



MENTAL HEALTH SERVICE BUSINESS RULE SESLHDBR/072

Name	Clozapine Roles and Responsibilities within the South Eastern Sydney Local Health District Mental Health Service		
What it is	It is a business rule articulating the roles and responsibilities of clinical staff providing Clozapine treatment to consumers of the South Eastern Sydney Local Health District (SESLHD) Mental Health Service (MHS).		
Risk Rating	Medium	Review Date	August 2022
What it is not	This document is not a step-by-step guide to the clinical care of consumers who are prescribed Clozapine within the SESLHD MHS. Refer to SESLHDPR/591 Clozapine – Guidelines for Prescribing, Administration and Monitoring .		
What to do	<p>Psychiatrists/Psychiatric Registrars/Medical Officers</p> <ol style="list-style-type: none"> 1. Register as a Clozapine prescriber with <i>ClopineCentral</i> (a website provided by the medication’s supplier). 2. Be familiar with Clozapine prescribing information, guidelines and protocols. 3. Provide medication information to the consumer (risks vs benefits). 4. Ensure the consumer has read the Clopine Monitoring System Privacy Statement, and signed the Clopine Consent Form (if the consumer is unable to give informed consent at the time of commencement, this must be documented). 5. Liaise with the Clozapine Coordinator or site Pharmacist to register the consumer with <i>ClopineCentral</i> before starting treatment with Clozapine. 6. Ensure all preliminary tests are completed, the consumer is suitable to commence Clozapine therapy and that ongoing monitoring occurs. 7. Clinically review the consumer, check all blood results (including Full Blood Count (FBC), cardiac and metabolic blood results) and enter the FBC into the <i>ClopineCentral</i> database or request the site Clozapine Coordinator to enter the results into the database. 8. Check for any interruption to treatment. 9. Monitor the consumer’s mental state and physical health. 10. Monitor and address the side effects of Clozapine. 11. Make prescribing decisions in consultation with the treating Consultant Psychiatrist. 12. Conduct metabolic monitoring unless there is proof of an actively involved General Practitioner (GP) and/or physician managing metabolic and other physical health issues. This includes appropriate referral (e.g. to a GP, medical specialist or the SESLHD Keeping the Body in Mind [KBIM] team where indicated) when physical health issues are identified. 		

13. In partnership with the treating Consultant Psychiatrist, optimise psychosocial functioning through referrals to appropriate agencies.
14. Liaise with the site Clozapine Coordinator on admission and discharge from an inpatient unit.
15. Provide the site Pharmacist with a prescription for Clozapine on discharge for enough supply until the consumer's next outpatient appointment, if required, and ensure relevant blood pathology, including FBC results, are current.
16. Ensure the consumer has been referred to the Clozapine Clinic on discharge.
17. Liaise with the relevant Community Mental Health team to ensure continuity of care upon discharge from hospital.
18. Ensure the consumer is aware of the appointment and there are appropriate arrangements for blood testing prior to the outpatient appointment.
19. The Outpatient Medical Officer is responsible for checking the FBC, writing a prescription for Clozapine at each appointment and ensuring that the Clozapine Monitoring Form is completed.
20. Document all clinical interactions pertaining to consumer treatment and care planning on the Clozapine Monitoring Form.
21. Attend to safety monitoring protocols as per the consumer's treatment plan, including echocardiograms and cardiometabolic health reviews as per [NSW Ministry of Health Policy - PD2012_005 Clozapine-induced Myocarditis – Monitoring Protocol](#).
22. Review the consumer at the Clozapine Clinic at varying frequencies depending on the presence of another usual treating Consultant Psychiatrist, or the treatment plan.
23. Face-to-face review of patients on Clozapine Maintenance by a Clozapine Clinic Consultant Psychiatrist or treating Consultant Psychiatrist at least every six months.
24. Dosing decisions are made in collaboration with the consumer, the Clozapine Clinic and the treating Consultant Psychiatrist.
25. Provide a written treatment update to:
 - a) The consumer's usual treating Psychiatrist at a minimum of every six months.
 - b) The consumer's GP at a minimum of every 12 months.

Pharmacists

1. Register as a Clozapine Pharmacist with *ClopineCentral*.
2. Ensure the consumer has a status of 'active/approved' on *ClopineCentral* prior to dispensing Clozapine.
3. Facilitate the registration of new inpatients with *ClopineCentral*.
4. Check that the FBC was conducted on the correct date and that results are in the 'green' range.
5. Ensure that appropriate monitoring has been organised if an 'amber' or 'red' FBC result has been obtained (twice weekly blood tests are required for the 'amber' range, and daily blood tests for the 'red' range, until results return to normal ('green' range).
6. Enter blood test details into *ClopineCentral* for inpatients.
7. Ensure continuity of supply of medication for consumers on discharge.

8. Provide information and education to inpatients/consumers, families and staff.
9. Liaise with the site Clozapine Coordinator.

Inpatient Mental Health Nurses

1. Complete nursing observations as per the Clozapine protocol.
2. Administer medication, monitor the consumer's progress and report any side effects to the medical team.
3. Liaise with the relevant Community Mental Health team to ensure continuity of care upon discharge from hospital.
4. Liaise with the site Clozapine Coordinator.

Mental Health Case Managers

1. Ensure the consumer attends pathology tests and review appointments weekly or monthly (as appropriate).
2. Ensure the consumer is linked to a pharmacy that is registered to dispense Clozapine.
3. Notify the prescribing doctor of any incidents or concerns in relation to the consumer's clinical status.
4. Assist medical staff during periodic safety monitoring for each consumer on Clozapine.
5. Ensure bi-annual (six-monthly) metabolic monitoring occurs (conducted at the Clozapine Clinic, by a Case Manager or a GP) and is documented.

Treating Team

The consumer's primary clinician is responsible for ensuring that the consumer:

1. Has an understanding of the potential positive and negative effects of Clozapine.
2. Has read all relevant information prior to the administration of Clozapine (if current mental state allows).
3. Has read the Clopine Monitoring System Privacy Statement, and signed the consent form (a Medical Officer is to document if a consumer is unable to give informed consent at the time of commencement of the medication).
4. Understands that he/she must attend scheduled appointments with the treating doctor.
5. Understands that he/she must attend pathology tests.
6. Understands that he/she must adhere to the medication prescribed.

Wherever possible, the consumer's designated carer should be included in this process.

Mental Health Service Clozapine Coordinator

1. Facilitate the registration of new outpatients with *ClopineCentral*.
2. Ensure the required blood tests are carried out for each consumer, the results checked promptly and appropriate action taken (i.e. that the medication, repeat FBC, white cell count and neutrophil level etc. are ordered where necessary).
3. Transmit all registrations, consumer data and blood results from the Clozapine Clinic to *ClopineCentral*.

	<ol style="list-style-type: none"> 4. Act as a point of contact for, and be aware of, all communications between the site Clozapine Clinic and <i>ClopineCentral</i>. 5. Ensure that the site Clozapine Clinic operates within the <i>ClopineCentral</i> protocol. 6. Ensure that <i>ClopineCentral</i> has the most up-to-date details as soon as they are available. If the Clozapine Clinic Coordinator relocates, the Clozapine Coordinator must nominate, in consultation with site executives, another registered person to take on the role of Clozapine Coordinator until a new coordinator is appointed and registered with <i>ClopineCentral</i>. 7. Ensure the provision of coordinated care by facilitating effective liaison between consumers, their families and carers, Case Managers, Medical Officers, Nursing staff, Pharmacists and GPs. 8. Document all clinical interactions pertaining to consumer treatment and care planning on the Clozapine Monitoring Form. 9. At the consumer's first visit, ensure referral documentation has been completed and is accurate. 10. Register with <i>ClopineCentral</i> and adhere to the <i>ClopineCentral</i> protocols. 11. Ensure that all Medical Officers prescribing Clozapine are registered with <i>ClopineCentral</i>. 12. Enter FBC results into the <i>ClopineCentral</i> database following the consumer's appointment at the Clozapine Clinic. 13. Follow up the blood results of consumers in the amber and red zones and conduct timely data entry of repeat blood tests and their results into <i>ClopineCentral</i>. (Twice weekly blood tests are required for the amber zone, and daily blood tests for the red zone, until results return to the normal 'green' range.) 14. Undertake physical observations i.e. blood pressure, temperature, respiratory rate and pulse rate of Clozapine Clinic attendees. 15. Monitor each consumer's weight, waist circumference and Body Mass Index (BMI) as per the Clozapine protocol. 16. If a consumer fails to attend an appointment, follow SESLHDBR/41 - Management of Missed Appointments. 17. Maintain the site contribution to the MHS Clozapine database by ensuring the Clozapine Monitoring Form is always up-to-date. 18. Facilitate dispensation from <i>ClopineCentral</i> for extra supply of medication if the consumer will miss a scheduled appointment due to travel. 19. Follow-up post-monitoring FBC blood tests (required for one month after cessation of clozapine, at the previous frequency).
Compliance	Compliance with the above requirements for MHS staff involved in providing Clozapine treatment to MHS consumers will be monitored via automatic triggers within <i>ClopineCentral</i> , through the Clozapine Monitoring Form and regular audits of consumers' physical health. IIMS reports relating to Clozapine will be reviewed.
When to use it	This business rule is to be used whenever a SESLHD MHS consumer is receiving Clozapine treatment.
Why the rule is necessary	This business rule is necessary to standardise and articulate the roles and responsibilities of clinical staff providing Clozapine treatment to consumers of SESLHD MHS.
Who is responsible	Responsible staff include all SESLHD MHS clinicians providing Clozapine treatment to consumers of the MHS.

Ministry of Health/ SESLHD reference	<p>NSW Ministry of Health</p> <ul style="list-style-type: none"> • NSW Ministry of Health Policy Directive - PD2012_005 Clozapine-induced Myocarditis – Monitoring Protocol • NSW Ministry of Health Policy Directive - PD2013_043 Medication Handling in NSW Public Health Facilities <p>SESLHD</p> <ul style="list-style-type: none"> • SESLHDBR/41 - Management of Missed Appointments • SESLHDPR/591 - Clozapine – Guidelines for Prescribing, Administration and Monitoring <p>Others</p> <ul style="list-style-type: none"> • National Safety and Quality Health Service (NSQHS): Standard 4. Medication Safety (4.1) • National Standards for Mental Health Services 2010: Standard 2. Safety (2.4); Standard 10. Delivery of Care (10.5.6)
Executive Sponsor	Dr Claire Gaskin, Clinical Director, Child and Youth, SESLHD MHS
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Revision and Approval History

Date	Revision Number	Author and Approval
September 2015	0v1	First draft by Robin Ellis, Eastern Suburbs Mental Health Service Community Service Manager.
November 2015 – February 2016	0v2	Reviewed by Angela Karooz, SESLHD MHS Clinical Nurse Manager. Sent to MHS Clinical Operations Managers (COMs) for broad dissemination. Comments received by STG COM, STG and TSH Clozapine Coordinators, STG Older Adults MH Clinical Nurse Consultant.
April 2016	0v3	Edits made to document at MHS District Document Development and Control Committee (DDDCC) meeting based on above feedback. Edits checked with STG Community MHS Manager.
May 2016	0v4	Document submitted to MHS Clinical Council; additional details requested around cardiometabolic monitoring.
July 2016	0v5	Additional information re cardiometabolic monitoring added to document by SESLHD Youth Mental Health Senior Staff Specialist Dr Jackie Curtis.
July 2016	0v5	Endorsed by SESLHD MHS Clinical Council.
August-September 2016	0v5	Minor edits by SESLHD Drug and Quality Use of Medicines Committee (DQUMC). Compliance section added by DDDCC as per DQUMC recommendation. Risk rating upgraded to Extreme by DDDCC (as this is a new document).
October 2016	0	Approved by Drug and Quality Use of Medicines Committee
September 2017	1	Reviewed by Robin Ellis, ESMHS Community Service Manager.
October 2017	1	Reviewed by Lisa John, POWH Pharmacist.
December 2017	1	Endorsed by DDDCC.
January 2018	1	Endorsed by SESLHD MHS Clinical Council.
February 2018	1	Processed by Executive Services prior to publishing.
May 2018	1	Risk rating changed from Extreme to Medium – approved by Executive Sponsor.

June 2019	2.0	Amended to reflect all patients on clozapine maintenance are to be reviewed by a Consultant Psychiatrist at least every six months.
August 2019	2.0	Minor review approved by Executive Sponsor. "Review" defined as "face-to-face" consultation. Endorsed by SESLHD MHS DDCC. Endorsed by SESLHD MHS Clinical Council. Published by Executive Services.