

Livewell Southwest

**Clozapine Policy
for Mental Health Staff
and
Plymouth GP Practice Staff**

Version No 5

Review: November 2023

Expires: November 2026

Notice to staff using a paper copy of this guidance

The policies and procedures page of LSW intranet holds the most recent version of this document and staff must ensure that they are using the most recent guidance.

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Asset Number: 314

Reader Information

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Author	Specialist Mental Health Pharmacist Clinical Lead for Acute Mental Health
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	<ol style="list-style-type: none"> 2. Mental Health ward and unit managers, LSW 3. Team leaders, CMHTs, LSW 4. Locality Managers and Deputies, LSW 5. Medicines Governance Group, LSW 6. Plymouth Area Joint Formulary 7. Risk Manager, LSW 8. Director / Deputy director of Pharmacy and Pharmacy Supply Manager at UHP Pharmacy 9. Medicines Optimisation Team, NEW Devon CCG 10. Primary Care Provider Performance, QOF & GP Revalidation, NHS Devon, Plymouth & Torbay 11. Medical Director / Deputy Medical Director, NHS England, Devon, Cornwall and isles of Scilly Area Team 12. Executive Chair, Devon LMC 13. Head of Medicines Management, Devon Partnership Trust <p>Version 2.2 contained technical amendments only relating to the change in dispensing location from UHP Pharmacy to Glenbourne Pharmacy so no further consultation required. Version 2.3 contains amendments due to a formal agreement between LSW and the LMC for Plymouth GP Practices to take blood samples and issue medication for patients on 4-weekly bloods only. Consultation:</p> <ul style="list-style-type: none"> • Consultant Psychiatrists, LSW • Team leaders, CMHTs, LSW • Locality Managers LSW • Medicines Governance Group, LSW • Clozapine Technician, LSW <p>Version 3.1 and 3.2, consulted with Pharmacy Team and Consultant Psychiatrists, LSW Version 3.4 consulted with LSW Pharmacy and Lead Psychiatry Consultants. Approach discussed with CCG. Version 5 consulted with LSW Pharmacy and Lead Psychiatry Consultants. Approach discussed at MGG.</p>
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	<p>7. The Pharmaceutical Press: Stockley's Drug Interactions 10th edition</p> <p>8. Gelder, M; Harrison, P; Cowen, P; Shorter Oxford Textbook of Psychiatry 6th edition 2012</p> <p>9. Denzapine Monitoring Service www.denzapine.co.uk Accessed 18/05/2023</p> <p>10. MHRA Drug Safety Update August 2020: Clozapine and other antipsychotics: monitoring blood concentrations for toxicity. Available at: https://www.gov.uk/drug-safety-update/clozapine-and-other-antipsychotics-monitoring-blood-concentrations-for-toxicity [Accessed 18.05.23].</p>
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Document review history

Version no.	Type of change	Date	Originator of change	Description of Change
For previous review history please contact the PRG secretary.				
1.3	Reviewed	05/04/12	PRG	Review date extended, no other changes made.
1.4	Reviewed	30/04/12	Author	Review date extended, no other changes made.
1.5	Reviewed	30/11/12	Author	Full review and alignment with the ICP
1.6	Updated	28/2/13	Author	Incorporated comments from consultation
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2.1	Updated	08/2015	Mental Health Pharmacist	Updated to include change of dispensing pharmacy and contact details.
2.2	Ratified	2/10/15	MGG	All changes accepted
2.3	Date Extension	6/11/17	Clinical Director of Pharmacy	Date extension
3	Reviewed	Ratified Nov 2017 MGG	Advanced Clinical Pharmacist	Amended due to a formal agreement between LSW and the LMC for Plymouth GP Practices to take blood samples and issue medication for patients on 4-weekly bloods only. Minor changes to clozapine prescription. Simplification of flow diagrams (appendix 7 & 8) and addition of appendix 9 (ordering of blood sample equipment)
3.1	Minor amendment – not published	February 2020	Advanced Clinical Pharmacist	Revision of plasma level monitoring advice. Addition of caution regarding overdose risk.
3.2	Updated	March 2020	Advanced Clinical Pharmacist	Further update following consultation of v 3.1
3.3	Extended	February 2021	Governance & Patient Safety Pharmacist	Extended no changes
3.4	Minor update	February 2021	Advanced Clinical Pharmacist	Inclusion of MHRA Alert August 2020.
3.5	Minor update	August 2021	Specialist Mental	Updates on CPMS blood limits following communication from CPMS

			Health Pharmacist	
4	Reviewed	May 2022	Consultant Psychiatrist (HTT) & Specialist Mental Health Pharmacist	<ul style="list-style-type: none"> -Amendment of process following a red result (info updated from CPMS) – section 6 -Amendment of process following a treatment break (info updated from CPMS) -Removal of reference to clozapine use in Parkinsons. - section 10 -Removal of GP involvement in clozapine plasma levels – section 6 -Added about non effects of vaping on clozapine levels – section 6 -Clarified clozapine initiation processes for ward based and community patients – section 6 -Addition of ICP forms in Appendix – section 7
5	Reviewed and split	Nov 2023	Specialist Mental Health Pharmacist & Clinical Lead for Acute Mental Health	Clozapine policy split into policy and clinical guideline (separate documents)

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Clozapine Policy for Mental Health Staff and Plymouth GP Practice Staff

1. Introduction

- 1.1 In Plymouth patients will be registered with the **Clozaril® Patient Monitoring Service (CPMS)** if taking clozapine tablets or with the **Denzapine® Monitoring Service (DMS)** if taking clozapine suspension.
- 1.2 Clozapine can only be prescribed by doctors and dispensed by pharmacies that are registered with CPMS and / or DMS. Within the South and West Devon Formulary clozapine is listed as a “hospital only drug” and is therefore prescribed by psychiatrists and dispensed by LSW and UHP pharmacies.

2. Overall aim of the policy

- 2.1 This policy aims to give the necessary information to allow Mental Health Staff to initiate and to continue to prescribe Clozapine safely, and to plan and monitor the patient’s ongoing care, which may involve their GP Practice.
- 2.2 It outlines the responsibilities of both Mental Health Staff and GP Practice staff for those patients that are to have blood samples taken and/or to collect their Clozapine supplies from their GP Practice and contains a formal agreement to be signed for each patient. It also aims to give the necessary information to GP Practice staff so that they are aware of the issues around Clozapine and are willing to take on this role.

3. Objectives that build toward the overall aim of the policy

- 3.1 To reduce risk to patients. To give adequate information and support to GP Practice staff.

4. Description of how you will measure its effectiveness

- 4.1 Monitoring of problems and errors via Clozapine Pharmacy Technician.
- 4.2 Feedback from GP Practice staff and Mental Health staff.

5. Workforce Planning Issues

- 5.1 GP practices will only take blood samples and handle medication for patients on 4-weekly blood monitoring. Therefore, mental health staff will remain responsible for blood samples and medication supplies for newly initiated patients until they have been on clozapine for at least twelve months. Mental health staff will also be responsible for patients who revert to weekly or 2-weekly blood samples as required by CPMS/DMS. This is a change from previous practice where mental health staff were responsible for blood samples and medication supplies for the first 18 weeks of treatment only.

- 5.2 GP Practice staff already deal with Clozapine on an informal basis and this policy has hopefully had a positive impact on the service they are already providing.

6. Clozapine General Information

6.1 Blood Monitoring Requirements (full blood count)

- 6.1.1 Clozapine patients must have their **WBC** (white blood cell count) and **ANC** (absolute neutrophil count) regularly monitored for the whole time they are taking Clozapine.

The frequency of monitoring is:

- One blood test within the 10 days prior to starting Clozapine
 - At least weekly for the first 18 weeks
 - At least every 2 weeks between weeks 18 and 52
 - At least every 4 weeks thereafter
 - Monitoring must continue during treatment and for at least 4 weeks after stopping
 - Frequency of monitoring may change following a treatment break or during treatment dependent on blood results – this will be advised by CPMS or DMS
- 6.1.2 The cost of monitoring the blood counts is factored into the price of Clozaril® tablets (or Denzapine® suspension). **Therefore, please ensure that CPMS (or DMS as appropriate) are used for this purpose.** The UHP combined labs should only be used in an emergency e.g. if insufficient time available until patient status goes RED (see section 14.2).
- 6.1.3 The patient can only receive medication if the blood results have been registered on the CPMS/DMS computer system and CPMS/DMS have approved the dispensing of further clozapine. Medication can only be dispensed for a specified number of days since the last blood test.

6.2 Clozapine Toxicity and Plasma Level Monitoring (MHRA Alert)

- 6.2.1 Clozapine dosages should be based on clinical presentation. Clozapine plasma levels may be beneficial in aiding the decision-making process around prescribing.
- 6.2.2 Plasma levels, if needed, can be requested via UHP Combined Laboratories or directly with KingsPath Laboratory. By requesting directly from UHP Combined Labs, the results will be available to view via System One.

N.B. Plasma levels are not processed locally; results can take days to return. If there are concerns about significant adverse effects from clozapine including toxicity, reducing or withholding clozapine should not wait for the results of serum levels. Action should be guided by the patient's clinical presentation.

- 6.2.3 Plasma level monitoring is not a substitute for assessing other adverse effects. For acutely

unwell patients, additional investigations should be completed as per patient presentation (e.g., if infection check FBC to rule out neutropenia, cardiovascular symptoms take BP, pulse, ECG etc.)

- 6.2.4 Information on drug interactions can be found in clinical guidelines for Clozapine and the online BNF.

7. Before Starting a Patient on Clozapine

- 7.1 There must a discussion between the patient/carers and healthcare professionals before starting clozapine, including the need for regular blood tests and potential adverse events. Obtain informed consent if capacitous or hold a best interest meeting if patient lacks capacity. For detained patients, ensure the relevant mental health act forms are in place.

Whilst not an absolute contraindication, prescribers should consider the risk of overdose. Significant fatalities have occurred even following non-intentional overdoses.

- 7.2 A full physical health check must be undertaken, including bloods and ECG. Discuss any physical health conditions/ concerns with CPMS pharmacists before proceeding. If a patient has been on clozapine before, contact the relevant monitoring service to ascertain if any contraindications to recommencing clozapine.
- 7.3 Inform the patient's GP. It is good practice for the GP Practice to include clozapine on the patient medication record for information and appropriate alerts.
- 7.4 Decide where and by whom ongoing blood tests will be taken. Note: Plymouth GP practices will only take blood samples for patients on 4-weekly blood monitoring.
- 7.5 Decide how the patient will receive continuing supplies of clozapine.
- 7.6 Decide which mental health team will monitor the patient during the first 12 months of treatment (see below). The patient should have a Care Co-ordinator (or someone responsible for co-ordinating their care) to ensure ongoing monitoring and support for the patient and any other agency involved.
- 7.7 Inform the Clozapine Pharmacy Technician (LSW pharmacy based at Glenbourne tel. 01752 439006 or internal 39006) of new patient details, including patient name, NHS number, prescriber, care co-ordinator, who will be taking bloods and delivery details.
- 7.8 For ward-based patients:
Liaise with ward pharmacist and Glenbourne pharmacy clozapine technician and arrange a date for the initial dose to be given. If a patient is on any other antipsychotics, these may need to be reduced prior to commencing clozapine. Once a date has been agreed, a full blood count must be done in the week preceding the start date and the patient must be registered with CPMS/DMS.

7.9 For community-based patients:

An MDT discussion will need to be undertaken to determine where the initial dose will be administered and how the hourly observations for the next 6 hours will be facilitated and who will be undertaking the next 2 weeks of monitoring. This may require a discussion with the HTT team or the relevant ward.

Liaise with pharmacist and Glenbourne pharmacy clozapine technician and arrange a date for the initial dose to be given. If a patient is on any other antipsychotics, these may need to be reduced prior to commencing clozapine. Once a date has been agreed, a full blood count must be done in the week preceding the start date and the patient must be registered with CPMS/DMS.

7.10 Registration:

If the GP Practice or another Mental Health Team will be involved in ongoing management and monitoring, then the decision to commence clozapine must be made with their full agreement and co-operation. A clozapine Agreement Form (see Appendix 5) must be completed for the involvement of a GP Practice.

There are two Integrated Care Pathways available on SystemOne:

ICPCL for the Initiation of Clozapine

ICPCLRT for the Re-Titration of Clozapine®

These can be located by creating a letter through the communications and letters function on SystemOne – both ICPs are available as letter templates (see Appendix 9 & 10).

If the Home Treatment Team (HTT) are to be involved in this process they must be contacted at the out-set (01752 314033 or internal 41033). There is a separate HTT Referral Process

8. Responsibility for blood monitoring and handling medication supplies

8.1 The first 12 months of treatment

- 8.1.1 The first 18 weeks of Clozapine treatment are the greatest risk for neutropenia and agranulocytosis (70% of cases), hence the weekly blood monitoring requirements. It is also the time when many of the other side-effects emerge and when non-adherence to treatment is likely to be greatest.
- 8.1.2 The following 34 weeks (i.e., until the patient has been on clozapine for 12 months) are also considered to be high risk for neutropenia and agranulocytosis and during this time 2-weekly blood monitoring is required.
- 8.1.3 For these reasons, **Mental Health Services should monitor patients closely during the first 12 months of treatment and will remain responsible for taking blood samples and handling supplies of medication.**

8.2 After the first 12 months of treatment

- 8.2.1 Patients will normally go on to 4-weekly blood monitoring. At this point the GP Practice can take over the blood sampling and take delivery of medication to issue to the patient.
- 8.2.2 If, at any point, the patient is required to revert to weekly or 2-weekly blood monitoring by CPMS/DMS (usually due to a reduction in WBC/ANC) responsibility for blood sampling and medication supplies will revert to Mental Health Services until the patient is back to 4-weekly blood monitoring. The clozapine technician will alert the prescriber who will take responsibility to ensure that the patient has blood tests taken and that the care of the patient reverts to the mental health team rather than the GP practice.

9. Information for Patients

- 9.1 All patients should be provided with a clozapine patient information leaflet which should be explained to them by a nurse, doctor, or pharmacist. These leaflets are available via <http://patient.info/medicine/clozapine-clozaril-denzapine-zaponex>
- 9.2 There is a DVD titled "A Journey into Light". These can be obtained from CPMS (tel. 0845 769 8269) or there may be copies available from the Clinical Pharmacy Team (tel. 01752 439006).
- 9.3 All patients should be offered the opportunity to meet with a specialist mental health pharmacist which can be arranged via the ward / unit or by calling the Clinical Pharmacy Team.

Remember that the patient may not be able to understand and retain information at the point of starting clozapine. It may be necessary to re-discuss the information once the patient is stable on clozapine.

10. Prescribing Clozapine

10.1 Writing Prescriptions

- 10.1.1 Clozapine can only be prescribed by doctors and dispensed by pharmacists who are registered with **CPMS (or DMS for suspension)**. Within the South and West Devon Formulary it is listed as a “hospital only drug” and can therefore only be prescribed by psychiatrists and within the Plymouth area only be dispensed by LSW pharmacy (areas outside of Plymouth, e.g., South Hams and West Devon, will be supplied by UHP Pharmacy).
- 10.1.2 When Clozapine treatment is first initiated the dose must be started low and gradually increased over 2 to 4 weeks to reduce the risk of side-effects. During this titration phase the prescription should be written using the **Standard Regimen for Inpatient Clozapine Titration** which is provided in Appendix 1 and should be completed in the titration section of the mental health in-patient prescription chart. The whole of the prescription chart must be emailed to LSW Pharmacy (livewell.clozapineservice@nhs.net) (01752 439006 or 39006 internal) for the attention of the clozapine technician **at least 24 hours before the first dose is due**.
- 10.1.3 Once a maintenance dose of clozapine is reached, the prescription should be written on either a mental health in-patient drug chart (for wards / units where these are used) or a **Clozapine Maintenance Prescription Form** (See Appendix 2). Prescription forms must be emailed to LSW Pharmacy (livewell.clozapineservice@nhs.net) by the end of the Tuesday of the dispensing week at the latest.
- 10.1.4 A **Clozapine Maintenance Prescription** is valid for a maximum of six dispensings (initial dispensing followed by five repeats). A new prescription must be written and emailed to LSW Pharmacy once this limit is reached.
- 10.1.5 If there is a change in the patient’s consultant/ team, an email needs to be sent to the LSW Pharmacy (livewell.clozapineservice@nhs.net) with all relevant information and updates. The clozapine technician will update local systems and CPMS database. The new Maintenance prescription should reflect the new details and forwarded to clozapine services.
- 10.1.5 If any alerts arrive, Glenbourne clozapine service should email the named consultant, team manager and the relevant medical secretaries.

10.2 Dose / initiating clozapine - Treatment resistant schizophrenia

- 10.2.1 In-patients (see appendix 1):** Start with 12.5mg given once on the first day, then increase slowly in increments of 25 to 50 mg to a dose of up to 300 mg/day within 2 to 3 weeks. Thereafter, if required, the daily dose may be increased in increments of 50 to 100 mg at half-weekly or, preferably, weekly intervals. In most patients, antipsychotic efficacy can be expected with 200 to 450 mg/day given in divided doses.
- 10.2.2 Outpatient Initiation:** a slower titration dose to that normally used for in-patient initiation should be used. The dosing schedule should be tailored to the individual circumstances, to include first dose with 6 x hourly monitoring, then the patient to be seen twice daily.

Dosage increases should not be made at weekends unless there is the same service support as on weekdays. A once daily dose may be used for the first week, changing to twice daily in the second week if this is preferable. The patient must be seen twice a day during the titration phase. Patients do not need to be seen at weekends if there are no changes to the dose.

10.2.3 The following are suggested target doses following the initial titration:

Female non-smokers: 250mg /day
Female smokers: 450mg / day
Male non-smokers: 350mg / day
Male smokers: 550mg / day

10.2.4 There is substantial individual variation, and the dose should be guided based on response and side-effects.

10.2.5 To obtain full therapeutic benefit, a few patients may require larger doses (the maximum dose 900 mg/day).

10.2.6 The total daily dose should be given as two divided doses, with a larger proportion in the evening if sedation is a problem.

10.2.7 Daily doses of up to 200mg may be given once a day in the evening.

10.3 Use in the elderly:

Start with 12.5 mg given once on the first day, with subsequent dose increments restricted to 25 mg/day.

11. Monitoring of Physical Health

11.1 During initiation the following physical observations should be made:

- Blood pressure lying down
- Blood pressure standing up
- Pulse
- Temperature

11.2 Frequency

- 1st day of clozapine treatment: Before administering the first dose and then hourly for 6 hours following the first dose check:
- Days 2-14 of clozapine titration check twice a day:
- Day 14 onwards check on alternate days until stable dose reached
- Subsequently at time of blood monitoring

11.3 A doctor should be informed and advice sought if the following are observed:

- Postural drop of >30mm/Hg
- Pulse >100bpm
- Temperature >38°C
- Over-sedation
- Other intolerable adverse effects

11.4 **The following monitoring is also recommended (after baseline measurements):**

- Weight, BMI and waist circumference, lipids and glucose: baseline, then 3 monthly for 1st year, then yearly thereafter.
- Hyperglycaemia should be managed but where the active medical management of this fails discontinuation of clozapine should be considered.
- Liver function tests: baseline, 4-6months, 12 months. If LFTs rise to >3 time the upper limit of normal, then clozapine should be stopped, and clozapine only restarted once LFTs are normal. In such cases LFTs should be closely monitored.

12. Treatment Breaks or Stopping Clozapine

12.1 If, at any point during their treatment, there is a treatment break for longer than 48 hours, the Clozapine must be re-introduced at a lower dose and gradually increased back to the treatment dose. **The patient must not re-start their Clozapine at the previous dose.**

12.2 Mental Health Services must inform:

- the Clozapine Technician (by telephone)
- CPMS (or DMS for suspension)
- GP Practice (if involved).

12.3 **Table of dosing and monitoring following treatment breaks²**

Note: The table below is taken from CPMS' website. For patients using DMS the advice differs slightly.

* Start at 12.5mg once or twice on the first day. May be possible to re-titrate at faster rate than initial titration.

Assessment Guidelines for Missed Doses

The following tables summaries information from the Summary of Product Characteristics for Clozaril® (clozapine) and CPMS processes on re-starting therapy after various periods of discontinuation of therapy:

Patients on Weekly Monitoring

Off treatment for less than two days

- No change to monitoring frequency
- Continue at usual prescribed dose

Off treatment for more than two days but less than 7 days

- No change to monitoring frequency
- Re-titrate patient starting from 12.5mg ONCE or TWICE on the first day
- Contact CPMS for advice if necessary

Off treatment for 7 days or more but less than 28 days

- Restart 18 weeks of weekly monitoring
- Re-titrate patient starting from 12.5mg ONCE or TWICE on the first day
- CPMS **MUST** be contacted

Off treatment for more than 28 days

- Restart 18 weeks of weekly monitoring
- Re-titrate patient starting from 12.5mg ONCE or TWICE on the first day
- New patient registration form required
- CPMS **MUST** be contacted

Patient on Fortnightly or 4 Weekly Monitoring

Off treatment for less than two days

- No change to monitoring frequency
- Continue at usual prescribed dose

Off treatment for more than two days but less than 3 days

- No change to monitoring frequency
- Re-titrate patient starting from 12.5mg ONCE or TWICE on the first day
- Contact CPMS for advice if necessary

Off treatment for more than 3 days but less than 28 days

- 'Treatment Break' scenario
- Patient must complete 6 weeks of weekly blood tests, then revert back to previous monitoring frequency
- Re-titrate patient starting from 12.5mg ONCE or TWICE on the first day
- CPMS **MUST** be contacted

Off treatment for more than 28 days

- Restart 18 weeks of weekly monitoring
- Re-titrate patient starting from 12.5mg ONCE or TWICE on the first day
- New patient registration form required
- CPMS **MUST** be contacted

The full Summary of Product Characteristic (SmPC) guidelines for Clozaril® (Clozapine) can be view at www.medicines.org.uk/emc/ (UK) or www.medicines.ie (Ireland).

As per section 4.2 of the SmPC for Clozaril®: In patients in whom the interval since the last dose of Clozaril exceeds 2 days, treatment should be re-initiated with 12.5 mg given once or twice on the first day. If this dose is well tolerated, it may be feasible to titrate the dose to the therapeutic level more quickly than is recommended for initial treatment. However, in any patient who has previously experienced respiratory or cardiac arrest with initial dosing but was then able to be successfully titrated to a therapeutic dose, re-titration should be carried out with extreme caution.

12.4 Re-titration

Clozapine re-titration requires regular monitoring and for community patients, HTT or SORT must be contacted before re-initiation.

12.5 Stopping Clozapine

Except where the urgent cessation of clozapine is required (see above), it is recommended that clozapine is gradually withdrawn (slow taper down over 3 weeks) to reduce the risk of withdrawal reactions (e.g., recurrence of psychotic symptoms and cholinergic rebound)⁵. CPMS and Glenbourne Clozapine service will need to be informed of any cessation or planned cessation of clozapine as soon as feasibly possible.

In all cases where clozapine is stopped, further blood samples will need to be taken as advised by CPMS.

13. Taking Full Blood Count Samples

- 13.1 Blood sampling equipment is provided by CPMS/DMS (including pre-paid PURPLE envelopes for posting blood samples directly to CPMS / DMS). The cost for this service is included in the contract price for Clozaril® / Denzapine® and should be used under normal circumstances. Equipment can be ordered on the CPMS website (see appendix 9) or by contacting CPMS/DMS directly (for CPMS call 0845 769 82 69 option 4).
- 13.2 In an emergency (i.e., if the blood sample will not reach CPMS / DMS in time by first class post) or under other circumstances (after discussion with the Clozapine Pharmacy Technician) blood samples can be sent to UHP Combined Labs but this will incur the usual charge and will increase pharmacy time in chasing-up the results. **The Clozapine Pharmacy Technician must be informed if the blood sample has been sent to UHP Combined Labs.** The clozapine technician will need to check the UHP combined labs results system and enter the full blood count results into the CPMS / DMS system.
- 13.3 If the GP Practice has agreed to take blood samples, their details will be registered with CPMS/DMS by the care co-ordinator. They will then receive an Information Pack and blood sampling equipment (including pre-paid envelopes for posting blood samples to CPMS /DMS). The GP Practice will be able to order further blood sampling supplies via the CPMS/DMS website. See Appendix 7
- 13.4 The GP Practice will also be alerted if a RED blood result is received (in addition to the Psychiatrist and Clozapine Pharmacy Technician). It is the responsibility of the Psychiatrist to take the appropriate action necessary following a red blood result.
- 13.5 CPMS / DMS will advise both the prescriber and the Clozapine Pharmacy Technician when monitoring frequency changes. The prescriber should inform the Care Co-ordinator (or designated person), and the GP Practice if involved.

13.6 Blood samples should be taken according to the following schedule:

NB: GP Practice staff should not be expected to take blood samples at weekends

Frequency of blood monitoring	Weekly	2 weekly		4 weekly			
Week of cycle:	Weeks 1-4	Week 1	Week 2	Week 1	Week 2	Week 3	Week 4
Sunday							
Monday							
Tuesday	Blood sample taken		Blood sample taken			Blood sample taken	
Wednesdays and Thursdays	Deliver one week's supply of medication		Deliver two weeks' supply of medication				Deliver four weeks' supply of medication
Friday / Saturday	Start new supply of medication		Start new supply of medication				Start new supply of medication

14. Notification from CPMS / DMS of late/missed blood test or amber/red alert

- 14.1 If a blood test is not registered on the CPMS / DMS system by the due date, CPMS / DMS will email an "Overdue Notification" to the consultant registered with CPMS for that patient, LSW Pharmacy and the patient's GP (if they are registered as the blood sampling site with CPMS / DMS). The email will inform them of the last date on which the patient can take Clozapine unless a blood test result is sent to CPMS.
- 14.2 If a blood test is still not registered on the CPMS / DMS system then a "Clozapine Prohibited" notice will be emailed on the last day that the patient is allowed to take Clozapine.
- 14.3 If the blood sample is sent to UHP Combined Labs instead of CPMS / DMS, the Clozapine Pharmacy Technician must look for the test result and manually enter the result on the CPMS/DMS system. The consultant should therefore check with the Clozapine Pharmacy Technician before acting on an alert.
- 14.4 If an amber or red test result is registered on the CPMS / DMS system, an alert will be emailed to the consultant registered with CPMS /DMS for that patient, LSW Pharmacy (liveswell.clozapineservice@nhs.net) and the patient's GP (if they are registered as the blood sampling site with CPMS /DMS). The email will inform the consultant of the action to be taken and the consultant must act immediately on this information.
- 14.5 It is very important that CPMS/DMS have the correct information registered for each patient so that the emails are sent to the correct person.

- 14.6 Red alert procedure:
For all red results, contact CPMS/DMS for advice regarding ongoing management.

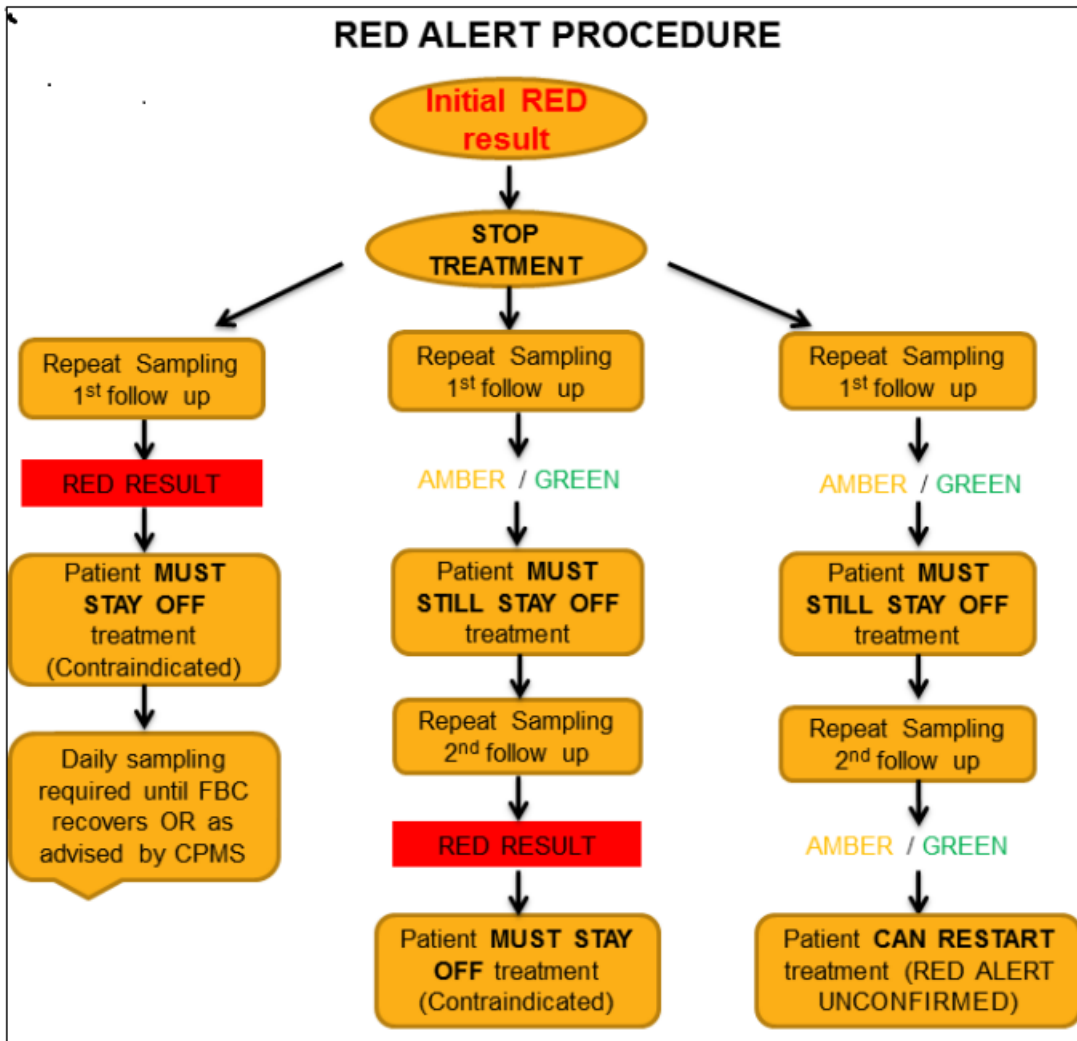


Figure 1: A flow diagram summarising the red results procedure ⁶

15. Dispensing Clozapine

- 15.1 All Clozapine supplies for patients in Plymouth (under LSW mental health services) are dispensed by LSW pharmacy based at the Glenbourne unit. Patients falling under other mental health services in the area (e.g., South Hams and West Devon) will be supplied via UHP pharmacy.
- 15.2 The LSW pharmacy clozapine service is available Monday – Friday 9am-5pm, outside of these hours emergency supplies will be provided by UHP pharmacy who can be contacted via UHP switchboard.
- 15.3 Supplies are issued on Wednesdays and Thursday (unless as agreed by prior arrangement with the Clozapine Pharmacy Technician) and are for a duration of one, two or four weeks corresponding to the blood monitoring frequency for the patient.

- 15.4 The patient can only receive medication if they have a current Green or Amber blood result registered on the CPMS or DMS computer system. **This blood result must be available to the Clozapine Pharmacy Technician by the Wednesday before the medication is due at the very latest.** It is therefore extremely important that the blood test is taken in plenty of time taking account of the maximum validity (See Section 15.3). If there is going to be a problem obtaining a blood result in time, the patient's Care Co-ordinator (or designated person) or Psychiatrist must be contacted for advice.
- 15.5 In general clozapine will be supplied as 25mg and 100mg tablets. If a liquid is required this will be obtained as Denzapine® suspension 50mg / ml, this product is supplied with 1ml and 10ml oral syringes (1ml syringe for doses of 50mg or less, 10ml syringe for higher doses). The patient and prescriber will need to be registered with DMS.
- 15.6 Clozapine tablets will normally be dispensed in cartons. If a compliance aid is required, then pharmacy should be contacted to discuss the most suitable options. Most patients will be supplied with a sealed Venalink® blister pack.
- 15.7 For patients using Medidose boxes, empty devices can be sent back to LSW Pharmacy for re-filling via the internal post (N.B. they must be empty of all medication). If the Medidose is not returned or not returned in a reusable condition, the unit/team will be charged for a new Medidose.

16. Control of Clozapine Supplies

- 16.1 Appropriate guidelines and monitoring need to be followed when prescribing, dispensing, administering or consuming clozapine in order to minimise any associated risks. There is a particular risk:
- In clozapine-naive persons
 - When taken in a standard dose following a treatment break of longer than 48 hours
 - When taken by a person with low WBC or ANC
 - If taken in overdose
- 16.2 **Clozapine supplies must only be used for the person for whom they have been dispensed.** In addition, they must only be used by that person during the treatment period for which they have been dispensed (unless otherwise directed by the Clozapine Pharmacy Technician).
- 16.3 **If there is any medication left unused at the end of a treatment period, or any excess medication found (e.g., at a patient's home, on an inpatient unit, at a GP Practice etc.) it must be returned to the Clozapine Pharmacy Technician for disposal. This is to reduce the risk of misuse or overdose.**
- 16.4 If a patient is short of medication the Clozapine Pharmacy Technician must be contacted for advice.

17. Change of Patient Details

- 17.1 It is very important that both CPMS/DMS and the Clozapine Pharmacy Technician are informed if a patient changes any of their personal details or changes Consultant, GP, Care Co-ordinator (or designated person) or Mental Health Team. This includes discharge from, or transfer between, a ward or inpatient unit. When appropriate a new clozapine maintenance prescription must be written (see section 10).
- 17.2 If the patient has been having blood tests or collecting medication from their GP Practice the Care Co-ordinator (or designated person) must be informed if the patient transfers to a new Practice. This is the responsibility of both the current Practice and the new Practice as it is not always a planned process. The Care Co-ordinator (or designated person) should inform all necessary persons (see above) of the change.
- 17.3 The patient should also be made aware of the need to inform their Care Co-ordinator (or designated person) if they change any of their personal details or move to a new GP Practice.

18. RAPA (Recurring Admission Patient Alert)

- 18.1 RAPA is a system set up to inform clinicians when a patient has been admitted to a general hospital (UHP), who are taking medication that is detrimental if changed, omitted or stopped.
- 18.2 The alerts are set up on SALUS and patients on clozapine are added to the alert.
- 18.3 When a patient attends ED or a ward, the RAPA alert automatically sends an email to the generic email attached to the alert, thereby informing the relevant teams.

19. Glossary

ANC	Absolute Neutrophil Count
BMI	Body Mass Index (weight in kg / height in metres squared)
BNF	British National Formulary
CPMS	Clozapine Patient Monitoring Service – provides mandatory monitoring for patients prescribed Clozapine tablets
CYP1A2	Cytochrome P450 enzyme mainly responsible for metabolising clozapine in the liver.
DMS	Denzapine Monitoring Service – mandatory monitoring for patients prescribed clozapine suspension.
HTT	Home Treatment Team
ICP	Integrated Care Pathway
LSW	Livewell Southwest
QTc interval	The corrected QT interval in the electrocardiogram. When extended in carries a risk of ventricular arrhythmias and torsades de pointes
SPC	Summary of Product Characteristics. Contains prescribing and safety information for each licensed drug. Produced by the drug manufacturer. Available online at medicines.org.uk
WBC	White Blood cell Count

All policies are required to be electronically signed by the Lead Director. Proof of the electronic signature is stored in the policies database.

The Lead Director approves this document and any attached appendices. For operational policies this will be the Locality Manager.

The Executive signature is subject to the understanding that the policy owner has followed the organisation process for policy Ratification.

Signed:

Date:

Suggested Regimen for Clozapine Titration

CLOZAPINE ORAL TABLETS / ORAL SUSPENSION (50mg / ml)*

Week No. 1	Time	Dose	mls susp	Week No.2	Time	Dose	mls susp
Day 1	0800	12.5mg	0.25	Day 1	0800	75mg	1.5
	(Test dose)				2200	100mg	2.0
Day 2	0800	12.5mg	0.25	Day 2	0800	100mg	2.0
	2200	12.5mg	0.25		2200	100mg	2.0
Day 3	0800	25mg	0.5	Day 3	0800	100mg	2.0
	2200	25mg	0.5		2200	125mg	2.5
Day 4	0800	25mg	0.5	Day 4	0800	100mg	2.0
	2200	50mg	1.0		2200	150mg	3.0
Day 5	0800	50mg	1.0	Day 5	0800	100mg	2.0
	2200	50mg	1.0		2200	175mg	3.5
Day 6	0800	50mg	1.0	Day 6	0800	100mg	2.0
	2200	75mg	1.5		2200	200mg	4.0
Day 7	0800	50mg	1.0	Day 7	0800	100mg	2.0
	2200	100mg	2.0		2200	200mg	4.0

The prescribing clinician should decide on the target clozapine dose and amend the above titration accordingly before commencing. The titration may need to be slowed depending on side effects and patient response. Please note that if the target dose is higher than 300mg total daily dose, then subsequent increases of 50-100mg should be made weekly.

*Clozapine suspension (Denzapine®) is presented as 50mg / ml (12.5mg / 0.25ml) suspension in 100ml bottles. A 1ml and a 10ml oral syringe are provided. For doses up to and including 50mg the 1ml syringe should be used. For doses over 50mg the 10.0ml syringe should be used.

Complete the Clozapine initiation page contained within the mental health prescription chart. Send or email ([emailed to livewell.clozapineservice@nhs.net](mailto:livewell.clozapineservice@nhs.net)) the whole of the prescription chart to LSW Pharmacy 01752 439006 (internal 39006).

Appendix 2

Maintenance Clozapine Prescription

Name..... Address..... NHS No.....DoB CPMS / DMS No..... Care Co-ordinator, or lead professional..... Mental Health Team:..... Consultant.....	Dispensing week (pharmacy to complete): <hr/> Monitoring Frequency (please circle): Weekly / 2-weekly / 4-weekly <hr/> Compliance aid required (please circle): <p style="text-align: center;">Medidose / Venalink / No</p> (For new patients requiring a compliance aid please contact the pharmacy clozapine team (4)39006 to discuss requirements) <hr/> Delivery Location:
Drug allergies and sensitivities:	PLEASE SUPPLY A NEW PRESCRIPTION WHEN DOSE(S)/DRUGS CHANGE. SEND PRESCRIPTION TO GLENBOURNE PHARMACY AND SCAN A COPY ONTO PATIENT'S ELECTRONIC RECORD. ALL PRESCRIPTIONS ARE VALID FOR 6 DISPENSINGS

Code	Drug Name	Tablets/ susp	Dose	Frequency (times if compliance aid)	Duration (if appropriate)	Prescriber's Initials
A	CLOZAPINE					
B	CLOZAPINE					
C						
D						
E						
F						
G						

Prescriber's Signature **Date**..... **Unit**.....
Print Name..... **Contact Number**

Pharmacy Use:

1st Disp. Date..... Quantity: Disp. by: Check by:	2nd Disp. Date..... Quantity: Disp. by: Check by:	3 rd Disp. Date..... Quantity: Disp. by: Check by:
4th Disp. Date..... Quantity: Disp. by: Check by:	5th Disp. Date..... Quantity: Disp. by: Check by:	6th Disp. Date..... Quantity: Disp. by: Check by:

Team Address

GP Practice Address

Dear

Re: Patient name
 Date of Birth NHS Number

The above patient, who is registered with your Practice, is to be started on treatment with the antipsychotic clozapine which requires regular blood monitoring for white blood cell count and absolute neutrophil count.

Once he/she is on 4-weekly blood monitoring (minimum 12 months after starting treatment) they would find it helpful to be able to attend your GP Practice for the following:

a. ***To have regular blood samples taken:** the samples will be sent directly to CPMS/DMS. Your Practice will be registered with CPMS/DMS and you will be able to order equipment and pre-paid envelopes via their websites. Your practice will need to register for payment for taking the blood samples

b. ***To collect their clozapine supplies:** clozapine dispensed for the patient will be sent to your Practice from LSW Pharmacy every 4 weeks.

***Delete as applicable**

If the patient reverts to more frequent blood monitoring, Mental Health Services will take over responsibility for blood tests and medication until the patient is back to 4-weekly blood tests.

We are writing to request whether you would be happy to be involved in this way. We have enclosed information on clozapine, a Clozapine Agreement Form and two flow diagrams detailing the process. The current LSW Clozapine Policy can be accessed via the LSW Website.

If you are happy to be involved please would you complete the Agreement Form and return it to the address above.

The following people can be contacted if you wish to discuss this or have any concerns:

Psychiatrist		Tel.
Care Co-ordinator (or Lead Professional)		Tel.

Yours faithfully,

Information on Clozapine Blood Monitoring and Issue of Medication for GP Practice Staff

Clozapine is an atypical antipsychotic that was first introduced in the 1960's. It has been shown to be **very effective** for schizophrenia, including that unresponsive to other antipsychotics, but was withdrawn from the UK market in the 1970's following fatal cases of agranulocytosis. It was re-introduced in the late 1980's but can only be used under the following conditions:

- Prescribed only for treatment resistant schizophrenia (or psychotic disorders occurring during the course of Parkinson's disease), in cases where standard treatment has failed
- Patients must be registered with the Clozaril Patient Monitoring Service (CPMS) or, for suspension, the Denzapine® Monitoring Service (DMS).
- Patients must have regular monitoring of white blood cell count and absolute neutrophil count at designated frequencies
- Prescribers and dispensing pharmacists must be registered with CPMS/DMS (**within Plymouth Area this means prescribed by psychiatrists and dispensed by LSW pharmacy** – GPs will not be able to prescribe clozapine)

Mental Health Services in Plymouth are keen to make clozapine as accessible to patients as possible. For some patients allowing them to attend their GP Practice for blood tests and/or for collecting their clozapine supplies can have a positive effect on the patient's compliance with treatment.

However, there are risks to taking clozapine and it is important that GP Practice staff are aware of these risks and are willing, and adequately supported, to take on this role. With this in mind the following conditions have been imposed:

- GP Practice staff must only be involved with their prior agreement and an **Agreement Form** must be completed for each patient detailing roles and responsibilities of both GP Practice Staff and Mental Health Staff
- The patient should have a named Care Co-ordinator, or Lead Professional, whom the GP Practice can contact to discuss any concerns. Names and contact details of mental health staff will be included on the GP Agreement Form
- Patients will only be allowed to have their blood tests taken at the GP Practice, or collect their clozapine supplies from the Practice when they are on a 4-weekly blood schedule.
- If the patient has to revert to more frequent blood monitoring, Mental Health Services will take over responsibility for blood tests and medication until the patient is back to 4-weekly blood tests
- GP Practice Staff must follow the procedures for blood monitoring and collection of clozapine supplies (see Clozapine Policy for Mental Health Staff and GP Practice Staff)
- GP Practice staff must inform the Care Co-ordinator (or Lead Professional) if there are concerns with the patient or the patient does not collect their clozapine

The full version of the LSW "Clozapine Policy for Mental Health Staff and GP Practice Staff" is available on the Livewell Southwest Website and on LSWnet (under Policies and Procedures)

Clozapine Agreement Form between Mental Health Services and GP Practice Staff

Patient Details (or use patient label)

GP Practice Details

Patient Name	Practice Name
Address	Address
.....
DoB	Tel No.
NHS Number	GP
CPMS/DMS Number:	Practice Manager

Roles and Responsibilities of GP Practice Staff

GP Practice Staff agree to undertake the following:

Taking Blood Samples YES / NO Start Date	Only when the patient is on 4-weekly blood monitoring. <ul style="list-style-type: none"> • Arranging appointments with the patient • Taking blood samples in a timely manner and sending to CPMS/DMS using the equipment provided • Re-ordering CPMS/DMS equipment as needed • Alerting the Care Co-ordinator (or designated person) if the patient does not attend for a blood test within the designated time scale (See Section 13 in main body of policy for information on blood tests)
Issuing clozapine Supplies to patient YES / NO Start Date	Only when the patient is on 4-weekly blood monitoring. <ul style="list-style-type: none"> • Accepting delivery of the patient's clozapine supplies from LSW pharmacy • Storing the medication in a secure place (preferably a locked cupboard) while waiting collection by the patient • Issuing each supply to the patient for the corresponding treatment period only (as stated on the pack) • Alerting the Care Co-ordinator (or Lead Professional) if the patient does not collect the clozapine supply during the treatment period • Returning uncollected supplies to the Clozapine Pharmacy Technician (telephone first)
Other responsibilities	<ul style="list-style-type: none"> • It is good practice to include clozapine on the patient medication record for information and appropriate alerts. • Inform the Care Co-ordinator (or Lead professional) if the patient transfers to another GP Practice

Issuing Clozapine Supplies to the Patient

Clozapine supplies will be received in a brown bag, labelled as below:

Patient Initials & DoB..... GP ADDRESS Issue Date..... IF UNCOLLECTED FOR 7 DAYS CONTACT GLENBOURNE
--

The supply must only be issued to the patient during the time stated on the bag label. If the supply has not been collected contact Glenbourne Pharmacy as a matter of urgency. They will contact the Care Co-ordinator (or Lead Professional) who will advise on the action to be taken.

Patient Name	NHS Number	CPMS / DMS Number
---------------------	-------------------	--------------------------

Responsibilities of Mental Health Staff

	Responsibility
Psychiatrist Name Team Contact number	Registration of self and patient with CPMS / DMS. Arranging initial blood test and physical check (including ECG). Liaising with patient and GP Practice concerning any blood frequency changes. Taking appropriate action on red or amber blood results. Taking action on information from CPMS/DMS concerning overdue blood tests. Prescribing clozapine. Prescribing any dose changes and letting relevant people know. Monitoring patient's mental health. Updating patient information with CPMS/DMS and the Clozapine Pharmacy Technician
Care Co-ordinator or Lead Professional Name Team Contact number	Monitoring patient's mental health. Arranging blood samples and supply of clozapine to the patient during the first 12 months of treatment and any time the patient is not on 4-weekly monitoring. Liaising with GP practice to ensure patient's compliance with medication and arrangements for blood tests and collecting medication. Collecting unused clozapine supplies from patient's home and arranging return to pharmacy. Informing the Clozapine Pharmacy Technician and psychiatrist if the patient stops taking their medication. Informing the GP Practice and Clozapine Pharmacy Technician if there is a change of Care Co-ordinator (or Lead Professional) or psychiatrist
Clozapine Pharmacy Team Contact number 01752 439006	Checking blood status on CPMS/DMS. Informing Care Co-ordinator (or Lead Professional) or GP Practice if blood test is overdue or extra tests are required. Dispensing clozapine and arranging delivery to GP Practice. Liaising with GP practice and mental health staff. Arranging destruction of returned clozapine. Advice and support to Mental Health Staff and GP Practice staff as required.
UHP Pharmacy On call service Contact via UHP switchboard.	Emergency contact out of hours (evenings or weekends) for urgent clinical or supply queries.

Support for GP Practice Staff

GP Practice Staff can contact any of the staff detailed above for help and advice on clozapine.

Signed on behalf of GP Practice
(by Clinical Governance or Prescribing Lead)

Signed..... Date.....
Name.....
Designation.....

Signed on behalf of Mental Health Services
(by psychiatrist or Care Co-ordinator)

Signed..... Date.....
Name.....
Designation.....

Once completed, the document should be scanned onto the patient's SystmOne record. The original copy should be kept by the GP Practice and a copy emailed to the Clozapine Pharmacy Technician



Care co-ordinator/Lead Professional or Clozapine Technician will advise GP Practice of date next blood test is due. Blood test to be taken on this date and then every 4 weeks

GP Practice arranges appointment with patient
(with assistance from care co-ordinator/Lead Professional if required)

Patient attends appointment

YES
FBC sample taken and posted to CPMS/DMS using equipment and envelopes supplied

Practice arranges next appointment with patient

NO
Clozapine Technician notes need for blood test and contacts care co-ordinator/Lead Professional to arrange blood test to be taken urgently

Care co-ordinator/Lead Professional arranges urgent blood test at GP Practice or via other means (i.e. mental health team or UHP)

If patient refuses blood test, care co-ordinator/Lead Professional to arrange urgent review and advise GP of situation

Blood sample sent to CPMS/DMS (or to UHP if outside sampling schedule – Clozapine Technician informed)

NB: an interim supply of medication may need to be issued until blood result received on CPMS/DMS

Practice arranges next appointment with patient

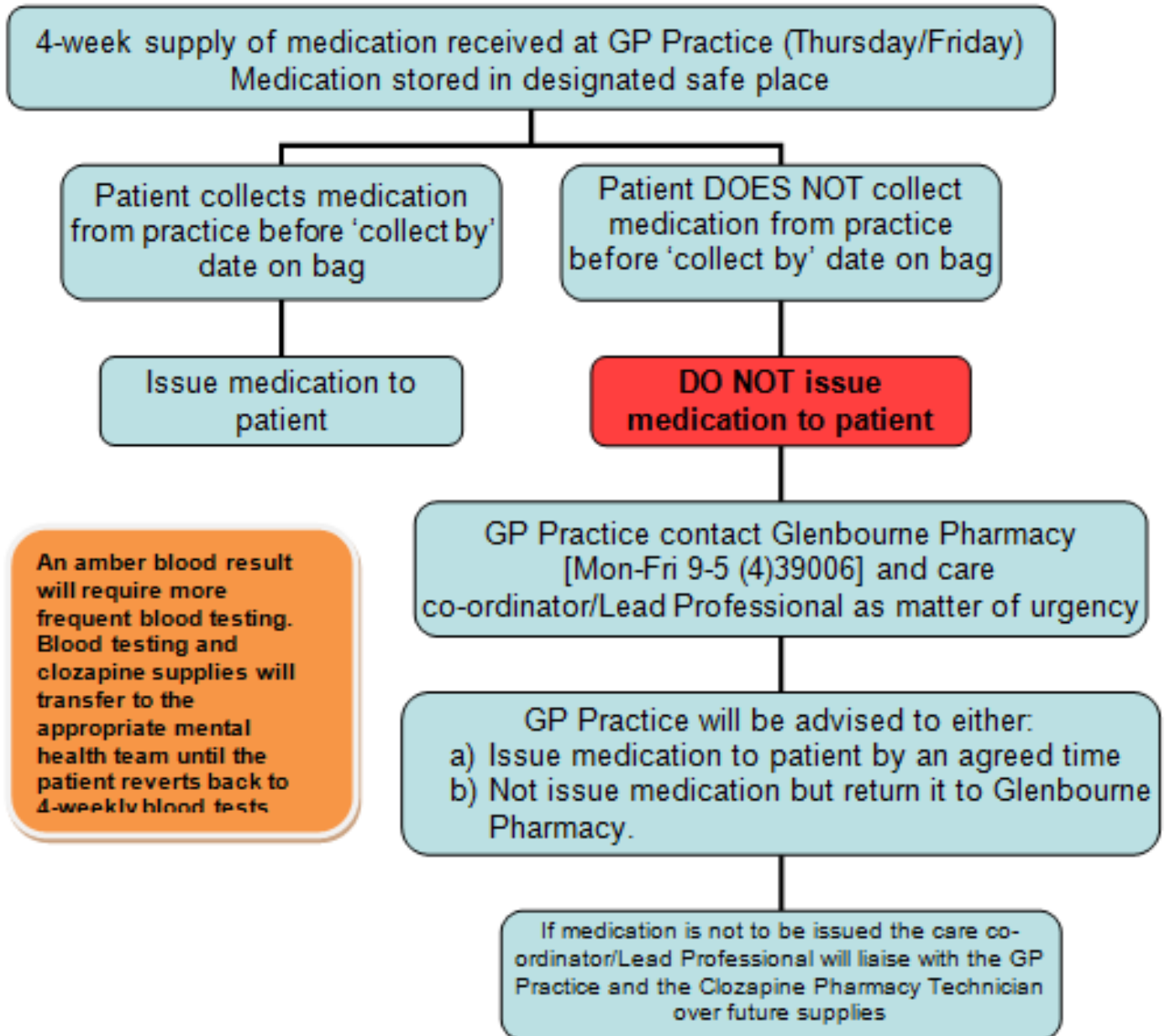
An amber blood result will require more frequent blood testing. Blood testing and clozapine supplies will transfer to the appropriate mental health team until the patient reverts back to

Contact Numbers
CPMS 0845 7 69 8269
DMS 0333 200 4141
UHP Combined Labs
01752 792401 (internal 52401)
Clozapine Pharmacy Technician (Glenbourne Pharmacy) 01752 439006 (internal 39006)
See Clozapine Agreement for contact details of individual mental health teams / staff

Appendix 7.

GP Clozapine supplies for patients

GP Clozapine Supplies for Patients



The bag of medication will be labelled:

Patient Initials & DoB.....
GP ADDRESS
Issue Date..... IF UNCOLLECTED FOR 7 DAYS CONTACT GLENBOURNE

<p>It is dangerous for a patient who misses their clozapine dose for more than 48 hours to continue on their current dose. In these circumstances the care co-ordinator/Lead Professional will contact the psychiatrist to arrange a review of the patient.</p>

Appendix 8.

How to order non-drug supplies from CPMS.

How to Order Non-drug Supplies



Log in to eCPMS and click Supplies on the Homepage, or go directly to www.cool-cpms.com



You are directed to the CPMS Non-Drug Supplies Order website where you can order blood taking kits and documents.

Welcome to the CPMS Non-Drug Supplies Online Order System. Please Enter your Login details :

Enter your eCPMS User ID and postcode of the delivery address on the login page.

User Id:

City / Post Code:

If ordering from a site in Ireland enter 'Ireland'

Click Sign In.

Select Centre from the drop down menu and click Order Entry.
Tip: Details of any orders from the previous 2 months are displayed on this page

CentreName:

TEST CENTRE - MYLAN
TEST CENTRE 2011

Centre Details

Centre Name: TEST CENTRE - MYLAN
Address: Frimley Business Park

Previous 2 months Order Details

Select Ward Name from the drop down menu and enter a contact name.
 You can add a new ward or department by clicking ADD NEW WARD, and completing the form which appears.
 Click Order

Centr-ID: 500549 Ward Name: Contact Name:

2
Test Centre
Test Orders Ward
ADD NEW WARD

Centre Name: TEST CENTRE
Address: Frimley Business Park

Previous 2 months Order Details

In the Select Group drop down menu, click KITS to order blood sampling kits or DOCS to order barcode labels and other documents.

Order Entry Form

Centre Name: TEST CENTRE - MYLAN
WardName: Test Centre
GroupCode: Contact Person: Xx

Item Code: Item Name: Unit: Qty:

Avl Quota: 0

The order entry form is displayed.
 Enter the quantity of the required item in the Qty box.
 Click continue to return the Order Entry Form to select KITS or DOCS again.
 When order is complete click Check Out.

Tip: Each centre has a quota for kits. If an "Avl quota" is not displayed or is insufficient for your centre, contact CPMS to update.

Order Entry Form

Centre Name: TEST CENTRE - MYLAN
WardName: Test Centre
GroupCode: Contact Person: Xx
Blood Monitoring Kits

Item Code	Image	Item Name	Unit	Qty
KTBLACK	Click Here	A FULL KIT - BLACK NEEDLE	1	
KTGREEN	Click Here	A FULL KIT - GREEN NEEDLE KIT	1	
KTMULTI	Click Here	A FULL KIT - MULTIPLY NEEDLE	1	
KTNOBAG	Click Here	A PARTIAL KIT - No Flex or Env	1	
KTBNED	Click Here	Black needle only	1	
KTCLAM	Click Here	CLAMSHHELL	1	
KTGNED	Click Here	Green needle only	1	
KTTFLEX1	Click Here	Lilac Flexible Envelope	1	
KTEDTA27	Click Here	Sample Tube Only 3ml - Standard	1	

Avl Quota: 0

To order barcode labels, on the DOCS page enter the number of patients for whom you require labels in the Qty box and click Check Out. A dialogue box appears. Enter the CPMS Numbers and click OK.
TIP: your browser pop-up blocker must be disabled in order to view this dialogue box.

LIST OF PATIENTS FOR ITEM BARCODE

Sl No	Patient No
1	<input type="text"/>
2	<input type="text"/>
3	<input type="text"/>
4	<input type="text"/>

Once Check Out is clicked you can view a summary of your order. Enter any shipping details or remarks and click Confirm to complete your order.

Order Details

Contact Person: Xx
Centre: TEST CENTRE - MYLAN
Address: Frimley Business Park, GU16 7SR

ItemNumber	Item Name	Qty
CPMS6	Haematology Request Pad	1
ASSAY	Plasma Assay Guidelines and Forms	10

Shipping Details

General Remarks

eCPMS QUICK GUIDE - ORDERING SUPPLIES

Issue 3 10 April 2017



ICP for the Initiation of Clozapine
(See Clozapine Policy for Mental Health Staff and GP Practice Staff)

Patient's Name		GP Name:	
Date of Birth:		Telephone No:	
Address:		GP Address:	
Telephone No:		Care Co-ordinator:	
Mobile No:		Telephone No:	
NHS No:		Social Services No:	
Hospital No:		CPMS/DMS No:	

Each Section of the ICP to be completed by the Clinician who performs the relevant action. If a variance (something different from standard detailed) occurs tick the column against the statement and record in the tabbed journal on SystemOne what the variance was and the action taken.

Var = Variance

CPMS= Clozaril Patient Monitoring Service

DMS= Denzapine Monitoring Service

Ref	Interventions	Date / Time	Signed	Var																																								
1.0	Pre administration actions (responsibility of Consultant Psychiatrist or Deputy)																																											
1.1	<input type="checkbox"/> Determine that it is appropriate for Patient to take Clozapine (see detail in Clozapine policy). Any queries or concerns must be discussed with CPMS/DMS <input type="checkbox"/> Check for contra indications (see Organisation Clozapine Policy , Clozapine/Denzapine SmPC or current edition of BNF) <input type="checkbox"/> Contact CPMS/DMS if necessary Sign and date when determination completed satisfactorily																																											
1.2	<input type="checkbox"/> Physical examination completed satisfactorily by the Doctor including :- <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th>Investigation</th> <th>Result seen</th> <th>Action req'd</th> </tr> </thead> <tbody> <tr> <td>1.2.1</td> <td>Detailed medical history</td> <td></td> <td></td> </tr> <tr> <td>1.2.2</td> <td>ECG – essential if history of cardiac disease</td> <td></td> <td></td> </tr> <tr> <td>1.2.3</td> <td>LFT</td> <td></td> <td></td> </tr> <tr> <td>1.2.4</td> <td>TFT</td> <td></td> <td></td> </tr> <tr> <td>1.2.5</td> <td>U&Es</td> <td></td> <td></td> </tr> <tr> <td>1.2.6</td> <td>Glucose</td> <td></td> <td></td> </tr> <tr> <td>1.2.7</td> <td>FBC</td> <td></td> <td></td> </tr> <tr> <td>1.2.8</td> <td>Cholesterol</td> <td></td> <td></td> </tr> <tr> <td>1.2.9</td> <td>Concurrent medication list compiled (including all medications)</td> <td></td> <td></td> </tr> </tbody> </table>		Investigation	Result seen	Action req'd	1.2.1	Detailed medical history			1.2.2	ECG – essential if history of cardiac disease			1.2.3	LFT			1.2.4	TFT			1.2.5	U&Es			1.2.6	Glucose			1.2.7	FBC			1.2.8	Cholesterol			1.2.9	Concurrent medication list compiled (including all medications)					
	Investigation	Result seen	Action req'd																																									
1.2.1	Detailed medical history																																											
1.2.2	ECG – essential if history of cardiac disease																																											
1.2.3	LFT																																											
1.2.4	TFT																																											
1.2.5	U&Es																																											
1.2.6	Glucose																																											
1.2.7	FBC																																											
1.2.8	Cholesterol																																											
1.2.9	Concurrent medication list compiled (including all medications)																																											
	<input type="checkbox"/> On completion of 1.2, consider whether complete hospital initiation is required (admission for two weeks) <input type="checkbox"/> Yes (Admission arranged for.....(Date) <input type="checkbox"/> No																																											

Ref	Interventions	Date / Time	Signed	Var										
1.3	Decision to commence Clozapine discussed and agreed with Patient by Doctor <input type="checkbox"/> Informed consent obtained and recorded <input type="checkbox"/> Check whether patient has made an advanced decision relating to Clozapine. <input type="checkbox"/> If Patient detained and not consenting, Second Opinion obtained <input type="checkbox"/> Patient given information leaflet about Clozapine and contents discussed with them.													
1.4	<input type="checkbox"/> Patient agrees to: <ul style="list-style-type: none"> • Weekly blood sampling • Day admission to an in-patient unit (if not already an inpatient) OR • Mental Health staff present at their residence for at least 6 hours on the first day • Twice daily visits by community team for at least 2 weeks (if not an inpatient during that time) • Transfer to PCLT Consultant and Care Co-ordinator at the end of the initial period (usually 14 days) – if appropriate 													
1.5	<input type="checkbox"/> Patient registered with CPMS/DMS <input type="checkbox"/> Inform Clozapine Pharmacy Technician Tel: 01752 439006 Internal: 39006													
1.6	<input type="checkbox"/> Consider how the Patient will continue to be monitored for the next 12 month: <ul style="list-style-type: none"> • Taking blood samples • Delivering medication <p>* GP Practices will not be involved during the first 12 months</p>													
1.7	<input type="checkbox"/> Inform GP of intention to start Clozapine, for awareness of supplementary prescribing													
1.8	<input type="checkbox"/> Take pre treatment blood samples (for WBC and ANC) and send to CPMS/DMS Blood sample valid for ten days													
1.9	<input type="checkbox"/> When CPMS/DMS confirm suitability and green blood count result obtained, Patient may commence Clozapine. Blood sample valid for ten days <input type="checkbox"/> Green result received													
1.10	<input type="checkbox"/> If not an inpatient, patient advised to have a relative / carer to stay with them overnight on day one and given relevant phone numbers to contact if any problems or if side effects arise													
1.11	<input type="checkbox"/> Prescribe titrating dose of Clozapine for first 7 days <input type="checkbox"/> Send /email prescription to Clozapine Pharmacy Technician email: livewell.clozapineservice@nhs.net at least 24 hours before first dose is due													
1.12	<input type="checkbox"/> Seven days of Clozapine supply received on ward / unit / team base <input type="checkbox"/> Contact Clozapine Pharmacy Technician if Clozapine not received													
1.13	<input type="checkbox"/> Patient admitted to ward / unit (if applicable)													
2.0	Commencing Clozapine Day One – usually on the Ward / Unit													
2.1	The following observations are taken and agreed to be acceptable (if any physical checks are abnormal, medical advice must be sought before proceeding). Review current physical state /health. <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 80%;"></th> <th style="width: 20%;">Result</th> </tr> </thead> <tbody> <tr> <td>Blood pressure lying down</td> <td></td> </tr> <tr> <td>Blood pressure standing</td> <td></td> </tr> <tr> <td>Pulse</td> <td></td> </tr> <tr> <td>Temperature</td> <td></td> </tr> </tbody> </table>		Result	Blood pressure lying down		Blood pressure standing		Pulse		Temperature				
	Result													
Blood pressure lying down														
Blood pressure standing														
Pulse														
Temperature														
2.2	Administer first dose of Clozapine (12.5 mg)													

Ref	Interventions	Date / Time	Signed	Var																																			
2.3	<p>The following hourly (at least) physical observations are taken for 6 hours (record results):</p> <table border="1"> <thead> <tr> <th></th> <th>BP lying down</th> <th>BP standing</th> <th>Pulse</th> <th>Temp</th> </tr> </thead> <tbody> <tr><td>1 hr</td><td></td><td></td><td></td><td></td></tr> <tr><td>2 hr</td><td></td><td></td><td></td><td></td></tr> <tr><td>3 hrs</td><td></td><td></td><td></td><td></td></tr> <tr><td>4 hrs</td><td></td><td></td><td></td><td></td></tr> <tr><td>5 hrs</td><td></td><td></td><td></td><td></td></tr> <tr><td>6 hrs</td><td></td><td></td><td></td><td></td></tr> </tbody> </table> <p>Checks are to monitor adverse side effects, particularly tachycardia, hypotension, hyperthermia and seizures. Notify Duty Doctor if there are any changes in physical observations (see Organisation Clozapine Policy) The prescriber should be informed and medical attention sought if the following are observed:</p> <ul style="list-style-type: none"> • Postural drop of >30mmHg • Pulse>100bpm • Temperature>38C • Over –sedation • Other intolerable adverse effects 		BP lying down	BP standing	Pulse	Temp	1 hr					2 hr					3 hrs					4 hrs					5 hrs					6 hrs							
	BP lying down	BP standing	Pulse	Temp																																			
1 hr																																							
2 hr																																							
3 hrs																																							
4 hrs																																							
5 hrs																																							
6 hrs																																							
2.4	<p>Note: A list of adverse side effects will be kept in the patient's notes and the nurse will check on every visit whether the patient is experiencing any. Medical advice must be sought if there are any changes in physical observations or problems with side effects Sign and date ICP to acknowledge agreement to standard</p>																																						
2.5	<p>Second blood test taken on the Monday or Tuesday of the week following initiation of Clozapine. (Regardless of the day Clozapine was started). Date blood test taken.....</p>																																						

Day	Am / pm	BP and pulse Lying	BP and pulse standing	Temp	Prescribed dose of Clozapine	Side effects monitored	Date	Time	Signed	Var
2	am									
2	pm									
3	am									
3	pm									
4	am									
4	pm									
5	am									
5	pm									
6	am									
6	pm									
7	am									
7	pm									

Ref	Interventions	Date / Time	Signed	Var						
3.1	<input type="checkbox"/> Prescribe titrating dose of Clozapine for days 8-14 <input type="checkbox"/> Send / email prescription to Clozapine Pharmacy Technician email: livewell.clozapineservice@nhs.net at least 24 hours before first dose is due									
4.0	Days 8 - 14 <ul style="list-style-type: none"> Nurse monitors blood pressure, temperature and pulse and records (to monitor trends) If physical observation within normal range:- Administer prescribed dose of Clozapine Check side effects									
Day	Am / pm	BP and pulse Lying	BP and pulse standing	Temp	Prescribed dose of Clozapine	Side effects monitored	Date	Time	Signed	Var
8	am									
8	pm									
9	am									
9	pm									
10	am									
10	pm									
11	am									
11	pm									
12	am									
12	pm									
13	am									
13	pm									
14	am									
14	pm									

Ref	Interventions	Date / Time	Signed	Var
5.0	Day 15 Onwards			
5.1	<input type="checkbox"/> Prescribe continuing titrating dose of Clozapine <input type="checkbox"/> Send / email prescription to Clozapine Pharmacy Technician email: livewell.clozapineservice@nhs.net at least 24 hours before first dose is due			
5.2	<input type="checkbox"/> Continue to take blood tests on the Monday or Tuesday of each week and send to CPMS/DMS			
5.3	<input type="checkbox"/> Review need for continued monitoring of blood pressure, temperature and pulse based on whether previous results have been in the normal range <input type="checkbox"/> If necessary, continue to monitor blood pressure and temperature and record on observation sheet in Patient's notes. Review on-going need on a regular basis (complete variance if further monitoring needed) <input type="checkbox"/> Duty Doctor notified if there are any changes in physical observations or problems with side effects			
5.4	Sign and date ICP when first review complete and acknowledge understanding of an intended adherence to standard			

Ref	Interventions	Date / Time	Signed	Var															
6.0	Blood Tests, Prescriptions and Clozapine Supplies																		
6.1	<p>Doctor continues to prescribe titrating dose until maintenance dose is achieved</p> <p>If maintenance dose is achieved the doctor prescribes Clozapine:</p> <ul style="list-style-type: none"> • on the inpatient Prescription Chart for all inpatient units, HTT and AOS • on a Maintenance Clozapine Prescription Form for all Community Patients 																		
6.2	<p>Medication will be issued by Glenbourne Pharmacy on a Thursday for all Community Teams and on a Friday for all inpatient units and GP Practices.</p> <p>The Patient will be issued with further supplies of Clozapine only if they have a satisfactory current WBC on the CPMS/DMS computer system. If the WBC is not satisfactory, CPMS/DMS will advise on the action to be taken</p> <table border="1" data-bbox="167 631 892 831"> <thead> <tr> <th>Prescription due on or before</th> <th>Date written</th> <th>Date sent to Derriford Pharmacy</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> </tbody> </table>	Prescription due on or before	Date written	Date sent to Derriford Pharmacy															
Prescription due on or before	Date written	Date sent to Derriford Pharmacy																	
6.3	<p>Patient must have weekly blood test (for WBC and ANC) for at least the first 18 weeks of treatment. Test should be taken on Monday or Tuesday of each week</p> <table border="1" data-bbox="167 920 892 1120"> <thead> <tr> <th>Blood test due on or before</th> <th>Date taken</th> <th>Date sent to CPMS</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> </tbody> </table> <p>Continue to monitor blood tests on a weekly basis until advised by CPMS/DMS</p>	Blood test due on or before	Date taken	Date sent to CPMS															
Blood test due on or before	Date taken	Date sent to CPMS																	
6.4	<p>If the Patient stops taking Clozapine for more than 48 hours the dose will need to be re-titrated and extra blood tests may need to be performed. The patient must have a valid blood result before re-starting (See ICP 8)</p> <p>See Organisations Clozapine Policy or contact CPMS/DMS for advice</p>																		
7.0	Arrangements if patients are transferred to another Team / Service in the Community																		

Ref	Interventions	Date / Time	Signed	Var
7.1	<p>Pre-transfer the following actions must be completed:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Care coordinator contacted and asked to make arrangements for the medication to be delivered to the patient on Fridays (Glenbourne pharmacy deliver Clozapine to community bases on Thursdays or Fridays). <input type="checkbox"/> If GP Practice is to be involved with bloods or medication an agreement must be completed (see organisations Clozapine policy) <input type="checkbox"/> Clozapine agreement between Mental Health Services and GP Practices agreed and signed by relevant bodies. <input type="checkbox"/> Inform GP practice of date next blood tests due (4 weekly patients only). <input type="checkbox"/> Phone CPMS/DMS and :- <ul style="list-style-type: none"> ▪ Complete and fax CPMS/DMS GP Sampling Venue Form. <input type="checkbox"/> Phone Clozapine technician and advise of transfer of patient and date <input type="checkbox"/> Responsible doctor to ensure Clozapine prescription is up to date <input type="checkbox"/> New Clozapine prescription faxed or emailed to Glenbourne Pharmacy as necessary. 			
7.2	<p>Actions to be taken on day of transfer:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Patient Transfer of Care form completed and faxed to CPMS/DMS. <input type="checkbox"/> Clozapine Technician contacted to ensure they are aware of transfer. <input type="checkbox"/> Standard discharge advice notification sent / faxed to GP <p>Contact Care Coordinator and confirm arrangements. If GP Practice to be involved:-</p> <ul style="list-style-type: none"> <input type="checkbox"/> Liaise with them and confirm arrangements are in place for next blood test 			

ICP for the Re-titration of Clozapine
(See Clozapine Policy for Mental Health Staff and GP Practice Staff)

Patient's Name		GP Name:	
Date of Birth:		Telephone No:	
Address:		GP Address:	
Telephone No:		Care Co-ordinator:	
Mobile No:		Telephone No:	
NHS No:		Social Services No:	
Hospital No:		CPMS/DMS No:	

Each Section of the ICP to be completed by the Clinician who performs the relevant action. If a variance (something different from standard detailed) occurs; tick the column against the statement and record in the tabbed journal on SystemOne what the variance was and the action taken.

Var = Variance

CPMS= Clozapine Patient Monitoring Service

DMS= Denzapine Monitoring Service

Ref	Interventions	Date / Time	Signed	Var
1.0	Pre administration actions (responsibility of Consultant Psychiatrist or Deputy)			
1.1	<input type="checkbox"/> Determine date and time that patient last took a dose of Clozapine <input type="checkbox"/> If the last dose of Clozapine was more than 4 weeks ago, follow the ICP for Initiation of Clozapine.			
1.2	<input type="checkbox"/> Determine that it is appropriate for Patient to re-start Clozapine <input type="checkbox"/> Contact CPMS/DMS to advise of break in treatment Sign and date when determination completed satisfactorily			
1.3	<input type="checkbox"/> Determine date of last blood test and result Date..... Result (colour).....			
1.4	<p>Patients who have had their Clozapine treatment interrupted for less than 3 days (or are still on weekly blood monitoring) can continue with their current frequency of blood monitoring providing they have a current green blood result when they re-commence Clozapine</p> <p>Patients who have been on Clozapine for more than 18 weeks and have had their treatment interrupted for 3 days or more (but less than 4 weeks – see 1.1 above) should have their WBC count and ANC monitored weekly for an additional 6 weeks. They must have a green blood result within 7 days of re-commencing Clozapine.</p> <input type="checkbox"/> Determine required frequency of blood monitoring..... <input type="checkbox"/> Verify date and result of blood test if required: Date..... Result (colour)..... <input type="checkbox"/> Contact CPMS/DMS for advice if necessary			
1.5	<input type="checkbox"/> Inform Clozapine Pharmacy Technician of treatment break			

Ref	Interventions	Date / Time	Signed	Var																								
1.6	<p>This section is relevant if the patient has not taken Clozapine for more than one week</p> <p><input type="checkbox"/> Detailed medical history completed, including all current medication</p> <p><input type="checkbox"/> Physical examination completed satisfactorily by a doctor</p> <p><input type="checkbox"/> Relevant clinical investigations</p> <table border="1"> <thead> <tr> <th></th> <th>Date undertaken</th> <th>Results approved</th> </tr> </thead> <tbody> <tr> <td>FBC</td> <td></td> <td></td> </tr> <tr> <td>U&Es</td> <td></td> <td></td> </tr> <tr> <td>LFTs</td> <td></td> <td></td> </tr> <tr> <td>TFTs</td> <td></td> <td></td> </tr> <tr> <td>Lipid screen</td> <td></td> <td></td> </tr> <tr> <td>Blood glucose</td> <td></td> <td></td> </tr> <tr> <td>ECG (if indicated)</td> <td></td> <td></td> </tr> </tbody> </table>		Date undertaken	Results approved	FBC			U&Es			LFTs			TFTs			Lipid screen			Blood glucose			ECG (if indicated)					
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TFTs																												
Lipid screen																												
Blood glucose																												
ECG (if indicated)																												
1.7	<p>After consideration of all factors, decision taken to either:</p> <p><input type="checkbox"/> Re-commence Clozapine in the community, or</p> <p><input type="checkbox"/> Re-commence Clozapine as an inpatient</p>																											
1.8	<p>Decision to re-commence Clozapine discussed and agreed with Patient by Doctor</p> <p><input type="checkbox"/> Informed consent obtained and recorded</p>																											
1.9	<p>Patient agrees to:</p> <p><input type="checkbox"/> Either: Day admission to an in-patient unit (if not already an inpatient) then daily visits by community team for at least one week</p> <p><input type="checkbox"/> OR: For Home re-titration, a healthcare professional to visit the patient at least once a day to deliver medication and monitor the patient during the titration period</p> <p><input type="checkbox"/> OR: For inpatient admission for the titration period</p> <p>NB: If the patient cannot be visited in the community during a weekend, do not increase the dose over the weekend</p>																											
1.10	<p><input type="checkbox"/> If GP Practice is involved with medication inform them of the break in treatment and the treatment plan</p> <p><input type="checkbox"/> If GP Practice is involved with blood tests inform them of the break in treatment and any changes to frequency of blood tests</p> <p><input type="checkbox"/> If more frequent than every 4 weeks, make arrangements for blood sampling and supplies to revert back to mental health services until patient is back to 4 weekly blood monitoring.</p>																											
1.11	<p><input type="checkbox"/> Prescribe titrating dose of Clozapine for first 7 days</p> <p>Note: start with 12.5mg once or twice on the first day but titration can then be quicker than for a new patient</p> <p><input type="checkbox"/> Send email prescription to Clozapine Pharmacy Technician email: livewell.clozapineservice@nhs.net at least 24 hours before first dose is due</p>																											
1.12	<p><input type="checkbox"/> Seven days of Clozapine supply received on ward / unit / team base</p> <p><input type="checkbox"/> Con Clozapine Pharmacy Technician if Clozapine not received</p>																											
1.13	<input type="checkbox"/> Patient admitted to ward / unit (if applicable)																											
2.0	Re-commencing Clozapine Day One																											
2.1	<p><input type="checkbox"/> Re-check for contra indications (see Organisation Clozapine Policy , Clozaril/Denzapine SmPC or current addition of BNF) and current physical health</p> <p>The following observations are taken and agreed to be acceptable (if any physical checks are abnormal, medical advice must be sought before proceeding)</p> <table border="1"> <thead> <tr> <th></th> <th>Result</th> </tr> </thead> <tbody> <tr> <td>Blood pressure lying down</td> <td></td> </tr> <tr> <td>Blood pressure standing</td> <td></td> </tr> <tr> <td>Pulse</td> <td></td> </tr> <tr> <td>Temperature</td> <td></td> </tr> </tbody> </table>		Result	Blood pressure lying down		Blood pressure standing		Pulse		Temperature																		
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2.2	Administer first dose of Clozapine (12.5 mg)																											

Ref	Interventions	Date / Time	Signed	Var								
3.2	<ul style="list-style-type: none"> o Ensure next blood test is taken according to schedule and sent to CPMS/DMS Date taken..... 											
3.3	<ul style="list-style-type: none"> <input type="checkbox"/> Prescribe titrating dose of Clozapine for days 8-14. <input type="checkbox"/> Send / email prescription to Clozapine Pharmacy Technician email: livewell.clozapineservice@nhs.net at least 24 hours before first dose is due 											
4.0	Days 8-14											
4.1	If titration continues: <ul style="list-style-type: none"> • Check for side effects • Nurse monitors blood pressure, temperature and pulse and records (to monitor trends). If physical observation within normal range:- • Administer prescribed dose of Clozapine 											
Day	Time	Lying		Standing		Temp	Dose of Clozapine	Side effects monitored	Date	Time	Signed	Var
		BP	Pulse	BP	Pulse							

Ref	Interventions	Date / Time	Signed	Var															
4.2	If the maintenance dose has been achieved the doctor prescribes Clozapine: <ul style="list-style-type: none"> • on the inpatient Prescription Chart for all inpatient units, HTT and AOS • on a Maintenance Clozapine Prescription Form for all Community Patients 																		
4.3	<ul style="list-style-type: none"> o Ensure next blood test is taken according to schedule and sent to CPMS/DMS Date taken..... 																		
5.0	Day 15 Onwards																		
5.1	<input type="checkbox"/> Maintenance dose should have been achieved by this time																		
5.2	<input type="checkbox"/> Continue to ensure blood tests are taken at the necessary frequency and sent to CPMS/DMS <input type="checkbox"/> If GP Practice is involved with medication or blood tests keep them informed of progress and when the patient is back on 4 weekly blood tests.																		
6.0	Blood Tests, Prescriptions and Clozapine Supplies																		
6.2	Medication will be issued by Glenbourne Pharmacy on a Thursday or Friday The Patient will be issued with further supplies of Clozapine only if they have a satisfactory current WBC on the CPMS/DMS computer system. If the WBC is not satisfactory, CPMS/DMS will advise on the action to be taken																		
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Prescription due on or before	Date written	Date sent to Glenbourne Pharmacy																	

Ref	Interventions	Date / Time	Signed	Var
6.4	If the Patient stops taking Clozapine for more than 48 hours the dose will need to be re-titrated again. Follow this ICP. See Organisation Clozapine Policy or contact CPMS/DMS for advice			

Organisational Approval		
Board Approval	Title	Interim Medical Director
	Organisation	Livewell Southwest
	Name	<i>Names and signatures held on the electronically signed copy</i>
	Signature	
	Date	
Supporting Pharmacist Approval	Title	Pharmacist
	Organisation	Livewell Southwest
	Name	<i>Names and signatures held on the electronically signed copy</i>
	Signature	
	Date	
Supporting Consultant Psychiatrist	Title	Consultant Psychiatrist
	Organisation	Livewell Southwest
	Name	<i>Names and signatures held on the electronically signed copy</i>
	Signature	
	Date	
MGG Approval	Title	Interim Chief
	Organisation	Livewell Southwest
	Name	<i>Names and signatures held on the electronically signed copy</i>
	Signature	

	Date	
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