

Community Initiation of Clozapine in Adults under 65 years

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Synopsis:	Clozapine has side effects which need to be monitored and the dose is carefully titrated to reduce the risk and adverse effects. This policy sets out initiation in the community so that the patient receives the same level of monitoring and assessment as they would if initiated as an inpatient.
Implementation Date:	February 2006
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Document Distribution	Intranet and Trustwide General Policy Folder
Document To Be Read In Conjunction With:	SPC for Clozapine Trustwide Clozapine Policy GP35
Training and resources:	Staff involved in caring for someone under going community initiation of clozapine must be familiar not just with this policy but with: <ul style="list-style-type: none"> • Trust Clozapine Policy – GP No. 35, • Handling and managing clozapine, • The summary of Product characteristics for clozapine. • The adverse effects of clozapine and their management. • The blood monitoring requirements for patient being treated with clozapine. • The working practices of the clozapine clinics and the pharmacy. • Good communication must be maintained with the clinic, care coordinator and pharmacy.
If new policy, reason for development:	License for Clozapine has changed to allow community initiation and not all patients want to be admitted to hospital for Clozapine to be initiated as is current practice

Document Change History:

Page	Changes made	Date

Background

Hospital admission for initiating Clozapine has been recommended in the past in view of some adverse reactions to Clozapine, e.g., hypotension, tachycardia, sedation, seizures, and hyperthermia. However, patients are often reluctant to be admitted to start a medication and furthermore, beds are often not available for initiating patients.

Following the European harmonisation of the Clozapine Summary of Product Characteristics (SmPC), there is no longer a mandatory regulatory requirement for inpatient initiation of Clozapine.

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 is also likely to result in decreased waiting times for other patients for psychiatric hospital beds.

Patients who are started on Clozapine in the community are subject to the same requirements and processes as in-patients. As would be expected for an in-patient, they should have a full medical history and clinical examination. Additionally they should be subject to the same amount of clinical monitoring as an in-patient. The protocol for the initiation of Clozapine must be followed.

Community initiation involves the patient attending a day care facility and being under the care of their healthcare staff or a healthcare professional visiting the patient at home. The number of hours the patient needs to be in contact with a healthcare professional is the same with both options (see care plan).

Day-care and home initiation should not be seen as separate entities. In some patients it may be most appropriate to use a combination of the two with patients attending day-care on some days and being visited by a healthcare professional in their homes on others.

N.B. Clozapine treatment can only be initiated by an appropriate specialist and all Clozapine-treated patients must remain under the supervision of such a specialist.

Essential Criteria

- Patients must be considered suitable for out-patient care in view of their current symptomatology and safety risk.
- Patients must consent to Clozapine treatment and blood tests and be aware of and agree to the necessity for daily attendance/home visits.
- Supportive family/carer network – ideally someone must be available to stay overnight and at weekends during the titration period.
- There must be access to an inpatient bed in the event that the patient's mental state deteriorates during the initiation.
- A carer or family member must be available to stay overnight and at weekends during the titration period.

Inclusion criteria

- The patient must be fairly mentally stable for community initiation.

- A maximum of one antipsychotic should be in use before switching to clozapine.
- The current drug regimen should not be complex.

Exclusion criteria

- Patients with diabetes mellitus or a history of cardiac disease, seizures, haematological disorders or NMS
- Patients over the age of 65 – as they are more susceptible to some side effects and require a slower dose titration.
- Patients under the age of 16 years – in accordance with the licensed age group for Clozapine treatment.
- Patients who are receiving potent sedatives or benzodiazepines.
- Patients whose drug regime will require complex cross-titration due to polypharmacy or interacting medicines. Examples of interacting medicines include those which can cause blood dyscrasia e.g. carbamazepine, carbimazole, antibiotics.
- Lives alone with no overnight family or carer support during the titration

Before starting

- Each case will be considered on an individual basis
- There are a maximum number of patients a team can initiate at any one time and still provide the required level of care. Suggest this would be 2 patients and there should be a treatment and waiting list. Pharmacy should be kept informed of patients on the list.
- There is a maximum of 2 patients under going community initiation that each dispensing pharmacy can provide clozapine tablets for during the titration period. The labelling and packaging of the Clozapine will be at the discretion of the locality pharmacy service providing it complies with good pharmacy dispensing practice.
- Patients, family members/carers will be provided with information about Clozapine and particularly:
 - realistic expectations for recovery including timeframe
 - recognition of adverse reactions to Clozapine and what to do if they occur.
- A full medical history – of particular interest are a history of cardiovascular problems, epilepsy, diabetes or haematological disorders (see inclusion/exclusion categories)
- Concomitant medications – looking for possible interactions, e.g. bone marrow suppressants, benzodiazepines, anticholinergics, antihypertensives, alcohol, MAOIs, CNS depressants, highly protein bound drugs, phenytoin, lithium (see inclusion/exclusion categories). If you are uncertain about the impact of the patient's drug regime on their suitability for home initiation please discuss with your local mental health pharmacist.
- Cross tapering or discontinuing the current antipsychotic, will be considered. Discuss this with the Mental Health Pharmacist if there is uncertainty about how to do this.

- A full physical examination – including weight, pulse, temperature, and blood pressure. An ECG should be done if not done in last 6 months. In addition to the initial full blood count patients will have an initial check of urea, electrolytes, liver function tests and random plasma glucose, plus other investigations if clinically indicated.
- Psychiatric baseline measurements wherever possible in order to act as a baseline against which to measure progress.
- Patient's GP must be informed of the initiation and provided with a copy of the initiation guidelines and supporting information on clozapine and an emergency contact number for the treating team.
- The patient must be provided with an emergency contact number for the treating team.
- There must be a contingency plan in case a patient defaults from visits or becomes non-compliant (NB. In patients in whom the interval since the last dose of Clozapine exceeds 48 hours, treatment should be re-initiated with 12.5 mg given once or twice on the first day and the dose re-titrated)
- Patient requires initial full blood count and registration with CPMS (No more than ten days prior to commencing on Clozapine). Suggest doing initial blood test the Wednesday prior to commencement.
- Prescriptions (signed copy of the administration chart) must reach the Pharmacy by the Thursday prior to starting treatment.
- It must be clear who is going to take the blood sample. (Member of the team, SHO, Phlebotomist, clozapine clinic).

Training needs

Staff involved in caring for someone under going community initiation of clozapine must be familiar not just with this policy but with:

- Trust Clozapine Policy – GP No. 35
- Handling and managing clozapine.
- The summary of Product characteristics for clozapine
- The adverse effects of clozapine and their management
- The blood monitoring requirements for patient being treated with clozapine
- The working practices of the clozapine clinics and the pharmacy.
- Good communication must be maintained with the clinic, care coordinator and pharmacy.

Procedure for community initiation

- Patient to attend day-care every weekday for the first 2 weeks or visited at home.
- This involves direct contact for 6 hours on the first two days and then twice a day during the weekdays for the duration of the titration.
- There should be somewhere for patient to sit or lie quietly should they need to.

- Pulse, temperature and standing and lying BP should be performed as per the care plan. If the results are of concern then patient should be reviewed. The monitoring frequency may need to be increased, dose titration slowed or initiation as an inpatient considered.
- The monitoring must be carried out by a trained nurse on the first day of treatment, on subsequent days a trained nurse should do it if possible. If the person carrying out these tests is not a trained nurse, the results must be discussed with one of the following:-
 - a) A trained nurse on the unit/community team.
 - b) Nurse in Charge or modern matron as agreed locally
 - c) Team S.H.O. if possible or S.H.O. on call.
- Clozapine should be prescribed using the approved prescription sheet (see appendix 1); if the dosage regime is not tolerated seek medical advice.
- Don't increase the dose of clozapine at the weekend or on bank holidays
- At each attendance the patient must be asked whether he/she has experienced any adverse reactions, using the Clozapine Side Effects Screening Checklist from CWPNT General Policy No. 35 (Clozapine Clinic Protocol). The Checklist must be completed and sent to the Patients Consultant in time for their next appointment.
- A doctor will see the patient regularly and at a minimum once every week. The doctor will assess the patient in a similar way to that which would be carried out if the patient was an inpatient, i.e. assessing the patient's progress, assessing any adverse reactions to Clozapine, adjusting the titration rate, managing antipsychotic medication cross-titration, reassuring the patient.
- Psychiatric observations, risk assessments and assessment of mental state and suicidality should be performed and progress monitored.
- Patient will have an emergency number to call in case of concern over treatment e.g. adverse effects or mental state. This contact must be available in the evening and at weekends.

CARE PLAN (Community Initiation of Clozapine)

Results of pulse, temperature and B.P. if not taken by a trained nurse, must always be checked by a trained nurse/doctor before the next dose is administered and 6 hours post dose.

All patients must be accompanied home either by a carer/relative or a healthcare worker every day if attending day care.

Clozapine tablets to be collected from Pharmacy on Day 1(Mon) and then on subsequent Thursdays (Day 4, Day 11 and Day 18). On these visits Pharmacy will provide Days 1-4 inclusive, Days 5-11inc., Days 12-18inc. and then a 7 day supply thereafter

DAY 1	Should be a Monday. Clozapine tablets collected from Pharmacy. Patient either attends day-care and remains there all day and receives Clozapine dose or a Qualified nurse remains with the patient in his/her own home for at least 6 hours after administering the dose. Pulse, BP and temperature are taken before giving the Clozapine, after fifteen minutes, and then at hourly intervals for 6 hours. Provide emergency helpline number to patient
DAY 2	(Tuesday) – patient attends day-care in the morning or is visited by a health care professional in his/her own home. Pulse, temperature and BP performed before receiving Clozapine dose. Pulse, temperature and BP should be recorded as for Day 1. Patient stays at day-care all day or health care professional remains with them for at least 6 hours.
DAY 3	(Wednesday) – patient attends day-care in the morning or is visited by a health care professional at home. Pulse, temperature and BP are taken on arrival before receiving Clozapine dose and then 2 hours and 6 hours post dose. Day care patients may be allowed to leave the unit during the day and patients at home may not need the company of a healthcare professional all day. FBC should be taken and sent to CPMS.
DAY 4	(Thursday) Patient attends day-care in the morning or is visited by a health care professional at home. Pulse, temperature and BP are taken on arrival before receiving Clozapine dose and then 2 hours and 6 hours post dose. Day care patients may be allowed to leave the unit during the day and patients at home may not need the company of a healthcare professional all day.
DAY 5	(Friday) –As per day 4 plus Clozapine tablets collected from Pharmacy. Patient is given weekend supply of medication (dose must not be increased over weekend). Patient’s information, as per General Policy No.35 (Clozapine Clinic Protocol) is sent to the Clozapine Clinic that the Patient will attend.
DAYS 6 & 7	(Saturday and Sunday) – patient should have an emergency number to call in case of adverse effects. Dose of clozapine to be taken same as Day 5.
DAY 8	(Monday) Patient attends day-care in the morning or is visited in own home by a healthcare professional. Day care patients may be allowed to leave the unit during the day and patients at home may not need the company of a health care professional all day. Pulse, temperature and BP are taken on arrival before receiving the Clozapine dose and then taken at 4 hours post dose (this also equates to the check done prior to the PM Clozapine dose). The PM Clozapine dose is given at 2pm and pulse, temperature and B.P. repeated 2 hours post this dose, before the patient leaves the unit or the healthcare professional leaves the patient’s home. FBC should be taken and sent to CPMS.
DAY 9	(Tuesday) – Patient attends day care in the morning or is visited in own home

	<p>by a healthcare professional. Day care patients may be allowed to leave the unit during the day and patients at home may not need the company of a health care professional all day. Pulse, temperature and BP are taken on arrival before receiving Clozapine dose and then at 4 hours post dose (this also equates to the check done prior to the PM Clozapine dose).</p> <p>The PM Clozapine dose is given at 2pm and pulse, temperature and B.P. repeated 2 hours post this dose, before the patient leaves the unit or the healthcare professional leaves the patient's home.</p>
DAY 10	(Wednesday) – As per Day 9
DAY 11	(Thursday) – As per Day 9 plus collect tablets from Pharmacy.
DAY 12	(Friday) – As per Day 9
DAYS 13 & 14	(Saturday and Sunday) - patient should have an emergency number to call in case of adverse effects. Dose of clozapine to be taken same as day 12.
Day 15	(Monday) – As per day 9 plus FBC should be taken and sent to CPMS.
Day 16	(Tuesday) – As per day 9
Day 17	(Wednesday) – As per day 9
Day 18	<p>(Thursday) – As per day 9 plus 7 days of tablets collected from Pharmacy for continuation treatment.</p> <p>As this is the end of the titration period ensure the patient knows when and where to attend for ongoing blood tests and tablet collection in future.</p> <p>Arrangements should be made for further follow-up of patient, by the patient's RMO's Community Team.</p>

N.B. Recommended that the AM dose of Clozapine is given between 9 – 10am
Recommended that the PM dose of Clozapine is given at 2pm to allow for monitoring.

Clozapine Prescription & Administration Card for Community Initiation. **Appendix 1.**

Patient Name..... Consultant..... Case Sheet No.....

If titrating another antipsychotic downwards please complete second column (usually discontinue the 2nd antipsychotic by the time clozapine dose reached 200mg/day)

Day	Date	Clozapine						
		Am		Pm		Am		Pm	
		Dose in Mg	Signature	Dose in Mg	Signature	Dose in Mg	Signature	Dose in Mg	Signature
1 (Collect tablets)		12.5		-					
2		25		-					
3 (Blood sample)		37.5		-					
4		50		-					
5 (Collect tablets)		75		-					
6		75		-					
7		75		-					
8 (Blood sample)		50		50					
9		50		75					
10		75		75					
11 (Collect tablets)		75		100					
12		100		100					
13		100		100					
14		100		100					
15 (Blood sample)		100		125					
16		100		150					
17		100		175					
18 (Collect tablets)		100		200					

Please review and continue on clozapine outpatient prescription and forward to the Pharmacy.
 Doctor signature..... Date.....

Clozapine Titration Chart for Community Initiation – Patient Copy.

Appendix 2

Patient Name.....

Day / Other notes	Date	Clozapine dose			
		Mornin g (Tick when dose taken)	Number of tablets	Evening (Tick when dose taken)	Number of tablets
1 (Monday) Collect tablets			Half a 25 mg tablet		None
2 (Tuesday)			1 x 25mg tablet		None
3 (Wednesday) Blood test			1 & a half x 25mg tablet		None
4 (Thursday)			2 x 25mg tablets		None
5 (Friday) Collect tablets			3 x 25mg tablets		None
6 (Saturday)			3 x 25mg tablets		None
7 (Sunday)			3 x 25mg tablets		None
8 (Monday) Blood test			2 x 25mg tablets		2 x 25mg tablets
9 (Tuesday)			2 x 25mg tablets		3 x 25mg tablets
10 (Wednesday)			3 x 25mg tablets		3 x 25mg tablets
11 (Thursday) Collect tablets			3 x 25mg tablets		1 x 100mg tablet
12 (Friday)			1 x 100mg tablet		1 x 100mg tablet
13 (Saturday)			1 x 100mg tablet		1 x 100mg tablet
14 (Sunday)			1 x 100mg tablet		1 x 100mg tablet
15 (Monday) Blood test			1 x 100mg tablet		1 x 100mg tablet and 1 x 25mg tablet
16 (Tuesday)			1 x 100mg tablet		1 x 100mg tablet and 2 x 25mg tablets
17 (Wednesday)			1 x 100mg tablet		1 x 100mg tablet and 3 x 25mg tablets
18 (Thursday) Collect tablets			1 x 100mg tablet		2 x 100mg tablets

Second Antipsychotic Titration Chart for Community Initiation – Patient Copy Appendix 3

Patient Name.....

This chart only needs completing if a second antipsychotic needs to be discontinued as Clozapine is started.

Day	Date	Antipsychotic dose (specify antipsychotic.....)			
		Mornin g (Tick when dose taken)	Number of tablets and dose	Evening (Tick when dose taken)	Number of tablets and dose
1 (Monday)					
2 (Tuesday)					
3 (Wednesday)					
4 (Thursday)					
5 (Friday)					
6 (Saturday)					
7 (Sunday)					
8 (Monday)					
9 (Tuesday)					
10 (Wednesday)					
11 (Thursday)					
12 (Friday)					
13 (Saturday)					
14 (Sunday)					
15 (Monday)					
16 (Tuesday)					
17 (Wednesday)					
18 (Thursday)					

Form Completed By..... Date.....

BP, Pulse and Temperature monitoring chart for Clozapine Titration

Appendix 4

Day 1	Before dose				15 minutes Post dose				1 hour Post dose				2 hours Post dose			
	BP lying	BP stand	Temp.	Pulse	BP lying	BP stand	Temp.	Pulse	BP lying	BP stand	Temp.	Pulse	BP lying	BP stand	Temp.	Pulse
	*				*				*				*			
	3 hours Post dose				4 hours Post dose				5 hours Post dose				6 hours Post dose			
	BP lying	BP stand	Temp.	Pulse	BP lying	BP stand	Temp.	Pulse	BP lying	BP stand	Temp.	Pulse	BP lying	BP stand	Temp.	Pulse
	*				*				*				*			
Day 2	Before dose				15 minutes Post dose				1 hour Post dose				2 hours Post dose			
	BP lying	BP stand	Temp.	Pulse	BP lying	BP stand	Temp.	Pulse	BP lying	BP stand	Temp.	Pulse	BP lying	BP stand	Temp.	Pulse
	*				*				*				*			
	3 hours Post dose				4 hours Post dose				5 hours Post dose				6 hours Post dose			
	BP lying	BP stand	Temp.	Pulse	BP lying	BP stand	Temp.	Pulse	BP lying	BP stand	Temp.	Pulse	BP lying	BP stand	Temp.	Pulse
	*				*				*				*			

IF TEMP/PULSE/BP NOT TAKEN BY A QUALIFIED NURSE FILL IN NEXT TO THE APPROPRIATE ‘*’ THE NAME OF THE NURSE/DOCTOR THE RESULT WAS DISCUSSED WITH, OTHERWISE SIGN THE ENTRY.

BLOOD PRESSURE MUST BE TAKEN LYING AND STANDING

BP, Pulse and Temperature monitoring chart for Clozapine Titration

Appendix 4

Day 3	Before dose				2 hours post dose				6 hours post dose			
	BP lying	BP standing	Temp	Pulse	BP lying	BP stand	Temp	Pulse	BP lying	BP stand	Temp	Pulse
	*				*				*			
Day 4	Before dose				2 hours post dose				6 hours post dose			
	BP lying	BP standing	Temp	Pulse	BP lying	BP stand	Temp	Pulse	BP lying	BP stand	Temp	Pulse
	*				*				*			
Day 5	Before dose				2 hours post dose				6 hours post dose			
	BP lying	BP standing	Temp	Pulse	BP lying	BP stand	Temp	Pulse	BP lying	BP stand	Temp	Pulse
	*				*				*			
Day 6 & 7 = Saturday & Sunday. Monitor only if concerned about previous results on these days												

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BLOOD PRESSURE MUST BE TAKEN LYING AND STANDING

BP, Pulse and Temperature monitoring chart for Clozapine Titration

Appendix 4

Day 8	Before morning dose				4 hours post AM dose & pre PM dose				2 hours post PM dose			
	BP lying	BP stand	Temp	Pulse	BP lying	BP stand	Temp	Pulse	BP lying	BP stand	Temp	Pulse
	*				*				*			
Day 9	Before morning dose				4 hours post AM dose & pre PM dose				2 hours post PM dose			
	BP lying	BP stand	Temp	Pulse	BP lying	BP stand	Temp	Pulse	BP lying	BP stand	Temp	Pulse
	*				*				*			
Day 10	Before morning dose				4 hours post AM dose & pre PM dose				2 hours post PM dose			
	BP lying	BP stand	Temp	Pulse	BP lying	BP stand	Temp	Pulse	BP lying	BP stand	Temp	Pulse
	*				*				*			
Day 11	Before morning dose				4 hours post AM dose & pre PM dose				2 hours post PM dose			
	BP lying	BP stand	Temp	Pulse	BP lying	BP stand	Temp	Pulse	BP lying	BP stand	Temp	Pulse
	*				*				*			

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BLOOD PRESSURE MUST BE TAKEN LYING AND STANDING

BP, Pulse and Temperature monitoring chart for Clozapine Titration

Appendix 4

Day 12	Before morning dose				4 hours post AM dose & pre PM dose				2 hours post PM dose			
	BP lying	BP stand	Temp	Pulse	BP lying	BP stand	Temp	Pulse	BP lying	BP stand	Temp	Pulse
	*				*				*			
Days 13 & 14 = Saturday & Sunday. Monitor only if concerned about previous results on these days												
Day 15	Before morning dose				4 hours post AM dose & pre PM dose				2 hours post PM dose			
	BP lying	BP stand	Temp	Pulse	BP lying	BP stand	Temp	Pulse	BP lying	BP stand	Temp	Pulse
	*				*				*			
Day 16	Before morning dose				4 hours post AM dose & pre PM dose				2 hours post PM dose			
	BP lying	BP stand	Temp	Pulse	BP lying	BP stand	Temp	Pulse	BP lying	BP stand	Temp	Pulse
	*				*				*			

IF TEMP/PULSE/BP NOT TAKEN BY A QUALIFIED NURSE FILL IN NEXT TO THE APPROPRIATE ‘*’ THE NAME OF THE NURSE/DOCTOR THE RESULT WAS DISCUSSED WITH, OTHERWISE SIGN THE ENTRY.

BLOOD PRESSURE MUST BE TAKEN LYING AND STANDING

BP, Pulse and Temperature monitoring chart for Clozapine Titration

Appendix 4

Day 17	Before morning dose				4 hours post AM dose & pre PM dose				2 hours post PM dose			
	BP lying	BP stand	Temp	Pulse	BP lying	BP stand	Temp	Pulse	BP lying	BP stand	Temp	Pulse
	*				*				*			
Day 18	Before morning dose				4 hours post AM dose & pre PM dose				2 hours post PM dose			
	BP lying	BP stand	Temp	Pulse	BP lying	BP stand	Temp	Pulse	BP lying	BP stand	Temp	Pulse
	*				*				*			

IF TEMP/PULSE/BP NOT TAKEN BY A QUALIFIED NURSE FILL IN NEXT TO THE APPROPRIATE ‘*’ THE NAME OF THE NURSE/DOCTOR THE RESULT WAS DISCUSSED WITH, OTHERWISE SIGN THE ENTRY.

BLOOD PRESSURE MUST BE TAKEN LYING AND STANDING