Rotherham Doncaster and South Humber Mental Health NHS Foundation Trust

NHS Doncaster Clinical Commissioning Group

# Shared Care Protocol for the Prescribing of Oral Antipsychotics

## 1.0 INTRODUCTION

This protocol sets out guidelines for the assessment and treatment of patients who are prescribed Antipsychotics and delineated responsibilities when care for the patient is to be shared between Primary Care and Specialist Services.

It is acknowledged that the detail contained within a Shared Care Protocol may need to be supplemented by personal dialogue between clinicians.

**This protocol is intended to be used when an antipsychotic has been prescribed for mental health uses, and treatment has been initiated by mental health services. If the antipsychotic is intended to be used for other purposes, this protocol is not appropriate.**

Shared Care Protocols are intended to provide clear guidance to General Practitioners (GPs) and hospital prescribers regarding the procedures to be adopted when clinical (and therefore prescribing and financial) responsibility for a patient's treatment with a shared-care disease is transferred from secondary to primary care.

GPs, as independent contractors, have the right to decline to take clinical and prescribing responsibilities for a patient on their medical list who is being treated elsewhere. However the reason for this action must be documented. In the view of the Doncaster & Bassetlaw APC, it would be the exception for a GP to refuse to take clinical and prescribing responsibilities for an individual drug, where shared care guidelines for that drug have become common practice and where shared care guidelines include adequate support, education, and information as approved by the Doncaster & Bassetlaw APC.

If a specialist asks a GP to prescribe these drugs in relation to this disease, the GP should reply to this request as soon as practicable. The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequence of its use.

### Traffic light system classification

Clinicians should refer to the Doncaster Traffic Light System on the CCG Medicines Management Website (http://medicinesmanagement.doncasterpct.nhs.uk/#) for the current classification for individual antipsychotics.

## 2.0 DEFINITION

Antipsychotic drugs are also known as ‘neuroleptics’ and (misleadingly) as ‘major tranquillisers’. Antipsychotic drugs generally tranquilise without impairing consciousness and without causing paradoxical excitement but they should not be regarded merely as tranquilisers. For conditions such as schizophrenia the tranquilising effect is of secondary importance.

In the short term they are used to calm disturbed patients whatever the underlying psychopathology, which may be schizophrenia, brain damage, mania, toxic delirium, or agitated depression. Antipsychotic drugs are used to alleviate severe anxiety but this too should be a short-term measure.

Antipsychotic drugs are considered to act by interfering with dopaminergic transmission in the brain by blocking dopamine $D_2$ receptors, which may give rise to the extrapyramidal effects, and also to hyperprolactinaemia. Antipsychotic drugs may also affect cholinergic, alpha-adrenergic, histaminergic, and sertonergic receptors.

## 3.0 BACKGROUND INFORMATION

### 3.1 National Institute for Health and Clinical Excellence (NICE)

Within both hospital and community settings, antipsychotic medicines remain the primary treatment for schizophrenia. There is well-established evidence for their efficacy in both the treatment of acute psychotic episodes and relapse prevention over time.

Antipsychotics are usually prescribed within the recommended Summary of Product Characteristics dosage range, and there is little evidence to support the use of higher dosage or combination with another antipsychotic if monotherapy proves to be ineffective. Antipsychotics are also used in combination with a range of other classes of drugs, such as anticonvulsants, mood stabilisers, anticholinergics, antidepressants and benzodiazepines.

In first-episode or early schizophrenia (including people with a recent onset of schizophrenia and people who have never been treated with antipsychotic medication), the evidence suggested there were no clinically significant differences in efficacy between the antipsychotic drugs.

### 3.2 Indications for use

**This shared care agreement includes, but it not restricted to the treatment of patients with antipsychotics and their corresponding licensed indications.**

## Schizophrenia

Schizophrenia is one of the terms used to describe a major psychiatric disorder (or cluster of disorders) that alters an individual's perception, thoughts, affect and behaviour. Individuals who develop schizophrenia will each have their own unique combination of symptoms and experiences, the precise pattern of which will be influenced by their particular circumstances.

## Bipolar Disorder

**Please refer to Lithium Shared Care document and Anti-Epileptic medications in the management of Bipolar Amber-G guidance document if being used for this indication.**

Bipolar Disorder, also known as manic-depressive illness, is a serious medical illness that causes shifts in a person's mood, energy, and ability to function. Different from the normal ups and downs that everyone goes through, the symptoms of bipolar disorder are severe.
Bipolar disorder causes dramatic mood swings from overly "high" and/or irritable to sad and hopeless, and then back again, often with periods of normal mood in between. Severe changes in energy and behavior go along with these changes in mood. The periods of highs and lows are called episodes of mania and depression.

## Dementia

Please refer to Dementia Shared Care documentation and BPSD (Behavioural and Psychological Symptoms in Dementia) if being used for this indication. All are available on **http://medicinesmanagement.doncasterpct.nhs.uk/**

Dementia is a decline in mental ability which affects memory, thinking, problem-solving, concentration and perception. Dementia is almost invariably a disease of ageing. About 1 in 20 people over the age of 65 are affected, and 1 in 5 people over the age of 80. Dementia in people under 65 is known as early onset or pre-senile dementia and is rare, affecting under 1 in 1000.
Dementia occurs as a result of the death of brain cells or damage in parts of the brain that deal with our thought processes. The most common form of dementia is Alzheimer's disease. We do not know what causes Alzheimer's disease but we do know that ageing seems to be a factor. The second most common type of dementia is vascular or multi-infarct dementia. This occurs as a result of lack of blood and oxygen to the brain in a series of tiny 'strokes'.

## Augmentation of Antidepressant in Resistant Depression

Resistant or refractory depression is difficult to treat successfully and requires a flexible approach with responses to a particular treatment option not readily predicted by pharmacology or previous treatments. While quetiapine is the only antipsychotic licenced for this use, The Maudsley Prescribing Guidelines in Psychiatry list olanzapine, quetiapine, risperidone and aripiprazole as potential first choice additions in resistant depression.

## Learning Disability key points

People with learning disabilities are more prone to common psychiatric illness's such as schizophrenia and bipolar illness. Other accepted indications for antipsychotics will be for challenging behaviours in those with developmental disorders in those with learning disability, where other non pharmacological interventions have failed to control the symptoms adequately.
For more specific guidance on challenging behaviour refer to the current Frith Guidelines, Maudsely and NICE guidelines and secondary care

In these instances the treatment will have been initiated and stabilised by secondary care, and before asking for shared care. A clear treatment plan including indication, advice on if dose adjustment is reasonable, when and how treatment will be reviewed by secondary care.

Valid consent can be an issue in LD where in people lacking the ability to consent, this treatment is given in best Interest of the patient under Section 5 of Mental Capacity Act, or this decision is taken by the LPA holder)

Specific considerations for LD

- people with LD are more susceptible to side effects, detection of which is harder than in the general population, typical antipsychotics may be better tolerated.
- Information should be in LD Easy Read Information forms
- Patients with LD are likely to be more sensitive to side effcts, so a slower titration and final dose may be required.
- They may require a longer period of treatment to assess proper response.
- Risk of interactions may be higher in people with LD on polypharmacy, especially those on Anti-epileptic medication.
- People with LD with comorbid conditions and/or polypharmacy may require more frequent monitoring.

Expected duration. If the treatment is long term then the physical health monitoring will be in line with the management of schizophrenia.

General reasons for contacting secondary care outside of routine review or patient specific guidance include:

- Lack of efficacy
- Intolerable side effects
- Significant interactions with newly prescribed medication
- New or changes to co-morbid illness which may impact on medication.

## Emotionally Unstable Personality Disorder (Borderline Personality Disorder)

Borderline personality disorder (BPD) is common in psychiatric settings, with a reported prevalence of up to 20%. In BPD, individuals have an increased vulnerability to all mental illness; specifically co-morbid depression, anxiety spectrum disorders and bipolar illness which occurs more frequently than would

be expected by chance association alone, and the lifetime risk of having at least one co-morbid mental disorder approaches 100%.

Although it is classified as a personality disorder, it is increasingly recognised to be, in part, an affective disorder and the stress/vulnerability model is particularly relevant to exacerbation of the disorder and presentation to health services. Several symptoms of BPD may intuitively be expected to respond to drug treatment (including affective instability, transient stress related psychotic symptoms, suicidal and self- harming behaviours and impulsivity). While no drug is specifically licensed for the treatment of BPD there is an increasing body of evidence for the use of second generation antipsychotics and mood stabilisers.

Three independent systematic reviews have been published. NICE guidance claims evidence is not sufficiently robust to support a recommendation of **routine** use of drug treatment for BPD or the individual symptoms/behaviours of the disorder, although they may be considered in the overall treatment of co-morbidities. The two further review's analysis concludes that the evidence was sufficiently robust to inform clinical practice.

However, the two year review published in 2011 by NICE reported that "new evidence on pharmacological therapies for patients with borderline personality disorder show some drugs as being clinically effective". This is supported by a Cochrane review and "several ongoing trials focusing on upon efficacy and safety of olanzapine and quetiapine, and the use of lamotrigine in patients with affective instability".

Although this evidence is not considered robust enough to amend the guidelines of 2009, some stakeholders feel this is a viable adjunct to care.

Any proposal for sharing of care with respect to the use of antipsychotics for the treatment of BPD will be part of a personal communication between consultant and GP prior to submission of the relevant proforma.

## 3.3 Side Effects

People's sensitivity and response to drugs varies enormously. One person may be able to tolerate standard doses with no significant side effects, while someone else may find the same dose has intolerable results.

Examples of side effects which may occur as a result of taking antipsychotics:

- **Neuromuscular effects** – e.g. parkinsonism, loss of movement (akinesia), restlessness (akathisia) and muscle spasms/dystonia
- **Sexual side effects** – e.g. breast development in men, drop in sexual desire, impotence, erection and ejaculation problems, loss of periods
- **Antimuscarinic or anticholinergic effects** – e.g. drowsiness, dry mouth, blurred vision, dizziness, constipation, feeling nauseas
- **Disturbances in heart rhythm**

- **Sedation**
- **Eye problems** – e.g. blurred vision, difficulty reading, degeneration of retina,glaucoma
- **Metabolic syndrome** – e.g. diabetes, weight gain and obesity, high BP, high cholesterol
- **Agranulocytosis**
- **Other physical effects** – e.g. Liver disorders, skin problems, unsettled body temperature
- **Emotional effects** – e.g. Excitement, agitation, aggression, depression, disturbed sleep

### 3.4 Side Effect Control

Adherence with antipsychotic medication is perhaps the main determinant of relapse in schizophrenia. The tolerability or experience of side effects of a particular antipsychotic medication has been regarded as both one of the key factors predicting continued adherence and crucially the experience of adverse antipsychotic side effects is commonly stated by patients as an important reason for non-adherence. This highlights the importance of an open and systematic discussion regarding medication-related side effects, as an acknowledgement of the risks as well as benefits of a particular treatment help to establish a collaborative approach between clinicians and service users and contribute to a therapeutic rapport. Antipsychotic side-effect rating scales have been used over the years to help identify and quantify the various side effects that can occur on these medications.

The Glasgow Antipsychotic Side Effect Scale (GASS) was developed in 2008 following a literature review, discussion with members of Glasgow mental health teams and feedback from service users. The scale is designed to allow a timely, sensitive and reliable method of gathering information on the number and severity of side effects an individual suffers from. The Scale and information for practitioners on how to use is included as appendix 1

## 4.0 TREATMENT

### 4.1 Non-Drug Treatment

NICE Clinical Guideline 178 for Psychosis and Schizophrenia February 2014 includes information on psychological therapies and psychosocial intervention evidence reviews on the following suggested non-drug treatments:

• Cognitive–behavioural therapy
• Cognitive remediation
• Counselling and supportive psychotherapy
• Family intervention
• Psychodynamic and psychoanalytic therapies
• Psychoeducation
• Social skills training

## 4.2 Drug Treatment

For contraindications or further information please see

- the current BNF (https://www.medicinescomplete.com/mc/bnf/current/ ) or
- summary of product characteristics for the individual drug (http://www.medicines.org.uk/ )

## 5.0 SHARED CARE ARRANGEMENTS

Once a stable medication regime has been established (usually 3 months), physical monitoring and prescribing of amber category drugs can be transferred to primary care with agreement.

Responsibility for the follow-up and management of test results lies with the clinician who orders the test result.

## 5.1 Aspects of care for which Secondary Care Team is responsible

- Diagnosis and assessment
- Initiation and stabilisation of drug therapy, usually but not exceptionally, a period of 3 months.
- Patient/ family education
- Ensure patient is fully informed of potential benefits and side effects of treatment. A positive decision to continue treatment should be communicated to the GP in writing, providing relevant details.
- Ensure patient is fully informed of, and engaged with the treatment plan.
- If the patient lacks mental capacity in this area then ensure that information is shared, if this is deemed to be in the best interests of the patient (Mental Capacity Act 2005)
- Ensure that Trust policy regarding informed consent is followed
- Provide a comprehensive treatment package in addition to medications including appropriate information/monitoring sheet(s)
- Ensure that shared care arrangements are in place before transfer of treatment
    - That the patient/carer is clear what is being monitored and by whom
    - That the patient knows what significant adverse effects/events to report urgently and to whom they should report (specialist or GP)
    - Following review the GP should be written to if there are any medication or clinical changes, any concerns regarding the mental health or clinical status or to raise awareness of any clinical abnormalities.
    - If the patient is stable, and no changes are made during the review then the minimum frequency for a letter to be sent to the GP is once in a 12 month period.

- Extra monitoring needed for dose changes will be organised by specialist team and conveyed to patient.
- Engagement and agreement with the GP regarding the management of tests and results, when clarification is required.
- Monitor side effects of medication.
- Monitor patient's response to treatment
- Provision of an accessible advisory service to the GP in regard to individual patient clinical queries raised by the GP:
    - For the Adult Mental Health service the preferred method of communication for **routine** (Monday to Friday) queries is by telephone to the principal managing team.
    - A record of the advice provided in a telephone discussion can be provided to the GP, should they wish to receive a copy. This will be done by sending a copy of the medical notes made by the RDASH FT Clinician.
    - A further option for routine (Monday to Friday) queries is via the following nhs.net email account:

      **rdash.psychiatristadvice@nhs.net**

      Receipt of emails are acknowledged within 48hours, prioritized and forwarded to the relevant team.

Emergency advice is via the ACCESS Team on:
01302 566999

- Report adverse events to the MHRA

## 5.2 Aspects of care for which Primary Care Team is responsible

- Ensure that shared care arrangements are in place before transfer of treatment
    - That the patient/carer is clear what is being monitored and by whom
    - That the patient knows what significant adverse effects/events to report urgently and to whom they should report (specialist or GP)
- When the specialist initiates treatment, **reply to the request for shared care as soon as practicable**
- Confirm that proposed therapy is not contra-indicated because of concurrent therapy for other conditions the patient may be suffering from e.g. check drug-contraindications and drug-interactions. Contact specialist team if possible interactions found.
- Confirm the specialists have provided the patient/carer with appropriate information sheet(s) for monitoring and/or to alert other clinical staff to the treatment they are receiving. If appropriate information has not been provided by the specialist, the GP must ensure the information is provided
- Ensure patient's parents/guardian/carer is fully informed of the treatment.
- Monitor treatment as stated in the shared care protocol

- Engagement and agreement with the Specialist service, through dialogue, regarding the management of tests and results, when clarification is required
- Amend prescription as per requests from secondary care for dose changes in patients on established treatment
- Confirm with specialist which changes in these or other parameters should trigger urgent referral back to the specialist
- Seek specialist advice promptly as advised in the shared care protocol or if signs/symptoms of changes occur
- Report adverse events to the MHRA
- If the drug has a black triangle status or is unlicensed, all events should be reported even if casual relationship is not known or if the adverse event is already known about
- Report adverse events to the consultant sharing the care of the patient
- Stop treatment on advice of specialist, or immediately if intolerable side effects occur provided that it is safer to do so than to continue this therapy

## 5.3 Patient (or Carer's) Responsibilities

- Discuss potential benefits and side effects of treatment with the specialist and GP. Identify whether they have a clear picture of these from the specialist and to raise any outstanding queries
- Check that where possible the specialists have provided a patient-held record or information sheet for monitoring and/or to alert other clinical staff to the treatment they are receiving
- Share any concerns they have in relation to treatment with the medicine
- Report any adverse effects to their specialist or GP whilst taking the medicine
- Report to the specialist or GP if they do not have a clear understanding of their treatment
- Participate in the monitoring of therapy and the assessment of outcomes, to assist health professionals to provide safe, appropriate treatment

## 6.0 PROCEDURE FOR ADOPTING SHARED CARE

### 6.1 General Procedure

**Shared Care (Amber) classification**
The specialist will send to the GP a diagnostic assessment report, a copy of the shared care protocol and a shared care referral specifying who is responsible for monitoring. Both the specialist and GP should sign the proforma with a record kept in the GP and specialist records. Full details will be given of the prescribing regime (brand, form, strength and dose of medication) and follow-up plan.
The patient will be asked to make arrangements with their GP for continued supply.

## 7.0 REFERENCES


- NICE Clinical Guideline 178: Psychosis and schizophrenia in adults: treatment and management Full Guideline February 2014
- A new self-rating scale for detecting atypical or second-generation antipsychotic side effects **-** L. Waddell and M. Taylor *J Psychopharmacol* 2008; 22; 238 DOI: 10.1177/0269881107087976
- Making sense of antipsychotics booklet: MIND (http://www.mind.org.uk)
- Scottish Medicines Consortium no 549/09 Quetiapine (Seroquel) for major depressive episodes associated with bipolar disorder
- http://www.nimh.nih.gov
- http://www.mentalhealth.org.uk


## 8.0 Shared Care Development

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**Approved by:**
Doncaster & Bassetlaw Area Prescribing Committee July 2015. Section 5.1 point 9 made more specific around communication following any Secondary Care appointments (Feb 2016)

**Appendix 1**

# Glasgow Antipsychotic Side-effect Scale (GASS)

**Name:** **Age:** **Sex: M / F**

**Please list current medication and total daily doses below:**

This questionnaire is about how you have been recently. It is being used to determine if you are suffering from excessive side effects from your antipsychotic medication.
Please place a tick in the column which best indicates the degree to which you have experienced the following side effects.
Also tick the end or last box if you found that the side effect was distressing for you.



| *Over the past <u>week</u>:* | *Never* | *Once* | *A few times* | *Every day* | *Tick this box if distressing* |
|---|---|---|---|---|---|
| 1. I felt sleepy during the day | | | | | |
| 2. I felt drugged or like a zombie | | | | | |
| 3. I felt dizzy when I stood up and/or have fainted | | | | | |
| 4. I have felt my heart beating irregularly or unusually fast | | | | | |
| 5. My muscles have been tense or jerky | | | | | |
| 6. My hands or arms have been shaky | | | | | |
| 7. My legs have felt restless and/or I couldn't sit still | | | | | |
| 8. I have been drooling | | | | | |
| 9. My movements or walking have been slower than usual | | | | | |
| 10. I have had uncontrollable movements of my face or body | | | | | |
| 11. My vision has been blurry | | | | | |
| 12. My mouth has been dry | | | | | |
| 13. I have had difficulty passing urine | | | | | |
| 14. I have felt like I am going to be sick or have vomited | | | | | |
| 15. I have wet the bed | | | | | |
| 16. I have been very thirsty and/or passing urine frequently | | | | | |
| 17. The areas around my nipples have been sore and swollen | | | | | |
| 18. I have noticed fluid coming from my nipples | | | | | |
| 19. I have had problems enjoying sex | | | | | |
| 20. **<u>Men only</u>:** I have had problems getting an erection | | | | | |

| ***Tick yes or no*** *for the* ***last <u>three months</u>*** | *No* | *Yes* | *Tick this box if distressing* |
|---|---|---|---|
| 21. **<u>Women only</u>**: I have noticed a change in my periods | | | |
| 22. **<u>Men and women</u>**: I have been gaining weight | | | |

# Staff Information (for interpreting GASS questionnaire)

1. Allow the patient to fill in the questionnaire themselves. All questions relate to the previous week.

2. Scoring for questions 1-20

| Patient answer | Points |
|---|---|
| Never | 0 |
| Once | 1 |
| A few times | 2 |
| Every day | 3 |

Scoring for questions 21-22

| Patient answer | Points |
|---|---|
| No | 0 |
| Yes | 3 |

Total for all questions=

3. For male and female patients a score of:
   0-21 absent/mild side effects
   22-42 moderate side effects
   43-63 severe side effects

4. Side effects covered include:

| Question | Parameter |
|---|---|
| 1-2 | sedation and CNS side effects |
| 3-4 | cardiovascular side effects |
| 5-10 | extra pyramidal side effects |
| 11-13 | anticholinergic side effects |
| 14 | gastro-intestinal side effects |
| 15 | genitourinary side effects |
| 16 | screening question for diabetes mellitus |
| 17-21 | prolactinaemic side effects |
| 22 | weight gain |

5. The column relating to the 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.