## Prescribing and Accessing Clozapine for Patients Admitted to the Bunbury Hospital Outside of Pharmacy Hours Procedure

**Current from: 7 February 2023** 

## 1. Guiding Principles

This procedure outlines the process by which to access clozapine for patients admitted to the Bunbury Hospital outside of Pharmacy operating hours.

#### Aim

The aim of this procedure is to minimise harm to the patient and ensure appropriate governance relating to the supply of medications. Information contained pertains both to the essential criteria required in order to supply clozapine and the resolution of various out of hours scenarios.

WACHS-SW Pharmacy Department (Bunbury Hospital) opening hours:

Monday to Friday 8.00am to 4.30pm Excluding Public Holidays

#### 2. Procedure

Clozapine must **not** be administered to patients without first determining the patient's registration, blood test frequency, date of next required blood test and level of compliance.

The following information outlines a step wise approach that the admitting nurse/s and/or medical staff are required to follow in order to obtain clozapine for a patient admitted after hours.

#### 2.1 Restrictions regarding the supply of clozapine

Clozapine is prescribed to treat schizophrenia in people unresponsive to, or intolerant of, other antipsychotics. It is a highly effective medication however it does possess some serious and potentially fatal side effects such as neutropenia, agranulocytosis, myocarditis and cardiomyopathy.

Following the discontinuation of this medication due to the aforementioned side effects, it was re-introduced for use in Australia with stringent monitoring and guidance for use in conjunction with the online clozapine monitoring system (ClopineCentral®).

Within WA Health Facilities, clozapine therapy may only be initiated for Indications specified within the <u>Formulary One</u> (WA Medicines Formulary).

Patients prescribed clozapine must be registered with <u>ClopineCentral</u>® (and subsequently given a registration number) and satisfy baseline testing requirements before they are able to be initiated on the medication.

Medical Practitioners must be registered with <u>ClopineCentral</u>® before prescribing clozapine. If a Medical Practitioner is working at more than one Centre, he or she must register with <u>ClopineCentral</u>® under each Centre.

It is the Medical Practitioner's responsibility to register the patient with <u>ClopineCentral</u>® before clozapine treatment is commenced.

White blood cell and neutrophil counts (taken as a full blood picture / FBC) must be performed and the results checked by the Medical Practitioner to ensure that they comply with the ranges before clozapine is prescribed.

White blood cell counts (full blood picture / FBC) and neutrophil counts must be performed weekly for the first 18 weeks of treatment with clozapine, and at least every 28 days (monthly) thereafter. In some situations, WBC and neutrophil counts must be monitored more frequently.

If the patient's white cell or neutrophil counts fall below a specific threshold, the patient may require more frequent monitoring, or the use of clozapine may even be ceased.

Clozapine Blood Results Monitoring System		Recommended Action	
Green Range	WBC greater than 3.5 x 10 <sup>9</sup> /L AND Neutrophils greater than 2.0 x 10 <sup>9</sup> /L	Continue clozapine therapy	
Amber Range	WBC 3.0 - 3.5 x 10 <sup>9</sup> /L AND/OR Neutrophils 1.5 - 2.0 x 10 <sup>9</sup> /L	Continue clozapine therapy with twice-weekly blood tests until return to "green" range	
Red Range	WBC less than 3.0 x 10 <sup>9</sup> /L AND/OR Neutrophils less than 1.5 x 10 <sup>9</sup> /L	Stop clozapine therapy immediately. Contact haematologist and Clozapine Monitoring Centre	

It is required that the patient's blood test results be entered into <u>ClopineCentral</u>® at the time of dispensing / supply. The maximum quantity of clozapine that may be dispensed to a patient is to supply them with enough stock until the date of their next blood test. (i.e. If a patient requires weekly blood tests, seven days of clozapine may be supplied from the date of the most recent blood test).

## 2.2 Implications of interruption in clozapine therapy (including patient non-compliance):

Obtain psychiatric review prior to recommencing clozapine.

If it is suspected or confirmed that the patient has not taken clozapine for more than 48 hours, the patient must be re-titrated on clozapine, beginning at 12.5mg once or twice daily. If the dose is tolerated, then it may be possible to titrate the doses upwards more quickly than an initial titration.

The standard observations required when titrating clozapine must also be conducted, refer to WA Health Medication Chart Policy (MP 0078/18) for further information.

Blood test frequencies are to change if there has been interruption in clozapinetherapy.

### **Less than 72 hours interruption:**

Continue monitoring as normal (no change in monitoring required).

#### More than three days and less than four weeks of interruption:

If the interruption in therapy occurs during the first 18 weeks of treatment i.e. while patients are on a schedule of weekly monitoring, weekly monitoring should continue for at least six weeks after treatment is recommenced, or for as long as is necessary to achieve a total of 18 weeks of weekly monitoring. For example, a patient whose therapy is interrupted after 15 weeks should have weekly blood tests for six weeks after therapy is reinstituted; a patient whose therapy was interrupted at week nine should be monitored for a further nine weeks after therapy is resumed.

Patients who were on a schedule of monthly monitoring when treatment was interrupted should be monitored weekly for six weeks on resumption of therapy, then monthly thereafter if no abnormalities have been detected.

### Four weeks or more interruption of therapy:

If treatment with clozapine is interrupted for more than four weeks, monitoring should recommence as for a new patient.

Refer to WA Health Medication Chart Policy (MP 0078/18) for further information.

### 2.3 Clinical signs of infection

If a patient on clozapine therapy develops symptoms of infection and/or of neutropenia (e.g. flu-like symptoms, mouth ulcers, sore throat or fever) the Medical Practitioner 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) WBC and neutrophil counts and clinical review until the symptoms resolve.

## 2.4 Procedure for accessing clozapine outside of pharmacy hours – steps to be taken by the admitting nurse / medical officer.

**Step 1** – Determine patient compliance, and ensure a Medical Practitioner excludes clinical signs of infection, refer to 2.1.2 & 2.1.3 above.

**Step 2** – A registered staff member can log into the online database, <u>ClopineCentral</u><sup>®</sup>. The patient's registration number, blood test frequency, date their next blood test is due, date their last blood test was taken, and the results of the last blood test are available from the patient's profile.

Alternatively, <u>ClopineCentral</u><sup>®</sup> can be contacted on 1800 656 403. Appropriate clinical staff can utilise this number, regardless of registration status with ClopineCentral<sup>®</sup>.

For the purposes of obtaining information from <u>ClopineCentral</u>® via phone for a particular patient, you are asked to provide the patient's initials, the patient's date of

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birth, your name, location and contact number. Ensure these are determined prior to sourcing the information.

If the request is after hours for <u>ClopineCentral</u>®, there is to be a prompt to call an "Emergency On-Call number" to obtain information. The on-call number varies day to day and therefore must be obtained on each occasion.

The "Emergency On-Call" message bank will ask for a message to be left containing the patient's initials, the patient's date of birth, your name, location and contact number. The on-call officer is to contact the caller within 30 minutes.

Obtain the patient's registration number, blood test frequency, date their next blood test is due, date their last blood test was taken and the results of the last blood test from the on-call officer. These details should be documented in the patient's clinical record (i.e. Bossnet, or handwritten Progress Notes).

**Step 3** – The patient may then be prescribed clozapine at the discretion of the Medical Practitioner. A titrating dose of clozapine should be prescribed on the MR170.4 WA Adult Clozapine Initiation and Titration Chart per WA Health Medication Chart Policy (MP 0078/18).

Stable doses should be charted directly onto the National Inpatient Medication Chart (refer to dosing above).

Step 4 – In the event that the patient has been admitted and possesses clearly labelled boxes of clozapine for themselves, this patient's own stock may be used until pharmacy services are available. Refer to the WACHS-SW <u>Handling and Storage of Patient's Own Medications – Including Schedule 4 Restricted And Schedule 8 Medications Procedure.</u>

Tablets must be in original strip packing to use patient's own supply.

If the patient has presented in the absence of their own medication or it is packed into alternative packaging (i.e. a Webster Pak or a dossette box), after hours stocks of clozapine can be utilised. These specifically labelled suspension and tablets are kept in the Psychiatric Intensive Care Unit (PICU) imprest cupboard. **These are not to be used during pharmacy business hours**.

**Step 5** – At the next available opportunity, the ward clinical pharmacist must be contacted in order to advise of the new admission, update the patient's online <a href="ClopineCentral">ClopineCentral</a>® profile and organise replacement of the after-hours stock. Also contact the Clopine coordinator if the patient is planned for discharge.

#### 2.5 ClopineCentral®

<u>ClopineCentral</u>® is the database containing information for all registered clozapine patients, such as their personal details, information regarding their clozapine therapy and blood tests and dispensing history. Doctors, nurses and pharmacists must register with this database in order to access the information. Registration forms to access <u>ClopineCentral</u>® and to register patients may be found on the ward.

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#### 3. Definitions

Nil

## 4. Roles and Responsibilities

#### **All Nursing Staff**

All nursing staff are to be familiar with the processes to obtain information to ensure administration of clozapine to patients is safe and accurate.

#### **All Medical Staff**

All medical staff are to be familiar with the processes to obtain information to ensure administration and prescription of clozapine to patients is safe and complies with the requirements for clozapine prescribing.

Medical Practitioners must be registered with ClopineCentral® before prescribing.

It is the Medical Practitioner's responsibility to ensure that each patient for whom he/she prescribes clozapine is monitored in accordance with the details above.

## 5. Compliance

Failure to comply with this policy document may constitute a breach of the WA Health Code of Conduct (Code). The Code is part of the <u>Integrity Policy Framework</u> issued pursuant to section 26 of the <u>Health Services Act 2016 (WA)</u> and is binding on all WACHS staff which for this purpose includes trainees, students, volunteers, researchers, contractors for service (including all visiting health professionals and agency staff) and persons delivering training or education within WACHS.

WACHS staff are reminded that compliance with all policies is mandatory.

## 6. Records Management

All WACHS corporate records must be stored in the approved Electronic Documents and Records Management System as per the WACHS Records Management Policy.

All WACHS clinical records must be managed in accordance with <u>Health Record Management Policy</u>.

### 7. Evaluation

Review of the compliance with this Procedure is to be reviewed on an as needed basis by the Nurse Unit Manager and / or Regional Chief Pharmacist to determine appropriate access to clozapine after hours.

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#### 8. Standards

National Safety & Quality Health Standards (2<sup>nd</sup> edition May 2021): 1.1, 1.6, 1.7, 1.10, 1.25, 1.27, 4.1, 4.2, 4.4, 4.5, 4.13, 4.14, 4.15, 6.11

National Standards for Mental Health Services 2010: 2.4

### 9. Legislation

<u>Health Services Act 2016</u> (WA) <u>Medicines and Poisons Act 2014</u> (WA) <u>Medicines and Poisons Regulations 2016</u> (WA)

#### 10. Related Forms

Nil

## 11. Related Policy Documents

WACHS-SW Accessing Medications from the WACHS-SW Pharmacy, located at Bunbury Hospital - Outside of Pharmacy Hours Procedure
WACHS-SW Handling and Storage of Patient's Own Medications – Including Schedule
4 Restricted And Schedule 8 Medications Procedure

## 12. Related WA Health System Mandatory Policies

MP 130/20 Medicines Handling Policy
MP 0078/18 WA Health Medication Chart Policy

## 13. Related WA Health System Policies

Public Health Policy Framework

## 14. Appendices

Appendix 1: Steps to be undertaken for patients taking clozapine admitted to Bunbury Hospital outside of pharmacy hours

This table simplifies the step-wise approach to sourcing clozapine for patients after hours. It may be used as a tool to ensure each aspect is covered when accessing clozapine for inpatients after hours.

Appendix 2: Registration form for Medical Practitioners

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Prescribing and Accessing Clozapine for Patients Admitted to Bunbury Hospital Outside of Pharmacy Hours Procedure

## This document can be made available in alternative formats on request for a person with a disability

Contact:	Regional Clinical Pharmacist		
Directorate:	Medical Services	TRIM Record #	ED-CO-16-10199
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## Appendix 1: Steps to be undertaken for patients taking clozapine admitted to Bunbury Hospital outside of pharmacy hours

STEP 1  Determine patient's compliance, and whether	PATIENT HAS BEEN TAKING CLOZAPINE CONTINUOUSLY: Patient to continue at prescribed dose.		
any interruption of administration has occurred.	<ul> <li>INTERUPTION TO CLOZAPINE THERAPY:</li> <li>Determine duration of interruption (including non-compliance) and assess whether clozapine requires retitration.</li> <li>(Refer to 2.2 Treatment interruption (including non-compliance), Procedure for Accessing Clozapine for Patients Admitted to Bunbury Hospital Outside of Pharmacy Hours Procedure)</li> </ul>		
STEP 2  Obtain patient information from Clopine Central®	Log into ClopineCentral® to obtain the patient's registration number, blood test frequency, date their next blood test is due, date their last blood test was taken and the results of the last blood test from the on-call officer. These details should be documented in the patient's notes.		
	OR		
	<ul> <li>Ensure the patient's initials, the patient's date of birth, your name, location and contact number are at hand.</li> <li>Contact ClopineCentral® on 1800 656 403.</li> <li>There is to be a prompt to call an "Emergency On-Call number" to obtain information. Leave a message containing the patient's initials, the patient's date of birth, your name, location and contact number. The on-call officer is to contact the caller within 30 minutes.</li> <li>Obtain the patient's registration number, blood test frequency, date their next blood test is due, date their last blood test was taken and the results of the last blood test from the on-call officer. These details are to be documented in the patient's notes.</li> </ul>		
STEP 3  Prescribe clozapine for the patient	The patient may then be prescribed clozapine, taking into consideration any required changes to doses based on patient compliance. Clozapine is to be prescribed on the National Inpatient Medication chart for stable doses or the MR170.4 WA Adult Clozapine Initiation and Titration Chart for titrating doses.		

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STEP 4  Access clozapine supplies for the patient	<ul> <li>Use patient's own clearly labelled boxes of clozapine for themselves.</li> <li>Tablets must be in original strip packaging to use patient's own supply.</li> </ul>	
	OR	
	Utilise the after hours stock kept in the PICU imprest cupboard	
STEP 5 Inform staff the next working day	<ul> <li>Contact the clinical pharmacist at the next available opportunity to notify them of the new admission.</li> <li>If the patient is planned for discharge, also contact the Clopine coordinator.</li> </ul>	

## **Appendix 2: Registration form for medical practitioners**

# REGISTRATION FORM FOR MEDICAL PRACTITIONERS

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

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

I agree to abide by the obligations of a Medical Practitioner 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

- Only patients who are registered with ClopineCentral™ may be prescribed Clopine®.
- 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.
- 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 PRACTITIONER:					
* FIRST NAME:					
* SURNAME:					
CLOPINE® CENTRE:					
* OR					
CLOPINE® CLINIC: (if applicable)					
* 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@pfizer.com, submitted online (www.clopine.com.au) or faxed to 1800 657 454. Registration will be confirmed by email. ClopineCentral™					

directed to ClopineCentral™.

Your personal information will be handled at all times in accordance with Pfizer Australia's Privacy Policy (available at Pfizer Privacy www.pfizer.com.au/privacy).

Phone 1800 656 403. Requests for access to your own personal information held for registration purposes may also be

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