

## GUIDELINES FOR OUTPATIENT INITIATION OF CLOZAPINE TREATMENT

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**VALIDITY – Documents should be accessed via the Trust internet to ensure the current version is used.**

### CHANGE RECORD

Version	Date	Change details
1.0	28.11.13	<i>Change of previous version with major updates- incorporation of additional standalone documents into guideline, changes to sampling days and changes to physical monitoring of patients</i>
2.0	06.03.15	<i>Review with no changes. Title amended (was previously titled 'Outpatient Initiation of Clozapine Guideline')</i>
2.1	19.10.16	<i>Changes to prescriber details and name of team responsible</i>
2.2	28.05.20	<i>General Review with minor changes to provide scope for joint working between Mental Health Resonse Team and CHMT to facilitate initiation</i>
2.3	28.09.23	<i>General Review, formatting, no changes required to guideline as processes will remain the same. Approved at Drug and Therapeutics Group (28 September 2023).</i>

## Contents

1. INTRODUCTION .....	3
2. SCOPE .....	3
3. PROCEDURES.....	3
3.1. Patient Selection.....	3
3.2. Before Starting Treatment.....	4
3.3. During Home Initiation Treatment .....	5
3.3.1. Frequency of Visits .....	5
3.3.2. Recording Administration of Medication .....	5
3.3.3. Monitoring.....	5
4. REFERENCES .....	5
Appendix 1 – Example Dose Titration Schedule for Home Initiation .....	6
Appendix 2 – Schedule for Observational Visits .....	7
Appendix 3 – Home Initiation Process Chart .....	8

## 1. INTRODUCTION

Hospital admission for initiating clozapine has been recommended in the past in view of some of the potential adverse reactions e.g., hypotension, tachycardia, sedation, seizures, hyperthermia. However, patients may be reluctant to be admitted to start a medication and furthermore, utilising beds for patients who may not necessarily be acutely ill is inappropriate for the patient and ineffective use of resources.

Out-patient initiation of clozapine improves the access of patients to an effective treatment. It allows patients to be treated in the environment most appropriate for them and result in decreased waiting times.

Patients who are started on clozapine as out-patients are subject to the same requirements and processes as in-patients, including taking a full history and receiving a clinical examination. Additionally they should be subject to the same amount of clinical monitoring as an in-patient regardless of the environment in which clozapine is initiated.

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

## 2. SCOPE

This document applies to all staff employed by Humber Teaching NHS Foundation Trust (HTFT) including agency staff and any non-employees of the Trust acting on behalf of the Trust. It should be applied for all patients undergoing outpatient initiation of clozapine treatment

## 3. PROCEDURES

### 3.1. Patient Selection

Patients must fulfil all the essential criteria to be considered for outpatient initiation. Additional factors should be considered and used to risk assess the potential success and safety of outpatient initiation. Patient selection should be made on an individual basis.

- **Essential criteria**

- Suitable for outpatient initiation in view of current symptomology and safety risk
- Consenting to clozapine treatment and blood tests or have appropriate S58 approval and consenting to blood tests
- Agreeing to daily monitoring schedule

- **Additional factors**

- Having a supportive family/carer network
- Availability of overnight support during first week of initiation
- Assessment of cautions related to diabetes, history of cardiac disease, seizures or previous neuroleptic malignant syndrome
- Consideration of cautions related to age and those with Parkinson's Disease who may be more susceptible to side effects and require a slower or more flexible dose titration
- Concomitant medications, particularly sedatives, benzodiazepines and medications known to suppress bone marrow

### 3.2. Before Starting Treatment

- The care co-ordinator and community Psychiatrist should ensure that there are adequate arrangements for supporting community initiation using support from the Mental Health Response Service
- Patients and family members/carers if appropriate should be provided with
  - Information about clozapine, particularly the timeframe and degree of recovery expected and the management of the usual side effects of clozapine.
  - Written information about clozapine included the relevant Choice and Medication leaflet and CPMS handbook
  - An emergency contact number and advice on when to seek support, including out of hours
- A full medical history must be taken and in particular any history or current cardiovascular disease, epilepsy, diabetes and haematological disorders should be taken into consideration
- A full medication history should be taken and in particular any concomitant sedatives, benzodiazepines and medications known to suppress bone marrow should be taken into consideration
- A full physical examination must be undertaken including weight, pulse, temperature, and blood pressure
- Baseline psychiatric tests should be undertaken when possible
- The patient's GP must be
  - Informed about the decision to initiate clozapine and provided with a start date
  - Informed of any changes to concomitant medication during the initiation phase and advised on any expectation to prescribe or amend prescribed medication during the initiation phase. Complex cross titration schedules should be avoided if possible and consideration should be given to the psychiatric team assuming responsibility for prescribing all psychotropic medication during initiation when
  - Provided with a copy of HTFT Clozapine GP fact sheet
  - An emergency contact number and advice on when to seek support, including out of hours
- A contingency plan should be available in case a patient defaults from visits or becomes non-adherent to treatment which should include the need to re-titrate from 12.5mg daily or twice daily if the interval since the last dose of clozapine exceeds 48 hours
- An initial full blood count must be taken on a Wednesday of the week before initiation by the team supporting initiation, ensuring a GREEN result is available by Friday
- Clozapine home initiation should start on a Monday
- A member of the team supporting initiation should liaise with Pharmacy to dispense a supply of clozapine to cover from the morning dose of day one to the morning dose of day five
- The Community Psychiatrist must
  - Register the patient under their care with CPMS
  - Prescribe clozapine on o/p prescriptions after period of home initiation
- The Community Psychiatrist will be responsible for prescribing clozapine from day 1 to day 21 inclusive using a Trust approved Medicines Administration Record Card, using the example titration schedule in Appendix 1
- When appropriate the Community Psychiatrist should use an adapted titration schedule, depending on specific patient factors such as age of fragility or co-prescribing of other medications

### **3.3. During Home Initiation Treatment**

#### **3.3.1. Frequency of Visits**

- The patient must be visited by a member of the team supporting initiation in accordance with the schedule outlined in Appendix 2
- The member of the team supporting initiation must remain with the patient for 6 hours on day one, consideration may be given to utilising day attendance on an inpatient unit

#### **3.3.2. Recording Administration of Medication**

- All doses administered must be signed for on a Trust approved Medicines Administration Record Card
- The team supporting initiation may continue to administer clozapine for up to 28 days
- Prescribing clozapine for initiation is the responsibility of the Community Psychiatrist

#### **3.3.3. Monitoring**

- The Community Psychiatrist must undertake an appropriate review of the patient's treatment regularly at a minimum of once every week. Only where necessary this may necessitate face to face assessment.
- The Community Psychiatrist will review the patient in a similar way to that which would occur if the patient were an inpatient
- A member of the team supporting initiation will monitor pulse, temperature and standing and lying BP in accordance with the schedule outlined in Appendix 2 and record this on the HTFT National Early Warning Score record sheet
- Enquiry should be made daily into the occurrence of the following adverse drug reactions (ADRs) with particular focus on hypersalivation, nausea, vomiting, drowsiness, dizziness, sore throat and infections. Additional symptoms suggestive of clozapine ADRs should be considered using the current BNF

## **4. REFERENCES**

CPMS guidance.  
Safe and secure handling of medicines procedures HTFT

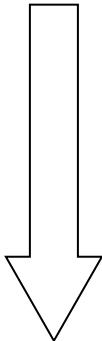
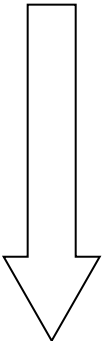
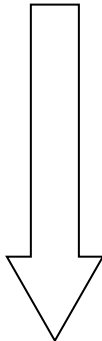
## Appendix 1 – Example Dose Titration Schedule for Home Initiation

DAY	MORNING DOSE 9.00 AM	AFTERNOON DOSE 15:30
1	12.5 mg	nil
2	12.5 mg	12.5 mg
3	12.5 mg	25 mg
4	25 mg	25 mg
5	25 mg	50 mg
6	25 mg	75 mg
7	25 mg	75 mg
8	50 mg	75 mg
9	50 mg	100 mg
10	50 mg	100 mg
11	50 mg	125 mg
12	100 mg	100 mg
13	100 mg	125 mg
14	100 mg	150 mg
DAY	MORNING DOSE 9.00 AM	EVENING DOSE 22:00
15	100 mg	175mg
16	100 mg	200mg
17	100 mg	200mg
18	100 mg	200mg
19	100 mg	200mg
20	100 mg	200mg
21	100 mg	200mg

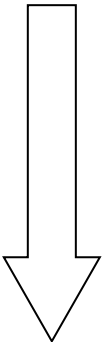
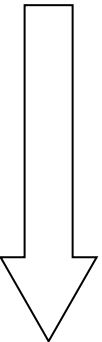
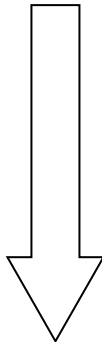
## Appendix 2 – Schedule for Observational Visits

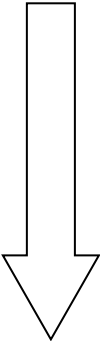
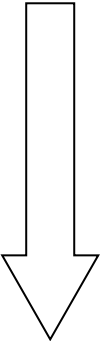
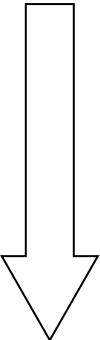
Administration of Clozapine by HTFT Staff						
Day	Clozapine Due	Physical monitoring of pulse, temp and standing/sitting BP		Clozapine Due	Physical monitoring of pulse, temp and standing/sitting BP	
		Morning	Record time		Afternoon-6hrs post morning dose	Record time
1	09:00			None		
2	09:00			15:30		
3	09:00			15:30		
4	09:00			15:30		
5	09:00			15:30		
6	09:00			15:30		
7	09:00			15:30		
8	09:00			15:30		
9	09:00			15:30		
10	09:00			15:30		
11	09:00			15:30		
12	09:00			15:30		
13	09:00			15:30		
14	09:00			15:30		
Self- Administration of Clozapine by Patient						
Day	Clozapine Due	Physical monitoring of pulse, temp and standing/sitting BP		Clozapine Due	Physical monitoring of pulse, temp and standing/sitting BP	
		Morning	Record Time		Afternoon-6hrs post morning dose	Record Time
15	09:00			22:00		
16	09:00			22:00		
17	09:00			22:00		
18	09:00			22:00		
19	09:00			22:00		
20	09:00			22:00		
21	09:00			22:00		

### Appendix 3 – Home Initiation Process Chart

WEEK ONE						
Day		Blood Sample/ Supplies	Medication	Monitoring	Frequency	Notes
1	Mon	<ul style="list-style-type: none"> <li>Obtain five days' supply from Pharmacy</li> </ul>	<ul style="list-style-type: none"> <li>Administer morning dose at 9:00am</li> </ul>	<ul style="list-style-type: none"> <li>Pulse, temperature and standing and sitting BP</li> </ul>	<ul style="list-style-type: none"> <li>Before giving morning Clozapine</li> <li>At six hours post morning dose</li> <li>Nurse must be available to patient for 6 hours post dose</li> <li>Nurse can be provided on a rota basis</li> </ul>	<p><b>REPORT ANY OF THE FOLLOWING TO THE COMMUNITY PSYCHIATRIST</b></p> <ul style="list-style-type: none"> <li>Abnormal pulse, temperature or BP</li> <li>Any adverse changes in mental state- monitor daily</li> <li>Occurrence of adverse drug reactions- monitor daily</li> </ul>
2	Tue		<ul style="list-style-type: none"> <li>Administer twice daily at 09:00 and 15:30</li> </ul> 	<ul style="list-style-type: none"> <li>Pulse, temperature and BP</li> </ul> 	<ul style="list-style-type: none"> <li>Before giving morning Clozapine</li> <li>At six hours post morning dose</li> </ul> 	
3	Wed	<ul style="list-style-type: none"> <li>Second blood sample</li> <li>Ensure seven days' supply of Clozapine has been ordered</li> </ul>				
4	Thur					
5	Fri	<ul style="list-style-type: none"> <li>Obtain seven days' supply of Clozapine from Pharmacy</li> </ul>				
6	Sat					
7	Sun					



WEEK TWO						
DAY		Blood Sample/ Supplies	Medication	Monitoring	Frequency	Notes
8	Mon	<ul style="list-style-type: none"> <li>• Third blood sample</li> <li>• Ensure seven days' supply of clozapine has been ordered</li> </ul>	<ul style="list-style-type: none"> <li>• Administer twice daily at 09:00 and 15:30</li> </ul>	<ul style="list-style-type: none"> <li>• Pulse, temperature and BP</li> </ul>	<ul style="list-style-type: none"> <li>• Before giving morning Clozapine</li> <li>• At six hours post morning dose</li> </ul>	<p><b>REPORT ANY OF THE FOLLOWING TO THE COMMUNITY PSYCHIATRIST</b></p> <ul style="list-style-type: none"> <li>• Abnormal pulse, temperature or BP</li> <li>• Any adverse changes in mental state- monitor daily</li> <li>• Occurrence of adverse drug reactions- monitor daily</li> </ul>
9	Tue					
10	Wed					
11	Thur	<ul style="list-style-type: none"> <li>• Obtain seven days' supply of Clozapine from Pharmacy</li> </ul>				
12	Fri					
13	Sat					
14	Sun					

<b>WEEK THREE</b>						
<b>DAY</b>		<b>Blood Sample/ Supplies</b>	<b>Medication</b>	<b>Monitoring</b>	<b>Frequency</b>	<b>Notes</b>
15	Mon	<ul style="list-style-type: none"> <li>• Fourth blood sample</li> </ul> Ensure seven days' supply of Clozapine has been ordered	<ul style="list-style-type: none"> <li>• Self-administration by patient at 09:00 and 22:00</li> </ul>	<ul style="list-style-type: none"> <li>• Pulse, temperature and BP</li> </ul>	<ul style="list-style-type: none"> <li>• In the morning</li> <li>• In the afternoon</li> </ul>	<ul style="list-style-type: none"> <li>• Psychiatrist to review pulse, temperature and BP charts</li> </ul>
16	Tue					<p><b>REPORT ANY OF THE FOLLOWING TO THE COMMUNITY PSYCHIATRIST</b></p> <ul style="list-style-type: none"> <li>• Abnormal pulse, temperature or BP</li> <li>• Any adverse changes in mental state- monitor daily</li> <li>• Occurrence of adverse drug reactions- monitor daily</li> </ul>
17	Wed					
18	Thur	Obtain seven days' supply of Clozapine from Pharmacy				
19	Fri					
20	Sat					
21	Sun					