



# 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 <u>inpatient</u> and <u>community</u> 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 <u>admitted</u> to and <u>discharged</u> 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.

<u>Break in treatment</u> - avoid missed doses; a break in treatment of >48 hours requires re-starting at 12.5–25 mg per day and retitration (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.

# <u>Therapeutic Drug Monitoring (plasma level assays)</u>

Trust guidance on the role of TDM in relation to clozapine is on the intranet <u>here</u>. 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 suboptimal 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 <u>Psychotropic Monitoring Guidelines</u> 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 <u>Trust quidance</u> 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:** <u>Clozapine Annual Review Checklist</u> 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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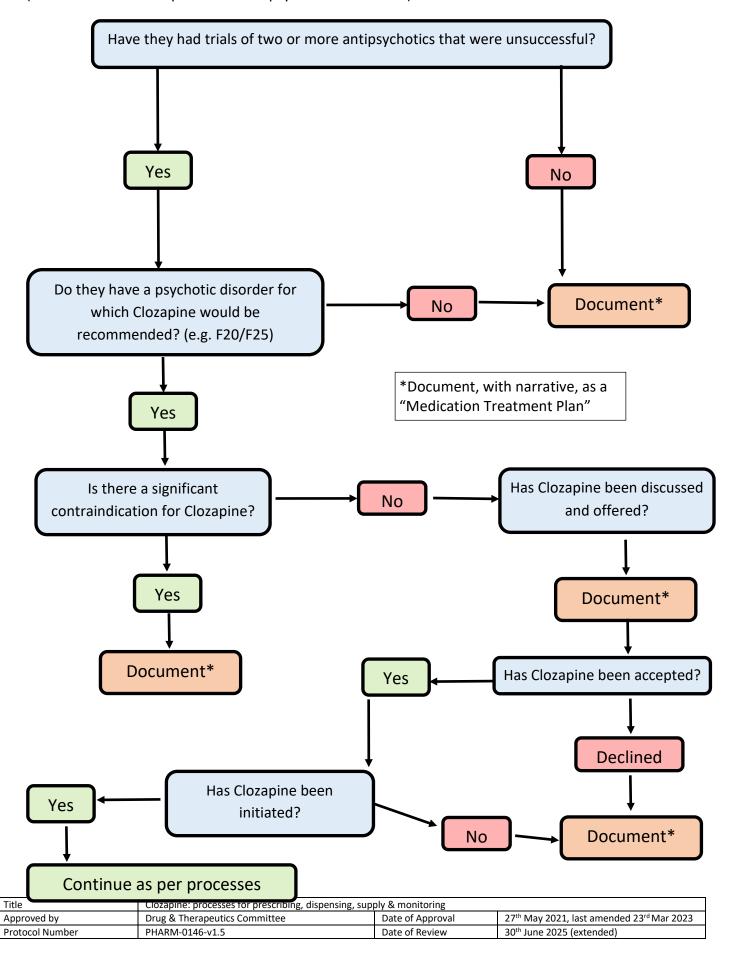




# **Prescribing**

## Is Clozapine indicated & appropriate?

(consider for all those prescribed antipsychotic medication)







# **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 <u>Trust guidelines</u> 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 <a href="Choice & Medication website">Choice & Medication website</a>.
- 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 restarted 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 recommencement 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:

- o RPH tewv.pharmacytees@nhs.net
- WPH tewv.pharmacycdd@nhs.net
- o FPH 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 <u>shared folders</u> [standard template in <u>appendix 3</u>]. Save the prescription in the relevant clinic folder on the pharmacy shared drive
- → Check if clozapine and any co-meds are on the patient summary care record if not, email GP practice to request addition. Print and attach SCR to 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'
- → NYY 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
- \* 1st password to open as read-only & print (share with prescriber in separate email) + 2nd 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. SCR to be checked as part of professional check
- → **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
- → Put prescription into <u>dispensing process</u> (N.B. prescription is valid for 6 months from date of <u>first</u> <u>dispensing</u>, not date of signing).

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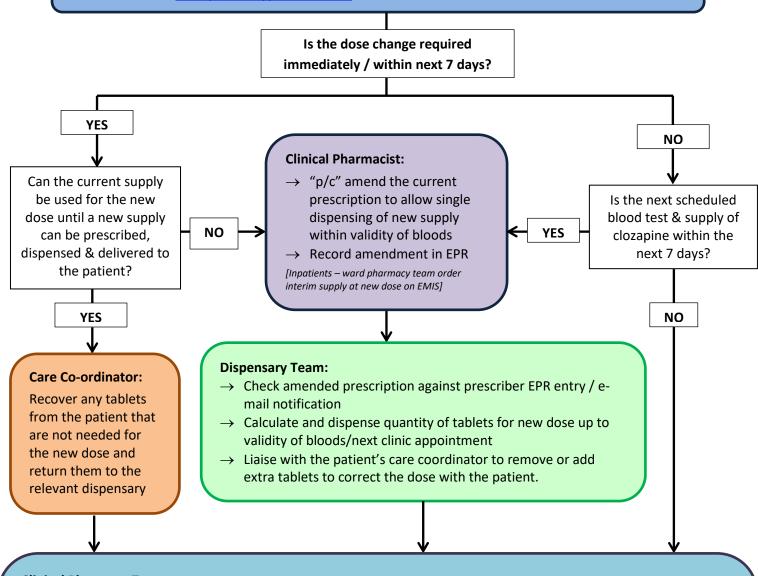


#### **Dose changes**

#### 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 <a href="mailto:appendix5">appendix 5</a> (cc'd to any colleagues and specific pharmacy staff who also need to be aware), indicating the urgency of the change:
  - o RPH <u>tewv.pharmacytees@nhs.net</u>
  - WPH tewv.pharmacycdd@nhs.net
  - FPH <u>tewv.pharmacyyork@nhs.net</u>



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

- → Produce a new electronic prescription with amended dose of clozapine or co-meds using the templates in the pharmacy <u>shared folders</u>. Save the prescription in the relevant clinic folder on the shared drive
- → Check if clozapine and any co-meds are on the patient summary care record if not, email GP practice to request addition. Print and attach SCR to prescription
- → **Tees/CDD** copy & paste the prescription into a "Pharmacy" case note on the EPR with the statement 'Clozapine prescription sent for checking and signing'; **NYY** 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





#### **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. SCR to be checked as part of professional check
- → **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
- → Put prescription into <u>dispensing process</u> (N.B. prescription is valid for 6 months from date of <u>first dispensing</u>, 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

Print and attach SCR to prescription

- → 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 <u>shared folders</u>. 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
- → **Tees/CDD** copy & paste the prescription into the existing case note on the EPR with the statement 'Clozapine prescription sent for checking and signing'; **NYY** 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
- \* 1st password to open as read-only & print (share with prescriber in separate email) + 2nd 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. SCR to be checked as part of professional check
- → **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
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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 <a href="mappendix13">appendix 13</a>. 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
- WPH tewv.pharmacycdd@nhs.net
- o FPH <u>tewv.pharmacyyork@nhs.net</u>

#### **Clinical Pharmacy / Clozapine Clinic Team:**

- → Inform CPMS (or equivalent) of discontinuation <a href="CPMS@viatris.com">CPMS@viatris.com</a>
- → **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.

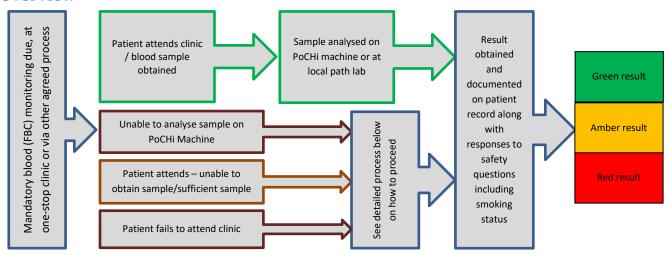
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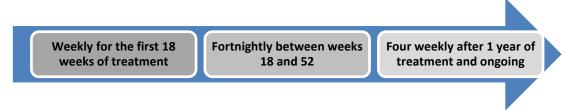


# **Dispensing, supply & monitoring**

#### **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 "<a href="Changes in monitoring frequency/weeks">Changes in monitoring frequency/weeks</a>" 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 "<u>Transfer</u> <u>between community clinics/ from in-patient settings</u>" 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 <sup>®</sup> / Denzapine <sup>®</sup>	Zaponex <sup>®</sup>
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 (<u>Appendix 7</u>). This medication can be issued according to the "<u>patient fails to attend</u> <u>clinic as scheduled</u>" 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 <u>not</u> 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
- → Qualified nurse to 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 <u>Appendix 8</u>) 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):

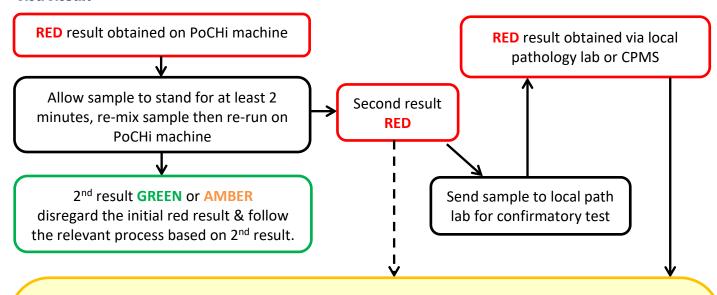
- → Review plasma level result (refer to Trust "Clozapine & the role of therapeutic Drug Monitoring Guidance")
- → Amend dose of clozapine if necessary & arrange for new prescription if dose is changed
- → Document actions on electronic patient record
- → Re-check plasma levels one week after dose change & 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:

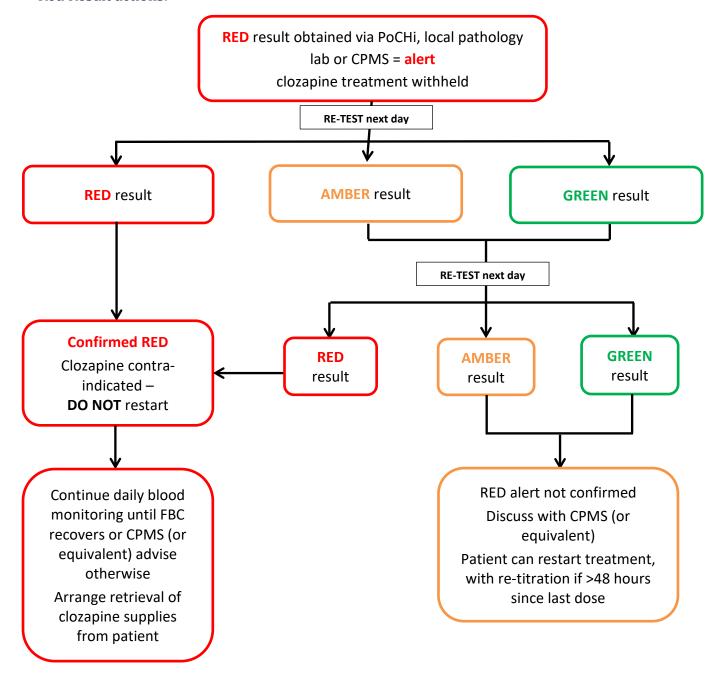
- → Inform the patient that they must **STOP** taking clozapine **IMMEDIATELY**
- → For in-patients ensure clozapine discontinued on prescription & administration record chart
- → For community patients arrange retrieval of all supplies of medication held by the patient and return any medication to relevant 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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# Tees, Esk and Wear Valleys

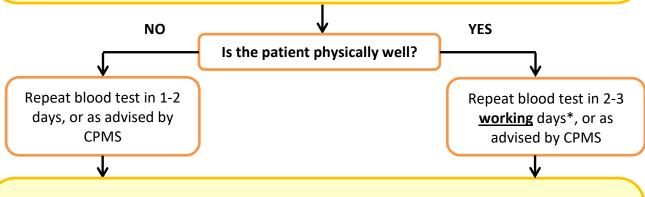
#### Amber result

AMBER result obtained on PoCHi machine

AMBER result obtained via local pathology lab or CPMS

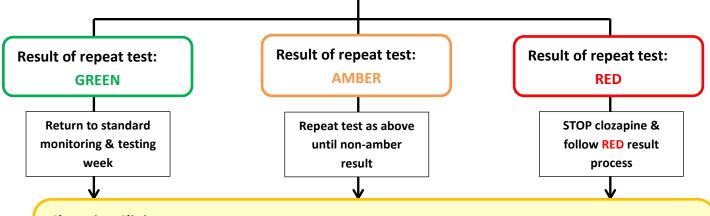
#### **Clozapine Clinic Team:**

- → 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)



#### **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



#### **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

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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 <u>Appendix 9</u> (One-stop clinic) or <u>Appendix 8</u>
   (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 "<u>Clozapine: Process for accessing out of hours</u>"
- 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:
  - O How many days' supply (approx.) were there?
  - O Where the supply was lost / last in the patient's possession?
  - O What has the patient/carer done to try and find it?
  - O Was any other medication lost with it?
  - o Has this happened before with this patient?
- Consider any risk to:
  - Patient loss of symptom control from missed doses; any safeguarding concerns?
  - o Family any risk of accidental ingestion by children if lost at home?
  - o 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

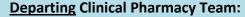
### Discharge from TEWV inpatient ward

See checklist of discharge tasks in appendix 12

Transfer between clinics / inpatient to clinic / ward to ward / 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



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

#### **Departing** ward team:

Ensure current Clozapine supplies are transferred with the patient

#### **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
  - o 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:
  - o Clozaril® CPMS 0845 7698269 or CPMS@viatris.com
  - o 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:

<u>Notify</u> 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: <u>Safety guidance - Clozapine on admission to an acute hospital ward - Tees Esk and Wear Valley NHS Foundation Trust (tewv.nhs.uk)</u>

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:**

<u>Update eVCB</u> (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:
  - o RPH tewv.pharmacytees@nhs.net
  - o WPH <u>tewv.pharmacycdd@nhs.net</u>
  - FPH tewv.pharmacyyork@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 <u>tewv.pharmacytees@nhs.net</u>
  - WPH <u>tewv.pharmacycdd@nhs.net</u>
  - o FPH <u>tewv.pharmacyyork@nhs.net</u>
- → 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 <u>T:\Clozapine</u> & 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.
  - o Enter all patient demographics in the relevant columns
  - Once editing is complete, go back to the "review" tab & select "protect sheet"
  - o A box will appear, enter the password used to unlock the sheet.
  - Another box will appear & ask you to reconfirm the password.
  - o 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 <u>T:\Clozapine</u> & 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 <u>T:\Clozapine</u> & 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 <u>T:\Clozapine</u> & 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.

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Apj	pendix 1: Clozaj	pine Tas	sk Checklist -	In-pat	tient in	itiation		
Pati	ient Name:		Date of Birth: .			NHS No:		
Waı	rd:		Consultant:			CPMS No.: .		
Note	e: CPMS = CPMS	or equiva	lent monitoring s	service	(ZTAS	or DMS)		
_	EP 1: PRIOR TO CO tasks must be comp	_				sarily in order l	listed	
✓							Initial	Date
	MDT decision made to MHA consent to treat							
	Education session wi document on electron asked							
	Ensure the following record as a physical out of range:							
	Physical examination	W	/eight (W)		U&Es			
	Blood pressure		alculate weight		Lipids			
	Temperature	(V	ocrease threshold W x 1.05) =		Prolactir	1		
	Pulse	ci	/aist rcumference		HbA1c			
	Height		CG		LFTs			
	Baseline FBC taken and sent to local Path Lab – this will only be valid for 10 days							
	from sample date  Confirm consultant re	agistared wi	ith CDMS					
	Inform ward Pharmac			nce cloz	anine			
	Patient registration for				•	s.com)		
	Confirmation of regis	tration and	green result from C	PMS (N	B: result o	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 d	on green titi	ration chart (either s	tandard	or individ	ualised)		
	Order initial supply of	f clozapine	from dispensary usi	ng one o	of the follo	owing options:		
	a) Ward staff - send kept in dispensar			chart to	dispensar	ry (copy will be		
	b) Pharmacy staff -	inpatient or	rder on EMIS after c	linical ch	neck by p	harmacist		
ST	EP 2: COMMENCE	MENT OF	CLOZAPINE, DA	Y 1:				
✓							Initial	Date
	Immediately prior to a	administrati	on of clozapine asse	ess NEV	VS and re	cord on chart		
	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  If first dose taken at night no further monitoring required that day							
	If first dose taken dur hours post dose				-	ourly for six		
	Enter alert on electro clozapine	nic patient	record: Significant n	nedicatio	n alert –	patient on		
	Arrange date of next FBC test							

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	EP 3: TITRATION OF CLOZAPINE, DAYS 2 – 14: tasks must be completed but not necessarily in order listed					
✓	,	Initia	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 Nausea Signs of enuresis					
	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					
ST	EP 4: STABILISATION OF CLOZAPINE THERAPY, DAY 15 ONWARDS:					
✓	In	itial	Date			
	Continue weekly 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.  • Constipation					
	Sedation					
	Hypersalivation					
	Nocturnal enuresis     Novees					
	<ul><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 □ HbA1c □ Lipids □					
	Continue physical health monitoring as per guidelines					
	Check weight <b>weekly</b> – see threshold in step 1; inform medical staff if weight is increasing. Rapid weight gain in early treatment (≥5% above baseline after 1 month of treatment) strongly predicts long-term weight gain & should prompt consideration of preventative or remedial measures					
	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

		atients may have CPMS approval		health mor	nitorina	
	•	Date of Birth:			•	
	rd:		CPMS No.:			
		equivalent monitoring service	· · · · · · · · · · · · · · · · · · ·			
		MMENCEMENT OF CLOZAP rior to commencement but not				
ali ✓	must be completed p	nor to commencement but not	Thecessarily in order listed	Initial	Date	
_	MDT decision made to	commence clozapine with patier	nt consent* or in line with MHA		Duto	
		equirements(*if off-label use, ensur				
		n patient re potential benefits, mo c patient record, including inform				
		ests are completed and results re ealth case note - <i>inform doctor of</i>				
	Physical examination	Weight (W)	U&Es			
	Blood pressure	Calculate weight	Lipids	]		
	Temperature	increase threshold (W x 1.05) =	Prolactin			
	Pulse	Waist circumference	HbA1c			
	Height	ECG	LFTs	1		
		nd sent to local Path Lab – this w	ill 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					
		ly, e.g. monitored dose system	ciozapine and any special			
	Patient registration for	m completed and sent to CPMS (	(CPMS@viatris.com)			
		ration and green result from CPM ple so clozapine must commence				
		n green titration chart (either stan	<u> </u>			
	,,,	clozapine from pharmacy using o	<b>J</b> 1			
	c) send titration char supply)	t to dispensary (will be kept in dis	pensary, copy returned with			
	d) outpatient prescrip	otion				
	Set up arrangements t	for seeing patient daily during ear	ly titration phase			
	Set up arrangements to patient.	for collection of clozapine from ph	armacy and/or delivery to			
ST	EP 2: COMMENCEN	IENT OF CLOZAPINE, DAY 1	•			
✓.			•	Initial	Date	
	Immediately prior to a	dministration of clozapine assess atient record	BP, pulse and temp and			
	If all above within norr	nal limits administer clozapine – a whether clozapine can be admin				
		ight no further monitoring required				
		ng the day BP, pulse, temp to be				

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to	change						NHS F	oundation Trust	
	Enter ale		patient rec	ord: Significant me	edication ale	rt – patient	t on		
	Arrange date of next FBC test								
	Check arrangements are in place for next FBC test and supply of clozapine								
ST	EP 3: TI1	RATION OF	CLOZAPII	NE, DAYS 2 – 1	4:				
				ssarily in order lis					
✓								Initial	Date
	baseline	test		clozapine clinic or	·				
				o at least once dail ary, and inform me					
	_			record on electro	•				
				effects with patier eek (at clozapine o					
		Constipation	Sedation	Hypersalivation	Nocturnal enuresis	Nausea	Signs of infection		
	Week 1								
	Week 2								
	Inform m	edical staff if pa	atient report	ts an increase in s	ide effects o	r 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:								
ST	EP 4: ST	ABILISATION	N OF CLO	ZAPINE THERA		5 ONWA	RDS:		
ST	EP 4: ST	ABILISATION	N OF CLO	ZAPINE THERA		5 ONWA	RDS:	Initial	Date
				ZAPINE THERA	APY, DAY 1		RDS:	Initial	Date
	Continue Arrange	weekly blood	sampling fo	or FBC at clozapin	e clinic or via	a path lab ble dose is	reached	Initial	Date
	Continue Arrange Monitor E	weekly blood further supplies BP, pulse and to	sampling for soft clozaping the sampling for	or FBC at clozapin	e clinic or via	a path lab ble dose is n if any par	reached	Initial	Date
	Continue Arrange Monitor E are out o Monitor s frequentl they have	weekly blood further supplies BP, pulse and to f range – alert is side effects, in p y if patient has e not been infor Constipation Sedation Hypersaliva Nocturnal e Nausea Signs of info	sampling for soft clozaping emp when to medical state particular the any issues. I med about a med about a med about a med a medical state a med a medical state a medical sta	or FBC at clozaping ne in line with titrat ploods are taken, of ff if any parameter ose below every ti Alert medical stat Record on electra	e clinic or via ion until stab or more ofter is are out of ime bloods a ff if any chan onic patient	a path lab ole dose is n if any par range ire taken, c ige in side	reached rameters	Initial	Date
	Continue Arrange Monitor E are out o Monitor s frequentl they have	weekly blood further supplies BP, pulse and to f range – alert is side effects, in p y if patient has e not been infor Constipation Sedation Hypersaliva Nocturnal e Nausea Signs of info	sampling for soft clozaping emp when to medical state particular the any issues. I med about a med about a med about a med a medical state a med a medical state a medical sta	or FBC at clozaping ne in line with titrat ploods are taken, of ff if any parameter ose below every ti Alert medical stat	e clinic or via ion until stab or more ofter is are out of ime bloods a ff if any chan onic patient	a path lab ole dose is n if any par range ire taken, c ige in side	reached rameters	Initial	Date
	Arrange  Arrange  Monitor is are out of the continued of	weekly blood further supplies BP, pulse and to frange – alert side effects, in paying a fine of the constitution of the consti	sampling for soft clozapin emp when the medical star particular the any issues. It is a section ection ection once the monitoring see threshout gain in earlicts long-test	or FBC at clozaping the in line with titrate to loods are taken, of the fif any parameter ose below every the Alert medical state. Record on electrons as per guidelines as per guidelines as per guidelines and in step 1; informative treatment (≥5% treatment (≥5% treatment).	e clinic or via cion until stab or more ofter rs are out of time bloods a ff if any chan onic patient of eached on medical sta	a path lab ple dose is n if any par range are taken, o ge in side record.  aff if weight	reached rameters or more effects  ht is 1 month of	Initial	Date
	Arrange  Arrange  Monitor is are out of the monitor is frequently they have  Arrange  Continue Check with increasing treatments preventare	weekly blood further supplies BP, pulse and to frange – alert side effects, in paying a patient has enot been information. Constipation Sedation Hypersaliva Nocturnal en Nausea Signs of information of the Signs of t	sampling for sof clozapin emp when the medical star particular the any issues. It is a continuous and the co	or FBC at clozaping the in line with titrate to loods are taken, of the in any parameter ose below every the Alert medical state. Record on electrons as per guidelines as per guidelines as per guidelines and in step 1; informative treatment (≥5% treatment) as seen as per guidelines and in step 1; informative treatment (≥5% treatment) as seen as per guidelines and the informative treatment (≥5% treatment) as seen as per guidelines and the informative treatment (≥5% treatment) as seen as per guidelines and the informative treatment (≥5% treatment) as per guidelines are treatment (≥5% treatment).	e clinic or via cion until stab or more ofter rs are out of time bloods a ff if any chan onic patient of eached on medical sta	a path lab ble dose is n if any par range are taken, o ge in side record.  aff if weigh	reached rameters or more effects  ht is 1 month of	Initial	Date
	Continue Arrange Monitor E are out o Monitor s frequentl they have  Arrange Continue Check w increasin treatmen preventa  At week	weekly blood further supplies BP, pulse and to frange – alert in side effects, in pay if patient has enot been information. Constipation Sedation Hypersaliva Nocturnal en Nausea Signs of information of the physical health eight weekly – g. Rapid weight to strongly predictive or remedia.	sampling for sof clozaping when the medical star particular the any issues. It is more than the cription once the monitoring see threshold gain in earlicts long-teal measures the control of the control	or FBC at clozaping the in line with titrate to loods are taken, of the in any parameter ose below every the Alert medical state. Record on electrons as per guidelines as per guidelines as per guidelines and in step 1; informative treatment (≥5% treatment) as seen as per guidelines and in step 1; informative treatment (≥5% treatment) as seen as per guidelines and the informative treatment (≥5% treatment) as seen as per guidelines and the informative treatment (≥5% treatment) as seen as per guidelines and the informative treatment (≥5% treatment) as per guidelines are treatment (≥5% treatment).	e clinic or viation until state or more often is are out of ime bloods aff if any chan onic patient is medical state above base should promp	a path lab ble dose is n if any par range ire taken, o ge in side record.  aff if weigh	reached rameters or more effects  ht is 1 month of	Initial	Date
	Continue Arrange Monitor E are out o Monitor s frequentl they have  Arrange Continue Check w increasin treatmen preventa At week Monitor p	weekly blood further supplies BP, pulse and to f range – alert in side effects, in pay if patient has e not been inform Constipation Sedation Hypersaliva Nocturnal en Nausea Signs of inform Musea Signs of inform physical health eight weekly – g. Rapid weigh to strongly predictive or remedia 12 repeat / che plasma clozapin	sampling for sof clozapin emp when the medical state particular the any issues. It is a section experience to monitoring see threshold the gain in earlicts long-teal measures. It is a section experience to the section experience to the section on the section experience to the section of the	or FBC at clozapine in line with titrate ploods are taken, off if any parameter ose below every ti. Alert medical state. Record on electrons as per guidelines old in step 1; informative treatment (≥5% rm weight gain & s	e clinic or viation until stabor more often is are out of ime bloods aff if any chan onic patient is medical stabove base should promp	a path lab ble dose is n if any par range tre taken, or tr	reached rameters or more effects  ht is 1 month of	Initial	Date

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# **Appendix 3: Standard clozapine prescription**

					, Esk and Wear			
	CLOZAPINE A		Confidentia		ND14			
	NB: ONLY	TO BE USED F	OR CLOZAPIN	E PATIENTS	PRM			
Surname:			DOB:					
Forename(s):			NHS no:					
Address:								
Team base/clinic:			Team EMI	S code:				
Consultant:			CPMS No:					
Lead professional:			EPR No.:					
			1					
Allergies (drug & nati	ure):		Smoking sta	atus (delete as	appropriate):			
			Non-smoke	er Smo	ker E	x-smoker		
Blood frequency	(delete as a	ppropriate)	Weekly	2-weekly	/ 4-wee	ekly		
Dispensing frequenc			Weekly 2-weekly 4-weekly					
Method of collection	(delete as a		Clinic	Clinic GP Other:				
Compliance aid Weekly packs								
Weekly packs	(delete as a	ippropriate)	No Yes					
Drug			Dose					
(amend brand name	e Ifnecessary)	08:00	12:00	18:00	22:00	Stop Date		
Clozapine (Clozar	il)							
NB: Pres	scription valid for	6 months from	n first dispensi	ng or until do	se is changed			
lī						4-		
-	Signat	ure	Name	(print)	Da	ate		
Prescriber:								
Pharmaoist: (Professional oheok):								
Clozapine on SCR?			Yes	No				
Co-meds on SCR?			Yes	No	N/A			
iond to: d/spensary addre	ss, emali, <mark>tel</mark> no x 3 vi	ersions			Versio	on: August 2020		

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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	Notificati on Date	Date Rx Sent to Consultant/Presc riber/Secretary	Method Rx Sent	Completed By	Review Date	Clozapine on SCR	Issues with SCR	Notes
Patient 1				Psyc 1	175mg DN	175mg			Clozapine Only		6 Month Review		13/07/20	Printed Copy	MC & MW	19092021	No	No	Email sent to GP to update SCR
Patient 2				Psyc1	2pm, 175mg 6pm,	750mg	Other	Lorazepam 1mg PFN, Trifluoperazine 5-10mg PFN	Clozapine Only		6 Month Review		14/07/20	Printed Copy	MC & MW	12/01/2021	Yes	No	
atient 3				Psyc 1	100mg SIX times a day, 50mg DN	650mg	Other	Lorazepam 1mg PRN, Sertraline 50mg DM	Clozapine Only	Weekly Medi Pack	6 Month Review		15/07/20	Printed Copy	MC & MW	13/01/2021	Yes	Yes	On Citalopram on SCR
stient 4				Psyc 1	75mg DM, 100mg ON	175mg	Aripiprazole ≤ 5mg	Aripiprazole 5mg DM	Clozapine Only		6 Month Review		16/07/20	Printed	MC 8 MW	14/01/2021	Yes	No	
stient 5				Payc 1	150mg CM, 100mg 6pm, 325mg CN	575mg	Other	Amitriptyline 25mg ON, Diazepam 2mg BD	Clozapine Only		6 Month Review		17/07/20	Printed Copy	MC & MW	15/01/2021	Yes	No	
stient 6				Psyc 1	100mg DM, 275mg DN	375mg	Other	Sertraline 200mg OM	Clozapine Only		6 Month Review		19/07/20	Printed Copy	MC & MW	16/01/2021	Yes	No	
dient7				Psyc 1	400mg CIN	400mg			Clozapine Only	Weekly Medi Pack	6 Month Review		19/07/20	Printed Copy	MC 8 MW	17/01/2021	Yes	Yes	On Clonazepam on SCR
atient 54				Psyc 3	100mg CIM, 125mg CIN	225mg			Clozapine Only		Dose Reduced		14/09/20	Printed Copy	MC & MW	19/03/2021	Yes	No	
alient 55				Psyc 3	100mg OM, 325mg ON	425mg		Depakote 500mg BD	Clozapine Only		Site Change		19/09/20	Printed Copy	MC & MW	19/03/2021	Yes	No	
stient 56				Psyc 3	50mg CIM, 500mg CIN	550mg			Clozapine Only		Dose Increased		18/09/20	Printed Copy	MC & MW	19/03/2021	Yes	No	
atient 57				Psyc 3	100mg DM, 250mg DN	350mg			Clozapine Only		New Patient		29/09/20	Printed Copy	MC & MW	29/03/2021	Yes	No	
atient 58				Psyc 3	200mg CM, 300mg CN	500mg			Clozapine Only		Dose Increased		02/10/20	Printed Copy	MC & MW	02/04/2021	Yes	No	
atient 59				Psyc 3	150mg DM, 300mg DN	450mg			Clozapine Only		Dose Reduced		09/10/20	Printed Copy	MC & MW	09/04/2021	Yes	No	
atient 60				Payc 3	250mg CM, 325mg CN	575mg	Other	Sertraline 150mg OM	Clozapine and Mental Health Co-Meds	Weekly Medi Pack	Mental Health Co- Meds		27/10/20	Printed Copy	MC & MW	27/04/2021	Yes	No	
atient 61				Psyc 3	150mg 12pm. 200mg DN	350mg			Clozapine Only		Dose Reduced		27/10/20	Printed Copy	MC & MW	27/04/2021	Yes	No	
atient 62				Psyc 3	150mg DM, 400mg DN	550mg			Clozapine Only		Dose Increased		27/10/20	Printed Copy	MC & MW	27/04/2021	Yes	No	
atient 63				Psyc 3	250mg ON	250mg			Clozapine Only		Dose Increased		25/11/20	Printed Copy	MC & MW	26/05/2021	Yes	No	
atient 64				Psyc 3	25mg CN	25mg			Clozapine Only		Dose Increased		29/12/20	Printed Copy	MC & MW	29/06/2021	No	No	
alient 65				Psyc 3	100mg CIM, 225mg CIN	325mg			Clozapine Only	Weekly Medi Pack	Dose Increased		29/12/20	Printed Copy	MC & MW	29/06/2021	Yes	No	
atient 66				Psyc 3	200mg ON	200mg	Amisulpride	Valproate MR 200mg DM & 400mg	Clozapine Only		Dose Reduced		29/12/20	Printed Copy	MC & MW	29/06/2021	Yes	No	
alient 67			,	Psyc 3	300mg OM, 300mg ON	600mg			Clozapine Only	Weekly Medi Pack	Dose Reduced		30/12/20	Printed Copy	ME & MW	30/06/2021	Yes	No	
atient 68				Psyc 3	75mg OM, 400mg ON	475mg			Clozapine Only		6 Month Review		08/01/21	Printed Copy	MC & MW	09/07/2021	Yes	No	
atient 69				Psyc 3	100mg DM, 225mg DN	325mg	Sulpiride	Sulpiride 200mg BD	Clozapine and Mental Health Co-Meds		6 Month Review		08/01/21	Printed Copy	MC & MW	09/07/2021	Yes	No	
atient 70				Psyc 3	275mg ON	275mg	Other	Sodium Valproate 400mg BD	Clozapine and Mental Health Co-Meds		6 Month Review		09/01/21	Printed Copy	MC & MW	09/07/2021	Yes	No	
Patient 71				Psyc 3	125mg CIM, 150mg CIN	275mg		Veniaraxine 337.5mg Liu, Sodium Valproate 400mg BD, Amisulpride #8max8DxBassacra.6mg FM	Clozapine Only		6 Month Fleview		08/01/21	Printed Copy	MC & MW	09/07/2021	Yes	No	Lots of meds

Tracker used in Harrogate – available <u>here</u>. 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): <a href="mailto:tewv.pharmacyyork@nhs.net">tewv.pharmacyyork@nhs.net</a>

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

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

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

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

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# **Appendix 6: Medication log**

Name:							
Date put into cupboard	Quantity In (packs)	Date removed from cupboard	Quantity Out (packs)	Remaining quantity (packs)	Signed Out By: (staff print name)	Delivered : ( • )	Patient/Proxy if collected

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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 <a href="here">here</a>). 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 <a href="mailto:must">must</a> 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 SignatureDate/					
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					

**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

Issue	Question	Supplementary questions / further information	Referral / Action criteria
Compliance	<ul> <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> <li>Reminder – rotate supplies so they don't expire</li> </ul>	<ul> <li>If any missed doses, find out when the last dose was taken and how much was taken.</li> <li>If taking Clozapine liquid, check they are aware of requirements around shaking the bottle before first use and each subsequent use</li> </ul>	<ul> <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 excess supply for business continuity)</li> <li>Request for different method of supply, e.g., compliance aid</li> </ul>
Side effects	<ul> <li>Do you have any side effects?</li> <li>In particular:</li> <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> <li>Consider using the Bristol stool chart as a tool to support these discussions</li> <li>Check for any changes in other medication or potential interacting lifestyle choices if new constipation is reported e.g., change to smoking status, caffeine intake</li> <li>Ask when they last had a bowel movement if none in last 2-4 days this requires urgent follow up</li> <li>Check for major infections that may be being treated with antibiotic e.g., pneumonia – this may affect Clozapine plasma level</li> <li>If they report palpitations, are they any other associated symptoms e.g. short of breath, finding it hard to sleep lying on their back, chest pain, sweating, fast heartbeat</li> <li>Check for signs of toxicity</li> </ul>	<ul> <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>

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		<ul> <li>Feeling sleep/tired</li> <li>Feeling dizzy when you stand up</li> <li>Having a fit or seizure</li> <li>Feel more confused</li> <li>Have a racing heart</li> <li>Have problems breathing</li> </ul>	
Smoking status	<ul> <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> <li>Document current number of cigarettes/days</li> <li>If they have stopped smoking, document when they stopped</li> <li>Check if they smoke other substances e.g., Cannabis, which can also impact clozapine levels if smoked</li> </ul>	<ul> <li>Any changes in smoking status, including switch from cigarettes to e-cigarette/vaping or vice versa</li> <li>Request for support from smoking cessation</li> </ul>
Alcohol/substance misuse/caffeine/mood	<ul> <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 amounts of caffeine containing drinks e.g., energy drinks, strong coffee?</li> <li>How is your mood?</li> </ul>	<ul> <li>Check for any changes in alcohol and caffeine consumption (NB. Caffeine also present in chocolate and some OTC painkillers)</li> <li>If they report that they've stopped drinking alcohol, check they haven't replaced it with something else e.g., energy drinks (high caffeine content)</li> <li>In relation to other substance use, check particularly for smoking cannabis which has the same impact on Clozapine levels as smoking tobacco</li> </ul>	<ul> <li>Regular alcohol use &gt;2 units per day</li> <li>Increase/change in alcohol or caffeine use</li> <li>Binge drinking*</li> <li>Any substance use not already documented</li> </ul>
Medication changes	<ul> <li>Do you still need 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>	<ul> <li>If new medication is e.g., an antibiotic, check what it is being used to treat, serious infections can impact Clozapine levels</li> <li>Some medication is contra-indicated with Clozapine e.g., Citalopram</li> <li>Check any OTC medicines are being taken within the recommended dose parameters</li> <li>Interactions can be checked via BNF OR Medscape interaction checker</li> </ul>	<ul> <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>

<sup>\*</sup>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 <a href="http://www.nhs.uk/Livewell/alcohol/Pages/Bingedrinking.aspx">http://www.nhs.uk/Livewell/alcohol/Pages/Bingedrinking.aspx</a>)

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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 equivaler	t monitoring s	ervices (ZTAS or DMS)	

/		Initial	Date
	Confirm brand of clozapine =		
	Confirm current dose =		
	Confirm date & time of last dose taken =		
	(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)		
	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 =		

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

ST	STEP 3 – Clinical pharmacy team / Prescriber				
✓			Initial	Date	
	Patient's own supply of clozapine brought in on admission? if yes then	YES / NO			
	Is Patient's own supply suitable for use on ward?  if no then	YES / NO			
	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: W	ard:	CPMS no.:
Note: CPMS = CPMS or equivalent monito	ring services (ZTAS or l	DMS)

ST	STEP 1 – Discharge formulation meeting. Ward team / Clinical Pharmacy team if possible				
✓		Initial	Date		
	Current dose: STABLE / TITRATING				
	If still titrating, make arrangements for continued monitoring of physical health, and review of dose by community consultant				
	Assess need for compliance aid: REQUIRED – short-term or long-term?  NOT REQUIRED				
	Is prescription of Co-meds required in community?: REQUIRED				
	NOT REQD (transfer to GP)				
	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: Time:				

✓		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		
	(only for patients on a stable dose, including dose adjustment from recommencement of smoking)		
	Add details of prescription to clozapine tracker		

ST	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**

	HT: Clin ponsibility for all steps: prescriber; re		-	equiv) no.:
	EP 1 – Routine Monitoring (as per TEW)			ina Guide):
<u>√</u>	Parameter	Result / comment		<u>,</u> ,.
	Blood Pressure			
	Pulse			
	Weight			
	Waist Circumference			
	Lipids			
	HbA1c			
	ECG (if c/v risk or otherwise clinically indicate	d)		
	General physical examination			
ST	EP 2 – Monitoring of side effects and eff	icacv:		Action / comment
la	s an appropriate ratings scale been used to asse	<u> </u>	YES / NO	
	RS, in past 12 months? he patient adherent to the medication regimen?	Are any se made still	TES / NO	
	uired?	Are any co-meds sun	YES / NO	
la A	s an appropriate ratings scale been used to asse SS for clozapine, SESCAM, LUNSERS, in past	ess side effects, e.g.	YES / NO	
<u> </u>	Check for:	TE MONUTO.	Present /	
	Hypersalivation?		changed? YES / NO	
	Constipation?		YES / NO	
	Sedation?		YES / NO	
	Seizures? if no, and taking valproate, consider ch	ecking levels & stopping	YES / NO	
	Changes to smoking status?	7. 0	YES / NO	
	Changes to overall physical health?		YES / NO	
	Any indication for checking clozapine levels?		YES / NO	
	(as per "Clozapine and the Role of Therapeuti	c Monitoring guidance")	. 207.110	
T	EP 3 – Documentation and follow up:			
_				
	Review plasma clozapine level (if measured/c	linically appropriate) and n	nake any dose	adjustments
	Ensure all monitoring information is recorded	on the electronic patient re	cord	
	Ensure any dose changes are clearly commun	nicated to the relevant disp	ensary	
	Ensure as part of routine communication that clozapine and/or any co-meds have been disc		sent to the patie	ent's GP, or GP is notified that
`T	EP 4 – Current prescription (for clozapine + co-m		a than a complete to the	Also maintains and an artistation of
	<u> </u>	eas prescribea by TEVVV, please ensur	e triese are included in	the primary care medication record).
Drug E Clozapine				

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# **Appendix 14: Template eVCB**

Week 1	Next Due Date				Clo	ozapine Clinic	:		Phar	rmacy	CII	nic	Relessed	Dek	ayed		С	are Co-Ordinator		
Clinic Date	Appointment Time	Patient	Specialty	Consultant	CPMS No:	Paris ID	Frequency	Dose	Dispensed	Crozapine Quarantined	Attended	Blood Status	crozaptne Released	Released (Pharmacist's Initiale)	Date	Name	Team	Telephone No:	contacted by (Initials)	Date and Time

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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.

 There are no specific antidotes • Gastric lavage / activated charcoal within 6 hours of ingestion Avoid adrenaline **Treatment**  Continuous cardiac monitoring •Surveillance of respiration Monitor electrolytes Monitoring Aspiration Pneumonia Convulsions Arrythmia Dyspnoea Serious risks •Neuroleptic Malignant Syndrome (NMS) •Can only occur after registered psychiatrist and care co-ordinator have been contacted due to risk of delayed reactions such as arrhythmias for up to 5 days post overdose Discharge

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# **Information for TEWV Clinicians**

Background	Signs and symptoms of clozapine overdose	Reporting of side effects	Follow up
<ul> <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> <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>Delayed reactions may be seen, including the late occurrence or recurrence of cardiac arrythmias<sup>3</sup>.</li> </ul>	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:  www.mhra.gov.uk/yellowcard	<ul> <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		
The Summary of Product	Drowsiness, lethargy, areflexia, coma,	Consult Toxbase <a href="https://www.toxbase.org/">https://www.toxbase.org/</a>		
Characteristics (SmPC) for clozapine <sup>1</sup> states:	confusion, hallucinations, agitation, delirium, extrapyramidal symptoms, hyperreflexia,	• There are no specific antidotes for clozapine.		
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	convulsions; hypersalivation, mydriasis, blurred vision, thermolability; hypotension, collapse, tachycardia, cardiac arrhythmias; aspiration pneumonia, dyspnoea, respiratory depression or failure.	<ul> <li>Gastric lavage and/or administration of activated charcoal within the first 6 hours after the ingestion of the drug.</li> <li>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> </ul>		
cardiac failure or pneumonia caused by aspiration and occurred at doses above 2000	There is a risk of neuroleptic malignant syndrome. <sup>5</sup>	• The use of adrenaline should be avoided in the treatment of hypotension because of the possibility of a 'reverse adrenaline' effect.		
mg.	Due to the high risk of cardiac arrhythmias, consider seeking advice from cardiology	<ul> <li>Close medical supervision is necessary for at least 5 days because of the possibility of delayed reactions, such as cardiac arrhythmias.</li> </ul>		
	specialists if clinically indicated.	<ul> <li>Any decision to discharge from medical care before this should be carried out by a consultant.</li> </ul>		
Potoroncos		<ul> <li>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.</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.
- 3. Le Blaye I et al. Acute Overdosage with Clozapine: a Review of the Available Clinical Experience. Pharm Med 1992; 6: 169-78.
- 4. Taylor D and Duncan D. The Use of Clozapine Plasma Levels in Optimising therapy. Psych Bulletin 1995; 19: 753-5.

This information was developed from the 2018 Mylan information leaflet CLZ-2018-0126  $\,$ 

5. Toxbase- clozapine. <a href="https://www.toxbase.org">www.toxbase.org</a> accessed 30 Sept 2022

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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** 



# Consultant (RC) Prescribe clozapine on inpatient chart with titration chart

- Sign 6month prescriptions and return to relevant dispensary (longtay patients)
- Record any changes to dose on EPR and notify relevant clinical pharmacy team and dispensary

#### NMP

- Sign 6month prescriptions (if within scope of practice) and return to relevar dispensary
- Record any changes to dose on EPR and notify relevant clinical pharmacy team and dispensary

### h Pharmacy Technician

- Set up 6month prescription once stable dose is reached (long stay patients)
- Add patient to relevant prescription tracker and update as necessary
- Produce new prescription when due (including reconciliation), or after changes to dose
- Archive old or discontinued
   prescriptions

### Clinical Pharmacist

 Check new 6month prescriptions before sending to RC

#### Dispensary Pharmacist

 Professionally check new signed 6 month prescriptions on receipt into dispensary

### Ordering



# Dispensing



#### Pharmacy Assistant (dispensary)

- SIS patients prepare clozapine supplies in advance of weekly clinic according to each patient's monitoring frequency
- Acute wards- prepare supplies according to technician orders

#### Accredited Accuracy Checker

Check prepared and clinicallyhecked clozapine supplies

#### Dispensary Pharmacist

- Check prepared clozapine supplies
- Archive old or discontinued prescriptions

# Monitoring

Consultant (RC)



- Oversight of all patients under their RC
- Regular assessment of mental state
- Arrange clozapine level assays if clinically indicated; review and act upon assay results
- SIS annual review of clozapine treatment according to checklist
- Notify pharmacy if clozapine is discontinued (i not due to red result)

#### **Postgraduate Doctor**

- Ensure repeat FBC within 10 days of baseline, and weekly thereafter
- Assess for sideffects during titration (weekl
- Check random blood glucose at 4 weeks
- Ensure repeat ECG, HbA1c & lipids at 12 weeks
   CASS for a least in a factor of the second se
- SIS complete GASS for clozapine (or other appropriate sideeffect rating scale) every 12 months

#### Ward staff nurse

- Oversight of all aspects of patient care
- Arrange and/or deliver all monitoring requirements: FBC- when due / prompted by pharmacy; physical obs daily; weight- weekly (new initiations); bowel functiorat least weekly\*; other side effects- at least weekly\*

\*depending on environment/individual patient factors

#### Pharmacy Technicia

 Retrieve blood results from ICE and input to CPMS (or equivalent) if blood not analysed o Pochi

#### HCA (inpatients)

- Physical health observations (NEWS)daily during titration, then as instructed
- Measure weight- weekly during titration, then as instructed

#### Clinical Pharmacist

- Inform CPMS (or equivalent) if discontinued
- Obtain plasma level assay results and communicate them to RC / enter on EPR

	(	1	,	1-			 ) -	 - ,
		]	_ 1		C-	5		

### Consultant (RC)

- Clinical decision to initiate clozapine
- Inform local pharmacy team of intention to initiate clozapine
- Arrange patient education re. monitoring requirements, sideffects, etc
- Obtain patient consent and record in EPR (or MHA basis for treatment
- Ensure baseline FBC and other tests are completed
- Register patient with CPMS (or equivalent)
- Enter significant medication alert [CLOZAPINE] on EPR

#### **Postgraduate Doctor**

 Complete baseline FBC and other tests, and record in EPR as a Physical Health case note

#### Clinical Pharmacist

- Deliver education to patient re. monitoring requirements, sideffects, etc and record in EPR
- Provide inpatient initiation checklist to ward
- Ensure arrangements in place to attend OSC after discharge

# Pharmacy Technician

- Acute wards order supplies of clozapine from dispensary according to dose and blood validity
- Recover supplies from ward after dose changes or cessation of treatment

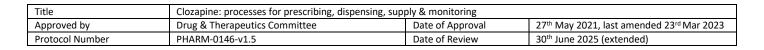
#### HCA (SIS) - for weekly clinic

- Venepuncture- obtaining blood sample for Pochi machine
- Operation of Pochi machine

# Administration

#### Ward staff nurse

 Administer clozapine according to prescription / titrationchart in line with good practice standards







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

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

### Initiation

Consultant (RC)

equivalent)

[CLOZAPINE] on EPR

to initiate clozapine



### **Prescribing**



#### Consultant (RC)

- Prescribe clozapine on Trust community clozapine prescription
- Sign 6month prescriptions and return to relevant dispensary
- Record any changes to dose or "eo meds" on EPR and notify relevant clinical pharmacy team and dispensary

- Sign 6month prescriptions (if within
- meds" on EPR and notify relevant

### Postgraduate Doctor (or CPN)

Complete baseline FBC and other tests, case note

Clinical decision to initiate clozapine

Inform local pharmacy team of intention

monitoring requirements, sideffects,

Obtain patient consent and record in

Ensure baseline FBC and other tests are

EPR (or MHA basis for treatment

Register patient with CPMS (or

Enter significant medication alert

Arrange patient education re.

#### Clinical Pharmacist (where available) / **CPN**

- Deliver education to patient re. monitoring requirements, sideffects, etc and record in EPR
- Provide community initiation checklist to
- Ensure arrangements in place to attend

- scope of practice) and return to relevan
- clinical pharmacy team and dispensary

#### Pharmacy Technician

- Set up 6month prescription once stable dose is reached
- Add patient to relevant prescription tracker and eVCB (where applicable), and update as necessary
- Produce new prescription when due (including reconciliation), or after changes to dose or comeds
- Archive old or discontinued

#### Clinical Pharmacist

Check new 6month prescriptions before sending to RC

#### Dispensary Pharmacist

 Professionally check new signed 6 month prescriptions on receipt into dispensary

### Dispensing



#### Pharmacy Assistant (dispensary)

 Prepare clozapine supplies in advance of OSCs according to each patient's monitoring frequency

#### Accredited Accuracy Checker

Check prepared and clinicallyhecked clozapine supplies for OSCs

#### Dispensary Pharmacist

- Check prepared clozapine supplies for **OSCs**
- Archive old or discontinued prescriptions
- Authorise release of quarantined medication outside OSC

### Supply



## **Monitoring**



#### Pharmacy Technician

- Check quarantine cupboard for uncollected medication, and any action
- Check delivered medication vs eVCB
- quarantine (green/amber result)
- Secure any unissued medication in quarantine cupboard
- Notify Care Coordinator if patient fails

quarantine (green/amber result)

#### Care co-ordinator / CPN

- · Arrange blood sampling and testing if patient fails to attend clinic
- Release of medication to patient from quarantine (with pharmacy approval)
- Recover supplies from patient after dose changes or cessation of reatment
- Inform patient to stop taking clozapine if notified of RED result

#### HCA

- Venepuncture- obtaining blood sample for Pochi machine
- Operation of Pochi machine

#### Consultant (RC)

- Oversight of all patients under their RC
- Regular assessment of mental state
- Arrange clozapine level assays if clinically indicated; review and act upon assay results
- Annual review of clozapine treatment according to checklis may be delegated to a suitably qualified prescriber in team)
- not due to red result)

#### Postgraduate Doctor (or CPN)

- Ensure repeat ECG, HbA1c & lipids at 12 week

#### Pharmacy Technician

- intake, or new / worsening sideffects

#### Care Co-ordinator

 Oversee patient care—arrange and/or deliver all monitoring requirements

#### HCA (with support of crisis team)

- Complete daily physical health obsP, ECG, weight-during titration and record in EPR as Physical Health case note
- Venepuncture-obtain blood sample for any necessary tests or plasma level assays

#### Clinical Pharmacist

- Inform CPMS (or equivalent) if discontinued
- Obtain plasma level assay results and communicate them to RC / enter on EPR

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