Clozapine Policy

Guidance and Procedure for the use of Denzapine (clozapine) in Hertfordshire Partnership University NHS Foundation Trust

Version: 4.1

Executive Lead: Executive Director - Quality & Medical Leadership
Lead Author: Head of Medicines Management
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Target Audience:
This Policy must be understood by staff working in:
- Teams/units/wards in HPFT where healthcare professionals are involved in the prescribing, dispensing, administration and monitoring of clozapine.
Preface

P1 - Version Control History:
Below notes the current and previous Version details - full history is in Part 3.

<table>
<thead>
<tr>
<th>Version</th>
<th>Date of Issue</th>
<th>Author</th>
<th>Status</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>V4</td>
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<td>V4.1</td>
<td>July 2014</td>
<td>Head of Medicines Management</td>
<td>Current</td>
<td></td>
</tr>
</tbody>
</table>

P2 - Relevant Standards:

a) NHSLA Risk Management Standards - Mental Health & Learning Disability 2012-2013
   6.9 Medicines Management Training. See Appendix 1 for full details.
   6.10 Medicines Management. See Appendix 1 for full details.

b) Care Quality Commission Outcomes:
   Outcome 1: Respecting and involving People who use services,
   Outcome 2: Consent to care and treatment, Outcome 4: Care and Welfare of People who use the Services,
   Outcome 6: Cooperating with other Providers and Outcome 9: Management of Medicines
   See Appendix 8

a) Equality and RESPECT: The Trust operates a policy of fairness and RESPECT in relation to the treatment and care of service users and carers; and support for staff.

P3 - The 2012 Policy Management System and the Policy Format:

- **Policy Template** is the essential format for most Policies. It contains all that staff need to know to carry out their duties in the area covered by the Policy.
- **Operational Policies Template** provides the format to describe our services, how they work and who can access them
- **Care Pathways Template** is at the moment in draft and only for the use of the Pathways Team as they are adapting the design on a working basis.

Symbols used in Full Policies:

**RULE** = internally agreed, that this is a rule & must be done the way described

**STANDARD** = a national standard which we must comply with, so must be followed

Managers must bring all relevant policies to the attention of their staff, where possible, viewing and discussing the contents so that the team is aware of what they need to do.

Individual staff/students/learners are responsible for implementing the requirements appropriate to their role, through reading the Policy and demonstrating to their manager that they understand the key points.

All Trust Policies will change to these formats as Policies are reviewed every 3 years, or when national Policy or legislation or other change prompts a review. All expired & superseded documents are retained & archived and are accessible through the Compliance and Risk Facilitator Policies@hertspartsft.nhs.uk

All current Policies can be found on the Trust Policy Website via the Green Button or http://trustspace/InformationCentre/TrustPolicies/default.aspx
## Contents Page

<table>
<thead>
<tr>
<th>PART:</th>
<th>Page:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preface:</td>
<td></td>
</tr>
<tr>
<td>P1 - Version Control History</td>
<td>2</td>
</tr>
<tr>
<td>P2 - Relevant Standards</td>
<td>2</td>
</tr>
<tr>
<td>P3 – The 2012 Policy Management System &amp; Document Formats</td>
<td>2</td>
</tr>
<tr>
<td>PART 1 Preliminary Issues:</td>
<td></td>
</tr>
<tr>
<td>1. Summary</td>
<td>4</td>
</tr>
<tr>
<td>2. Purpose</td>
<td>4</td>
</tr>
<tr>
<td>3. Definitions</td>
<td>4</td>
</tr>
<tr>
<td>4. Duties and Responsibilities</td>
<td>4</td>
</tr>
<tr>
<td>PART 2 What needs to be done and who by:</td>
<td></td>
</tr>
<tr>
<td>5. Introduction</td>
<td>5</td>
</tr>
<tr>
<td>6. Standards for prescribing</td>
<td>5</td>
</tr>
<tr>
<td>6.1 Indications</td>
<td>5</td>
</tr>
<tr>
<td>6.2 Prescribing</td>
<td>5</td>
</tr>
<tr>
<td>6.3 Unlicensed/Off-label use</td>
<td>6</td>
</tr>
<tr>
<td>6.4 Consent</td>
<td>6</td>
</tr>
<tr>
<td>7. Service user information</td>
<td>7</td>
</tr>
<tr>
<td>8. Initiation and monitoring of clozapine</td>
<td>8</td>
</tr>
<tr>
<td>8.1 Routine baseline assessment for initiation</td>
<td>9</td>
</tr>
<tr>
<td>8.2 Maintenance monitoring for follow-up</td>
<td>9</td>
</tr>
<tr>
<td>8.3 Use of clozapine in residential care placements</td>
<td>10</td>
</tr>
<tr>
<td>8.4 Discontinuing therapy</td>
<td>10</td>
</tr>
<tr>
<td>8.5 Restarting therapy</td>
<td>11</td>
</tr>
<tr>
<td>8.6 Blood Monitoring</td>
<td>11</td>
</tr>
<tr>
<td>8.7 Clozapine Plasma Levels</td>
<td>12</td>
</tr>
<tr>
<td>9. Risk Management</td>
<td>12</td>
</tr>
<tr>
<td>9.1 Contraindications to the use of clozapine</td>
<td>12</td>
</tr>
<tr>
<td>9.2 Special precautions for the use of clozapine</td>
<td>13</td>
</tr>
<tr>
<td>9.3 Interactions with clozapine</td>
<td>14</td>
</tr>
<tr>
<td>9.4 Serious adverse events</td>
<td>15</td>
</tr>
<tr>
<td>9.5 Common side-effects</td>
<td>17</td>
</tr>
<tr>
<td>9.6 Communication</td>
<td>17</td>
</tr>
<tr>
<td>10. Training</td>
<td>18</td>
</tr>
<tr>
<td>11. Embedding a culture of Equality and RESPECT</td>
<td>19</td>
</tr>
<tr>
<td>12. Process for Monitoring compliance with this document</td>
<td>19</td>
</tr>
<tr>
<td>PART 3 Associated Issues</td>
<td></td>
</tr>
<tr>
<td>13. Version Control</td>
<td>21</td>
</tr>
<tr>
<td>14. Archiving Arrangements</td>
<td>21</td>
</tr>
<tr>
<td>15. Associated Documents</td>
<td>21</td>
</tr>
<tr>
<td>16. Supporting References</td>
<td>21</td>
</tr>
<tr>
<td>17. Comments and Feedback</td>
<td>21</td>
</tr>
<tr>
<td>Appendices</td>
<td>22</td>
</tr>
</tbody>
</table>
1. Summary

This document includes the standards to be followed for the prescribing, dispensing, administration and monitoring of clozapine.

2. Purpose

This document sets out the practice criteria to be followed by HPFT healthcare professionals for the prescribing, dispensing, administration and monitoring of clozapine.

3. Definitions

- **STANDARD**
  - Denzapine – This is an antipsychotic and is the clozapine brand used in HPFT.
  - DMS – Denzapine Monitoring Service. This is a comprehensive web-accessed database of service user profiles – it includes a full blood monitoring and dispensing history for each service user prescribed Denzapine.
  - Britannia Pharmaceuticals Ltd – the pharmaceutical company that produces Denzapine.
  - Summary of Product Characteristics (SPC) - the SPC is the basis of information for healthcare professionals on how to use the medicinal product safely and effectively. The SPC forms an intrinsic and integral part of the marketing authorisation.

4. Duties and Responsibilities

The Trust has an obligation to provide an effective medicines management service to service users, appropriate training to staff and provide a suitable infrastructure to establish and continue support for these activities.

It is the responsibility of the Executive Director, Quality and Medical Leadership, to ensure compliance with this document throughout the organisation.

Healthcare professionals involved with service users taking clozapine are required to read this document on joining the Trust and following updates.

*PLEASE NOTE: The technical information contained within this policy is the most up-to-date information available at the time of publication.*
5. Introduction

Hertfordshire Partnership University NHS Foundation Trust (HPFT) will support the use of the antipsychotic clozapine in all appropriate cases. The brand currently approved for use in the Trust is Denzapine, produced by Britannia Pharmaceuticals Ltd, who is also responsible for providing the patient monitoring service.

RULE

6. Standards for prescribing

Guidance and Procedure for the use of Denzapine (clozapine) represents the view of the HPFT Drugs and Therapeutics Committee, following careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual service user, in consultation with the service user and/or relative or carer.

6.1 Indications

The licensed indications for clozapine are:

- treatment resistant schizophrenia i.e. failed trials of a minimum of two antipsychotics in adequate dosage, one of which should be an atypical, prescribed for an adequate duration (each for a minimum of 6 weeks)

- service users who have severe, untreatable neurological adverse reactions to other antipsychotics including an atypical

- psychotic disorders occurring during the course of Parkinson’s disease when standard treatment has failed

- when other antipsychotic drugs have proved ineffective or intolerable

6.2 Prescribing

- The initiation of clozapine in HPFT is restricted to Consultant Psychiatrists registered with the Denzapine Monitoring Service (DMS). Nominated pharmacists and service users must also be registered. DMS can be accessed via www.denzapine.co.uk or www.denzapinesupport.co.uk. These are secure websites which require a user name and a password. Alternatively, telephone the DMS on 0333 200 4141. The health care professional registered with the DMS is referred to as the ‘registered contact’. DMS staff can be contacted via the following e-mail: denzapine@britannia-pharm.com

- The relevant pharmacy department must be notified when the decision is made to initiate treatment with clozapine.

- For ongoing prescribing, clozapine is normally prescribed by the service user’s Consultant Psychiatrist, but may be prescribed by another registered medical
practitioner involved in the care of the service user.

- The Summary of Product Characteristics for Denzapine (SPC) is available from www.medicines.org.uk or may be obtained directly from the DMS (0333 200 4141).

- The registered contact should notify the DMS of any change, e.g. change of consultant name for an individual service user. This is important in case of a red alert.

- The Consultant Psychiatrist initiating clozapine must document in the electronic patient record (EPR) the service user’s DMS number and details of the individual(s) to be contacted should a query/problem arise. An alert informing other healthcare professionals that clozapine is prescribed, must also be placed on the record.

6.3 Unlicensed/Off-label use

- For unlicensed use refer to the HPFT Medicines Policy (Including Unlicensed /Off-label Medicines).

- The Consultant Psychiatrist for an individual service user must accept clinical responsibility for any unlicensed/off-label use of clozapine.

- The DMS must be contacted prior to unlicensed/off label prescribing by the consultant, regarding the correct procedure to be followed. An off-label treatment agreement form, available from the DMS website, should be completed

- Clozapine is unlicensed for use in children under the age of 16 years. The Trust will support the appropriate use of clozapine in children under the age of 16 years and adolescents, if they fulfil the indications.

6.4 Consent

- In the case of adult service users, clozapine is usually given after informed consent has been obtained. Prior to the commencement of therapy, agreement must be reached with the service user to comply with the treatment/ blood monitoring regime as clinically indicated. This also applies to those detained under the Mental Health Act. Detained service users who have given informed consent to clozapine treatment must then have a form T2 completed, under s58 of the Act. This must be completed just before the end of 3 months of detention.

- The Mental Capacity Act (MCA) 2005 Code of Practice provides the legal framework for acting and making decisions on behalf of individuals who lack the mental capacity to make particular decisions for themselves.\(^2\) Everyone working with and/or caring for an adult who may lack capacity to make specific decisions must comply with this Act when making decisions or acting for that person. (Please refer to the MCA Code of Practice and the Hertfordshire Policy on Mental Capacity\(^3\) for further information and assessment of capacity and best interest documentation).
• A valid, applicable advance decision to refuse treatment by an individual who currently lacks capacity, has the same effect as a decision that is made by an individual with capacity.

• Consideration must be given to whether a service user without capacity to consent to the procedure will comply with the blood testing regime. Blood tests are part of the treatment and can be taken from service users without capacity, who do not object to the procedure, if it is in their best interests and has been agreed within the requirements of the Mental Capacity Act.

• When a service user is detained for treatment under the Mental Health Act and withholds consent, blood testing is legal under s63 (i.e. during the first 3 months of treatment for mental disorder) and then if necessary a Second Opinion Approved Doctor may be called and a Form T3 completed under s58 certificate. It must be deemed necessary at that particular time having considered the benefits to outweigh the adverse effects to the service user and minimal force must be used.

• Consent may be given by adolescents if they are considered by the treating Consultant Psychiatrist to have the capacity to consent to clozapine treatment i.e. are aged 16 or 17 years old and have sufficient understanding to give consent to that treatment (Family Law Reform Act 1969, s8(1)). If the individual does not have the capacity to consent to treatment with clozapine, the requirements of the Mental Capacity Act 2005 should be followed.

• A child under the age of 16 years can give valid consent if they have “sufficient understanding and intelligence to enable him or her to understand fully what is proposed”. If the child is considered not to have this understanding, a person with parental responsibility will normally give consent except where the interests of that person and the young person are not compatible.

• It is good practice to involve the family/carers in the decision to initiate treatment with clozapine.

RULE
7. Service user information

Prior to initiation, service users and where appropriate their family/carers, must have a full discussion with their clinicians regarding the risks and benefits of treatment with clozapine and the need for lifestyle changes, e.g. avoidance of alcohol and activities such as driving or operating machinery, especially during the initial weeks of treatment. The range of common side-effects and potential medical complications should be discussed, including the need for regular contact with their clinicians.

Clinicians must ensure that service users and their family/carers are familiar with the local “out-of-hours” arrangements.

All service users should be provided with information about Denzapine, for example the reason for regular blood tests and possible side effects. Each service user commenced on Denzapine should be given the booklet titled “Your journey with Denzapine”. These booklets are available from Britannia Customer Services on 01635 568500. Britannia Customer Services may also be contacted via the following e-mail: customerservices@britannia-pharm.com
Patient Information Leaflets (PIL) for Denzapine is available from www.medicines.org.uk. A PIL for clozapine can also be accessed via the Choice and Medication website at www.choiceandmedication.co.uk. Staff can access this PIL via TrustSpace. To get the leaflet in large print contact Britannia Customer Services on 01635 568500. For each service user there should be an entry made in the relevant EPR about the form (written and/or verbal) in which this information was shared.

The SPC for Denzapine contains a comprehensive list of cautions and contraindications. This should be available in all relevant units and to prescribing doctors involved in the care of service users on clozapine. The SPC for Denzapine is available from www.medicines.org.uk.

Leaflets and other educational material about mental illness and its treatment should be available in all relevant units. One source of information is the Choice and Medication website which can be accessed via Trust Space.

The treatment, care, and information service users are given should meet the individual’s communication needs and take into consideration the individual’s cultural needs. For example, people with additional needs such as physical, sensory or learning disabilities and people who do not speak or read English. The HPFT Policy on Communicating with Service Users from Diverse Communities provides guidance on communication needs and the procedure on the interpreting service.

Clinicians must discuss with service users any cultural constraints that might affect their treatment with clozapine.

8. Initiation and monitoring of clozapine

The SPC for Denzapine includes the recommended regime for dosage titration in adults. Clinicians may decide to titrate doses more slowly depending on the service user’s needs and presentation. Staff should familiarise themselves fully with these guidelines which are available from www.medicines.org.uk. A procedure for initiation in adults in day care and outpatients is available as Appendix 5.

The Britannia publication "The Pocket Guide to Denzapine Treatment" is available to healthcare professionals and can be ordered through Britannia Customer Services on 01635 568500.

Relevant medical conditions and special precautions should be considered prior to initiation of clozapine. Any contraindicated medicines should be discontinued before initiation and other antipsychotics cross-tapered with caution. Refer to the SPC for Denzapine.

The relevant GP must be notified when a service user commences treatment with clozapine, to enable an alert to be placed on his/her record. Also, on initiation, a copy of the Clozapine Policy - Guidance and Procedure for the use of Denzapine (clozapine) in HPFT must be sent to the GP, together with the GP summary document.

Inpatient units are obliged to keep a running stock balance for clozapine if requested to do so by the supplying pharmacy.
RULE

8.1 Routine baseline assessment for initiation

Full medical and psychiatric history

The appropriate risk assessment

Blood tests - Full blood count
Fasting blood glucose / random if fasting not possible and HbA1c
Urea and Electrolytes
Liver Function Tests
Fasting lipids

Blood Pressure and pulse – frequently during titration, then repeated at intervals during the first six months of treatment

Weight baseline, weekly for 6 weeks, at 12 weeks and at 6 months (plotted on a chart)
Waist circumference baseline (plotted on a chart)

Electrocardiogram (ECG) if clinically indicated

RULE

8.2 Maintenance monitoring for follow-up

Blood tests - Full blood count - as per monitoring guidelines
Fasting blood glucose / random if fasting not possible and HbA1c at 1, 4 – 6 and 12 months. 6 monthly thereafter
Urea and Electrolytes - annually
Liver Function Tests – at 4 – 6 months. Annually thereafter
Fasting lipids - at 3, 4 - 6 months and 12 months. Annually thereafter

Blood Pressure and pulse - minimum 6 monthly

Weight – minimum 6 monthly, or at each review (plotted on a chart)
Waist circumference – annually (plotted on a chart)

Electrocardiogram (ECG) annually if high dose >600mg/day, or otherwise indicated

- Service users must be monitored at specified intervals for Full Blood Count (FBC), monitoring of routine health parameters and side effects, as set out in the SPC. Please refer to Appendix 3 – Checklist for Monitoring Service Users Prescribed Clozapine. Pharmacy cannot dispense Denzapine unless there is a valid blood test result.

The named consultant is responsible for ensuring that all required physical health checks and side effect monitoring is carried out.

At every annual review or CPA meeting, the care co-ordinator must confirm that health checks are being done.
• Service users on clozapine must have an annual physical health check to determine the risk of metabolic syndrome, as they are at increased risk of both cardiovascular disease and diabetes. Unless specifically agreed otherwise, this should be carried out by HPFT. It must include the relevant annual blood tests and measurement of blood pressure and weight. Smoking status, alcohol and illicit drug use must be established and documented and relevant health promotion advice offered. Lifestyle factors contributing to overall health such as diet and exercise should be considered and relevant advice given and documented. Results of the assessment and blood tests must be scanned on to the electronic patient record (EPR) and also forwarded to the GP.

Please refer to the HPFT “Guidelines for the Physical Health Assessment and Ongoing Physical Monitoring for HPFT Service Users” for further guidance. This policy is available on the HPFT staff website. The routine physical examination performed within HPFT is primarily an evaluation of risk of metabolic syndrome and lifestyle related physical issues. It does not constitute a full physical health screen and service users/carers and their GPs should be aware of this.

• As part of the CPA/annual review process, service users must be offered health promotion advice and up-to-date information about their illness and medication. Medication concordance should be checked with the primary care records if necessary and an accurate record of all medication (psychotropic and physical) currently taken by the service user must be documented on the EPR.

RULE
8.3 Use of clozapine in residential care placements

At the point of considering a residential care placement for a HPFT service user prescribed clozapine, the care co-ordinator must consider the competence of the staff in the placement in relation to clozapine. Practitioners who do not feel confident in doing this must seek advice/help from a nursing/medical colleague.

Clozapine has very specific monitoring requirements and is associated with a number of serious risks. In order to minimise the potential for clozapine related incidents, staff must demonstrate knowledge about this medicine.

A copy of the Clozapine Policy must be given to the manager at the residential care placement by the care co-ordinator. All staff must familiarise themselves with its content. (Refer to the Social Care Placement Checks Pre-Placement and Review Checklist).

STANDARD
8.4 Discontinuing therapy

(Refer to the Denzapine SPC and The Pocket Guide to Denzapine Treatment)

Clozapine should be discontinued if the patient has a blood dyscrasia, intolerable side-effects and/or a failure to respond.

The dose should be reduced gradually over at least a 1 to 2 week period unless abrupt discontinuation is necessary.

If abrupt discontinuation is necessary observe the patient carefully for return of psychotic symptoms & symptoms related to cholinergic rebound (profuse sweating, headache,
nausea, vomiting and diarrhoea).

The DMS and the supplying pharmacy should be notified.

Follow-up blood samples should be taken for four weeks after cessation of treatment with clozapine. This means sample once more for four weekly monitoring, twice for fortnightly monitoring and four times for weekly monitoring.

**STANDARD**

8.5 Restarting therapy\(^1,6\)

(Refer to the Denzapine SPC and The Pocket Guide to Denzapine Treatment)

In service users in whom the interval since the last dose of clozapine exceeds 2 days, treatment should be re-initiated with 12.5 mg (half a 25 mg tablet) given once or twice on the first day. If this dose is well tolerated, it may be feasible to titrate the dose to a therapeutic level more quickly than is recommended for initial treatment.

However, in any service user who has previously displayed evidence of compromised respiratory or cardiac function with initial dosing, but was then able to be successfully titrated to a therapeutic dose, re-titration should be carried out with extreme caution. (See the SPC section 4.4 Special warnings and precautions for use of Denzapine).

Following a break in treatment the DMS must be contacted to clarify the necessary monitoring requirements. The supplying pharmacy should also be informed prior to restarting clozapine.

8.6 Blood Monitoring\(^6\)

Clozapine can cause a reduction in the number of white blood cells in a minority of people and regular blood sampling is required as set out in the SPC.

A Spire Full Blood Count (FBC) pack should be used for blood samples that are sent to Spire Pathology Laboratory for full blood count analysis (routine blood monitoring). This blood pack can be ordered via Spire Pathology Laboratory on 0208 238 6830. The pack contains a Denzapine Request Form which must be completed and sent together with the sample.

The DMS provides an alert system which gives guidance on the suitability of each service user’s blood result for dispensing by assigning alert colours. These are as follows:

Green – OK to dispense and administer.

Amber - Dispense and administer with caution. Repeat bloods twice a week until either green or red. Review trends. Refer to Appendix 7 – Denzapine (clozapine) Amber Protocol.

Red – Do not dispense or administer. STOP clozapine immediately and follow the HPFT Management following a Clozapine Red Alert Result - Appendix 2. This must be strenuously followed and may be expanded for local implementation. Also refer to Appendix 6 – Denzapine (clozapine) Red Protocol.

Access to the DMS website can be granted to HPFT staff, as long as the relevant form is completed and signed by a pharmacist from the Medicines Management Team. The
website user access form is available to download from www.denzapine.co.uk

8.7 Clozapine Plasma Levels\(^1,6\)

Clozapine plasma levels can be checked via the Plasma Clozapine Assay Service, KingsPath Clinical Diagnostic Pathology Services, Kings College Hospital.

A Spire Full Blood Count (FBC) pack should be used for taking blood for clozapine plasma level analysis. The pack contains a plasma clozapine assay request form which must be completed and sent together with the sample to Spire Pathology Laboratory. Spire will then send the pack to KingsPath for clozapine plasma level analysis. This blood pack can be ordered via Spire Pathology Laboratory on 0208 238 6830.

*Please note the same Spire Full Blood Count (FBC) pack is used both for clozapine plasma level analysis and for the routine full blood count analysis. The forms for both types of analyses are however different. Staff must ensure the correct form is used.

A plasma clozapine assay request form can also be downloaded from the KingsPath website www.kingspath.co.uk

The blood sample must be at least 2mls collected into an EDTA tube. Blood sampling must take place in the morning before a morning dose is administered. For those service users who are not prescribed a dose in the morning, the sample must still be taken at this time (trough sample). It is important to note the time of sampling. Sampling less than 6 hours post-dose may make the results difficult to interpret / compare with previous results.

Clinicians can register for results on line via the KingsPath web address or ring 0203 299 5881 to enquire about results. Cost for each analysis is £25.00.

Plasma clozapine levels of 0.35 mg/L and above have been associated with a good response, with the risk of convulsions increasing above 0.60 mg/L.

Levels should be checked as and when clinically indicated for example when:

- there are symptoms suggestive of excessive side effects
- there is lack of clinical response
- following stabilisation when a reduction of dose is being considered
- clozapine metabolism may be altered e.g. due to a drug interaction

9. Risk Management

The relevant doctor is responsible for reviewing results of routine monitoring on an ongoing basis and transmitting this information to the GP for any necessary action.

The points below are not exhaustive and reference should be made to the Denzapine SPC for further information.

9.1 Contraindications to the use of clozapine\(^1\)
(Refer to the Denzapine SPC for a full list)

- Concurrent prescription with drugs known to have a substantial potential for
causing agranulocytosis e.g. depot antipsychotics, carbamazepine and cytotoxic agents

- History of toxic or idiosyncratic granulocytopenia/agranulocytosis (with the exception of granulocytopenia/agranulocytosis from previous chemotherapy)
- History of clozapine induced agranulocytosis
- Service users unable to undergo regular blood tests
- Impaired bone marrow function
- Hypersensitivity to the active substance or to any of the excipients
- Uncontrolled epilepsy
- Alcoholic and other toxic psychoses, drug intoxication, comatose conditions
- Circulatory collapse and/or CNS depression of any cause
- Severe renal or cardiac disorders e.g. myocarditis
- Active liver disease associated with nausea, anorexia or jaundice; progressive liver disease, hepatic failure
- History of paralytic ileus
- Service users with rare hereditary problems of galactose intolerance, the Lapp lactose intolerance deficiency or glucose-galactose malabsorption should not take this medicine

9.2 Special warnings and precautions for the use of clozapine
(Refer to the Denzapine SPC for a full list)

- The SPC states that "for clozapine, there are only limited clinical data on exposed pregnancies. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonic/foetal development, parturition or postnatal development. Caution should be exercised when prescribing to pregnant women." Consultants to make decisions with the service user regarding the appropriate course of treatment.
- Animal studies suggest that clozapine is excreted in breast milk and has an effect in the nursing infant; therefore, mothers receiving clozapine should not breast feed.
- In women of child-bearing potential a return to normal menstruation may occur as a result of switching from other antipsychotics to clozapine. Adequate contraceptive measures must therefore be advised in women of childbearing potential.
- Use in the elderly requires a lower dose at initiation of treatment, and the dose titrated up more slowly as the elderly are more susceptible to side effects.
- When using clozapine in people with a learning disability, consideration should be
given to any underlying medical condition which may affect their tolerability to clozapine.

- Owing to the ability of clozapine to cause sedation and lower the seizure threshold, activities such as driving or operating machinery should be avoided especially during the initial weeks of treatment.

9.3 Interactions with clozapine
(Refer to the Denzapine SPC for a full list)

All healthcare professionals responsible for prescribing medication to clozapine treated service users should be aware of potential drug interactions.

- Concomitant use of clozapine with drugs known to prolong the QT interval may increase the risk of ventricular arrhythmias, including Torsades de pointes, therefore concomitant use of these products is not recommended. Examples include certain antihistamines (such as terfenadine), other antipsychotics (phenothiazines, pimozide, sertindole and haloperidol), certain tricyclic antidepressants (such as amitriptyline). This list is not exhaustive.

- Concomitant use of lithium or other CNS-active agents may increase the risk of development of neuroleptic malignant syndrome (NMS).

- Clozapine may enhance the central effect of CNS depressants such as narcotics, antihistamines and benzodiazepines. Particular caution is advised when clozapine is initiated in service users who are receiving a benzodiazepine or any other psychotropic drug. These individuals are at increased risk of circulatory collapse, which on rare occasions may lead to cardiac and/or respiratory arrest.

- Clozapine potentiates the action of anticholinergic drugs and service users should be observed for anticholinergic side-effects e.g. constipation.

- Concurrent use of drugs causing electrolyte imbalance is not recommended. Diuretics, in particular those causing hypokalaemia should be avoided. If necessary, potassium-sparing diuretics are preferred.

- Drugs such as depot antipsychotics and carbamazepine that can potentiate the risk of agranulocytosis are contraindicated with clozapine.

- Service users known to abuse alcohol should not be prescribed clozapine. It may be appropriate to test Gamma GT and MCV if there is doubt about alcohol abuse.

- Clozapine is metabolised through the CYP1A2 enzyme (cytochrome P450 1A2). In smokers, metabolism of clozapine is increased and so plasma clozapine levels are reduced. On cessation of smoking, reversal of the induction of CYP1A2 occurs resulting in a reduction in CYP1A2 activity. Plasma clozapine levels rise and probably achieve steady state approximately 7-10 days after smoking cessation.

- The plasma concentration of clozapine is increased by caffeine intake and decreased by nearly 50% following a 5-day caffeine-free period. Dosage changes of clozapine may be necessary when there is a significant change in caffeine-drinking habit.
• Certain drugs e.g. the SSRI antidepressant fluvoxamine can affect the metabolism of clozapine and thereby increase plasma clozapine levels. Other drugs such as carbamazepine and phenytoin can also affect the metabolism of clozapine and decrease plasma clozapine levels

• Care must be taken to avoid substances including alcohol that compound the sedating effects of clozapine.

9.4 Serious Adverse Events\(^{1,7,8}\)  
(Refer to the Denzapine SPC and BNF)

Any drug may produce unwanted or unexpected adverse reactions. Detection and recording of these, together with prompt management is important.

All serious adverse reactions should be reported to the Medicines and Healthcare Products Regulatory Agency (MHRA). Doctors, pharmacists, nurses and service users are all eligible to report. Pre-paid yellow cards for reporting can be found at the back of the British National Formulary (BNF) or electronic submissions made at:  
[www.yellowcard.gov.uk](http://www.yellowcard.gov.uk)

**Neutropenia/Agranulocytosis**

• Routine blood monitoring will identify sub-clinical cases.
• Particular attention must be paid to flu-like symptoms such as sore throat and pyrexia which may be indicative of neutropenia.
• The DMS provides guidance on procedures to be followed in the event of neutropenia or agranulocytosis developing.

**Pyrexia**

• Mild hyperthermia occurs in approximately 5% of service users, with the peak incidence within the first 3 weeks of treatment and is usually not significant.
• If a service user develops pyrexia and a flu-like illness, a medical examination and full blood count should be performed as soon as possible.
• If the body temperature exceeds 38.5°C, clozapine should be suspended until the blood count is checked.
• The DMS must be contacted and their advice followed.
• In the presence of a high fever, the possibility of neuroleptic malignant syndrome (NMS) must be considered.

**Seizures**

• Clozapine lowers the seizure threshold and service users may develop a seizure disorder especially on high doses.
• The minimum effective dose should be prescribed.
• Those service users requiring doses of clozapine that cause them seizures may be concomitantly prescribed an anticonvulsant that is not associated with bone marrow suppression.
• Prophylactic sodium valproate should be considered for service users who are at high risk of clozapine induced seizures e.g. those on doses of 600mg daily and above.
Cardiovascular events

- Clozapine treated service users may have an increased risk of pulmonary embolism and sudden death.

- Clozapine has been associated with cardiomyopathy and fatal myocarditis. The risk of myocarditis is highest during the first 2 months of treatment. Cardiac complications should be suspected if service users experience persistent tachycardia at rest, palpitations, arrhythmias, chest pain or heart failure develops. In these cases clozapine should be promptly stopped, and the service user referred to a cardiologist by their psychiatrist. Such service users should never be re-exposed to clozapine.

- Consultants should consider performing a baseline ECG before clozapine treatment is initiated and again when the maintenance dose is reached. This is not currently a requirement, however the decision should be a clinical judgement based on an assessment of risk factors.

- The risk of orthostatic hypotension can be minimised by increasing the dose slowly and spreading doses through the day.

- Any contributing factors e.g. raised BP and/or a history of diabetes should be drawn to the attention of the GP for further investigation.

Acute Intestinal Obstruction

- Due to slowing of intestinal peristalsis, clozapine can cause constipation, obstruction, and a paralytic ileus which may be fatal. (Refer to Constipation Decision Making Algorithm – Appendix 8)

- Acute obstruction is a medical emergency. Symptoms include abdominal distension, pain and vomiting. When suspected the medical team must be alerted and a surgical referral initiated if appropriate.

- Concomitant prescribing of medicines which have anticholinergic side effects should be avoided, as these may exacerbate the obstruction by slowing peristalsis further.

Diabetes and impaired glucose tolerance

Clozapine has been strongly linked to hyperglycaemia, impaired glucose tolerance and diabetic ketoacidosis. Up to one third of clozapine treated service users develop diabetes after 5 years of treatment, the majority of these within the first 6 months. Service users and carers should be aware of the symptoms of diabetes and be encouraged to report these if present. Routine baseline screening in the early months of treatment should detect evidence of glucose dysregulation, however if there is suspicion of abnormal glucose metabolism, a random blood glucose measurement should be undertaken. If this is abnormal, a fasting specimen should be obtained.
9.5 Common side-effects\textsuperscript{1,7,8} 
(Refer to the Denzapine SPC and BNF)

These include constipation, tachycardia hypersalivation, dizziness, urinary problems, sweating, dry mouth, nausea, blurred vision, weight gain and sedation. Obsessional symptoms and sexual dysfunction may occur. These should be screened for at regular intervals and at the annual health check. (Refer to the Checklist of Side Effects Monitoring for Service Users Prescribed Clozapine – Appendix 4). Advice on management should be given in consultation with the medical team if appropriate.

To avoid constipation, a high fibre diet is recommended and bulk forming laxatives should be used. It is not advisable to use stimulant laxatives on a long-term basis due to the potential for developing a paralytic ileus. Additional constipating medications should be avoided. (Refer to Constipation Decision Making Algorithm – Appendix 8)

Obesity measure must be monitored and dietary advice made available to service users.

9.6 Communication

RULE

Close liaison must exist between the clozapine prescriber, clinic / community nurse, dispensing pharmacy, general practitioner and if relevant, staff at residential care placements.

On initiation, the service user’s GP must be notified that the service user has commenced clozapine, to enable an alert to be placed on their record.

- Alteration in dosage of clozapine must be made on the prescription chart and the pharmacy, clinic / community nurse and GP notified of the change in writing. If the prescription chart is not immediately available the change should be communicated in writing and faxed to the pharmacy, clinic/community nurse and GP.

- The consultant must share the results of the annual health check and any relevant results from routine monitoring with the GP.

- A clear written plan must exist, defining arrangements for collecting medication or delivery of medication via Lloydspharmacy to community team bases.

- If clozapine clinic staff are notified of abnormal blood test results by the DMS, the clozapine clinic / community psychiatric nurse requests the service user to attend for a further blood test and notifies the prescriber.

- Anyone suspecting non-concordance with clozapine should notify the relevant prescriber, supplying pharmacy and clozapine clinic if appropriate. The DMS must also be informed if clozapine is missed for more than 2 days. Appropriate action must be taken to follow this up with the service user.

- Clozapine clinic staff or relevant care co-ordinators are responsible for following up non-attendance for blood tests and liaison with the prescribing doctors.

- Inpatient units, community teams and residential care placements should have out-of-hours procedures for clozapine related issues. Clozapine clinic staff or care co-
ordinators are responsible for ensuring that service users and carers are familiar with the local out-of-hours arrangements if they have concerns. It is the responsibility of the care co-ordinator to pass on this information to residential care placement staff.

Initially, a copy of this current policy will be distributed to each GP Practice in Hertfordshire via the CCG Pharmaceutical Advisors. When a service user is commenced on clozapine, the relevant GP must be informed and a further copy of this policy and GP summary document must also be sent. The prescriber is responsible for ensuring that this takes place.

Managers at residential care placements where service users prescribed clozapine are housed must also be provided with a copy of the current policy, in order for the staff there to familiarise themselves with the content. This is the responsibility of the care co-ordinator.

10. Training

<table>
<thead>
<tr>
<th>Course</th>
<th>For</th>
<th>Renewal Period</th>
<th>Delivery Mode</th>
<th>Contact Information</th>
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</thead>
<tbody>
<tr>
<td>Clozapine-prescribing, monitoring &amp; risks</td>
<td>Staff involved in the prescribing, administration and monitoring of clozapine</td>
<td>As required</td>
<td>Taught course – half day (once a year)</td>
<td>Contact Andrew Smith – Medicines Management Team to book a place: <a href="mailto:andrew.smith@hpft.nhs.uk">andrew.smith@hpft.nhs.uk</a></td>
</tr>
<tr>
<td>Physical Health Checks required for people with mental illness</td>
<td>As above</td>
<td>As above</td>
<td>Taught course – half day (once a year)</td>
<td>As above</td>
</tr>
<tr>
<td>Administration of Medicines for Nurses</td>
<td>All registered nurses</td>
<td>Every 3 years</td>
<td>E-learning</td>
<td>OLM E-learning</td>
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<tr>
<td>QCF Medication Unit for Unregistered Staff</td>
<td>Unregistered staff such as Support workers, STR workers, social workers and Occupational therapists who handle medicines.</td>
<td>NVQ equivalent one off course</td>
<td>Taught</td>
<td><a href="mailto:Barbara.delgaudio@hpft.nhs.uk">Barbara.delgaudio@hpft.nhs.uk</a> for all information and relevant paperwork for application.</td>
</tr>
</tbody>
</table>

11. Embedding a culture of Equality & RESPECT
The Trust promotes fairness and RESPECT in relation to the treatment, care & support of service users, carers and staff.

RESPECT means ensuring that the particular needs of ‘protected groups’ are upheld at all times and individually assessed on entry to the service. This includes the needs of people based on their age, disability, ethnicity, gender, gender reassignment status, relationship status, religion or belief, sexual orientation and in some instances, pregnancy and maternity.

Working in this way builds a culture where service users can flourish and be fully involved in their care and where staff and carers receive appropriate support. Where discrimination, inappropriate behaviour or some other barrier occurs, the Trust expects the full cooperation of staff in addressing and recording these issues through appropriate Trust processes.

**RULE:** Access to and provision of services must therefore take full account of needs relating to all protected groups listed above and care and support for service users, carers and staff should be planned that takes into account individual needs. Where staff need further information regarding these groups, they should speak to their manager or a member of the Trust Inclusion & Engagement team.

Where service users and carers experience barriers to accessing services, the Trust is required to take appropriate remedial action.

### 12. Process for monitoring compliance with this document

#### STANDARD

<table>
<thead>
<tr>
<th>Action</th>
<th>Lead</th>
<th>Method</th>
<th>Frequency</th>
<th>Report to</th>
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</thead>
<tbody>
<tr>
<td>Review : arrangements for the administration of medicines in all care environments</td>
<td>Medicines Management Team (MMT)</td>
<td>1. Audit - Safe and Secure Handling of Medicines in the Trust. 2. Clinical Pharmacist Interventions. 3. Medication Incidents.</td>
<td>1. Ongoing 2. Ongoing 3. Ongoing</td>
<td>HPFT Drug and Therapeutics Committee (DTC) (For frequency of reporting see below)</td>
</tr>
<tr>
<td></td>
<td>Britannia Pharmaceuticals Ltd</td>
<td>4. Denzapine Monitoring Service (DMS)</td>
<td>4. Ongoing</td>
<td>DTC reports annually to Quality and Risk Management Committee</td>
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<td></td>
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<td></td>
<td>Registered contact will be alerted to any problems</td>
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</table>

#### 1. Audit - Safe and Secure Handling of Medicines in the Trust

MMT Pharmacists carry out this audit inspection in all HPFT sites on an on-going/ad-hoc basis. As part of this audit the pharmacists check correct storage of clozapine and issues related to administration i.e. correct completion of the administration record on the relevant prescription chart(s). Any problems would be highlighted to the Team Leader and their manager. The Team Leader would be expected to submit an action plan to the
pharmacist and to promptly rectify any issues.

An annual report is presented at the DTC.

2. Clinical Pharmacist Interventions
This is where a pharmacist steps in to influence events or prevent undesirable consequences with respect to medicines including clozapine. These occur on all units receiving clinical pharmacist input. Examples include ensuring prescriptions for clozapine are written correctly, that staff are signing the prescription chart following administration, providing advice on monitoring for service users prescribed clozapine – this may include advice about routine blood monitoring or plasma level monitoring.

All interventions are reported back to the unit/ward staff and are logged on a MMT excel database.

A report is produced and disseminated to Consultants and their teams for wider learning.

The most serious interventions, including those involving clozapine are reported to the DTC on a quarterly basis.

3. Medication Incidents
A medication incident is an event that actually caused harm or had the potential to cause harm. It may involve an error in the process of prescribing, dispensing, preparing, administering, monitoring or providing medicines advice.

Team/unit staff, doctors and pharmacists report medication incidents, including those involving clozapine. Team Leaders and MMT pharmacists (when appropriate) investigate such incidents, details of which are documented on Datix. MMT pharmacists are also involved in the monitoring of incidents involving HPFT service users prescribed clozapine, who are residing in residential care placements.

A Medication Incident Report is presented to the DTC on a quarterly basis.

4. Denzapine Monitoring Service (DMS)
This is a comprehensive web-accessed database of service user profiles – it includes a full blood monitoring and dispensing history for each service user prescribed Denzapine. Should any issues/problems arise e.g. with blood monitoring, DMS will inform the registered contact, who will be a healthcare professional involved in the service user’s care and registered with DMS.

PART 3: Associated Issues

13. Version Control
14. Archiving Arrangements

**STANDARD:** All policy documents when no longer in use must be retained for a period of 10 years from the date the document is superseded as set out in the Trust Business and Corporate (Non-Health) Records Retention Schedule available on the Trust Intranet.

A database of archived policies is kept as an electronic archive administered by the Policy Coordinator. This archive is held on a central server and copies of these archived documents can be obtained from the Policy Coordinator on request.

15. Associated Documents

**STANDARD**
- HPFT Medicines Policy (Including Unlicensed /Off-label Medicines)
- HPFT Policy on Communicating with Service Users from Diverse Communities
- Guidelines for the Physical Health Assessment and Ongoing Physical Monitoring for HPFT Service Users
- Care Co-ordinators Policy

16. Supporting References

**STANDARD**
- Denzapine Summary of Product Characteristics: 28/03/12
- Mental Capacity Act 2005 Code of Practice
- Hertfordshire Policy on Mental Capacity 2009
- Family Law Reform Act 1969
- Your journey with Denzapine – Genus Pharmaceuticals May 2012
- The Pocket Guide to Denzapine Treatment - Genus Pharmaceuticals June 2012
- BNF 63 March 2012

17. Comments and Feedback

**STANDARD**
The following people/groups were involved in the consultation:

<table>
<thead>
<tr>
<th>Head of Medicines Management</th>
<th>Principal Clinical Pharmacists</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultant Psychiatrists</td>
<td>Clozapine Clinic Nurses</td>
</tr>
</tbody>
</table>
## APPENDICES

<table>
<thead>
<tr>
<th>Appendix</th>
<th>Title</th>
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<tbody>
<tr>
<td>Appendix 1</td>
<td>NHSLA Risk Management Standards 2012 - 2013</td>
</tr>
<tr>
<td>Appendix 2</td>
<td>Management following a Clozapine Red Alert Result</td>
</tr>
<tr>
<td>Appendix 3</td>
<td>Checklist for Monitoring Service Users Prescribed Clozapine</td>
</tr>
<tr>
<td>Appendix 4</td>
<td>Checklist of Side Effects Monitoring for Service Users Prescribed Clozapine</td>
</tr>
<tr>
<td>Appendix 5</td>
<td>Procedure for Initiation of Clozapine for Day Care or Outpatient Service Users between the ages of 18 to 65</td>
</tr>
<tr>
<td>Appendix 6</td>
<td>Denzapine (clozapine) RED Protocol</td>
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<tr>
<td>Appendix 7</td>
<td>Denzapine (clozapine) AMBER Protocol</td>
</tr>
<tr>
<td>Appendix 8</td>
<td>Constipation Decision Making Algorithm</td>
</tr>
<tr>
<td>Appendix 9</td>
<td>GASS for Clozapine</td>
</tr>
<tr>
<td>Appendix 10</td>
<td>Care Quality Commission Outcomes 1, 2, 4, 6 and 9</td>
</tr>
</tbody>
</table>
6.9 Medicines Management Training
Organisations providing MH & LD services must have an approved documented process for medicines management which sets out the medicines management training requirements for all permanent staff.

**Level 1**
Your documented process must include:

a) **Duties**
   - How the organisation records that all permanent staff complete relevant medicines management training, in line with the training needs analysis
   - How the organisation follows up those who do not complete relevant medicines management training
   - Action to be taken in the event of persistent non-attendance
   - How the organisation monitors compliance with all of the above.

**Level 2**
You must evidence implementation of your documented process in relation to:

- How the organisation records that all permanent staff complete relevant medicines management training, in line with training needs analysis
- How the organisation follows up those who do not complete relevant medicines management training.

**Level 3**
You must evidence monitoring of your documented process in relation to:

- How the organisation records that all permanent staff complete relevant medicines management training, in line with training needs analysis
- How the organisation follows up those who do not complete relevant medicines management training.

When monitoring has identified less than 95% completion of training, you must evidence that changes have been made to address this.

6.10 Medicines Management
Organisations providing MH & LD services must have an approved documented process for medicines management in all care settings.

**Level 1**
Your documented process must include:

a) How medicines are prescribed
b) How the organisation makes sure that all prescriptions are accurate
c) How side effects of prescribed medicines are monitored
d) How the organisation learns from medication errors PILOT
e) How medication is administered, including patient identification
f) Patient self administration
g) How a patient’s medicines are managed on handover between care settings PILOT
h) How medicines are disposed of safely
i) How the organisation monitors compliance of all the above.
Level 2
You must evidence implementation of your documented process in relation to:
- How the organisation makes sure that all prescription charts are accurate.

The assessor will look at between 10 and 30 health records in current use in order to assess compliance. This will typically be equivalent to 10% of all daily admissions. To award a score the assessor will need to be assured that 75% of the records presented for this criterion meet the above minimum requirement.

Level 3
You must evidence monitoring of your documented process in relation to:
- How the organisation makes sure that all prescription charts are accurate.

When your monitoring has identified shortfalls, you must evidence that changes have been made to address them.
The assessor will look at between 10 and 30 health records in current use in order to spot check the organisations monitoring results. This will typically be equivalent to all daily admission numbers.
If the spot check of health records does not demonstrate 75% compliance, these findings will override the evidence provided by the organisation and will result in no score being provided for the criterion.
Management following a Clozapine Red Alert Result

1. INTRODUCTION
Clozapine can cause serious blood disorders which may be life threatening if not detected.

This document outlines the protocol to be followed when a confirmed red alert is issued by the Denzapine Monitoring Service (DMS). The document will also assist health professionals in the management of a red alert.

A red alert is a clinical emergency, the service user is at risk of harm and immediate action must be taken.

Clozapine toxicity has been shown to cause neutropenia although the reason is not fully understood. A red result occurs when the neutrophil count is below 1.5x10^9/L. Other physical signs are flu-like symptoms e.g. fever, rapid pulse and respiration, sore throat, hypotension, mouth ulcers, swollen and tender gums and skin infections.

*If the neutrophil count is below 1.5x10^9/L and the service user develops or shows signs of fever, their management must be guided by a haematologist.

2. PURPOSE
To ensure the minimisation of harm to a service user experiencing a red alert.

3. PROCEDURE FOLLOWING A RED ALERT
RULE

3.1 ACTION TO BE TAKEN WHEN A RED ALERT IS RECEIVED

- When the DMS detects a red alert a registered contact will be notified. The registered contact would normally be the consultant psychiatrist or nominated deputy or a designated pharmacist or their deputy.

- The registered contact must arrange for this procedure to be carried out without delay.

- **STOP CLOZAPINE IMMEDIATELY.** Advise the service user to stop taking clozapine until further notice (remove the tablets as soon as possible). Due to the risk of depressing white blood cells further, another antipsychotic must be used with caution. If necessary, choose an antipsychotic with a lower risk of neutropenia.

- Fully explain to the service user/carers the implications and the procedure to be followed.

  The information which service users are given must meet the individual’s communication needs. The Trust Policy on Communicating with Service Users from Diverse Communities provides guidance on communication needs and the procedure on the interpreting service.

- The following people to be made aware:
  
  Consultant psychiatrist or nominated deputy
  Team leader/ward manager or deputy
  Dispensing pharmacist
• The consultant psychiatrist or deputy/nurse in charge must arrange an emergency local blood test as soon as possible via the nearest pathology laboratory.

• The person arranging the blood test must ensure that the pathology laboratory will inform a named member of staff of the result as soon as possible. Arrangements for receiving the result of the test (in or out of working hours) must be in place.

• The person receiving the blood result from the pathology laboratory must relay it to the DMS as soon as it has been received. This must be done immediately by fax.

• The telephone number for the DMS is 0333 2004141 and this is the telephone number that should be used out-of-hours.

3.2 CLINICAL MANAGEMENT

• Management of a red result is under the clinical leadership of the service user's consultant psychiatrist.

• The consultant psychiatrist must liaise with the DMS.

• Keep the service user and carer(s) informed of progress.

• Monitor daily FBC. (Do not use the Denzapine blood pack as this takes at least two days to process). Service user should have local blood tests and the results should be faxed to the DMS on 0333 200 4142. There must be close liaison with the DMS.

• Healthcare professionals to carry out daily checks as a minimum on the service user's temperature, BP, pulse rate and respiratory rate. Monitor for clinical signs and symptoms of infection (e.g. fever, sore throat, mouth ulcers etc.). The doctors must be involved.

• If clozapine has been withdrawn and either a further drop in the WBC count below \(2.0 \times 10^9/L\) occurs or the Absolute Neutrophil Count (ANC) falls below \(1.0 \times 10^9/L\), the management of this condition must be guided by a haematologist.

• Monitor mental state on an on-going basis as a psychotic relapse can occur following sudden withdrawal of clozapine.

• Other side effects of sudden withdrawal of clozapine may be restlessness, agitation, confusion, profuse sweating, diarrhoea, dyskinesia, headache, insomnia, nausea and vomiting.

• Update risk assessment, record all results and events on the electronic patient record as soon as possible, in order that the information is readily available to healthcare professionals.

• When the neutrophil count returns to within the normal range (green result) introduce an alternative antipsychotic drug regime.

• Following a red alert the Central Non-Rechallenge Database is informed by the consultant psychiatrist. For further information call DMS on 0333 200 4141.
• If re-challenge with clozapine is being considered by the consultant psychiatrist, he/she must liaise with the DMS and HPFT Medicines Management Team.

• Continue monitoring as advised by the DMS.

**Additional guidance if the service user is being managed in the community**

• A member of the community team must visit at least daily. In the event of needing weekend monitoring, community teams must arrange with support teams who operate 7 day services to provide cover.

• The service user must have a local blood test (FBC) every day until the results are within the normal recommended range. This may include transportation of the service user to have their blood sample taken, especially if the service user lives alone or does not have transport. In the event of this not being possible, taxi services may need to be provided - approved by CMHT manager or deputy.

• In red pen write a request on the blood request form to fax results to the registered contact or their deputy and to the DMS on a daily basis. The relevant fax numbers to be included on the request form.

• Community team to liaise with consultant psychiatrist or designated deputy on a daily basis and inform service user’s GP in relation to blood results and service user’s physical health observations.

• Advise service user to avoid mixing with others due to the increased risk of infection.

• Observe for signs of secondary infection i.e. sore throat, fever and ensure the service user/carer(s) and other team members are aware of the need to watch for signs of infection. If there are any concerns about the identification of signs of secondary infection, consider admitting the service user to hospital.

Please refer to: Appendix 6 – Denzapine RED Protocol
Appendix 7 – Denzapine AMBER Protocol

4. **REFERENCES**
1. Denzapine Summary of Product Characteristics March 2012
2. The Pocket Guide to Denzapine Treatment - Genus Pharmaceuticals June 2012
# Checklist for monitoring service users prescribed clozapine

<table>
<thead>
<tr>
<th>Maintenance monitoring</th>
<th>Date:</th>
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</thead>
</table>

- *Weight (min. 6 monthly)*
- *Waist circumference (annually)*
- Blood pressure (min. 6 monthly)
- Pulse (min. 6 monthly)
- Temperature (°C) how often?
- Fasting blood glucose OR random blood glucose and HbA1c (1 month, 4-6 months, 12 months, then annually)
- Fasting Lipids (3 months, 4-6 months, 12 months, then annually)
- Urea and Electrolytes (annually)
- Liver Function Tests (4-6 months, then annually)
- ECG if high dose >600mg/day (annually)

* Weight and waist circumference to be plotted on a chart

Full blood count to be carried out as per monitoring guidelines

Smoker Y/N How many smoked per day

Any change in smoking habit

Any new medicines prescribed/changes to current medication

Signature of staff member completing form

This chart to be scanned in to EPR

Copy of this checklist to be sent to Consultant Psychiatrist at 3 monthly intervals, or sooner if any problems noted
Checklist of side effects monitoring for service users prescribed clozapine

Service User: ____________________ Date of Birth: ____________ DMS number: ____________ Consultant: ____________

To be completed at monthly intervals for service users prescribed clozapine.

<table>
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<tr>
<td>Urinary Problems</td>
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<td>Tremor</td>
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<tr>
<td>Obsessional symptoms</td>
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<tr>
<td>Signs of infection e.g. sore throat and fever</td>
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<td>Other</td>
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</tr>
</tbody>
</table>

Signature of staff member completing form

This chart to be scanned in to EPR

Copy of this checklist to be sent to Consultant Psychiatrist at 3 monthly intervals, or sooner if any problems
Procedure for Initiation of Clozapine for Day Care or Outpatient Service Users between the ages of 18 to 65

(Adapted from: Novartis “Out-patient initiation of Clozaril” – May 2012 & Norfolk and Suffolk NHS Foundation Trust “Guidelines for starting patients aged 18 to 65 on clozapine therapy as a day or out-patient” – March 2009)

1. Introduction

Clozapine treatment initiation formerly recommended hospital admission in view of some adverse reactions to clozapine e.g. hypotension, tachycardia, sedation, seizures and hyperthermia. There is no longer a regulatory requirement for hospital admission and service users can be commenced on clozapine treatment as day/outpatients.

The introduction of the initiation of clozapine within day or outpatient services will allow service users to be treated in the environment most appropriate for them.

Service users who are initiated on clozapine by day or outpatient services are subject to the same requirements and processes as inpatients including a full history and clinical examination. They must be subject to the same amount of clinical monitoring as inpatients.

To offer this service the prescriber must liaise with the appropriate community team managers involved, to ensure that there is capacity within the team to administer the programme. (Refer also to section 4.1 of this appendix for further considerations).

The EPR must be available to the teams in case of out-of-hours problems.

2. Criteria for acceptance

Each case should be considered on an individual basis

Service users must:

- Fulfil the standard product and Trust criteria for receiving clozapine as set out in the Denzapine SPC and this policy.
- Be considered suitable for outpatient care in view of their current symptomatology and safety risk.
- Have a supportive carer or relative who is willing to stay with the service user during clozapine initiation for a period of two weeks. This will include being available for the service user at night and weekends for the two-week initiation programme.
- Consent to regular blood tests and be aware of and agree to the necessity for daily visits.
Considerations:
  o Caution with day care and outpatient initiation in service users with diabetes or a history of cardiac disease, seizures or NMS.
  o Caution with outpatient initiation in elderly service users as they may be more susceptible to some side-effects and require a slower dose titration.
  o Caution with outpatient initiation in service users who are receiving sedatives or benzodiazepines. Such service users may be more appropriate for inpatient initiation.

3. The service user's consultant psychiatrist must ensure:

3.1 The decision to start clozapine as a day care or outpatient should be a team decision and recorded in the care record.

3.2 That in addition to the standard consent process, the consultant is satisfied that the service user has given informed consent to commencing clozapine in day care or as an outpatient.

   This process must include:
   ▪ An explanation about the risks associated with starting clozapine outside of an inpatient facility
   ▪ Giving the service user and carer the Denzapine patient information leaflet and the booklet titled ‘Your journey with Denzapine’
   ▪ Advice about the realistic expectations about recovery and timeframes
   ▪ Information about adverse side effects and what action to take if they occur

   An entry should be made in the service user's care record confirming the consultant has carried out the above.

3.3 The treatment, care, and information service users are given should meet the individual’s communication needs and take into consideration the individual's cultural needs. For example, people with additional needs such as physical, sensory or learning disabilities and people who do not speak or read English. The HPFT Policy on Communicating with Service Users from Diverse Communities provides guidance on communication needs and the procedure on the interpreting service.

3.4 The consultant must discuss with the service user any cultural constraints that service users may face through the initiation period.

3.5 Undertake a full medical history. Of particular relevance is a history of epilepsy, diabetes, cardiovascular, renal or hepatic disorders.

3.6 Service users who have had a history of previous problems associated with clozapine initiation should not be routinely considered for day care or outpatient initiation.

3.7 Ensure a team doctor sees the service user regularly during initiation; minimum can be defined as once a week. The service user's mental state should be reviewed and risk of suicide considered.
3.8 Ensure a team doctor from the prescribing team is readily available by telephone during the two-week initiation period to provide support and advice to community nursing staff. Out-of-hours the duty doctor will be available.

3.9 There is access to an inpatient bed via CATT should the need arise.

3.10 Existing medication including prescribed medicines, purchased over-the-counter medicines and herbal remedies, to be reviewed by the medical team prior to starting treatment. Some drugs will need to be discontinued, for example carbamazepine and antipsychotic depot injections. Other drugs may include those that may interact to alter plasma levels.

Beware of possible interactions with other medicines e.g., bone marrow suppressants, benzodiazepines, anticholinergics, antihypertensives, alcohol, MAOIs, CNS depressants, highly protein bound drugs, phenytoin and lithium.

3.11 That the service user is registered with the Denzapine Monitoring Service (DMS) and that an initial blood sample is taken (once a start date has been agreed).

3.12 The following are informed:

- Service user’s GP should be informed of the clozapine start date and provided with a copy of the guidelines and an emergency contact number for the treating team
  - The appropriate pharmacy department
  - The identified ‘out-of-hours’ team to be informed in case problems are identified and referred to them

3.13 See also section 6.4 for a list of potential side-effects.

4. **Initiation programme for Day Care or Outpatient Service Users**

4.1 To offer this service the prescriber must liaise with nurse managers to ensure that registered nurses with suitable experience and knowledge to deliver the programme are available. (See section 6.3 of this appendix “Information for registered nurses supervising service users starting clozapine in day care or outpatients”).

4.2 The provision of this service is at the discretion of the lead teams. They will be responsible for the organisation of the required monitoring of physical observations as required for initiation purposes. Every effort will be made to accommodate service users, but agreement will be dependent on staffing levels and the number of other service users using the service.
5. **Treatment programme**

5.1 The basic treatment programme is as per Denzapine SPC.

- The initial dose of clozapine will be a single morning dose of 12.5 mg on Day 1.
- If tolerated, the Day 2 dose will be 12.5 mg morning and late afternoon.
- Thereafter, dose titration will need to be adjusted in accordance with the service user’s response to clozapine.
- It would normally be expected that a service user would achieve a dose of 300mg within two to three weeks.

5.2 The physical observation schedule given is a minimum and may need to be adapted in accordance with the physical observation readings obtained.

5.3 Dosage times for the first two weeks should be morning and late afternoon to allow physical observations monitoring to be carried out.

5.4 Treatment should start on a Monday. This should **not** be the fortnight before a Bank Holiday weekend.

5.5 The registered nurse should monitor:
   - Blood pressure, both sitting and standing twice a day
   - Pulse
   - Body temperature - pyrexia may occur in the first few weeks of treatment but usually resolves quickly
   - The service user’s mental state with particular reference to any suicidal ideas
   - The emergence of side-effects

_N.B If a temperature in excess of 38.5°C, tachycardia or hypotension develops and persists (e.g. in two successive measurements) clozapine should be stopped and the patient immediately referred to medical staff._

Fever may indicate possible blood dyscrasia or Neuroleptic Malignant Syndrome; a Full Blood Count (FBC) should be taken. All possible causes of pyrexia should be considered. If the FBC is satisfactory, the pyrexia has resolved or the cause is unrelated to clozapine the service user may restart clozapine as per the standard titration schedule.

5.6 Service users and carers must be given advice about:
   - Any flu-like symptoms or rise in body temperature and must know who to contact
   - Common side-effects e.g. hypotension
   - Abstaining from driving or operating machinery for at least the first two weeks
   - The necessity for regular blood tests throughout the treatment
   - The need to arrange collection or delivery of supplies of medication

6. **Recommended Initiation Monitoring Schedule – Day Care or Outpatient Service Users; as per attached schedule**
### Recommended Initiation Monitoring Schedule – Day Care or Outpatient Service Users

<table>
<thead>
<tr>
<th>WEEK ONE</th>
<th>MONDAY Day 1</th>
<th>TUESDAY Day 2</th>
<th>WEDNESDAY Day 3</th>
<th>THURSDAY Day 4</th>
<th>FRIDAY Day 5</th>
<th>SAT/SUN Day 6&amp;7</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOSE</td>
<td>Initial morning dose of 12.5 mg</td>
<td>12.5 mg morning 12.5mg teatime</td>
<td>Follow suggested titration schedule</td>
<td>On arrival, then six hours after receiving dose</td>
<td>On arrival, then six hours after receiving dose</td>
<td>CRHT - On arrival, then six hours after receiving dose</td>
</tr>
<tr>
<td>Temp/Pulse/ Blood pressure</td>
<td>Baseline on arrival, then one hourly for six hours after receiving dose</td>
<td>Morning - On arrival, then two hours and six hours after receiving morning dose (not necessary after teatime dose)</td>
<td>On arrival, then six hours after receiving dose</td>
<td>On arrival, then six hours after receiving dose</td>
<td>On arrival, then six hours after receiving dose</td>
<td></td>
</tr>
</tbody>
</table>

**Note:** Increase visit frequency if there is any sustained change in temperature, pulse or blood pressure.

### Other instructions

- Nurse to:
  - Ensure patient understand treatment
  - Answer queries
  - Give clozapine leaflet to patient
  - Give out of hours contact number
  - Clarify no driving or operating machinery

- Patient to have routine blood test for DMS as agreed
- Patient advised not to drive / operate machinery
- Weekend supply of medication to be given
- N.B. Dose must not be increased over weekend
- Health Records to be made available in case of problems over weekend
- Give out of hours contact number to patient & carer for weekend
- Give out of hours contact number to patient & carer for weekend

### WEEK TWO

<table>
<thead>
<tr>
<th>MONDAY Day 8</th>
<th>TUESDAY Day 9</th>
<th>WEDNESDAY Day 10</th>
<th>THURSDAY Day 11</th>
<th>FRIDAY Day 12</th>
<th>SAT/SUN Day 13/14</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temp/Pulse/ Blood pressure</td>
<td>On arrival, then six hours after receiving dose</td>
<td>On arrival, then six hours after receiving dose</td>
<td>On arrival, then six hours after receiving dose</td>
<td>On arrival, then six hours after receiving dose</td>
<td>Programme ends Follow up arrangements explained</td>
</tr>
</tbody>
</table>
6.1 Before commencing the initiation programme in day care or outpatients

- A physical examination - including weight, pulse, temperature and blood pressure and substance misuse related history.

- A baseline mental state examination.

- Service user requires initial full blood count and registration with DMS. The initial full blood count is valid for 10 days before a repeat is required.

- The service user must be provided with an emergency contact number for the treating team.

- There should be a contingency plan in case a service user defaults from visits or becomes non-concordant (NB. In service users in whom the interval since the last dose of clozapine exceeds 2 days, treatment should be re-initiated with 12.5 mg given once or twice on the first day and the dose re-titrated).

6.2 Procedure for Day Care or Outpatient initiation

- Service user to be reviewed face-to-face daily for the first 2 weeks.

- Pulse, temperature and standing and lying BP should be performed at least twice during each review.

- Utilise a flexible dosage titration - some service users may require slow dosage titration.

- Do not increase the dose of clozapine at the weekend or on bank holidays.

- Clozapine dose may be divided after one week depending on preference for type of dosing regimen and adverse reactions experienced.

- At each review the service user should be asked whether he/she has experienced any side-effects/adverse reactions. This must be documented.

- A doctor should see the service user regularly and at a minimum of once a week. The doctor should assess the service user in a similar way to that which would be carried out if the service user was an inpatient, i.e., assessing the service user’s progress, assessing any adverse reactions to clozapine, adjusting the titration rate, managing antipsychotic medication cross-titration and reassuring the service user.

- The service user’s mental state must be reviewed at regular intervals

- Service users must be accompanied home either by a carer/relative or a healthcare worker, if applicable.

- At the end of the two week period, follow up arrangements including blood monitoring requirements should be explained and appointments made as necessary.
6.3 **Information for registered nurses supervising service users starting clozapine in day care or outpatients**

You must ensure that you are thoroughly familiar with:
- Clozapine Policy (Guidance and Procedure for the Use of Denzapine (clozapine) in HPFT)
- The immediate and longer-term potential side effects of clozapine and how these may present. Refer to the Denzapine SPC / product literature and British National Formulary (BNF)
- The information that service users and carers will need about taking clozapine
- The treatment programme
- Accurate monitoring of temperature, pulse and blood pressure

Your role is to:
- Monitor and report the development of any side-effects
- Observe and report the service user’s progress
- Provide information and support to the service user and their carer(s)/relative(s)
- Discuss the effects of alcohol, caffeine and smoking on clozapine therapy
- Ensure that that the service user and carer(s) have been given an information leaflet and verbal information about clozapine
- Check if any clarification is needed and look for opportunities to reinforce information in a form the service user understands

You should be prepared to discuss:
- Common immediate side-effects and practical advice for their management
- The importance of not driving (because of possible drowsiness) and not travelling alone during weeks 1 and 2 (due to small but known risk of collapse)
- The signs of neutropenia including sustained temperature elevation with flu-like symptoms or a sore throat
- Why regular blood tests are essential
- Why you are taking regular temperature, pulse and blood pressure measurements
- Longer-term side effects such as weight gain and how this can be minimised
- Breaks in treatment; if the service user stops clozapine for longer than 48 hours he/she should contact their care co-ordinator, the pharmacy or the prescribing doctor before recommencing. If out-of-hours, CATT must be contacted

You should ensure that the service user/carer(s) are aware of who to contact if problems arise in working hours and out-of-hours

6.4 **Potential side-effects**

This list is not exhaustive. More information can be obtained from the Denzapine SPC, The Pocket Guide to Denzapine Treatment or the hospital pharmacy. Seek advice if unsure.

**Remember:**
Service users are more likely to continue treatment with clozapine if they are prepared for possible side-effects that may occur. The side-effects that concern you are not necessarily the ones that will concern the service user most – you must take their views seriously.
• **Pyrexia**
  Temperature above 38°C is often normal in the first three weeks of treatment. However, if the temperature is 38.5°C or above, a blood sample should be taken to exclude neutropenia / agranulocytosis and exclude causes of infection. Paracetamol may be beneficial in the short-term.

• **Seizures**
  Any evidence of seizures should be referred to the medical team immediately. In established treatment regimes if the dose exceeds 600mg, stop clozapine for 24 hours and re-introduce at a lower dose. Consider prophylactic sodium valproate. Refer for EEG and neurological examination if appropriate.

• **Tachycardia**
  Very common in the early stages but is usually benign. If persistent / when at rest / associated with fever or chest pain, consider referral to a cardiologist.

• **Drowsiness**
  This is usually within the first four weeks. Can be managed by giving more of the dose at bedtime and increasing the dose more slowly.

• **Hypersalivation**
  Can appear early in treatment. If troublesome consider hyoscine hydrobromide 300mcg which should be used as first line treatment. Tablets should be sucked.

• **Hypotension**
  Common in the first four weeks. Instruct service user to stand up slowly. Consider rate of titration, split the dose, with a larger proportion at bedtime or reduce rate of dose titration.

• **Nausea/vomiting**
  An anti-emetic may be of use.

• **Constipation**
  Enquire about possible constipation and if present offer advice about diet. Consider a laxative. Ensure adequate fluid intake. (Refer to Constipation Decision Making Algorithm – Appendix 8)

• **Weight gain**
  Give advice about exercise and diet. Refer to dietician if appropriate.

• **Mental State**
  The service user's mental state must be reviewed at regular intervals.
DENZAPINE (clozapine)

RED PROTOCOL

RED RESULT GENERATED
WBC <3.0 and/or ANC <1.5 and/or PLATELETS <50 (x 10^9/L)

HCP & PATIENT RED PROTOCOL

1. Collection centre need to bring in patient for DAILY blood testing in order to confirm RED result not spurious. Analyse bloods locally

2. Dispensing NOT permitted. Excess medication should be retrieved to ensure patient ceases therapy

3. Consultant should be made aware of the situation immediately

4. Under NO circumstances should the patient be restarted on Denzapine, until the 'RE-CHALLENGE' procedure has been completed

DMS TEAM RED PROTOCOL

1. Collection centre are made aware of the RED result via phone

2. Pharmacy is made aware via phone and fax

3. RED letter faxed and posted to the patient's consultant

4. Britannia Haematologist made aware of RED patient

5. If the RED result is considered 'SPURIOUS' by Britannia Haematologist, DMS team will remove RED result and patient will resume normal monitoring unless there has been a break in treatment of >48 hours

6. DMS team will notify you of the relevant documents that are required

Contact the DMS team to initiate a re-challenge

BEN & 'Special Monitoring' patients are treated on a patient by patient basis

Reference: Denzapine (clozapine) RED PROTOCOL: Genus Pharmaceuticals Dec 2011
DENZAPINE (clozapine)
AMBER PROTOCOL

DENZAPINE PATIENT

AMBER RESULT GENERATED
WBC 3.0 – 3.5 and/or ANC 1.5 – 2.0 (x 10^9/L)

1. Collection centre need to bring in patient for twice weekly monitoring. Best to get bloods analysed locally

2. Pharmacy can dispense a maximum of 4 days from the date of the blood sample

3. Consultant should be made aware of the situation

4. Normal monitoring can resume once patient produces a green result

It is vital that the primary contacts for every patient are kept updated – in case of adverse events

DMS TEAM
AMBER PROTOCOL

1. Collection centre are made aware of the AMBER result via phone

2. Pharmacy is made aware via phone. Fax AMBER letter to pharmacy

3. AMBER letter faxed and posted to the patient’s consultant

Multiple ambers: DMS team only notify the collection centre and pharmacy by phone. Also notify Britannia Haematologist

Multiple ambers: the above process should continue

HCP & PATIENT
AMBER PROTOCOL

BEN & ‘Special Monitoring’ patients are treated on a patient by patient basis

Reference: Denzapine (clozapine) AMBER PROTOCOL: Genus Pharmaceuticals Dec 2011
CONSTIPATION DECISION MAKING ALGORITHM

Day 1: Constipated without symptoms
- Ward/Clinic to provide healthy lifestyle advice
  - Take any laxatives as prescribed
  - Increase fruit, vegetable and fibre intake
  - Increase fluid intake to at least 2-3 litres per day
  - Increase activity levels
- Ward or Clinic to follow up by contacting service user the following day

Day 2 and 3: Constipated without symptoms
- Ward/Clinic contacts Care Coordinator to advise
- Care Coordinator/Clinic/Pharmacy facilitates GP appointment
- GP to review/prescribe laxatives and to advise Clinic/Care Coordinator of plan

Day 2 and 3: Constipated with Symptoms or Day 4 or beyond: Constipated with or without Symptoms
- Ward/Clinic contacts Care Coordinator and Consultant Psychiatrist to Advise
- Ward/Clinic contacts local acute Trust A&E or Fast Response Team. Full description of presentation and risks is given
- Ward or Clinic facilitates transfer to local acute Trust A&E or Fast Response team.

Source: East London NHS Foundation Trust Clozapine Policy May 2013
GASS for Clozapine
(Adapted from the Glasgow Antipsychotic Side-effect Scale)

Name: _______________________________  Current Medications: __________________________

Date: ___________________________________________

Caffeine intake: ........... cups/day
Smoker: Y / N.
........... cigarettes/day

Has there been a recent change in your smoking habit?: Increase/Decrease by ...........
................. cigarettes/day

This questionnaire is being used to determine if you are suffering from excessive side effects from your medication. Please put a tick in the column which best indicates how often or how severely you have experienced the following side effects.

<table>
<thead>
<tr>
<th>Over the past week:</th>
<th>Never</th>
<th>Once</th>
<th>A few times</th>
<th>Everyday</th>
<th>Tick if severe or distressing</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I felt sleepy during the day</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>I felt drugged or like a zombie</td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>3</td>
<td>I felt dizzy when I stood up or have fainted</td>
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<td></td>
<td></td>
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<tr>
<td>4</td>
<td>I have felt my heart beating irregularly or unusually fast</td>
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<td></td>
<td></td>
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<tr>
<td>5</td>
<td>I have experienced jerking limbs or muscles</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>I have been drooling</td>
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<td></td>
<td></td>
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<tr>
<td>7</td>
<td>My vision has been blurry</td>
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<td></td>
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</tr>
<tr>
<td>8</td>
<td>My mouth has been dry</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>I have felt sick (nauseous) or have vomited</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>I have felt gastric reflux or heartburn</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>I have had problems opening my bowels (constipation)</td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>12</td>
<td>I have wet the bed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>I have been passing urine more often</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>I have been thirsty</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>I have felt more hungry than usual or have gained weight</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>16</td>
<td>I have been having sexual problems</td>
<td></td>
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</tr>
</tbody>
</table>

I have also experienced:
(please write down any other side effects OR PHYSICAL PROBLEMS OR COMPLAINTS that you may have experienced over the past week)

| 17 |
| 18 |
| 19 |
| 20 |
Staff Information

1. Allow the service user to fill in the side-effects scale themselves. All questions relate to the previous week.

2. Scoring

<table>
<thead>
<tr>
<th>Points</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>“Never”</td>
</tr>
<tr>
<td>1</td>
<td>“Once”</td>
</tr>
<tr>
<td>2</td>
<td>“A few times”</td>
</tr>
<tr>
<td>3</td>
<td>“Everyday”</td>
</tr>
</tbody>
</table>

3. Results

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-16</td>
<td>absent/mild side-effects</td>
</tr>
<tr>
<td>17-32</td>
<td>moderate side-effects</td>
</tr>
<tr>
<td>33-48</td>
<td>severe side-effects</td>
</tr>
</tbody>
</table>

4. Side-effects covered include:

<table>
<thead>
<tr>
<th>Range</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-2</td>
<td>Drowsiness and sedation</td>
</tr>
<tr>
<td>3</td>
<td>Postural hypotension</td>
</tr>
<tr>
<td>4</td>
<td>Tachycardia</td>
</tr>
<tr>
<td>5</td>
<td>Myoclonus, possible epilepsy</td>
</tr>
<tr>
<td>6</td>
<td>Hypersalivation</td>
</tr>
<tr>
<td>7-8</td>
<td>Anticholinergic side-effects</td>
</tr>
<tr>
<td>9-10</td>
<td>Gastrointestinal side-effects</td>
</tr>
<tr>
<td>11</td>
<td>Constipation</td>
</tr>
<tr>
<td>12</td>
<td>Nocturnal enuresis, possible epilepsy</td>
</tr>
<tr>
<td>13-14</td>
<td>Screening for diabetes mellitus</td>
</tr>
<tr>
<td>15</td>
<td>Weight gain</td>
</tr>
<tr>
<td>16</td>
<td>Sexual dysfunction</td>
</tr>
</tbody>
</table>

5. The column relating to the severity/distress experienced with a particular side effect is not scored, but is intended to inform the clinician of the service user’s views and condition.

6. Questions 17 to 20 invite the service user to report any other side-effects or problems not already mentioned. These questions should not be scored but may instigate a discussion with the service user if clinically appropriate.
Essential Standards of Quality and Safety

What should people who use services experience?

Outcome 1: Respecting and Involving People who use Services

People who use services:
- Understand the care, treatment and support choices available to them.
- Can express their views, so far as they are able to do so, and are involved in making decisions about their care, treatment and support.
- Have their privacy, dignity and independence respected.
- Have their views and experiences taken into account in the way the service is provided and delivered.

Those acting on behalf of people who use services:
- Understand the care, treatment and support choices available to the people who use services.
- Can represent the views of the person using the service by expressing these on their behalf, and are involved appropriately in making decisions about their care, treatment and support.

This is because providers who comply with the regulations will:
- Recognise the diversity, values and human rights of people who use services.
- Uphold and maintain the privacy, dignity and independence of people who use services.
- Put people who use services at the centre of their care, treatment and support by enabling them to make decisions.
- Provide information that supports people who use services, or others acting on their behalf, to make decisions about their care, treatment and support.
- Support people who use services, or others acting on their behalf, to understand the care, treatment and support provided.
- Enable people who use services to care for themselves where this is possible.
- Encourage and enable people who use services to be involved in how the service is run.
- Encourage and enable people who use services to be an active part of their community in appropriate settings.

Outcome 2: Consent to Care and Treatment

People who use services:
- Where they are able, give valid consent to the examination, care, treatment and support they receive.
- Understand and know how to change any decisions about examination, care, treatment and support that has been previously agreed.
- Can be confident that their human rights are respected and taken into account.

This is because providers who comply with the regulations will:
- Have systems in place to gain and review consent from people who use services, and act on them.
Outcome 4: Care and Welfare of People who use Services

People who use services:
- Experience effective, safe and appropriate care, treatment and support that meets their needs and protects their rights.

This is because providers who comply with the regulations will:
- Reduce the risk of people receiving unsafe or inappropriate care, treatment and support by:
  - assessing the needs of people who use services
  - planning and delivering care, treatment and support so that people are safe, their welfare is protected and their needs are met
  - taking account of published research and guidance
  - making reasonable adjustments to reflect people's needs, values and diversity
  - having arrangements for dealing with foreseeable emergencies.

Outcome 6: Cooperating with other Providers

People who use services:
- Receive safe and coordinated care, treatment and support where more than one provider is involved, or they are moved between services.

This is because providers who comply with the regulations will:
- Cooperate with others involved in the care, treatment and support of a person who uses services when the provider responsibility is shared or transferred to one or more services, individuals, teams or agencies.
- Share information in a confidential manner with all relevant services, individuals, teams or agencies to enable the care, treatment and support needs of people who uses services to be met.
- Work with other services, individuals, teams or agencies to respond to emergency situations.
- Support people who use services to access other health and social care services they need.

Outcome 9: Management of Medicines

People who use services:
- Will have their medicines at the times they need them, and in a safe way.
- Wherever possible will have information about the medicine being prescribed made available to them or others acting on their behalf.

This is because providers who comply with the regulations will:
- Handle medicines safely, securely and appropriately.
- Ensure that medicines are prescribed and given by people safely.
- Follow published guidance about how to use medicines safely.
Our vision

‘to be the leading provider of mental health and specialist learning disability services in the country’

To be a leading provider, we must offer high quality care with excellent treatment outcomes, within a safe environment which meets the needs of service users.

Our vision is underpinned by eight goals which inform our entire strategy.

- To deliver high quality integrated health and social care services in accordance with recovery principles
- To be the provider of choice for service users, carers, the community and commissioners
- To work in partnership with the community to promote the wellbeing of others, whilst making a positive contribution to the environment
- To be the employer of choice where staff are highly valued, well supported and rewarded
- To create a dynamic and flexible working environment where staff are motivated and committed to providing high quality care
- To embed a learning culture where staff develop their full potential and deliver excellent care
- To ensure a sustainable future through income growth and efficient use of resources
- To be an innovative and learning organisation that embraces new and modern approaches to health and social care