

## Clozapine: processes for prescribing, dispensing, supply and monitoring

### Initiation of clozapine:

Use the appropriate checklist to ensure all actions are completed day by day - there is a separate checklist for [inpatient](#) and [community](#) initiations.

Use the standard supplementary chart for the initial titration up to target dose. Target doses are:

- For female non-smokers: 250 mg per day
- For male non-smokers: 350 mg per day
- For female smokers: 450 mg per day
- For male smokers: 550 mg per day

Then adjust dose according to response and tolerance – BNF maximum daily dose = 900 mg per day.

There are also checklists to follow when a patient is [admitted](#) to and [discharged](#) from an inpatient ward.

### Continuing clozapine:

The Trust is fully responsible for the ongoing prescription, monitoring and supply of clozapine to all patients. Processes for the prescription, monitoring and supply via “one-stop” and other clinic models are below in this document.

Break in treatment - avoid missed doses; a break in treatment of >48 hours requires re-starting at 12.5–25 mg per day and re-titration (but at a faster rate, using a non-standard supplementary chart). A break of >72 hours also requires a return to weekly blood monitoring. Ask pharmacy / the relevant monitoring service for advice.

### Therapeutic Drug Monitoring (plasma level assays)

Trust guidance on the role of TDM in relation to clozapine is on the intranet [here](#).

Key points:

- Routine (annual) monitoring of plasma levels is not currently required.
- Checking plasma levels is useful to:
  - Confirm non-compliance.
  - Inform dose adjustment if sub-optimal response (after 3-6 months)\*;
  - Adjust dose after a change in smoking status, or if co-prescription of an enzyme-inducing or inhibiting drug is unavoidable or desirable\*;
  - Diagnose and adjust dose in response to dose-related side-effects or signs of toxicity, particularly if the patient has pneumonia or other serious infection;
  - Inform if anticonvulsant prophylaxis is required with higher doses (>600 mg daily) – recommended at levels >0.6 mg/litre
  - Inform dose reviews and adjustments in older patients who are at higher risk of toxicity\*

*\*aim for plasma levels in the range 0.35-0.50 mg/litre (12 hours post-dose)*

### Safety monitoring:

Baseline / pre-treatment tests are covered in the initiation checklists – see above

The Trust [Psychotropic Monitoring Guidelines](#) set out the minimum requirements for on-going monitoring of patients in relation to full blood counts (mandatory), weight, waist circumference, blood lipids, blood glucose (HbA1C), blood pressure, pulse and ECG.

Things to ask or check (using appropriate language/phrasing) whenever you see a patient who is taking clozapine:

- What dose have you been taking? Has anyone told you to change your dose? Have you missed any doses?
- Any changes to your other medication, prescribed or over-the-counter?
- Do you smoke? Have you recently stopped or started smoking? [*see [Trust guidance](#) for advice on what to do*]
- How is your bowel function? Any signs of constipation? [*see [Choice & Medication handy fact sheet](#)*]
- Do you drink alcohol or caffeine-containing drinks? If so, how much?
- Any other side-effects?.....sedation, hypersalivation, nausea, bed-wetting, reflux/heartburn, palpitations?
- Any fever or other signs of infection, e.g. sore throat?

For each question/response – **RECORD, ASSESS RISK & TAKE ACTION** as appropriate

### **NEVER events:**

- NEVER initiate clozapine without a thorough physical health check, including an ECG
- NEVER issue a supply of clozapine to a patient following a confirmed RED blood result
- NEVER ignore the signs & symptoms of potentially life-threatening side-effects such as constipation

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## Quality standards for all clozapine caseloads (introduced – August 2022)

These standards will be monitored every 12-18 months and for the first time early 2023.

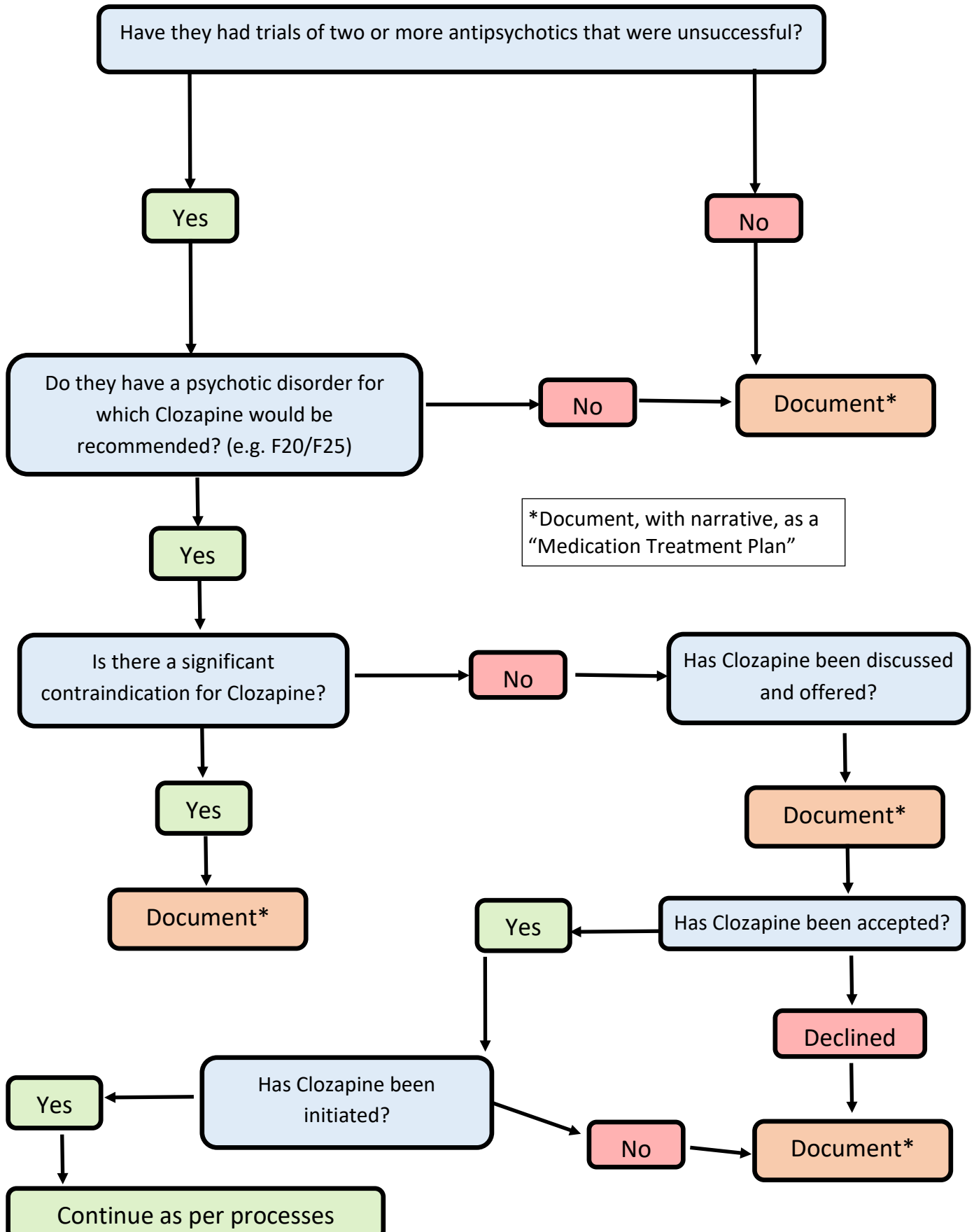
1. **Annual review:** [Clozapine Annual Review Checklist](#) completed (or the content of the checklist evident in annual review).
  - a. Process standard: every 12 months for all patients
  - b. Audit standard: within the last 15 months for all patients
2. **Clozapine on Summary Care Record:** Clozapine listed on current Summary Care Record for all patients
3. **Side Effect Monitoring:** [GASS for clozapine](#) or other rating scale completed at least once in the last 12 months
4. **Bowel monitoring:** Bristol Stool Chart (during constipation counselling) used and recorded at least once in the last 3 months.
5. **Education & Training:** Evidence of completion of appropriate clozapine training / CPD for all clinic staff & clozapine prescribers within last 3 years (TEWV ESR training search “clozapine” – course title: 346 Online Clozapine Theory)

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## Prescribing

### Is Clozapine indicated & appropriate?

(consider for all those prescribed antipsychotic medication)



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## Initiation of clozapine in an inpatient setting

See checklist in [appendix 1](#)

## Initiation of clozapine in a community setting

See checklist in [appendix 2](#)

### Approval for unlicensed/off-label use

If clozapine is being considered for a patient who has previously stopped treatment due to a RED result (re-challenge), or in whom standard mandatory blood monitoring is unlikely to be achieved (e.g. frail Parkinson's disease), or who has another listed contra-indication, the responsible clinician MUST seek approval for initiation from the CPMS (or relevant monitoring service) in the first instance. This approval should be documented in the electronic patient record (e.g. copy and paste of email). Trust approval should then be sought via the relevant lead psychiatrist or AMD using the [single application form](#).

Initiation for an off-label indication does not need prior CPMS (or equivalent) or Trust approval, but must be notified to CPMS (or equivalent) on the patient registration form. All other requirements of off-label prescribing in [Trust guidelines](#) apply, e.g. informed patient consent.

### Patient education & information provision

- When clozapine is being considered, to inform consent to treatment, the responsible clinician must arrange for an appropriate clinician (e.g. clinical pharmacist) to discuss all aspects of treatment with the patient and/or carer - potential benefits, side-effects and monitoring requirements – and provide appropriate level information leaflet(s) from the [Choice & Medication website](#).
- Once the patient has provided consent to treatment, the same clinician (ideally) should go through the C&M patient information with the patient and particularly bring their attention to the following key points:
  - **AVOID MISSING DOSES** – if doses are not taken for >48 hours, treatment will need to be re-started at low dose
  - **AVOID DRINKING ALCOHOL** – will enhance any drowsiness caused by clozapine; too much alcohol can be dangerous; tell somebody if alcohol consumption increases
  - **AVOID EXCESSIVE CAFFEINE**-containing drinks – may increase the effects of clozapine; tell somebody if caffeine intake changes (increase or decrease)
  - **SMOKING** – tell somebody if you start or stop smoking, this will affect clozapine levels and dose may need to be adjusted
  - **CONSTIPATION** – tell somebody if you can't poo, or have stomach pains or feel sick
  - **FEVER** – tell somebody if you get an unexpected fever, sore throat or other flu-like symptoms

A record of the above discussion and provision of information to the patient/carer must be documented in the electronic patient record, including any questions asked and the responses given.

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## Initial 6-month prescription

Following successful titration and dose stabilisation (including adjustment of dose for re-commencement of smoking after discharge):

### Prescriber:

Notify pharmacy team that an “electronic prescription” for clozapine is now required – by direct contact with a pharmacy staff member and/or email to the relevant dispensary:

- RPH - [tewv.pharmacytees@nhs.net](mailto:tewv.pharmacytees@nhs.net)
- WPH – [tewv.pharmacycdd@nhs.net](mailto:tewv.pharmacycdd@nhs.net)
- FPH – [tewv.pharmacyyork@nhs.net](mailto:tewv.pharmacyyork@nhs.net)

N.B. notify pharmacy staff/dispensary of any “co-meds” that need to be included on this prescription, pending transfer to the GP (where possible)



### Clinical Pharmacy Team:

- Produce an electronic prescription for clozapine (plus any required co-meds) using the template for the relevant locality in the pharmacy [shared folders](#) [standard template in [appendix 3](#)]. Save the prescription in the relevant clinic folder on the pharmacy shared drive
- Pharmacist – check new prescription is correct against current prescription, i.e. inpatient chart or most recent outpatient prescription
- **Tees/CDD** - copy & paste the prescription into a “Pharmacy” case note on the electronic patient record (EPR) with the statement ‘*Clozapine prescription sent for checking and signing*’
- **NY** – print prescription
- Send prescription to the prescriber for signing via the locally agreed method for that prescriber/clinic, i.e. print & send/hand deliver hard copy OR attach to an email with appropriate password protection\* in locally agreed format.
- Add patient and prescription details to relevant prescription tracker
- **Tees/CDD only** - check clozapine dose on eVCB and amend if necessary

\* 1<sup>st</sup> password to open as read-only & print (share with prescriber in separate email) + 2<sup>nd</sup> password for editing (not to be shared with prescriber)



### Prescriber:

- Print (if emailed), check and sign/date prescription; return to pharmacy staff member or directly to relevant dispensary using the most appropriate locally agreed method (e.g. scan & email, via pharmacy drivers, via internal or Royal Mail post).



### Dispensary Team:

- Confirm prescription matches dispensary record of “stable” dose, e.g. copy of inpatient titration chart, copy on EPR (Tees/CDD), latest outpatient prescription - pharmacist signs “professional check” box once confirmed
- **Tees/CDD** - add to the existing Pharmacy case note on the EPR, e.g. ‘*Signed prescription received & professionally checked*’.
- **York** – copy and paste signed prescription into a Pharmacy case note on the EPR
- Update prescription tracker with details of prescription received
- Check if clozapine and any co-meds are on the patient summary care record – if not, email GP practice to request addition
- Put prescription into [dispensing process](#) (N.B. prescription is valid for 6 months from date of first dispensing, not date of signing).

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## Dose changes

### Prescriber:

When a dose change is needed to clozapine or any “co-meds”:

- Clearly document the required change on the electronic patient record, including the date from when the new dose is to commence
- Notify pharmacy of the dose change via email to the relevant dispensary, using the communication form in [appendix 5](#) (cc'd to any colleagues and specific pharmacy staff who also need to be aware), indicating the urgency of the change:
  - RPH - [tewv.pharmacytees@nhs.net](mailto:tewv.pharmacytees@nhs.net)
  - WPH - [tewv.pharmacycdd@nhs.net](mailto:tewv.pharmacycdd@nhs.net)
  - FPH - [tewv.pharmacyyork@nhs.net](mailto:tewv.pharmacyyork@nhs.net)

Is the dose change required immediately / within next 7 days?

YES

Can the current supply be used for the new dose until a new supply can be prescribed, dispensed & delivered to the patient?

YES

**Care Co-ordinator:**  
Recover any tablets from the patient that are not needed for the new dose and return them to the relevant dispensary

### Clinical Pharmacist:

- “p/c” amend the current prescription to allow single dispensing of new supply within validity of bloods
- Record amendment in EPR  
*[Inpatients – ward pharmacy team order interim supply at new dose on EMIS]*

### Dispensary Team:

- Check amended prescription against prescriber EPR entry / e-mail notification
- Calculate and dispense quantity of tablets for new dose up to validity of bloods/next clinic appointment
- Liaise with the patient’s care coordinator to remove or add extra tablets to correct the dose with the patient.

### Clinical Pharmacy Team:

- Produce a new electronic prescription with amended dose of clozapine or co-meds using the templates in the pharmacy [shared folders](#). Save the prescription in the relevant clinic folder on the shared drive
- Pharmacist – check prescription is correct against prescriber EPR entry and/or email notification.
- **Tees/CDD** - copy & paste the prescription into a “Pharmacy” case note on the EPR with the statement ‘*Clozapine prescription sent for checking and signing*’; **NYN** – print prescription
- Send prescription to the prescriber for signing via the locally agreed method for that prescriber/clinic, i.e. print & send/hand deliver hard copy OR attach to an email with appropriate password protection
- Add prescription details to relevant prescription tracker
- **Tees/CDD** only – amend clozapine dose on eVCB
- Suspend current prescription held in dispensary with note, e.g. “new dose change prescription in process”

NO

Is the next scheduled blood test & supply of clozapine within the next 7 days?

NO



**Prescriber:**

- Print (if emailed), check and sign/date prescription; return to pharmacy staff member or directly to relevant dispensary using the most appropriate locally agreed method (e.g. scan & email, via pharmacy drivers, via internal or Royal Mail post).



**Dispensary Team:**

- Confirm dose on prescription matches prescriber EPR entry / email notification of dose change – pharmacist to sign “professional check” box once confirmed
- **Tees/CDD** - add to the existing Pharmacy case note on the EPR, e.g. ‘Signed prescription received & professionally checked’.
- **York** – copy and paste signed prescription into a Pharmacy case note on the EPR
- Update prescription tracker with details of prescription received
- Check if clozapine and any co-meds are on the patient summary care record – if not, email GP practice to request addition
- Put prescription into [dispensing process](#) (N.B. prescription is valid for 6 months from date of first dispensing, not date of signing).

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## Renewal of 6-month prescriptions

### Clinical Pharmacy Team:

When the 6-month prescription is due for renewal (either for individual patients ad-hoc or as a batch process for a clinic cohort):

- Check the current Responsible Clinician (RC) – this may have changed
- Check and reconcile the current clozapine dose using two sources of information, e.g. prescription on file and electronic patient record (search case notes for last month to identify any unknown/uncommunicated dose changes)
- If patient is prescribed “co-meds” – access SCR (if patient consent in place) or contact GP practice (if consent to access SCR not granted or unknown) to ensure no duplication of prescribing.
  - If clozapine not on SCR/GP record – email GP practice to add as non-prescribed item
  - Consider potential transfer of prescribing of co-meds
- Record details of the clozapine and co-meds reconciliation as a “Pharmacy” case note (not a “medicines reconciliation” case note) on the EPR
- Produce an electronic prescription for clozapine plus any required co-meds using the templates in the pharmacy [shared folders](#). If SCR checked above, indicate presence/absence of clozapine & co-meds at bottom of prescription. Save the prescription in the relevant clinic folder on the shared drive
- If reconciliation done by technician - pharmacist to check prescription against the case note entry on EPR
- **Tees/CDD** - copy & paste the prescription into the existing case note on the EPR with the statement ‘*Clozapine prescription sent for checking and signing*’; **NY** – print prescription
- Send prescription to the prescriber for signing via the locally-agreed method for that prescriber/clinic, i.e. print & send/hand deliver hard copy OR attach to an email with appropriate password protection\* in locally-agreed format.
- Add patient and prescription details to relevant prescription tracker
- **Tees/CDD only** - check clozapine dose on eVCB and amend if necessary

\* 1<sup>st</sup> password to open as read-only & print (share with prescriber in separate email) + 2<sup>nd</sup> password for editing (not to be shared with prescriber)



### Prescriber:

- Print (if emailed), check and sign/date prescription; return to pharmacy staff member or directly to relevant dispensary using the most appropriate locally agreed method (e.g. scan & email, via pharmacy drivers, via internal or Royal Mail post).



### Dispensary Team:

- Confirm prescription matches details in Pharmacy case note entry – pharmacist to sign “professional check” box once confirmed
- **Tees/CDD** - add to the existing Pharmacy case note on the EPR, e.g. ‘*Signed prescription received & professionally checked*’.
- **York** – copy and paste signed prescription into the existing Pharmacy case note on the EPR
- Update prescription tracker with details of prescription received
- Put prescription into [dispensing process](#) (N.B. prescription is valid for 6 months from date of first dispensing, not date of signing).

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## Annual review

Every 12 months, in addition to renewing the repeat 6-month prescription, the patient's responsible clinician, or a suitably qualified prescriber in their team, should conduct a full review of the patient and their clozapine treatment according to the checklist in [appendix 13](#). A copy of the completed checklist should be sent to the patient's GP after the review to ensure that the GP/summary care record includes clozapine and any co-meds prescribed by TEWV.

## Prescription tracker

See example in [Appendix 4](#)

### Clinical Pharmacy Team:

- Locate the prescription tracker for the relevant clinic in the individual clinic folder on the Trust Shared Drive ([T:\Clozapine](#))
- Log a new entry on the prescription amendment tracker whenever a prescription is produced electronically (new prescriptions & dose changes), completing all relevant columns before sending the prescription to the prescriber for signature.



### Dispensary Team:

- On receipt of a signed prescription, update the prescription amendment tracker "prescription received" columns

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## Discontinuation of clozapine

Clozapine discontinued by prescriber:

### Prescriber (ward team if inpatient):

Notify pharmacy team that clozapine has been discontinued via email to the relevant dispensary (cc'd to any colleagues and specific pharmacy staff who also need to be aware):

- RPH - [tewv.pharmacytees@nhs.net](mailto:tewv.pharmacytees@nhs.net)
- WPH – [tewv.pharmacycdd@nhs.net](mailto:tewv.pharmacycdd@nhs.net)
- FPH – [tewv.pharmacyyork@nhs.net](mailto:tewv.pharmacyyork@nhs.net)

### Clinical Pharmacy / Clozapine Clinic Team:

- Inform CPMS (or equivalent) of discontinuation – [CPMS@viatris.com](mailto:CPMS@viatris.com)
- **Tees/CDD** only - update relevant eVCB – in dose column enter “discontinuing clozapine” (when patient attends clinic - select “blood monitoring” only in attended column).
- Ensure post discontinuation bloods are taken at usual frequency for 4 weeks, i.e. if weekly – 4 x bloods; two-weekly – 2 x bloods; four-weekly – 1 x blood or as per instructions from CPMS (or equivalent) if discontinuing due to a red result
- **Tees/CDD** only – once the required post-discontinuation monitoring has been completed, remove the patient from the eVCB

### Clinical Pharmacy Team:

- Move electronic prescription on S drive to a “discontinued/archive” folder\*
- Add comment to the most recent prescription entry on electronic patient record:  
“Clozapine Discontinued, Prescription No Longer Valid”

\* review content of this folder at least annually and permanently delete prescriptions after 12 months

### Dispensary Team:

- Cancel any future issues of medication and file/archive paper copy of prescription (*to be stored for 2 years on premises*)

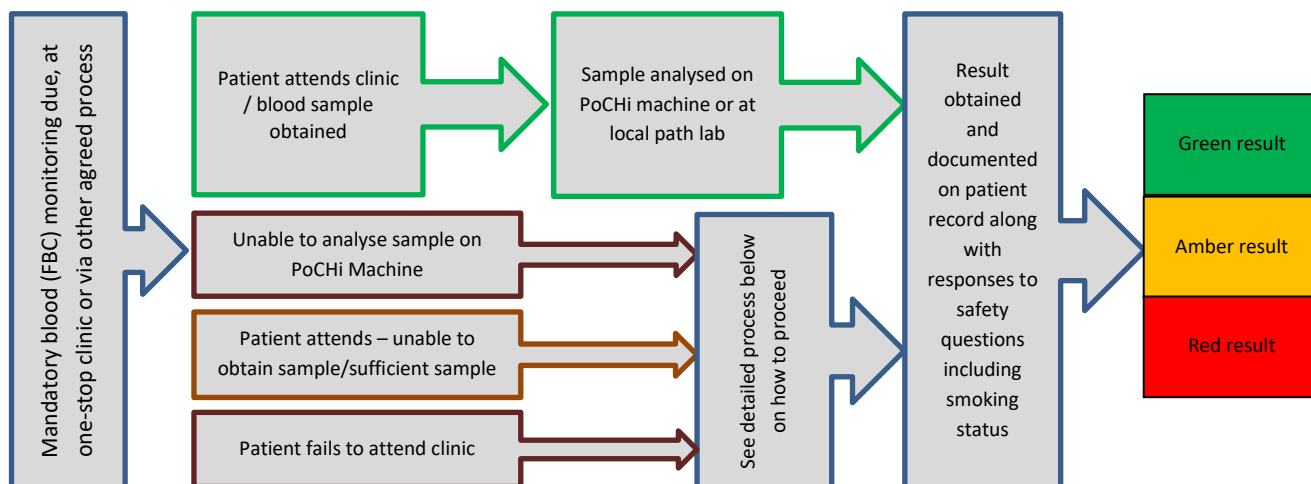
Patient deceased:

- Complete relevant notification, removal, and archiving steps as above.
- Whoever notifies CPMS (or equivalent) that the patient is deceased, should notify the relevant dispensary and relevant colleagues when this has been completed.

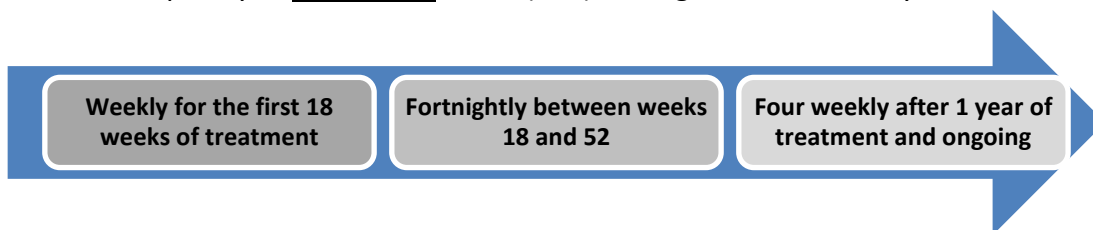
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## Dispensing, supply & monitoring

### Overview



- The frequency of mandatory blood (FBC) testing is determined by the duration of treatment:



*N.B. the duration of weekly or fortnightly monitoring may be extended if amber results occur during these periods*

- Patients due to attend each week (1, 2, 3 or 4) are detailed on the specific tab of the clinic eVCB, or equivalent paper folder (in York)
- Notification is sent by CPMS (or equivalent monitoring service) to the relevant dispensary when a patient's monitoring frequency can change - the eVCB / clinic list should be updated accordingly following the "[Changes in monitoring frequency/weeks](#)" process. The notification should be forwarded to the relevant RC and care co-ordinator
- Patients are allocated to their nearest local clozapine clinic when newly initiated/discharged or transferred to the Trust; patients can be transferred between clinics following the "[Transfer between community clinics/ from in-patient settings](#)" process.
- Medication to be supplied to patients at each clinic, following completion of required monitoring, should be prepared, delivered and stored according to the "[Preparation, delivery, receipt & return of clozapine \(one stop clinics\)](#)" process

### Clozapine blood result validity:

The maximum amount of medication that can be supplied from the date of the most recent GREEN blood result is:

Monitoring frequency	Clozaril® / Denzapine®	Zaponex®
Weekly	10 days	14 days
2-weekly	21 days	21 days
4-weekly	42 days	42 days

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## Preparation, delivery, receipt & return of clozapine

### Dispensary Team:

- If prescription requests a supply greater than the monitoring interval, prepare instalments to be issued in line with the monitoring interval, e.g. 6 weeks requested, 2-weekly monitoring – prepare 3 x 2-week instalments
- Dispense, and prepare for delivery, the medication for each week by the agreed day before the cohort's clinic / blood sampling day
  - Where a non-batch process applies, notify the clinical pharmacy team when the last instalment of a 6-monthly script has been dispensed so that a new script can be produced prior to the next scheduled supply
- Deliver the medication to the clinic / relevant GP surgery in sealed tamper evident tote boxes, clearly labelled 'Quarantined Clozapine', with a copy of the eVCB (or equivalent in York), and relevant prescriptions



### Community team / GP practice staff:

Appropriate team member signs delivery note and places sealed boxes in agreed secure location



### Pharmacy Technician (one-stop clinics):

#### On arrival at the clinic:

- Check delivery boxes are still sealed. If the seals are broken contact the dispensary team immediately.
- Check medication against the eVCB (or equivalent) at the start of clinic, notifying the dispensary of any discrepancy immediately.
- Enter quarantined medication onto eVCB (or equivalent) for each patient.
- Transfer medication to quarantine cupboard, or suitable secure location, in a logical manner.
- Check other medication cupboards on site for any clozapine not collected since previous clinic. If there is any uncollected medication, contact the relevant care coordinator to ascertain reason why not collected and whether any action is required from a break in treatment, i.e. re-titration

#### Before leaving the clinic:

- For patients on 4-weekly monitoring with a green result who collect their medication weekly, the remaining 3 weeks' supply should be transferred to the main clinic medicines cupboard, **NOT** the quarantine cupboard, and an entry made on the medication log sheet. ([Appendix 6](#))
- Any other medication not issued (i.e. for non-attenders) should be returned to the quarantine cupboard; in the absence of a separate quarantine cupboard this medication should be put into the main medication cupboard with a "quarantined medication" sticker attached ([Appendix 7](#)). This medication can be issued according to the "[patient fails to attend clinic as scheduled](#)" process.
- Any returned medication and the file containing the prescriptions should be placed in a suitable, securely sealed container for collection and return to the relevant dispensary on the next pharmacy driver run.
- The eVCB (or equivalent in York) for each clinic should be checked at an appropriate time each week to follow up any non-issued clozapine for that week.

## Monitoring & supply at one-stop clinics

### Patient attends, sample obtained and analysed on POCHI:

#### Clozapine Clinic Team:

- Follow standard venepuncture procedure – take relevant bloods for mandatory FBC monitoring and complete physical health monitoring
- Follow operating instructions for PoChi machine, ensure correct patient details selected, confirm blood result (red/amber/green) on CPMS and document details on the eVCB (Tees/CDD/NY) or paper record (York)
- Perform physical observations as appropriate, recording results on electronic patient record
- Assess patient mental state and presentation, record on electronic patient record

### Unable to obtain immediate result:

Patient fails to attend clinic as scheduled:

#### Pharmacy Technician (in One-stop clinic):

- Do not release medication
- If clinic has a cupboard specifically for quarantined clozapine – secure the patient’s medication in this cupboard (with a copy of the prescription) until a RAG blood result is obtained
- If clinic does not have a separate cupboard for quarantined clozapine – attach a “Quarantined clozapine” sticker to the outer bag and secure the medication (with a copy of the prescription) in the general medicines cupboard, separate to other medication
- Record details on the “Quarantined clozapine log sheet” ([Appendix 7](#))



#### Clozapine Clinic Team / Care Co-ordinator:

Contact patient to arrange attendance at clinic or a home visit to obtain a blood sample



#### Clozapine Clinic Team: once sample has been obtained....

- If possible, analyse sample on PoChi machine; if not possible, follow alternative process (see below) to obtain & document the blood result
- Contact relevant dispensary to request authorisation to release quarantined clozapine



#### Dispensary Team (Pharmacist or Pharmacy Technician):

- Check for RAG blood test result on CPMS – if GREEN, supply code to release the key for the quarantine cupboard and/or permission to release quarantined medication to the patient
- Under no circumstances should the supply be released in the absence of a valid blood result**
- Make a case note entry on the electronic patient record recording permission for release from quarantine & notify the clinic pharmacy technician to record on eVCB



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**Clozapine Clinic Team / Care Co-ordinator (qualified nurse):**

- Record the name of authorising pharmacy staff on the quarantine cupboard log
- If a “Quarantined clozapine” sticker is attached, attach a “Green result” sticker covering the “quarantined” sticker”.
- Check the following prior to handing medication to patient:
  - Patient name
  - Whether they still have any medication at home in excess of their validity
- Ask patient to sign for receipt on the “quarantine cupboard log sheet”
- Counsel patient as appropriate (See [Appendix 8](#)) – refer to another clinician/pharmacist when necessary
- Ensure patient knows the date of their next blood test/clinic appointment

Unable to obtain sample/sufficient sample

- Check if any other phlebotomy trained staff are available on-site to obtain required sample.
- If not, make alternative arrangements to access phlebotomy services elsewhere e.g. local hospital or GP then follow process [below](#).

Unable to analyse sample

- **T2 error on PoCHi machine - Allow** sample to settle for 2 minutes, re-mix sample on mixer and re-run sample **ONCE** only. If T2 error still occurs, follow process on next page.
- **PoCHi failure** - PoCHi machine not working, or stops working during clinic, contact CPMS / Sysmex and follow process on next page.
- **Patient prescribed a brand other than Clozaril®** - PoCHi machine can’t be used, follow process on next page.

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**If an immediate result is not available for whatever reason, the following steps should be followed:**

**Clozapine Clinic Team:**

- Discuss with/explain to patient reasons for being unable to obtain a result within one stop clinic.
- Follow locally agreed route for analysis of sample, this may involve posting to CPMS or sending to local pathology laboratory; this will also depend on sampling frequency and previous blood result validity
- Check with patient the length of supply remaining in their possession & ascertain whether a further supply will be needed to cover the period until the result is available (this will depend on/determine where the blood sample has been/should be sent).
- Inform dispensing pharmacy that a result is not available obtaining advice regarding the number of days of medication supply allowed, taking into account blood result validity



**Pharmacy Technician (One-stop clinic):**

- If possible, supply partial medication as determined above, document amount supplied on electronic patient record and quarantine any remaining supply.
- If the “one-stop” medication cannot be used for a partial supply, e.g. in a compliance aid, return it to the quarantine cupboard or the relevant dispensary.



**Clozapine Clinic Team:**

- Agree with patient/clinical staff how full or remainder of medication supply will be collected or delivered from community clinic once result is obtained
- If sample sent to local pathology laboratory, a clinical team member should be nominated to retrieve the result via the electronic patient record and enter it onto the CPMS system (or email/telephone CPMS@viatris.com, 0845 7698269)
- Proceed according to the result on CPMS (Red / Amber / Green)
- If partial supply given, arrange with relevant dispensary/clinical pharmacy team for appropriate supplementary supply to be prepared.
- If full quarantined one-stop medication to be used, follow steps for release in “[patient fails to attend](#)” process



**Dispensary Pharmacy Team:**

- Once result obtained, release medication from quarantine (one-stop – follow process outlined in “[patient fails to attend](#)”) or directly from dispensary if providing a supplementary supply to re-align supplies to next clinic week.



**Clozapine Clinic Team / Care Co-ordinator:**

- If the quarantined one-stop medication supply is used, follow steps for release in “[patient fails to attend](#)” process
- Ensure patient receives their supply of clozapine and next clinic appointment



Result obtained and responses to safety questions recorded on electronic patient record & eVCB (or equivalent)

**Smoking status**

**Clozapine Clinic Team:**

At every clinic attendance check each patient’s smoking status & record on their electronic patient record:

- If there is no change to smoking status, take no further action.
- If smoking status has changed, clarify when the patient stopped / started smoking & notify consultant / care co-ordinator so that an early review can be arranged.



**Prescriber/Clinician:**

- Refer to “Stop Smoking Products” guidelines and/or “Clozapine and the role of therapeutic drug monitoring” guidelines (via Intranet) to determine whether a check of plasma clozapine levels is appropriate & notify clozapine clinic team of any action needed

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Clozapine plasma level requested by RC (or appropriate clinician):

- This is not a routine or mandatory blood test that can be completed in the one-stop clinic
- A plasma level assay is only done if clinically indicated, e.g. to assess compliance\*, to help assess poor response or dose-related side-effects, to monitor the effect of changes in smoking habit – see “[Clozapine & the role of Therapeutic Drug Monitoring guidance](#)”.
- While the blood sample for a plasma level assay may be taken in the one-stop clinic, it cannot be analysed on the PoCHi machine or at the local hospital path lab – it must be sent to the commissioned external specialist laboratory (currently Viapath)
- The result of a plasma assay is reported after 3-5 days as a “level” in **mg per litre (mg/L)** – not as red/amber/green (this terminology is only used in relation to the routine, mandatory FBC monitoring)

*\*the result of the plasma level assay (clozapine vs norclozapine levels) will indicate if there has been non-compliance or poor compliance with the prescribed dose in the preceding few days, regardless of the patient’s self-reported compliance.*

**Clozapine Clinic Team:**

- Contact patient and advise to omit morning dose (if applicable) on day of next clinic visit
- At clinic visit, draw additional blood sample (within 12 hours of last dose); complete plasma clozapine assay request form, check time last dose taken & smoking status
- Pack in envelope/packaging provided & post to relevant laboratory for analysis
- Record blood sampling and purpose on electronic patient record
- Advise patient to take omitted morning dose (if applicable) as soon as possible

**Clinical Pharmacist / Pharmacy Team / Care co-ordinator:**

When email notification of a plasma clozapine level is received:

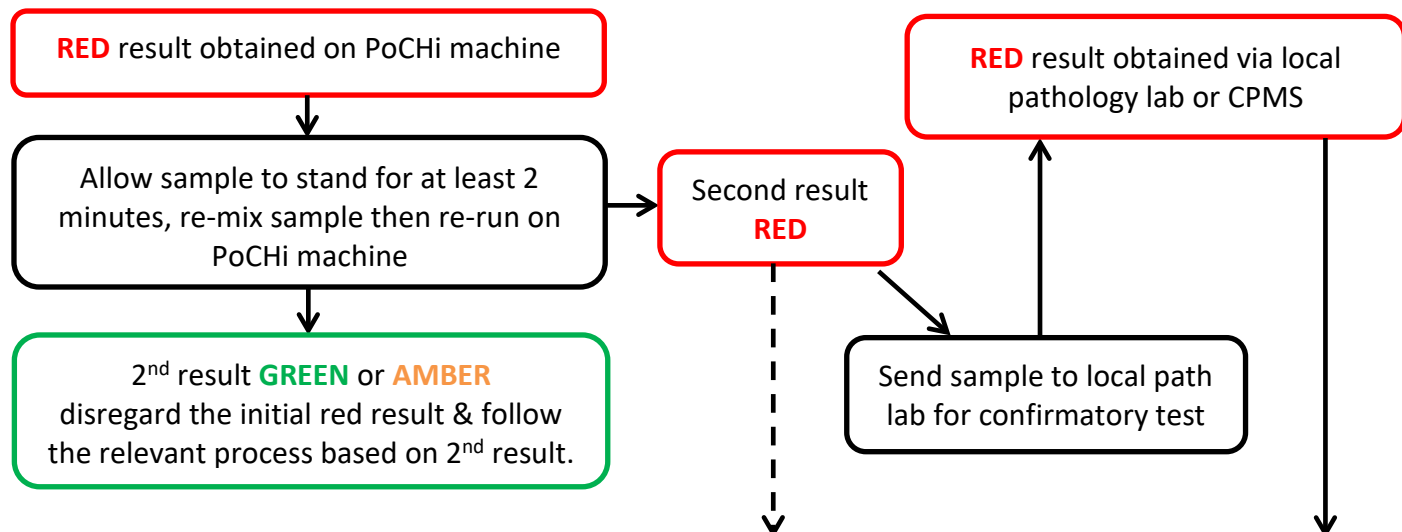
- Access relevant online results gateway
- Copy and paste result into electronic patient record
- Notify RC/appropriate clinician of level by most appropriate route (dependent on urgency) and agree any action required

**Prescriber / appropriate clinician (inc.pharmacy team):**

- Review plasma level result (refer to Trust “Clozapine & the role of therapeutic Drug Monitoring Guidance”)
- Amend dose of clozapine if necessary & arrange for new prescription if dose is changed
- Document actions on electronic patient record
- Re-check plasma levels one week after dose change & until clinical indication for checking levels has resolved (e.g. resolution of side-effects, compliance confirmed)

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Red Result



**Clozapine Clinic Team:**

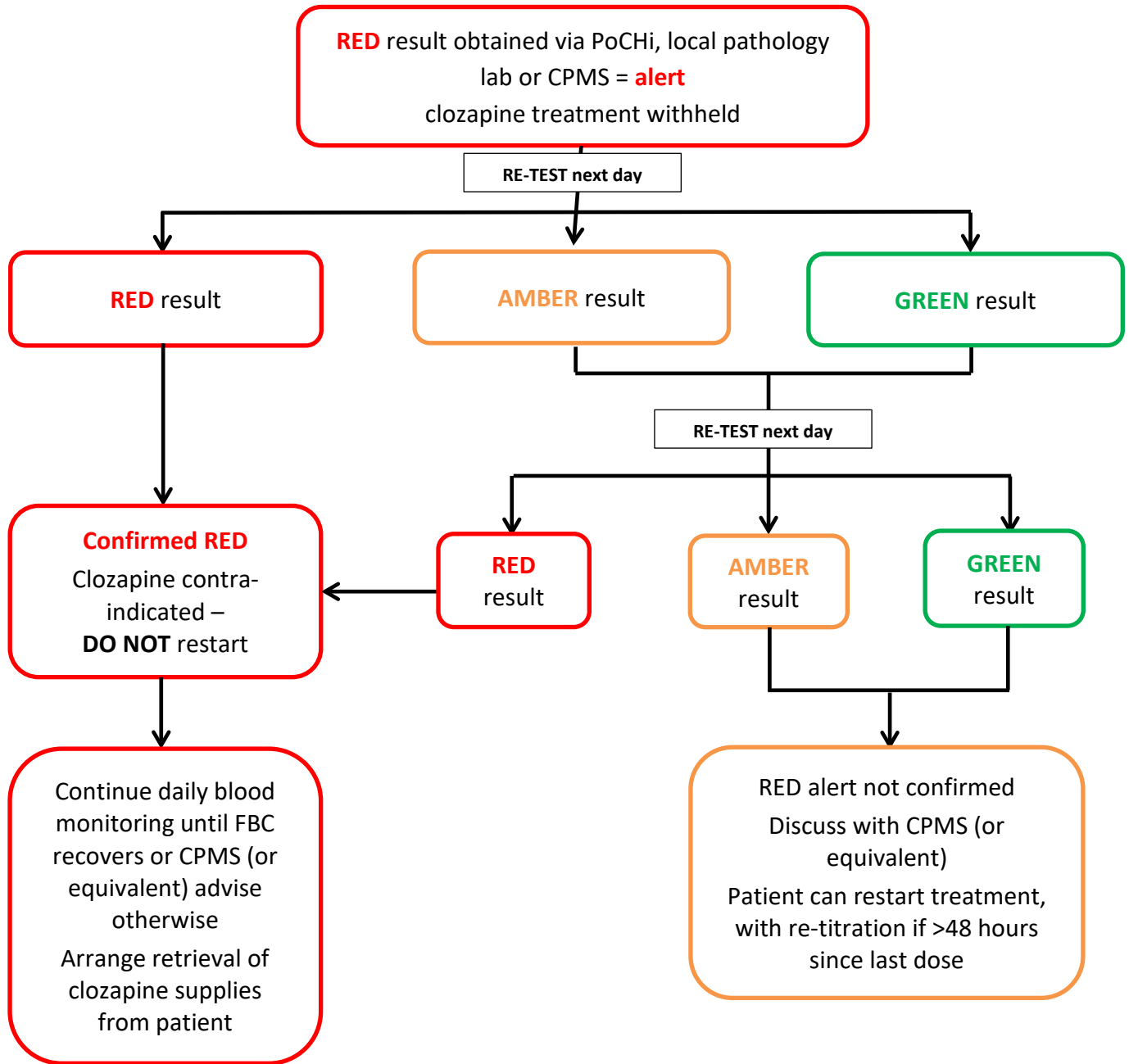
- Inform RC, care co-ordinator, ward team (if inpatient) and relevant dispensary of RED result
- Tell patient to **STOP** taking clozapine **IMMEDIATELY**. If patient is not present at time of result, agree who will contact them.
- Contact CPMS (or other monitoring service where relevant) for advice regarding further blood testing & share this information with the RC, care co-ordinator, ward team (inpatients) and relevant dispensary
- Ensure further monitoring is completed as per CPMS instruction until advised that it can cease (ongoing frequency may vary depending on actual results)
- Update eVCB or equivalent (York)

**Person identified to contact the patient:**

- Inform the patient that they must **STOP** taking clozapine **IMMEDIATELY**
- For in-patients – ensure clozapine discontinued on prescription & administration record chart
- For community patients – arrange retrieval of all supplies of medication held by the patient and return any medication to relevant Trust dispensary using secure transport
- Check with the patient to see if they are experiencing any signs of infection e.g. sore throat
- Ensure blood sampling is undertaken in accordance with CPMS advice
- If RED result is received out of hours follow advice above & arrange which staff will retrieve further blood results, ensuring arrangements are made for the next blood test. (If staff member retrieving result out of hours is unable to access CPMS, contact on call pharmacist to have results entered onto CPMS, results must be reported as soon as they are available).

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Red Result actions:



Footnotes:

1. Sudden cessation of treatment with clozapine can lead to physical & mental withdrawal effects which may occur within 2-3 days, usually within the first two weeks. Patients may experience a rapid deterioration in their mental state with rebound psychosis. Abrupt withdrawal of clozapine has also been associated with symptoms such as nausea, vomiting, diarrhoea, headache, restlessness, agitation & sweating.
2. Following a RED result, daily blood monitoring must be completed for at least TWO days, if either of these two results is RED, this is a confirmed RED result & the patient is non-challengeable with clozapine. If the second result is AMBER or GREEN, the third daily test must still be completed. This means that a red result will almost always necessitate re-titration of clozapine as the patient will have a treatment break of >48 hours.
3. Clozapine can be re-titrated if a patient does not get a second RED result, but this should be a clinical decision & must be discussed with the appropriate monitoring service.

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Amber result

AMBER result obtained on PoChi machine

AMBER result obtained via local pathology lab or CPMS

**Clozapine Clinic Team:**

- Inform RC, care co-ordinator, ward team (if inpatient) and relevant dispensary of AMBER result.
- Enter AMBER result details onto the eVCB (or equivalent) & document details in the electronic patient record
- Complete physical health observations, medication can be issued (as per [green result](#) process)

NO

Is the patient physically well?

YES

Repeat blood test in 1-2 days, or as advised by CPMS

Repeat blood test in 2-3 working days\*, or as advised by CPMS

**Clozapine Clinic Team:**

- Inform clinical team of date next blood sample is required. (If a patient has regular amber results, contact CPMS 0845 769 8269, repeat samples may not be required as frequently)
- Arrange appointment & enter the date of the next blood test into eVCB comments column (or equivalent in York) & document details on electronic record
- Take repeat blood sample as arranged

Result of repeat test:  
**GREEN**

Result of repeat test:  
**AMBER**

Result of repeat test:  
**RED**

Return to standard monitoring & testing week

Repeat test as above until non-amber result

STOP clozapine & follow RED result process

**Clozapine Clinic Team:**

- Inform patient, RC, care co-ordinator and relevant dispensary of result and any actions required
- Update the eVCB (or equivalent), arrange the next appointment & document details in the electronic patient record

**\*Initial amber result on:**

Monday, next test Wednesday/Thursday;  
Tuesday, next test Thursday/Friday;  
Wednesday, next test Friday  
Thursday/Friday, next test Monday

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Green result

**GREEN** result obtained on PoCHi machine or via local pathology lab or CPMS



**Pharmacy Team (One Stop Clinic or Dispensary):**

→ Enter the blood test date and result on the supply log on the prescription and initial (this should be done BEFORE medication is issued to ensure medication is not given out before blood result is received).

**Medication can be released to the patient after checking the following against the CPMS (or equivalent) record & the prescription:**

- Patient’s name
- Patient’s date of birth
- CPMS (or equivalent) number
- Dose of each medication
- Whether the dose has been changed by anyone, including the patient, since the last supply of medication
- Whether the patient has missed any doses recently
- Whether patient only collects one week of medication at a time due to compliance issues
- Check the amount remaining from previous supply – this should not exceed the amount needed until the end of the current blood testing week, i.e. a rolling excess of 3-4 days’ supply (excluding any buffer supplied for business continuity purposes)
- Counsel patient as appropriate - see [Appendix 9](#) (One-stop clinic) or [Appendix 8](#) (Dispensary/community team)

**Refer to pharmacist/RC/care co-ordinator/clozapine clinic team when necessary depending on responses to questions above**

- A standard minimum entry must be made on the electronic patient record ([Appendix 10](#)) and any additional information should be added as necessary.
- Update the eVCB (or equivalent) and arrange the next appointment

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## Lost supplies

### Reported by patient/carer

- If a patient/carer reports that a supply of clozapine has been lost the priority must be to consider how missed doses can be avoided such that re-titration is unnecessary (doses missed >48 hours). This will usually require an interim/emergency supply while the loss is investigated.
- In working hours - contact the usual supplying Trust dispensary and agree a quantity to be ordered/supplied, taking into consideration:
  - The risk of overdose or diversion (if the reported loss is potentially false)
  - The validity of the most recent blood result / date of next clinic visit
  - The capability of the patient to collect or team to deliver further interim supplies until next full supply
- Out of hours – contact on-call pharmacist and refer to “[Clozapine: Process for accessing out of hours](#)”
- Once an emergency supply has been arranged and missed doses avoided, the clinical team should investigate the validity and circumstances of the loss and report it as a medication incident on Datix and in the EPR, including the following details:
  - How many days’ supply (approx.) were there?
  - Where the supply was lost / last in the patient’s possession?
  - What has the patient/carer done to try and find it?
  - Was any other medication lost with it?
  - Has this happened before with this patient?
- Consider any risk to:
  - Patient – loss of symptom control from missed doses; any safeguarding concerns?
  - Family – any risk of accidental ingestion by children if lost at home?
  - Public (e.g. if left on a bus) - has it been reported to bus company?
- If repeat incident, review capability of patient to manage current supply arrangements – are weekly supplies required (within 2-weekly / 4-weekly monitoring)?

### Reported by inpatient ward

- If a ward reports that a supply of clozapine for a particular patient has been lost the priority must be to consider how missed doses can be avoided such that re-titration is unnecessary (doses missed >48 hours). This will usually require an interim/emergency supply while the loss is investigated.
- In working hours - contact the usual supplying Trust dispensary and agree a quantity to be ordered/supplied, taking into consideration the validity of the most recent blood result / date of next clinic visit
- Out of hours – refer to “[Clozapine: Process for accessing out of hours](#)”
- Once an emergency supply has been arranged and missed doses avoided, the ward team should investigate the loss and report it as a medication incident on Datix
- If repeat incident on this ward, review arrangements for safe medicines storage and management of patient-specific supplies

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## Transfer between care settings

### Admission to TEWV inpatient ward

See checklist of admission tasks in [appendix 11](#)

### Discharge from TEWV inpatient ward

See checklist of discharge tasks in [appendix 12](#)

## Transfer between clinics / inpatient to clinic / from another Trust

### **Departing Clozapine Clinic Team:**

Notify relevant dispensary of patient transfer – including all relevant patient details, any comments from eVCB (or York equivalent) and any outstanding monitoring or supply issues, e.g. waiting for plasma levels



### **Departing Clinical Pharmacy Team:**

Remove patient from eVCB (or York equivalent) and update electronic patient record using a standard pharmacy case note entry



### **Receiving Clinical Pharmacy Team:**

- Inform monitoring service of any changes in consultant, blood sampling venue, dispensing pharmacy, etc.
- Add patient to receiving clinic eVCB (or York equivalent) updating details & electronic patient record using a standard case note entry



### **Receiving Clinical Pharmacy team:**

- Internal transfer:
  - update the site & consultant details (if required) on the electronic prescription template
  - check if any comments are still relevant
  - ensure that dispensing pharmacy details are amended in the footer of the script or transfer to the dispensary-specific prescription template
- Transfer from another Trust – generate new prescription with details provided by departing Trust
- Save updated / new prescription in relevant pharmacy shared folders

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## Emergency supply for non-TEWV patient

- On rare occasions it may be necessary to arrange an emergency supply of Clozapine to a patient from another Trust (e.g. a holidaymaker who has forgotten to bring their own supply, or admitted to a TEWV inpatient unit)
- CPMS and the other Clozapine monitoring services have a “Memorandum of Understanding” that such a supply may be made under these conditions to ensure continuity of treatment. If more than 7 days’ supply is required, the patient must be registered with the relevant monitoring service before further supplies may be made

### Prescriber (e.g. Crisis Team):

- Contact home Trust/team and confirm patient details (name, DOB, NHS number and monitoring service number) with medical or nursing staff
- Check the current “blood status” with the appropriate blood monitoring service:
  - Clozaril® CPMS 0845 7698269 or [CPMS@viatris.com](mailto:CPMS@viatris.com)
  - Zaponex® ZTAS 0207 3655842 Mon-Fri 9am-5pm only
  - Denzapine® DMS 0333 2004141
- Issue a prescription for a maximum of 7 days of Clozaril® if all facts validated and a current **GREEN** blood result valid for the prescribing period is in place
- Inform the relevant Trust dispensary to expect the prescription (NB. can’t be dispensed by a community pharmacy)



### Dispensary Team:

- Issue up to 7-day supply of medication as per prescription
- Ensure prescriber is aware of arrangements needed to enable further supplies where relevant

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## Patient admitted to acute hospital

**Elective admission** - patients should ensure their current own supply of Clozapine is taken into hospital with them.

### Emergency admission:

**Whichever TEWV team is informed of admission e.g. Liaison Team:**

Notify the relevant clozapine clinic team / dispensary that the patient has been admitted and their current location



**Clozapine Clinic Team / Care Co-ordinator:**

Arrange for standard monitoring of FBC / pick up admission blood results as appropriate and ensure result is entered onto CPMS



**Dispensary Team:**

- Issue 7-day supplies of medication as needed (from current 6-month prescription if valid or request a new handwritten prescription)
- Transfer medication to Acute Trust using whichever method of supply is most appropriate at the time, using scheduled delivery runs if possible & maintaining an audit trail
- Establish communication with acute Trust pharmacy team to arrange further supplies

See: [Safety guidance - Clozapine on admission to an acute hospital ward - Tees Esk and Wear Valley NHS Foundation Trust \(tewv.nhs.uk\)](https://www.tewv.nhs.uk)

N.B. a small supply of clozapine 25 mg and 100 mg tablets is held in the emergency cupboard at York District Hospital, but not at any other acute hospital within the TEWV footprint

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## Miscellaneous processes

### Changes in monitoring frequency / weeks

**Dispensary Team:**

- Receive email from relevant monitoring service authorising change in monitoring frequency
- Determine which clinic patient attends
- Notify relevant pharmacist/technician



**Clinical Pharmacist / Pharmacy Team:**

[Update eVCB](#) (or equivalent in York) & electronic prescription



**Clozapine Clinic Team:**

Notify patient & Care Co-ordinator of the change & next clinic appointment

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## Notification of any changes to treatment

### Prescriber:

#### Notify the relevant dispensary via email:

- When a patient has reached a maintenance dose of Clozapine
- When there are any dose changes of Clozapine.
- If a co-med has been started or stopped or a dose has changed.

Any changes must also be recorded as a case note on the electronic patient record

→ Select the appropriate dispensary email address:

- RPH – [tewv.pharmacytees@nhs.net](mailto:tewv.pharmacytees@nhs.net)
- WPH – [tewv.pharmacycdd@nhs.net](mailto:tewv.pharmacycdd@nhs.net)
- FPH – [tewv.pharmacyork@nhs.net](mailto:tewv.pharmacyork@nhs.net)

→ Cc to any clinical colleagues or specific pharmacy staff who need to be aware

→ Entitle the email “Clozapine/Co-med dose change” **do not** use patient details within the title field

→ Within the body of the email include:

- Electronic patient record ID
- Date of relevant electronic patient record entry
- Required start date of any dose changes (if non-urgent, default will be next clinic date)

### Clinical Team member:

#### A notification should be sent to the relevant dispensary

- When a new patient is initiated on clozapine or transferred to TEWV on clozapine
- When there is a change in monitoring frequency
- When there is a change in monitoring setting e.g. change of community clinic, discharge from in-patients
- Where a patient is admitted to hospital e.g. acute Trust
- To share any other relevant information

→ Select the appropriate dispensary email address:

- RPH – [tewv.pharmacytees@nhs.net](mailto:tewv.pharmacytees@nhs.net)
- WPH – [tewv.pharmacycdd@nhs.net](mailto:tewv.pharmacycdd@nhs.net)
- FPH – [tewv.pharmacyork@nhs.net](mailto:tewv.pharmacyork@nhs.net)

→ Cc to any clinical colleagues or specific pharmacy staff who need to be aware

→ Entitle the email “Clozapine notification” **do not** use patient details within the title field

→ Within the body of the email include

- Electronic patient record ID
- Date of any relevant electronic patient record entry

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## Clozapine eVCB

(Not applicable in York)

See template in [appendix 14](#)



eVCB MUST be saved at the end of EVERY step. NEVER save a copy

Make changes/add patients to the eVCB:

### Clinical Pharmacy Team:

- Access Clinic eVCB on the T drive – [T:\Clozapine](#) & enter relevant passwords to open the excel spreadsheet
- To make changes e.g. add patients or move patients between clinic weeks
  - Click on the “review” tab at the top of the spreadsheet & select “unprotect sheet”.
  - A box will appear, type the sheet protection password in, to unlock the sheet for editing.
  - Enter all patient demographics in the relevant columns
  - Once editing is complete, go back to the “review” tab & select “protect sheet”
  - A box will appear, enter the password used to unlock the sheet.
  - Another box will appear & ask you to reconfirm the password.
  - Enter the password **in the same format**.
  - Take care not to change the password when you re-enter it. If you make any changes you will create a new password & all users must be informed.
  - **If you change & forget the password, you will not be able to unlock the sheet in the future – contact IT if locked**
- Click on the “save” button to save any changes

Update dispensing information on eVCB:

### Dispensary Team:

- Access Clinic eVCB on the T drive – [T:\Clozapine](#) & enter relevant passwords to open the excel spreadsheet
  - Complete column headed Dispensed (Yes/No).
  - Complete quarantine column for clinics without a one-stop facility (Yes/No)
- Note: these columns link to the date of clinic column**

Update medication quarantine information (one stop clinic):

### Pharmacy Technician (One Stop Clinic):

- Access Clinic eVCB on the T drive – [T:\Clozapine](#) & enter relevant passwords to open the excel spreadsheet
  - After medication has been checked and quarantined in agreed area, update quarantine column. If any medication is missing contact the relevant dispensary and make arrangements for medication to be delivered.
- Note: quarantine column links to date of clinic column**

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### Add to/update eVCB during one stop clinic:

#### Clozapine Clinic Team:

- If not already open - access Clinic eVCB on the T drive – [T:\Clozapine](#) & enter relevant passwords to open the excel spreadsheet
- Complete clinic date column
- For each patient, enter details in “Attended” column and “Blood Status” column, selecting the relevant options for the patient from the lists.
- Make appropriate entries on the electronic patient record
- Notify red or amber result to clinical team as per relevant process
- Inform pharmacy teams if blood sample or blood result is unobtainable for any reason as per relevant process
- At the end of the clinic change ‘Clinic Date’ column after each weekly clinic to the date when the next clinic is due in its rotation

### Update issue of medication to patient at one stop clinic:

#### Pharmacy Technician (One Stop Clinic):

- eVCB should already be open
- If blood and physical monitoring is within correct guidelines, (i.e. Green Blood Result) release medication to patient
- Complete “clozapine released” column
- Report any delays in collection of medication to the Care Coordinator (obtain current details from electronic patient record)
- After the clinic is finished, complete any follow up work as necessary

### Update issue of medication to patient from dispensary:

#### Dispensary Team:

- Access Clinic eVCB on the T drive – [T:\Clozapine](#) & enter relevant passwords to open the excel spreadsheet
- If blood & physical monitoring is within correct guidelines, (i.e. Green Blood Result) release medication to patient.
- Complete “clozapine released” column
- If blood results are delayed and a subsequent valid Green result is reported fill in details of release date and initial in column “Released (pharmacy staff initials)” when clozapine is released from quarantine
- Report any delays in collection of medication to the Care Coordinator (obtain current details from electronic patient record)
- At the end of each week, reset the Dispensed and Clozapine Quarantined columns to “No” for all patients.

Title	Clozapine: processes for prescribing, dispensing, supply & monitoring		
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## Appendix 1: Clozapine Task Checklist – In-patient initiation

Patient Name: ..... Date of Birth: ..... NHS No: .....

Ward: ..... Consultant: ..... CPMS No.: .....

Note: CPMS = CPMS or equivalent monitoring service (ZTAS or DMS)

STEP 1: PRIOR TO COMMENCEMENT OF CLOZAPINE:																															
all tasks must be completed prior to commencement but not necessarily in order listed																															
✓		Initial	Date																												
	MDT decision made to commence clozapine with patient consent* or in line with MHA consent to treatment requirements (*if off-label use, ensure consent covers this)																														
	Education session with patient re potential benefits, monitoring & side effects – document on electronic patient record, including information provided & questions asked																														
	Ensure the following tests are completed and results recorded on electronic patient record as a physical health case note - <i>inform doctor of any readings consistently out of range:</i>																														
	<table border="1"> <tr> <td>Physical examination</td> <td></td> <td>Weight (W)</td> <td></td> <td>U&amp;Es</td> <td></td> </tr> <tr> <td>Blood pressure</td> <td></td> <td rowspan="2">Calculate weight increase threshold (W x 1.05) =</td> <td></td> <td>Lipids</td> <td></td> </tr> <tr> <td>Temperature</td> <td></td> <td>Prolactin</td> <td></td> </tr> <tr> <td>Pulse</td> <td></td> <td>Waist circumference</td> <td></td> <td>HbA1c</td> <td></td> </tr> <tr> <td>Height</td> <td></td> <td>ECG</td> <td></td> <td>LFTs</td> <td></td> </tr> </table>	Physical examination		Weight (W)		U&Es		Blood pressure		Calculate weight increase threshold (W x 1.05) =		Lipids		Temperature		Prolactin		Pulse		Waist circumference		HbA1c		Height		ECG		LFTs			
Physical examination		Weight (W)		U&Es																											
Blood pressure		Calculate weight increase threshold (W x 1.05) =		Lipids																											
Temperature			Prolactin																												
Pulse		Waist circumference		HbA1c																											
Height		ECG		LFTs																											
	Baseline FBC taken and sent to local Path Lab – this will only be valid for 10 days from sample date																														
	Confirm consultant registered with CPMS																														
	Inform ward Pharmacy Team of intention to commence clozapine																														
	Patient registration form completed and sent to CPMS ( <a href="mailto:CPMS@viatris.com">CPMS@viatris.com</a> )																														
	Confirmation of registration and green result from CPMS (NB: result only valid for 10 days from date of sample so clozapine must commence within this time)																														
	Prescribe clozapine on prescription and administration record with dose 'as per titration chart'																														
	Prescribe clozapine on green titration chart (either standard or individualised)																														
	Order initial supply of clozapine from dispensary using one of the following options: a) Ward staff - send or scan/email signed titration chart to dispensary (copy will be kept in dispensary, original returned to ward) b) Pharmacy staff - inpatient order on EMIS after clinical check by pharmacist																														
STEP 2: COMMENCEMENT OF CLOZAPINE, DAY 1:																															
✓		Initial	Date																												
	Immediately prior to administration of clozapine assess NEWS and record on chart																														
	If all NEWS parameters within normal limits administer clozapine – any abnormalities, contact doctor for advice as to whether clozapine can be administered <i>If first dose taken at night no further monitoring required that day</i>																														
	If first dose taken during the day NEWS parameters to be checked hourly for six hours post dose																														
	Enter alert on electronic patient record: Significant medication alert – patient on clozapine																														
	Arrange date of next FBC test																														

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<b>STEP 3: TITRATION OF CLOZAPINE, DAYS 2 – 14:</b>								
all tasks must be completed but not necessarily in order listed								
✓							Initial	Date
	Blood sample obtained for FBC and sent for analysis (Pochi machine or path lab) within 10 days of baseline test							
	Monitor and record NEWS at least once daily (ideally 2-6 hours post-dose) and inform medical staff if parameters out of range							
	Day 7 & day 14 – check weight and record on prescription chart and electronic patient record							
	Discuss the following common side effects with patient and record presence/absence in electronic patient record each week							
		Constipation	Sedation	Hypersalivation	Nocturnal enuresis	Nausea	Signs of infection	
	Week 1							
	Week 2							
	Inform medical staff if patient reports an increase in side effects or weight is increasing							
	Brief assessment of mental state completed including mood, thinking and behaviour							
<b>STEP 4: STABILISATION OF CLOZAPINE THERAPY, DAY 15 ONWARDS:</b>								
✓							Initial	Date
	Continue <b>weekly</b> blood sampling for FBC tests							
	Once titration to target dose completed, prescribe on main prescription chart (but retain titration chart for reference)							
	Order further supplies of clozapine according to dose titration, validity of blood results and frequency of ward visits							
	Monitor NEWS as per physical health policy or when bloods are taken (whichever is the most frequent), or more often if any parameters are out of range – alert medical staff if any parameters are out of range							
	Monitor side effects, in particular those listed below every time bloods are taken, or more frequently if patient has any issues. Alert medical staff if any change in side effects they have not been informed about. Record presence/absence on electronic patient record. <ul style="list-style-type: none"> <li>• Constipation</li> <li>• Sedation</li> <li>• Hypersalivation</li> <li>• Nocturnal enuresis</li> <li>• Nausea</li> <li>• Signs of infection</li> </ul>							
	Arrange 6 monthly script once stable dose is reached on long stay or rehabilitation wards							
	At week 12 repeat / check: ECG <input type="checkbox"/> HbA1c <input type="checkbox"/> Lipids <input type="checkbox"/>							
	Continue physical health monitoring as per guidelines Check weight <b>weekly</b> – see threshold in step 1; inform medical staff if weight is increasing. <i>Rapid weight gain in early treatment (≥5% above baseline after 1 month of treatment) strongly predicts long-term weight gain &amp; should prompt consideration of preventative or remedial measures</i>							
	Monitor plasma clozapine levels if clinically indicated (see Trust guidance)							
	Check smoking status regularly and inform medical staff of any changes							
	Regular, brief assessment of mental state completed including mood, thinking and behaviour							

**RECORD COMPLETION OF EACH TASK IN THE ELECTRONIC PATIENT RECORD (OR SCAN COMPLETED CHECKLIST)**

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## Appendix 2: Clozapine Task Checklist – Community initiation

*N.B. Parkinson's disease patients may have CPMS approval for reduced blood & physical health monitoring*

**Patient Name:** ..... **Date of Birth:** ..... **NHS No.:** .....

**Ward:** ..... **Consultant:** ..... **CPMS No.:** .....

*Note: CPMS = CPMS or equivalent monitoring service (ZTAS or DMS)*

<b>STEP 1: PRIOR TO COMMENCEMENT OF CLOZAPINE:</b>																																
all must be completed prior to commencement but not necessarily in order listed																																
✓		Initial	Date																													
	MDT decision made to commence clozapine with patient consent* or in line with MHA consent to treatment requirements(*if off-label use, ensure consent covers this)																															
	Education session with patient re potential benefits, monitoring & side effects – document on electronic patient record, including information provided & questions asked																															
	Ensure the following tests are completed and results recorded on electronic patient record as a physical health case note - <i>inform doctor of any readings consistently out of range:</i>																															
	<table border="1"> <tr> <td>Physical examination</td> <td></td> <td>Weight (W)</td> <td></td> <td>U&amp;Es</td> <td></td> </tr> <tr> <td>Blood pressure</td> <td></td> <td rowspan="2">Calculate weight increase threshold (W x 1.05) =</td> <td></td> <td>Lipids</td> <td></td> </tr> <tr> <td>Temperature</td> <td></td> <td></td> <td>Prolactin</td> <td></td> </tr> <tr> <td>Pulse</td> <td></td> <td>Waist circumference</td> <td></td> <td>HbA1c</td> <td></td> </tr> <tr> <td>Height</td> <td></td> <td>ECG</td> <td></td> <td>LFTs</td> <td></td> </tr> </table>	Physical examination		Weight (W)		U&Es		Blood pressure		Calculate weight increase threshold (W x 1.05) =		Lipids		Temperature			Prolactin		Pulse		Waist circumference		HbA1c		Height		ECG		LFTs			
Physical examination		Weight (W)		U&Es																												
Blood pressure		Calculate weight increase threshold (W x 1.05) =		Lipids																												
Temperature				Prolactin																												
Pulse		Waist circumference		HbA1c																												
Height		ECG		LFTs																												
	Baseline FBC taken and sent to local Path Lab – this will only be valid for 10 days from sample date																															
	Confirm consultant registered with CPMS																															
	Inform pharmacy department of intention to commence clozapine and any special requirements for supply, e.g. monitored dose system																															
	Patient registration form completed and sent to CPMS ( <a href="mailto:CPMS@viatris.com">CPMS@viatris.com</a> )																															
	Confirmation of registration and green result from CPMS ( <i>NB: result only valid for 10 days from date of sample so clozapine must commence within this time</i> )																															
	Prescribe clozapine on green titration chart (either standard or individual)																															
	Order initial supply of clozapine from pharmacy using one of the following options: c) send titration chart to dispensary (will be kept in dispensary, copy returned with supply) d) outpatient prescription																															
	Set up arrangements for seeing patient daily during early titration phase																															
	Set up arrangements for collection of clozapine from pharmacy and/or delivery to patient.																															

<b>STEP 2: COMMENCEMENT OF CLOZAPINE, DAY 1:</b>			
✓		Initial	Date
	Immediately prior to administration of clozapine assess BP, pulse and temp and record on electronic patient record		
	If all above within normal limits administer clozapine – any abnormalities contact doctor for advice as to whether clozapine can be administered <i>If first dose taken at night no further monitoring required that day</i>		
	If first dose taken during the day BP, pulse, temp to be checked hourly for six hours post dose		

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	Enter alert on electronic patient record: Significant medication alert – patient on clozapine		
	Arrange date of next FBC test		
	Check arrangements are in place for next FBC test and supply of clozapine		

**STEP 3: TITRATION OF CLOZAPINE, DAYS 2 – 14:**  
all must be completed but not necessarily in order listed

✓		Initial	Date																					
	Blood sample obtained for FBC at clozapine clinic or sent to path lab within 10 days of baseline test																							
	Monitor and record BP, pulse, temp at least once daily (ideally 2-6 hours post-dose), with crisis team support as necessary, and inform medical staff if out of range																							
	Day 7 & day 14 – check weight and record on electronic patient record																							
	Discuss the following common side effects with patient and record presence/absence on electronic patient record each week (at clozapine clinic or separate consultation)																							
	<table border="1"> <thead> <tr> <th></th> <th>Constipation</th> <th>Sedation</th> <th>Hypersalivation</th> <th>Nocturnal enuresis</th> <th>Nausea</th> <th>Signs of infection</th> </tr> </thead> <tbody> <tr> <td>Week 1</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Week 2</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>		Constipation	Sedation	Hypersalivation	Nocturnal enuresis	Nausea	Signs of infection	Week 1							Week 2								
	Constipation	Sedation	Hypersalivation	Nocturnal enuresis	Nausea	Signs of infection																		
Week 1																								
Week 2																								
	Inform medical staff if patient reports an increase in side effects or weight is increasing.																							
	Brief assessment of mental state completed including mood, thinking and behaviour																							
	Arrange attendance at one-stop clozapine clinic or ensure alternative arrangements are in place for monitoring and supply if one-stop clinic is not accessible																							

**STEP 4: STABILISATION OF CLOZAPINE THERAPY, DAY 15 ONWARDS:**

✓		Initial	Date
	Continue <b>weekly</b> blood sampling for FBC at clozapine clinic or via path lab		
	Arrange further supplies of clozapine in line with titration until stable dose is reached		
	Monitor BP, pulse and temp when bloods are taken, or more often if any parameters are out of range – alert medical staff if any parameters are out of range		
	Monitor side effects, in particular those below every time bloods are taken, or more frequently if patient has any issues. Alert medical staff if any change in side effects they have not been informed about. Record on electronic patient record. <ul style="list-style-type: none"> <li>• Constipation</li> <li>• Sedation</li> <li>• Hypersalivation</li> <li>• Nocturnal enuresis</li> <li>• Nausea</li> <li>• Signs of infection</li> </ul>		
	Arrange 6 monthly prescription once stable dose is reached		
	Continue physical health monitoring as per guidelines Check weight <b>weekly</b> – see threshold in step 1; inform medical staff if weight is increasing. <i>Rapid weight gain in early treatment (≥5% above baseline after 1 month of treatment) strongly predicts long-term weight gain &amp; should prompt consideration of preventative or remedial measures</i>		
	At week 12 repeat / check: ECG <input type="checkbox"/> HbA1c <input type="checkbox"/> Lipids <input type="checkbox"/>		
	Monitor plasma clozapine levels if clinically indicated (see Trust guidance)		
	Check smoking status regularly and inform medical staff of any changes		
	Regular, brief assessment of mental state completed including mood, thinking and behaviour		

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## Appendix 4: Prescription tracker example

Patient's Name	PARIS ID	NHS No.	D.O.B	Consultant	Clozapine Dose	Total Clozapine Dose	Augmentation	Co-Meds	Type of Prescription	Dispensing Type	Type of Change	Notification Date	Date Rx Sent to Consultant/Prescriber/Secretary	Method Rx Sent	Completed By	Review Date	Clozapine on SCR	Issues with SCR	Notes
Patient 1				Psyc 1	175mg CN	175mg			Clozapine Only		6 Month Review		13/07/20	Printed Copy	MC & MW	19/07/2021	No	No	Email sent to GP to update SCR
Patient 2				Psyc 1	1/2mg am, 1/2mg 2pm, 175mg 6pm, 75mg 9pm	750mg	Other	Lorazepam 1mg PRN, Trifluoperazine 5-10mg PRN	Clozapine Only		6 Month Review		14/07/20	Printed Copy	MC & MW	13/07/2021	Yes	No	
Patient 3				Psyc 1	100mg SIX times a day, 50mg CN	650mg	Other	Lorazepam 1mg PRN, Sertraline 50mg CM	Clozapine Only	Weekly Med Pack	6 Month Review		15/07/20	Printed Copy	MC & MW	13/07/2021	Yes	Yes	On Citalopram on SCR
Patient 4				Psyc 1	75mg CM, 100mg CN	175mg	Aripiprazole 5mg	Aripiprazole 5mg CM	Clozapine Only		6 Month Review		16/07/20	Printed Copy	MC & MW	14/07/2021	Yes	No	
Patient 5				Psyc 1	150mg CM, 100mg 6pm, 325mg CN	575mg	Other	Amitriptyline 25mg CN, Diazepam 2mg BD	Clozapine Only		6 Month Review		17/07/20	Printed Copy	MC & MW	15/07/2021	Yes	No	
Patient 6				Psyc 1	100mg CM, 275mg CN	375mg	Other	Sertraline 200mg CM	Clozapine Only		6 Month Review		18/07/20	Printed Copy	MC & MW	16/07/2021	Yes	No	
Patient 7				Psyc 1	400mg CN	400mg			Clozapine Only	Weekly Med Pack	6 Month Review		19/07/20	Printed Copy	MC & MW	17/07/2021	Yes	Yes	On Clonazepam on SCR
Patient 54				Psyc 3	100mg CM, 125mg CN	225mg			Clozapine Only		Dose Reduced		14/09/20	Printed Copy	MC & MW	19/03/2021	Yes	No	
Patient 55				Psyc 3	100mg CM, 325mg CN	425mg		Depakote 500mg BD	Clozapine Only		Site Change		18/09/20	Printed Copy	MC & MW	19/03/2021	Yes	No	
Patient 56				Psyc 3	50mg CM, 500mg CN	550mg			Clozapine Only		Dose Increased		18/09/20	Printed Copy	MC & MW	19/03/2021	Yes	No	
Patient 57				Psyc 3	100mg CM, 250mg CN	350mg			Clozapine Only		New Patient		28/09/20	Printed Copy	MC & MW	29/03/2021	Yes	No	
Patient 58				Psyc 3	200mg CM, 300mg CN	500mg			Clozapine Only		Dose Increased		02/10/20	Printed Copy	MC & MW	02/04/2021	Yes	No	
Patient 59				Psyc 3	150mg CM, 300mg CN	450mg			Clozapine Only		Dose Reduced		09/10/20	Printed Copy	MC & MW	09/04/2021	Yes	No	
Patient 60				Psyc 3	250mg CM, 325mg CN	575mg	Other	Sertraline 150mg CM	Clozapine and Mental Health Co-Meds	Weekly Med Pack	Mental Health Co-Meds		27/10/20	Printed Copy	MC & MW	27/04/2021	Yes	No	
Patient 61				Psyc 3	150mg 12pm, 200mg CN	350mg			Clozapine Only		Dose Reduced		27/10/20	Printed Copy	MC & MW	27/04/2021	Yes	No	
Patient 62				Psyc 3	150mg CM, 400mg CN	550mg			Clozapine Only		Dose Increased		27/10/20	Printed Copy	MC & MW	27/04/2021	Yes	No	
Patient 63				Psyc 3	250mg CN	250mg			Clozapine Only		Dose Increased		25/11/20	Printed Copy	MC & MW	26/05/2021	Yes	No	
Patient 64				Psyc 3	25mg CN	25mg			Clozapine Only		Dose Increased		25/12/20	Printed Copy	MC & MW	29/09/2021	No	No	
Patient 65				Psyc 3	100mg CM, 225mg CN	325mg			Clozapine Only	Weekly Med Pack	Dose Increased		25/12/20	Printed Copy	MC & MW	29/09/2021	Yes	No	
Patient 66				Psyc 3	200mg CN	200mg	Amisulpride	Amisulpride 400mg CM, Sodium Valproate MR 200mg CM & 400mg CN, Venlafaxine CR 75mg CN	Clozapine Only	Weekly Med Pack	Dose Reduced		25/12/20	Printed Copy	MC & MW	29/09/2021	Yes	No	
Patient 67				Psyc 3	300mg CM, 300mg CN	600mg			Clozapine Only	Weekly Med Pack	Dose Reduced		30/12/20	Printed Copy	MC & MW	30/09/2021	Yes	No	
Patient 68				Psyc 3	75mg CM, 400mg CN	475mg			Clozapine Only		6 Month Review		08/01/21	Printed Copy	MC & MW	09/07/2021	Yes	No	
Patient 69				Psyc 3	100mg CM, 225mg CN	325mg	Sulpride	Sulpride 200mg BD	Clozapine and Mental Health Co-Meds		6 Month Review		08/01/21	Printed Copy	MC & MW	09/07/2021	Yes	No	
Patient 70				Psyc 3	275mg CN	275mg	Other	Sodium Valproate 400mg BD	Clozapine and Mental Health Co-Meds		6 Month Review		08/01/21	Printed Copy	MC & MW	09/07/2021	Yes	No	
Patient 71				Psyc 3	125mg CM, 150mg CN	275mg		Venlafaxine 33.75mg LC, Sodium Valproate 400mg BD, Amisulpride 400mg BD, Risperidone 2mg CN	Clozapine Only		6 Month Review		08/01/21	Printed Copy	MC & MW	09/07/2021	Yes	No	Lots of meds

Tracker used in Harrogate – available [here](#). Formatting of “review date” column calculates an expiry date with RAG colour-coding to facilitate non-batch processing of prescriptions, spreading the new prescription task through the year.

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## Appendix 5: Dose change communication form

### Clozapine / co-meds dose change request

Email completed sheet to usual supplying dispensary:

Foss Park (York): [tewv.pharmacyork@nhs.net](mailto:tewv.pharmacyork@nhs.net)

Roseberry Park (Middlesbrough): [tewv.pharmacytees@nhs.net](mailto:tewv.pharmacytees@nhs.net)

West Park (Darlington): [tewv.pharmacycdd@nhs.net](mailto:tewv.pharmacycdd@nhs.net)

<b>Patient Name:</b>	
<b>PARIS number:</b>	
<b>Date of birth:</b>	
<b>CPMS number (if known)</b> or other relevant monitoring service if not taking Clozaril	
<b>Current dose of clozapine/co-meds</b>	
<b><u>NEW DOSE REQUIRED</u></b>	
<b>Urgency of change</b> (tick)	<input type="checkbox"/> immediately <input type="checkbox"/> within the next 7 days (on usual clinic day) <input type="checkbox"/> next clinic appointment
<b>Reason for change</b>	

**Please see PHARMACY case note from last clinic for current dose / date of next clinic appointment**

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## Appendix 7: Quarantine sticker, cupboard notice & log sheet

**GREEN  
RESULT**

**Do not Quarantine**

**\*\*QUARANTINED\*\***

**\*\*CLOZAPINE\*\***

**DO NOT GIVE TO PATIENT WITHOUT  
AUTHORISATION FROM PHARMACIST**

**QUARANTINED  
CLOZAPINE**

**NOT TO BE RELEASED WITHOUT  
AUTHORISATION FROM PHARMACY**

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**Quarantined Clozapine Log Sheet**

Date put into cupboard	Patient ID	Date removed from cupboard	Nurse Signature	Nurse name	Name of Pharmacy staff authorising release	Patient Signature

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## Appendix 8: Supplying clozapine to a patient outside of one-stop clinic

All staff handing out clozapine, whether a nurse or member of the pharmacy team should check the following three questions with the patient before handing over clozapine medication:

1. what dose of clozapine you are taking?
2. Has anyone told you to change the dose of clozapine you take since you last collected it?
3. Have you missed any doses of clozapine recently?

If the patient states yes to question 2, and “more than one dose” to question 3 above then refer to the relevant clozapine clinic for advice before handing supply to the patient.

If any problems are identified these should be recorded on the electronic patient record

### Supplies collected from TEWV bases without a clinic and GP practices

Clozapine to be supplied to patients via their CMHT base or GP surgery (pending a GREEN blood result) should be prepared with a collection pro-forma attached (see next page for example, versions for each dispensary are [here](#)). The CMHT / GP surgery staff should ask the patient to sign this form, then scan and email it back to the relevant TEWV dispensary. If the medication is not collected by the date indicated, the relevant TEWV dispensary must be notified.

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TEWV Pharmacy Department  
 West Park Hospital  
 Edward Pease Way  
 Darlington,  
 DL2 2TS

Please Scan Back to the dispensary at  
 West Park Hospital  
 tewv.pharmacycdd@nhs.net

Tel: 01325 552296

**Message – FAO Clozapine Pharmacy Technician**

**Clozapine Medication Collection Confirmation**

Patient Name.....

Patient Signature.....Date...../...../.....

Collection Location.....

**Please scan this form to the TEWV Trust Pharmacy team once the patient has signed, dated and collected their medication from your practice**

**Please contact the Trust Pharmacy Team on 01325 552296 if medication has not been collected by the date detailed below**

Medication should be  
 collected by -

...../...../.....

**Confidentiality Statement:** The information contained in this document is legally privileged and confidential information intended for the above named only. If you are NOT the intended recipient you are hereby notified that any dissemination, distribution or copy of this document is strictly prohibited. If this has come to you in error, please immediately notify us by telephoning the above number and return the original copy to us by post to the above address. The cost will be reimbursed to you.

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## Appendix 9: Counselling checklist for clozapine patients

For use by Pharmacy Technicians at One Stop Clozapine Clinics, or by nurse in clinic without pharmacy presence

Frequency	Issue	Question	Referral / Action criteria
At every clinic contact	Compliance	<ul style="list-style-type: none"> <li>What is your current dose?</li> <li>Have you missed any doses?</li> <li>Have you taken any extra doses?</li> <li>Have you any clozapine tablets left at home?</li> <li>How many clozapine tablets do you have left at home?</li> <li>Are you managing with how clozapine is supplied to you?</li> </ul> Reminder – rotate supplies so they don't expire	<ul style="list-style-type: none"> <li>Dose not as per script / prepared supply</li> <li>More than odd doses missed; &gt;48 hours since last dose taken</li> <li>Any extra doses taken</li> <li>More than required until end of current week (excluding any extra supply for business continuity)</li> <li>Request for different method of supply, e.g. compliance aid</li> </ul>
	Side effects	<ul style="list-style-type: none"> <li>Do you have any side effects?</li> </ul> In particular: <ul style="list-style-type: none"> <li>Constipation?</li> <li>Diarrhoea? – may be a sign of overflow from constipation</li> <li>Hypersalivation?</li> <li>Any other physical symptoms that you don't usually have (e.g. sore throat, flu like symptoms, palpitations)</li> </ul>	<ul style="list-style-type: none"> <li>Constipation if no treatment has commenced or not resolving with treatment</li> <li>Diarrhoea</li> <li>Worsening treated hypersalivation; untreated hypersalivation which has not already been discussed with a prescriber</li> <li>Any other physical health symptoms not normally experienced</li> </ul>
	Smoking status	<ul style="list-style-type: none"> <li>Do you smoke cigarettes?</li> <li>Have you recently stopped smoking cigarettes, or cut down a lot?</li> <li>Have you recently started smoking cigarettes or increased the amount you smoke a lot?</li> </ul>	<ul style="list-style-type: none"> <li>Any change in smoking status, including switch from cigarettes to e-cigarette/vaping or vice versa</li> <li>Request for support with smoking cessation</li> </ul>
	Alcohol / substance misuse	<ul style="list-style-type: none"> <li>Do you drink any alcohol at all?</li> <li>If so, how much do you drink?</li> <li>Do you use any other substances?</li> <li>Do you drink excessive caffeine-containing drinks?</li> </ul>	<ul style="list-style-type: none"> <li>Regular alcohol use &gt;2 units daily</li> <li>Increase in alcohol or caffeine use</li> <li>Binge drinking *</li> <li>Any substance use not already documented</li> </ul>
	Medication changes	<ul style="list-style-type: none"> <li>Any change in medication prescribed for you by GP or secondary care?</li> <li>Do you take any medicines you buy OTC, and have you changed the doses of any of these?</li> </ul>	<ul style="list-style-type: none"> <li>Any change in psychotropic medication</li> <li>Any new medication which interacts with clozapine or co-meds (check BNF)</li> <li>Any OTC medication taken regularly but not already recorded</li> </ul>
Every 6 months (for new prescription)	Compliance (if medication supplied in medipack)	<ul style="list-style-type: none"> <li>Do you still need your medication supplied in a compliance aid?</li> <li>Is there something else that would help you take your medication, e.g. app, reminder chart?</li> </ul>	

\*Binge drinking defined as: In a short space of time (e.g. 1hr) drinking more than 8 units for males or 3 units for female, or drinking to get drunk (Ref <http://www.nhs.uk/Livewell/alcohol/Pages/Bingedrinking.aspx> )

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## Appendix 10: Template entries for electronic patient record

- Staff should make appropriate entries for the actions they have taken. Any specific issues should be noted.
- The entry will vary according to whether the full supply is given to the patient or just one weeks supply and whether co meds are also given to the patient.
- The following are suggested case note entries for the blood results and actions taken in one stop clinics:

### For Green Result:

Bloods analysed on POCHi machine for 'X weekly' clozapine FBC monitoring, GREEN result obtained. 'X' week(s) supply of clozapine given to patient. (Further 'x' weeks supply transferred to medication cupboard for weekly issue).

### For Amber Result:

Bloods analysed on POCHi machine for 'X weekly' clozapine FBC monitoring, AMBER result obtained. Patient now requires twice weekly blood monitoring until green result achieved. 'X' week(s) supply of clozapine given to patient. (Further 'x' weeks supply transferred to medication cupboard for weekly issues).

### For Red Result:

Bloods analysed on POCHi machine for clozapine FBC monitoring, RED result obtained. NO clozapine given to patient. Patient advised to STOP CLOZAPINE IMMEDIATELY. Advice taken from CPMS re. further blood monitoring

### For retrieving blood results from WebICE and entering on CPMS - example from York:

X got a GREEN clozapine blood result on xx/yy/zzzz. Blood results given over the phone from YDH path lab and inputted onto CPMS by myself

Eosinophils - x

Platelets x

WBC x

Neutrophils x

Medication issued - 4 weeks

Clozapine xxx mg ON

Next bloods due in 4 weeks, xx/xx/xxxx

Medication will go on Thursday transport to Worsley Court XX/YY/ZZZZ for collection

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## Appendix 11: Clozapine Task Checklist – Inpatient Admission

**Patient Name:** ..... **DOB:** ..... **NHS no.:** .....

**Admission date:** ..... **Ward:** ..... **CPMS no.:** .....

*Note: CPMS = CPMS or equivalent monitoring services (ZTAS or DMS)*

STEP 1 – MUST BE COMPLETED BEFORE STEP 2 Ward team / Clinical Pharmacy team			
✓		Initial	Date
	Confirm brand of clozapine =		
	Confirm current dose =		
	Confirm date & time of last dose taken = <i>(If more than 48 hours since last dose, re-titration will be necessary, do not administer usual dose, see clozapine guidance or contact pharmacy for advice)</i>		
	Confirm date of last FBC: ..... and status: Red / Amber / Green		
	Confirm frequency of FBC monitoring - weekly / 2-weekly / 4 weekly		
	Date next blood test due =		

STEP 2 – MUST NOT BE COMPLETED UNTIL STEP 1 COMPLETE Prescriber			
✓		Initial	Date
	Prescribe clozapine on prescription & administration chart: <i>(ONLY if dose can be verified, it is less than 48 hours since last dose was taken AND patient has a valid green result)</i>		

STEP 3 – Clinical pharmacy team / Prescriber			
✓		Initial	Date
	Patient's own supply of clozapine brought in on admission? <b>YES / NO</b> <b>if yes then.....</b>		
	Is Patient's own supply suitable for use on ward? <b>YES / NO</b> <b>if no then.....</b>		
	Order new supply of clozapine from relevant dispensary		

STEP 4 – Ward team / Clinical pharmacy team / clozapine team			
✓		Initial	Date
	Confirm usual dispensary and notify of admission (if not already aware at step 1-3)		
	Dispensary – suspend 6-month prescription & notify clinic pharmacy technician		
	Inform CMHT of admission Name of person informed: ..... Date: .....		
	Clinical pharmacy team - inform <a href="mailto:CPMS@viatris.com">CPMS@viatris.com</a> of any changes to consultant / dispensing pharmacy / monitoring clinic / laboratory etc.		
	Check that any supplies held by CMHT / Clozapine clinic have been returned to dispensing pharmacy		
	Update usual clinic eVCB / paper records		
	Update in-patient eVCB with dates of next FBC test		
	Ensure regular monitoring (weekly on acute admission wards, in line with FBC monitoring on long-stay wards) of physical health side-effects, e.g. constipation, using GASS for clozapine		

**RECORD COMPLETION OF EACH TASK IN THE ELECTRONIC PATIENT RECORD (OR SCAN COMPLETED CHECKLIST)**

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## Appendix 12: Clozapine Task Checklist – Inpatient Discharge / Transfer

Patient Name: ..... DOB: ..... NHS no.: .....

Planned discharge date: ..... Ward: ..... CPMS no.: .....

Note: CPMS = CPMS or equivalent monitoring services (ZTAS or DMS)

STEP 1 – Discharge formulation meeting. Ward team / Clinical Pharmacy team if possible			
✓		Initial	Date
	Current dose: <b>STABLE / TITRATING</b>		
	If still titrating, make arrangements for continued monitoring of physical health, and review of dose by community consultant		
	Assess need for compliance aid: <b>REQUIRED – short-term or long-term?</b> <b>NOT REQUIRED</b>		
	Is prescription of Co-meds required in community?: <b>REQUIRED</b> <b>NOT REQD (transfer to GP)</b>		
	Identify any information needs for patient / carer regarding clozapine, e.g. PIL, reminder chart, MAR chart		
	Bloods samples taken on ward for FBC if due		
	Sufficient discharge medication ordered to correlate with next clozapine clinic and blood validity		
	Appointment made at relevant monitoring clinic and given to patient: Clinic: ..... Date: ..... Time: .....		

STEP 2 – Prior to discharge Ward team			
✓		Initial	Date
	Inform clinical pharmacy team of intended discharge date		
	Inform in-patient dispensary of intended discharge date		
	Inform relevant one-stop clozapine clinic of intended discharge date		
	Inform CMHT of intended discharge date and clinic appointment details Name of person informed: ..... Date: .....		
	Six month prescription prepared for signing and sent to consultant by agreed route <i>(only for patients on a stable dose, including dose adjustment from re-commencement of smoking)</i>		
	Add details of prescription to clozapine tracker		

STEP 3 – After discharge Pharmacy team			
✓		Initial	Date
	Receiving Clinical pharmacy team inform <a href="mailto:CPMS@viatris.com">CPMS@viatris.com</a> of any change in consultant, dispensing pharmacy, monitoring clinic		
	Update eVCB / paper records as needed		

**RECORD COMPLETION OF EACH TASK IN THE ELECTRONIC PATIENT RECORD (OR SCAN COMPLETED CHECKLIST)**

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## Appendix 13: Clozapine Annual Review Checklist

(community patients only)

Patient Name: ..... DOB: ..... NHS no.: .....

CMHT: ..... Clinic: ..... CPMS (or equiv) no.: .....

**Responsibility for all steps: prescriber; responsible consultant**

STEP 1 – Routine Monitoring (as per <a href="#">TEWV Psychotropic Medication Monitoring Guide</a> ):		
✓	Parameter	Result / comment
	Blood Pressure	
	Pulse	
	Weight	
	Waist Circumference	
	Lipids	
	HbA1c	
	ECG (if c/v risk or otherwise clinically indicated)	
	General physical examination	

STEP 2 – Monitoring of side effects and efficacy:		Action / comment
	Has an appropriate ratings scale been used to assess symptoms, e.g. BPRS, in past 12 months?	YES / NO
	Is the patient adherent to the medication regimen? Are any co-meds still required?	YES / NO
	Has an appropriate ratings scale been used to assess side effects, e.g. GASS for clozapine, SESCAM, LUNSERS, in past 12 months?	YES / NO
✓	<b>Check for:</b>	Present / changed?
	Hypersalivation?	YES / NO
	Constipation?	YES / NO
	Sedation?	YES / NO
	Seizures? <i>if no, and taking valproate, consider checking levels &amp; stopping</i>	YES / NO
	Changes to smoking status?	YES / NO
	Changes to overall physical health?	YES / NO
	Any indication for checking clozapine levels? (as per “Clozapine and the Role of Therapeutic Monitoring guidance”)	YES / NO

STEP 3 – Documentation and follow up:	
✓	
	Review plasma clozapine level (if measured/clinically appropriate) and make any dose adjustments
	Ensure all monitoring information is recorded on the electronic patient record
	Ensure any dose changes are clearly communicated to the relevant dispensary
	Ensure as part of routine communication that a copy of this checklist is sent to the patient’s GP, or GP is notified that clozapine and/or any co-meds have been discontinued.

STEP 4 – Current prescription (for clozapine + co-meds prescribed by TEWV; please ensure these are included in the primary care medication record):	
Drug	Dose
Clozapine	

Review completed by: ..... On (date): ..... Tel: .....

**RECORD DETAILS IN THE ELECTRONIC PATIENT RECORD (OR SCAN COMPLETED CHECKLIST)**

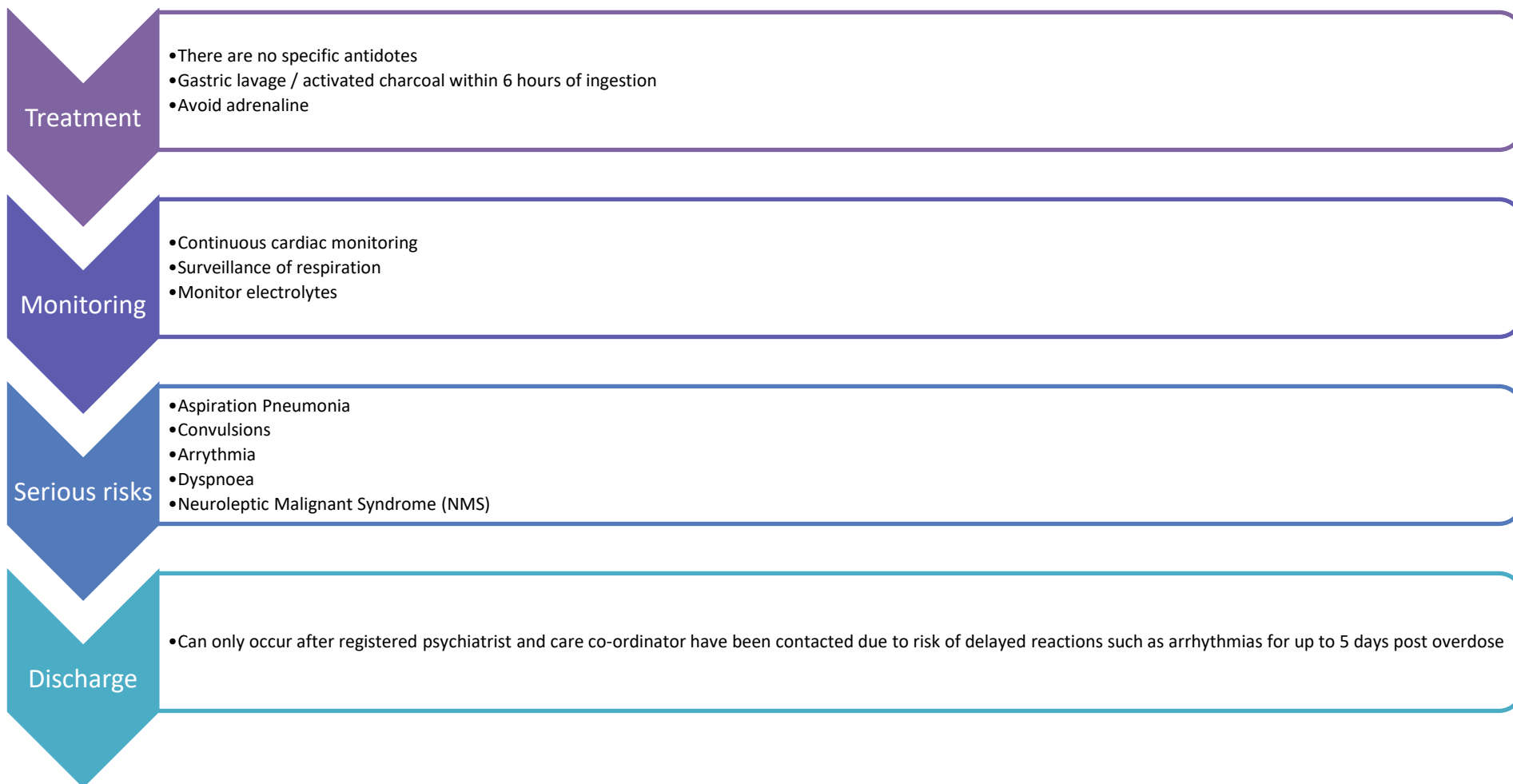
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## Appendix 15: Managing Clozapine Overdose

The information below is not intended to be a definitive treatment strategy, but a suggested approach for clinicians. It is based on previous successful experience. Each case should, of course, be considered individually. This information is provided for healthcare professionals and should not be used as a patient information leaflet. If notified of a potential overdose in the community, the importance of attending A&E should be reiterated and followed up to ensure the patient has been reviewed.



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## Information for TEWV Clinicians

Background	Signs and symptoms of clozapine overdose	Reporting of side effects	Follow up
<ul style="list-style-type: none"> <li>▪ Patients with treatment-resistant schizophrenia have a higher incidence of suicide compared to the general population<sup>2</sup>. Both intentional and accidental overdoses have been reported with clozapine.</li> <li>▪ As noted in the SmPC, mortality associated with clozapine overdose is about 12%<sup>1</sup>. Most of the fatalities reported were associated with cardiac failure or pneumonia caused by aspiration and occurred at doses &gt; 2000mg<sup>1</sup>. In a few adult individuals, primarily those not previously exposed to clozapine, the ingestion of doses as low as 400mg led to life-threatening comatose conditions and, in one case, to death<sup>1,2</sup>.</li> <li>▪ Seizures have been reported to occur in patients with plasma clozapine levels above 1 mg/L following overdose.<sup>4</sup></li> </ul>	<ul style="list-style-type: none"> <li>▪ All of the side-effects associated with clozapine at therapeutic dose may be seen following overdose except those seen with long-term therapy only, e.g. constipation, weight gain and agranulocytosis<sup>3</sup>. In addition, altered respiratory function and aspiration may be observed and these are seldom seen at therapeutic doses. Pulmonary oedema is not a recognised side-effect but has occurred following overdose<sup>3</sup>.</li> <li>▪ The central nervous, cardiovascular and respiratory systems are most commonly affected following acute overdose. The signs and symptoms listed in the SmPC are stated above. There is a risk of neuroleptic malignant syndrome</li> <li>▪ <b>Delayed reactions may be seen, including the late occurrence or recurrence of cardiac arrhythmias<sup>3</sup>.</b></li> </ul>	<p>Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the product. Healthcare professionals are asked to report any suspected adverse reactions via the yellow card system: <a href="http://www.mhra.gov.uk/yellowcard">www.mhra.gov.uk/yellowcard</a></p>	<ul style="list-style-type: none"> <li>▪ Clozapine remains the antipsychotic of choice for schizophrenia patients with a history of suicidality. Overdose is not a reason to discontinue clozapine treatment, but to institute measures (e.g. restricted supplies) to minimise recurrence.</li> <li>▪ The patient needs to be reviewed with a view to ongoing treatment, overdose risk and quantities to prescribe / supply.</li> <li>▪ Consideration needs to be made as to any supplies at home and whether these need to be returned to pharmacy for disposal.</li> <li>▪ A plan for ongoing treatment doses and blood monitoring needs to be carefully made, discussed with the patient and clearly documented in the patient's electronic record. Refer to the information elsewhere in this document for guidance on action to take following a break in treatment, e.g. notifying and re-registration with CPMS, re-titration</li> </ul>

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## Information for clinicians in acute hospitals







Clozapine overdose	Signs and Symptoms	Treatment
<p><i>The Summary of Product Characteristics (SmPC) for clozapine<sup>1</sup> states:</i></p> <p><i>In cases of acute intentional or accidental clozapine overdose for which information on the outcome is available, mortality to date is about 12%. Most of the fatalities were associated with cardiac failure or pneumonia caused by aspiration and occurred at doses above 2000 mg.</i></p>	<p>Drowsiness, lethargy, areflexia, coma, confusion, hallucinations, agitation, delirium, extrapyramidal symptoms, hyperreflexia, convulsions; hypersalivation, mydriasis, blurred vision, thermolability; hypotension, collapse, tachycardia, cardiac arrhythmias; aspiration pneumonia, dyspnoea, respiratory depression or failure.</p> <p>There is a risk of neuroleptic malignant syndrome.<sup>5</sup></p> <p><b>Due to the high risk of cardiac arrhythmias, consider seeking advice from cardiology specialists if clinically indicated.</b></p>	<ul style="list-style-type: none"> <li>• Consult Toxbase <a href="https://www.toxbase.org/">https://www.toxbase.org/</a></li> <li>• There are no specific antidotes for clozapine.</li> <li>• Gastric lavage and/or administration of activated charcoal within the first 6 hours after the ingestion of the drug. Peritoneal dialysis and haemodialysis are unlikely to be effective. Symptomatic treatment under continuous cardiac monitoring, surveillance of respiration, monitoring of electrolytes and acid-base balance.</li> <li>• The use of adrenaline should be avoided in the treatment of hypotension because of the possibility of a ‘reverse adrenaline’ effect.</li> <li>• <b>Close medical supervision is necessary for at least 5 days because of the possibility of delayed reactions, such as cardiac arrhythmias.</b></li> <li>• <b>Any decision to discharge from medical care before this should be carried out by a consultant.</b></li> <li>• <b>Work with the liaison psychiatry team and care co-ordinator prior to discharge for help and advice, and to arrange ongoing treatment and follow up.</b></li> </ul>

### References

1. Clozapine Summary of Product Characteristics <https://www.medicines.org.uk/emc/product/4411>
  2. Dev VJ, Krupp P. Adverse Event Profile and Safety of Clozapine. Rev Contemp Pharmacother 1995; 6: 197-208.
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  4. Taylor D and Duncan D. The Use of Clozapine Plasma Levels in Optimising therapy. Psych Bulletin 1995; 19: 753-5.
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## Appendix 16: Summary of roles and responsibilities (inpatient settings)

Clozapine: roles & responsibilities (inpatients) – see processes & checklists for detail of tasks				
Initiation 	Prescribing 	Ordering 	Dispensing 	Monitoring 
<p><b>Consultant (RC)</b></p> <ul style="list-style-type: none"> <li>Clinical decision to initiate clozapine</li> <li>Inform local pharmacy team of intention to initiate clozapine</li> <li>Arrange patient education re. monitoring requirements, sideeffects, etc</li> <li>Obtain patient consent and record in EPR (or MHA basis for treatment)</li> <li>Ensure baseline FBC and other tests are completed</li> <li>Register patient with CPMS (or equivalent)</li> <li>Enter significant medication alert [CLOZAPINE] on EPR</li> </ul>	<p><b>Consultant (RC)</b></p> <ul style="list-style-type: none"> <li>Prescribe clozapine on inpatient chart with titration chart</li> <li>Sign 6month prescriptions and return to relevant dispensary (long stay patients)</li> <li>Record any changes to dose on EPR and notify relevant clinical pharmacy team and dispensary</li> </ul>	<p><b>Pharmacy Technician</b></p> <ul style="list-style-type: none"> <li>Acute wards order supplies of clozapine from dispensary according to dose and blood validity</li> <li>Recover supplies from ward after dose changes or cessation of treatment</li> </ul>	<p><b>Pharmacy Assistant (dispensary)</b></p> <ul style="list-style-type: none"> <li>SIS patients- prepare clozapine supplies in advance of weekly clinic according to each patient's monitoring frequency</li> <li>Acute wards- prepare supplies according to technician orders</li> </ul>	<p><b>Consultant (RC)</b></p> <ul style="list-style-type: none"> <li>Oversight of all patients under their RC</li> <li>Regular assessment of mental state</li> <li>Arrange clozapine level assays if clinically indicated; review and act upon assay results</li> <li>SIS- annual review of clozapine treatment according to checklist</li> <li>Notify pharmacy if clozapine is discontinued (not due to red result)</li> </ul>
<p><b>Postgraduate Doctor</b></p> <ul style="list-style-type: none"> <li>Complete baseline FBC and other tests, and record in EPR as a Physical Health case note</li> </ul>	<p><b>NMP</b></p> <ul style="list-style-type: none"> <li>Sign 6month prescriptions (if within scope of practice) and return to relevant dispensary</li> <li>Record any changes to dose on EPR and notify relevant clinical pharmacy team and dispensary</li> </ul>	<p><b>HCA (SIS) – for weekly clinic</b></p> <ul style="list-style-type: none"> <li>Venepuncture- obtaining blood sample for Pochi machine</li> <li>Operation of Pochi machine</li> </ul>	<p><b>Accredited Accuracy Checker</b></p> <ul style="list-style-type: none"> <li>Check prepared and clinically checked clozapine supplies</li> </ul>	<p><b>Postgraduate Doctor</b></p> <ul style="list-style-type: none"> <li>Ensure repeat FBC within 10 days of baseline, and weekly thereafter</li> <li>Assess for sideeffects during titration (weekly)</li> <li>Check random blood glucose at 4 weeks</li> <li>Ensure repeat ECG, HbA1c &amp; lipids at 12 weeks</li> <li>SIS- complete GASS for clozapine (or other appropriate sideeffect rating scale) every 12 months</li> </ul>
<p><b>Clinical Pharmacist</b></p> <ul style="list-style-type: none"> <li>Deliver education to patient re. monitoring requirements, sideeffects, etc and record in EPR</li> <li>Provide inpatient initiation checklist to ward</li> <li>Ensure arrangements in place to attend OSC after discharge</li> </ul>	<p><b>Pharmacy Technician</b></p> <ul style="list-style-type: none"> <li>Set up 6month prescription once stable dose is reached (long stay patients)</li> <li>Add patient to relevant prescription tracker and update as necessary</li> <li>Produce new prescription when due (including reconciliation), or after changes to dose</li> <li>Archive old or discontinued prescriptions</li> </ul>		<p><b>Dispensary Pharmacist</b></p> <ul style="list-style-type: none"> <li>Check prepared clozapine supplies</li> <li>Archive old or discontinued prescriptions</li> </ul>	<p><b>Ward staff nurse</b></p> <ul style="list-style-type: none"> <li>Oversight of all aspects of patient care</li> <li>Arrange and/or deliver all monitoring requirements: FBC- when due / prompted by pharmacy; physical obs daily; weight- weekly (new initiations); bowel function at least weekly*; other side effects- at least weekly*</li> </ul> <p><i>*depending on environment/individual patient factors</i></p>
	<p><b>Pharmacy Technician</b></p> <ul style="list-style-type: none"> <li>Retrieve blood results from ICE and input to CPMS (or equivalent) if blood not analysed on Pochi</li> </ul>			<p><b>HCA (inpatients)</b></p> <ul style="list-style-type: none"> <li>Physical health observations (NEWS) daily during titration, then as instructed</li> <li>Measure weight- weekly during titration, then as instructed</li> </ul>
	<p><b>Clinical Pharmacist</b></p> <ul style="list-style-type: none"> <li>Check new 6month prescriptions before sending to RC</li> </ul>			<p><b>Clinical Pharmacist</b></p> <ul style="list-style-type: none"> <li>Inform CPMS (or equivalent) if discontinued</li> <li>Obtain plasma level assay results and communicate them to RC / enter on EPR</li> </ul>
	<p><b>Dispensary Pharmacist</b></p> <ul style="list-style-type: none"> <li>Professionally check new signed 6 month prescriptions on receipt into dispensary</li> </ul>			
			<p><b>Administration</b> </p> <p><b>Ward staff nurse</b></p> <ul style="list-style-type: none"> <li>Administer clozapine according to prescription / titration chart in line with good practice standards</li> </ul>	

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## Appendix 17: Summary of roles and responsibilities (community settings)

### Clozapine: roles & responsibilities in **community** settings – see processes & checklists for detail of tasks

Initiation 	Prescribing 	Dispensing 	Supply 	Monitoring 
<p><b>Consultant (RC)</b></p> <ul style="list-style-type: none"> <li>Clinical decision to initiate clozapine</li> <li>Inform local pharmacy team of intention to initiate clozapine</li> <li>Arrange patient education re. monitoring requirements, sideeffects, etc</li> <li>Obtain patient consent and record in EPR (or MHA basis for treatment)</li> <li>Ensure baseline FBC and other tests are completed</li> <li>Register patient with CPMS (or equivalent)</li> <li>Enter significant medication alert [CLOZAPINE] on EPR</li> </ul>	<p><b>Consultant (RC)</b></p> <ul style="list-style-type: none"> <li>Prescribe clozapine on Trust community clozapine prescription</li> <li>Sign 6month prescriptions and return to relevant dispensary</li> <li>Record any changes to dose or “eo meds” on EPR and notify relevant clinical pharmacy team and dispensary</li> </ul>	<p><b>Pharmacy Assistant (dispensary)</b></p> <ul style="list-style-type: none"> <li>Prepare clozapine supplies in advance of OSCs according to each patient’s monitoring frequency</li> </ul>	<p><b>Pharmacy Technician</b></p> <ul style="list-style-type: none"> <li>In OSC: <ul style="list-style-type: none"> <li>Check quarantine cupboard for uncollected medication, and any action required</li> <li>Check delivered medication vs eVCB</li> <li>Release medication to patient from quarantine (green/amber result)</li> <li>Secure any unissued medication in quarantine cupboard</li> </ul> </li> <li>Notify Care Coordinator if patient fails to attend clinic as scheduled</li> </ul>	<p><b>Consultant (RC)</b></p> <ul style="list-style-type: none"> <li>Oversight of all patients under their RC</li> <li>Regular assessment of mental state</li> <li>Arrange clozapine level assays if clinically indicated; review and act upon assay results</li> <li>Annual review of clozapine treatment according to checklist may be delegated to a suitably qualified prescriber in team)</li> <li>Notify pharmacy if clozapine is discontinued (not due to red result)</li> </ul>
<p><b>Postgraduate Doctor (or CPN)</b></p> <ul style="list-style-type: none"> <li>Complete baseline FBC and other tests, and record in EPR as a Physical Health case note</li> </ul>	<p><b>Non Medical Prescriber</b></p> <ul style="list-style-type: none"> <li>Sign 6month prescriptions (if within scope of practice) and return to relevant dispensary</li> <li>Record any changes to dose or “eo meds” on EPR and notify relevant clinical pharmacy team and dispensary</li> </ul>	<p><b>Accredited Accuracy Checker</b></p> <ul style="list-style-type: none"> <li>Check prepared and clinically checked clozapine supplies for OSCs</li> </ul>	<p><b>NMP</b></p> <ul style="list-style-type: none"> <li>Release of medication to patient from quarantine (green/amber result)</li> </ul>	<p><b>Postgraduate Doctor (or CPN)</b></p> <ul style="list-style-type: none"> <li>Ensure repeat FBC within 10 days of baseline, and weekly thereafter</li> <li>Assess for sideeffects during titration (weekly)</li> <li>Check random blood glucose at 4 weeks</li> <li>Ensure repeat ECG, HbA1c &amp; lipids at 12 weeks</li> </ul>
<p><b>Clinical Pharmacist (where available) / CPN</b></p> <ul style="list-style-type: none"> <li>Deliver education to patient re. monitoring requirements, sideeffects, etc and record in EPR</li> <li>Provide community initiation checklist to team</li> <li>Ensure arrangements in place to attend OSC</li> </ul>	<p><b>Pharmacy Technician</b></p> <ul style="list-style-type: none"> <li>Set up 6month prescription once stable dose is reached</li> <li>Add patient to relevant prescription tracker and eVCB (where applicable), and update as necessary</li> <li>Produce new prescription when due (including reconciliation), or after changes to dose or comeds</li> <li>Archive old or discontinued prescriptions</li> </ul>	<p><b>Dispensary Pharmacist</b></p> <ul style="list-style-type: none"> <li>Check prepared clozapine supplies for OSCs</li> <li>Archive old or discontinued prescriptions</li> <li>Authorise release of quarantined medication outside OSC</li> </ul>	<p><b>Care co-ordinator / CPN</b></p> <ul style="list-style-type: none"> <li>Arrange blood sampling and testing if patient fails to attend clinic</li> <li>Release of medication to patient from quarantine (with pharmacy approval)</li> <li>Recover supplies from patient after dose changes or cessation of treatment</li> <li>Inform patient to stop taking clozapine if notified of RED result</li> </ul>	<p><b>Pharmacy Technician</b></p> <ul style="list-style-type: none"> <li>Complete counselling checklist in OSC</li> <li>Notify RC if change of smoking status or alcohol intake, or new / worsening sideeffects</li> <li>Complete GASS for clozapine (or other appropriate sideeffect rating scale) every 12 months</li> <li>Retrieve blood results from ICE and input to CPMS (or equivalent) if blood not analysed on Pochi</li> </ul>
	<p><b>Clinical Pharmacist</b></p> <ul style="list-style-type: none"> <li>Check new 6month prescriptions before sending to RC</li> </ul>		<p><b>HCA</b></p> <ul style="list-style-type: none"> <li>Venepuncture- obtaining blood sample for Pochi machine</li> <li>Operation of Pochi machine</li> </ul>	<p><b>Care Co-ordinator</b></p> <ul style="list-style-type: none"> <li>Oversee patient care – arrange and/or deliver all monitoring requirements</li> </ul>
	<p><b>Dispensary Pharmacist</b></p> <ul style="list-style-type: none"> <li>Professionally check new signed 6 month prescriptions on receipt into dispensary</li> </ul>			<p><b>HCA (with support of crisis team)</b></p> <ul style="list-style-type: none"> <li>Complete daily physical health obs BP, ECG, weight – during titration and record in EPR as Physical Health case note</li> <li>Venepuncture – obtain blood sample for any necessary tests or plasma level assays</li> </ul>
				<p><b>Clinical Pharmacist</b></p> <ul style="list-style-type: none"> <li>Inform CPMS (or equivalent) if discontinued</li> <li>Obtain plasma level assay results and communicate them to RC / enter on EPR</li> </ul>

Title	Clozapine: processes for prescribing, dispensing, supply & monitoring		
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