

STANDARD OPERATING PROCEDURE CLOZAPINE DISPENSING

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VALIDITY - All local SOPS should be accessed via the Trust intranet

CHANGE RECORD

Version	Date	Change details
1.0	28.09.2023	New SOP. Approved at Drugs and Therapeutics Group (28 September 2023).
2.0	Sept 2024	Location of dispensing has been updated throughout Updated section 3 – added pharmacy assistant Updated section 4 – added clozapine patient spreadsheet Updated section 4.1 – changed the process of ordering a prescription Added section 4.2 – added verification process Added section 4.4 – dispensing for inpatients Updated section 4.5 – altered wording regarding NOMADS Added section 4.6 – MAR charts Added section 4.7 – Re-titration Removed section 4.10 – Plasma levels Updated section 4.12 – Added information related to missed deliveries Updated section 4.13 – Changed delivery address for the delivery of clozapine Removed appendix 4. Approved at Drugs and Therapeutics Group (26 September 2024).

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1. INTRODUCTION

This standard operating procedure (SOP) aims to ensure that all pharmacy staff working in the clozapine clinic can obtain, label and assemble prescribed medications safely and efficiently, for use by patients of Humber Teaching NHS Foundation Trust.

2. SCOPE

This SOP applies to the dispensing of clozapine within the Pharmacy office in the Mary Seacole Building and the pharmacy staff employed by the Trust, who will be responsible for obtaining, labelling and assembly of the prescribed medicines dispensed for the patients who are treated there.

3. DUTIES AND RESPONSIBILITIES

Chief Pharmacist and Controlled Drugs Accountable Officer

The Chief Pharmacist is responsible for optimising the use of medicines within the Trust, ensuring that the relevant standards relating to medicines optimisation set by the Care Quality Commission (CQC) and the National Institute for Health and Clinical Excellence (NICE) are achieved. The Chief Pharmacist is also the Controlled Drugs Accountable Officer (CDAO) who is responsible for the safe and effective use of Controlled Drugs within the Trust.

Clinical Pharmacists

These Pharmacists are responsible for ensuring prescribed medications have been assessed as clinically appropriate via clinical verification (Lorenzo)

Student Technicians

Are responsible for obtaining, labelling and assembly of prescribed medicines for outpatients and inpatients (Humber centre patients will be supplied by pharmacy at Humber centre)

Pharmacy Assistants

Are responsible for ordering new prescriptions through the RC, obtaining, labelling and assembly of prescribed medicines for outpatients and inpatients (Humber centre patients will be supplied by pharmacy at Humber centre).

Medicine Optimisation Technicians

These Medicine Optimisation Technicians will be responsible for ordering new prescriptions through the RC, being available to complete a check (either physically or via remote video checking) on assembled and labelled medicines. If trained to do the Medicines Optimisation Technicians can also access CPMS to check patients' blood results.

Responsible Clinician (RC)

This clinician is responsible for the prescribing of clozapine, completing Rx's, medication reviews and overall care of the patient with regards to their clozapine treatment as per NICE guidelines.

4. PROCEDURES

Clozapine prescriptions for dispensing can be found in the folder within the locked cupboard located in the pharmacy office.

There are three folders one for deliveries, one for fast track and one for NOMAD trays.

The current week / Clozapine Clinic group dates are identified on the calendar in the pharmacy office. Each week the worklists are printed from the clozapine patient spreadsheet.

"V:\Corporate\Pharmacy\Pharmacy Team\Shared\Clozapine Monitoring Database\Clozapine Patient Details

- Select the most up to date listing

4.1. Ordering a Prescription

The Medicines Optimisation Technician and/or Pharmacy Assistant will contact the RC regarding the current prescription expiry date and place a new prescription request a month before it is due to expire.

The dispensing team will order the new prescription by emailing the RC, cc in the relevant clinical lead and the nominated pharmacist.

A template for the email and an up-to-date contact list for the CMHT clinical leads can be found on the V drive:

"V:\Corporate\Pharmacy\Pharmacy Team\Shared\Clozapine Monitoring Database\Clozapine Patient Details\Clozapine Clinical Leads-Email template.docx"

Once a prescription is received the medicines optimisation technician and/or pharmacy assistant will request it is clinically verified by a pharmacist.

4.2. Verification of clozapine prescriptions

After the prescription has been completed by the RC, the dispensing team should email the pharmacist to verify the prescription and copy in the relevant clinical lead.

Pharmacist checks include:

- ECG QTc interval only
- LFTs
- U&Es
- Lipids
- HbA1c
- Prolactin

(all above should be done at least annually as per NICE guidance on antipsychotic monitoring)

- Prescription is checked for dose changes.
- Physical health monitoring on the monthly monitoring form should be checked so any significant weight changes and/or BP/pulse changes can be flagged.

Trust policy (SOP19-011) stipulates clozapine serum levels are done annually or more frequently if smoking status changes, non-compliance is suspected or if side effects increase on the same dose.

If pharmacist is happy with all the above they will "reply to all" on the relevant verification request email to confirm the prescription is verified and can be dispensed for the duration specified by the prescriber.

If there are any results which give cause for concern, the pharmacist would contact either the responsible clinician, the GP or both depending on the nature of the concern.

If any of the above results are not available then pharmacist should "reply to all" on the relevant verification request email to request. Using the table below, they should add the missing requirements in the end column.

Forename	Surname	CPMS/DMS	NHS Number	Monitoring	Additional
		NUMBER		Frequency	monitoring
					required?
Patient	Name	093847	2938475564	4 <u>weekly</u>	

The pharmacist will authorise one month supply at a time until the recommended monitoring is completed.

If the recommended monitoring has not been completed by the second supply, the pharmacist will submit a datix.

After the prescription has been verified, the Medicines Optimisation Technician and/or Pharmacy Assistant will add further details on EPMA regarding delivery options e.g. fast track and will add the correct delivery week.

Before dispensing, the prescription will be printed off and placed in the correct delivery file.

The old prescription is then marked as completed, scanned onto the patient's electronic record and filed for two years.

4.3. Dispensing Outpatient Prescriptions

Before dispensing, the prescription should be checked for its validity by ensuring it is in date and has been clinically verified by a pharmacist.

The dispenser should then proceed to dispense the prescription and endorse the prescription with quantities dispensed, their initials and the date once complete.

The dispenser then places the dispensed prescription into the checking basket for accuracy checking by the Medicine Optimisation Technician. Where the dose is half a tablet, the tablets should be supplied to the patient already halved and should be labelled accordingly. i.e., "tablets already halved".

4.4. Dispensing in-patient supply

Check the patient's inpatient chart to ensure the dose is the same or that any change of dose is verified on the chart. Technically validate the chart and print the supply sheet. Dispense and accuracy check the clozapine using the inpatient chart.

4.5. NOMAD Tray

Before dispensing the prescription should be checked for its validity by ensuring it is in date and has been clinically verified by a pharmacist.

Any medication prescribed by the consultant on the clozapine prescription dispensing form can be dispensed directly into a NOMAD tray, once dispensed the dispenser should endorse the prescription with quantities dispensed, their initials and the date once complete.

The dispenser then places the dispensed NOMAD tray into the checking basket for accuracy checking by the Medicine Optimisation Technician.

If the patient is on other medications prescribed by their GP via an FP10 which are to be placed into a NOMAD tray, the dispenser will dispense the clozapine and after being accuracy checked this will then be delivered to Morrill Pharmacy where they will be dispensed into a NOMAD tray alongside the medicines the patient has been prescribed on an FP10 by their GP.

NOMAD trays are collected from Morrill Pharmacy on a weekly basis. A bag label is placed onto the NOMAD tray, bagged and sealed by a medicines optimisation technician as per supply routine (e.g. weekly or 4 weekly) according to the Clozaril worklist

(V:\Corporate\Pharmacy\Pharmacy\Pharmacy\Team\Shared\Clozapine Monitoring Database).

4.6. MAR Chart

Prescriptions requiring a MAR chart will be highlighted as such, when dispensing these prescriptions an extra set of labels will need to be printed to place on the MAR chart. (Appendix 1). This can also include DOMMAR and MRC as per local authority policy.

4.7. Re-titration

Patients requiring re-titration of clozapine should be provided with a re-titration sheet (Appendix2) to help them understand their dosing schedule this will be checked by the medicines optimisation technician before giving to the patient.

4.8. Checking the Clozaril Patient Monitoring system (CPMS)

Before any patient can be given their supply of clozapine they must have had a GREEN blood result recorded on CPMS monitoring System https://www.clozaril.co.uk/

A patient's results can be found by accessing the search function on the menu and entering their name in the correct boxes. The date of last blood test must be checked to ensure you are checking the most up to date result, if the result is GREEN, it is safe to give the patient the medication.

If a patients' result is AMBER, then another blood test must be taken, the patient can still be given their clozapine medication.

If a patients' result is RED the patient is advised not to take any more clozapine tablets and to return to the clinic the next day for a further blood test. The RC is advised of the RED result.

If the blood results are not available on the CPMS system then the sampling venue/team would be contacted for further information.

4.9. Monitoring frequency and associated supply.

Monitoring frequency can be found on CPMS QUICK GUIDE.

Supply would be 7 days,14 days and 28 days of medication and would not exceed the maximum cover for relevant monitoring frequency.

4.10. Checking the Denzapine Monitoring System (DMS)

A patient's results can be found by accessing the search function on the menu and entering their name in the correct boxes. The date of last blood test must be checked to ensure you are checking the most up to date result if the result is GREEN, it is safe to give the patient the medication.

If a patients' result is AMBER then another blood test must be taken, the patient can still be given their clozapine medication.

If a patients' results are RED, the patient is advised not to take any more clozapine tablets and to return to the clinic the next day for a further blood test. The RC is advised of the RED result.

4.11. Clozapine Monitoring Database

The clozapine spreadsheet is a useful tool for anyone who is dispensing clozapine in the clinic and can be found here: V:\Corporate\Pharmacy\Pharmacy\Pharmacy\Pharmacy\Pharmacy\Pharmacy\Clozapine Monitoring Database\Clozapine Patient Details.

The database contains the details of every patient receiving clozapine whilst under the care of Humber NHS Teaching Hospitals Foundation Trust.

The spreadsheet can be referred to for patient's CPMS/DMS number, monitoring frequency and CMHT it also contains information relating to NOMADs, FP10s and MAR charts. This is a live document and should not be altered by anyone other than an authorised member of staff.

4.12. Deliveries

The delivering schedule is as follows:

Thursday - Goole, Beverley, Driffield, Market Weighton and Hull Friday – Bridlington and Hornsea

If a patient is not at home, the patient will be contacted where possible to confirm that they have enough medication and to rearrange a suitable delivery date. If the patient is unavailable then the patient's CMHT will be informed. The driver will liaise with the CMHT as to whether the delivery is attempted the next working day or delivered to CMHT base for the care-co to organise delivery to the patient.

In relation to this, colleagues within the CMHT should refer to section 10.3 of the Clozapine Clinic SOP.

Delivery Check List

Print a list from the Clozapine data base for the corresponding week, the deliveries are checked against this.

Delivery checklist is located here: <u>V:\Corporate\Pharmacy\Pharmacy\Pharmacy\Team\Shared\Clozapine Monitoring Database\Clozapine Patient Details</u>

For patient's who have both clozapine and medication prescribed by their GP via FP10 in a compliance aid; in order for all medicines to be within the same compliance aid, Clozapine is delivered to Morrill Pharmacy. Morrill Pharmacy will then dispense the Clozapine and FP10 medicines into one compliance aid.

The Delivery Consignment Sheet (Appendix 6) should be used every time there is a movement of clozapine from one area to another; this will provide a clear trail should any discrepancies occur.

CPMS check list

- Log on to CPMS
- Access the pharmacist's worksheet
- Check each patient has a valid green result
- Click on dispensing and enter quantity dispensed.
- Click ok (this will be removed from the check list and go into the patients file)
- On the delivery checklist, mark the patients name with GREEN highlighter to indicate that the bloods have been checked and removed from the pharmacist worklist
- The delivery check list is given to the delivery person in the pharmacy office.
- If the results haven't been received on CPMS worksheet the medicines optimisation technician must follow up to obtain the results.

4.13. Ordering Clozapine

Email hospitalorders@viatris.com direct to place order using the account number Clozapine A/C0500010567 give details of quantities required e.g.

Please send the following:

Clozapine 100mg x 84 x 100 Clozapine 25mg x 84 x 50

To be delivered to:

Pharmacy Office Mary Seacole Building Willerby Hill Hull HU10 6ED

Humber centre will request stock when needed for their patients.

To order Denzapine fill in specific form and email see appendix 5

4.14. Near miss and error reporting

Near misses are to be recorded on the Near Miss Log (appendix 3)

A copy of the near miss log should be printed and available during the dispensing and accuracy checking phase of the process.

Each month, sheets containing entries should be scanned and saved on the v:drive here: V:\Corporate\Pharmacy\Pharmacy\Pharmacy\Team\Shared\Ward-Based Dispensing\Near Miss Log Once scanned onto the v:drive, paper copies can be disposed of via confidential waste.

All dispensing errors must be reported via Datix.

5. REFERENCES

Clozapine Clinic SOP (SOP19-011)
Clozapine Guidelines (G362)
Medicines Optimisation Policy (M-006)
Safe and Secure Handling of Medicines Procedures (Proc431)
Ward-based dispensing Procedure (Proc 483 WBD20-01)

Appendix 1 – MAR Chart

MEDICATION ADMINISTRATION RECORD

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A - Absent N - Nausea or Vomiting H - Hospitalised D - Destroyed R - Refused NT - Not Taken C - Carer's Notes (overleaf)

O - Other (define)

Appendix 2 – Re-Titration Chart

Clozapine Re-Titration Chart

Patient Name:
IHS Number
CPMS Number
D.O.B

CLOZAPINE	MORNING DOSE	NIGHT DOSE
DAY-1	Take 25mg tablets	Take 25mg tablets
	Take100mg tablets	Take100mg tablets
DAY - 2	Take 25mg tablets	Take 25mg tablets
	Take100mg tablets	Take100mg tablets
DAY- 3	Take 25mg tablets	Take 25mg tablets
	Take100mg tablets	Take100mg tablets
DAY- 4	Take 25mg tablets	Take 25mg tablets
	Take100mg tablets	Take100mg tablets
DAY- 5	Take 25mg tablets	Take 25mg tablets
	Take100mg tablets	Take100mg tablets
DAY- 6	Take 25mg tablets	Take 25mg tablets
	Take100mg tablets	Take100mg tablets
DAY- 7	Take 25mg tablets	Take 25mg tablets
	Take100mg tablets	Take100mg tablets
DAY-8	Take 25mg tablets	Take 25mg tablets
	Take100mg tablets	Take100mg tablets
DAY- 9	Take 25mg tablets	Take 25mg tablets
	Take100mg tablets	Take100mg tablets
DAY- 10	Take 25mg tablets	Take 25mg tablets
	Take100mg tablets	Take100mg tablets

Form Prepared by	Date	
Checked		Date

Appendix 3 - Near Miss Log

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ıv	ca		1113	-	•	

NHS Humber Teaching

Unit:	1133 10										Humber NHS Four	Teaching Idation Trus
Date	Time	Name and brai prescrib	-	Type of	error	Dispensed by	Checked b	у Р	ossible ca inform	use/other ation	Action ta	iken
Kev: Type	of error											
D= incorrect drug	F=		S = incorrect strength	E = out of date	X = transpose labels	P = mis prescrip		MDS= m dosage s		N = incorrect patient name	M = missing item	O=other (please detail)
Reviewed by:				Signed		'			Dated:		•	

Near Miss Log v1

 $\verb|\corp.humber.nhs.uk| shares \verb|\corporate| Pharmacy Team| Shared \verb|\Policy Procedure Protocol \& Guideline| SOPs \verb|\Ward-Based Dispensing| SOPs \verb|\corporate| Pharmacy Team| Shared \verb|\Policy Procedure Protocol & Guideline| SOPs \verb|\Ward-Based Dispensing| SOPs \verb|\corporate| Pharmacy Team| Shared \verb|\Policy Procedure Protocol & Guideline| SOPs \verb|\Ward-Based Dispensing| SOPs \verb|\corporate| Pharmacy Team| Shared Sh$

Appendix 4 – Denzapine Ordering Sheet



OP03F01 V05

DENZAPINE ORDER FORM

Pharmacy Name	Clozapine Clinic	Date:
Address:	Miranda House	Account No.:130578
	Gladstone Street	
Town:	Hull	
Postcode:	HU3 2RT	

Product Description	Britannia SKU	Quantity
Denzapine 25mg x 84 tabs	148481	
Denzapine 100mg x 84 tabs	148484	
Denzapine 25mg x 100 tabs	148482	
Denzapine 50mg x 100 tabs	162744	
Denzapine 100mg x 100 tabs	148485	
Denzapine 200mg x 100 tabs	162745	
Denzapine Suspension 50mg/ml	148487	

Email to:	customerservices@britannia-pharm.com							
Internal Use (Only:							
Pharmacy DM	IS No:							
Order Numbe	r:	Date:						
Order Process	sed by:							

Appendix 5 – Delivery Consignment sheet.

Delivery Week 1 Date	Patient Initials	Miranda	Morrill Drop Off	Morrill Pick Up	Delivery Week 3 Date	Patient Initials	Miranda	Morrill Drop Off	Morrill Pick Up
Delivery Week 2 Date	Patient Initials	Miranda	Morrill Drop Off	Morrill Pick Up	Delivery Week 4 Date	Patient Initials	Miranda	Morrill Drop Off	Morrill Pick Up