General instructions for completing clozapine protocol forms

- In order to comply with medical record standards, all components of the form must be completed in full. Incomplete entries are not valid.
- Please ensure that when completing the weekly/4 weekly review all boxes have information entered.
- All entries must be completed with a date, signature, name, designation and time.
- The review must be within 48 hours of a CBE, during a face to face assessment for signs and symptoms of infection.
- The full completion of this form is the minimum requirement for all participants prescribed clozapine under the TGA endorsed clozapine management protocols. Further monitoring may be required by individual health networks.
- All staff involved in monitoring clozapine must be registered with the monitoring provider (refer to your local clozapine Coordinator or SA Health Pharmacist for more information).
- On transfer to another clozapine centre, the original form is to go with the participant. A copy of the form is to be made for the Medical Record.

Clozapine Review Guidelines

Clinical Information	At each review document any important information (e.g. side effects, constipation, fever, chest pain, seizure activity, extra monitoring required etc.) in the clinical information box.
Annual review	Complete blood examination (CBE) Clozapine level C-Reactive Protein (CRP) Troponin Electrolytes Liver function test (LFT) Fasting blood glucose level Fasting lipids Electrocardiograph (ECG) Echocardiogram (ECHO)
6 monthly review	Complete blood examination (CBE) Clozapine level Electrolytes Liver function test (LFT) Fasting blood glucose level Fasting lipids
Shared Care	Contact monitoring doctor 3 monthly Assess clozapine management plan Collect physical and metabolic health data Remind/advise doctor regarding 6 month and annual review pathology and cardiac monitoring requirements 6 Monthly psychiatrist review

Cardiac Monitoring Guidelines

At all times	Educate participants and carers to report flu-like symptoms, GI upsets, dizziness or chest pain.
Pre-Commencement, within 6 months, then annually	Echocardiogram.
First 28 Days	Measure body temperature at the same time each day.
Baseline, days 7, 14, 21 and 28, week 12 then annual review	Troponin T or I, CRP, ECG (except day 21), Pulse, Blood Pressure, Respiratory rate.
If at any time • Temperature > 38ºC or flu-like symptoms	CRP, Troponin and CBE.
• Troponin > 2 ULN and CRP elevated	Urgent transfer to Emergency department. Urgent cardiology consultation – query myocarditis. Urgent echocardiography.
• Troponin > 2 ULN and normal CRP	Urgent transfer to Emergency department. Urgent cardiology consultation – query acute coronary syndrome.
• Troponin 1 to ≤ 2 ULN and elevated CRP	Urgent cardiology consultation. Daily assess: troponin, CRP and symptoms until features normalise. Clozapine treatment can continue if not contraindicated by ongoing assessment.

CLOZAPINE PROTOCOL INFORMATION

This form is for 4 weekly monitoring of clozapine, and is designed to meet the checks and observational needs of the participant. What is documented on this form should be documented on electronic equivalent where required.

Clozapine is a medication regulated by the TGA, subsidised under the *Highly Specialised Drugs Program*. It is a third line treatment for chronic schizophrenia refractory to treatment with other medications. Participants may only be prescribed clozapine when mandatory blood testing and other monitoring can be achieved in the community.

Side effects

- Weight gain
- Metabolic syndrome
- Diabetes
- Hyper-salivation *(more often at night)*
- Nausea
- Sedation
- Severe constipation
- Increased heart rate
- Myoclonic jerks
- Obsessional traits
- Nocturnal enuresis

Life threatening events

- Agranulocytosis/neutropenia
- Severe infections
- Seizures
- Hypertension/hypotension
- Myocarditis
- Cardiomyopathy
- Pulmonary embolus
- Acute renal failure

If any of the above adverse events are noted, please refer to the *Adverse Event Protocols*.

Recommencing clozapine after a period of interruption:

Clozapine must be re-titrated from 12.5mg if the participant has missed the medication for more than 48 hours to reduce the risk of serious side effects. There are also additional monitoring requirements depending on the period of interruption. See table below:

Period of Interruption (time since last dose was taken)	Dosage / Monitoring Requirements)
≤ 48 hours	No change to dosage or monitoring
> 48 hours & ≤ 72 hours	Start on 12.5mg and titrate up No additional monitoring requirements
> 72 hours & ≤ 28 days	Start on 12.5mg and titrate up **For 4 Weekly participants:** Weekly monitoring for 6 weeks. If no abnormality, resume 4 weekly monitoring **For Weekly participants:** Weekly monitoring for 6 weeks or as long as needed to reach 18 weeks (whichever is the greatest).
> 28 days	New participant registration form New pre-treatment result and monitoring same as new participant (18 weeks); no 6 hour vital signs monitoring required Start on 12.5mg and titrate up.

WCC and NC	Range	Action
WCC >3.5 x 10^9/L and NC >2.0 x 10^9/L	GREEN	Clozapine therapy can continue or be titrated upwards as required
WCC 3.0-3.5 x 10^9/L and/or NC 1.5-2.0 x 10^9/L	AMBER	Requires increasing frequency of monitoring, to twice weekly
WCC <3.0 x 10^9/L and/or NC <1.5 x 10^9/L	RED	STOP clozapine immediately and repeat blood test within 24 hours. Contact Consultant Psychiatrist and arrange urgent medical review

Government of South Australia
SA Health

CLOZAPINE PARTICIPANT PROTOCOL - 4 WEEKLY - (MR77D)

Facility: .....

Affix participant identification label in this box

UR No: .....

Surname: .....

Given Name: .....

Second Given Name: .....

D.O.B: ..... Sex: .....

Community/Private Psychiatrist: ..... **Participant CPN:** .....

CLOZAPINE PARTICIPANT PROTOCOL (4 Weekly) WCC > 3.5 x 10^9/L AND NC > 2.0 x 10^9/L

NB Remeasure arm circumference if weight ± 5kg

Blood Group: O+ ☐ O- ☐ A+ ☐ A- ☐ B+ ☐ B- ☐ AB+ ☐ AB- ☐		Diagnosed Diabetes Yes / No	Family Hx Diabetes Yes / No
Dispensing pharmacy:	Monitoring clinic/GP:	Height (m):	Diagnosed Hypertension Yes / No — Family Hx Heart Disease Yes / No

CLINICAL REVIEW	Annual Review	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12
Review date (DD/MM/YYYY)												
Review time (HH:MM)												
Total Daily Dosage (mg)												
Arm Circumference (cm)												
Weight (kg)												
BMI (weight/height^2)												
Waist measurement (cm)												
Blood pressure 1st												
Blood pressure 2nd												
Temperature (°C)												
Manual pulse												
Respiratory Rate												
Blood glucose level (BGL)		Random BGL due next month	Due		Random BGL due next month	Due		Random BGL due next month	Due		Random BGL due next month	Due
No of Tobacco cigarettes/day												
Clinical Information (constipation, fever, chest pain, seizure activity etc.)												
CLINICAL REMINDERS												
Serum clozapine level						Order clozapine level	Due					Order clozapine level for annual review
Pathology	Annual pathology review due					Order 6 month pathology screens	6 month pathology screens due					Order annual pathology screens
Cardiac	Annual cardiac review due											Order annual cardiac screens
Shared Care	Liaison due contact the treating doctor			Liaison due contact the treating doctor			Liaison due contact the treating doctor			Liaison due contact the treating doctor		
Details of person filling in this column												
Signature												
Name *(please print)*												
Designation												

Medication

SA Health

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