in the Clozapine Product Monograph when prescribing. In addition, where a patient will be known to be missing blood work, AA Pharma asks that this information be passed onto the AASPIRE team for accurate reporting back to Health Canada.

Given that COVID-19 presents HCP's with a unique situation as to the care of patients prescribed Clozapine, please note the following hematological recommendations:

1. Patients **confirmed/suspected with COVID-19**

- Admit Patient to infectious disease hospital with isolation wards
- The staff there should take full personal protection equipment to provide medical care and then their blood work should be monitored as scheduled.

Note: COVID-19 patients may have lymphopenia but without neutropenia, the parameters of total white counts can be eliminated during the monitoring in order to avoid false alarms and unnecessary interruption of clozapine therapy.

2. **Quarantined Patients: With/without COVID-19 symptoms +With/without Travel history**

- The management of quarantined patients depends on local policy
- Recommend self-quarantine for 14 days
- Skip blood counts ONLY if patient have stable blood counts previously and the psychiatrist considers the benefits of treatment outweigh the risk during the quarantine period.

Note: It will be the best solution if the patient's family MD or a community nurse can go to their place of living to do the blood work, but staff should take full personal protection equipment to provide medical care

3. Patients with **No Travel history + No COVID-19 Symptoms or Cannot get CBC done**

- On Clozapine for **12 or more months (with no significant hematological adverse effects):** Postpone the blood work up to **8 weeks maximally**.
 - **[Dispensing of meds and quantity depends on treating physician]**
- On Clozapine for **less than 12 months:** Do not recommend postponing or skipping the scheduled blood work.
 - **[Dispensing of meds and quantity depends on treating physician]**
- If patients have missing blood work for more than 3 months or if patients develop fever or symptoms suggestive of infection, CBC should be check immediately at a local hospital.

As always the AASPIRE team will continue to help in monitoring patients for missing or late WBC/ANC Testing, and will advise Health Care Partners as these arise. In addition, our team is also available to assist in ensuring continuity of supply for patients during these challenging times.



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For more information the Product Monograph may be accessed at AASPIRE.ca and AAClozapine.ca. Should you need assistance, please contact the AASPIRE Program @1-877.276.2569 or one of our two nurse coordinators:

Michele Way: 604.505.1484

Garry Reid: 306.251.1484

Sincerely,

AA Pharma and the AASPIRE AA-CLOZAPINE Patient Care Network