



# Community clozapine initiation and re-titration guidelines

For use by the Community and Home Treatment Teams within the London ELFT sites only

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Name of originator/author:	Dorcas Olupona, Clinical Pharmacist Masuma Hussain, Clinical Pharmacist
Executive Director lead :	Paul Gulilley
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2.0	July 2017	Andrea Okoloekwe	Final	<p>Updated sections:</p> <ul style="list-style-type: none"> <li>• Roles &amp; responsibility of staff involved in clozapine titration (section 3)</li> <li>• Review of inclusion, exclusion criteria (section 4)</li> <li>• Addition of information on clozapine and smoking (section 7, Appendix 10),</li> <li>• Procedure for community initiation at home (section 8)</li> <li>• Update of clozapine clinic details</li> <li>• Review of clozapine titration (appendix 6 &amp; 7)</li> <li>• Addition of new clozapine titration form (appendix 6 &amp; 7)</li> <li>• Review of staff assessment checklist to include symptoms of neutropenia &amp; cardiomyopathy (Appendix 3)</li> <li>• Addition of troponin and CRP monitoring to guidelines (appendix 6 &amp; 7)</li> </ul>

3.0	Jan 2021	Dorcas Olupona Masuma Hussain (Clinical Pharmacists)	Final	<p>Updated Sections:</p> <ul style="list-style-type: none"> <li>•Scope (Section 3.1)</li> <li>•Roles and Responsibility <ul style="list-style-type: none"> <li>-Responsible Consultant (Section 4.1.2, Section 4.1.6, section 4.1.12)</li> <li>- Care co-ordinator (Section 4.2.3, section 4.2.8)</li> <li>- Clozapine Clinic (4.3.2)</li> </ul> </li> <li>•General staff requirements (Section 5)</li> <li>•Inclusion criteria (Section 6.1.1)</li> <li>•Exclusion criteria (section 6.2.1, Section 6.2.3, section 6.2.5)</li> <li>•Special consideration (Section 6.3.2, section 6.3.6)</li> <li>•Before starting clozapine (section 7.7)</li> <li>•Initiation dose (Section 8.0)</li> <li>•Procedure for community clozapine initiation at home <ul style="list-style-type: none"> <li>- Section 10.2</li> <li>- Section 10.7</li> <li>- Section 10.11</li> <li>- Section 10:13</li> <li>- Section 10.14</li> </ul> </li> <li>•Discharge from the Home Treatment Team (Section 12.3)</li> <li>•Updated contact information – Section 13.0</li> <li>•Appendix 5 Clozapine Patient, Carers and GP Information Leaflet <ul style="list-style-type: none"> <li>• Addition of hyperlink to ELFT Clozapine PIL</li> <li>• Update contact details to relevant Crisis Line</li> </ul> </li> <li>•Addition of Appendix 9 Summary of roles and responsibilities.</li> </ul>
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## **1.0 Introduction**

- 1.1. Clozapine is a second generation (atypical) antipsychotic, used in patients with treatment resistant schizophrenia. As potentially life-threatening side effects are more common at the start of treatment, it has previously warranted hospital admission for initiation of the medication. Some of the adverse reactions of particular concern are: cardiomyopathy, constipation, hypotension, tachycardia, sedation, seizures and hyperthermia. However, patients are often reluctant to be admitted to start a medication especially if they are coping with residual symptoms in the community and beds are often not available for initiating Service Users.
- 1.2. Following the European harmonisation of the clozapine Summary of Product characteristics (SPC), there is no longer a mandatory regulatory requirement for in-patient initiation of clozapine.
- 1.3. Initiation of clozapine in the community will improve the access of patients to an effective treatment. It will allow patients to be treated in the environment most appropriate for them. It may also decrease waiting times for other patients for psychiatric hospital beds.
- 1.4. The National Audit of Schizophrenia 2014 examined the quality of prescribing, access to psychological treatments and the assessment and treatment of physical health conditions for people with schizophrenia with standards 12 and 13 aimed at clozapine. Standard 12 (S12) focused on the pathway to clozapine; examining patients not in remission and not on clozapine without a reason. If there was no or inadequate response to two antipsychotic drugs, one of which should be a second-generation antipsychotic at optimum dose, clozapine was offered. S13 looked at frequency of augmentation strategy in patients on clozapine.
- 1.5. There are a variety of different schemes for community initiation that may be employed, including combinations of community initiation (home or crisis house) with Home Treatment Team (HTT) involvement. These guidelines cover community initiation of clozapine with HTT involvement.

## **2.0 Purpose**

- 2.1 To describe the process for out-patient initiation of clozapine. To minimise the potential adverse effects of clozapine during initiation and ensure appropriate support is in place.
- 2.2 This guideline is to form an integral part of the Trust's Clozapine Clinic Operational Policy. It must be read in conjunction with this guideline.

## **3.0 Scope**

- 3.1 These guidelines are intended for use by the Community and Home Treatment Teams within the London ELFT sites.

## 4.0 Roles and responsibilities

### 4.1 Consultant Psychiatrist

- 4.1.1 Clozapine can only be initiated by a Consultant Psychiatrist registered with the clozapine monitoring service in locality (ideally the community team consultant where applicable).
- 4.1.2 Decision to initiate clozapine has been agreed by the team and all relevant parties. Please refer to the Pre-Treatment Checklist (Appendix 4).
- 4.1.3 To ensure patient has given valid consent to be initiated on clozapine. Valid consent to be documented in patient's notes and to include: patient being given information about treatment and possible side effects in a form and language that is understood. Information should include discussion on management of side effects, the consequence of not starting clozapine treatment and other alternatives.
- 4.1.4 Capacity of patient to make decision to start treatment must be assessed and documented.
- 4.1.5 The Consultant Psychiatrist must communicate with all teams involved in clozapine titration.
- 4.1.6 Establish clear lines of responsibility during titration period between Consultant Psychiatrists in community and HTT. (See appendix 9)
- 4.1.7 Existing medication to be reviewed and some drugs such as carbamazepine and antipsychotic depot to be discontinued prior to initiation of clozapine.
- 4.1.8 Ensuring clozapine titration chart is reviewed, full blood count completed in a timely manner to ensure uninterrupted supply of medication from ELFT pharmacy.
- 4.1.9 The community team must make the referral to the local/relevant clozapine clinic and organise registration of patient with clozapine monitoring service. Where HTT is to be involved for monitoring of titration the referring community team should make a referral coordinating with HTT, to ensure HTT is able to accept the monitoring role at the expected time.
- 4.1.10 If patient is not care-co-ordinated the psychiatrist must make the referral to the HTT for community titration.
- 4.1.11 Inform the General Practitioner and provide information on clozapine including any physical tests completed and ongoing physical health issues regarding clozapine and emergency contact details.
- 4.1.12 When the community team is referring to HTT for clozapine titration they should ensure medical workup to assess safety of initiation has been carried out (i.e. blood investigations, ECG) along with initiation of clozapine monitoring service registration process. Validity of baseline FBC is 10 days and ZTAS registration ensure the blood results are GREEN before titration.
- 4.1.13 When patients are discharged back to clozapine clinic, to ensure all teams (including Pharmacy) involved are notified. [Clozapine Clinic Referral Form](#) will need to be completed (refer to ELFT intranet).

4.1.14 To ensure that outpatient clozapine prescription is completed on day of discharge and sent to local ELFT pharmacy to mitigate against delay in supply of clozapine or incorrect dose being supplied.

## **4.2 Care co-ordinator**

4.2.1 Must communicate with all teams involved in the clozapine titration.

4.2.2 Must make the referral to the HTT for community titration.

4.2.3 If patient is not accepted by HTT, patient will need to be titrated in an inpatient setting.

4.2.4 Nurse must use care plan for titration and develop crisis plans for non-compliance of medication over 48 hours and DNA.

4.2.5 Monitor and report any side effects including signs of neutropenia-elevated temperature, sore throat, flu like symptoms.

4.2.6 Regular observation and report of patient progress to be discussed with consultant or team doctor.

4.2.7 Information and support to be provided to both patient and carers. Patient and carer to be made aware who to notify both within working and out of hours in the event of a crisis.

4.2.8 Pharmacy and clozapine clinic should be notified as soon as discussion on possibility of patient starting clozapine treatment to mitigate against delay in starting treatment or dispensing of clozapine.

## **4.3 Clozapine Clinic**

4.3.1 Must communicate with all teams involved in the clozapine titration.

4.3.2 To facilitate blood monitoring while patient is being titrated and to communicate results to relevant teams

## **4.4 ELFT Pharmacy**

4.4.1 To ensure clozapine prescriptions are in date.

4.4.2 To ensure timely dispensing of clozapine medication.

4.4.3 To communicate with all teams involved in clozapine titration.

## **4.5 General Practitioner**

4.5.1 GP to assist in ensuring that patients prescribed clozapine have that recorded in their notes.

4.5.2 To inform psychiatric team of any changes in mental and physical state, suspected side effects or changes to any medication prescribed by them.

4.5.3 To be aware of potential drug interactions when co-prescribing other medication for clozapine patients.

4.5.4 If involved in smoking cessation campaign with clozapine patients to notify psychiatric team due to interaction of nicotine smoke and clozapine.

## 5.0 General staff requirements

5.1 Staff involved in caring for someone undergoing community initiation of clozapine must be familiar with this policy as well as:

- The Trust Clozapine Clinic Operational Policy.
- The Trust Clozapine Policy
- Summary of Product Characteristic which gives detailed information on clozapine clinical particulars including possible side effects. Refer to up to date version of clozapine brand used in your locality via <https://www.medicines.org.uk/emc/medicine/> Blood monitoring requirements for Service Users being treated with clozapine (refer to clozapine policy).
- Access to patient information leaflet on ELFT [intranet](#).

## 6.0 Criteria for initiation of clozapine in community-based patients

### 6.1 Inclusion criteria

6.1.1 Patients must be considered suitable by consultant psychiatrist for out-patient care in view of their current symptomology and safety risk. The patient must be fairly mentally and physically stable for community initiation. The acute clinical presentation of a patient should not warrant an automatic decision for inpatient initiation.

6.1.2 Patients must consent to clozapine treatment and required blood tests for initiation and titration and be aware of and agree to the necessity for daily monitoring which might involve attendance/ home visits.

6.1.3 Patient should be aware and understand the possible side effects that could occur and what to in the event of that occurring (especially the rare but serious side effects such as cardiomyopathy, agranulocytosis, and intestinal obstruction).

6.1.4 For titration being carried out at home environment supportive family/carer network – ideally someone must be available to stay overnight and at weekends during the titration period. Patient should be readily contactable.

6.1.5 There must be access to an in-patient bed in the event that the patient's mental or physical state deteriorates during the initiation.

6.1.6 A maximum of ONE antipsychotic should be in use before switching to clozapine.



## **6.2 Exclusion criteria**

6.2.1 Medical conditions contra-indicated in the SPC or co-morbidities that are deemed unsafe by the titrating team or clozapine clinic for initiation of clozapine in the community such as those with unstable diabetes mellitus or other significant physical health disease, history of seizures, significant cardiac disease.

6.2.2 Patients under the age of 16.

6.2.3. Patients with unreliable or chaotic lifestyles which could impact on concordance with medication or monitoring regimen.

6.2.4 Patients who have polysubstance misuse such as alcohol or other drugs which are likely to increase potential side effects

6.2.5 Patients that have had the following:

- Developed severe side effects upon previous initiation of clozapine or other antipsychotics
- Have unmanaged high or low blood pressure
- Have a history of neuroleptic malignant syndrome
- Have a history of seizures

6.2.6 Initiating treatment in patients who live alone or with no overnight family or carer support (alternatives such as Crisis House may be sought). Titration of clozapine for people living alone in the community with no support on site is not advisable due to the potential effects on physical health. Record details in patient notes

6.2.7 Patients who have a propensity for amber or red results

## **6.3 Special considerations**

6.3.1 Patients receiving potent sedatives or benzodiazepines.

6.3.2 Patients with complex drug regimes who will require cross titration due to polypharmacy.

6.3.3 Consider interactions

6.3.4 Consider additive side effects (especially with other psychotropics) – hypotension, sedation, effect on QTc.

6.3.5 Restarting treatment in patients who live alone or with no overnight family or carer support (alternatives such as Crisis House may be sought). This is to be considered on a case-by-case basis and the following factors should be considered:

- The patient should have been compliant with clozapine in the previous 4 weeks. If clozapine stopped over 4 weeks ago re-titration in community not recommended)
- The patient has been stable on clozapine and has had GREEN clozapine monitoring results
- The patient is not willing to consider informal admission and mental state does not warrant anything more formal
- On balance the benefits of restarting clozapine outweigh potential risks of re-titration
- Record details in patient notes

### 6.3.5 Risks of clozapine include:

- **Agranulocytosis.** Clozapine has caused fatalities, but the incidence has decreased with the institution of a strict prescribing protocol and rigorous regimen for blood tests.
- **Myocarditis.** Which has been associated with fatalities, most often occurs in the first two months of clozapine treatment.
- **Cardiomyopathy.** Generally occurs an average of 14 months after starting clozapine treatment, ensure relevant monitoring is being completed, if confirmed clozapine should be discontinued.
- **Impaired intestinal peristalsis.** Clozapine can cause constipation, intestinal obstruction, faecal impaction and paralytic ileus; these effects have been associated with fatalities. It is therefore essential to follow the official recommendations on the use of clozapine and on registering patients in the patient monitoring service
- **Lower seizure threshold,** caution taken with other medications which can also effect seizure threshold.
- **Hypersalivation** (excessive drooling, sialorrhoea), which can be very embarrassing for the patient and compromise adherence to treatment but it can also be life-threatening if saliva is aspirated. Hypersalivation is often dose related and improves with time, but it can occasionally be persistent.

## 7.0 Before starting clozapine

7.1 Each case is to be considered on an individual basis.

7.2 There will be a maximum number of patients on community initiation in the HTT. This is to ensure the adequate supply of care to each patient to be decided by the team leader and consultant for the team. There may be a treatment waiting list and pharmacy should be informed of this.

7.3 Initial baseline tests to include ECG, FBC, LFT, U&E, Troponin, CRP, Random blood glucose (non-diabetic patients), BMI, temperature (monitored daily whilst on titration) BP, pulse (refer to appendix 4 & appendix 7).

7.4 Clozapine tablets will be provided by the ELFT pharmacy. Pharmacy and clozapine clinic should be notified as soon as discussion on possibility of patient starting clozapine treatment to mitigate against delay in starting treatment or dispensing of clozapine.

7.5 Patients, family members/carers will be provided with information about clozapine in particular:

- Realistic expectations for recovery including time frame.
- Recognition of adverse effects to clozapine and what to do if they occur.

- Contact numbers in case of emergencies (refer to Appendix 5).
- 7.6 There must be a contingency plan in case a patient defaults from visits or is non-concordant.
- 7.7 It must be clearly documented who is going to take the blood sample: Ideally clozapine clinic, however contingency plan in place e.g. HTT team or doctor
- 7.8 The Community Team Doctor deciding on initiation of Clozapine must follow the Trust's Clozapine Clinic Policy which outlines the necessary requirements for initiation of clozapine. Briefly, these include:
- Complete a full medical history and physical examination; including history of cardiac problems, epilepsy, diabetes, or haematological disorders, monitoring of baseline weight, pulse, temperature, blood pressure, routine bloods (FBC, U&Es, Troponin, CRP, LFTs, TFTs, lipids, glucose, HbA1c) and ECG if not done in the previous 6 months.
  - Identify the patient's usual bowel habits, any signs or symptoms of constipation should be queried and treated prior to starting clozapine
  - Full medication review – Looking for possible interactions, e.g., bone marrow suppressants (e.g., carbamazepine or cytotoxics), highly protein bound drugs, phenytoin. Contact the mental health pharmacist for advice.
  - Where relevant make a referral to the HTT for monitoring of titration.
  - Provide plan for cross titration of antipsychotic medication.
  - Inform the patient's GP of initiation and provide information about clozapine.
  - Register the Service User with clozapine monitoring service and ensure they are GREEN before titration.
  - Refer the patient to the Clozapine Clinic as described in the Clozapine Clinic Operational Policy.

## **8.0 Initiation dose**

8.1 Clozapine initiation should start at 12.5mg if patient has access to enhanced monitoring such as crisis house and availability of staff in HTT. A lower starting dose of 6.25mg may be started if clinically warranted. Any decision would need to be documented in the patient's notes.

## 9.0 Clozapine and smoking

9.1 Nicotine/tobacco smoking causes enzyme induction. This means that certain enzymes produced by the liver that are responsible for metabolism of certain drugs are produced. The consequence of this is that level of some drugs, such as clozapine, in the body are reduced. Smokers prescribed clozapine often require higher clozapine doses compared to non-smokers (see appendix 8). Smoking cessation can therefore increase clozapine to high levels which can be toxic. Patients should be informed that they would need to notify the clinical team in the event there is a change in their smoking habits.

## 10.0 Procedure for community clozapine initiation at home

10.1 The patient is to be visited at home by the HTT as per local operational policy. Staff involved in management of clozapine patients in community need to be aware of their local services available.

10.2 If there are no concerns, monitoring frequency can be initially reviewed on day 4 and reduced to a minimum of once daily for the first two weeks (Appendices 1). After the first two weeks the monitoring frequency may be reduced to alternate days.

10.3 Visits to the patient at home should be by a least one mental health practitioner who is competent at taking physical observations.

10.4 Day one of the initiation will ideally be a MONDAY so that there are full staff levels for the first five days of treatment.

10.5 For the first two days of the titration the patient will be advised to remain at home or relevant local service for at least 6 hours after the dose of medication and supervised by a family member or carer who has emergency contact phone numbers.

10.6 There should be somewhere for the patient to lie or sit should they need to.

10.7 Pulse, temperature, lying and sitting/standing BP should be performed as per the care plan and documented on the Trust's physical observation sheet (NEWS) daily and documented on the patients notes. If the results are abnormal, the team doctor should be alerted as soon as possible to review the patient. The monitoring frequency may need to be increased, dose titration slowed or initiation as an in-patient considered. Refer to [Physical Healthcare Policy](#) on ELFT intranet.

10.8 Clozapine should be prescribed on the Trust's Clozapine Community Titration Form (see appendix 6). If the dosage is not tolerated seek medical advice. The dosage should not be increased over weekends or bank holidays.

10.9 If the patient defaults on clozapine for more than 48 hours and the decision has been taken to restart clozapine, this will need to be re-titrated to the original dose. The Clozapine Clinic will need to be informed as blood testing may need to be repeated before restarting. The Clozapine Clinic Pharmacist and Consultant Psychiatrist will devise a suitable re-titration prescription based on the patient's clinical situation.

10.10 If a patient misses less than 48 hours of medication the patient should be recommenced at the dose prescribed before the event. Do not administer extra tablets to catch up.

10.11 It is important to identify what the patient's bowel habits are and Constipation should be queried and treated prior to starting clozapine. The patient should be asked in as sensitive and as detailed a way as possible whether they are experiencing side effects, particularly constipation and should not be ignored as it can be fatal. Refer to [Clozapine Policy](#).

List of common side effects:

#### **Common Side Effects of Clozapine**

- Sedation/drowsiness
- High pulse rate
- Low pulse rate
- High blood pressure
- Low blood pressure
- Hypersalivation
- Dizziness
- Constipation
- Nausea/Vomiting
- Dry mouth
- Urinary frequency/urgency
- Headaches

10.12 The Clozapine Clinic's observation form (appendix 3) which lists side effects should be used as a guideline and any side effects reported/observed should be documented in the clinical notes and discussed with the team doctor. The monitoring frequency may need to be increased, dose titration slowed or initiation as an in-patient considered. Refer to [Health Record Keeping](#) on ELFT intranet.

10.13 Staff responsible for taking physical observations should inform the doctor immediately if:

- Temperature rises above 38°C
- Pulse is > 100bpm
- Blood pressure postural drop of > 30mmHg
- Patient is clearly over-sedated
- Any other adverse effect is evident
- Flu-like symptoms, malaise, fatigue etc.
- Chest pain, shortness of breath, dyspnoea, tachypnoea
- Any signs of constipation

10.14 In the event of a 'red' blood result, the responsible consultant should be notified as soon as possible. If out of hours, duty doctor must liaise with on-call consultant.

- 10.15 Alternatively, where NEWS charts are used, NEWS scores of 1-2; nurse in charge to be alerted. News scores of 3-6 would require a medic (including an on-call doctor) is alerted. NEWS scores higher than 6 would require a visit to A&E or contacting ambulance service.
- 10.16 A doctor will see the patient regularly and at a minimum once every week. The patient must be admitted as an in-patient if there are any concerns for the patient titrating in the community.

## **11.0 Re-titration**

- 11.1 Patients who miss 48 hours or more of clozapine and in whom the decision has been taken to re-start this drug will require re-titration to their original dose.
- 11.2 The speed of this re-titration will be dependent on the duration of clozapine abstinence, the patient's mental state, medical co-morbidities as well as team specific operational factors.
- 11.3 Re-titration is patient specific and the Clozapine Clinic Pharmacist and Consultant Psychiatrist should devise a suitable and appropriate re-titration prescription for each individual. In some cases it may be possible to undertake an accelerated re-titration (that is, faster than the standard titration set out in the Clozapine Clinic Policy).

## **12.0 Discharge from the Home Treatment Team**

- 12.1 When discharging the patient from the care of the HTT please ensure the following actions are performed:
- 12.2 Patient is offered discharge counselling with emphasis on signs and management of constipation, cardiomyopathy or pulmonary pneumonia and what to do in the event of any of these conditions arising within and outside working hours.
- 12.3 The Clozapine Clinic and the Pharmacist are informed of impending discharge using the [Clozapine Clinic Referral Form](#) Outpatient prescription must be provided to the Clozapine Clinic Pharmacist.
- 12.4 The patient has a follow up appointment with the Clozapine Clinic.
- 12.5 An HTT Discharge Summary is sent to the Clozapine Clinic, Pharmacy Department, the Service User's GP and the Community Mental Health Team.
- 12.6 The clozapine patient and GP information sheet (Appendix 5) is included in the information sent to the GP on discharge.

## 13.0

**Clozapine contact details**

<b>Locality</b>	<b>Contact details</b>
City & Hackney	<p>Isma Kayani (Clozapine Clinic Manager) Tel: 07970 786656</p> <p>2<sup>nd</sup> Clinic 23 Primrose Square, London E9 7TS Tel: 0208 525 1115 Email: <a href="mailto:elft.CityandHackneyClozapine@nhs.net">elft.CityandHackneyClozapine@nhs.net</a></p>
Newham	<p>Matthew Oppong (Clozapine Clinic Manager)</p> <p>115 Balaam Street, Plaistow, London E13 8AF Tel: 020 8548 5160 Email: <a href="mailto:elft.ClozapineTeamNewham@nhs.net">elft.ClozapineTeamNewham@nhs.net</a></p>
Tower Hamlets	<p>Makeda Douglas (Clozapine Clinic Manager)</p> <p>86 Old Montague Street, London E1 5NN Tel: 0207 426 2350 or 0207 426 2352 (for appointments) Mob: 07572 140 863 Email: <a href="mailto:elft.TH-Clozapine@nhs.net">elft.TH-Clozapine@nhs.net</a></p>

<b>Clozapine Monitoring Systems</b>	
Zaponex	<p>Email: <a href="mailto:info@ztas.co.uk">info@ztas.co.uk</a> Tel: 0207 365 5842</p>
Denzapine	<p>Email: <a href="mailto:Denzapine@Britannia-pharm.com">Denzapine@Britannia-pharm.com</a> Tel: 0333 200 4141</p>

## 14.0 References

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- Manchester Mental Health and Social Care Trust (2014), Clozapine Guideline-Community
- South West Yorkshire NHS Mental Health Trust (2015), Guidelines for Community Clozapine initiation.
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## APPENDIX 1: Care Plan

Service User		Date of birth	
Consultant		ZTAS no	
Address			
Service User Phone no.		Clozapine clinic number	

- The dose of clozapine will not be increased over the weekend or at bank holidays.
- The Service User will be reviewed at least once per week by a doctor.
- The consultant should be contacted immediately with any concerns over compliance or adverse effects.

DAY ONE	MORNING Around 10am	<p>HTT/Community staff (1 to be a registered nurse) to see Service User. During this visit <b>Service User to take first dose of clozapine.</b> BP and pulse (lying and standing) to be measured prior to dose.</p> <ul style="list-style-type: none"> <li>• Ensure Service User and Carers have emergency contact numbers</li> <li>• Advise Service Users and carers – If Service User is over sedated, 'looks under the weather' to phone HTT community staff immediately and seek advice.</li> <li>• If Service User collapses, is having trouble breathing or are at all worried about the Service User to bring to A&amp;E.</li> </ul>
	NIGHT Around 8pm	<p><b>HTT where home visit has been agreed</b> will visit Service User at home or if patient is on the premises to monitor blood pressure( lying and standing), pulse and temperature. Monitor for any adverse effects. Advise the Service User and carer/family of the need to get out of bed slowly because of possible hypotension and other side effects.</p>
	NIGHT Around 10pm	<p><b>HTT</b> to make phone contact with the Service User/carer progress on this medication.</p> <ul style="list-style-type: none"> <li>• Advise the Service User's carers/family of contact number should they need to contact the team about any concerns.</li> <li>• Advise the Service User and carer/family of the need to get out of bed slowly because of possible hypotension and other side effects.</li> </ul>
DAY TWO	MORNING Around 10am	<p><b>HTT</b> will visit Service User where agreed to monitor blood pressure (lying and standing), pulse and temperature prior to administer of dose of clozapine. <b>Service User to take prescribed Clozapine dose.</b></p>
	MORNING Approx 2 hours after dose	<p><b>HTT</b> will visit Service User where agreed to monitor blood pressure (lying and standing), pulse and temperature. <b>HTT</b> will monitor for any other adverse effects experienced by the Service User.</p>

	EVENING Around 6pm	<b>HTT</b> staff to visit and <b>administer prescribed clozapine dose</b> to Service User and monitor blood pressure (lying and standing), pulse and temperature prior to administer of dose of clozapine
	EVENING Approx 2 hours after dose	<b>HTT</b> will visit Service User at home and monitor their blood pressure (lying and standing), pulse and temperature <b>HTT</b> to check for any adverse effects and document.
	NIGHT Around 10pm	<b>HTT</b> to make phone contact with the Service User progress on this medication.
DAY THREE	MORNING Around 10am	<b>HTT</b> will visit Service User and monitor blood pressure (lying and standing), pulse and temperature prior to administer of dose of clozapine. <b>HTT to administer clozapine dose prescribed.</b>
	MORNING Approx 2 hour after dose	<b>HTT</b> will visit Service User and monitor blood pressure (lying and standing), pulse and temperature. <b>HTT</b> will monitor for any other adverse effects experienced by the Service User and document.
	EVENING Around 6pm	<b>HTT</b> staff to visit and monitor blood pressure (lying and standing), pulse and temperature then <b>HTT to administer clozapine dose prescribed</b>
	EVENING Approx 2 hours after dose	<b>HTT</b> will visit Service User at home and monitor their blood pressure (lying and standing), pulse and temperature. <b>HTT</b> to check for any adverse effects and document.
	NIGHT Around 10pm	<b>HTT</b> to make phone contact with the Service User progress on this medication.
DAY FOUR	<b>Clinical Decision made by Team as to frequency of monitoring to be undertaken.</b>	
	<p><b>If no concerns:</b></p> <p><b>AM</b></p> <p><b>HTT</b> will visit Service User and monitor blood pressure (lying and standing), pulse and temperature prior to administering dose of clozapine. If vitals are unspectacular, they will leave night time dose of clozapine for Service User to take as TTA.</p> <p><b>PM</b></p> <p>Service User takes their night time dose of clozapine as a TTA. <b>HTT</b> to make phone contact with service user progress on medication.</p>	<p><b>If more monitoring required:</b></p> <p><b>AM</b></p> <p><b>HTT</b> will visit Service User and monitor blood pressure (lying and standing), pulse and temperature prior to administering dose of clozapine.</p> <p><b>PM</b></p> <p><b>HTT</b> will visit Service User and monitor blood pressure (lying and standing), pulse and temperature prior to administer of dose of clozapine</p>
DAY FOURTEEN ONWARDS	<b>Clinical Decision made by Team as to frequency of monitoring to be undertaken.</b>	
	Monitoring may be reduced to alternate days if appropriate.	

## **Appendix 2 Newham Management Plan for the Commencement of Clozapine Treatment Whilst Under the Care of Home treatment Team (HTT).**

**THE SERVICE USER & CARER MUST BE GIVEN A COPY OF THIS PLAN.**

Name:..... DOB: .....  
RiO:.....  
Address:

**Service User contact number Tel:**

**Service User Carer Tel:**

**Home Treatment Team: 0207 540 6782**

**Clozapine Clinic: 0208 548 5160/5179**

**Pharmacy Department: Contact reception on 0207 540 4380 and ask to be put through to pharmacy bleep**

Community titration in Newham is done at the Home Treatment Team (HTT). If patient is acutely mentally unwell or has no relative at home, then titration is done on the ward as an inpatient.

Prior to commencing Clozapine treatment the Service User must be attending the Home Treatment Team.

The GP must be informed of the initiation of the Clozapine treatment.

The service user should have a thorough physical and mental health assessment carried out by the referring team

Medical team: Baseline full screen of bloods and an ECG is carried out also before commencing Clozapine and get the service user registered with ZTAS monitoring Service. There will also be an identified worker at the Home Treatment Team to co-ordinate the care for this service user..

Service User to attend the HTT for at least 2 weeks whilst treatment is in progress. This will include weekends and transport can be provided throughout.

## **Prior to Start of Titration**

1.1. All Vital signs: The initial baseline tests to include ECG, FBC, LFT, U&E, Troponin, CRP, Random blood glucose (non-diabetic patients), Weight, Height, BMI, temperature (monitored daily whilst on titration) Blood Pressure, Pulse and oxygen saturation.

Staff to also refer to the Trust Clozapine policy and Community Clozapine titration guidelines for more information if needed.

Patient need to have a blood test in order to have a valid blood result to start titration.

## **During the Period of Titration**

Blood pressure, pulse (lying and standing) and temperature prior to administration of dose of Clozapine prescribed. Blood pressure and pulse should be repeated after 1-2hrs post clozapine administration. If observations are not within normal range, inform the RMO and maintain 4hourly observation. This is to be done daily until titration is completed.

The Troponin and CRP also need to be monitored weekly for the first four weeks of titration unless otherwise stated by the RMO.

Starting dose is decided by the prescribing doctor and increase according to the titration guidelines.

Home Treatment Team doctor to assess the service user progress, any adverse reaction to Clozapine, adjust the titration range and manage the antipsychotic medication cross tapering.

Advise the Service User's carers/family of contact number should they need to contact the team about any concerns. The Service User will also have a Crisis Card.

Advise the Service User and carer/family of the need for getting out of bed slowly because of possible hypotension and other side effects.

Service User will remain under the care of the HTT until the Service User is stabilised on medication and fit to be discharged to the clozapine clinic.

## **Clozapine Clinic**

It is advisable that the Service User should start to attend the Clozapine Clinic before discharge from HTT to familiarise themselves with the clinic routine.

The Newham Clozapine Clinic open Monday to Friday 10.00-16.00hrs except bank holidays.

The Clinic operates an appointment system so please contact the Clinic first to obtain an appointment before attending.

Whilst patients are with the HTT, blood sample are taken by the ward Phlebotomist where available and brought to the clozapine clinic for analysis.

In the event of a blood result that is not 'green' the Clinic will notify the HTT immediately.

### **Discharge Planning**

Prior to discharge the HTT should liaise with the clozapine clinic and make a referral to the clinic.

HTT should obtain an appointment date for the Service User from the clozapine clinic and inform the care coordinator and relatives of this.

HTT should inform their allocated pharmacist to supply sufficient clozapine medication for the patient until the appointment date with the clozapine clinic. They also need to complete the community clozapine prescription and send to pharmacy to ensure a continuous supply of clozapine to the clinic.

**NB.** If at any time anyone involved in the service user's care is concerned about side effects or any other aspect of the service user's presentation, they should contact Newham HTT

### **Common Side Effects of Clozapine**

- . Sedation/drowsiness
- . High pulse
- . Low pulse
- . High blood pressure
- . Low blood pressure
- . Hypersalivation
- . Dizziness
- . Constipation
- . Nausea/Vomiting
- . Dry mouth
- . Urinary frequency/urgency
- . Headaches.

Patient on Clozapine medication are monitored by their psychiatrist and remain in Secondary Mental Health Services.



Nausea/Vomiting								
Dry Mouth								
Urinary Problems								
Other								

## Appendix 4: Pre Treatment Checklist

<b>1 Pre-treatment information</b>	<b>Met (date &amp; initial)</b>	<b>Comments</b>
1.1 Information leaflet given to Service User?		
1.2 Information explained?		
1.3 Family/carer provided with information about Clozapine including expected timeframe for recovery, side effects, and what to do?		
1.4 Pharmacist informed		
1.5 Clozapine clinic informed		

	<b>Yes (date &amp; initial)</b>	<b>No (date and initial)</b>	<b>Comments</b>
1.6 Are there any concerns regarding :non-concordance?			
1.9 Has a physical health exam been completed?			
1.10 Has routine blood monitoring and ECG been completed? (ECG within last 6 months)			
1.11 Does the Service User have a history of epilepsy?			
1.12 Is Service User agreeing to treatment?			
1.13 Is Service User suitable for O/P initiation?			

<b>2. Out-Patient Considerations</b>	<b>Met (date &amp; initial)</b>	<b>Comments</b>
2.1 Service User aware of necessity for daily attendance/home visits?		
2.2 GP informed of Clozapine start date and provided with guidelines and emergency contact number?		
2.3 Family/carer available to stay overnight?		
2.4 Emergency contact number provided to Service User?		
2.5 Service User provided with information regarding side effects and what to do if they occur?		
2.6 Family/Carer provided with information regarding side effects and what to do if they occur?		



## Appendix 5: Clozapine Patient, Carers and GP Information Leaflet

### Clozapine (Zaponex®, Clozaril®, Denzapine®)

- Clozapine is an atypical antipsychotic, indicated for the treatment of schizophrenia in Service Users unresponsive or intolerant of at least two other antipsychotics. Currently three different brands available zaponex, clozaril and denzapine.
- ELFT provide Service Users within City and Hackney, Newham and Tower Hamlets with Zaponex® and Service Users' are monitored using the Zaponex Service User Access System (ZTAS) and the clozapine clinic. Service Users in Luton & Bedfordshire are provided with Denzapine® and are monitored using the Denzapine Monitoring Service (DMS).

**Clozapine is prescribed ONLY by a Consultant Psychiatrist  
Clozapine is dispensed ONLY by the registered pharmacy**

- Service Users on clozapine may present at a GP surgery with side effects of clozapine. These can generally be treated safely and effectively by the general practitioner.
- Please ensure all clozapine Service Users are easily identifiable on the EMIS system when they present for an appointment.
- Please inform the psychiatrist and the clozapine clinic about treatment of clozapine induced side effects so that dose adjustments can be made where appropriate.
- Patient Information Leaflet, to be presented to patients and carers, can be found [here](#).

#### Adverse effects

Common adverse effects of clozapine: Please see Clozapine SPC for full adverse effects.

<input type="checkbox"/> Constipation – which may lead to obstruction, and <u>can be life threatening</u> .	<input type="checkbox"/> Weight gain.
<input type="checkbox"/> Drowsiness / sedation / dizziness	<input type="checkbox"/> Fever / benign hyperthermia / disturbance in sweating and temperature regulation
<input type="checkbox"/> Tachycardia (palpitations) / ECG changes	<input type="checkbox"/> Urinary incontinence / urinary retention
<input type="checkbox"/> Postural hypotension / syncope / hypertension	<input type="checkbox"/> Seizures / convulsions / myoclonic jerks
<input type="checkbox"/> Hypersalivation / dry mouth	<input type="checkbox"/> Blurred vision / headache / tremor
<input type="checkbox"/> Nausea , vomiting, anorexia	<input type="checkbox"/> Akathisia / rigidity / extrapyramidal symptoms.
<input type="checkbox"/> Elevated liver enzymes.	<input type="checkbox"/> Eosinophilia / leukocytosis

#### Contact Numbers for Advice and Support

##### **East London NHS foundation Trust**

City and Hackney Crisis Line	Tel: 0800 073 0006
Newham Crisis Line	Tel: 0800 073 0066
Tower Hamlets Crisis Line	Tel: 0800 073 0003

# Appendix 6



## CLOZAPINE Community Prescription and Administration Chart

Surname: Forenames:		Date of birth / Age:	Sex:	Hospital no.	ZTAS no.
Team:	Consultant:	Ward Doctor:	Drug Allergies	Pregnant?	

Blood Pressure and Pulse must be taken at baseline and then twice a day (BEFORE and TWO HOURS after dose) during titration. Prescribers also PRESCRIBE CLOZAPINE ON REGULAR CHART quoting 'please see titration chart'



BASELINE OBSERVATIONS													
DATE			BP		Pulse		Temp	Weight		Troponin			
Day no.	Date to be given	Time	Oral Dose	Admin by. Sign	BP Pre/Post	Pulse	Time	Oral Dose	Admin by Sign	BP Pre/Post	Pulse	DR Sign for each day	
1		0900					1800	-----	-----				
2		0900					1800						
3		0900					1800						
4		0900					1800						
5		0900					1800						
6		0900					1800						
7		0900					1800						
<b>Week One Troponin Level:</b>													
8		0900					1800						
9		0900					1800						
10		0900					1800						
11		0900					1800						
12		0900					1800						
13		0900					1800						
14		0900					1800						
<b>Week Two Troponin Level:</b>													
15		0900					1800						
16		0900					1800						
17		0900					1800						
Pharmacy							<b>PLEASE CONTINUE TROPONIN LEVELS FOR A FURTHER TWO WEEKS.</b>						

## Appendix 7 : Mandatory Monitoring Parameters for Patients Prescribed Clozapine in ELFT

### 4.10 Summary Matrix of Mandatory Monitoring Parameters for Clozapine Treatment in in ELFT.

Monitoring Parameter	Week of Clozapine Treatment																																				
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52		
FBC+ differential	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Troponin level + CRP	✓	✓	✓	✓																																	
BP and pulse	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Weight/Height (BMI)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Temperature	Monitored daily whilst on titration and remains as inpatient. In community measured at clinical discretion if service user appears unwell or there is cause for concern.																																				
Random Blood Glucose (Non-DM)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Constipation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Seizures	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

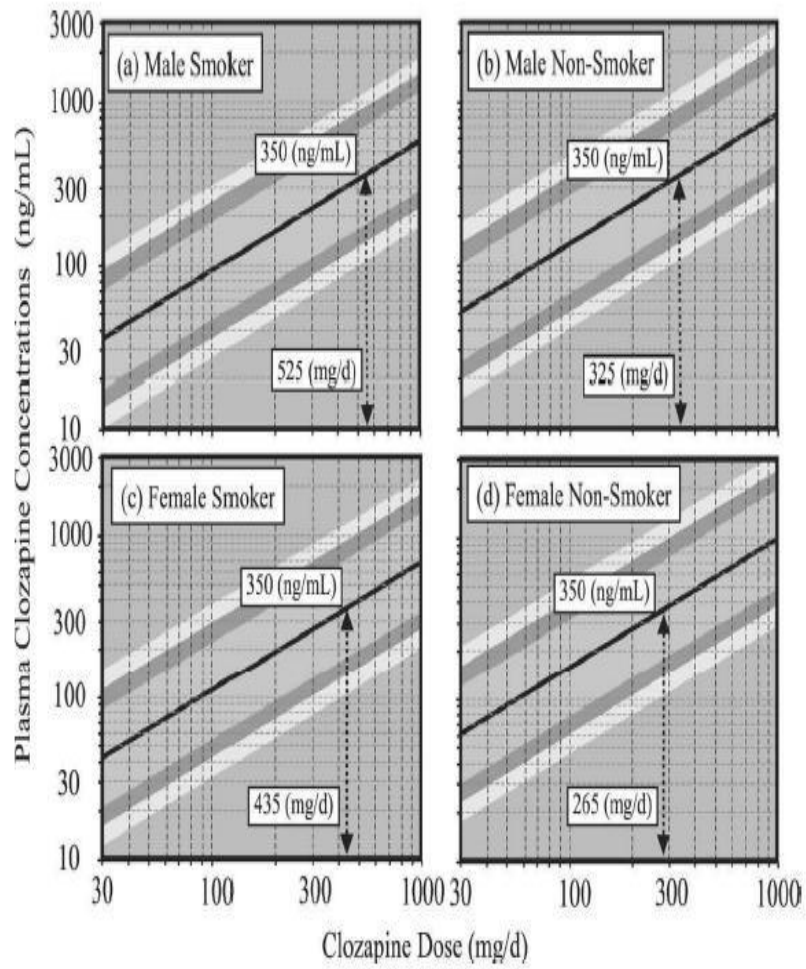
\* Beyond first year of treatment, all tests with exception of Troponin, CRP and temperature should be undertaken on a monthly basis.

\*\*In the case of a treatment break, the blood test frequency will be altered. See section 11.0 for further details.

Adapted from ELFT Clozapine Policy

## Appendix 8: Effect of smoking on clozapine levels

Concentration-Dose Nomograms from Rostami-Hodjegan et al. (2004)



**Appendix 9: Summary of Roles and Responsibilities**

Patient identified as suitable for clozapine titration in community.

**The community team must:**

- Make the referral to the local/relevant clozapine clinic and organise registration of patient with clozapine monitoring service ensure they are GREEN before titration.
- They should also ensure medical work up to assess safety of initiation has been carried out (i.e. blood investigations, ECG) along with initiation of clozapine monitoring service registration process. (Validity of baseline FBC must be within 10 days of ZTAS registration)
- Where HTT is to be involved for monitoring of titration the referring Community team should make a referral coordinating with HTT, to ensure HTT is able to accept the monitoring role at the expected time.

**Care- coordinator:**

- Must make the referral to the HTT for community titration
- If patient is **not accepted** by HTT, identify staff who are able to complete the physical health checks (including blood pressure, temperature, pulse, respiration, weight) of the patient
- Regular observation and report of patient progress to be discussed with consultant or team doctor.
- Information and support to be provided to both patient and carers. Patient and carer to be made aware who to notify both within working and out of hours in the event of a crisis.
- Pharmacy and clozapine clinic should be involved with discussions about possibility of initiating clozapine, to mitigate against delay in starting treatment or dispensing of clozapine.

**Consultant Psychiatrists**

- If patient is **not** care-co-ordinated the psychiatrist must make the referral to the HTT for community titration.
- To communicate with all relevant teams or healthcare professional e.g. Care co-ordinator, Clozapine clinic, HTT, pharmacy and GP.
- To inform the General Practitioner and provide information on clozapine including any physical tests completed and ongoing physical health issues regarding clozapine and emergency contact details.
- To review existing medication and clozapine titration chart.

**HTT:**

- The patient is to be visited at home by the HTT as per local operational policy.
- To liaise with pharmacy to ensure supply of clozapine doses as per the titration protocol.
- Visits to the patient at home should be by a least one mental health practitioner who is competent at taking physical observations and side effects. (See appendix 3)
- To ensure there are full staff levels for at least the **five days of treatment**.
- Must communicate with all teams involved in the clozapine titration.

**Clozapine clinic:**

- To facilitate blood monitoring while patient is titrated and communicate results.
- Must communicate with all teams involved in the clozapine titration.