

Options for the Initiation of Clozapine

Background

A review of clozapine services in NHS Greater Glasgow & Clyde undertaken in 2011 recommended that out patient clozapine initiation be adopted as standard. However whilst seeing this as potentially desirable the Mental Health Services Governance group requested that an options paper be prepared describing a range of solutions for the initiation of clozapine treatment. This paper has been prepared by a subgroup of the MHS Clozapine Review Group and is endorsed by the overall group. The options described are those that services with appropriate resources, planning and co-ordination can implement.

It should be noted these options relate to new patients starting clozapine not re-titration of existing patients after a treatment break.

Standards

The group believes that it is a fundamental standard that the minimum monitoring parameters must apply to all patients starting clozapine regardless of where that might be. The monitoring will be mandatory and that requirement has influenced the options described in this document. The monitoring standards are as follows

1. Mandatory full blood count monitoring as required by the clozapine marketing authorisation.
2. Cardiac parameters as describe in the following table

Day	Parameters	Frequency
1	Temperature, pulse, blood pressure (standing & lying)	Immediately before dose then hourly for 6 hours
2	Temperature, pulse, blood pressure (standing & lying)	Immediately before dose then after 2 and 6 hours
3 - 15	Temperature, pulse, blood pressure (standing & lying)	Immediately before dose then after 6 hours

It is also recommended that patients be assessed daily for evidence of dizziness, drowsiness, hypersalivation, constipation and urinary problems. Any abnormal parameters or emerging side effects must be reported to medical staff immediately.

For community based initiation, during days 1 & 2, it is advisable that the patient remain in the monitoring area, for the remainder of the titration they may leave and return after 6 hours for monitoring. If they leave they should be advised to contact the service immediately if they experience any unusual symptoms.

Options

The group believes there are three feasible options for the initiation of clozapine

1. Hospital admission.

This is standard practice at present and will remain necessary for many patients. With the exception of ensuring in patient services observe the monitoring standards the group will not comment further on this option.

2. Shared Care

This option represents a flexible solution that incorporates brief admission (of varying duration) and early transfer to a community based approach. Patient assessment, planning and properly resourced community services will be essential to the success of this option. The elements of this option are

- Pre-assessment, patient selection and registration within Community Mental Health Teams
- Short term admission to hospital.
- Discharge to community support when clinically appropriate (minimum of three days after commencing clozapine).

3. Community initiation

Where patient assessment deems it appropriate clozapine treatment may be commenced in a community setting, this may be achieved either by attending a resource centre on a daily basis or in the patient's home. It is the responsibility of the community mental health team to ensure they can safely deliver this option within the resources that they have available. With this option treatment must always commence on a Monday.

The following issues are associated with this option

- Patient assessment
- Resources – staffing and infrastructure

For options 2 & 3 where there is a community component to the titration there must be a named individual who is responsible for co-ordinating the process. Their role will include

- Communication with RMO, Pharmacy, the ward as appropriate
- Identifying who is seeing patient where and when
- Ensuring the patient and their carers/relatives have all the relevant information including information about the drug, services and how to get support routinely and in an emergency etc

There is an expectation that community services within the CHP including Crisis or similar services will provide support to deliver community based clozapine initiation.

Patient assessment/selection

To be eligible for option 2 or 3 patients must be assessed against the following criteria

- Patients must meet the licensed indications for community clozapine initiation (see the Summary of Product Characteristics)
- Patients should be considered suitable for out patient care in view of their current symptoms and safety risk. A thorough clinical assessment will be undertaken to determine suitability.
- Prior to treatment patients should be counselled and given standard information on clozapine treatment (ZTAS patient booklet & Choice and Medication literature) and then give consent (documented in care notes) to clozapine treatment and blood testing. Details of information provided should be recorded in the care notes. Patients must be aware of and agree to the requirement for attendance at a local mental health base in some circumstances, for daily home visits or that admission to local mental health hospital may be required. It is the responsibility of the multi-disciplinary team to ensure that patients are appropriately informed of the relevant aspects of Clozapine treatment.

- An adequately resourced healthcare team must be in place.
- Sites should consider their capacity to support community initiation.
- It is advised that the patient is not left alone during the first week of treatment. Ideally someone (family/social carer) should stay overnight with the patient during that period.
- Patients must be able to contact the clinical team and out of hours support at all times (for option 2 from discharge onwards). If they can't then admission is the only option.
- Community initiation will not be appropriate for patients with a history of diabetes, cardiac disease, seizures or neuroleptic malignant syndrome or where they continue to misuse alcohol or drugs.
- Mandatory pre-treatment screening will be undertaken by the community mental health team and is primarily a medical responsibility and will include

Full medical history particularly: diabetes, cardiovascular, seizure, or haematological disorders, smoking status, use of caffeine.

Baseline measurement of mental state using a standardised tool e.g. CGI

Full physical examination including: weight, pulse, temperature, and blood pressure (standing and lying), and recent electrocardiogram (ECG). Recent is defined as within the last 6 months assuming no change in cardiac status or risk factors. If anything has changed an ECG should be performed as part of the pre-assessment process.

Baseline blood screening: full blood count including differential white cell count, liver function tests, random plasma glucose, HBA1c, lipids, blood pressure, C-Reactive protein (CRP), troponin 1, pulse, weight, urea and electrolytes.

Registration with the clozapine monitoring service currently ZTAS.

Where any of the following circumstances apply titration in hospital is recommended

- Patient has significant difficulties in tolerating regime
- Patient continues to misuse alcohol/substances
- Patient or carer requests Hospital admission due to deterioration in mental state
- Titration cannot be fully undertaken due to service demands

Prescribing

Standard clozapine titration regimes are used for in patient services. The group recommends that a standard prescription be adopted for options 2 & 3. Due to the constraints of community initiation that regime will differ from the in patient regime and will be as follows

	Day	Dose
1	Monday	12.5mg in the morning
2	Tuesday	25mg in the morning
3	Wednesday	37.5mg in the morning
4	Thursday	50mg in the morning
5	Friday	75mg in the morning
6	Saturday	75mg in the morning
7	Sunday	75mg in the morning
8	Monday	100mg in the morning
9	Tuesday	100mg in the morning & 25mg in the evening
10	Wednesday	100mg in the morning & 50mg in the evening

	Day	Dose
11	Thursday	100mg in the morning & 50mg in the evening
12	Friday	100mg in the morning & 75mg in the evening
13	Saturday	100mg in the morning & 75mg in the evening
14	Sunday	100mg in the morning & 75mg in the evening
15	Monday	100mg in the morning & 100mg in the evening

Please note that for option 3 treatment must commence on a Monday.

Implications & issue for each option

Option	Implications & issues	Comments
Hospital Admission	Only issue is in delayed access to a bed for a planned admission to initiate clozapine.	Status quo option. Excessive delays could raise issues with meeting waiting times for treatment.
Community	Team resources Environment Monitoring at weekends Systems development Support networks	Patient preference
Shared care	As for community option plus Planning & co-ordination Communication Delayed access to a bed	

Appendix 1

Pre clozapine physical and baseline blood screening

	Date/sign	Results
Blood test;		
FBC		
U&E's		
LFT		
Random Glucose		
HBA1c		
Lipids		
C-reactive protein (CRP)		
Troponin 1		
ECG		
History of		
?Renal disease		
?liver disease		
?Cardiac disease		
?Neutropenia		
?Agranulocytosis		
?Bone marrow disorder		
?GI disease		
? PTE or DVT		
Epilepsy		
Active alcoholism		
Glaucoma		
BP		
Pulse		
Temperature		
Baseline weight & measured height		
Smoking status		
Pregnancy status		
List of medication/history of compliance		
Sort paperwork and complete ZTAS registration		
Diagnosis appropriate		
Confirm patients understanding , consent and commitment		
Complete clozapine titration prescription		
Fax first week's prescription to Leverndale pharmacy		

Suitable for community clozapine initiation; YES/NO
Planned start date;
Keyworker informed;
Crisis team informed;

Appendix 2

Patient Label with chi

CLOZAPINE CLINIC CONTACT INFORMATION

Treatment centre-

Telephone- Monday to Friday – 9am to 5pm

Out with these hours, in case of Emergency,

Crisis Team-

Out of Hours Service-

Very common side effects are :

- Drowsiness
- Dizziness
- Fast heartbeat
- Constipation
- Increased production of saliva.

You Must :

Tell doctor/nurse immediately before taking the next clozapine tablet:

- if you get signs of a cold, fever, flu-like symptoms, sore throat or any other infection.
- if you feel unwell in any way
- if you have constipation.