Justice Health and
Forensic Mental Health Network

NSW GOVERNMENT

Justice Health NSW Guideline

Guidelines for the Management of Patients on Clozapine

Issue Date: 22 April 2025

Together for
Healthier Tomorrows

Guidelines for the Management of Patients on Clozapine

Guideline Number 6.053

Guideline Function Continuum of Care

Issue Date 22 April 2025

Next Review Date 22 April 2027

Summary The aim of this guideline is to ensure the correct management of patients with schizophrenia on Clozapine and to minimise the risk of patients prescribed Clozapine developing agranulocytosis or neutropenia or other serious adverse effects by adhering to strict haematological monitoring. This procedure manual is an adjunct to the ClopineCentral™ Protocol for staff managing patients on Clozapine within Justice Health and Forensic Mental Health Network (Justice Health NSW).

Responsible Manager Drugs and Therapeutics Committee

Applicable Sites

☐ Administration Centres

☐ Community Sites and programs

☒ Health Centres - Adult Correctional Centres or Police Cells

☒ Health Centres - Youth Justice Centres

☒ Long Bay Hospital

☒ Forensic Hospital

☒ Pharmacy Department

CM Reference GUIJH/6053

Change summary Reviewed by the D&TC for currency.

- Updated monitoring to include point of care testing for glucose.
- Consolidated monitoring information in relation to Clinical Specialty Protocols and pathology sets.
- Reference to JHeHs eForms included and summarised required forms throughout clozapine treatment.

Authorised by Drugs and Therapeutics Committee

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Printed copies of this document, or parts thereof, must not be relied on as a current reference document.
Always refer to the electronic copy for the latest version.

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Revision History

#	Issue Date	Guideline Name and Number	Change Summary
1	November 2015	Guidelines for the Management of Patients on Clozapine	Reviewed by the JH&FMHN Drugs and Therapeutics Committee (D&TC) for currency as part of the D&TC Annual Work Plan
2	August 2016	Guidelines for the Management of Patients on Clozapine	Reviewed by the JH&FMHN D&TC for currency as part of the D&TC Annual Work Plan
3	March 2017	Guidelines for the Management of Patients on Clozapine	Addition of Supplementary Protocol for Initiation of Clozapine in MRRC MHSU in accord with D&TC determination 18.01.2017 Addition of "Capillary Blood Collection" in accord with D&TC determination 22.02.2017
4	February 2018	Guidelines for the Management of Patients on Clozapine	Reviewed by the JH&FMHN D&TC for currency as part of the D&TC Annual Work Plan Addition of "Initial Target Dose" Revision of Appendices 10, 11 & 12
5	November 2018	Guidelines for the Management of Patients on Clozapine	Reviewed by the JH&FMHN D&TC for currency as part of the D&TC Annual Work Plan (including addition of 13.6 and 13.7, update of 5.1)
6	April 2021	Guidelines for the Management of Patients on Clozapine	Updated by the Network D&TC to include clozapine dispensation
7	October 2021	6.053 - Guidelines for the Management of Patients on Clozapine	Reviewed by the Network D&TC for currency as part of the D&TC Annual Work Plan
8	February 2023	6.053 - Guidelines for the Management of Patients on Clozapine	Clozapine initiation in custodial settings updated to LBH MHU, MRRC MHSU and SWCC MHSU only. Update reference of Monitoring Clozapine-induced Myocarditis to GL2022_011. Update myocarditis monitoring up to day 42. Update troponin/CRP monitoring to baseline, weekly from week 1 to 6 and then 6-monthly.
9	February 2024	6.053 - Guidelines for the Management of Patients on Clozapine	Addition of section 12.1 Management of Clozapine-Induced Hypersalivation to add in guidance for atropine use.
10	April 2025	6.053 - Guidelines for the Management of Patients on Clozapine	Reviewed by the D&TC for currency. • Updated monitoring to include point of care testing for glucose. • Consolidated monitoring information in relation to Clinical Specialty Protocols and pathology sets. • Reference to JHeHs eForms included and summarised required forms throughout clozapine treatment.

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CONTACT DETAILS OF CLOZAPINE CO-ORDINATOR

[redacted]

1. INTRODUCTION

The aims of this procedure manual are to ensure the correct management of patients with schizophrenia on Clozapine and to minimise the risk of patients prescribed Clozapine developing agranulocytosis or neutropenia or other serious adverse effects by adhering to strict haematological monitoring.

This procedure manual is an adjunct to the ClopineCentral™ Protocol for staff managing patients on Clozapine within Justice Health and Forensic Mental Health Network (Justice Health NSW). It is important to review this procedure manual, the ClopineCentral™ Protocol, Ministry of Health *Guideline GL2022_011_Clozapine-induced_Myocarditis* and the full product information for Clozapine before prescribing this medication.

Clozapine is an atypical antipsychotic agent indicated for the treatment of schizophrenia in patients intolerant of or unresponsive to greater than or equal to two other antipsychotics (treatment resistant schizophrenia). Clozapine can improve both positive and negative symptoms of schizophrenia while producing minimal extra pyramidal side effects.

A serious adverse drug reaction associated with Clozapine is neutropenia and agranulocytosis and for this reason, strict haematological monitoring is required.

A range of cardiac disorders have been associated with the use of clozapine, the most serious being myocarditis and cardiomyopathy. Clozapine is available in many brands (e.g. Clozaril®, Clopine®, Clozitor®). Clozapine can only be accessed through a monitoring system (e.g. Clozaril Patient Monitoring System (CPMS) for Clozaril®, ClopineCentral™ for Clopine®, Juno Connected for Clozitor®. Clopine® is the brand of Clozapine used in Justice Health NSW.

Prior to any involvement with Clozapine all stakeholders must be registered with ClopineCentral™, those being patients, medical personnel, dispensing pharmacists and centre co-ordinator.

Figure 1 summarises the required forms and tests required for a patient on clozapine.

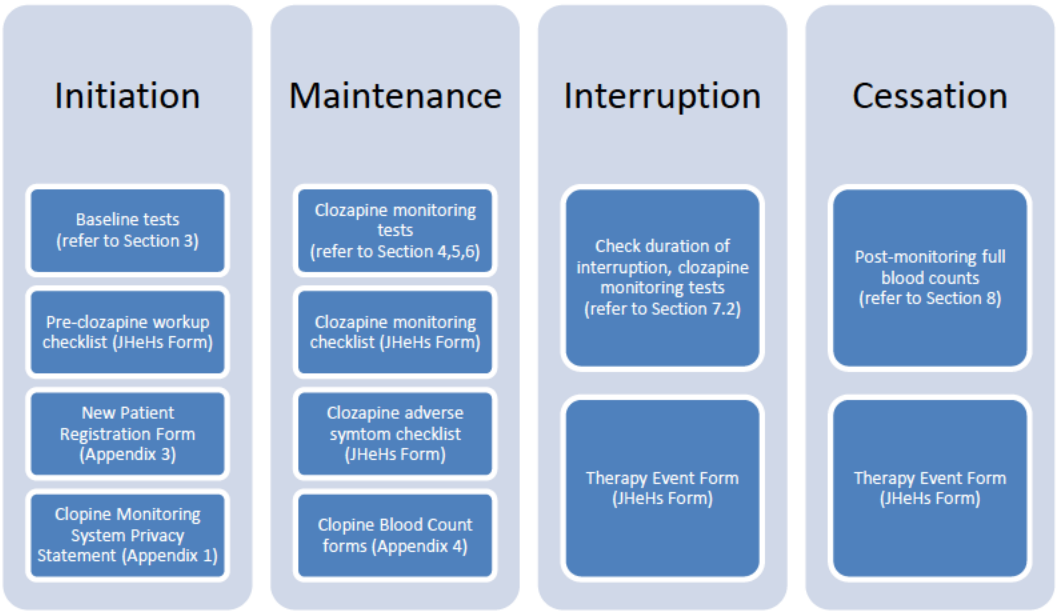

Figure 1: Summary of forms and tests to complete during clozapine therapy

1.1 Clopine® Privacy Statement

In line with the changes to the *Privacy Act 1988 (Cth)*, Pfizer the specialty pharmaceutical and medication delivery company that supports ClopineCentral™ protocol has updated their patient privacy policy for the Clopine Monitoring System (Appendix 1) [1].The patient Notification Form has been replaced by the Clopine Monitoring System Privacy Statement. This provides important information and privacy notification to patients and to ensure that they are aware that de-identified data from the ClopineCentral™ database may be used as part of a cross-check with existing databases to ensure non-rechallenge if they are or have been terminated for haematological reasons and may also be used for research which may subsequently be published.

All new Clopine patients, including transfers from other brands of clozapine, are required to acknowledge an understanding of the Clopine Monitoring System Privacy Statement by signing their consent. For patient confidentiality the signed copy is to be kept in the patient records, it should also be captured in ClopineCentral™ database [1]. Confirmation must also be provided to the Pharmacy Department that the patient has been advised of the Privacy Statement. If the patient is involuntary or under age, medical officers should follow the treating institution's policy and the consent requirements of the Mental Health Act 2007 (NSW) to treat the patient with Clozapine (2) and advise the Clinical Director Forensic Hospital / Clinical Director Custodial Mental Health.

2. REGISTRATION

This requires that all stakeholders - medical personnel, patients, dispensing pharmacists and centre co-ordinator - are registered with ClopineCentral™ prior to any involvement with clozapine. Forms are available in this procedure manual (See appendices 2 and 3).

2.1 The Role of the Clozapine Co-ordinator

The Clozapine Co-ordinator acts to facilitate the smooth running of the Clopine Centre and to ensure it complies with the Clopine Protocol [1].

The role of the Clozapine Co-ordinator is to:

- Ensure the necessary blood tests are performed, reviewed and acted upon accordingly.
- Communicate all registrations, patient information, and blood results from Justice Health NSW to ClopineCentral™.
- Channel all correspondence to ClopineCentral™, so that the Co-ordinator is aware of all outgoing correspondence from Justice Health NSW.
- Ensure that Justice Health NSW complies with the ClopineCentral™ Protocol.
- Distribute all necessary communication with respect to patient monitoring to registered centre staff (e.g. medical officer, pharmacist) as appropriate
- Approve all other personnel registrations.
- Enter all blood test results onto the ClopineCentral™ database.
- Ensure all Justice Health NSW staff are familiar with the "Management of Patients on Clozapine" procedure manual through regular education sessions.

If a medical officer, pharmacist or patient relocates, the Co-ordinator should communicate this information to ClopineCentral™. If the Clozapine Co-ordinator resigns, the centre should nominate

another registered person to take on the responsibility of the Centre Co-ordinator until a new Co-ordinator is registered [(1)].

Only the centre Co-ordinator may notify ClopineCentral™ of personnel no longer active at Justice Health NSW. The Clozapine Co-ordinator is based in the Pharmacy Department at Malabar.

2.2 The Role of the Medical Officer

Only ClopineCentral™ registered medical officers may prescribe Clozapine to patients who are registered with ClopineCentral™ [(1)].

Before prescribing Clozapine, medical officers must review the approved Product information. It is the medical officer's responsibility to ensure that Clozapine is prescribed in accordance with the approved product information and to ensure that each patient for whom he/she prescribes Clozapine is monitored in accordance with the requirements of this procedure manual and the ClopineCentral™ protocol [(1)].

The prescription of Clozapine must not occur until a satisfactory White Blood Count (WBC) and Neutrophil Count (NC) has been reviewed and signed off by the ClopineCentral™ registered Medical Officer and complies with the acceptable WBC and NC ranges and the patient has been registered with ClopineCentral™.

In the first 18 weeks of treatment each prescription for Clozapine must be for no more than 7 days' supply. After the first 18 weeks treatment, up to four weeks (28 days) supply may be prescribed.

The medical officer must ensure that each prescription for Clozapine and blood count results is forwarded by the medical officer to the Clozapine Co-ordinator for review before Clozapine can be dispensed.

2.3 Patient Registration Procedure

For all new Clozapine (Clopine®) patients including transfers from other brands of Clozapine, the medical officer must discuss with the patient the risks and benefits of treatment with Clozapine and the mandatory blood testing requirements. All patients should have the Clopine Monitoring System Privacy Statement explained to them and those who have capacity to consent should be asked to acknowledge an understanding of the statement by signing their consent. To ensure patient confidentiality, the signed copy must be kept in the patient's records and is not required to be sent to ClopineCentral™. The Clozapine Coordinator will record confirmation of patients' consent to the privacy statement within ClopineCentral™.

A patient registration form (appendix 3) and a clozapine work up checklist (JHeHS eForm) must be completed and a baseline white blood cell and neutrophil count obtained for that patient. The blood sample must be collected and results obtained no more than 10 days prior to commencing Clozapine. The results must be entered on the registration form. These forms must be sent to the Clozapine Co-ordinator who will in turn enter them onto the ClopineCentral™ database.

ClopineCentral™ staff will then cross check the patient's details against other Clozapine databases and will check its own database to determine if the patient has previously discontinued Clozapine due to neutropenia or agranulocytosis [(1)].

If the patient has a history of clozapine induced neutropenia or agranulocytosis (in red range), the patient is ineligible for treatment with Clozapine because of the high risk of recurrence if he or she is rechallenged with Clozapine. The only exception to this rule is where the ClopineCentral™ haematologist has been consulted and has given approval for a specific patient to recommence Clozapine [(1)].

The medical officer must also determine any reasons that may make the patient unsuitable for treatment with Clozapine.

In Justice Health NSW, to ensure that the patient's physical status can be monitored and any adverse effects associated with Clozapine can be detected and treated immediately, Clozapine therapy may only be initiated in the Long Bay Hospital Mental Health Unit (LBH MHU), Forensic Hospital, MRRC Mental Health Screening Unit (MRRC MHSU) and Silverwater Women's Correctional Centre Mental Health Screening Unit (SWCC MHSU).

After initiation of Clozapine, the patient should remain in the MRRC MHSU/SWCC MHSU/LBH MHU/Forensic Hospital for the first eighteen weeks or longer if clinically indicated unless deemed clinically safe to transfer care. It would also be a recommendation to initiate Clozapine therapy in patients whose movements between correctional centres will be kept to a minimum especially in the initial titration phase of Clozapine.

Please refer to appendices 6 and 7 for clinical and operational management of patients on clozapine in MRRC MHSU and SWCC MHSU.

2.4 Intramuscular Clozapine

Intramuscular (IM) clozapine is not listed under the Therapeutics Goods Administration (TGA) Australian Register of Therapeutic Goods (ARTG) formulary. It is a treatment of last resort for patients who qualify for IM clozapine under specific parameters. Refer to the Intramuscular (IM) Clozapine Procedure.

3. CLOZAPINE INITIATION

3.1. Pre Clozapine work up Checklist (JHeHS eForm)

1. Check the patient's history for any previous episodes of bone marrow disorder, neutropenia or previous complications of Clozapine therapy. Also check for any history of past cardiac events, any family history of diabetes and record any risk factors for diabetes.

2. Complete a physical examination and order BGL (fasting, point of care testing), LFTs, lipids, troponin assay I or T, C - reactive protein (CRP), blood group, ECG and echocardiogram (ECHO) (completed within 3 months prior to commencement of treatment). Commence weight chart.

   If an excessive delay in completing an echocardiogram is expected and treatment with clozapine is required urgently then only the Clinical Director of Forensic Hospital or the Clinical Director Custodial Mental Health or their delegate may give approval for the patient to commence Clozapine prior to having the echocardiogram. This test must still be completed at the earliest opportunity.

3. Cease any contra-indicated medications prior to commencement of Clozapine. Long acting depot antipsychotics should be ceased.

4. Send the completed patient registration form to the Clozapine Co-ordinator, the Clopine Monitoring Patient Privacy Statement and a copy of an ECHO within 3 months. The pre-clozapine work up checklist is to be completed via the JHeHS eForm.

5. Registration of the patient includes allocation of a Clozapine Patient Number (CPN). This patient identification number MUST be used or all further correspondence with the Clozapine co-ordinator and ClopineCentral™

3.2 Initiation of Clozapine Therapy

Once registration of the patient is complete, Clozapine therapy can be initiated. The dosage must be adjusted individually. For each patient the lowest effective dose should be used. Appropriate resuscitative facilities should be available and the patient adequately supervised during initiation of therapy.

3.3 Recommended Dose Titration of Clozapine

The starting dose of Clozapine is 12.5mg (half a 25mg tablet) once or twice daily on the first day, followed by 25-50mg on the second day. (Refer to Appendix for MRRC MHSU and Silverwater Women's MHSU for local protocols on dosing). If well tolerated the dose may be slowly increased by increments of 25 to 50mg up to a daily dose of 300mg within 2 to 3 weeks [3]. Thereafter if required, the daily dose may be increased by increments of 50 to 100mg at half-weekly or, preferably, weekly intervals. Rapid dose escalation is thought to be associated with an increased risk and severity of adverse effects and should be avoided.
A Clozapine titration guide is also available.

3.4 Initial Target Dose

The purpose of suggesting an initial target dose is to take into account a patient's smoking history, weight, sex and age to avoid an unacceptable risk of toxicity whilst still achieving a serum level above the 0.35mg/L suggested.

To calculate an initial target dose first select one of the 4 doses below based on sex and smoking history:

425mg/day in male smokers

250mg/day in male non-smokers

325mg/day in female smokers

225mg/day in female non-smokers

Subsequently adjust the above dose depending on the patient's weight because for every 10kg over 80kg the expected concentration is reduced by 5%.

Weight	Male Smoker	Female Smoker	Male Non-Smoker	Female Non-Smoker
60kg	-50	-25	-50	-25
80kg	Reference	Reference	Reference	Reference
100kg	+75	+50	+50	+0

Further adjust the dose depending on the patient's age because for every 5 years over the age of 40 the expected concentration is reduced by 5%.

Age	Male Smoker	Female Smoker	Male Non-Smoker	Female Non-Smoker
20	+100	+100	+50	+25
40	Reference	Reference	Reference	Reference
50	-50	-25	-25	-25

The suggested initial dose thresholds will therefore vary from under 200mg to 600mg depending a patient's age, smoking history, sex and weight. [4]

3.5 Maximum Dose

The maximum licensed dose of clozapine is 900mg [5] [6] [7]. For most patients the dose of 600mg a day is sufficient. However, a few patients may require larger doses to obtain the maximum therapeutic benefit in which case increments of not more than 100mg are permissible up to a maximum dose of 900mg/day.

Doses above the maximum recommended in product information must be acknowledged by underlining and initialling and also annotating in the patients' medical record.

3.6 Maintenance Dose

After achieving optimum therapeutic benefit, many patients can be maintained effectively on lower doses.

Careful downward titration is recommended. With daily doses not exceeding 300mg, a single administration in the evening may be appropriate. Larger doses may need to be divided to minimise adverse effects [6] [5].

3.7 Observations – Nursing Staff

Baseline observations of temperature, pulse, blood pressure and heart rate must be recorded before patient is started on Clozapine on the adult general observation chart (SAGO chart).
Also refer to Ministry of Health Guideline GL2022_011 Clozapine-induced Myocarditis

During the initial stage of therapy, the patient must be closely supervised and the following vital signs (temperature, pulse, respiratory rate, blood pressure and heart rate) monitored as follows:

- Hourly for the first six hours after the first dose of Clozapine
- Then, twice daily for two weeks
- Then, daily thereafter (for 18 weeks or more often as clinically indicated)
- Then weekly thereafter (or more often as clinically indicated)
- Direct enquiry regarding symptoms must also occur

In patients being started on Clozapine the first dose should be administered no later than 12 noon so that the necessary observations can be carried out.

The patient should also be observed for side effects of Clozapine and any adverse effects to be documented on the Clozapine adverse symptoms checklist, (JHeHS eForm) and in the patient's notes. Clozapine can affect the entire gastrointestinal system and may cause bowel obstruction, ischemia, perforation and aspiration. The prescription of Clozapine should be accompanied by regular physical monitoring, appropriate and timely use of laxatives and early referral of constipated patients, before life threatening pathologic processes develop.

If the patient is accommodated in LBH MHU, MRRC MHSU or SWCC MHSU the Nursing Unit Managers (NUMs) at LBH, MRRC and SWCC must be informed that there is a patient commencing on Clozapine so that the patient can be discussed at clinical handover and all nurses are aware of the patient.

4. CARDIAC SAFETY AND MONITORING

It is recommended that patients who are to start on Clozapine therapy undergo a baseline ECG and determination of baseline markers of myocardial damage troponin I or T and C-reactive protein (CRP), ECG and an ECHO.

In addition, medical officers and nursing staff should be alert for any symptoms of heart failure in patients on Clozapine such as tachypnoea, low or falling blood pressure, increased jugular venous pressure possibly associated with arrhythmias, fever or chest pain.

On days 7, 14, 21 and 28 of treatment the ECG and troponin I or T assay and CRP should be repeated weekly for the first 4 weeks of treatment.

Prior to initiation of therapy and at 6 months of treatment patients must undergo an echocardiogram to check for the development of chronic adverse cardiac events. Thereafter, if clinically indicated. (11) (12)

4.1 Further Investigations inclusive of cardiac monitoring

Clozapine monitoring checklist is available in the JHeHS eForm.
This form is to be completed by the treating medical officer/psychiatrist following each test

Table 1: Summary of required monitoring during clozapine treatment

Period	Category	Test
Baseline	Cardiac	- Troponin I or T - CRP - ECG - ECHO
	Haematological	- Blood group (order via form) - FBC
	Metabolic	- Plasma glucose (fasting) - Lipids - LFTs - EUC
Week 1-18	Haematological	- FBC (testing schedule prone to change depending on results)
Week 1 **Week 2** **Week 3** **Week 4**	Cardiac	- Troponin I or T - CRP - ECG
	Metabolic	- BGL point of care (fasting) - Weight - BMI - Waist Circumference
Week 5	Cardiac	- Troponin I or T - CRP
	Metabolic	- BGL point of care (fasting)
Week 6	Cardiac	- Troponin I or T - CRP
	Metabolic	- BGL point of care (fasting) - Lipids - LFTs

3 months	Metabolic	- BGL point of care (fasting) - Lipids - Weight - BMI - Waist Circumference
Week 18	Cardiac	- Troponin I or T - CRP
	Metabolic	- BGL point of care (fasting)
Every 28 days	Haematological	- FBC (testing schedule prone to change depending on results)
6 months	Cardiac	- Troponin I or T - CRP - Echocardiogram - ECG
	Metabolic	- BGL (fasting, point of care testing) - Lipids - HbA1c - LFTs - Weight - BMI - Waist Circumference
9 months	Metabolic	- BGL (fasting, point of care testing) - Lipids
12 months	Cardiac	- Troponin I or T - CRP
	Metabolic	- BGL (fasting, point of care testing) - Lipids - EUC
Thereafter	All	Every 3 months - BGL point of care (fasting) - Lipids - LFTs - Height - Weight - BMI - Waist Circumference Every 6 months - Troponin I or T - CRP - Urea and electrolytes Every 12 months - ECG unless clinically indicated - ECHO if clinically indicated

Refer to Clinical Specialty Protocol for pathology order sets

- FMH – Clozapine Monitoring
- FMH – Clozapine Haematological Monitoring
- FMH – Metabolic Monitoring

5. MYOCARDITIS MONITORING DURING THERAPY WITH CLOZAPINE

Ministry of Health Guideline GL2022_011 Clozapine-induced Myocarditis

5.1 Typical Clinical Course of Myocarditis

- Myocarditis is an inflammation of the heart muscle that may lead to cardiomyopathy. It can be life threatening if not detected and treated early. Myocarditis is most commonly observed early in treatment. However, in rare occasions myocarditis can develop spontaneously throughout treatment.
- The first indications of the onset of myocarditis are non-specific symptoms of illness such as fever with features commonly associated with influenza, including shortness of breath and fatigue but symptoms may include chest pain, severe diarrhoea, vomiting or dysuria (painful or difficult urination). However, in some cases myocarditis may develop without symptoms.
- C reactive protein (CRP) usually begins to increase around this time. CRP is produced by the liver and can be detected by blood tests. CRP level rises when there is inflammation throughout the body (range: <5mg/L).
- High sensitivity cardiac troponin typically increases with a delay of as much as five days after both the onset of symptoms and commencement in the rise of CRP or high sensitivity C-reactive protein (hs-CRP)
- A sudden drop in systolic blood pressure may occur around this time and the patient may report chest pain.
- The first appearance of non-specific electrocardiogram (ECG) changes also occurs at this point (Point 3, Figure 2).
- An ECHO may show impairment of left ventricular function (Point 3, Figure 2)
- Heart rate typically increases a few days following initiation of clozapine in all patients including those not developing myocarditis

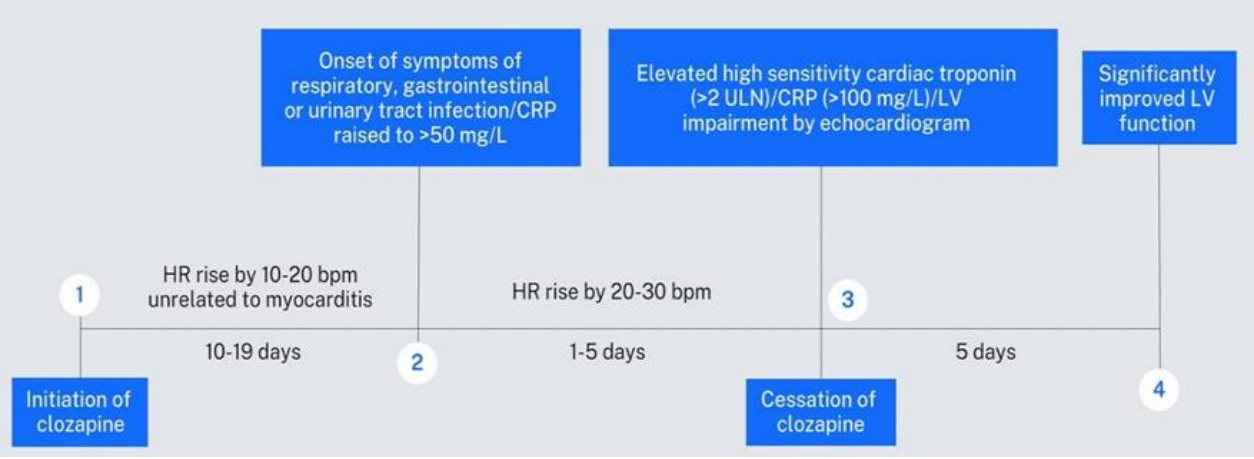

Figure 2: The typical evolution of clozapine-induced myocarditis (Ronaldson, KJ, et al)

5.2 Monitoring Protocol

- Most cases of myocarditis occur within the first six weeks of treatment and routine monitoring for myocarditis up to day forty-two is recommended. Patients with pre-existing cardiac and metabolic risks treated with clozapine will require close monitoring.
- Consumers with mild signs and symptoms of unidentified illness will require closer monitoring while continuing with clozapine treatment. The only known potential risk factors for myocarditis are rapid titration and possible concomitant use of Valproate.
- The monitoring protocol recommends obtaining baseline troponin I or T, CRP, ECG and ECHO. Refer to section 4.1 for complete information regarding further investigations.
- During the first four weeks, vital signs and direct enquiry regarding symptoms must be assessed. Refer to section 3.7 for observations and frequency of observations.
- In the presence of relevant symptoms, an abnormally increased heart rate or raised CRP (50-100mg/L), measure high sensitivity troponin and CRP daily as well as performing daily ECG and the patient monitored for developing illness.
- If high sensitivity cardiac troponin levels are only slightly raised (less than twice the upper limit of normal) and CRP remains less than 100mg/L, clozapine may be continued.
- Discontinuation of clozapine and investigation by echocardiography is advised if either high sensitivity cardiac troponin is in excess of twice the normal maximum or CRP is more than 100mg/L.
- Routine monitoring for myocarditis up to day 42 is recommended. Refer to section 4.1 for complete information regarding investigation schedule.
- Refer consumers early to cardiologist services for cardiology assessment if there are clinical and/or biomarker blood test concerns regarding clozapine-induced myocarditis.

5.2.1 Heart rate

- Clozapine frequently causes benign tachycardia.
- Monitoring heart rate from baseline during first 4 weeks will mean that trends and tendencies for the individual patient can be identified and an abnormal increase associated with the onset of myocarditis is more likely to be correctly interpreted. Refer to section 3.7 for observations and frequency of observations. [13]

5.2.2 C-Reactive Protein (CRP) in Early Diagnosis

- Measuring CRP or hs-CRP along with high sensitivity cardiac troponin is part of the routine monitoring for myocarditis.
- CRP is generally a non-specific marker of inflammation; however, elevated CRP is an early diagnostic indicator of the presence of myocarditis where other cardiac biomarkers are elevated. A source of underlying infection (e.g., urinary tract infection, chest infection) or systemic sepsis must be excluded based on clinical symptoms.
- A CRP of more than 50mg/L may predict the onset of myocarditis.

5.2.3 ECG and Echocardiography (ECHO)

- ECG may be used to monitor heart rate and clinicians may find diagnostic benefit in monitoring evolving ECG changes. In order to use ECHO as a diagnostic tool in suspected myocarditis, a baseline ECHO prior to clozapine treatment is recommended to exclude pre-existing dysfunction.
- Refer to Appendix 5: Review Procedures for ECG for Patients on Clozapine in Justice Health NSW [13]

5.2.4 Eosinophilia

- Elevation of eosinophil count is typically delayed in the course of myocarditis and must not be used to screen for myocarditis after the initiation of clozapine. [13]

5.2.5 High Sensitivity Cardiac Troponin

- High sensitivity cardiac troponin is a sensitive and specific marker of myocyte damage and is raised in conditions such as myocardial infarction and myocarditis, pulmonary embolism and other medical conditions. Elevated high sensitivity cardiac troponin must prompt early review with a cardiology service.

5.2.6 Fever

- Fever above 38 degrees Celsius may be an early indicator of myocarditis. However, this can also indicate the presence of other serious adverse reactions such as Neuroleptic Malignant Syndrome, secondary infection due to agranulocytosis or aspiration pneumonia from sialorrhea. Clinicians may wish to use forehead sensing thermometers as an alternative to oral or auxiliary thermometers to measure temperature.

5.2.7 Cardiac Magnetic Resonance Imaging

- A cardiac magnetic resonance imaging (MRI) is a non-invasive scan that uses a magnetic field and radio waves to take detailed pictures of the heart and tissues. It is the gold standard non-invasive test to diagnose myocarditis. In consumers suspected of clozapine-induced myocarditis, early consultation to a cardiology team will determine ongoing cardiac needs, including if a cardiac MRI is indicated

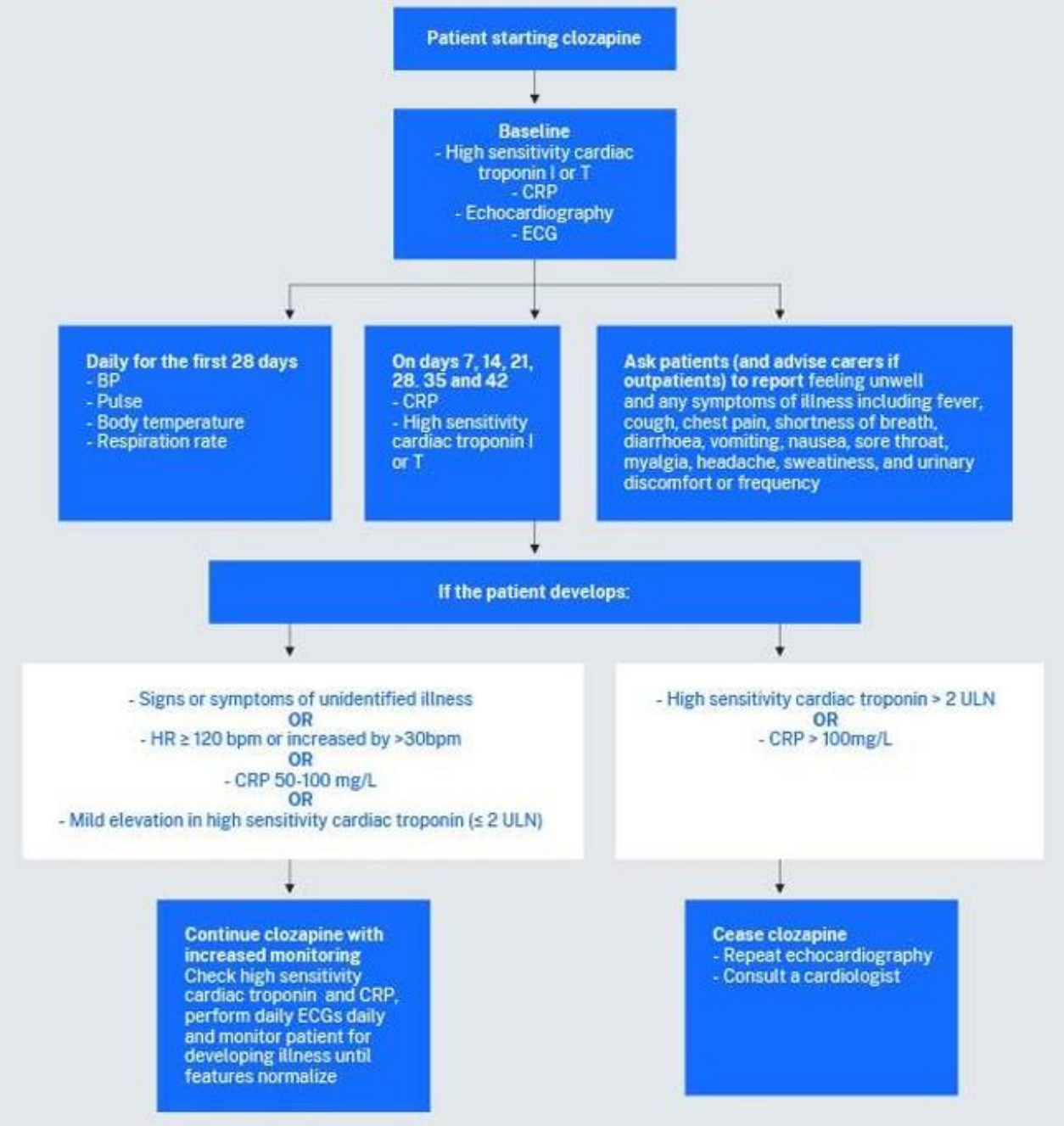

Figure 3: Proposed protocol for monitoring patients commenced on clozapine for clozapine-induced myocarditis (Ronaldson, KJ, et al)

5.3 Continuation of Clozapine with Mild Disease

- Given the potential success of clozapine, every opportunity for continuation of clozapine should be taken provided it can occur safely.
- If deciding to continue clozapine treatment, it is important to ensure that cardiac function is not at risk. This can be further assessed by checking high sensitivity cardiac troponin, and/or echo and/or cardiac magnetic resonance imaging (MRI). A cardiologist is to be consulted. This consult will determine whether an echo is an appropriate alternative where a cardiac MRI is not available. Slow titration of clozapine dose is advised, in consultation with the treating team.

5.4 Managing Myocarditis

- Once clozapine-induced myocarditis has been suspected or diagnosed, clozapine treatment must cease.
- There is evidence that the early cessation of clozapine treatment with the onset of myocarditis improves clinical outcomes.
- Where myocarditis is suspected, investigation for clozapine-induced impairment should be conducted promptly following the withdrawal of clozapine. A cardiologist should be consulted about the need for referral.
- If no significant impairment of cardiac function is measured, no specific therapy apart from cessation of clozapine is required.
- However, where the echocardiography reveals moderate or severe left ventricular impairment a cardiology consult should be sought to further assess the need for drug or mechanical intervention. [13]

6. HAEMATOLOGICAL MONITORING DURING THERAPY WITH CLOZAPINE

6.1 Mandatory Haematological Monitoring

- **Weekly** blood tests for the first 18 weeks
- **Monthly (4-weekly)** blood tests thereafter

The following must be completed within a 48 hour period.

1. Blood tests must be completed on Mondays and sent to pathology laboratory (it is very important that all pathology paperwork for Clozapine is completed and ready for blood taking on Mondays and that a certified blood taker is rostered on duty).

2. Psychiatrist/Medical Officer reviews patient for clinical signs of neutropenia (e.g. fever, upper respiratory tract infection, mouth ulcers). Documentation of same in progress notes.

3. Obtain blood test result from pathology laboratory.

4. Assessment of results

Table 2: Clozapine haematological monitoring ranges

"Green range"	WBC > 3.5 x 10^9/L AND neutrophils > 2.0 x 10^9/L Continue weekly/monthly (4-weekly) FBCs.
"Amber range"	WBC 3.0 – 3.5 x 10^9/L and/or neutrophils 1.5 – 2.0 x 10^9/L. Perform twice weekly. FBCs until results are in "Green range".
"Red range"	WBC < 3.0 x 10^9/L and/or neutrophils < 1.5 x 10^9/L. Stop Clozapine immediately. Perform daily FBCs until patient has a 'green' blood test result. Contact ClopineCentral ™ immediately on 1800 656 403 and Clozapine Co-ordinator on 02 9700 3888.

5. The blood results are reviewed by a ClopineCentral™ registered Psychiatrist/Medical Officer and medication order/prescription is written.

6. The blood count form must be completed in full by a ClopineCentral™ registered psychiatrist/medical officer and emailed to the Clozapine Co-ordinator email.

7. Clozapine medication is dispensed by the Centre Co-ordinator pharmacist after review of blood results.

8. Centre Co-ordinator enters all blood results onto the ClopineCentral™ database.

Any change to the patient's monitoring range will show up on the ClopineCentral™ patient profile as an "ACTIVE OVERRIDE" [1] [8].

6.2 Situations Requiring Increased Frequency of Blood Testing

If a patient on Clozapine therapy develops symptoms of infection and/or of neutropenia (for example flu-like symptoms, mouth ulcers, sore throat or fever) the Medical Officer/Psychiatrist should obtain an immediate differential blood count in addition to performing a clinical assessment of the patient. If both are normal, clozapine therapy should continue in conjunction with twice-weekly (i.e. within four days of each other) white blood cell count and neutrophil counts and clinical review until the symptoms resolve.

At each consultation the patient should be reminded to advise medical staff immediately if any kind of infection, sore throat or flu-like symptoms develop so that the treating Medical Officer/Psychiatrist can review this patient immediately.

Any change to the patient's monitoring frequency will show up on ClopineCentral™ patient profile as an "Active Override" or revised "week 18 date".

6.3 Eosinophilia

Unexplained eosinophilia may occur, especially in the initial weeks of treatment with Clozapine. Discontinuation of therapy is recommended if the eosinophil count rises above 3.0 x 10^9/L. Therapy should restart only after the eosinophil count has fallen below 1.0 x 10^9/L.

6.4 Authority to Perform Venepuncture on an Unco-operative Patient

If the patient receiving clozapine, or having recently discontinued clozapine, is a patient detained within the Forensic Hospital or the Long Bay Hospital Mental Health Unit (under the *Mental Health Act 2007* or the *Mental Health and Cognitive Impairment Forensic Provisions Act 2020)*:

- Venepuncture may proceed without the patient's consent, according to section 84 of the Mental Health Act, as haematological monitoring is a necessary condition of the prescribing and administration of clozapine, for the safety of the patient [(2).]
- The persistent refusal of a patient to accede to venepuncture must be communicated promptly to the treating consultant psychiatrist, to consider the implications for the patient's ongoing management.

If the patient receiving clozapine is detained elsewhere in custody, other than within a declared mental health facility, then that patient may refuse to consent to a venepuncture procedure. In such a case, the Clozapine must be discontinued, unless the patient is subsequently transferred to a declared mental health facility. (Refer to section 11)

6.5 Capillary Blood Collection

Capillary blood collection may only be performed for patients who have difficult venous access with approval from the relevant Clinical Director or Deputy Clinical Director and dependent on the pathology provider.

Guided phlebotomy can also assist with the poor venous access.

6.6 Clozapine Dispensation

Dispensation requests the extension of a blood test and medication supply. Dispensations can occur in events such as:

- Public holidays
- Missed full blood count (e.g. due to difficulty obtaining access, patient refusal, human error)
- Issues with blood sample (e.g. lost sample, clotted blood)
- Assistance in the transfer of patients to another community mental health team

In the event that a dispensation is to be requested the below is to be considered.

Clozapine patients with a green history of blood tests:
Approval for dispensation is made by the relevant Clinical Director or their delegate and documented in the patient's progress notes.
The clozapine coordinator is to document in ClopineCENTRAL™ the patient as 'non-compliant' as an adverse event.
Dispensation maximum approvals:

- Weekly Patients: Maximum 2 days dispensation
- Monthly Patients: Maximum 14 days dispensation

Clozapine patients with an amber history of blood tests:
Approval for dispensation is made by the relevant Clinical Director or their delegate and documented in the patient's progress notes.
The clozapine coordinator is to document in ClopineCENTRAL™ the patient as 'non-compliant' as an adverse event.

7. TROUBLESHOOTING

If there is a change to the Clozapine dose, it should be notified to the Justice Health NSW Clozapine Co-ordinator immediately to ensure adequate supply for the patient up to the next due blood test and to ensure tablets are not cut in half for smaller doses.

It is imperative that a Psychiatrist/Medical Officer reviews all WBC and neutrophil counts and clinically assesses the patient (in the first 18 weeks of treatment) before writing the next Clozapine prescription.

1. On Wednesdays/Thursdays the Clozapine Co-ordinator will email all health centres/wards (who have patients on Clozapine) a list of blood tests that are due the following week. This will enable all pathology paperwork to be organised in advance of due bloods and to ensure staff who are accredited in venepuncture are working on the day of blood tests.

2. Clozapine medication does not have to be withheld for blood tests, only when a Clozapine plasma level has been ordered. Clozapine dosage should primarily be guided by clinical response and any adverse effects noted. The measurement of Clozapine plasma levels may be useful in the following situations:

    I. Patients showing a poor response to therapy
    II. For the assessment of compliance in patients refractory to therapy
    III. To identify interactions between Clozapine and other medications, which may result in changes in Clozapine plasma levels and possible toxicity

    The claimed therapeutic range for Clozapine is approximately 400-1000mcg/L. Levels above 1000mcg/L are more likely to be associated with seizures.

    A trough level should be obtained for clozapine level monitoring. Blood samples should be taken immediately before the next dose of clozapine is to be administered. Note: there is a poor relationship between efficacy and serum levels. Plasma levels do seem to predict ECG changes and seizure are more frequent with levels above 1000 micrograms/L. [7]

    Steady state levels are reached after 2-3 days [7]

    There is roughly a linear dose/plasma level relationship [14].

    The development of neutropenia and agranulocytosis is independent of dosage or plasma level.

3. From time to time it may be necessary to reschedule blood tests for patients on Clozapine due to public holidays etc.; the Clozapine Co-ordinator will inform the relevant health centres/wards in advance of such changes as needed.

4. When blood tests are completed on patients on Clozapine these must be sent as soon as possible to pathology lab for testing, as if the blood is left longer than 6 hours erroneous results are possible.

7.1 What happens if a blood count is not received within 48 hours after the blood due date?

The Pharmacy Department cannot supply any Clozapine unless the necessary blood test has been completed and the results sent to the Pharmacy Department within the 48-hour period. Contact the Clozapine Co-ordinator on (02) 9700 3888 if there will be any delay to the above process.

7.2 Interruption of Clozapine Therapy: Haematological Monitoring and Dosage Recommendations after

The medical officer/psychiatrist must complete the Therapy Event Form (JHeHS eForm) and notify the Clozapine Co-ordinator.

Period of Interruption (time since last dose was due)	Dosage / Monitoring Requirements
<48 hours	No change to dosage or monitoring
>48 hours and ≤72 hours	Start on 12.5mg once or twice daily on first day and then titrate up if dose tolerated. Continue monitoring as normal
≥72 hours and ≤28 days	Start on 12.5mg forensic once or twice daily on first day and then titrate up if dose tolerated For monthly patients: Weekly monitoring for 6 weeks. If no abnormality, resume monthly monitoring For weekly patients: Weekly monitoring for 6 weeks or as long as needed to reach 18 weeks (whichever is the greatest).
>28 days	Recommence monitoring (18 weeks) in accord with new patient. Start on 12.5mg and titrate up.

Any change to the patient's monitoring frequency will show up on the ClopineCentral™ patient profile as an "Active Override" or revised "week 18" date.

7.3 Re-Registration of a Patient

If a patient has been discontinued clozapine therapy for 3 months or more, the patient must be re-registered with ClopineCentral™ by submitting a new Patient Registration Form (Appendix 3) to the Clozapine Co-ordinator.

Clozapine must not be recommenced in a patient who has previously developed blood dyscrasias related to clozapine therapy unless discussed with the Clopine Haematologist. [1]

8. DISCONTINUING THERAPY WITH CLOZAPINE

If Clozapine therapy needs to be stopped, reducing the dose gradually over one to two weeks is recommended where possible.

If abrupt discontinuation is necessary, the patient should be carefully observed for rebound exacerbation of their psychotic symptoms. The patient should also be carefully observed for symptoms related to cholinergic rebound such as headache, nausea, vomiting and diarrhoea.

The medical officer/psychiatrist must also complete the Therapy Event Form (JHeHS eForm) and notify the Clozapine Co-ordinator.
The Clozapine Co-ordinator must inform ClopineCentral™ of each patient discontinuation within 24 hours.

8.1. Post – Monitoring for Weekly Patients

For patients on weekly blood test monitoring a WBC and neutrophil count should be performed at the time of discontinuation and then at least weekly for 4 weeks after discontinuing due to non-haematological reasons (four consecutive weeks of 'green' FBC results are required until the patient can be inactivated from ClopineCentral™).

8.2. Post – Monitoring for Monthly Patients

For patients on monthly blood test monitoring one further blood count should be performed one month (28 days) after discontinuation due to non-haematological reasons. Note that the patient should have a blood test performed close to the time of discontinuation and then four weeks later. If a patient was to discontinue close to the time of their next blood test and no test was done until 4 weeks later; it would be nearly 8 weeks between blood tests, which would be too long.

8.3. For Patients on more Frequent Monitoring

Patients who are on increased monitoring due to symptoms of infection and/or an "amber result" (WBC 3.0 - 3.5 x 10^9/L and/or NC 1.5 - 2.0 x 10^9/L) at the time of cessation are required to be tested at least twice weekly until the WBC >3.5 x 10^9/L, neutrophil count is > 2.0 x 10^9/L and/or symptoms of infection have resolved. Once back in the "green range", their post-monitoring blood test frequency should reflect their pre-amber protocol (refer to 11.1 and 11.2).

Patients who have been discontinued due to a RED (WBC < 3.0 x 10^9/L and/or neutrophils < 1.5 x 10^9/L) result must continue to have daily blood count monitoring until WBC >3.5 x 10^9/L, neutrophil count is > 2.0 x 10^9/L (green range). Once back in the "green range", perform WBC and neutrophil count weekly for 4 weeks for weekly patients and a monthly patient must have a blood test 28 days after that green result.

9. REPORTING ADVERSE EVENTS

Any person who becomes aware of any adverse event whether expected or unexpected that occurs while a person is treated with Clozapine should report that event immediately no later than three working days after the event to ClopineCentral™ on 1800 656 403 and the Clozapine Co-ordinator on 9700 3888.

The Psychiatrist/Medical Officer is also expected to report the adverse event to Adverse Drug Reactions Advisory Committee (ADRAC).

ADRAC reporting cards can be accessed through the TGA (Report of suspected adverse reaction to medicines or vaccines) https://www.tga.gov.au/sites/default/files/blue-card-adverse-reaction-reporting-form.pdf or by contacting the Clozapine Co-ordinator.[15]

An IMS+ detailing the adverse event must also be completed. The adverse event must also be noted in the patient's health and medication record.

9.1. Management of Clozapine-Induced Hypersalivation

Atropine
Atropine 1% eye drops is restricted to the Forensic Hospital for the use in the management of clozapine-induced hypersalivation or on advice by a Custodial Mental Health prescriber in the custodial setting.

The following risk mitigation strategies apply to minimise the risk of inappropriate use:

- Administration: must be prepared and administered by a registered nurse whilst an inpatient or in custody. It is not for self-administration.
- Dose:
  - 1-2 drops buccally daily to twice daily as required
  - 1-5 drops diluted in 5-10mL of water used as a mouthwash daily as required – do not swallow
- Supply:
  - Medication is not to be supplied on discharge or release unless a prescriber has reviewed and documented appropriateness for self-administration and supplied and labelled by the Pharmacy Department
  - Forensic Hospital: medication to be available on imprest
  - Custodial Settings: to be supplied from the Pharmacy Department with labelled directions including "not to be supplied on release"
- Education: Prescribers and nursing staff are to provide education/advise to patients to monitor for systemic side effects (e.g. constipation, blurred vision, urinary retention)

10. PROCEDURES FOR PATIENTS ADMITTED TO CORRECTIONAL CENTRES/YOUTH JUSTICE CENTRE ON CLOZAPINE

10.1. Patient on Clozapine admitted to Correctional Centre/Youth Justice Centre (out of hours)

When a patient arrives to a reception centre and on questioning is found to be on Clozapine, standard referral to Mental Health should take place. The necessary physical observations should be completed on the patient (e.g. BP, pulse, temperature, clinical signs of neutropenia e.g. upper respiratory tract infection, mouth ulcers).

A blood test needs to be performed to determine white cell count and blood group. The on-call psychiatrist or psychiatry registrar must be informed of the new reception as soon as possible.

The dose of Clozapine and monitoring frequency of bloods needs to be verified with both the previous treating team and ClopineCentral® if patient is on Clopine®, CPMS if patient is on Clozaril®, Juno Connected if patient is on Clozitor®.

ClopineCentral phone:	1800 656 403
CPMS phone:	1800 501 768
Juno Connected phone:	1800 271 186

If the patient has medication with them and only after medical consultation and verification that there has been no treatment interruption, the patient can use their own medication. This medication can be used until a supply of Clozapine is organised by the Clozapine Co-ordinator (Pharmacy Department). Contact the Clozapine Co-ordinator by email immediately after a new reception arrives who is on Clozapine. After hours, this process can be facilitated through the After Hours Nurse Manager (AHNM) and on-call pharmacist on duty.

10.2. Patient on Clozapine admitted to Correctional Centre/Youth Justice Centre without their Medication

If a patient is admitted to a correctional centre and states that they are on Clozapine but have no medication, standard referral should take place and the necessary physical observations should be completed on the patient. A blood test needs to be performed to determine WBC count, neutrophil count and blood group as soon as possible. The on-call psychiatrist/registrar must be informed of the new reception so that an interim management plan can be put in place until the patient can be started on Clozapine.

The dose of Clozapine and monitoring frequency of bloods needs to be verified with both the previous treating team and the clozapine monitoring system.

Contact the Justice Health NSW Clozapine Co-ordinator by email immediately after a new reception arrives who is on Clozapine. Afterhours, this process can be facilitated through the AHNM and on-call pharmacist on duty.

10.3. Special Procedures for Public Holidays

When the Pharmacy Department is closed and a patient prescribed clozapine is admitted with no supply, the on-call pharmacist on duty must be contacted via the After Hours Nurse Manager. Standard referral should take place and the necessary physical observations should be completed on the patient. Pathology is required to determine WBC count, neutrophil count and blood group as soon as possible. The on call psychiatrist must be informed of the

new reception so that an interim management plan can be put in place until the patient can be started on Clozapine.

It is very important that when a patient who is prescribed Clozapine and is admitted to a Justice Health NSW health centre or ward that the patient is not administered Clozapine from another source and that the Clozapine Co-ordinator is contacted by phone or email as soon as possible. This is a mandatory requirement of ClopineCentral ™.

10.4. Patient transferred, paroled or discharged from Hospital or Correctional Centre/Youth Justice Centre on Clozapine

It is important that when a patient who is prescribed Clozapine is to be transferred, paroled, discharged or released from a Correctional Centre/Youth Justice Centre or Hospital, that the Clozapine Co-ordinator must be informed immediately so that a supply of medication can be organised for the patient and transfers can be facilitated to another Clozapine centre as appropriate.

Appropriate clinical handover and recent investigations needs to be provided to community or hospital clinicians continuing care upon transfer, discharge or release.

10.5. Special Note

The After Hours Nurse Manager based at Malabar can be contacted for any further clarification on the Justice Health NSW Procedure Manual for the Management of Patients on Clozapine outside of the Pharmacy Departments operating hours following consultation with the on Pharmacist On-Call if required.

10.6. Patient admitted on Clozapine, who is a smoker

Patients who are received into the custody of Justice Health NSW will no longer be allowed to smoke tobacco and will be required to cease immediately. The tar in the cigarettes affects clozapine metabolism which will result in a rise of clozapine blood levels when the patient ceases smoking. (16) (11)

Upon ceasing smoking the patient should be monitored and doses adjusted accordingly.

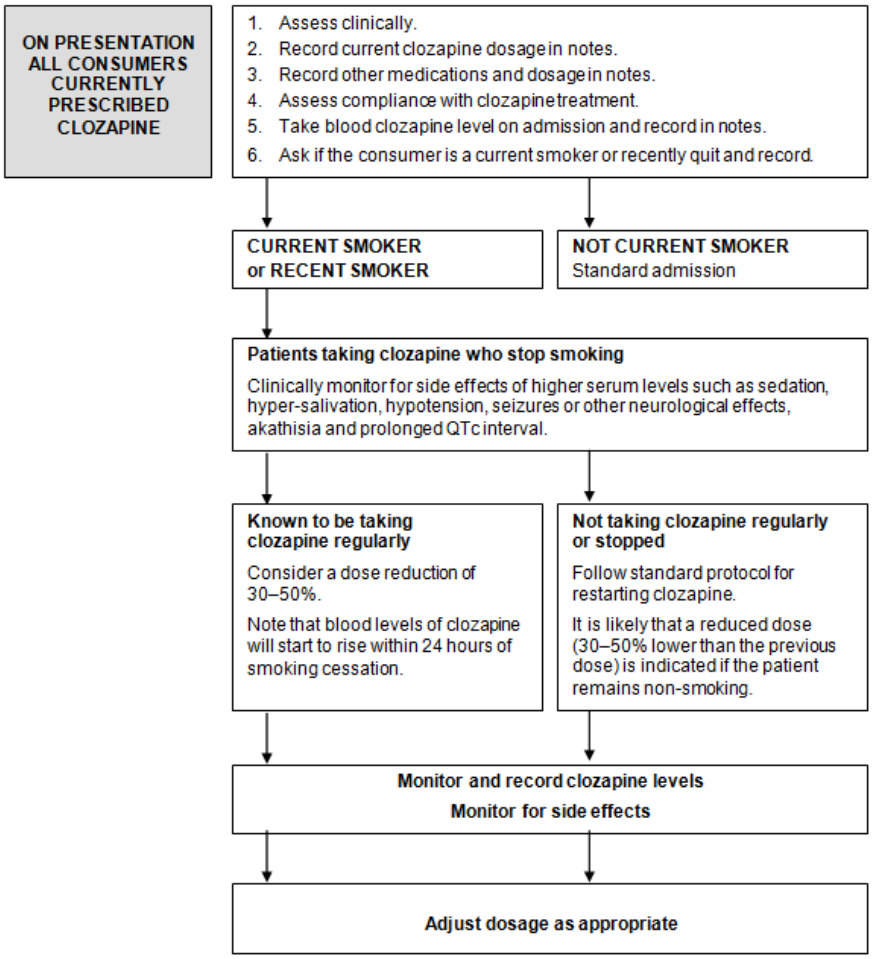

Figure 4: Clozapine and Smoking Cessation, NSW Health Tool 3 2011

10.7 Patient on Clozapine who is due to be released who might recommence smoking

When a patient is released from Justice Health NSW and it is possible that the patient will recommence smoking when they are in the community it is important that education is provided to patients to discuss the impact of smoking on their clozapine levels. [17]

11. RELATED DOCUMENTS

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3. **Australian Commisson on Safety and Quality in Health Care.** National Adult Clozapine Tiration Chart User Guide. *Australian Commisson on Safety and Quality in Health Care.* [Online] January 2013. [Cited: 31/05/2021] https://www.safetyandquality.gov.au/sites/default/files/migrated/NIMC-clozapine-titration-User-Guide.pdf.

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5. **MIMS Australia.** MIMS ONLINE. *MIMS ONLINE.* [Online] [Cited: 31/05/2021.] https://www.mimsonline.com.au.acs.hcn.com.au/Search/Search.aspx.

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7. **Taylor M, Barnes T, Young A.** *The Maudsley - Prescribing Guidelines in Psychiatry 14th Edition.* s.l. : Wiley Blackwell, 2021.

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11. *Clozapine Monitoring in Clinical Practice: Beyond the Mandatory Requirement.* **Nilamadhab K, Socorro B, Rahul C.** 2016.

12. *A new monitoring protocol for clozapine-induced myocarditis based on an analysis of 75 cases and 94 controls.* **Ronaldson KJ, Fitzgerald PB, Taylor AJ, Topliss DJ, McNeil JJ.** 6, s.l. : Australian & New Zealand Journal of Psychiatry, 2011, Vol. 45.

13. **Ministry of Health.** Clozapine-induced Myocarditis. *GL2022_011.* 2022.

14. *Multiple-Dose Pharmacokinetics of Clozapine in Patients With Chronic Schizophrenia.* **Guitton C, Abbar M, Kinowski J, Chabrand P, Bresolle F.** 1998, Journal of Clinical Psychopharmacology, pp. 470-476.

15. **Therapeutics Goods Administration.** TGA - Blue Card Form. [Online] [Cited: 31/05/2021] https://www.tga.gov.au/sites/default/files/blue-card-adverse-reaction-reporting-form.pdf

16. **NSW Health.** Tool 03 - Clozapine and Smoking Cessation. s.l. : NSW Health, 2011.

17. Tool 08 - Clozapine and consumers who resume or might resume smoking. s.l. : NSW Health, 2011.

18. *The Clozapine Handbook*. **Meyer J, Stahl S.** 2020 Cambridge University Press

Appendix 1 CLOPINE MONITORING SYSTEM PRIVACY STATEMENT

CLOPINE® (clozapine) MONITORING SYSTEM PATIENT PRIVACY STATEMENT

Introduction to the ClopineCentral™ Monitoring System

It is a Therapeutic Goods Administration (**TGA**) requirement that your healthcare professionals undertake regular monitoring of your white blood cell counts whilst you are taking Clopine. The ClopineCentral™ monitoring system is a web based application that assists your healthcare professionals to monitor certain health indicators, and safeguard against potentially fatal adverse reactions associated with Clopine.

ClopineCentral is facilitated by Pfizer Australia Pty Ltd (**Pfizer** or "**we**"), which is the Australian supplier of Clopine and a part of the Pfizer group of companies (**Pfizer Group**). Pfizer is bound by the Privacy Act 1988 (Cth) (**Privacy Act**) and the Australian Privacy Principles (**APPs**).

This Statement provides important information about how, and why your personal information is handled by Pfizer and the Pfizer Group in any use of ClopineCentral. It also describes the categories of information disclosed to Pfizer by your healthcare professionals, and by Pfizer to your healthcare professionals, the Pfizer Group and service providers.

For clarity, your personal information disclosed to Pfizer or any of your healthcare professionals will be handled generally under your healthcare professional(s) privacy policy and applicable privacy terms. Your healthcare professional(s) can provide such policy and terms.

Personal information processed by ClopineCentral

Collection and Processing of information: Pfizer may be provided with the following personal information about you - whether by your relevant healthcare professionals, or otherwise - for inclusion in ClopineCentral:

Scope of Information	Details
Registration Information	As part of the registration process, we or your healthcare professionals will enter into ClopineCentral: • your initials, date of birth, weight (optional), blood group and gender • your name, address and telephone number, where necessary for administrative purposes • the name of your healthcare professionals and their respective places of business (this includes your GP, specialist medical practitioner and/or any other prescriber) • your dose of Clopine • our initial blood test results (white blood cell and neutrophil counts) including date of blood test • your relevant medical history (as applicable) including of any bone marrow disorder, neutropenia, cardiac concerns etc.
Pathology and Other Information	Your ongoing blood tests and pathology results will be entered into ClopineCentral, along with: • any changes to your dose of Clopine • if you stop Clopine therapy for any reason • the name of the pharmacy which dispenses Clopine to you • your dose of Clopine • any adverse events potentially associated with your general treatment and your use of Clopine.
Additional information that may be processed	Additional healthcare professional notes and information collected by healthcare professionals to assist in monitoring and facilitating clinical management of additional health issues (which may be unrelated to symptoms being treated by Clopine) including potential cardiac changes, cholesterol levels, blood glucose levels, and other general health related parameters. You may choose to withdraw your consent at any time to the collection, storage, use and disclosure of this additional information. You may do this by informing your relevant healthcare professionals.

If you do not provide Pfizer, or your relevant healthcare professionals, with the personal information set out under 'Registration Information' and 'Pathology and Other Information' above, your healthcare professionals may not be able to commence or continue to provide Clopine to you, or use ClopineCentral to support your treatment.

Use and Disclosure of your Personal Information under ClopineCentral

Pfizer will always handle all personal information in accordance with its Privacy Policy, located at www.pfizer.com.au/privacy. The Pfizer Privacy Policy contains full information about how you may access and/or correct the personal information held about you in ClopineCentral, as well as information on making a complaint about any breach of the Privacy Act and APPs, and how Pfizer will deal with any complaints.

Information provided by Pfizer to Healthcare professionals

Pfizer may provide your healthcare professionals involved with access to personal information about you as processed by ClopineCentral to assist them to manage your treatment with Clopine. These healthcare professionals may include your GP, specialist medical practitioner, other prescriber (as applicable), pharmacist and / or the coordinator at your hospital, clinic or other health facility.

Your healthcare professionals may, from time to time, engage Pfizer's consultant hematologist and/or cardiologists for advice to assist them in the monitoring of your treatment with Clopine and these type of specialists may also be provided with your personal information.

Pfizer Group and third party service providers

Pfizer may use and disclose to any member of Pfizer Group your personal information processed and stored on ClopineCentral for a number of reasons, including:

- to administer, develop and improve ClopineCentral;
- to satisfy its (and the Pfizer Group's) regulatory and reporting requirements; and
- as otherwise permitted to disclose the information under the Privacy Act and APPs.

In addition, Pfizer may also engage members of its Group and/or third party service providers (including IT contractors) to administer, support and host ClopineCentral. Your personal information may be disclosed to such Group members and third party service providers in order for them to perform their relevant services to and on behalf of Pfizer.

Some of these recipients may be located outside of Australia (as outlined in the Pfizer Privacy Policy) in locations that may not offer an equivalent level of protection for personal information to the laws of Australia. Pfizer implements appropriate measures to ensure your personal information remains protected and secure when it is transferred outside of Australia in accordance with the Privacy Act, APPs and applicable data protection and privacy laws.

Clozapine Exclusion Database and patient files

In order for Pfizer to comply with its regulatory obligations, some of your personal information in ClopineCentral will be included in the Clozapine Exclusion Database (CED). The CED is a database of patients who have received Clozapine from Pfizer, or other Australian suppliers of Clozapine (including Mylan Health Pty Limited), who are no longer eligible to receive Clozapine due to adverse blood test results. If your blood tests results indicate you should discontinue treatment with Clopine, certain information (including your initials, date of birth, gender, blood group, name of treating healthcare professional and white cell/neutrophil count) will be added to the CED and will be accessible by other Australian suppliers of Clozapine in order to ensure that you do not recommence treatment with Clozapine.

If you have been treated with another brand of Clozapine prior to commencing or resuming treatment with Clopine, your healthcare professional may request that Pfizer arrange for the transfer of your previous blood test results and relevant medical history (including your initials, date of birth, gender, blood group, name of treating healthcare professional, white cell/neutrophil count and specialist notes) (Patient File) to ClopineCentral. Similarly, your healthcare professional may direct Pfizer to transfer your ClopineCentral Patient File to another supplier of Clozapine if you discontinue treatment with Clopine. In either case certain information may be disclosed by Pfizer to the other supplier of Clozapine to facilitate the transfer.

Use of de-identified information

Pfizer may use, collect, store and disclose de-identified and aggregated information for research, statistical and publication purposes. Any information disclosed will be removed of any personal identifiers and will not identify you or any individual. As such, de-identified and aggregated information is not personal information under the Privacy Act or APPs.

If you experience any adverse event associated with your Clopine treatment, Pfizer is also required to provide de-identified information about the adverse event to the TGA. In addition, Pfizer is required to provide de-identified statutory reports to the TGA regarding the national use of Clozapine.

Patient Consent

- ☐ I understand and consent to the collection, use and disclosure of my personal information (including my sensitive health information) for the purposes of my healthcare professionals, Pfizer, and members of the Pfizer Group monitoring and facilitating clinical management for health conditions, including monitoring of blood test results as part of my Clopine treatment, each in the manner set out in this Privacy Statement.
- ☐ I also understand that my healthcare professionals and Pfizer will collect, use, disclose and handle my personal information in accordance with their respective Privacy Policies

Patient name (and authorised representative, if applicable) _____

Patient (or authorised representative) **signature** _____

Date: _____

Medical Practitioner Acknowledgment

I am the patient's medical practitioner / healthcare professional and I confirm that I have explained to my patient why the collection, storage, use and disclosure of their personal information is required for their treatment with Clopine and have received consent from the patient to collect, use and disclose their personal information (including sensitive health information) to Pfizer, each member of the Pfizer Group and each required recipient as set out in the Privacy Statement for the purposes of: (i) providing the patient with Clopine treatment; and (ii) and monitoring blood test results and monitoring for health conditions that are subject to special warnings and precautions as described in the Clopine Product Information and as otherwise set out in the Privacy Statement.

Medical practitioner name _____

Medical practitioner signature _____

Date: _____

Appendix 2 MEDICAL OFFICER REGISTRATION FORM

REGISTRATION FORM FOR MEDICAL OFFICERS

Registration can also be submitted online (www.clopine.com.au) by the Centre Co-ordinator.

By prescribing Clopine® (clozapine) I intend to participate in ClopineCentral™ and the ClopineCentral™ Protocol.

I agree to abide by the obligations of a Medical Officer as described in the ClopineCentral™ Protocol and I agree that, notwithstanding these obligations, I remain solely responsible for the management of patients for whom I prescribe Clopine®.

PRESCRIBING REMINDERS

1. Only patients who are registered with ClopineCentral™ may be prescribed Clopine®.
2. For the first 18 weeks of treatment, no more than 1 week supply of Clopine® may be prescribed at once. After 18 weeks, no more than 28 days supply may be prescribed. The patient's haematological profile must be assessed before each prescription for Clopine® is written.
3. A WBC and Neutrophil count no more than 48 hours old must accompany each prescription or be entered online (www.clopine.com.au) for Clopine® to be supplied.

*** Indicates areas that must be completed before form may be submitted**

MEDICAL OFFICER

* FIRST NAME:

* SURNAME:

* CLOPINE® CENTRE:

OR

CLOPINE® CLINIC: (if applicable)

* • DO YOU WISH TO BE REGISTERED WITH OTHER CLOPINE® CENTRES WITHIN YOUR AREA HEALTH SERVICE? YES / NO (please circle)

* PRACTICE NAME:

* PRACTICE ADDRESS:

* STATE: * POSTCODE:

* PHONE: * FAX:

MOBILE PHONE NUMBER: PAGER:

EMAIL ADDRESS:

☐ General Practitioner ☐ Consultant ☐ Registrar ☐ Other

Note: To be registered with ClopineCentral™, this completed form must be emailed to ClopineCentral@hospira.com, submitted online (www.clopine.com.au) or faxed to 1800 657 454. Registration will be confirmed by email. ClopineCentral™ Phone 1800 656 403. Requests for access to your own personal information held for registration purposes may also be directed to ClopineCentral™.

Appendix 3 NEW PATIENT REGISTRATION FORM

REGISTRATION FORM FOR NEW PATIENTS

Patient registrations can also be submitted online (www.clopine.com.au) by the Centre Co-ordinator or Medical Officer.

Clopine® (clozapine) therapy must not be commenced until ClopineCentral™ has approved this registration and a Clopine® Patient Number is generated.

*** Indicates areas that must be completed before this form may be submitted**

* PATIENT INITIALS: _____ * DATE OF BIRTH: / /

* BLOOD GROUP: _____ * SEX: WEIGHT: KG

* 1. HAS THE PATIENT EVER HAD AN EPISODE OF DRUG-INDUCED NEUTROPENIA? YES ☐ / NO ☐

* 2. HAS THE PATIENT EVER HAD A BONE MARROW DISORDER? YES ☐ / NO ☐

* 3. HAS THE PATIENT AGREED AND SIGNED THE PRIVACY STATEMENT? ? YES ☐ / NO ☐

4. DOES THE PATIENT HAVE A FAMILY HISTORY OF SCHIZOPHRENIA? YES ☐ / NO ☐

5. DOES THE PATIENT HAVE DIABETES? YES ☐ / NO ☐

6. HAS THE PATIENT AGREED TO RECOMMENDED TEST CONSENT? YES ☐ / NO ☐

If the answer is 'yes' to either question 1 and/or 2, do not initiate Clopine® (clozapine) therapy in this patient.

* DATE OF PRE-TREATMENT BLOOD TEST: / /

* WHITE BLOOD CELL COUNT#: _____ x 10^9/L

* NEUTROPHIL COUNT#: _____ x 10^9/L

The results for the pre-treatment WBC/neutrophil count must be from a blood sample collected within 10 days of the date of treatment initiation.

* CLOPINE® CENTRE:

* CLOPINE® CLINIC: (if applicable)

* MEDICAL OFFICER NAME:

* PHONE: _____ * EMAIL: _____

CENTRE CO-ORDINATOR NAME:

* NAME OF PERSON COMPLETING FORM:

(Please Print Name)

Note: This form must be emailed to ClopineCentral@hospira.com or submitted online (www.clopine.com.au) or faxed to ClopineCentral™ on 1800 657 454. Registration will be confirmed by email. ClopineCentral™ Phone: 1800 656 403.

Appendix 4 CLOPINE BLOOD COUNT RECORD FORM

ALL FIELDS ARE MANDATORY AND MUST BE COMPLETED IN FULL BY A MEDICAL OFFICER/PSYCHIATRIST

CLOPINE® (clozapine) BLOOD COUNT RECORD FORM

* Indicates areas that must be completed before this form may be submitted

Blood count results can also be submitted online (www.clopine.com.au) by either the Medical Officer, pharmacist or Centre Co-ordinator.

This form is for recording the patient's WBC and neutrophil count at commencement of Clopine® therapy, during treatment and after discontinuation of therapy.

Each prescription for Clopine® must be accompanied by a WBC and neutrophil count no more than 48 hours old. Unless a current WBC and neutrophil count has been performed and assessed as satisfactory, the next prescription for Clopine® cannot be dispensed.

PATIENT STATUS (Tick appropriate box)

☐ ON TREATMENT

☐ DISCONTINUED DATE DISCONTINUED: / /

• TERMINATION OF TREATMENT FORM COMPLETED? YES/NO (please circle)

COMMENCEMENT DATE: / /

(PLEASE PRINT ALL DETAILS)

* Clopine® PATIENT NUMBER:

* DATE BLOOD TAKEN: / / WEIGHT: kg

LABORATORY:

* WBC COUNT: x 10^9/L

* NEUTROPHIL COUNT: x 10^9/L

* PRESCRIBED CLOPINE® DOSAGE: mg/DAY

PRESENTATION: ☐ TABLET ☐ CLOPINE® SUSPENSION

* CENTRE:

* MEDICAL OFFICER NAME:

* MEDICAL OFFICER SIGNATURE:

* PHARMACIST NAME:

* PHARMACIST SIGNATURE:

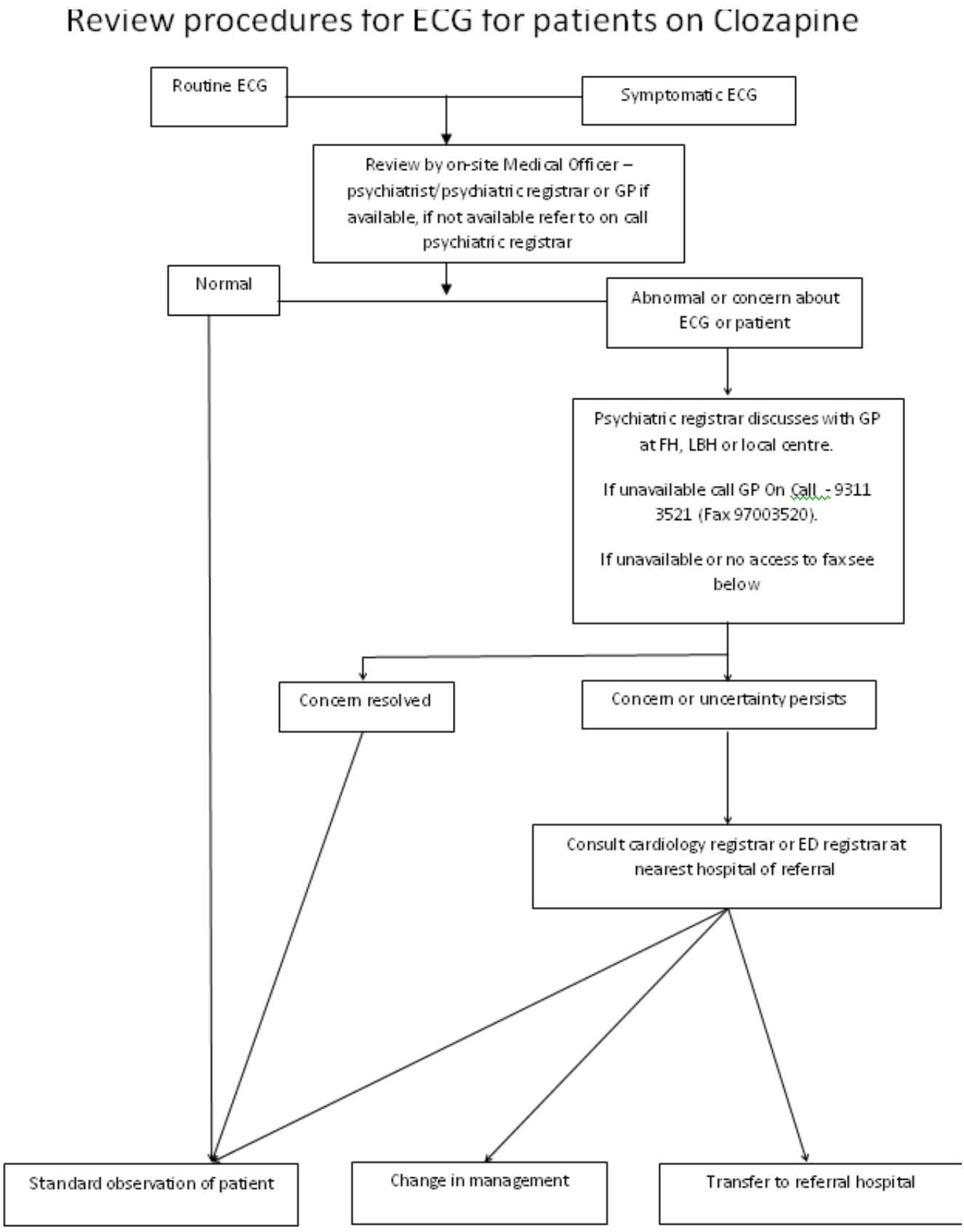
PRESCRIPTION FILLED? YES ☐ / NO ☐ DATE DISPENSED: / /

DAYS DISPENSED:

PHARMACY NAME:

Note: This form must be emailed to ClopineCentral@hospira.com or submitted online (www.clopine.com.au) or faxed to ClopineCentral™ on 1800 657 454. Registration will be confirmed by email. ClopineCentral™ Phone: 1800 656 403.

Appendix 5 REVIEW PROCEDURES FOR ECG



Appendix 6 CLOZAPINE USE IN SILVERWATER WOMENS MHSU

Supplementary protocol to Procedure Manual for the Management of Patients on Clozapine for use in Silverwater Women's MHSU (SWCC MHSU)

All procedures and monitoring requirements for Clozapine use are set out in the "Procedure Manual for the Management of Patients on Clozapine" and must be referred to at every stage of management of patients prescribed Clozapine.

This supplementary protocol only describes the operational management of patients who have their clozapine therapy initiated in the SWCC MHSU.

Key points with regard to this setting are:

1. Only one patient can be started on Clozapine therapy in any given week and consideration should be given to the total number of patients who are within the first 18 weeks of treatment in SWCC MHSU. The prescriber should contact the CDCMH and NM CMH to discuss the number of patients on weekly bloods and the most appropriate place for clozapine initiation.
2. Patients must remain in SWCC MHSU until at least week 18.
3. Only morning doses of clozapine will be prescribed for the initial 2 weeks.
4. The SWCC MHSU NUM will have overall responsibility for the co-ordination of the process.

Pre-Treatment

- A patient accommodated in SWCC MHSU is identified as being suitable for Clozapine. The Clozapine treatment will be discussed at the MHSU clinical ward round.
- Appointment is made with Psychiatrist to explain process and obtain consent
- Psychiatrist and patient agree to Clozapine. The psychiatrist contacts the Pharmacy Clozapine Co-Ordinator (ph. 9700 3888) and the MH NUM SWCC (ph. 9289 5456)
- Psychiatrist requests ECHO via Medical Appointments unit (phone 9700 3244)
- A medical hold is requested as per Justice Health NSW protocols for a minimum of 18 weeks
- A Health Problem Notification Form (HPNF) must be completed and forwarded to CSNSW advising of the need for access to complete physical observations on the patient. Two copies are to be provided to CSNSW with the original placed in health record in accord with policy Health Problem Notification Form (Adults)

Initiation of treatment

Day One

- On day one of the prescription of Clozapine, the first dose of Clozapine must be given prior to 9am to allow 6 hours monitoring of physical observations (temperature, pulse, and BP) to occur within the day shift.
- Mental Health nursing staff will check on patient prior to end of shift at 1530hrs and hand over to the main clinic staff that provides 24 hour cover to the centre.
- Correctional Staff will be aware that this is a patient of concern and will have a low threshold to alerting clinic staff if there is any concern.

Day Two (2) to Day Fourteen (14) of Treatment

- Morning doses only are to be administered. Patients must have twice daily observations (temperature, respiratory rate, pulse, and BP), morning and late afternoon or evening.
- Mental Health nursing staff will check on patient prior to end of shift at 1530hrs and hand over to the main clinic staff that provides 24 hour cover to the centre.
- Correctional Staff will be aware that this is a patient of concern and will have a low threshold to alerting clinic staff if there is any concern.

Week three (3) to Week Eighteen (18) of Treatment

- Slow titration twice daily is required to achieve therapeutic doses. Daily observations must occur at a minimum (temperature, pulse, blood pressure).
- MHSU CMH nursing staff will check on the patient prior of the shift at 1530 hours and provide a clinical handover to the main clinic nursing staff who provides 24 hour nursing coverage to the Centre.
- At morning clinical handover the progress of the patient is to be updated and CSNSW staff reminded that the patient is a *patient of concern* and to have a low threshold to alerting clinical staff if there is any concern.
- The patient will require weekly blood monitoring for the first 18 weeks of treatment and the results sent to the Clozapine Co-ordinator email along with a Clozapine blood count record form (Appendix 4).
- Patients on Clozapine are only to be discharged from the MHSU following a multidisciplinary discussion at the clinical ward round.

Follow up of Treatment

- When a patient on Clozapine is to be transferred from the MHSU to other correctional centres (for example, because of the patient's CSNSW security classification), the NUM I MHSU or delegate must advise CSNSW of locations with appropriate levels of mental health services.
- Prior to transfer, it is the responsibility of the NUM I MHSU or delegate to ensure a thorough clinical handover is attended to the receiving nursing staff and/or Nursing Unit Manager. Clinical handover of the patient to the receiving centre staff must be documented in the patient's medical record.

- The NUM I MHSU or delegate should also inform the Clozapine Co-ordinator in the Pharmacy Department of the transfer and ensure that the patient's supply of Clozapine is sent with them on transfer.
- If the patient is considered to be unstable for medical or psychological reasons, a further medical hold must be completed recommending that the patient remain in the MHSU.
- After the first 18 weeks of treatment, the patient will require four-weekly blood monitoring from this time. The results and the Clozapine blood count form (Appendix 4) must be faxed to the Clozapine co-ordinator.

Release of patient's on Clozapine

- Ideally patient's commenced on Clozapine in the MHSU should be either sentenced with greater than eighteen weeks until release or parole. If a patient is on remand, court days should be monitored by the NUM I MHSU or delegate.
- If a patient on Clozapine is released from custody the NUM I MHSU or delegate will need to liaise with the receiving community mental health team, and the Justice Health NSW Clozapine Co-ordinator to ensure transfer of patient care.

Appendix 7 CLOZAPINE USE IN MRRC MHSU

Supplementary protocol to Procedure Manual for the Management of Patients on Clozapine for use in the Mental Health Screening Unit at the Metropolitan Remand and Reception Centre.

All procedures and monitoring requirements for Clozapine are set out in the 'Procedure Manual for the Management of Patients on Clozapine' which must be referred to at every stage of the management of patients prescribed clozapine.

This supplementary protocol only describes the operational management of patients who have their Clozapine therapy initiated in the Mental Health Screening Unit (MHSU) at the Metropolitan Remand and Reception Centre (MRRC), Silverwater.

Key points with regard to the initiation of Clozapine treatment in this setting are that:

1. Only one patient can be started on Clozapine therapy in any given week and consideration should be given to the total number of patients who are within the first 18 weeks of treatment in MRRC MHSU when considering to initiate a patient on clozapine treatment. The treating clinician should contact the Clinical Director Custodial Mental Health (CDCMH) and Nurse Manager Custodial Mental Health (NMCMH) to discuss initiating the treatment and they will consider the appropriate setting and timeframe.
2. Patients must remain in MRRC MHSU until at least week 18.
3. Only morning doses of Clozapine may be prescribed for the initial 2 weeks, and the NUM I MHSU or delegate has overall responsibility for the co-ordination of the process.
4. All changes to the prescribed dose will be communicated with the MSHU clinical team including the NUM I MHSU or delegate.

Pre-treatment

- A patient accommodated in the MRRC MHSU is identified as being suitable for Clozapine. The Clozapine treatment will be discussed at the MHSU clinical ward round.
- The treating psychiatrist will explain the process and obtain the consent of the patient to commence Clozapine.
- The psychiatrist and patient agree to Clozapine. The psychiatrist then contacts the Pharmacy Clozapine Co-ordinator (Tel: 9700 3888) and the NUM MHSU.
- The psychiatrist requests an ECHO via the Justice Health NSW Medical Appointments Unit. This requires a PAS referral to be attended and signed by the psychiatrist and faxed to the Medical Appointments Unit (Tel: 9700 3244).
- A medical hold in the MRRC is requested in accord with Justice Health NSW Policy 1.263 Medical Holds for a minimum of 18 weeks.
- A Health Problem Notification Form (HPNF) must be completed and forwarded to CSNSW advising of the need for access to complete physical observations on the patient. Two copies must be provided to CSNSW with the original placed in the patient's health record in accordance with policy Health Problem Notification Form (Adults)

Initiation of treatment

Day One (1)

- An appropriate alert (Mental Health-Clozapine) is placed on PAS by the NUM I MHSU or delegate.
- Clozapine alert is placed in the medical file.
- On day one of the prescription of Clozapine, the first dose of Clozapine must be given prior to 0900 hours to allow 6 hours monitoring of physical observations (temperature, pulse, and blood pressure) to occur within the day shift. MHSU nursing staff will be responsible for administration of Clozapine and routine physical observation and pathology collection.

Day two (2) to Day Fourteen (14) of Treatment

- Morning doses are only to be administered. Patients must have twice daily observations (temperature, pulse and blood pressure), morning and late afternoon.
- MHSU mental health nursing staff will review the patient prior to the end of the afternoon shift. MHSU CMH staff will also provide a clinical handover of the patient to the main clinic nursing staff who provides 24 hour nursing coverage to the Centre.
- At morning clinical handover the progress of the patient is to be updated and CSNSW staff must be informed that the patient is a *patient of concern* and that they should have a low threshold to alerting clinic staff if there is any concern.
- The patient will require weekly blood monitoring and the results will be sent to the Clozapine Co-ordinator along with a Clozapine blood count record form (Appendix 4). Medical officers will take responsibility of completing the blood count record form and the nursing staff will be responsible for the routine pathology and sending to the Clozapine coordinator.

Week three (3) to Week Eighteen (18) of Treatment

- Slow titration twice daily is required to achieve therapeutic doses. Daily observations must occur at a minimum (temperature, pulse, blood pressure).
- MHSU CMH nursing staff will check on the patient prior to end of the afternoon shift at 1900 hours and provide a clinical handover to the main clinic nursing staff who provides 24 hour nursing coverage to the Centre.
- At morning clinical handover the progress of the patient is to be updated and CSNSW staff reminded that the patient is a *patient of concern* and to have a low threshold to alerting clinical staff if there is any concern.
- The patient will require weekly blood monitoring and the results sent to the Clozapine email along with a Clozapine blood count record form (Appendix 4).
- Patients on Clozapine are only to be discharged from the MHSU following a multidisciplinary discussion at the clinical ward round.

Follow up of Treatment

- When a patient on Clozapine is to be transferred from the MHSU to other correctional centres (for example, because of the patient's CSNSW security classification), the NUM I MHSU or delegate must advise CSNSW of locations with appropriate levels of mental health services.
- Prior to transfer, it is the responsibility of the NUM I MHSU or delegate to ensure a thorough clinical handover is attended to the receiving nursing staff and/or Nursing Unit Manager.

Clinical handover of the patient to the receiving centre staff must be documented in the patient's medical record.

- The NUM I MHSU or delegate should also inform the Clozapine co-ordinator in the pharmacy department of the transfer and ensure that the patient's supply of Clozapine is sent with them on transfer.
- If the patient is considered to be unstable for medical or psychological reasons, a further medical hold must be completed recommending that the patient remain in the MHSU.
- After the first 18 weeks of treatment, the patient will require four-weekly blood monitoring from this time. The results and the Clozapine blood count form (Appendix 4) must be sent to the Clozapine Co-ordinator.

Release of patient's on Clozapine

- Ideally patient's commenced on Clozapine in the MHSU should be either sentenced with greater than eighteen weeks until release or parole. If a patient is on remand, court days should be monitored by the NUM I MHSU or delegate.
- If a patient on Clozapine is released from custody the NUM I MHSU or delegate will need to liaise with the receiving community mental health team, and the Justice Health NSW Clozapine Co-ordinator to ensure transfer of patient care.