Shared Care Protocol

Antipsychotic Medications (excluding clozapine) in the treatment of patients with psychosis, schizophrenia, bipolar disorder, and challenging behavior & learning disabilities

This shared care protocol (SCP) sets out details for the sharing of care for ***patients who are prescribed antipsychotics.***

It should be read in conjunction with the latest Summary of Products Characteristics (SmPC) available at http://www.medicines.org.uk/emc/

As outlined in NHS England Guidance 2018 (07573), 'Responsibility for Prescribing Between Primary & Secondary/Tertiary Care': When a specialist considers a patient's condition to be stable or predictable, they may seek the agreement of the GP concerned (and the patient) to share their care.

This document provides information on drug treatment for the shared commitment between the specialist and GP concerned. GPs are invited to participate. If the GP is not confident to undertake these roles, then they are under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. The doctor who prescribes the medication has the clinical responsibility for the drug and the consequences of its use.

N.B. If the GP decides not to participate in shared care for a particular patient, they must inform the relevant specialist in writing, within 2 weeks of receipt of a request to share care.

Introduction:

Antipsychotic drugs are effective in the treatment of schizophrenia and other psychotic disorders. Typically, they can be given as oral medication or in the form of long-acting injections according to patient preference. Second generation antipsychotics are less likely to cause extrapyramidal side effects and are often used in preference to first generation antipsychotics. They are however more likely to cause weight gain. Many patients will require long term treatment with these drugs, and detection and management of side effects will be very important in promoting mental and physical wellbeing. This guideline sets out standards for physical monitoring.

Licensed indication and Contra-indications
Please see BNF and individual Summary of Product Characteristics (SPCs)
https://www.medicines.org.uk/EMC
Interactions | BNF content published by NICE

Shared Care Responsibilities

New patients initiated on antipsychotic medication (oral or long-acting injections) under the care of a Somerset specialist in psychiatry can have a request for the prescribing of their medication transferred to their GP when the psychiatrist considers the patients' condition to be stable enough (between 6 – 12 weeks) and they are on an effective dose. The patients' GP should consider accepting responsibility for prescribing thereafter under this shared care agreement.

Responsibilities of the Psychiatric Service

- To make a diagnosis and decision to initiate treatment.
- To perform baseline physical monitoring checks including ECG and blood tests (there may be exceptional circumstances where GP practices will be asked to help in provision of baseline checks)
- Advise on initiation and titration to a stable dose. Confirmation that the patient has demonstrated benefit and lack of adverse effects.
- Provide the patient with written patient information about the medication.
- Undertake physical monitoring for initial 12 month period or until the patients' condition has stabilized (whichever is longer), with specific reference to weight, cardiovascular and metabolic indicators of morbidity. Monitoring should be in line with NICE guidance CG178 for patients with schizophrenia/psychosis, NICE guidance CG185 in the case of bipolar disorder, or guidance NG11 for patients with challenging behavior and learning disabilities.

  The psychiatric service should communicate the results to the GP - refer to Table 1 below: **Monitoring requirements**
- Stop or modify the dosage as appropriate.
- Notify the GP promptly and in writing of any changes in medication regime.
- Provide sufficient information about the medication to allow the GP to prescribe. This should include advice on recommended monitoring requirements and likely duration of treatment.
- Provide contact information should further assistance be needed.
- Be available to discuss any problems with the GP and other team members and to review the patient if side effects emerge or there is a deterioration in mental health.
- To review antipsychotic medication where metabolic problems do occur, to ensure that a dose/ drug change is considered where appropriate.
- Review the patient as clinically indicated and determine when a patient could be managed in primary care and only be referred back to the psychiatrist if further problems arise.
- Review patient / provide advice as requested by the GP
- Report serious adverse reactions to the MHRA via the Yellow Card scheme https://yellowcard.mhra.gov.uk/

- For challenging behavior & learning disabilities, as per NICE guidance NG11
  - Review the effectiveness and any side effects of the medication after 3-4 weeks
  - Stop the medication if there is no indication of a response at 6 weeks, reassess the behaviour that challenges and consider further psychological or environmental interventions
  - If there is a positive response to antipsychotic medication, conduct a full multidisciplinary review after 3 months and then at least every 6 months covering all prescribed medication (including effectiveness, side-effects and plans for stopping).
- Patients with dementia (and do not suffer functional psychotic disorders)
  - Dementia patients started on antipsychotics should have their medication reviewed by 4-6 weeks and the process of withdrawal started to avoid a sudden stop with potential of rebound/discontinuation effect. Medication should be withdrawn by 6 weeks as per licensing.
  - The antipsychotic should only be continued after Multidisciplinary Team (MDT) review which should include input from the dementia specialist/ Mental Health Team and should consider deprivation of liberty to meet the requirements of the law (e.g., MHA, MCA, DoLS and Liberty Protections Safeguards legislation when it comes into force). The patient should be assessed at least every 6 weeks and the antipsychotic should be stopped (gradual withdrawal) if it is not helping or is no longer needed.
  - In patients with dementia, refer to NICE and consider checking B_{12} and folate levels if not already done so in accordance with latest guidance.
  - Actively support primary care and be involved in MDT reviews when necessary / requested.

Table 1 - Monitoring requirements

Monitoring Requirement	At baseline (specialist)	At 3 months (specialist)	At 12 months & annually
Patient & Family Medical History:			
Cardiovascular risk	☑	☑	☑
Diabetic risk	☑	☑	☑
Respiratory risk	☑	☑	☑
Pulse & BP	☑	☑	☑
BMI	Weekly for first 6/52	☑	☑
Waist measurement	☑		☑
Blood tests (ideally fasting):			
FBC	☑	☑	☑
Glucose	☑	☑	
Lipid profile	☑	☑	☑
U&E's	☑	☑	☑
LFT's	☑	☑	☑
GGT	☑	☑	☑
TFT's	☑	☑	☑
HbA1c		☑	☑
Annual Prolactin Levels Indicated for most antipsychotics unless postmenopausal. Raised prolactin levels can cause amenorrhea in women and impotence in men as well as breast swelling/tenderness and galactorrhoea. Seek advice from mental health services if found to be raised.	☑	☑ **NOT** indicated with aripiprazole, quetiapine, clozapine or olanzapine (unless dose of olanzapine exceeds 20mg.)	☑
Extrapyramidal side effects Glasgow Antipsychotic Side effect Scale (GASS) recommended	☑	☑	☑
Smoking status and offer of intervention to stop (in keeping with NICE guidance) Cigarette smoking has a significant impact on the increased metabolism of antipsychotics, most notably olanzapine and clozapine	☑	☑	☑
Healthy eating/physical activity programme offered	☑	☑	☑
ECG:			
Baseline	☑		
Treatment stabilisation		☑	
Annually or as clinically indicated			☑
Annually for high dose antipsychotics			☑
Annually when more than one antipsychotic prescribed			☑

General Practitioner responsibilities

- Referral back to the psychiatric service if any problems arise related to antipsychotic medication or the patient's psychiatric condition, for a review of medication and consideration of change where indicated.
- Issue prescriptions as advised by the psychiatrist.
- Start appropriate treatment, in accordance with relevant NICE guidance when cardiometabolic disorders are detected by the psychiatric service or GP practice such as the initiation of statins or metformin.
- After the initial 6–12-week period and if the patient's condition has stabilized enough, take over prescribing.
- After 12 months the patient's specialist and GP should agree who will take responsibility for seeing the patient at 12 months post initiation and completing required physical health monitoring after which the GP would retain responsibility for physical health monitoring as outlined in the table above. This should pay attention to endocrine disorders such as diabetes, hyperprolactinaemia, weight, cardiovascular risk factors (blood pressure, lipids) medication side effects and lifestyle factors such as smoking advice with referral to SmokeFreeLife Somerset. Treatment of metabolic disorders should be in accordance with NICE Guidance for specific conditions. GPs may find the Lester UK adaptation of the Positive Cardiometabolic Health Resource a useful tool to support them in monitoring for cardiometabolic side effects in patients who are taking antipsychotics.
- Where abnormalities arise in patients under shared care of the GP it may be appropriate to liaise with psychiatric services to determine whether there is a need for a review of the appropriateness of the antipsychotic medication in the context of the patients' physical and mental health.
- Contact the psychiatric service for management advice as required.
- Patients with dementia (and do not suffer functional psychotic disorders)
    - Dementia patients started on antipsychotics should have their medication reviewed by 4-6 weeks and the process of withdrawal started to avoid a sudden stop with potential of rebound/discontinuation effect. Medication should be withdrawn by 6 weeks as per licensing.
    - The antipsychotic should only be continued after Multidisciplinary Team (MDT) review which should include input from the dementia specialist/ Mental Health Team and should consider deprivation of liberty to meet the requirement of the law (e.g., MHA, MCA, DoLS and Liberty Protections Safeguards legislation when it comes into force). The patient should be assessed at least every 6 weeks and the antipsychotic should be stopped (gradual withdrawal) if it is not helping or is no longer needed.
    - Primary Care colleagues can seek the advice and assistance of the Older Persons Community Mental Health Team (OPCMHT) as required.
    - Every Primary Care Network (PCN) should have a dedicated Mental Health specialist as part of their MDT.
    - In patients with dementia, refer to NICE and consider checking B_{12} and folate levels if not already done so in accordance with latest guidance.
- Report suspected adverse events to the psychiatrist, care co-ordinator and to the MHRA via the yellow card reporting scheme https://yellowcard.mhra.gov.uk/

Patient/Carer responsibilities

- To attend appointments with the Somerset NHS Foundation Trust service for monitoring of medication and possible side effects.
- To report any significant signs or symptoms relating to their condition, including side effects, to the GP or member of the Community Mental Health Team.
- To inform the Somerset NHS Foundation Trust service or GP if they have stopped taking their medication.

Special warnings and precautions

- **Pregnancy and Breastfeeding** You can find information from:
  Mental Health Prescribing - NHS Somerset ICB
  Somerset Printable Leaflets (choiceandmedication.org)
  Pan-London Perinatal Mental Health: Guidance for Newborn Assessment Aug22
  Antipsychotics in pregnancy (rcpsych.ac.uk)
  Patients should be given information before and during pregnancy about their medication and consideration should be made to avoid unnecessary switching for people who will be planning pregnancy and breastfeeding in the future/ breastfeeding at the end of a current pregnancy too.

- **Pregnancy planning or pregnancy** – as a general principle, refer back to Psychiatric Services. Treatment choice should consider the benefits and risks of treatment to fetus, parent and subsequently born child, as well as the potential benefits to the fetus/ child from the parent being treated, the risks of not being adequately treated should also be considered - this should be discussed with the patient for a shared decision-making approach.
  Further information and advice can be sought from the Perinatal Mental Health Team – perinatalMHReferrals@somersetft.nhs.uk
  The UK Teratology Information Service can be contacted on Tel: 0844 892 0909 for specific advice relating to medicines prescribed in pregnancy.
  Infants exposed to antipsychotics during the third trimester of pregnancy may be at risk of adverse reactions including extrapyramidal and/or withdrawal symptoms that may vary in severity and duration following delivery.
  There have been reports of agitation, hypertonia, hypotonia, tremor, somnolence, respiratory distress, or feeding disorder. Consequently, newborns should be monitored carefully.

- **Breast feeding** – as a general principle, refer back to Psychiatric Services for advice. UK Drugs In Lactation Service (UKDILAS) can also be accessed.
  Consideration should be made regarding the effect of certain drugs on prolactin levels such as aripiprazole which will lower milk supply.
- **Hepatic and renal impairment** – refer to individual SPCs.
- **Cardiovascular disease** - antipsychotics can have variable effects on the QTc interval and caution is advised when prescribing to patients with known cardiovascular disease or alongside medication known to prolong QT interval.
  Atypical antipsychotics are also a risk factor in the development of the Metabolic Syndrome, predisposing to obesity, abnormal lipid profiles, hypertension and impaired glucose tolerance.

- **Parkinson disease** - Physicians should weigh the risks versus the benefits when prescribing antipsychotics to patients with Parkinson's Disease or Dementia with Lewy Bodies (DLB) since both groups may be at increased risk of Neuroleptic Malignant Syndrome as well as having an increased sensitivity to antipsychotics. Manifestation of this increased sensitivity can include confusion, obtundation, postural instability with frequent falls, in addition to extrapyramidal symptoms.
- **Epilepsy** - antipsychotics may lower seizure threshold, use with caution.
- **Adolescents younger than 18 years of age** - some antipsychotics are licensed for use in this group but there may be special monitoring requirements. Please refer to individual SPCs and NICE guidance https://www.nice.org.uk/guidance/cg155.
- **Elderly patients** are particularly susceptible to postural hypotension, and to hyper- and hypothermia in hot or cold weather.
- May interfere with activities requiring mental alertness. Patients should be advised not to drive or operate machinery until their individual susceptibility is known.
- Dementia, Learning Disabilities, autism or both - further information can be found at the end of this guidance.
- Physical Health Checks for people with Serious Mental Illness as commissioned.

Drug interactions

There are many theoretical interactions which may or may not be clinically relevant (see individual SPC's). Caution is advised when prescribing antipsychotics with centrally acting drugs e.g. alcohol due to additive depressant effects, and with drugs known to prolong the QT interval. Antipsychotics may antagonise the effect of levodopa/ dopamine agonists in patients with Parkinson's disease.

Adverse effects

These fall into two main groups:

- **extra-pyramidal symptoms (EPS):** Atypical antipsychotics are associated with lower EPS than the typical antipsychotics. The incidence of EPS is often dose related. Tardive dyskinesia may occur on long term administration.
- **weight gain**: atypical antipsychotics are more likely to promote weight gain than typicals. Olanzapine requires particular care with reference to weight monitoring.

Individual atypical antipsychotics have different side effect profiles. In general, other side effects worth noting are:

- orthostatic hypotension (especially during initiation of treatment). May lead to syncope or reflex tachycardia.

- symptoms of hyperprolactinaemia including galactorrhoea (not relevant for quetiapine or aripiprazole), menstrual disturbances, gynaecomastia.
- hyperglycaemia and sometimes diabetes may occur.
- neuroleptic malignant syndrome.

Refer to individual SPCs for further information
https://www.medicines.org.uk/EMC

Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme https://yellowcard.mhra.gov.uk/

Further support

Further support can be accessed via the patient's appropriate local mental health team.

People with dementia

- Behavioural and psychological symptoms are often experienced by people living with dementia. These symptoms can include agitation, aggression, hallucinations and delusions.

- Good practice recommendations recommend psychosocial and environmental interventions to reduce distress. For example, checking for and addressing pain, delirium or inappropriate care. Many people will experience an improvement in behavioural and psychological symptoms over a four to six week period.
  See NICE NG97 Dementia: assessment, management and support for people living with dementia and their carers.

- CQC states that antipsychotic medicines should only be used if people living with dementia are either:
  - at risk of harming themselves or others or
  - experiencing agitation, hallucinations or delusions that are causing them severe distress.
- Antipsychotic medicines are more likely to cause side effects, harm and death for people living with dementia.

- Risperidone is the only licensed antipsychotic for use in dementia. It is licensed for short term treatment (up to 6 weeks) of persistent aggression in patients with moderate to severe Alzheimer's dementia unresponsive to non-pharmacological approaches and when there is a severe risk of harm to self or others.

- Before starting antipsychotics NICE recommends discussing the benefits and harms with the person living with dementia and their family members or carers (as appropriate). An antipsychotic should be used at the lowest dose that helps the person, and for the shortest possible time. The person should be assessed at least every 6 weeks and the antipsychotic should be stopped if it is not helping or is no longer needed.

People with a learning disability, autism or both

- Psychotropic medicines are more likely to be taken by people with a learning disability and autistic people. These medicines need regular monitoring. They can cause side effects that affect people's wellbeing, physical and mental health.

- Psychotropic medicines are sometimes used to control how a person behaves or to restrain them. This behaviour could be because of physical health issues being masked by the person's LD and/or autism, ignorance of socio-environmental triggers and/or because staff do not know how to communicate with a person or to meet their needs to maintain a good quality of life.

- Psychotropic medicines should only be used as the least restrictive option after thoughtful consideration of all the medicolegal risks associated with these medicines.

- Any medication prescribing must be included in a person-centred care plan.

- STOMP stands for stopping overmedication of people with a learning disability and autistic people with psychotropic medications. STOMP is a national project to reduce prescribing and administration of psychotropic medicines. It is about helping people to stay well and have a good quality of life.

- CQC states that psychotropic medicines should only be considered if:
    - psychological or other interventions, such as treatment for any coexisting mental or physical health problem have not helped to improve the person's quality of life or
    - the risk of harm to the person or others is very severe. See NICE NG11 Challenging behaviour and learning disabilities: prevention and interventions for people with learning disabilities whose behaviour challenges.

  Oliver McGowan Mandatory Training on Learning Disability and Autism
  The Government has introduced a requirement for Care Quality Commission (CQC) registered service providers to ensure their employees receive learning disability and autism training appropriate to their role. This is to ensure the health and social care workforce has the right skills and knowledge to provide safe, compassionate and informed care to autistic people and people with a learning disability. This requirement is set out in the Health and Care Act 2022.

  The Oliver McGowan Mandatory Training on Learning Disability and Autism is the government's preferred and recommended training for health and social care staff.

Use of antipsychotics to restrain or control behaviour

- Psychotropic medicines, of which antipsychotics are one example, are sometimes given to people who do not suffer functional psychotic disorders in order to restrain or control behaviour seen as challenging by others. Patients in this group may have Learning Disabilities, Autism or both, or dementia.
- A clear rationale for prescribing antipsychotic medicines should be recorded in the patient's clinical notes (which should be explained to the patient, and everyone involved in their care). This should be completed by an adequately trained, supervised specialist, such as a psychiatrist. The notes should also include evidence that non-pharmacological interventions have been exhausted, a description of what improvement is expected, a plan for monitoring side effects, how long the medicine should be taken for and when and how the treatment should be reviewed and stopped. There should be a clear link between treatment and evidence of proposed diagnosis.
- Frequent use of sedation/medication to control behaviour is listed as a feature which if present in addition to the two acid test questions below, could be regarded a deprivation of liberty and a deprivation of liberty application should be considered.
  The 'acid test' questions:
  •Is the person subject to continuous supervision and control? **and**
  •Is the person free to leave? –with the focus not on whether a person seems to be wanting to leave, but on how those who support them would react if they did want to leave.[17]
- Whenever practical and possible patients should be involved in decisions around their care. When care providers are putting together the care plans of persons who are unable to consent to their care, they should consider whether any restrictions or restraint being proposed in the best interests of the person amount to a deprivation of liberty. This should be done at the point of starting medication and at every review.
- Extra safeguards are needed if the restrictions and restraint used will deprive a person of their liberty. These are called the Deprivation of Liberty Safeguards (DoLS) and ensures people who cannot consent to their care arrangements in a care home or hospital are protected if those arrangements deprive them of their liberty.
- Under the Mental Capacity (Amendment) Act 2019, Deprivation of Liberty Safeguards (DoLS) will be replaced by Liberty Protection Safeguards (LPS). The LPS will provide protection for people aged 16 and above in any setting, including a person's own home. *(It was expected that LPS would come into force by April 2022 but this is now delayed - Liberty Protection Safeguards: delay to implementation - GOV.UK (www.gov.uk))*
- **STOMP** Stopping the over medication of people with a learning disability, autism or both with psychotropic medicines. Reviewing the use of antipsychotics to restrain or control behaviour: https://www.england.nhs.uk/learning-disabilities/improving-health/stomp/

References:

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4. NICE CG 178 Psychosis and schizophrenia in adults: prevention & management https://www.nice.org.uk/guidance/cg178 Published February 2014 Last updated March 2014
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16. MCA Mental Capacity Act 2005 at a glance | SCIE
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18. Liberty Protection Safeguards: what they are - GOV.UK (www.gov.uk)
19. Deprivation of Liberty Safeguards (DoLS) | Alzheimer's Society (alzheimers.org.uk)
20. Overview | Shared decision making | Guidance | NICE

Version:	Reviewed by:	Date:
Version 1.1	Dr Rosemary Brook, Chair of SomPar Drugs and Therapeutics Group Jill Leppard, Lead Nurse For Medicines Management (Mental Health)	June 2014
Version 1.2	Amendments agreed by Somerset CCG prescribing and Medicines Management Committee	Oct 2014
Version 1.3	Amendments agreed by Somerset CCG prescribing and Medicines Management Committee following meeting with Somerset Partnership Representatives	April 2015
Version 1.4	Amendments made by Somerset CCG Prescribing and Medicines Management Committee following further discussion with Somerset Partnership Representatives	June 2015
Version 1.5	Minor amendments made by Somerset CCG Prescribing and Medicines Management Committee following further discussion with Somerset Partnership Representatives	July 2015
Version 1.6	Minor amendments in line with CQUIN target	Feb 2018
Version 1.7	Amendments to include regular FBC and HbA1c monitoring, clarification on prolactin monitoring and hyperlink to GASS scale	June 2018
Version 1.8	Three yearly review. Amendments agreed by Somerset NHS FT Mental Health Drugs & Therapeutics Group	March 2021
Version 2.0	Version 1.8 reformatted and updated by Hels Bennett and Sam Morris Medicines Manager, Somerset CCG. Amendments include review time scales for LD and dementia patients on antipsychotics, including the need for deprivation of liberty reviews. Links to DoLS and STOMP STAMP added.	June 2021
Version 2.1	Updated following comments from PAMM & SFT Mental Health Drugs & Therapeutics Group. Section added around use of antipsychotics to restrain or control behaviour.	October 2021
Version 2.2	Clarified monitoring position following comments from PAMM.	
Version 3.0	3 year review. Updated to NHS Somerset format. Lester tool link updated to 2023 version. Details of Oliver McGowan training added. LPS delay added. Further information and links added to Pregnancy and breastfeeding section.	August 2024
Version 3.1	Updated to clarify responsibilities for MHRA Yellow Card reporting following MPB.	Sept 2024
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